Evidence Table 1. Natural History of Otitis Media with Effusion

[The six components of study quality are: a prospective cohort study; outcome clearly defined; time point at which outcome measured clearly defined; subjects followed without any intervention; blinded assessment of outcome; and point and variability estimates provided for main outcome measures. 1 indicates presence and 0 indicates absence. OME resolution rates, not otherwise specified, represent the proportion without OME at follow-up compared to those with OME at baseline.]

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
862 Birch and Elbrønd 1984	Study Type: prospective single cohort Study Quality Score (0–6): 3(111000) OME definition: type B tympanogram signified middle-ear effusion otherwise not defined Group: Children attending a day-care center in a municipality under investigation for incidence of OME N=373 subjects	Time: Jan.–Apr./1982 Place: 10 day-care centers in a municipality of about 20,000 inhabitants; Dept. of Oto-Rhino-Laryngology, University of Aarhus, Denmark Inclusion: • attending day-care centers in investigated municipality Exclusion: • tympanometry not practicable (n=15 children) • parental consent not given (n=5 children) • ill or absent at all examinations (n=3 children)	Type of OME: Newly diagnosed OME of unknown duration; OME persisting for weeks or months Age: 0.75–7 years, mean 4.5 years Examiner(s): unknown OME diagnostic method: a B tympanogram defined as “compliance below 0.25 ml” signified middle-ear effusion Interventions: The authors did not mention control for interventions such as antibiotics during the course of the study, though the number receiving surgical procedures was noted. Interval of screening: every 2 weeks for twelve weeks	Data not abstractable. The authors present an equation to estimate OME resolution, most likely cumulative rates, reportedly based on the study data. $Y=Y_0e^{-kt}$ Y= number of ears with OME Y_0=number of ears with OME a time 0 t=time in weeks k=0.30 Derived OME resolution rates by ear Week % remain % resolved 0 100 0 1 74 26 2 55 45 3 41 59 4 30 70 5 22 78 6 17 83 7 12 88 8 9 91 9 7 93 10 5 95 11 4 96 12 3 97 13 2 98 14 1 99 15 1 99 16 1 99 17 1 99 18 0 100

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
1000 Casselbrant, Brostoff, Cantekin, Doyle, Bluestone, and Fria 1985 [This cohort is also in article 2929.]	Study Type: prospective comparative cohort Study Quality Score (0–6): 3(111000) OME definition: inflammation of the middle ear accompanied by collection of liquid in the middle ear cleft without the signs and symptoms of acute infection such as otalgia, fever, and a red or white tympanic membrane that is full or bulging Group: Children, 2–5 years of age, attending a nursery school and examined from Sep 1981 through Aug 1983 N=103 [103 children were entered into the study, 66 in the first year and 37 in the second year. 37 of the 66 children entered in the first year were also observed during the second year. Therefore in data analysis, the 103 children were treated as 140 'individuals' to account for the 37 children who were observed for both years.]	Time: ~9/1981–8/1983 Place: A nursery school in Verona, a suburb of Pittsburgh Inclusion: • 2–5 years old • nursery school in Verona, a suburb of Pittsburgh Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: 2 year old 23, 3 year old 25, 4 year old 38, 5 year old 17 Gender: male 81, female 59 (37 children in years 1 and 2 were counted twice by the authors) Race/ethnicity: black 4, oriental 1, white 98 Examiner(s): otolaryngologist, nurse trained in tympanometry, and an audiologist; also, validated otoscopists OME diagnostic method: an algorithm combining pneumatic otoscopy, tympanometry, and acoustic reflex measurements Interventions: The authors informed parents if OME was present 3 consecutive months. 11 children received tympanostomy tubes, and 26 children were treated for 32 episodes of acute otitis media of which 13 were associated with a new episode of OME. Interval of screening: monthly in school and every 4 months at the Children's Hospital of Pittsburgh for 2 years after the initial evaluation	Cumulative OME resolution by **episode** (Figure 3) Resolution Time # resolved/# at risk (%) <1 month 92/137 (67.2%) <2 months 109/137 (79.6%) <3 months 130/137 (94.9%) <4 months 134/137 (97.8%) <5 months 136/137 (99.3%) <6 months 137/137 (100%) [This table only includes episodes of known duration without missing exam either prior to onset, during the episode, at resolution, or tympanostomy tubes inserted.]

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings[a]
2929 Casselbrant, Brostoff, Cantekin, Ashoff, and Bluestone 1990 [The 2–5-year-old cohort is also in article 1000.]	Study Type: prospective comparative cohort Study Quality Score (0–6): 3(111000) OME definition: not defined[a] Group 1: Children, 2–5 years of age, attending a nursery school and examined from Sep 1981 through Aug 1983[a] Group 2: School children, 5–12 years of age, attending an elementary school and examined from Sep 1984–May 1985 N=214 N1=103[a] N2=111	Time: Group1~9/1981–8/1983[a]; Group2~9/1984–5/1985 Place: A nursery school in Verona, a suburb of Pittsburgh, [a] and Falk Elementary School, Pittsburgh, PA Inclusion: • Group 1: 2–5 years old and in Verona nursery school • Group 2: 5–12 years old and in Falk Elementary School Exclusion: None[a]	Type of OME: newly diagnosed OME of unknown duration[a] Age: Group1~2–5 years old[a] Group2~5–12 years old Examiner(s): otolaryngologist and nurse practitioner validated otoscopists, nurse trained in tympanometry, and an audiologist[a] OME diagnostic method: an algorithm combining pneumatic otoscopy, tympanometry, and acoustic reflex measurements[a] Interventions: Intervention was advised if OME persisted after 3 months. Up to three months, the authors report no intervention though how control was monitored is not mentioned. [a] Interval of screening: monthly after the initial evaluation[a]	Cumulative OME resolution by **episode** for both groups combined[b] (page 29) Time at resolution % resolved <1 month ≈ 60% <2 months ≈ 80% [b]Actual counts are not given, just approximate percentage of OME resolution at 1 and 2 months.

[a] See 1000 Casselbrant, Brostoff, Cantekin, Doyle, Bluestone, and Fria (1985).

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
1202 Ernstson and Sundberg 1984	Study Type: prospective single cohort embedded in a controlled trial (not randomized) Study Quality Score (0–6): 2(100100) OME definition: "nonpurulent effusion behind an intact tympanic membrane at otomicroscopy…supported by a type "B" tympanogram" Group 1: A~Untreated children with OME at least 3 months scheduled for myringotomy Group 2: B~Treated children with OME at least 3 months scheduled for myringotomy (erythromycin orally 20–30 mg/kg body weight twice a day 10 days preceding surgery) N=98 subjects N1=72 N2=26	Time: not specified Place: The ENT Department, Central Hospital, Karlskrona, Sweden Inclusion: • OME on one or both sides for at least 3 months Exclusion: • cleft palate; immotile cilia syndrome • received antibiotics during the period of observation	Type of OME: OME persisting for weeks or months, i.e. at least 3 months, laterality not specified Age: 1–11 years Laterality: both unilateral and bilateral, proportions not specified Examiner(s): unknown OME diagnostic method: otomicroscopy tympanometry Interventions: The authors did not mention control for interventions such as antibiotics during the pre-operative period prior to the 10 days before myringotomy. Interval of screening: 2–5 weeks, median 3 weeks, between decision to operate and the operation itself.	OME resolution in Group 1 (A) over 2–5 weeks by **child** (page 768) Resolution Time # resolved/# at risk (%) <5 weeks 11/72 (15.3%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 1237, 1242, and 1245 for other findings]
1235 Fiellau-Nikolajsen 1979 [1976 cohort is also in articles 1237, 1242, and 3051. 1978 cohort is also in article 1245.]	Study Type: two cross-sectional studies Study Quality Score (0–6): [a] OME definition: not defined [a] Group 1: Children aged 36–48 months in January, 1976, living in the municipality of Hjoerring, Denmark Group 2: Children aged 36–48 months in August, 1978, living in the municipality of Hjoerring, Denmark N1=503 children, 1001 ears, tested out of 523 [a] N2=435 children, 867 ears, tested out of 465 [a]	Time: Not specified[a] Place: ENT Clinic, Hjoerring Hospital, Denmark[a] Inclusion: [a] • Age: 3 years • residing in Hjoerring, Denmark • had tympanometric screening and rescreening Exclusion: None[a]	Type of OME: newly diagnosed OME of unknown duration[a] Age: 36–48 months old[a] Gender: Group 1 263 males, 260 females; Group 2 234 males, 229 females[a] Daycare: Group 1 18.5% in public day-care center, 30.0% in private home day-care, 53.5% in own home; Group 2 31.1% in public day-care center, 23.8% in private home day-care, 46.2% in own home[a] Examiner(s): unknown[a] OME diagnostic method: tympanometry • A: > –99 mmH_20 • B: ≤ 0.1 relative gradient • C1: –100 to –199 mmH_2O • C2: <–200 mmH_2O Interventions: The authors did not mention control of interventions. [a] Interval of screening: 1, 3 and 6 months after initial diagnosis. Other articles on the 1976 cohort note that once type A tympanogram was noted; follow-up was discontinued.	Cumulative OME resolution by **ear** for Group 2 1978 cohort with denominator from Aug. 1978 (Tables V and VII) **<1 month resolution–all subjects** Type # resolved/# at risk (%) B to A 7/64 (10.9%) B to A/C1 14/64 (21.9%) B to A/C1/C2 22/64 (34.4%) B/C2 to A 23/107 (21.5%) B/C2 to A/C1 36/107 (33.6%) B/C2/C1 to A 76/203 (37.4%) **<1 month resolution–subjects in Daycare** Type # resolved/# at risk (%) B to A 3/35 (8.6%) B to A/C1 6/35 (17.1%) B to A/C1/C2 12/35 (34.3%) B/C2 to A 11/58 (19.0%) B/C2 to A/C1 16/58 (27.6%) B/C2/C1 to A 28/102 (27.5%) **<1 month resolution–subjects at home** Type # resolved/# at risk (%) B to A 4/29 (13.8%) B to A/C1 8/29 (27.6%) B to A/C1/C2 10/29 (34.5%) B/C2 to A 12/49 (24.5%) B/C2 to A/C1 20/49 (40.8%) B/C2/C1 to A 48/101 (47.5%) *Continued on next page*

[a] See 1237 Fiellau-Nikolajsen and Lous (1979) and 1245 Fiellau-Nikolajsen (1983).

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 1237, 1242, and 1245 for other findings]
Continued 1235 Fiellau-Nikolajsen 1979 [1976 cohort is also in articles 1237, 1242, and 3051. 1978 cohort is also in article 1245.]				***Continued*** **<3 month resolution–all subjects** Type # resolved/# at risk (%) B to A 16/62 (25.8%) B to A/C1 25/62 (40.3%) B to A/C1/C2 35/62 (56.5%) B/C2 to A 31/104 (29.8%) B/C2 to A/C1 47/104 (45.2%) B/C2/C1 to A 83/200 (41.5%) **<3 month resolution–subjects in Daycare** Type # resolved/# at risk (%) B to A 4/34 (11.8%) B to A/C1 10/34 (29.4%) B to A/C1/C2 15/34 (44.1%) B/C2 to A 9/56 (16.1%) B/C2 to A/C1 20/56 (35.7%) B/C2/C1 to A 27/100 (27.0%) **<3 month resolution–subjects at home** Type # resolved/# at risk (%) B to A 12/28 (42.9%) B to A/C1 15/28 (53.6%) B to A/C1/C2 20/28 (71.4%) B/C2 to A 22/48 (45.8%) B/C2 to A/C1 27/48 (56.3%) B/C2/C1 to A 56/100 (56.0%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 1242 for longer term findings]
1237 Fiellau-Nikolajsen and Lous 1979 [This cohort is also in article 1235 1242, and 3051.]	Study Type: prospective single cohort Study Quality Score (0–6): 4(111001) OME definition: none given but tympanogram B and C2 were regarded as abnormal Group: Children 3 years of age, born in 1972, and living in the municipality of Hjoerring, Denmark N=523 children fulfilled criteria; 504 (1005 ears) tested. N for type B at cohort inception=98 ears, 56 males and 14 females. N for type B/C2 at cohort inception=220 ears, 112 males and 108 females. N for type B/C2/C1 at cohort inception=372 ears, 186 males and 186 females.	Time: Jan–July, 1976 Place: Municipality of Hjoerring, Denmark (provincial town with about 20,000 inhabitants) Inclusion: • 3 years old born in 1972 in the municipality of Hjoerring, Denmark Exclusion: during follow up: Moved out of area; airtight fitting of probe in auditory canal proved impossible; fistula developed in the pars flaccida	Type of OME: newly diagnosed OME of unknown duration Age: 3 years old (born in 1972) Examiner(s): unknown OME diagnostic method: tympanometry • A: > –100 mm$H_2$0 and gradient > 0.1 • B: 200 to –400 mmH_2O or indeterminable and ≤ 0.1 gradient • C1: –100 to –199 mmH_2O and >0.1 gradient • C2: –200 to –400 mmH_2O and >0.1 gradient Interventions: The authors state that "surgical procedures were avoided as much as possible." Six children had adenoidectomy. Interval of screening: 1, 3, and 6 months after the initial diagnosis. Once a child had a type A tympanogram follow-up was discontinued.	Cumulative OME resolution by **ear** (Figure 7) **<1 month resolution–all subjects (Fig 7)** Time # resolved/# at risk (%) B to A 14/94 (14.9%) B to A/C1 20/94 (21.3%) B to A/C1/C2 38/94 (40.4%) B/C2 to A 54/212 (25.5%) B/C2 to A/C1 75/212 (35.4%) B/C2/C1 to A 83/266 (31.2%) **<1 month resolution–males** Time # resolved/# at risk (%) B to A 0/52 (0.0%) B to A/C1 3/52 (21.3%) B to A/C1/C2 17/52 (32.7%) B/C2 to A 18/107 (16.8%) B/C2 to A/C1 30/107 (28.0%) B/C2/C1 to A 26/127 (20.5%) **<1 month resolution–females** Time # resolved/# at risk (%) B to A 14/42 (33.3%) B to A/C1 17/42 (40.5%) B to A/C1/C2 21/42 (50.0%) B/C2 to A 36/105 (34.3%) B/C2 to A/C1 45/105 (42.9%) B/C2/C1 to A 57/139 (41.0%) **<3 month resolution–all subjects (Tab 2)** Time # resolved/# at risk (%) B to A 22/91 (24.2%) B to A/C1 30/91 (33.0%) B/C2 to A 85/204 (41.8%) B/C2 to A/C1 106/204 (51.5%) *Continued on next page*

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 1242 for longer term findings]
Continued 1237 Fiellau-Nikolajsen and Lous 1979 [This cohort is also in article 1235 1242, and 3051.]				*Continued* **<3 month resolution–male subjects** Time # resolved/# at risk (%) B to A 5/49 (10.1%) B to A/C1 9/49 (18.4%) B/C2 to A 33/103 (32.0%) B/C2 to A/C1 46/103 (44.7%) **<3 month resolution–female subjects** Time # resolved/# at risk (%) B to A 17/42 (40.5%) B to A/C1 21/42 (50.0%) B/C2 to A 52/101 (51.5%) B/C2 to A/C 60/101 (59.4%) **<6 month resolution–all subjects** Time # resolved/# at risk (%) B to A 32/91 (35.2%) B to A/C1 41/91 (45.1%) B/C2 to A 120/204 (58.8%) B/C2 to A/C1 136/204 (66.7%) **<6 month resolution–male subjects** Time # resolved/# at risk (%) B to A 12/49 (24.5%) B to A/C1 16/49 (32.7%) B/C2 to A 54/103 (52.4%) B/C2 to A/C1 63/103 (61.1%) **<6 month resolution–female subjects** Time # resolved/# at risk (%) B to A 20/42 (47.6%) B to A/C1 25/42 (59.5%) B/C2 to A 66/101 (65.3%) B/C2 to A/C1 73/101 (72.3%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 1237 for earlier findings]
1242 Fiellau-Nikolajsen 1981 [This cohort is also in article 1237, 1235 and 3051.]	Study Type: prospective single cohort within two cross-sectional studies[a] Study Quality Score (0–6): 4(111001) [a] OME definition: not defined, but tympanogram B and C2 were regarded as abnormal[a] Group 1: Children born in 1972 and domiciled in the city of Hjoerring, Denmark in Jan 1976 Group 2: Children born in 1972 and domiciled in the city of Hjoerring, Denmark in Jan 1979 N1=523; 503 tested (in article 1237 n=504 were reported tested out of 523)[a] N2=505; 498 tested; 352 screened in 1976)[a] N for type B at cohort inception=98 ears. N for type B/C2 at cohort inception=220. N for type B/C1/C2 at cohort inception=372.	Time: 3-year followup (1/1976–1/1979) [a] Place: Testing done in classrooms; the municipality of Hjoerring, Denmark[a] Inclusion: [a] • Age: 3–6 years (cohort born in 1972~screened at ages 3 & 6) • living in Hjoerring, Denmark Exclusion: [a] • showed A tympanograms in both ears at a pminimum of one test	Type of OME: newly diagnosed OME of unknown duration[a] Age: 3–6 years (cohort born in 1972~screened at ages 3 & 6) [a] Examiner(s): unknown[a] OME diagnostic method: tympanometry • A: 200 to –99 mm$H_2$0 and relative gradient > 0.1 • B: 200 to –400 mmH_2O or indeterminable and ≤ 0.1 relative gradient • C1: –100 to –199 mmH_2O and >0.1 relative gradient • C2: –200 to –400 mmH_2O and >0.1 relative gradient Interventions: The authors did not mention control of medications. Some received surgical treatment during the follow-up period; 46 paracentesis and adenoidectomy and later 14 of those myringostomy with insertion of grommets; 10 paracentesis and adenoidectomy and later 4 of those myringostomy[a] Interval of screening: 1, 3, and 6 months after the initial diagnosis at 3 years of age as reported in article 1237. This articles describes follow-up at 6 years of age. Once a child had a type A tympanogram follow-up was discontinued. [a]	Cumulative OME resolution by **ear** with denominators from initial Jan. 1976 exam in Figure 1 article 1237 (Table IIa) **<3 years resolution** Type / # resolved/# at risk / (%) B to A: 33/65 (51%) B to A/C1: 43/65 (66%) B to A/C1/C2: 50/65 (77%) B/C2 to A: 85/153 (56%) B/C2 to A/C1: 113/153 (74%) B/C1/C2 to A: 142/159 (89%) [The authors of article 1242 did not report on the middle-ear status during the three-year interval between the two screenings but comment that there must have been "periodical spontaneous improvements…" (page 98)] With respect to subgroups, the authors of article 1242 mention that "When tested at 6 years,…the named subgroups (gender, public institutions versus home, and urban versus rural) showed no difference, either with respect to impedance test or tone audiometry, and the prognostic role of the tympanogram type at 3 years was the same in all subgroups." Data are not provided on this question. (page 100)

[a] See 1237 Fiellau-Nikolajsen and Lous (1979).

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 1235 for further findings]
1245 Fiellau-Nikolajsen 1983 [This cohort is also in article 1235.]	Study Type: prospective cohort study Study Quality Score (0–6): 3(111000) OME definition: middle-ear effusion with intact tympanic membrane and absence of symptoms of acute inflammation Group: Children screened (underwent audiometry testing and pneumatic otoscopy four times during study period) N=404 subjects screened; N had OME at cohort inception=82.	Time: 1978–1979 (four screens: Aug, Sep & Nov, 1978, Feb 1979) Place: Subject identified in municipality of Hjoerring (medium-size urban town with a population of approximately 20,000); further testing and surgeries performed at ENT Dept., Hjoerring Hospital, Denmark Inclusion: • Age: 3 years (36–48 months) • living in municipality of Hjoerring, Denmark Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: 3 years (36–48 months) Examiner(s): unknown OME diagnostic method: tympanometry • middle-ear effusion: flat curve, or pressure ≤100 mmH_2O with absent middle ear reflexes • no middle-ear effusion Interventions: The authors did not mention control of medications. None reportedly had adenoidectomy, myringotomy, tubes, or paracentesis during the study period. Interval of screening: 1, 3, and 6 months after initial diagnosis	Cumulative OME resolution by **child** (page 173) Resolution Time # resolved/# at risk (%) <1 month 28/78 (35.9%) <3 months 46/78 (59.0%) <6 months 53/78 (68.0%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 543 for further findings]
1486 Holm-Jensen, Sørenson, and Tos 1981 [This cohort is also in articles 2636, 543, 2639, 2642, 4834, and 4835.]	Study Type: prospective cohort study Study Quality Score (0–6): 3(111000) OME definition: not defined though equated to type B tympanogram Group: Healthy children, 4 years old and born on the first-tenth day of each month in 1975, who resided in two Copenhagen counties N=335 children at the first follow-up exam and 333 children at the second follow-up exam N for type B at cohort inception=102 ears (101 in article 2631) N for type B/C2 at cohort inception=318 ears N for type B/C2/C1 at cohort inception=477 ears	Time: February, May, and August, 1979 Place: two counties in Copenhagen, Denmark Inclusion: • born on the 1st–10th of every month in 1975 in two Copenhagen counties • healthy Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: 4 years Examiner(s): unknown OME diagnostic method: tympanometry • A: 0 to –99 mmH_2O • B: flat curve • C1: –100 to –199 mmH_2O • C2: –200 to –350 mmH_2O Interventions: The authors did not mention control of interventions. Interval of screening: 3 and 6 months after initial diagnosis	OME resolution by **ear** the initial Feb. 1979 denominators (Tables I, III, and V) **<3 months resolution** Type # resolved/# at risk (%) B to A 3/92 (3.3%) B to A/C1 14/92 (15.2%) B to A/C1/C2 54/92 (58.7%) B/C2 to A 53/285 (18.6%) B/C2 to A/C1 113/285 (39.6%) B/C2/C1 to A 113/424 (26.7%) **<6 months resolution** Type # resolved/# at risk (%) B to A 14/93 (15.1%) B to A/C1 25/93 (26.9%) B to A/C1/C2 54/93 (58.1%) B/C2 to A 59/282 (20.9%) B/C2 to A/C1 131/282 (46.5%) B/C2/C1 to A 106/418 (25.4%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
1494 Holmquist, Fadala, and Qattan 1987	Study Type: prospective cohort study Study Quality Score (0–6): 3(111000) OME definition: middle-ear effusion behind an intact tympanic membrane Group: Children in grade two who were examined at baseline and three months later by tympanometry and otoscopy N=817 children, 1,634 ears; 788 examined three months later)	Time: 2/1983–4/1983 Place: Eight primary schools distributed in the four educational areas of Kuwait with one male and one female school selected randomly from each area Inclusion: • primary schools Exclusion: • incomplete data • refused to be submitted to examination • occluding ear canal wax • tympanic membrane perforations	Type of OME: newly diagnosed OME of unknown duration Age: 7–9.5 years Examiner(s): the authors whose roles are not specifically identified, one is an MD/PhD, one a surgeon, and one an MS OME diagnostic method: tympanometry • A: +50 to –99 mmH_2O • B: flat curve • C: +100 to –300 mmH_2O Interventions: The authors did not mention control of interventions. Interval of screening: follow-up 3 months after initial diagnosis	OME resolution by **ear** (page 117) **<3 month resolution** Type # resolved/# at risk (%) B/C to A 251/512 (49.0%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
1714 Lamothe, Boudreault, Blanchette, Tetreault, and Poliquin 1981	Study Type: prospective single cohort Study Quality Score (0–6): 4(111100) OME definition: not defined Group: first-grade children N=958 children of which 68 had OME by otoscopy and pneumatic otoscopy after six week follow-up. N of OME at inception: total=68 target ears, male=29, female=39, left ear=38, and right ear=30.	Time: 10/9/1979–12/15/1979 Place: elementary schools in the Sherbrooke metropolitan area, Canada Inclusion: • First graders attending elementary schools in the Sherbrooke metropolitan area, Canada Target ear at first visit was: A) diagnosed with OME if unilateral, B) most affected if bilateral, C) chosen at random if bilateral and evolution was same in both ears Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: First graders Gender: 29 boys, 39 girls Examiner(s): otolaryngologist performed otoscopy and pneumatic otoscopy; audiologist performed tympanogram and audiogram OME diagnostic method: otoscopy and pneumatic otoscopy establishing • abnormal: air-fluid level, bubbles or complete effusion in the middle ear and hypo- or immobility of the eardrum plus two of the three following signs, eardrum retraction, opaque and thickened eardrum, or slight hyperemia tympanometry • abnormal: <= 200 mmH20 or amplitude <= 3 audiogram • abnormal: threshold >= 25 dB Interventions: The authors specifically state the patients were left untreated. Interval of screening: 3 and 6 weeks after initial diagnosis	OME resolution rate by target **ear** (Figure 2) **<3 week resolution** Subjects # resolved/# at risk (%) Total 24/64 (37.5%) Male 7/27 (25.9%) Female 17/37 (45.9%) Left ear 7/35 (20.0%) Right ear 17/29 (58.6%) **<6 week resolution** Subjects # resolved/# at risk (%) Total 25/53 (47.2%) Male 6/23 (26.1%) Female 20/33 (60.6%) Left ear 10/29 (34.5%) Right ear 16/27 (59.3%) Cumulative OME resolution rate by target **ear** (Figure 2) **<3 week resolution** (Total same as above) **<6 week resolution** Subjects # resolved/# at risk (%) Total 38/53 (71.7%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
1735 Leiberman and Bartal 1986	Study Type: retrospective-prospective single cohort Study Quality Score (0–6): 2 (110000) OME definition: not defined Group: Children with persistent middle ear effusion who had follow-up after 2-1/2 year delay in insertion of ventilating tubes N=79 children, 158 ears	Time: 2 1/2 years (actual dates not specified) Place: The Soroka Medical Center in Beer-Sheva, Israel Inclusion: • children with persistent MEE and scheduled for myringotomy and insertion of ventilating tubes which was delayed 2 1/2 years Exclusion: • otomicroscopic findings of fluid and atelectasis, attic retractions, cholesteatoma, perforations, or tympanosclerosis	Type of OME: OME persisting for weeks or months, i.e. 3 months or greater, laterality not specified Age: 2–12 years, mean 6 years Gender: 1:1 (male: female ratio) Examiner(s): unknown who assessed for OME; certified audiologist performed audiometry OME diagnostic method: not stated Interventions: The authors did not mention control for interventions such as antibiotics during the course of the 2-1/2 year delay in surgical intervention. Interval of screening: follow-up greater than 2.5 years after decision to operate for persistent middle-ear effusion of greater-than 3 months	OME resolution by **ear**-(page 876) Resolution Time # resolved/# at risk (%) 2.5 years 49/158 (31.0%) [Authors noted that the middle-ear effusion noted could be either persistent or recurrent. Follow-up for effusion after such a prolonged period may have little meaning.]

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
1777 Lous and Fiellau-Nikolajsen 1981	Study Type: prospective single cohort Study Quality Score (0–6): 3(111000) OME definition: type B tympanogram signified middle-ear effusion Group: First graders in two municipalities (Hirtshals and Sindal, Denmark) who started school in August, 1978 N=387 children at initial exam with 345 tested at all 10 sessions N=100 with known onset and recovery time. N=31 with unknown onset and recovery time	Time: 8/1978–8/1979 Place: First graders in two rural municipalities (Hirtshals and Sindal, Denmark) [24 classes at 14 different schools] Inclusion: • started first grade in 8/1978 in two rural municipalities (Hirtshals and Sindal, Denmark) Exclusion: None	Type of OME: newly diagnosed OME of unknown duration; OME persisting for weeks or months Age: 6 1/2–7 1/2 year (first graders) Examiner(s): specially trained audiometricians performed the tympanogram and audiology testing OME diagnostic method: tympanometry • A: pressure > –100 mmH_2O • B: otoadmittance < 0.20 millimhos, absolute gradient < 0.04 millimhos, and absence of ipsilateral acoustic reflex • C: ≤ –100 mmH_2O Interventions: The authors did not mention control of medications. One child had adenoidectomy and paracentesis and three had adenoidectomy alone. Interval of screening: 1, 3, 4, 6, 7, 8, 9, 10, 12 months after initial exam	OME resolution rate by **case/child** **<3 months resolution – all subjects** Onset Season # resolved/# at risk (%) Sep–Feb 46/69 (66.7%) Mar–Aug 60/70 (86.0%) **<3 months resolution – on subjects with known onset or resolution time only, excluding unknowns[a]** Onset Season # resolved/# at risk (%) Sep–Feb 46/63 (73.0%) Mar–Aug 41/45 (91.1%) [a] [Onset and resolution time unknown in 3, onset time unknown in 19, and resolution time unknown in 9.]

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
9 Marchisio, Principi, Passali, Salpietro, Boschi, Chetri, Caramia, Longhi, Reali, Meloni, DeSantis, Sacher, and Cupido 1998	Study Type: prospective single cohort embedded in a randomized controlled study Study Quality Score (0–6): 3(111000) OME definition: asymptomatic middle-ear effusion, demonstrated by an abnormal appearance of the tympanic membrane, diffusely opaque, with impaired mobility or presence of air-fluid levels associated with a flat, type B tympanometric curve Group: Children attending the first year of primary school in one of eleven primary schools in Italy N=485 children with OME from 3413 screened. N=62 children with OME at 12-week follow-up randomized to placebo.	Time: October–January during 1993–4 and 1994–5 Place: Eleven primary schools visited by an otoscopist from either one of 9 Pediatric or 2 Otolarynogology departments in different regions of Italy Inclusion: • Attending year 1 in one of eleven participating primary schools in Italy • persistent unilateral or bilateral middle-ear effusion Exclusion: • craniofacial abnormality • any major congenital malformation • serious underlying disease • acute upper respiratory infection including AOM • high risk of sensorineural hearing loss • chronic suppurative OM • perforation of tympanic membrane • previous ear surgery	Type of OME: newly diagnosed OME of unknown duration; OME persisting for weeks or months, i.e. at least 12 weeks Age: 16 were 5 years old, 211 were 6 years old, and 258 were 7 years old Gender: 248 males, 237 females Laterality: 219 unilateral, 262 bilateral Month of exam: 296 in Oct–Nov, 189 in Dec–Jan Examiner(s): validated otoscopist OME diagnostic method: pneumatic otoscopy • abnormal: abnormal tympanic membrane appearance with impaired mobility or air-fluid levels and portable tympanometry • B: flat curve Interventions: It appears none of the children received antibiotics in the last month of the follow-up period and did not receive any surgical intervention during the follow-up interval. Interval of screening: 12 weeks after initial diagnosis; then 16 and 20 weeks after initial diagnosis for children randomized to placebo after 12 weeks	OME resolution by **child** (Page 559) Resolution Time # resolved/# at risk (%) <12 weeks 331/451 (73.4%) <16 weeks[a] complete 7/59 (11.9%) partial 13/59 (22.0%) <20 weeks[a] complete 11/59 (18.6%) partial 17/59 (28.8%) [a] OME resolution (time after initial diagnosis, i.e. 12 weeks plus time after randomization to placebo) of subgroup of children with OME at 12-week follow-up randomized to placebo. (Table III)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
1927 Mills and Vaughan-Jones 1992	Study Type: prospective single cohort embedded in a prospective comparative cohort Study Quality Score (0–6): 1(100000) OME definition: not defined Group: New cases of childhood OME (patients < 15 years of age) who presented at principal author's clinic between 10/1986–10/1988 N=192 children	Time: 10/1986–10/1988 Place: Clinics, Department of Otolaryngology, Ninewells Hospital and Medical School, Dundee, UK Inclusion: • <15 years old Exclusion: • impedance findings suggested effusion was in fact due to thickening of the tympanic membrane	Type of OME: newly diagnosed OME of unknown duration Age: 1–14 years old, mean 5.5 years Examiner(s): unknown OME diagnostic method: pneumatic otoscopy tympanometry Interventions: Most of the children had myringotomies at the 2 month follow-up. Two children had "conservative treatment" at some unspecified point in time. Interval of screening: usually 2 months after initial exam	OME resolution by **child** (Figure 4) Resolution Time # resolved/# at risk (%) <2 months 57/192 (29.7%) [Authors reported uncertainty in the timing of the follow-up visit.]

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
1946 Moller and Tos 1990	Study Type: prospective single cohort Study Quality Score (0–6): 3(111000) OME definition: not defined Group: Healthy children attending a kindergarten in Copenhagen, Denmark N=51 children, 100 ears	Time: 11/1/1989–11/30/1989 (21 days of screening) Place: A kindergarten in Copenhagen, Denmark; Gentofte Hospital/University of Copenhagen Inclusion: • kindergartners Exclusion: • ears with grommets inserted (two ears excluded) • definite type of tympanogram could not be identified • child defected from study or refused the examination w/either one or the other instrument	Type of OME: newly diagnosed OME of unknown duration Age: 37–68 months old Gender: 21 males, 30 females Examiner(s): unknown OME diagnostic method: tympanometry • A: +99 to –99 mmH2O • B: • AZ 7: flat curve without impedance minimum or with a measurable impedance minimum and relative gradient below 0.1 • ZS 331: flat training or compliance below 0.25 ml and absent ipsilateral stapedial reflex • C1: –100 to –199 mmH_2O • C2: >–200 mmH_2O Interventions: The authors did not mention control of interventions. Interval of screening: daily for 30 days	OME resolution by **ear** for OME noted at start of study (page 938 and 939 and Tables IV and V) **AZ7[Impedance audiometer]** Time Resolved Type # resolved/# at risk (%) <3 days B to A 1/4 (25.0%) B to A/C1 1/4 (25.0%) <10 days B to A 1/4 (25.0%) B to A/C1 3/4 (75.0%) <15 days B to A not done B to A/C1 3/4 (75.0%) <30 days B to A 0/2 (0.0%) B to A/C1 1/2 (50.0%) **ZS331 [Impedance tympanoscope]** Time Resolved Type # resolved/# at risk (%) <3 days B to A 2/7 (28.6%) B to A/C1 2/7 (28.6%) <10 days B to A 4/7 (57.1%) B to A/C1 6/7 (85.7%) <15 days B to A not done B to A/C1 5/6 (83.3%) <30 days B to A 0/3 (0.0%) B to A/C1 1/3 (33.3%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
2184 Portoian-Shuhaiber and Cullinan 1984	Study Type: prospective single cohort Study Quality Score (0–6): 3(111000) OME definition: abnormal defined as an abnormal tympanometric curve and/or absent acoustic reflex Group: Children, 5–6 years old, attending selected primary schools in SE London N=130 children with OME from 318 screened	Time: March 1979 and May 1979 Place: Twelve primary schools in SE London Inclusion: • 5–6 years old • attending one of the twelve selected schools in SE London Exclusion: • conditions predisposing to glue ear such as Down's syndrome and cleft palate	Type of OME: newly diagnosed OME of unknown duration Age: 5–6 years Ethnicity: African-American: 57; Indian: 16; White: 234; unknown: 11. Examiner(s): unknown OME diagnostic method: tympanometric and acoustic reflex measurements • abnormal: abnormal curve and/or absent reflex • normal: normal tympanogram curve with positive acoustic reflex Interventions: The authors did not mention control of interventions. Interval of screening: 10 weeks after initial diagnosis	OME resolution by **child** (page 1112) **<10 weeks resolution** Ethnicity # resolved/# at risk (%) Total 65/130 (50.0%) African-American 5/7 (71.4%) Indian 5/9 (55.6%) White 55/110 (50.0%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 2627 and 2634 for further findings]

2189
Poulsen and Tos
1978
[This cohort is also in 2627, 2631, 2634, 2639, 2642, 4834, and 4835.]
	Study Type: prospective single cohort
	
	Study Quality Score (0–6): 3(111000)
	
	OME definition: not defined
	
	Group: Infants born between January–April, 1977, in the Gentofte maternity ward
	
	N=151 screened initially, 109 children (218 ears) at all examinations.
	
	N=0 for type B or C2 at cohort inception.
		Time: recruitment 1/1997 to 4/1997 with last follow-up 6 months after initial exam
		
		Place: Copenhagen, Denmark
		
		Inclusion:
		• healthy newborns born between January and April 1977 in the Gentofte maternity ward
		
		Exclusion: None
			Type of OME: newly diagnosed OME of unknown duration
			
			Age: Newborns
			
			Gender: 82 males, 69 females
			
			Examiner(s): unknown
			
			OME diagnostic method: tympanometry
			• A: >–100 mmH_2O
			• B: flat curve with impedance slope ≤0.1
			• C: –100 to –300 mmH_2O with impedance slope >0.1
			  • C1: –100 to –199 mmH_2O
			  • C2: –200 to –350 mmH_2O
			
			Interventions: The authors did not mention control of interventions.
			
			Interval of screening: 3 and 6 months after initial diagnosis at 2–4 days of age
				OME resolution by **ear** (Figure 1)
				
				Resolution from C1 to A
				
				Time # resolved/# at risk (%)
				<3 months 19/24 (79.2%)
				
				<6 months 13/24 (54.2%)
				
				Cumulative OME resolution by **ear** (Figure 1)
				
				Resolution from C1 to A
				
				Time # resolved/# at risk (%)
				<3 months 19/24 (79.2%)
				<6 months 21/24 (87.5%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 2629, 2634, and 2593 for further findings]
2190 Poulsen and Tos 1980 [This cohort is also in articles 2629, 2631, 2634, 2593, 2639, 2642, 4834, and 4835.]	Study Type: prospective single cohort Study Quality Score (0–6): 3(111000) OME definition: not defined Group: Healthy two-year-old children born between the first and tenth day of every month in 1976 residing in two municipalities in the northern part of Copenhagen county N=278 children at initial exam but N=240 children who presented at both follow-up exams N for type B at cohort inception=60. N for type B/C2 at cohort inception=172. N for type B/C2/C1 at cohort inception=290.	Time: 11/1977–5/1978 Place: Two municipalities in the northern part of Copenhagen county, Denmark Inclusion: • Age: 2 years • born between the 1st and the 10th day in every month of 1976 in 2 Copenhagen county municipalities • healthy Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: 2 year old at final exam Examiner(s): unknown OME diagnostic method: tympanometry • A: 0 to –99 mmH_2O • B: flat curve • C1: –100 to –199 mmH_2O • C2: –200 to –350 mmH_2O Interventions: The authors did not mention control of medications. Three children received ear tubes, and three had adenoidectomy. Interval of screening: 3 and 6 months after initial diagnosis	OME resolution by **ear** using the initial Nov. 1977 denominators from Table I in article 2631 (Table III) **<6 month resolution** Type / # resolved/# at risk / (%) B to A 15/59 (25.4%) B to A/C1 25/59 (42.4%) B to A/C1/C2 38/59 (64.4%) B/C2 to A 37/152 (24.3%) B/C2 to A/C1 74/152 (48.7%) B/C2/C1 to A 87/248 (35.1%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
2240 Renvall, Lidén, Jungert, and Nilsson 1978	Study Type: prospective single cohort Study Quality (0–6): 3 (111000) OME definition: not defined. Group: Children aged 10–11 years who were initially examined at age 7 [only ears with a middle ear pressure <=–100 mm H2O or a flat tympanogram at the initial exam were included] N=210 children, 335 ears	Time: not specified Place: Göteborg, Sweden Inclusion: • 10–11 years (initially evaluated at age 7) • only includes ear that at the initial evaluation (age 7) had middle ear pressure of <=–100 mmH_2O or a flat tympanogram Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: 10–11 years (initially evaluated at age 7) Examiner(s): otologic examination by experienced otologist, audiologic examiner unknown OME diagnostic method: tympanometry and stapedius reflex measurements and otoscopic exam initial screen • abnormal: ≤–100 mmH_2O or flat tympanogram follow-up • abnormal: ≤–150 mmH_2O or flat tympanogram, stapedius reflex threshold > 95 dB H.L., and effusion by otologic exam Interventions: The authors did not mention control of interventions. Interval of screening: 3 years after initial diagnosis	OME resolution by **ear** (Table III and I) **<3 years resolution** Diagnostic Method # resolved/# at risk (%) Tympanogram 282/335 (84.2%) Otologic exam 250/335 (74.6%) [The authors concluded that "reduced middle ear pressure is more common in ears once having had subnormal middle ear pressure than in a nonselected group. They did not suggest that these necessarily represent persistent OME.]

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
2242 Renvall, Anniansson, and Lidén 1982	Study Type: prospective single cohort Study Quality (0–6): 4(111100) OME definition: not defined Group 3: 4-year-old children with abnormal tympanograms after hearing screen and comprehensive evaluation N=5928 initially screened and N=223 ears with abnormal tympanogram. N for type B at cohort inception=58 ears. N for type B/C at cohort inception=223 ears.	Time: During 1980 Place: S1~Healthy-baby-clinics in Goteborg, Sweden; S2~children who failed screening were referred to two oto-audiological health centers in Goteborg Inclusion: • Age: 4 years • S2~failure criterion >20db Exclusion: None	Type of OME: Newly diagnosed OME of unknown duration Age: 4 years Examiner(s): unknown OME diagnostic method: tympanometry, audiology, and otologic exams • abnormal: middle-ear pressure ≤–150 mmH_2O, hearing ≤20 dB HL, and/or retraction pocket on otologic exam • normal: middle-ear pressure > –150 mmH_2O, no tympanic membrane retraction, and hearing <= 20 dB HL Tympanogram classification: • Flat to >150 mmH_2O [similar to type B to A] • Flat or –150 to –400 mmH_2O to >=150 mmH_2O [similar to type B or C to A] Interventions: The children did not receive any treatment for four months after initial diagnosis. Interval of screening: 6 and 12 weeks after initial diagnosis. Those with normal exams at any point did not receive follow-up.	Cumulative OME resolution by **ear** (Figures 2 and 3) **<6 weeks resolution** Type # resolved/# at risk (%) B to A 10/40 (25.0%) B/C to A 56/144 (38.9%) **<12 weeks resolution** Type # resolved/# at risk (%) B to A 16/40 (40.0%) B/C to A 86/144 (59.7%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
2243 Reves, Budgett, Miller, Wadsworth, and Haines 1985	Study Type: prospective single cohort Study Quality (0–6): 3(111000) OME definition: not defined Group: Children 3 months to 6 years old on 10/31/1983 recruited from age-sex register and successfully tested by tympanometry N=232 children, 452 ears, of whom n=220 had adequate exams	Time: 11/1983–2/1984 Place: General practice at a health centre in north west London (situated on a council housing estate and serves a deprived population) Inclusion: • 3 months–6 years on 10/31/1983 • listed in age-sex register Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: 3 months–6 years on 10/31/1983; <1 year old 59 ears, 1 year old 73 ears, 2 years old 94 ears, 3 years old 86 ears, 4 years old 82 ears, 5 years or older 58 ears Laterality: unilateral 29, bilateral 39 Examiner(s): unknown OME diagnostic method: tympanometry • A: normal pressure (–100 to +50 mmH_20), normal compliance (>0.3), peak at normal pressure • As: normal pressure, low compliance, small peak at normal pressure • B: low compliance and middle-ear pressure < –100 mmH_20 or indeterminate, usually flat or peak < –100 mmH_20 (signified middle-ear effusion) • C: negative pressure, normal compliance, peak at negative pressure Interventions: The authors did not mention control of interventions. Interval of screening: every 2–4 weeks after initial diagnosis for 6 months	OME resolution by **child** (comment in abstract) Resolution Time # resolved/# at risk (%) <3 months 40/68 (58.8%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
2262 Roberts, Johnson, Carlin, Turczyk, Karnuta, and Yaffee 1995	Study Type: prospective single cohort Study Quality Score (0–6): 4(111010) OME definition: not defined Group: Healthy, full-term infants born in MetroHealth Medical Center, Cleveland, Ohio, were enrolled on day 1 of life N=68 subjects	Time: not specified Place: Normal newborn nursery of MetroHealth Medical Center, a county hospital in Cleveland, Ohio, and a county pediatric clinic Inclusion: • healthy, full-term newborn Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: Newborns (max follow-up ~ 2months) Race/ethnicity: white 47%, African American 43%, Hispanic 10% Examiner(s): 2 otoscopists; tympanometry and acoustic reflex measurements by an audiologist on day 1 and 3 and by a research assistant at 2 weeks and 2 months OME diagnostic method: pneumatic otoscopy • middle-ear effusion: tympanic membrane mobility markedly decreased or air-fluid level tympanometry • middle-ear effusion: peak susceptance < 0 millisiemens • no effusion: > 0 millisiemens acoustic reflex measurement • middle-ear effusion: threshold at 110dB HL or absent reflex • no effusion: threshold up to 100dB HL Interventions: Asymptomatic infants were not treated with antibiotics. No indication of how many infants required intervention. Interval of screening: 2 weeks and 2 months after birth of infants whose parents chose to receive well-child care from the research team	Cumulative OME resolution by otoscopy by **ears** (page 875) Resolution Time # resolved/# at risk (%) <2 weeks 22/24 (91.7%) <2 months 24/24 (100%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
2270 Robinson, Allen, and Root 1988	Study Type: prospective single cohort Study Quality (0–6): 1(110000) OME definition: not defined Group: Children, primarily lower socioeconomic status infants between 3–6 months of age, who underwent tympanometry as part of the study N=137 subjects initially tested of whom n=63 had OME). N for B/C/Cs at cohort inception=63.	Time: not specified Place: 12 Health Department clinics in two metropolitan Detroit counties (Wayne and Oakland); (8 Oakland County clinics are "well baby" clinics; 4 Wayne County clinics serve Medicaid patients) Inclusion: • Age: 6–13 months • income limits are imposed to qualify for Tx at all clinics involved Exclusion: None	Type of OME: Age: 6–13 months, mean 9.7 months (standard deviation 2.3 months) Gender: 65 male, 72 female Race/ethnicity: 63 black, 74 white Examiner(s): second-year audiology master of arts student OME diagnostic method: tympanometry • A: –149to +50 mmH_20 and compliance > 0.2 ml • failures: all other types As, C, Cs, and B Interventions: The authors did not mention control of interventions. Interval of screening: minimum 6 weeks from initial screen if failed	OME resolution by **ear** (pages 343–344) **<6 weeks resolution**[a] Type # resolved/# at risk (%) B to A 10/25 (40.0%) B to A/As 11/25 (44.0%) B to A/As/Cs 13/25 (52.0%) B/C to A 22/41 (53.7%) B/C to A/As 23/41 (56.1%) B/C to A/As/Cs 24/41 (58.5%) B/C/Cs to A 20/34 (58.8%) [a]minimum 6-week interval but exact intervals not reported

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
2457 Sly, Zambie, Fernandes, and Frazer 1980	Study Type: two prospective single cohorts Study Quality Score (0–6): 3(111000) OME definition: not defined Group 1: February, 1977 screening children in 4–5 year old classes at Memorial Baptist Kindergarten (n=94 children, 188 ears) Group 2: September, 1977 screening children in 4–5 year old classes at Memorial Baptist Kindergarten N1=94 children, 188 ears N2=94 children, 188 ears	Time: February and September, 1977 Place: Memorial Baptist Kindergarten, New Orleans, LA; from the Dept. of Pediatrics, Louisiana State University Medical Center Inclusion: • Age: 4–5 years • written parental permission & child willingness Exclusion: • presence of functional ventilating tube (ear) • not able to obtain adequate seal in the ear canal (ear)	Type of OME: newly diagnosed OME of unknown duration Age: Kindergartners (4–5 years) Examiner(s): unknown OME diagnostic method: tympanometry • abnormal: flat type B without discernible peak in compliance with decrease in pressure to –400 mmH_2O, compliance < 0.3 cc, or peak compliance occurred at or below pressure –100 mmH_2O Interventions: Group 1 antibiotics with or without antihistamines and decongestants in 2 children and antihistamines and decongestants in 9, Group 2 antibiotics with or without antihistamines and decongestants in 5 children and antihistamine and/or decongestants in 21. Interval of screening: every two weeks after initial diagnosis for six weeks	OME resolution by **child/ear** as unit of measure (only those without any treatment). (Table VII) **<2 weeks resolution – February 1997** Unit Type # resolved/# at risk (%) Child B to A 1/7 (14.3%) Child B/C to A 8/24 (33.3%) Ear B to A 1/9 (11.1%) Ear B/C to A 8/32 (25.0%) **<2 weeks resolution – September 1997** Unit Type # resolved/# at risk (%) Child B to A 0/3 (0.0%) Child B/C to A 2/14 (14.3%) Ear B to A 0/5 (0.0%) Ear B/C to A 4/22 (18.2%) **<4 weeks resolution – February 1997** Unit Type # resolved/# at risk (%) Child B to A 3/7 (42.9%) Child B/C to A 12/24 (50.0%) Ear B to A 4/9 (44.4%) Ear B/C to A 14/32 (43.8%) **<4 weeks resolution – September 1997** Unit Type # resolved/# at risk (%) Child B to A 0/3 (0.0%) Child B/C to A 3/14 (21.4%) Ear B to A 0/5 (0.0%) Ear B/C to A 5/22 (22.7%) *Continued on next page*

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
Continued 2457 Sly, Zambie, Fernandes, and Frazer 1980				*Continued* **<6 weeks resolution – February 1997** Unit Type # resolved/# at risk (%) Child B to A 5/7 (71.4%) Child B/C to A 16/24 (66.7%) Ear B to A 6/9 (66.7%) Ear B/C to A 18/32 (56.3%) **<6 weeks resolution – September 1997** Unit Type # resolved/# at risk (%) Child B to A 0/3 (0.0%) Child B/C to A 7/14 (50.0%) Ear B to A 0/5 (0.0%) Ear B/C to A 11/22 (50.0%) Note: Denominator at each time is most likely same as total with OME, however defined.

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 2629, 2190, and 2634 for further findings]
2593 Thomsen and Tos 1981 [This cohort is also in articles 2190, 2629, 2631, 2634, 2639, 2642, 4834, and 4835.]	Study Type: [a] Study Quality (0–6): [a] OME definition: [a] Group: [a] N=184 children who presented at all 5 follow-up exams N for type B at cohort inception=60. N for type B/C2 at cohort inception=172. N for type B/C2/C1 at cohort inception=477.	Time: 11/1977 to 2/1980 Place: [a] Inclusion: [a] Exclusion: [a]	Type of OME: [a] Age: [a] Gender: males 92, females 92 Examiner(s): unknown OME diagnostic method: [a] Interventions: [a] Interval of screening: extended to 5 years old	OME resolution by **ear** (Table IV and Figure 1) **<2 years resolution** Type # resolved/# at risk (%) B to A 9/48 (18.8%) B to A/C1 19/48 (39.6%) B to A/C1/C2 40/48 (83.3%) B/C2 to A 26/121 (21.5%) B/C2 to A/C1 53/121 (43.8%) B/C2/C1 to A 50/199 (25.1%) **Resolution based on B to A/C1/C2** Resolution Time # resolved/# at risk (%) <3 months 25/48 (52.1%) <6 months 27/48 (56.3%) <9 months 39/48 (81.3%) <12 months 35/48 (72.9%) <24 months 40/48 (83.3%) Cumulative OME resolution by **ear** **Resolution based on B to A/C1/C2** Resolution Time # resolved/# at risk (%) <3 months 25/48 (52.1%) <6 months 30/48 (62.5%) <9 months 39/48 (81.3%) <12 months 42/48 (87.5%) <24 months 47/48 (97.9%)

[a] See 2190 Poulsen and Tos (1980).

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 2189 and 2634 for further findings]
2627 Tos 1979 [This cohort is also in articles 2189, 2631, 2634, 2639, 2642, 4834, and 4835]	Study Type: [a] Study Quality Score (0–6): [a] OME definition: [a] Group: [a] N=90 children who presented for all 5 follow-up exams N for type B at cohort inception=4 in this article but was 3 in articles 3189 and 2631. N for type B/C2 at cohort inception=27. N for type B/.C2/C1 at cohort inception=91.	Time: recruitmen1t 1/1997 to 4/1997 with last follow-up 12 months after initial exam Place: [a] Inclusion: [a] Exclusion: [a]	Type of OME: In this evidence table, we are looking at those from the original cohort with tympanogram type B (n=4 in article 2627 and n=3 in article 2189), C1 (n=20 in article 2189), or C2 (n=58 in article 2189) at the 6-month follow-up visit and presented for all 5 follow-up visit. Type B was not seen until the 6-month follow-up visit. Type C1 was seen in 24 patients at 2–4 days of age and 32 at the 3-month follow-up. Type C2 was seen initially in 1 patient at the 3-month follow-up. [a] Age: [a] Gender: 50 males, 40 females Examiner(s): [a] OME diagnostic method: [a] Interventions: [a] Interval of screening: 1, 3, 6, 9, and 12 months after initial diagnosis at 2–4 days of age. [a]	OME resolution by **ear** using the 6-month exam denominators from Table IV in article 2189 (Tables III and V) **<3 months resolution** Type — # resolved/# at risk — (%) B to A — 1/4 — (25.0%) B to A/C1 — 1/4 — (25.0%) B to A/C1/C2 — 1/4 — (25.0%) B/C2 to A — 5/20 — (25.0%) B/C2 to A/C1 — 11/20 — (55.0%) B/C2/C1 to A — 24/75 — (32.0%) **<6 months resolution** Type — # resolved/# at risk — (%) B to A — 1/4 — (25.0%) B to A/C1 — 1/4 — (25.0%) B to A/C1/C2 — 1/4 — (25.0%) B/C2 to A — 2/20 — (10.0%) B/C2 to A/C1 — 8/20 — (40.0%) B/C2/C1 to A — 25/75 — (33.3%)

[a] See 2189 Poulsen and Tos (1978).

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 2190, 2634, and 2593 for further findings]
2629 Tos 1979 [This cohort is also in articles 2190, 2631, 2634, 2593, 2639, 2642, 4834, and 4835.]	Study Type: [a] Study Quality Score (0–6): [a] OME definition: [a] Group: Healthy two-year-old children residing in two Copenhagen county municipalities N=278 children at initial exam; N=222 children who presented at all 3 follow-up exams. N for type B at cohort inception=60. N for type B/C2 at cohort inception=172. N for type B/C2/C1 at cohort inception=280.	Time: 11/1977–8/1978 [a] Place: [a] Inclusion: [a] Exclusion: [a]	Type of OME: [a] Age: [a] Examiner(s): [a] OME diagnostic method: [a] Interventions: [a] Interval of screening: 3, 6, and 9 months after initial diagnosis [a]	OME resolution by **ea**r using the initial 11/1977 denominators from Table I in article 2631 (Table III) **<9 months resolution** Type # resolved/# at risk (%) B to A 19/51 (37.3%) B to A/C1 36/51 (70.6%) B to A/C1/C2 43/51 (84.3%) B/C2 to A 63/138 (45.7%) B/C2 to A/C1 100/138 (72.5%) B/C2/C1 to A 118/229 (51.5%)

[a] See 2190 Poulsen and Tos (1980).

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 2629, 2190, and 2593 and 2189 and 2627 for further findings]
2634 Tos 1980 [The 1976 cohort is also in articles 2190, 2629, 2631, 2593, 2639, 2642, 4834, and 4835. The 1977 cohort is also in articles 2189, 2627, 2631, 2639, 2642, 4834, and 4835.]	Study Type: [a] Study Quality Score (0–6): [a] OME definition: [a] Group: [a] N=[a]	Time: [a] Place: [a] Inclusion: [a] Exclusion: [a]	Type of OME: [a] Age: [a] Examiner(s): [a] OME diagnostic method: [a] Interventions: [a] Interval of screening: [a]	OME resolution by **ear** (Table III) **<3 months resolution** Type # resolved/# at risk (%) B to A 6/51 (11.8%) B to A/C1 13/51 (25.5%) B to A/C1/C2 27/51 (52.9%) **<6 months resolution** Type # resolved/# at risk (%) B to A 15/51 (29.4%) B to A/C1 21/51 (41.2%) B to A/C1/C2 30/51 (58.8%) **<9 months resolution** Type # resolved/# at risk (%) B to A 19/51 (37.3%) B to A/C1 36/51 (70.6%) B to A/C1/C2 43/51 (84.3%) Cumulative OME resolution by **ear** **<3 months resolution** (same as above) **<6 months resolution** Type # resolved/# at risk (%) B to A 16/51 (31.4%) B to A/C1 24/51 (47.1%) B to A/C1/C2 34/51 (66.7%) **<9 months resolution** Type # resolved/# at risk (%) B to A 24/51 (47.1%) B to A/C1 34/51 (66.7%) B to A/C1/C2 44/51 (86.3%)

[a] See articles 2190 Poulsen and Tos (1980) and 2189 Poulsen and Tos (1978).

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 1486 for further findings]
543 Tos, Holm-Jensen, Sørenson, and Mogensen 1982 [This cohort is also in articles 1486, 2636, 2639, 2642, 4834, and 4835.]	Study Type: [a] Study Quality (0–6): [a] OME definition: [a] Group: [a] N=288 children who attended all 4 follow-up exams N for type B at cohort inception=101 ears (note difference from article 1486). N for type B/C2 at cohort inception=317 ears (note difference from article 1486). N for type B/C2/C1 at cohort inception=477 ears.	Time: The authors identify this study as their 1976 birth cohort, but it is actually their 1975 birth cohort. [a] Place: [a] Inclusion: [a] Exclusion: [a]	Type of OME: [a] Age: [a] Examiner(s): two experienced technicians [a] OME diagnostic method: [a] Interventions: [a] Interval of screening: [a]	OME resolution by **ear** **<3 months resolution** (Figure 1) Type / # resolved/# at risk / (%) B to A 3/87 (3.4%) B to A/C1 12/87 (13.8%) B to A/C1/C2 51/87 (58.6%) B/C2 to A 49/265 (18.5%) B/C2 to A/C1 102/265 (38.5%) B/C2/C1 to A 103/393 (26.2%) **<6 months resolution** (Figure 1) Type / # resolved/# at risk / (%) B to A 14/87 (16.1%) B to A/C1 22/87 (25.3%) B to A/C1/C2 49/87 (56.3%) B/C2 to A 51/265 (19.2%) B/C2 to A/C1 118/265 (44.5%) B/C2/C1 to A 96/393 (24.4%) **<9 months resolution** (Figures 3 and 4) Type / # resolved/# at risk / (%) B to A/C1 20/82 (24.4%) B to A/C1/C2 39/82 (47.6%) B/C2 to A/C1 106/247 (42.9%) **<12 months resolution** (Figures 3 and 4) Type / # resolved/# at risk / (%) B to A/C1 15/82 (18.3%) B to A/C1/C2 42/82 (51.2%) B/C2 to A/C1 76/247 (30.8%)

[a] See 1486 Holm-Jensen, Sørenson, and Tos (1981) and 2636 Tos (1981).

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings [See 1486 for further findings]
543 Tos, Holm-Jensen, Sørenson, and Mogensen 1982 [This cohort is also in articles 1486, 2636, 2639, 2642, 4834, and 4835.]				Cumulative OME resolution by **ear** **<3 months resolution** (same as above) **<6 months resolution** (Figure 1) Type # resolved/# at risk (%) B to A 17/87 (19.5%) B to A/C1 31/87 (35.6%) B to A/C1/C2 62/87 (71.3%) B/C2 to A 85/265 (32.1%) B/C2 to A/C1 152/265 (57.4%) B/C2/C1 to A 152/393 (38.7%) **<9 months resolution** (Figures 3 and 4) Type # resolved/# at risk (%) B to A/C1 37/82 (45.1%) B to A/C1/C2 60/82 (73.2%) B/C2 to A/C1 166/247 (67.2%) **<12 months resolution** (Figures 3 and 4) Type # resolved/# at risk (%) B to A/C1 41/82 (50.0%) B to A/C1/C2 64/82 (78.1%) B/C2 to A/C1 174/247 (70.5%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
91 van Balen, de Melker, Touw-Otten 1996	Study Type: prospective single cohort embedded in a randomized controlled trial Study Quality (0–6): 3(111000) OME definition: presence of fluid in the middle-ear cavity behind an intact tympanic membrane without signs or symptoms of acute infection Group: children with bilateral OME N=433	Time: recruited 12/1992 to 8/1994 and then followed for 3 months Place: 57 general practices in the Netherlands Inclusion: • 6 months to 6 years old • bilateral OME Exclusion: none	Type of OME: newly diagnosed OME of unknown duration Age: 6 months to 6 years old Laterality: all bilateral Examiner(s): general practitioner trained in tympanometry OME diagnostic method: tympanometry • A: –99 to +200 dPa and max compliance >= 0.2 mmho • B: <= –400 dPa and max compliance < 0.2 mmho • C1: –199 to –100 dPa and max compliance >=0.2 mmho • C2: –399 to –200 dPa and max compliance >= 0.2 mmho • Middle-ear effusion defined by B or C2 curves. Interventions: Authors stated children received no treatment for their ear problems and noted that "In the Netherlands it is not common to treat OME with antimicrobial drugs." It is possible antibiotics were used during the watchful waiting period. Interval of screening: 3 months after initial exam	OME resolution by **child** (Figure) Time # resolved/# at risk (%) **<3 months** 223/433 (51.5%) [Authors did not distinguish between partial and complete resolution.]

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
2791 Williamson 1994	Study Type: prospective single cohort Study Quality Score (0–6): 2(110000) OME definition: not defined Group: Children attending four adjacent Infant and First schools in South West Hampshire participating schools and screened by tympanometry once per term at a four-month interval until they left primary school N=856 subjects	Time: Recruitment 9/1988–3/1989; study period ended summer 1991 Place: School medical room in four adjacent Infant and First Schools in the SW Hampshire area Inclusion: • 5–8 years old • attending four attending four adjacent Infant and First schools in South West Hampshire Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: 5–8 years old Examiner(s): unknown OME diagnostic method: tympanometry • A: 200 to –99 pressure • B: lack of defined compliance maximum • C1: –100 to –199 pressure • C2: –200 to –400 pressure Interventions: The authors report that 27 children had grommets in situ during the study period. This includes 6 children in the Spring 1990 cohort with type B tympanograms whose OME resolution is reported. Interval of screening: once per term at a four-month interval until the child left primary school	OME resolution of a cohort with **type B tympanogram** in Spring of 1990 (We assume the denominator at each time is the total.) (page 932) **Resolution by CHILD** Resolution Time # resolved/# at risk (%) <4 months 22/50 (44.0%) <8 months 38/50 (76.0%) <1 year 45/50 (90.0%) **Resolution by EAR** Resolution Time # resolved/# at risk (%) <4 months 35/67 (52.2%) <8 months 52/67 (77.6%) <1 year 61/67 (91.0%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Inclusion/Exclusion Criteria	Influencing Factors	Findings
2863 Zielhuis, Rach, and van den Broek 1990	Study Type: prospective single cohort Study Quality Score (0–6): 3(111000) OME definition: type B tympanogram signified OME but otherwise not defined Group: Preschool children seen in follow-up for OME every 3 months from 2–4 years of age (n=609 children had all nine total screenings out of 1328 whose parents agreed to participate) N=1328 subjects	Time: Follow-up from age 2–4 years in children born between 9/1/1982–8/31/1983 Place: Measurements carried out at the children's home in Nijmegen, The Netherlands Inclusion: • Age: 4 years • born in Nijmegen during the period 9/1/1982–8/31/1983 and living in Nijmegen on their 2nd birthday • screened every 3 months since 2 years of age • parental consent Exclusion: None	Type of OME: newly diagnosed OME of unknown duration Age: 4 years old Examiner(s): three trained audiologic assistants OME diagnostic method: tympanometry • A: compliance ≥0.2 ml and pressure ≥–99 dPa • B: compliance <0.2 ml and pressure ≤ –400 dPa • C1: compliance ≥0.2 ml and pressure –100 to –199 dPa • C2: compliance ≥0.2 ml and pressure –200 to –399 dPa • B: compliance <0.2 ml and pressure ≤ –400 dPa Interventions: The authors did not mention control of medications. 56 of the children were treated with ventilating tubes. Interval of screening: every 3 months after initial screen until 4 years old	The authors presented an equation to estimate resolution of first OME episode by **ear** based on the study data. (page 217) y=2exp(–0.33x) y=probability of OME x=follow-up in months r^2=0.98 Duration of all OME by ear (Figure 4) Mean: 5.0 months Standard error of mean: 0.08 months 5th %ile: 3 months 25th %ile: 3 months median: 3 months 75th %ile: 6 months 95th %ile: 12 months [mixture of OME diagnosed at initial screen and OME arising during the study period] Estimated cumulative OME resolution by **ear** based on the above equation and numbers given in Figure 2 (N=1631 ears of 816 children) Time # resolved/# at risk (%) <3 months 816/1631 (50.0%) <6 months 1223/1631 (75.0%)

Evidence Table 1. Natural History of Otitis Media with Effusion (Continued)

Record# Author Year	Findings
2863 Zielhuis, Rach, and van den Broek 1990	Duration of all OME episodes by ear by influencing factors (Table 3)

Factor	Category	% with duration of 3 months	6 months	9 months or more	Mean Duration	p-value
Season at start of OME	Autumn	59.7%	19.5%	20.8%	4.8	<0.001
	Winter	65.6%	17.7%	16.7%	4.5	
	Spring	61.3%	24.2%	14.5%	4.6	
	Summer	69.0%	20.2%	10.8%	4.3	
Age at end of episode	24-29	77.9%	22.1%	0.0%	3.7	<0.001
	30-35	60.4%	19.5%	20.1%	4.8	
	36-41	64.4%	20.7%	14.9%	4.5	
	42-48	56.6%	19.4%	20.0%	5.0	
Sex	Male	64.4%	20.9%	14.7%	4.5	0.44
	Female	63.7%	19.7%	16.6%	4.6	
Upper respiratory tract infection	Yes	64.4%	19.5%	16.1%	4.6	0.24
	No	63.8%	22.2%	14.0%	4.5	
History of acute otitis media	Yes	62.1%	23.0%	14.9%	4.6	0.77
	No	57.1%	24.5%	18.4%	4.8	

[mixture of OME diagnosed at initial screen and OME arising during the study period]

[Actual counts were not presented and could not be derived.]

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development

[The eight components of study quality score are: study cohort clearly defined; subjects assembled at a uniform time point; pathway of subject entry clearly described; complete follow-up achieved; withdrawals/drop-outs described; objective outcomes used; outcome assessment blinded; and extraneous factors adjusted. 1 indicates presence and 0 indicates absence.]

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
877 Black 1993	Prospective Cohorts Study Study Quality Score (0–8): 3 (00001101) OM Diagnosis: By otologic examination by unspecified examiner. OM Groups: Group 1: OM+: High Infant Otitis Media (at least two cases of otitis media within the first year of life documented by otologic examination) Group 2: OM–: No Infant Otitis Media (Had not experienced otitis media during first year of life) N=31 subjects N1=21 N2=10	Time: 4-year follow-up (actual time of study not specified) Place: Inner-city sample in Baltimore, Maryland Characteristics: • 87% had African-American primary caregivers • 61% had not completed high school • 81% single women • 91% received medical assistance • all children were enrolled in kindergarten or Head Start I Inclusion: • Age: 4 years follow-up of the original cohort of infants • partipated in authors earlier study • Born at term with appropriate weight for gestational age • No medical problems beyond OM Exclusion: None	Age: OM history: first year of life Outcomes: 4–6 years of age OM History: At least 2 episodes of OM within the first year documented of otologic exam. A child could receive credit for only one bout of OM within each 29-day period. Outcome Measures: *Cognitive development*: McCarthy Scales of Children's Abilities (verbal, perceptual processing, quantitative, memory, and motor). Each has a mean score of 50 and a standard deviation (SD) of 10. Scores on the first 3 scales are summed to give a GCI with a mean (SD) of 100 (15). *Language development*: Peabody Picture Vocabulary Test-Revised, an assessment of receptive language. Has mean (SD) of 100 (15).	OM+ / OM– Test: Mean (SD) / Mean (SD) McCarthy Scales Verbal: 46.7 (11.5) / 41.0 (10.7) Perceptual: 47.5 (12.8) / 43.2 (11.4) Quantitative: 43.6 (8.6) / 39.1 (10.5) Memory: 46.0 (10.6) / 41.5 (12.0) Motor: 53.0 (12.4) / 36.4 (10.2) GCI[a]: 92.6 (19.5) / 84.9 (19.3) PPVT–R[b]: 82.9 (17.3) / 72.4 (17.6) [a] General cognitive index [b] Peabody Picture Vocabulary Test–Revised

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1219 Feagans 1987	Prospective cohort study Study Quality Score (0–8): 5 (11100101) OM Diagnosis: OM diagnosed by 2 pediatricians and 2 nurse practitioners using pneumatic otoscopy. Beginning 1978 tympanometry was used to corroborate the diagnosis Group: Children who were part of a medical and day care intervention project N=44 subjects	Time: 1972–1982 Place: Children were sampled from a day care center in Pennsylvania Characteristics: • Black • Low socioeconomic status; • Attended day care center 50 weeks per year from 6 weeks to 5 years of age. Inclusion: • Age: 5–7 years (measures at both time points) • children who were followed from birth to 2nd grade • biologically normal at birth • high risk for general developmental delays in language and intelligence due to low SES Exclusion: None	Age: OM History: 0–3 year of life Outcomes: at 5–7 years of age OM History: Frequency of OM Duration of OM Outcome Measures: Mean length of utterance (MLU) at age 5 Mean length of utterance (MLU) at age 6 Paraphrase score at age 5 Paraphrase score at age 6 Predictors in the study: Mother's IQ at birth Mother's education Home environment (HOME) at 18 months Language (WPPSI IQ) at age 5 Frequency of OM in 0–3 years of life Duration of OM in 0–3 years of life	Mean (SD) Length of utterance At age 5 10.3 (2.9) At age 7 12.4 (3.8) Paraphrase score At age 5 7.2 (1.4) At age 7 8.0 (1.0) **Multiple regression analysis-Age 5** MLU: R^2 = 0.07, p>0.10, no variable significant. Paraphrase score: R^2 = 0.47, p<0.001, WPPSI IQ most significant followed by frequency of OM. **Multiple regression analysis-Age 7** MLU: R^2 = 0.13, p<0.20; IQ was the only significant predictor (R^2= 0.12, p<0.02). Paraphrase score: R^2 = 0.22, p>0.11; WPPSI and duration of OM were significant predictors (R^2= 0.18, p<0.02)

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1255 Fischler 1985	Retrospective-prospective study Study Quality Score (0–8): 5 (11001110) OM Diagnosis: By medical record review of documented physician's clinical diagnosis. OM Groups: Group 1: HR/REC (HR-High risk status,REC-recurrences of OM attacks after age 2) ~ >=2 attacks by age 2 yr and >=3 attacks after age 2 yr Group 2: HR/NREC ~ >=2 attacks by age 2 yr and <3 attacks after age 2 yr Group 3: NHR/NREC ~ <2 attacks by age 2 yr and <3 attacks after age 2 yr N=167 N1=33 N2=63 N3=71	Time: Start date~7/1974 Place: Four Indian reservations in Arizona Characteristics: • 50% had family income under $5000 per year • 37% had housing below average • 13% primarily Apache speaking at home Inclusion: • Age: 6–8 years • healthy Apache Indian children who had been followed since birth Exclusion: • moved during study period • absent or not tested because of time constraints • medical reasons (specific conditions not specified)	Age: OM history: 0–2 years of life Outcome: at 6–8 years Examiner(s): • Unspecified physicians for diagnosis of otitis media; • School nurse for hearing tests; • Pediatrician/otolaryngologist for otoscopic examinations; • Certified speech pathologists for language testing. OM history: Groups defined by number of OM episodes by age 2 Outcome measures: • Four subtests of the Test of Language Development (TOLD). • Two receptive language subtests (picture vocabulary [PV] and grammatic understanding [GU]) • Two expressive subtests (grammatic completion [GC] and oral vocabulary [OV]) • Articulation: informally scored as normal or suspect • Nonverbal intelligence by the block-design subtest of the Wechsler Intelligence Scale for Children-Revised (WISC-R) [For all subtests raw scores were converted into age standardized scores. Standard scores were based on national norms having mean (SD) of 10 (3).]	Mean (SD) Group 1 / Group 2 / Group 3 OM risk: High / Moderate / Low TOLD subtest Receptive language PV 5.6 (2.3) / 6.8 (2.8) / 6.1 (2.7) GU 7.2 (2.2) / 8.1 (2.3) / 7.9 (2.1) TOLD subtest Expressive language GC 5.0 (1.7) / 5.7 (1.9) / 5.4 (2.4) OV 6.1 (3.0) / 7.7 (2.8) / 7.1 (2.7) WISC-R block design Non-verbal intelligence 10.6 (2.9) / 10.4 (3.1) / 10.0 (2.7)

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1277 Freeark 1992	Retrospective-Prospective Cohort Study Study Quality Score (0–8): 4 (10000111) OM Diagnosis: By whom, not specified; How diagnosed, not specified. (OM history obtained from medical records). OM Groups: Group 1: High OM: Above median of OM severity defined by frequency of OM episodes and days with effusion. Group 2: Low OM: Below median of OM severity defined by frequency of OM episodes and days with effusion. N=54 subjects N1=26 N2=28	Time: not specified Place: university-based pediatric clinic, Michigan Characteristics: • 86% white • 82% of mothers and 91% of fathers with at least some college education • 77% of fathers in lower middle to upper middle class occupations or were full-time graduate students • 75% of mothers employed Inclusion: • Age: 3–4 years • in patient roster of a university-based pediatric clinic • both parents living in home • parents had at least a high school ed. and not receiving public assistance • family had no more than four children • child did not suffer from a chronic illness or disability Exclusion: None	Age: OM history: 0–3 years of life Outcome: 3–4 years Examiner(s): Trained examiners for language testing. OM History: OM severity defined by a) number of separate episodes of otitis and b) total number of days of effusion over the first 3 years. Outcome measures: Verbal Scale Index (VSI) of the McCarthy Scale of Children's Abilities – a summary measure of the child's verbal abilities derived from 6 subtests assessing verbal fluency and memory, word knowledge, and verbal reasoning. Stratification Factor: Parent Verbal Stimulation (PVS) – total frequency of mothers' and fathers' descriptive and reflective statements and questions during the first 10 minutes of the dyadic interaction.	VSI below mean (# and %) High OM / Low OM High PVS Group: 2/14 (14%) / 10/14 (71%) Low PVS Group: 8/12 (67%) / 4/14 (29%) Total: 10/26 (38%) / 14/28 (50%) Hierarchical multiple regression analysis showed that interactions between parent verbal stimulation and otitis severity were significant in predicting the VSI and the VIP score for the interaction segment with fathers.

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1373 Gravel 1992 Same cohort in 1941, 2295 and 4728. See 1941, 2295, and 4728 for further comments.	Prospective Cohort Study Study Quality Score (0–8): 5 (11001110) OM Diagnosis: Pediatric nurse practitioners completed pneumo-otoscopic examinations. OM Groups: Group 1: OM+: Otitis positive children – when bilateral OM was detected at 30% or more of the baby's first year visits. (Also, had poorer auditory sensitivity by click ABR.) Group 2: OM–: Otitis negative children – when middle ear status was rated as normal in both ears during 80% or more of the first year visits. N=23 N1=10 N2=13	Time: not specified Place: Clinical Research Center for Communicative Disorders (which draws subjects from the LIFE Program of the R.F. Kennedy Center, Albert Einstein College of Med. Bronx, NY Characteristics: • low socioeconomic urban neighborhoods based on Hollingshead's (1975) index • none had sensorineural hearing loss Inclusion: • Age: 4 years (measures taken during first year of life as well) • all children were enrolled at 40 wks postconceptional age for follow-up through the LIFE Program • either high-risk infant graduates of a NICU or FT graduates of the well-baby nursery of Jacobi Hospital • English reported as the primary language spoken Exclusion: • neurologically compromised	Age: OM history: 0–1 of life Outcome: at 4 years of age Examiner(s): Not specified OM history: OM groups were defined by otoscopic histories. Outcome measures: *Cognitive measures* (Stanford-Binet 4th Edition): Composite IQ Score Verbal reasoning Abstract/visual reasoning Quantitative reasoning, Short-term memory *Language measure* (Sequenced Inventory of Communication Development-Revised (SICD-R) – a standardized measure of communicative functioning combining parental report with direct assessment: Expressive scale Receptive scale	Mean (SD) OM+ / OM– Cognitive N: 9 / 13 Global IQ: 87.8 (14.8) / 86.0 (8.6) Verbal IQ: 88.3 (15.9) / 84.3 (9.4) Expressive language in months N: 8 / 12 Mean (SD): 36.0 (5.2) / 39.0 (6.2) Receptive language in months N: 8 / 13 Mean (SD): 35.5 (5.4) / 37.8 (5.3)

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
4728 Gravel 1996 Same study subjects as 1373, 1941, 2295 See 1373, 1941, and 2295 for further comments.	Prospective Cohort Study Study Quality Score (0–8): 3 (01000110) OM Diagnosis: Pediatric nurse practitioners completed pneumo-otoscopic examinations. OM Groups: Group 1: Otitis positive children – when bilateral OM was detected at 30% or more of the baby's first year visits. Group 2: Otitis negative children – when middle ear status was rated as normal in both ears during 80% or more of the first year visits. N=17 subjects N1=10 N2=7	Time: not specified Place: Clinical Research Center for Communicative Disorders (which draws subjects from the LIFE Program of the R.F. Kennedy Center, Albert Einstein College of Med. Bronx, NY Characteristics: • low socioeconomic urban neighborhoods based on Hollingshead's (1975) index • all had normal hearing and normal middle-ear function on test day Inclusion: • Age: 9 years • born in the same urban hospital • auditory testing conducted during first year of life and at 9 years of age Exclusion: None	Age: OM history: 0–1 of life Outcome: at 9 years of age Examiner(s): Not specified OM history: OM groups were defined by otoscopic histories. Outcome measures: • Binaural masking level difference (MLD) • Speech-in-competition task-adapted from the Pediatric Speech Intelligibility (PSI) test • Selected auditory attention task – An experimental version of the PSI • Story memory tasks – a subset of the standardized Wide Range Assessment of Memory and Learning (WRAML) • Clinical Evaluation of Language Fundamentals-Revised (CELF-R)	No raw data were reported. The following were reported between OM+ and OM– groups: 1. A significant difference between the early OM+ and early OM– groups was found on the story-recall memory task (t=2.42; p=0.032). 2. No significant differences between the groups were found on the MLD, competitive listening tasks, language screen, the PSI selective auditory attention task, or the story recognition-memory task.

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1435 Harsten 1993	Prospective Cohort Study Study Quality Score (0–8): 6 (11101110) OM Diagnosis: AOM was diagnosed by otomicropscopy, performed by an otolaryngologist and defined as an acute episode of earache in a child, with red bulging eardrum(s) or purulent discharge, occasionally febrile and with signs of upper respiratory tract infection. OM Groups: Group 1: Children with recurrent AOM (RAOM defined as at least six episodes of AOM during a 12-month period) during the first 3 years of life Group 2: Children without any AOM episode during the first 3 years of life N=42 subjects N1=13 N2=29	Time: not specified Place: University Hospital of Lund, Sweden Characteristics: • 45% first-borns • 71% mother educated at college level Inclusion: • Age: Birth cohort • monolingual, Swedish children, born at University Hospital of Lund Exclusion: None	Age: OM history: 0–3 year of life Outcomes: at 4 and 7 year of age Examiner(s): Otolaryngologist for otomicroscopy, tympanometry, tone-audiograms Phoniatrician and clinical linguist for hearing and speech OM history: Groups defined by number of episodes of AOM during a 12 month period. Outcomes: • Phonology – based on material from *the phoneme test* and producing word pairs of the *auditory discrimination task*. • Grammar – from the *Ringsted material* • Interaction – *Thematic pictures* were used for this analysis • Grammatical and interactional analysis – based on sequential pictures and thematic pictures	Phonology % (#) had traces of deviance/deviant RAOM Healthy Age 4 69% (9/13) 76% (22/29) Age 7 83% (10/12) 54% (15/28) Grammar % (#) abnormal RAOM Healthy Age 4 0% (0/13) 0% (0/29) Age 7 0% (0/12) 0% (0/28) Interaction % (#) had traces of deviance RAOM Healthy Age 4 31% (4/13) 21% (6/29) Age 7 17% (2/12) 39% (11/28) RAOM=recurrent acute otitis media

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1623 Kaplan 1973	Prospective Cohort Study Study Quality Score (0–8): 6 (11001111) OM Diagnosis: A research nurse visited the cohort children 4 times a year during first 2 years and at least 2 times a year for the next 2 years. During each visit, information concerning middle ear abnormality was obtained and medical records of the time between visits were reviewed. Only OM described with otorrhea was used for analysis. OM Groups: Group 1: age of onset of first otorrhea at 0–1 year of age Group 2: age of onset of first otorrhea at age 2–10 years Group 3: no history of otorrhea N=489 N1=291 N2=83 N3=115	Time: Birth cohort (10/1960–12/1962); follow-up conducted between 9/1969–7/1971 Place: 28 Eskimo villages located in the Yukon and Kuskokwim River Delta areas of Southwestern Alaska Characteristics: Not described. Inclusion: • Age: Birth Cohort born between 10/1960–12/1962 and followed up between 9/1969–7/1971 • born in 25 villages w/in Alaska specified under place and/or residing in 3 additional villages at follow-up Exclusion: • Children with pure sensory hearing loss were excluded from analysis	Age: OM history: 0–1 year of life Outcome: at 10 years of age Examiner(s): Experienced audiologist for air and bone conduction measurements Two psychologists administered speech and intelligence testing OM history: Groups based on onset of first episode of otorrhea during 0–1 year; during 2–10 years or no history. Outcomes: • Wechsler Intelligence Scale for Children (WISC) – modified • Bender-Gestalt test • Draw-A-Person test Stratification Factor: Concurrent hearing status: No hearing loss or conductive component or hearing loss at 26+dB	**No Hearing Loss Group** 1st om at: Group 1 0–1y / Group 2 2–12y / Group 3 noOM N: 88 / 32 / 53 Verbal Score Mean: 80 / 79 / 81 Range: (50–100) / (55–105) / (55–105) Performance Score Mean: 100 / 100 / 102 Range: (70–140) / (70–125) / (70–135) **Conductive Component Group** 1st om at: Group 1 0–1y / Group 2 2–12y / Group 3 noOM N: 42 / 8 / 17 Verbal Score Mean: 70 / 80 / 76 Range: (45–90) / (60–100) / (55–90) Performance Score Mean: 92 / 100 / 95 Range: (55–125) / (85–110) / (75–115) **Hearing Loss 26+dB Group** 1st om at: Group 1 0–1y / Group 2 2–12y / Group 3 noOM N: 32 / 5 / 6 Verbal Score Mean: 72 / 71 / 80 Range: (55–100) / (55–85) / (60–100) Performance Score Mean: 95 / 94 / 101 Range: (55–125) / (70–120) / (70–115)

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
4651 Klein 1988	Prospective Cohort Study Study Quality Score (0–8): 4 (10100101) OM Diagnosis: By pediatricians using pneumatic otoscopy until age 3 and both pneumatic otoscopy and tympanometry in years 4 through 7. OM Groups: Group 1: Time spent with effusion <32 days during first 2 years of life Group 2: Time spent with effusion 33–108 days during first 2 years of life Group 3: Time spend with effusion >108 days during first 2 years of life. N=196 subjects Number of subjects by groups not given	Time: Enrollment of infants began in 1975 & continued for 2 yrs (7-year follow-up) Place: Private practices in Holliston and Framingham, MA, and an urban health center in East Boston Inclusion: • Random sample of children still active in the practices at age 7. Exclusion: • parental refusal • nonwhite race • English not the primary language spoken at home • Seizures • mental retardation, cerebral palsy • hearing loss >20db at time of testing (deferred until able to pass hearing test)	Age: OM history: first 3 years of life (recruited at <3 months of life) Outcome: at 7 years of age Examiner(s): Pediatricians for OM history. Not mentioned for speech and language testing. OM History: • Criteria for effusion – otorrhea, gas-liquid levels visible on otoscopy or marked reduction of mobility. Tympanometric criterion: type B curve. • Time spent with effusion – assigned a 'window' of 23 days to each observation of effusion, whether accompanied by signs of illness or not. It could be shortened or extended by multiple examinations. Outcome measure: • Wechsler Intelligence Scale for Children-Revised (WISC-R) • Goldman-Fristoe-Woodcock test • WUG test • Peabody Picture Vocabulary Test • Boston Naming Test • A recorded language sample • Metropolitan Achievement Test (reading and mathematics)	No raw data were given. Multivariate results were reported as follows: Least square (LS) mean and standard error (SE) of full scale WISC-R controlling for socioeconomic status and sex: Effusion Group Group 1 <32 d / Group 2 33–108 d / Group 3 >108 d LS mean 113.4 / 107.5 / 105.6 SE 1.41 / 1.49 / 1.34 Group 1 vs Group 2, p=0.005 Group 1 vs Group 3, p<0.0001 Group 2 vs Group 3, p=NS. The investigators report that 'similar results were found in both the performance and verbal scores. Speech and language measures significantly associated with otitis media during the first 3 years of life included aspects of speech production, speech perception, morphologic production, morphologic comprehension, lexical production, and syntactic production.

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1941 Mody 1999 Same study as 4780 Mody 1996 Same cohort as 1373, 2295, and 4728. See 1373, 2295, and 4728 for further comments.	Prospective Cohort Study Study Quality Score (0–8): 4 (11000101) OM Diagnosis: By trained and validated pediatric nurse practitioner (PNP) using a pneumatic otoscope under the supervision of a pediatric otolaryngologist. The PNP recorded a description of TM characteristics for each ear, using a 9-item otoscopic checklist and made the determination of "clear," "suspicious," or "positive" for OM. OM Group: Group 1: OM+: (Children who had 30% or more of the 13 first-year visits with otitis media bilaterally) Group 2: OM–: (Children who had 80% or more of the 13 first-year visits with normal middle ear findings bilaterally) N=14 subjects N1=7 N2=7	Time: Follow-up from birth to 9 years (actual dates not specified) Place: Subjects recruited from Longitudinal Infant Follow-up and Evaluation (LIFE) program of the Rose F. Kennedy Center, Albert Einstein College of Medicine, New York, NY Characteristics: • 71% high risk births • 64% male • 57% African-American • 36% Hispanic • 64% low SES • 36% middle SES Inclusion: • Age: 9 years (followed from birth) • English is the primary language spoken in the home • received all medical, audiological, and developmental assessments through the LIFE program at monthly evaluations from birth through first year • normal hearing and normal middle ear function on test day Exclusion: • neurologically compromised as an infant	Age: OM history: first year of life Outcome: at 9 years of age Examiner(s): Trained and validated pediatric nurse practitioner for OM history; Type of examiner(s) not specified for speech and language testing. OM history: Defined by pneumatic otoscopy findings during first year of life. Outcome measures: • Four nonsense syllables (/sβ /, /zβ /, /kβ /, /gβ /) presented auditorily • Test on identification and temporal order recall using 4 synthetic speech syllables, /ba/, /da/, /sa/ and /a/.	**Mean number of items correctly reported** OM+ / OM– Serial Position 1: 64 / 69 2: 47 / 53 3: 41 / 57 4: 38 / 53 **Errors by type and number of phonetic features** OM+ / OM– Transposition Errors: 92% / 95% Total errors: 146 / 104 0 shared features: 30 / 18 1 shared feature: 35 / 21 2 shared features: 81 / 65 **Mean (SD) number of errors on identification and temporal order judgment (TOJ)[a]** OM+ / OM– 1. /ba/-/da/ Identification: 1.0(1.0) / 0.4(0.8) TOJ 400: 0.7(1.5) / 0.0(0.0) TOJ (100/50/10): 4.3(3.7) / 1.1(0.9) 2. /sa/-/a/ Identification 2.1(2.3) / 1.7(1.4) TOJ 400 3.1(2.5) / 0.6(0.8) TOJ (100/50/10) 6.7(5.7) / 3.6(3.2) [a] From article 4780.

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
4675 Owen 1996	Prospective Cohort Study Study Quality Score (0–8): 4 (11000101) OM Diagnosis: By trained technicians using automated screening tympanometers with a 226 Hz probe tone. Acoustic reflectivity was also measured using acoustic otoscope at 30% of visits. OME diagnoses were based on type B tympanogram or >= 5 acoustic reflectivity or visible purulent otorrhea without an otoscope. OM Groups: Group 1: High OME (children who had extended OME across first three years of life) Group 2: Early OME (children who had OME which peaked from 0–6 months of age) Group 3: Later OME (children who had OME which peaked from 6–12 months of age) Group 4: Low OME (children who experienced relatively low levels across first 3 yrs of life) N=294 subjects Sample size for each group not specified.	Time: Infants enrolled in program between 1984–1989 (5 yr follow-up) Place: Texas Characteristics: • 49% male • 56% Euro-American • 30% African-American • 14% English-speaking Hispanic • wide socioeconomic range • Half breast fed at birth • 41% had cigarette smoke exposure • 19% mother smoked • 63% attended day care Inclusion: • Age: 5 years (follow-up from birth) • healthy-term infant from English-speaking family Exclusion: None	Age: OM history: 0–3 years of life Outcome: at 5 years of age Examiner(s): Trained technicians for OM history Trained graduate students for language and cognitive testing. OM history: If 2 consecutive visits showed OME, the intervening days were counted as days with OME. If one visit showed OM and the next normal status, or vice versa, half of the intervening days were counted as days with OME. OME duration was defined as the proportion of time a subject spent with OME (total OME days divided by total days) in the period examined. Outcome measures: • Test for Auditory Comprehension of Language-Revised (TACL-R) • Auditory discrimination subtests of the Carrow Auditory Visual Abilities Test (CAVAT) • Goldman-Fristoe test for articulation (G-F) • Carrow Elicited Language Inventory (CELI) • Stanford-Binet Fourth Edition for cognition Covariates: Gender, Ethnicity, Birth rank, Day care attendance, Duration of breast feeding, Cigarette smoke exposure, SES, Educational stimulation at home, Mother's intelligence	Raw results were not reported. The following findings were reported: 1. CELI, a measure of child's productive control of grammar, showed a significant inverse relation to duration of OME [t(266)=–2.62; p=0.01]. 2. Goldman-Fristoe, a measure of articulation errors, OME amount was positively related to articulation errors [t(213)–6.42;p=0.01] 3. CAVAT yielded significant relations for auditory blending and auditory discrimination in quiet modified by ethnicity and breast feeding. 4. TACL-R total and word class scores were also related to OME cluster group. 5. High OME cluster group tended to be most adversely affected, but all relations were moderated, chiefly by ethnicity, breast feeding and home stimulation scores. 6. Association of duration of OME in first 18 months of life and Stanford Binet composite scores: r=–0.11, p<0.05. 7. Association of duration of OME and nonverbal reasoning and visualization factor scores: r=0.13, p<0.05) 8. Associations in 5 and 6 were not substantiated when effects of environmental and demographic variables were controlled in multivariate analysis.

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
2135 Paul 1993	Retrospective-Prospective Cohort Study Study Quality Score (0–8): 3 (00100101) OM Diagnosis: Based on parental reporting. OM Group: Middle ear involvement was defined as either the placement of myringotomy tubes or the presence of six or more ear infections treated by a physician before the second birthday, by parent report. Group 1: OM+: defined by middle ear involvement, stratified by normal or late talkers Group 2: OM–: lack of such middle ear involvement, also stratified by normal or late talkers. N=44 subjects N1=20 (8 normal and 12 late talkers) N2=24 (13 normal and 11 late talkers)	Time: Not specified Place: Portland Oregon. Subjects are subset of those participating in the Portland Language Development Project (PLDP), a longitudinal study of outcomes of early expressive language delay. Characteristics: • all passed speech reception screenings • 15–33% of each subgroup had abnormal tympanograms Inclusion: • Age: 20–34 at entrance • subjects recruited from children participating in the Portland Language Development Project (PLDP) Exclusion: None	Age: OM history: first 2 years of life Outcome: at 3 and 4 years of age Examiner(s): Certified audiologist in sound-treated booth. OM History: Based on parental reports. Outcome measures: • Goldman-Fristoe Test of Articulation at age 3 • Word Articulation subtest of the Test of Language Development-Primary at age 4. • Sample of free speech collected during a 15-minute play interaction between mother and child at ages 3 and 4. • Speech samples were used to compute mean length of utterance (MLU) in morphemes for each sample. Stratification groups: Children were placed in normal versus late talking (LT) groups on the basis of their expressive vocabulary size as reported by parents on the Language Development Survey (LDS) at intake into the PLDP.	**MLU – Mean (SD)** OM+ / OM– Normal Talkers n=8 / n=13 Age 3 4.26 (1.56) / 4.05 (0.85) Age 4 4.82 (0.32) / 4.55 (0.89) Late Talkers n=12 / n=11 Age 3 2.42 (0.60) / 2.61 (0.79) Age 4 4.08 (1.05) / 3.91 (1.09) **Goldman-Fristoe %tile – Mean (SD)** OM+ / OM– Normal Talkers[a] n=8 / n=13 Age 3 58.9 (33.0) / 62.3 (32.4) Age 4 57.1 (26.0) / 54.5 (37.8) Late Talkers[a] n=12 / n=11 Age 3 12.3 (10.8) / 18.9 (19.8) Age 4 17.8 (19.0) / 31.6 (28.6) [a] Children who at 20 to 34 months of age used fewer than 50 words were assigned to the LT group. About one-third of the LT subjects showed some delay in receptive language abilities, but they generally scored within 6 months of age level on the Reynell Receptive Language Scales.

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
4657 Roberts 1986 4656 Roberts 1989 Same study subjects as in 4806/ 3118, 3117, and 4319. See 4806/ 3118, 3117, and 4319 for further comments.	Prospective Cohort Study Study Quality Score (0–8): 6 (10101111) OM Diagnosis: By pediatricians and pediatric nurse practitioners based on pneumatic otoscopy. 60% time tympanometry was used to corroborate the OME diagnosis. OM Groups: Based on total OME duration in days during first 3 years of life. Group 1: Days with total OME between 0–87 days. Group 2: Days with total OME between 88–181 days. Group 3: Days with total OME over 181 days. N=61 subjects up to 6 years N1=20 N2=20 N3=21 N=44 subjects up to 8 years N1=15 N2=14 N3=15	Time: 9/1972–12/1984 (follow-up from birth to third year of school) Place: Frank Porter Graham Child Development Center, U of North Carolina at Chapel Hill, NC Characteristics of 61 subjects • African American • 57% boys • Average of 10.5 years of education of mother • Mother's mean IQ score was 84. • Hearing was within normal limits at time of testing Inclusion: • Age: 3.5–6 years of age at followup • participant in longitudinal on-site research day-care program • attended the Frank Porter Graham Child Development Center, 5 full days/wk, 50 wks/yr through 5 yrs of age • identified at birth as biologically normal • Classified as at risk for poor school performance Exclusion: • incomplete data	Age: OM history: 2 months–3 years; Outcome: at 3.5–8 years of age Examiner(s): Pediatricians and pediatric nurse practitioners for clinical history Psychologists for measurements of child development. OM History: Duration of each episode of unilateral and bilateral was calculated by subtracting the date of onset of OME from the resolution date. Days of total Outcome measures: Cognitive capacity: • Stanford-Binet Intelligence Scale • McCarthy Scale of Children's Abilities (McCarthy) • Wechsler Preschool and Primary Scale of Intelligence (WPPSI) • Wechsler Intelligence Scale for Children-Revised (WISC-R) verbal scale • Classroom Behavior Inventory (CBI) verbal intelligence Academic achievement: • Peabody Individualized Achievement Test (PIAT) • Woodcock-Johnson Psychoeducational Battery (WJPB)	**Age 3.5–4 years** Mean (SD) McCarthy — Group 1 (n=20), Group 2 (n=20), Group 3 (n=21) Cognitive 103 (12), 104 (10), 100 (8) Verbal 52 (7), 54 (7), 52 (5) Stanford-Binet Intelligence (n=20), (n=20), (n=19) 101 (11), 98 (8), 99 (11) **Age 4.5 years** Mean (SD) McCarthy — Group 1 (n=19), Group 2 (n=20), Group 3 (n=19) Cognitive 100 (13), 103 (9), 97 (10) Verbal 53 (9), 55 (6), 52 (8) **Age 5 years** WPPSI Intelligence (n=19), (n=20), (n=20) Full-scale 102 (12), 101 (10), 98 (11) Verbal 104 (11), 101 (9), 97 (12) Performance 100 (13), 101 (11), 100 (11) **Age 8 years** Groups by OME days <82d (n=15), 83–157d (n=14), >157d (n=15) Intelligence – Verbal IQ WISC-R 98 (13), 96 (14), 94 (10) CBI 14 (5), 12 (3), 12 (3)

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
4806 Roberts 1988 3118 Roberts 1988 Same study subjects as in 4657/ 4656, 3117, and 4319. See 4657/ 4656, 3117, and 4319 for further comments	Prospective Cohort Study Study Quality Score (0–8): 4 (10100101) OM Diagnosis: By pediatricians and pediatric nurse practitioners based on pneumatic otoscopy. 60% time tympanometry was used to corroborate the OME diagnosis. OM Groups Based on total OME duration in days during first 3 years of life. Duration of each episode of unilateral and bilateral was calculated by subtracting the date of onset of OME from the resolution date. Group 1: lower third–OME days (8–143 days) Group 2: middle third–OME days (144–269 days) Group 3: upper third–OME days (314–931 days) N=55 children tested for speech at different ages. 12 tested once; 7 tested 2 times; 19 tested 3 times; 6 tested 4 times and 11 tested 5 times. N=34 in the language study	Time: 1975–1986 study period (8 yr follow-up reported); speech and language measured between 1982–1986 Place: Frank Porter Graham Child Development Center, Un. of North Carolina at Chapel Hill, NC Characteristics: • 93% black, 7% white • 67% boys • All passed hearing screen and had type A or C tympanogram. Inclusion: • Age: 8 years (followed from <3 months) • Attended Frank Porter Graham Child Development Center for 5 days/wk, 50 wks/yr until entry into kindergarten • Socioeconomically disadvantaged • identified at birth as biologically normal • Classified as at risk for poor school performance • Tested for speech and language between 1982–1986 Exclusion: None	Age: OM history: 2 months–3 years; Outcome: at 2.5–8 years of age Examiner(s): Pediatricians and pediatric nurse practitioners for clinical history. Psychologists for measurements of child development. Master's level speech-language pathologists and graduate research assistants collected speech data. OM History: Days of total OME was analyzed both as a continuous and categorical variable. Outcome measures: Speech • Goldman-Fristoe Test of Articulation to which 6 additional words were added. Transcription and Phonology • CER – total number of consonants in error • TPP – total number of phonological processes Language – 15-minute elicited conversational speech sample of language play situation. • Number of words per communication unit (cu) • Dependent clauses per cu • Ratio of total different words to total cu • Ratio of total different conjunction words (excluding 'and' to total cu • Number of utterances per turn.	Spearman coefficient of correlation (R) between number of phonologic processes and total OME days Age(yr) N R P-Value 3 27 –0.04 0.85 4 25 0.29 0.16 5 24 0.31 0.15 6 30 0.29 0.13 7 29 0.18 0.34 8 19 0.10 0.69 Spearman coefficient of correlation (R) between language measures and total OME days at age 5 (n=34) Measure R P-Value Words/cu –0.04 0.83 Dependent Clauses/cu 0.17 0.33 Different Words/cu –0.03 0.89 Different Conjunctions/cu 0.20 0.26 Different Pronouns/cu 0.09 0.62 Regression analysis revealed that (a) children with more OME tended to have a greater total number of phonological processes and (b) Unilateral OME(0–3) provided independent prediction of median TPP given Bilateral OME(0–3), but that Bilateral OME(0–3) was a nonsignificant predictor given Unilateral OME(0–3).

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
3117 Roberts 1991 Same study subjects as in 4657/ 4656, 4806/3118and 4319. See 4657/ 4656, 4806/ 3118, and 4319 for further comments.	Prospective Cohort Study Study Quality Score (0–8): 2 (00000101) OM Diagnosis: By pediatricians and pediatric nurse practitioners based on pneumatic otoscopy. 60% time tympanometry was used to corroborate the OME diagnosis. OM Groups: Based on total OME duration in days during first 3 years of life. Duration of each episode of unilateral and bilateral was calculated by subtracting the date of onset of OME from the resolution date. N=63 subjects Subjects were stratified into two groups SES status: Group 1: LSES (Children from families of lower socioeconomic status) Group 2: MSES (Children from families of middle socioeconomic status) N1=33 N2=30	Time: Cohort of 8–12 children entered every 1–2 years between 1978 and 1985 Place: Attended the Frank Proter Graham Child Development Center (FPG), a research day-care center, University of North Carolina at Chapel Hill Characteristics: LSES / MSES male 64% / 50% black 88% / 33% single mom 82% / 3% • all passed hearing screen, had type A or C tympanogram, and did not have OME Inclusion: • Age: 6 years (follow-up from birth) • attended the Frank Porter Graham Child Development Center • identified at birth as biologically normal • Classified as at risk for poor school performance Exclusion: None	Age: OM history: 2 months–3 years; Outcome: at 4.5–6 years of age Examiner(s): Pediatricians and pediatric nurse practitioners for clinical history. Psychologists for measurements of child development. Master's level speech-language pathologists and research assistants for speech data. OM History: Days of total OME was analyzed both as a continuous and categorical variable. Outcome measures: Language tests Age 4–5 years • Miller-Yoder Language Comprehension Test (M-Y) • Bankson Language Screening Test (Bankson) • Clinical Evaluation of Language Functions (CELF) • Peabody Picture Vocabulary Test-Revised (PPVT-R) At Age 5, 15-minute elicited sample of language play situation • Words/communication unit (cu) • Dependent clauses per cu • Ratio: total different words to total cu • Ratio: total different conjunction words (excluding 'and') to total cu • Ratio: different pronouns to total cu • Number of utterances per turn.	Spearman's correlation coefficient (R) between language outcomes and total OME days during first 3 years of life Measure / LSES N / LSES R / MSES N / MSES R *Standardized Tests* Bankson 25 0.13 22 0.02 M-Y 25 0.08 22 0.14 PPVT-R 24 –0.08 20 0.03 CELF receptive 25 0.25 21 0.24 CELF expressive 24 0.23 21 0.17 *Language Sample* Words/cu 28 0.05 26 –0.22 Dependent Clauses/cu 28 0.04 26 –0.02 Different Words/cu 28 0.26 26 0.00 Different Conjunctions/cu 28 0.02 26 0.13 Different Pronouns/cu 28 0.24 26 –0.12

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings

4319
Roberts
1995
 	
This is a continuation of study by Roberts.
4657
4656
 	
Same study subjects as in 4657/ 4656, 4806/ 3118 and 3117
 	
See 4657/ 4656, 4806/ 3118, and 3117 for further comments.
	Prospective Cohort Study
	
	Study Quality Score (0–8):
	3 (00000111)
	
	OM Diagnosis:
	By pediatricians and pediatric nurse practitioners based on pneumatic otoscopy. 60% time tympanometry was used to corroborate the OME diagnosis.
	
	OM Groups: Based on total OME duration in days during first 3 years of life.
	
	Group: African American children enrolled as infants in research child-care program (follow-up to 12 years of age)
	
	N=56 of 61 subjects reported in 4657 and 4656.
		Time: Cohort assembled 9/1972–12/1984, follow-up from birth to 12 years of age)
		
		Place: Frank Porter Graham Child Development Center, U of North Carolina at Chapel Hill, NC
		
		Characteristics of 61 subjects:
		• African American
		• 57% boys
		• Average of 10.5 years of education of mother
		• Mother's mean IQ score was 84.
		• Hearing was within normal limits at time of testing
		
		Inclusion:
		• Age: 12 years of age at followup
		• participant in longitudinal on-site research day-care program
		• attended the Frank Porter Graham Child Development Center, 5 full days/wk, 50 wks/yr through 5 yrs of age
		• identified at birth as biologically normal
		• Classified as at risk for poor school performance
		
		Exclusion:
		• incomplete data
			Age:
			OM history: 2 months–3 years; Outcome: at 12 years of age
			
			Examiner(s):
			Pediatricians and pediatric nurse practitioners for clinical history
			
			Psychologists for measurements of child development.
			
			OM History:
			Duration of each episode of unilateral and bilateral was calculated by subtracting the date of onset of OME from the resolution date.
			
			Summary measures:
			• No. OME – total number of OME episodes
			• ML/OME – mean length in number of days of the OME episodes
			• Duration OME – number of days with either bilateral or unilateral OME.
			
			Outcome measures:
			Cognitive capacity:
			• Wechsler Intelligence Scale for Children-Revised (WISC-R)
			  • Full-scale IQ
			  • verbal IQ
			  • performance IQ
			  • Freedom from Distractibility Factor
			
			Academic performance:
			• Woodcock-Johnson Psychoeducational Battery
			
			Behavior
			• Child Behavior Checklist
				Correlation coefficient, R, between language outcomes and total OME days during first 3 years of life
				
				At Age 12
				Measure N R1 R2
				Intelligence-WISC-R
				Full scale IQ 56 –0.17 –0.12
				Verbal IQ 56 –0.10 –0.08
				Performance IQ 56 –0.18 –0.13
				
				Where R1 is the simple correlation coefficient and R2 is the standardized regression coefficient adjusted for gender and home environment.
				
				The multivariate tests of the relationships between the ranks of No. OME(0–3) and ML/OME(0–3) during early childhood and the Full-Scale, Verbal, and Performance IQ were not significant either when the HOME or gender were considered or ignored.

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
2295 Ruben 1997 Same study cohort as 1373, 1941, and 4728 by Gravel See 1373, 1941, and 4728 for further comments.	Prospective Cohort Study Study Quality Score (0–8): 5 (11001110) OM Diagnosis: Pediatric nurse practitioners completed pneumo-otoscopic examinations. OM Groups: Group 1: Otitis positive children – when bilateral OM was detected at 30% or more of the baby's first year visits. Group 2: Otitis negative children – when middle ear status was rated as normal in both ears during 80% or more of the first year visits. N=30 subjects N1=18 N2=12	Time: not specified Place: Clinical Research Center for Communicative Disorders (which draws subjects from the LIFE Program of the R.F. Kennedy Center, Albert Einstein College of Med. Bronx, NY Characteristics: • low socioeconomic urban neighborhoods based on Hollingshead's (1975) index Inclusion: • Age: 9 years • born in the same urban hospital • auditory testing conducted during first year of life and at 9 years of age Exclusion: None	Age: OM history: 0–1 of life Outcome: 2–9 years of age Examiner(s): Not specified OM history: OM groups were defined by otoscopic histories. Outcome measures: 18 measures of communicative function was measured. Data were summarized by calculating the mean score for OM– group and then comparing the score of each child in the OM+ group with that of the mean for the OM– group. Each OM+ score that was >= the mean of the OM– group was counted and the percent of children in the OM+ group who had higher scores than the OM– was calculated for each measure. Differences between the groups were considered meaningful when less than 40% of the OM+ children in the group exceeded the score of the OM– group.	Percent OM+ children performed more poorly than the OM- in the following measure: Measure % Expressive language at 1 yr 0% Expressive language at 2 yr 8% Expressive language at 4 yr 25% Receptive language competition at 4 yr 38% Speech in competition ratio as measured adaptively at 4 yr 30% Comprehension of grammatical structures at 6 yr 11% School readiness at 6 yr 0% Recall of a narrative at 9 yr 14%

Evidence Table 2. Early Life OM and Long-Term Speech and Language Development (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
2583 Teele 1990 Same cohort as 2579	Prospective Cohort Study Study Quality Score (0–8): 6 (10101111) OM Diagnosis: By physicians and nurse practitioners using a standard sealed pneumatic otoscope. To resolve ambiguous diagnoses, otoadmittance was used sporadically at 0–3 years of age, but frequently at 4–7 years. Group: Children followed prospectively from birth until age 7 years and whose cognitive and linguistic abilities were assessed at age 7 N=194 subjects	Time: Enrollment of infants began 6/1975 (follow-up during first 7 yrs of life) Place: Subjects drawn from larger cohort of children enrolled at an urban health center in East Boston and a private practice in the Holliston/Framingham area of MA Characteristics: • 54% male • 57% high SES • 69% from private practice Inclusion: • Age: 7 years (followed from birth) • Caucasian Exclusion: • seizures • mental retardation • cerebral palsy • two languages spoken in home • non-white	Age: OM history: 0–2 years Outcome: at 7 years of age Examiner(s): Physicians and nurse practitioners for clinical history. Experienced psychometricians for intelligence and achievement tests Certified speech clinicians administered speech and language tests. OM history: Used the number of days with MEE by age 3 years as a predictor variable. Unless documented to be shorter, each episode of MEE lasted 29 days. Outcome measures: Cognitive assessment • WISC-R Speech and language • Subsample of Goldman-Fristoe and Goldman-Fristoe-Woodcock Tests • WUG test • Peabody Picture Vocabulary Test • Boston Naming Test • Complex sentences and set of pictures for story telling Academic achievement • Metropolitan Achievement Test	Cognitive ability (mean IQ by WISC-R) at 7 years of age after adjusting for SES status and gender. Time with MEE <30d (n=58) / 30–129d (n=77) / >130d (n=59) Full Scale 113 / 108 / 105 Verbal 112 / 106 / 106 Performance 112 / 108 / 104 Linguistic abilities (mean score) after adjusting for SES status and gender Time with MEE <30d (n=58) / 30–129d (n=77) / >130d (n=59) Goldman-Fristoe-Woodcock Articulation 106 / 66 / 56 Discrimination 34 / 30 / 28 WUG Receptive 1.5 / 1.8 / 2.2 Expressive 2.4 / 2.0 / 1.9 Morphologic markers 31 / 26 / 20 Lexical use 1.5 / 1.5 / 1.5 Speech sample score 83 / 80 / 78

Evidence Table 3: Early Life OM and Long-Term Hearing

[The eight components of study quality score are: study cohort clearly defined; subjects assembled at a uniform time point; pathway of subject entry clearly described; complete follow-up achieved; withdrawals/drop-outs described; objective outcomes used; outcome assessment blinded; and extraneous factors adjusted. 1 indicates presence and 0 indicates absence.]

Record# Author Year	**Study Quality OME Definition Group(s) and Sample Size**	**Time/Place Subject Characteristics Inclusion/Exclusion Criteria**	**Risk Groups Predictors Outcome Measures**	**Findings**
147 Sorri 1995	Prospective Cohort Study Study Quality Score (0–8): 4 (01001101) OM diagnosis: By whom not specified; How not specified. OM Groups: Group 1: No otitis media until 7 years of age (NoOM) Group 2: Recurrent otitis media (>=4 episodes of OM until the age of two) (RAOM) Group 3: Secretory otitis media until the age of two (SOM) N=99 N1=35 N2=51 N3=13	Time: Birth cohort 1985–1986 Place: Health care centers, hospital and private surgeries in Northern Finland Inclusion: • Age: Born in Northern Finland between 1985–1986 (examined through age 2 and at 7 years) • history of OM meticulously controlled up until the age of 2 yrs Exclusion: • middle ear effusion at time of audiometry at age 7 (14 excluded) • 6 children had meningitis, 1 totally deaf child, 1 w/atresia of the ear canal, 5 lacked cooperation, 5 lacked information after age 2 years	Age: OM history: 0–2 years of life Outcomes: At age 7 years Examiner(s): Not specified OM history: OM history groups defined by number of recurrent otitis media or serous otitis media. Outcomes: • Pure tone average, type not specified • Mean air-conduction (AC) thresholds	**Number and percent children exceeding 20 dB (hearing loss)** NoOM RAOM SOM 7/35 28/51 5/13 20% 55% 38% **Pure tone (dB), right ear: mean±SD** NoOM RAOM SOM 3.82±3.50 4.88±4.42 6.44±6.27 **Pure tone (dB), left ear: mean±SD** NoOM RAOM SOM 3.24±2.21 3.63±2.65 6.54±6.56

Evidence Table 3. Early Life OM and Long-Term Hearing (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1255 Fischler 1985	Retrospective-prospective study Study Quality Score (0–8): 5 (11001110) OM Diagnosis: By medical record review of documented physician's clinical diagnosis. OM Groups: Group 1: HR/REC (HR-High risk status,REC-recurrences of OM attacks after age 2) ~ >=2 attacks by age 2 yr and >=3 attacks after age 2 yr Group 2: HR/NREC ~ >=2 attacks by age 2 yr and <3 attacks after age 2 yr Group 3: NHR/NREC ~ <2 attacks by age 2 yr and <3 attacks after age 2 yr N=167 N1=33 N2=63 N3=71	Time: Start date~7/1974 Place: Four Indian reservations in Arizona Characteristics: • 50% had family income under $5000 per year • 37% had housing below average • 13% primarily Apache speaking at home Inclusion: • Age: 6–8 years • healthy Apache Indian children who had been followed since birth Exclusion: • moved during study period • absent or not tested because of time constraints • medical reasons (specific conditions not specified)	Age: OM history: 0–2 years of life Outcomes: At 6–8 years Examiner(s): • Unspecified physicians for diagnosis of otitis media; • School nurse for hearing tests; • Pediatrician/otolaryngologist for otoscopic examinations; • Certified speech pathologists for language testing. OM history: Groups defined by number of OM episodes by age 2 Outcomes: All children received a hearing screen using a recently calibrated pure tone audiometer (dB hearing level American National Standards Institute [ANSI] 1969). Children whose hearing was better than the following thresholds were considered normal: 25 dB at 500 Hz; 20 dB at 1,000 Hz; 20 dB at 2,000 Hz; 25 dB at 4,000 Hz; 25 dB at 6,000 Hz; Otherwise, abnormal or hearing loss.	**Number and percent of children with hearing loss** Group 1 Group 2 Group 3 OM risk High Moderate Low 5/33 4/63 1/71 15% 2% 1%

Evidence Table 3. Early Life OM and Long-Term Hearing (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1373 Gravel 1992	Prospective Cohort Study Study Quality Score (0–8): 5 (11001101) OM Diagnosis: Pediatric nurse practitioners completed pneumo-otoscopic examinations. OM Groups: Group 1: Otitis positive children – when bilateral OM was detected at 30% or more of the baby's first year visits. (Also, had poorer auditory sensitivity by click ABR.) Group 2: Otitis negative children – when middle ear status was rated as normal in both ears during 80% or more of the first year visits. N=23 N1=10 N2=13	Time: not specified Place: Clinical Research Center for Communicative Disorders (which draws subjects from the LIFE Program of the R.F. Kennedy Center, Albert Einstein College of Med. Bronx, NY Characteristics: • low socioeconomic urban neighborhoods based on Hollingshead's (1975) index • none had sensorineural hearing loss Inclusion: • Age: 4 years (measures taken during first year of life as well) • all children were enrolled at 40 wks postconceptional age for follow-up through the LIFE Program • either high-risk infant graduates of a NICU or FT graduates of the well-baby nursery of Jacobi Hospital • English reported as the primary language spoken Exclusion: • neurologically compromised	Age: OM history: 0–1 of life Outcome: at 4 years of age Examiner(s): Not specified OM history: OM groups were defined by otoscopic histories. Outcomes: Pediatric Speech Intelligibility (PSI) sentence (S) items/competing messages (CM) ratio Pure-tone averages – based on a conventional clinical staircase procedure (descending-ascending). Thresholds for each ear of all subjects were obtained at octave frequencies from 500 through 4000 Hz (at a minimum) (ANSI, 1969).	**PSI S/CM (dB)** OM+ / OM– Mean±SD: -6.8±2.8 / -9.7±2.6 **Pure-tone (dB), right ear** OM+ / OM– Mean±SD: 15.8±4.1 / 14.9±3.2 **Pure-tone (dB), left ear** OM+ / OM– Mean±SD: .8±4.1 / 14.6±3.3

Evidence Table 3. Early Life OM and Long-Term Hearing (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1435 Harsten 1993	Prospective Cohort Study Study Quality Score (0–8): 6 (11101110) OM Diagnosis: AOM was diagnosed by otomicropscopy, performed by an otolaryngologist and defined as an acute episode of earache in a child, with red bulging eardrum(s) or purulent discharge, occasionally febrile and with signs of upper respiratory tract infection. OM Groups: Group 1: Children with recurrent AOM (RAOM defined as at least six episodes of AOM during a 12-month period) during the first 3 years of life Group 2: Children without any AOM episode during the first 3 years of life N= 42 N1=13 N2=29	Time: not specified Place: University Hospital of Lund, Sweden Characteristics: • 45% first-borns • 71% mother educated at college level Inclusion: • Age: Birth cohort • monolingual, Swedish children, born at University Hospital of Lund Exclusion: None	Age: OM history: 0–3 year of life Outcomes: at 4 and 7 year of age Examiner(s): Otolaryngologist for otomicroscopy, tympanometry, tone-audiograms Phoniatrician and clinical linguist for hearing and speech OM history: Groups defined by number of episodes of AOM during a 12-month period. Outcomes: Tone-audiometry: abnormal defined as >=25 dB threshold at any frequency. (Tone-audiograms were recorded at frequencies from 125 to 8000 Hz.)	**Tone-audiometry at age 4** RAOM / Healthy Abnormal hearing: 3/26 (12%) / 4/58 (7%) **Tone-audiometry at age 7** RAOM / Healthy Abnormal Hearing: 2/24 (8%) / 3/56 (5%)

Evidence Table 3. Early Life OM and Long-Term Hearing (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
1623 Kaplan 1973 Same study subjects as 2233 which reported 3–5 year follow-up. This study reported 10-year follow-up.	Prospective Cohort Study Study Quality Score (0–8): 5 (11001110) OM Diagnosis: A research nurse visited the cohort children 4 times a year during first 2 years and at least 2 times a year for the next 2 years. During each visit, information concerning middle ear abnormality was obtained and medical records of the time between visits were reviewed. Only OM described with otorrhea was used for analysis. OM Groups: Group 1: age of onset of first otorrhea at 0–1 year of age Group 2: age of onset of first otorrhea at age 2–10 years Group 3: no history of otorrhea N=489 N1=291 N2=83 N3=115	Time: Birth cohort (10/1960–12/1962); follow-up conducted between 9/1969–7/1971 Place: 28 Eskimo villages located in the Yukon and Kuskokwim River Delta areas of Southwestern Alaska Characteristics: Not described. Inclusion: • Age: Birth Cohort born between 10/1960–12/1962 and followed up between 9/1969–7/1971 • born in 25 villages w/in Alaska specified under place and/or residing in 3 additional villages at follow-up Exclusion: • Children with pure sensory hearing loss were excluded from analysis	Age: OM history: 0–1 year of life Outcome: at 10 years of age Examiner(s): Experienced audiologist for air and bone conduction measurements Two psychologists administered speech and intelligence testing OM history: Groups based on onset of first episode of otorrhea during 0–1 year; during 2–10 years or no history. Outcomes: Air and bone conduction measurements were made using a portable audiometer recently calibrated to the ISO 1964 standard. All children were tested at frequencies of 250, 500, 1000, 2000, 4000, and 8000 Hz to evaluate air conduction and at frequencies of 500, 1000, 2000, and 4000 Hz to evaluate bone conduction. • Normal hearing: 0 to –25 dB; • Normal hearing with a conductive component: 0 to –25 dB with a 15 dB air-bone gap; • Hearing loss: –26 dB or greater. (Children with pure sensory hearing loss were excluded from analysis.)	**Hearing Loss at 10 years of age** Group 1 / Group 2 / Group 3 1st om at: 0–1y / 2–12y / noOM Conductive hearing loss (air-bone gap) 42/162 / 8/45 / 17/76 28% / 18% / 22% Hearing loss at 26+dB 32/162 / 5/45 / 6/76 20% / 11% / 8%

Evidence Table 3. Early Life OM and Long-Term Hearing (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
2233 Reed 1967 Same study population as 1623. This article reported findings at 3–5 years. Article 1623 reported findings at 10 years of age.	Prospective Cohort Study Study Quality Score (0–8): 4 (11000101) OM Diagnosis: A research nurse visited the cohort children 4 times a year during first 2 years and at least 2 times a year for the next 2 years. During each visit, information concerning middle ear abnormality was obtained and medical records of the time between visits were reviewed. Only OM described with otorrhea was used for analysis. OM Groups: Defined by frequency of otorrhea episodes during first 2 years of life. Group 1: None Group 2: <1 episode per year Group 3: 1 or more episode per year N=378 N1=198 N2=180	Time: Two birth cohorts (born between 10/1960–12/1962); follow-up conducted between Sept.-Dec.,1965 Place: Testing conducted in schoolhouses or in a community building in 24 of the original 27 Eskimo villages located in the Yukon and Kuskokwim River Delta areas of SW Alaska where the cohort was born Characteristics: Not described. Inclusion: • Age: Follow-up from birth to 4 years (0–47 months) • Born in one of 27 Eskimo villages between 10/1960–12/1962 and available for testing at follow-up • audiometric tests completed Exclusion: • Children with pure sensory hearing loss was excluded from analysis	Age: OM history: first 2 years of life Outcome: at 3–5 years of age Examiners: Audiologist OM history: Groups defined by frequency of otorrhea episodes during first 2 years of life: none, <1 per year of risk, and 1+ per year of risk Outcomes: Air and bone conduction measurements were made using the Zenith ZA-100-T Diagnostic Portable Audiometer, calibrated to the ISO 1964 standards. Children were classified according to averages of pure tone air hearing thresholds at 500, 1000, and 2000 CPS: • normal: 0 to 25 dB • mild impairment: 26 to 40 dB • moderate to severe impairment: 41 to 70+ dB	**Mild and Severe Hearing Loss at 3–5 years of age** OM history, first 2 years of life none: 21/143, 15% <1/yr: 48/139, 35% 1+/yr: 47/96, 49%

Evidence Table 3. Early Life OM and Long-Term Hearing (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
2309 Ryding 1997	Prospective Cohort Study Study Quality Score (0–8): 5 (01100111) OM Diagnosis: AOM was diagnosed by otomicroscopy, performed by an otolaryngologist and defined as an acute episode of earache in a child, with red bulging eardrum(s) or purulent discharge, occasionally febrile and with signs of upper respiratory tract infection. OM Groups: Group 1: RAOM Children (>=6 episodes of purulent AOM during a 12-month period) Group 2: Healthy Children (no AOM and <6 other RTI episodes during the study period) N=33 N1=12 N2=21	Time: Birth cohort (born between 11/1982–2/1984); 10 yr follow-up Place: University Hospital, Lund, Sweden Characteristics: • 45% first-borns • 71% mother educated at college level Inclusion: • 10 years old • member of this birth cohort Exclusion: • moved out of Lund	Age: OM history: 0–3 years of life Outcome: at 10 years of age Examiner(s): Audiologist Instrument: tone audiometry GSI 16 audiometers OM history: Groups defined by number of recurrent AOM. Recurrent AOM was defined as >= 6 episodes of purulent AOM during a 12-month period. Outcomes: Children were tested using GSI 16 audiometers with TDH39 earphones calibrated according to ISO 389. Air conduction hearing levels for both ears were individually determined at the frequencies 1000, 1500, 2000, 3000, 4000, 6000, 8000, 500, 250 and 125 Hz, tested in that order. The test was conducted according to the ascending method. Pure tone average (PTA) values for frequencies 500, 1000 and 2000 Hz (PTA: 0.5-2) and 500, 1000, 2000 and 4000 Hz (PTA: 0.5-4) were calculated for each ear.	**Median level in dB, right ear** RAOM / Healthy PTA(0.5-2): 5 / 5 PTA(0.5-4): –2 / –2 **Median level in dB, left ear** RAOM / Healthy PTA(0.5-2): 7 / 3 PTA(0.5-4): –2 / 0

Evidence Table 3. Early Life OM and Long-Term Hearing (Continued)

Record# Author Year	Study Quality OME Definition Group(s) and Sample Size	Time/Place Subject Characteristics Inclusion/Exclusion Criteria	Risk Groups Predictors Outcome Measures	Findings
2854 Zargi 1992	Retrospective prospective cohort study Study Quality Score (0–6): 2 (10000100) OME definition: Not specified Group 1: Experimental – Children treated for recurrent acute unilateral or bilateral suppurative otitis media at 0–2 years of age. Group 2: Control – Children who experienced <=1 episodes of OM in the first 2 years of life) N=62 N1=33 N2=29	Time: not specified Place: University Department of Otorhinolaryngology and Head and Neck Surgery, Ljubljana, Slovenia Inclusion: • Age: 8–10 years • attended similar pre-school, kindergarten, and elementary school programs • no evidence of mental retardation nor behavioral or emotional disorders Exclusion: None	Age: Followup examination at 8–10 years of age Examiner(s): Otolaryngologist OM history: During first two years of life. Outcomes: At age 8–10 years pure-tone audiometry was performed. The criterion for normal hearing was based on the air-conduction threshold results, which had to be at or above the level of 10 dB. Isolated audiometric dips (notches) to 15 dB at not more than one high frequency (6kHz or 8kHz) were not considered to be sensorineural hearing loss.	Hearing loss — Group 1 OM+ / Group 2 OM– Sensorineural: 10/33 30% / 4/29 14% Conductive or mixed: 8/33 24% / 0/29 0% Both types: 18/33 55% / 4/29 14%

Evidence Table 4: Diagnostic Methods

[The six components of Study Quality Score are: appropriate reference standard; test and reference standard assessed independently of each other; blinded reading of results; patient sample included an appropriate spectrum as in clinical practice; reproducibility and interpretation of test results determined; and description of test method sufficient to permit replication. 1 indicates presence and 0 indicates absence.]

Record# Author Year	**Study Quality Examiner(s) Group(s) and Sample Size**	**Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics**	**Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints**	**Findings**
759 Avery 1986	Diagnostic study Study Quality Score (0–6): 2 (100001) Examiner(s): • pneumatic otoscopy: two validated otoscopists • acoustic reflectometry (Acoustic Otoscope [Endeco Medical]): not specified Study Cohort: Children with proven chronic OME treated surgically (2-year follow-up) N=451 subjects, 4147 observations	Time: not specified Place: Not specified Affiliation: Otitis Media Study Center, Santa Rosa Med. Center & The Univ. of Texas Health Sciences Center, San Antonio, TX Inclusion: • proven chronic OME and treated surgically as part of an ongoing clinical trial • ears with intact tympanic membranes Exclusion: None Patient Characteristics: • age range 4–8 years old	Comparisons: 1. Acoustic reflectometry Dx– : ≤ 3 dB Dx+ : > 3 dB Validated pneumatic otoscopy GS– : fluid absent GS+ : fluid present 2. Acoustic reflectometry Dx– : ≤ 4 dB Dx+ : > 4 dB Validated pneumatic otoscopy GS– : fluid absent GS+ : fluid present 3. Acoustic reflectometry Dx– : ≤ 5 dB Dx+ : > 5 dB Validated pneumatic otoscopy GS– : fluid absent GS+ : fluid present	Unit of measure: Observation Comparison 1: sensitivity 77.74% (908/1168) specificity 68.28% (2034/2979) PPV 49.00% (908/1853) NPV 88.67% (2034/2294) accuracy 70.94% (2942/4147) prevalence 28.17% (1168/4147) Comparison 2: sensitivity 65.24% (762/1168) specificity 83.08% (2475/2979) PPV 60.19% (762/1266) NPV 85.91% (2475/2881) accuracy 78.06% (3237/4147) prevalence 28.17% (1168/4147) Comparison 3: sensitivity 50.43% (589/1168) specificity 92.25% (2748/2979) PPV 71.83% (589/820) NPV 82.60% (2748/3327) accuracy 80.47% (3337/4147) prevalence 28.17% (1168/4147)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
766 Babonis 1991	Diagnostic study Study Quality Score (0–6): 5 (111011) Not defined Examiner(s): • tympanometry (MicroTymp [Welch Allen]) and acoustic reflectometry (model 501 [ENT Medical Devices]): one of the authors, specialty not specified • myringotomy: unspecified "surgeon" Study Cohort: Ears in children scheduled for elective myringotomy and PE tube placement N=120 potential subjects and 240 potential ears; 220 ears studied.	Time: 12/1988–11/1989 Place: Not specified Affiliation: Department of Pediatrics, Madigan Army Medical Center, Tacoma, WA Inclusion: • scheduled for elective myringotomy and PE tube placement Exclusion: • poor patient cooperation • mechanical malfunction precluding hard-copy recordings • patient PE tubes • ears microtic, patient undergoing myringotomy and PE tube placement in only 1 ear, and chronic TM perforation Patient Characteristics: • mean age 37.8 months, median 30 months, range 6 months to 10 years 9 months • male 139 ears	Comparisons: 1. Portable tympanometer Dx– : 59–151 daPa Dx+ : >151 daPa Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Portable tympanometer Dx– : A, CI, Ch, As, pA Dx+ : B Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Acoustic reflectometry Dx– : ≤ 5 RU Dx+ : > 5 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 85.59% (101/118) specificity 57.84% (59/102) PPV 70.14% (101/144) NPV 77.63% (59/76) accuracy 72.73% (160/220) prevalence 53.64% (118/220) Comparison 2: sensitivity 77.97% (92/118) specificity 82.35% (84/102) PPV 83.64% (92/110) NPV 76.36% (84/110) accuracy 80.00% (176/220) prevalence 53.64% (118/220) Comparison 3: sensitivity 57.63% (68/118) specificity 88.24% (90/102) PPV 85.00% (68/80) NPV 64.29% (90/140) accuracy 71.82% (158/220) prevalence 53.64% (118/220)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
784 Barnett 1998	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (Race Car Model® [American Electromedics]): research assistant • acoustic reflectometry (EarCheck PRO® [MDI Instruments]): research assistant • myringotomy: not specified *The two models used to measure acoustic reflectometry gave identical results – only reporting the results for EarCheck PRO Study Cohort: Children enrolled in study who had a scheduled surgery for or were receiving placement of tympanostomy tubes that day N=193 subjects enrolled Visit1~N=150 subjects, 274 ears Visit2~N=155 subjects, 299 ears *150 children were examined at visit 1; surgery was performed on 155 children and 299 ears were examined at visit 2.	Time: not specified Place: Children's Hospital, Boston, MA Affiliation: as above Inclusion: • Age: 6 months–14 yrs • scheduling surgery for or receiving placement of tymp. tubes that day Exclusion: • craniofacial abnormality • tympanostomy tubes in place or having had them placed w/in past 6 months • fluid draining from ear Patient Characteristics: • mean age 4.07 years, range 0.51–14.6 years • male 101 • Caucasian 102, Black 25, Asian 3, other 25	Comparisons: 1. Professional tympanometry Dx– : peak compliance > 0.1 Dx+ : peak compliance ≤ 0.1 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry Dx– : peak compliance > 0.2 Dx+ : peak compliance ≤ 0.2 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Acoustic reflectometry Dx– : > 95 degr. (spec.grad. angle) Dx+ : ≤ 95 degrees Myringotomy (sedated) GS– : Fluid absent GS+ : Fluid present 4. Acoustic reflectometry Dx– : ≥ 49 degrees (spec. grad.) Dx+ : < 49 degrees Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 54.29% (95/175) specificity 83.87% (104/124) PPV 82.61% (95/115) NPV 56.52% (104/184) accuracy 66.56% (199/299) prevalence 58.53% (175/299) Comparison 2: sensitivity 62.86% (110/175) specificity 75.00% (93/124) PPV 78.01% (110/141) NPV 58.86% (93/158) accuracy 67.89% (203/299) prevalence 58.53% (175/299) Comparison 3: sensitivity 95.43% (167/175) specificity 31.45% (39/124) PPV 66.27% (167/252) NPV 82.98% (39/47) accuracy 68.90% (206/299) prevalence 58.53% (175/299) Comparison 4: sensitivity 38.29% (67/175) specificity 92.74% (115/124) PPV 88.16% (67/76) NPV 51.57% (115/223) accuracy 60.87% (182/299) prevalence 58.53% (175/299)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
810 Beery 1975	Diagnostic study Study Quality Score (0–6): 2 (100001) Examiner(s): • tympanometry (Grason-Stadler 1720): not specified • myringotomy: not specified Study Cohort: Children with history of recurrent AOM, or evidence otoscopically of persistent MEE, or both N=70 subjects, 129 ears	Time: not specified Place: Not specified Affiliation: Dept. of Otolaryngology, Tufts Univ., MA Inclusion: • Age: 2–15 years • candidate for bilateral myringotomy and insertion of tubes on basis of children's history with concurrent or recent middle ear disease Exclusion: None Patient Characteristics: • mean age 6.7 years, range 2–15 years • male 43, female 27	Comparisons: 1. Professional tympanometry[a] Dx– : See notes section below Dx+ : See notes section below; Class II (at B220) if ≥ 0.3mmh Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 95.65% (66/69) specificity 90.00% (54/60) PPV 91.67% (66/72) NPV 94.74% (54/57) accuracy 93.02% (120/129) prevalence 53.49% (69/129)

[a] DM - pos. cutpoint: For trace at B660 Hz: Class I if suscept. <0.4 mmho, Class III, Class IV; For trace at B220 Hz - Class II if susceptance <0.3 mmho.
DM - negative cutpoint: For trace at B660 Hz - Class I if susc. > or = 0.4 mmh; For trace at B220 Hz - Class II if susceptance ≥0.3 mmho.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
817 Ben-David 1981	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • audiometry (Maico MA-24 and Beltone 15 CX): not specified • tympanometry (Amplaid 702 and American 83): not specified • myringotomy: operating surgeon *Air-bone gap was used in this study as the tested diagnostic method. Study Cohort: Children who underwent tympanometric and audiometric evaluations as well as myringotomy N=157 subjects, 311 ears	Time: not specified Place: Not specified Affiliation: Rothschild Univ. Hospital, Haifa, Israel Inclusion: • Age: 6 months–14 years • evidence of SOM, which failed to ease after conservative Tx with decongestants, antibiotics, and systemic steroids • candidate for myringotomy and tympanostomy-tube insertion Exclusion: None Patient Characteristics: • age range 6 months–14 years	Comparisons: 1. Professional tympanometry[a] Dx– : Type A and Type C Dx+ : Type B Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Audiometry–air and bone conduction thresholds[b] Dx– : < 15 db air-bone gap Dx+ : 15–40 db air-bone gap Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 78.00% (195/250) specificity 63.93% (39/61) PPV 89.86% (195/217) NPV 41.49% (39/94) accuracy 75.24% (234/311) prevalence 80.39% (250/311) Comparison 2: sensitivity 73.91% (153/207) specificity 68.18% (45/66) PPV 87.93% (153/174) NPV 45.45% (45/99) accuracy 72.53% (198/273) prevalence 75.82% (207/273)

[a] We assumed they considered Type B as positive for effusion and all other types negative although they never state this in the text.
[b] The authors never officially define negative and positive cutoff points for the diagnostic method; we assumed that the cutoff points we have supplied above are correct based on their comments in the discussion section.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
886 Block 1998	Diagnostic study Study Quality Score (0–6): 6 (111111) Examiner(s): • tympanometry (American Electromedic RaceCar®): not specified • acoustic reflectometry (EarCheck PRO®): not specified • validated pneumatic otoscopy: validated experienced pediatric otoscopists Study Cohort: Children who participated in study to assess diagnostic accuracy of EarCheck PRO and tympanometry *(Three additional studies were reported in this article but none reported findings relevant to key question four.) N=528 subjects, 870 ears	Time: not specified Place: Validation study recruited from four sites: Barstown, KY; Pittsburgh, PA; Scottsdale, AZ; Rochester,NY/ Long. Study ~ Weston Pediatrics, Weston, MA Affiliation: Kentucky Pediatric Research, Inc.; Children's Hospital of Pittsburgh; Scottsdale Pediatric Center; Elmwood Pediatric Group (NY); Weston Pediatric Physicians; MDI Instruments, Inc. (MA); Capital Management Consulting, Inc. (MA) Inclusion: • Age: 6 months–18 yrs • Exclusion: Myringotomy tubes last 6 months • Perforated tympanic membrane • Cerumen that projected into >50% of the radius of the ear canal • Any serious or psychologic illness • Immunodeficiencies • craniofacial deformities and/or middle ear abnormalities Patient Characteristics: • Age: 6–11 months (N=27); 5 years (N=261); 6–10 years (N=161); 11–18 years (N=79) • Male 51%, Female 49%	Comparisons: 1. Professional tympanometry[a] Dx– : See notes below. Peak-compensated static acoustic admittance 0.22–1.5 mmhos Dx+ : See notes below. Peak acoustic admittance <0.22 mmhos Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 2. Acoustic reflectometry Dx– : ≥70 degrees SG-AR Dx+ : ≤ 69 degrees SG-AR Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present	Unit of measure: Ear Comparison 1: sensitivity 33.92% (58/171) specificity 89.12% (598/671) PPV 44.27% (58/131) NPV 84.11% (598/711) accuracy 77.91% (656/842) prevalence 20.31% (171/842) (Note: PPV and NPV numbers in Table 1 of the article are incorrect.) Comparison 2: sensitivity 67.43% (118/175) specificity 87.05% (605/695) PPV 56.73% (118/208) NPV 91.39% (605/662) accuracy 83.10% (723/870) prevalence 20.11% (175/870)

[a] DM – negative cutoff: equivalent ear canal volume 0.4–2.3 cc; tympanometric peak pressure +200 to –400 daPa; tympanometric Width <180 daPa; DM – positive cutoff: absent tympanometric peak; tympanometric Width >180.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
888 Bluestone 1973	Diagnostic study Study Quality Score (0–6): 2 (100001) Examiner(s): • tympanometry (Madesen ZO-70 Electroacoustic Impedance Bridge): not specified • audiometry (Maico portable audiometer): not specified Study Cohort: Children who were studied to determine the relative validity of air-conduction audiometry and tympanometry in predicting presence of middle ear effusion N=84 subjects Comparison 1: 52 subjects, 87 ears Comparison 2: 55 subjects, 91 ears	Time: not specified Place: Not specified Affiliation: Cleft Palate Center and the Depts. Of Otolaryngology and Pediatrics, Univ. of Pittsburgh, PA; Children's Hospital of Pittsburgh; Dept. of Otolaryngology, Tufts Univ. Boston City Hospital, MA Inclusion: • Age: 2 months–15 years • history of recurrent AOM, or evidence otoscopically of persistent MEE, or both (considered candidates for myringotomy and tympanostomy tube insertion) Exclusion: None Patient Characteristics: • mean age 5.3 years • male 64, female 20	Comparisons: 1. Professional tympanometry[a] Dx– : Patterns 1,2, and 3 Dx+ : Patterns 4 and 5 Myringotomy (sedated) GS– : Effusion absent GS+ : Effusion present 2. Audiometry – air conduction threshold Dx– : Below 25 dB Dx+ : ≥ 25 dB Myringotomy (sedated) GS– : Effusion absent GS+ : Effusion present 3. Audiometry – air and bone conduction thresholds Dx– : Not Defined Dx+ : Not Defined Myringotomy (sedated) GS– : Effusion absent GS+ : Effusion present	Unit of measure: Ear Comparison 1: sensitivity 100.00% (58/58) specificity 55.17% (16/29) PPV 81.69% (58/71) NPV 100.00% (16/16) accuracy 85.06% (74/87) prevalence 66.67% (58/87) Comparison 2: sensitivity 51.72% (30/58) specificity 75.76% (25/33) PPV 78.95% (30/38) NPV 47.17% (25/53) accuracy 60.44% (55/91) prevalence 63.74% (58/91) Comparison 3[b]: Not done

[a] Pattern 1 = Normal Compliance, Normal Pressure; 2 = Nml comp, negative pressure; 3 = High comp, nml pressure; 4 = low comp, nml pressure; 5 = low comp, pressure high negative, positive, or indeterminate.
[b] Could not be completed because negative and positive cut-points are not defined for Air-Bone Gap.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
889 Bluestone 1979	Diagnostic study Study Quality Score (0–6): 4 (110011) Examiner(s): • otoscopy: two otolaryngologists, two pediatricians • tympanometry and middle ear muscle reflex (Model Z073 [Madsen Electronics]): by or under the direction of an audiologist, classified independently by two audiologists • myringotomy: surgeon Study Cohort: Validity of diagnosing OME by otoscopy, tympanometry, and middle ear muscle reflex ~ gold standard: Myringotomy (referenced as Study 2 in article) *(an additional study was reported in this article but findings were not relevant to key question four) N=239 subjects, 425 ears	Time: S2 ~ 9/1/1977–2/22/1978 Place: not specified Affiliation: Dept. of Otolaryngology, Children's Hospital of Pittsburgh, PA Inclusion: • Age: 7 months–15 years • patients scheduled for bilateral myringotomy and insertion of tympanostomy tubes on basis of a history of recurrent acute and/or persistent OME Exclusion: None Patient Characteristics: As above	Comparisons: 1. Pneumatic otoscopy – examiner Validation not specified Dx– : OME absent (– cases) Dx+ : OME present (+ and +/– cases) Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry[a] Dx– : Paradise classification variants 1–6, 9,15 Dx+ : Paradise classification variants 7,8,10–14 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Examiner type (Otolaryngologist) Pneumatic otoscopy – unvalidated examiner Dx– : OME absent (– cases) Dx+ : OME present (+ and +/– cases) Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 94.53% (242/256) specificity 77.51% (131/169) PPV 86.43% (242/280) NPV 90.34% (131/145) accuracy 87.76% (373/425) prevalence 60.24% (256/425) Comparison 2: sensitivity 93.75% (240/256) specificity 70.41% (119/169) PPV 82.76% (240/290) NPV 88.15% (119/135) accuracy 84.47% (359/425) prevalence 60.24% (256/425) Comparison 3: sensitivity 100.00% (29/29) specificity 22.73% (5/22) PPV 63.04% (29/46) NPV 100.00% (5/5) accuracy 66.67% (34/51) prevalence 56.86% (29/51) *Continued on next page*

[a] Middle ear muscle reflex testing was also evaluated as a diag. method in this study, but wasn't included in the list of diagnostic test choices.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 889 Bluestone 1979			*Continued* 4. Examiner type (Pediatrician) Pneumatic otoscopy – unvalidated examiner Dx– : OME absent (– cases) Dx+ : OME present (+ and +/– cases) Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 5. Examiner type (Pediatrician) Pneumatic otoscopy – unvalidated examiner Dx– : OME absent (– cases) Dx+ : OME present (+ and +/– cases) Myringotomy (sedated) GS– : fluid absent GS+ : fluid present)	*Continued* Unit of measure: Ear Comparison 4: sensitivity 96.30% (26/27) specificity 25.00% (5/20) PPV 63.41% (26/41) NPV 83.33% (5/6) accuracy 65.96% (31/47) prevalence 57.45% (27/47) Comparison 5: sensitivity 76.00% (19/25) specificity 50.00% (7/14) PPV 73.08% (19/26) NPV 53.85% (7/13) accuracy 66.67% (26/39) prevalence 64.10% (25/39)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
989 Cantekin 1977	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • tympanometry (types described under each comparison): not specified • myringotomy: not specified Study Cohort: Children scheduled for bilateral myringotomy and insertion of tympanostomy tubes for recurrent acute otitis media history or persistent middle ear effusion by otoscopy N=68 subjects, 120 ears	Time: not specified Place: Not specified Affiliation: Dept. of Otolaryngology, Children's Hospital of Pittsburgh and the Univ. of Pittsburgh, PA Inclusion: • Age: 18 months–14 years • history of recurrent AOM or otoscopic evidence of persistent MEE, or both • scheduled for bilateral myringotomy and insertion of tympanostomy tubes for recurrent acute otitis media history or persistent middle ear effusion by otoscopy Exclusion: None Patient Characteristics: • median age 6.5 years • male 43, female 25	Comparisons: 1. Professional tympanometry[a] (Madsen Electro-Acoustic Impedance Bridge, model ZO-70) Dx– : air pressure ≥ –100 mm H2O; compliance <5.0 OR (See notes.) Dx+ : air press <–100 mm H_2O; compliance ≥ 5 OR (See notes.) Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry[b] (Grason-Stadler Otoadmittance meter, model 1720) Dx– : See notes below. Dx+ : See notes below. Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 84.13% (53/63) specificity 87.72% (50/57) PPV 88.33% (53/60) NPV 83.33% (50/60) accuracy 85.83% (103/120) prevalence 52.50% (63/120) Comparison 2: sensitivity 84.13% (53/63) specificity 87.72% (50/57) PPV 88.33% (53/60) NPV 83.33% (50/60) accuracy 85.83% (103/120) prevalence 52.50% (63/120)

[a] Negative cutoff point (continued): air pressure <–100 mm H2O; compliance <5.0 Madsen units; gradient ≥ 0.5 Madsen units. Positive Cut Point (continued): air pressure <–100 mm H2O; compliance ≥5.0 Madsen units; gradient <0.5 Madsen units.

[b] Negative cutoff: Class I curve with peak susceptance > or = .4mmho at 660 Hz; Class II curve with peak ≥.3 mmhos at 220 Hz. Postive cutoff: Class I curve, peak < .4mmho at 660 Hz; Class II curve, peak <.3mmho at 220 Hz; Class III and IV.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
990 Cantekin 1980	Diagnostic study Study Quality Score (0–6): 4 (110011) Examiner(s): • otoscopy: two otolaryngologists • tympanometry and middle ear muscle reflex (Model ZO73 [Madsen Electronics]): by or under the direction of an audiologist, independently classified by two investigators • myringotomy: surgeon Study Cohort: Children who underwent myringotomy ~ myringotomy findings were compared to OME diagnosis based on otoscopy, tympanometry and ME muscle reflex N=333 subjects, 599 ears	Time: not specified Place: Not specified Affiliation: Dept. of Otolaryngology, Univ. of Pittsburgh School of Medicine, and Children's Hospital of Pittsburgh, PA Inclusion: • Age: 7 months–15 years • patients scheduled for bilateral myringotomy and insertion of tympanostomy tubes • history of recurrent AOM, or otoscopic evidence of persistent OME, or both Exclusion: None Patient Characteristics: • median age 6 years • male 203, female 130	Comparisons: 1. Pneumatic otoscopy[a] – unvalidated examiner Dx– : OME absent Dx+ : OME present Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Pneumatic otoscopy[b] – unvalidated examiner Dx– : OME absent Dx+ : OME present Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Quantitative tympanometry[c] Dx– : ME muscle reflex threshold ≤105dB Dx+ : Absence of ME muscle reflex Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 4. Quantitative tympanometry[d] Dx– : ME muscle reflex threshold ≤105dB Dx+ : Absence of ME muscle reflex Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 96.96% (223/230) specificity 81.43% (114/140) PPV 89.56% (223/249) NPV 94.21% (114/121) accuracy 91.08% (337/370) prevalence 62.16% (230/370) Comparison 2: sensitivity 87.56% (176/201) specificity 80.54% (120/149) PPV 85.85% (176/205) NPV 82.76% (120/145) accuracy 84.57% (296/350) prevalence 57.43% (201/350) Comparison 3: sensitivity 96.30% specificity 34.60% PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 4: sensitivity 92.90% specificity 52.00% PPV unknown NPV unknown accuracy unknown prevalence unknown *Continued on next page*

[a] These are results for otolaryngologist A.
[b] These results are for otolaryngologist B.
[c] ME muscle reflex measured using ipsilateral stimulation and ambient pressure; Stimulus frequency = 1000.
[d] ME muscle reflex measured using ipsilateral stimulation and tympanogram's peak pressure; Stimulus frequency = 1000.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 990 Cantekin 1980			*Continued* 5. Quantitative tympanometry[a] Dx– : ME muscle reflex threshold ≤105dB Dx+ : Absence of ME muscle reflex Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 6. Quantitative tympanometry[b] Dx– : ME muscle reflex threshold ≤105dB Dx+ : Absence of ME muscle reflex Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 7. Quantitative tympanometry[c] Dx– : ME muscle reflex threshold ≤105dB Dx+ : Absence of ME muscle reflex Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 5: sensitivity 97.90% specificity 24.80% PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 6: sensitivity 95.50% specificity 37.40% PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 7: sensitivity 95.50% specificity 37.40% PPV unknown NPV unknown accuracy unknown prevalence unknown *Continued on next page*

[a] ME muscle reflex measured using contralateral stimulation and ambient pressure; Stimulus frequency = 1000.
[b] ME muscle reflex measured using contralateral stimulation and tympanogram's peak pressure; Stimulus frequency = 1000.
[c] ME muscle reflex measured using ipsilateral stimulation and ambient pressure; Stimulus frequency = 2000.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 990 Cantekin 1980			*Continued* 8. Quantitative tympanometry[a] Dx– : ME muscle reflex threshold ≤105dB Dx+ : Absence of ME muscle reflex Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 9. Quantitative tympanometry[b] Dx– : ME muscle reflex threshold ≤105dB Dx+ : Absence of ME muscle reflex Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 10. Quantitative tympanometry[c] Dx– : ME muscle reflex threshold ≤105dB Dx+ : Absence of ME muscle reflex Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear Comparison 8: sensitivity 91.90% specificity 50.70% PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 9: sensitivity 97.10% specificity 29.40% PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 10: sensitivity 93.30% specificity 39.40% PPV unknown NPV unknown accuracy unknown prevalence unknown

[a] ME muscle reflex measured using ipsilateral stimulation and tympanogram's peak pressure; Stimulus frequency = 2000.
[b] ME muscle reflex measured using contralateral stimulation and ambient pressure; Stimulus frequency = 2000.
[c] ME muscle reflex measured using contralateral stimulation and tympanogram's peak pressure; Stimulus frequency = 2000.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1238 Fiellau-Nikolajsen 1980	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (Madsen Impedance Meter, type ZO-73, testing tone 220Hz): the author • myringotomy: two otosurgeons *Same study population as record #1241 Study Cohort: Children whose ear(s) persistently showed abnormal screening-tympanometry over 6 months; myringotomic aspiration of any MEE was performed N=44 subjects (21 children bilateral, 23 unilateral), 88 ears	Time: Intitial screening in Aug. 1978; operation (if needed) in Feb. 1979 Place: Subjects identified from tympanometric screening in a Danish provincial municipality Affiliation: ENT Dept. Hjoerring Hospital, Denmark Inclusion: • Age: 3 years at initial screening • one or both ears consistently showed abnormal screening-tympanometry in Aug., Sept., Nov. 1978 and Feb. 1979 • living in municipality of Hjoerring, Denmark Exclusion: None Patient Characteristics: • mean age 47.2 months, range 42–54 months • male 23, female 21	Comparisons : 1.1 Professional tympanometry Dx– : Compliance value >.10 ccm Dx+ : Compliance value ≤.10 ccm Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 1.2 Professional tympanometry Dx– : Compliance value >.20 ccm Dx+ : Compliance value ≤.20 ccm Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 1.3 Professional tympanometry Dx– : Compliance value >.30 ccm Dx+ : Compliance value ≤.30 ccm Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1.1[a]: sensitivity 19.57% (9/46) specificity 100.00% (42/42) PPV 100.00% (9/9) NPV 53.16% (42/79) accuracy 57.95% (51/88) prevalence 52.27% (46/88) Comparison 1.2 [a]: sensitivity 45.65% (21/46) specificity 95.24% (40/42) PPV 91.30% (21/23) NPV 61.54% (40/65) Accuracy 69.32% (61/88) prevalence 52.27% (46/88) Comparison 1.3 [a]: sensitivity 65.22% (30/46) specificity 76.19% (32/42) PPV 75.00% (30/40) NPV 66.67% (32/48) Accuracy 70.45% (62/88) prevalence 52.27% (46/88) *Continued on next page*

[a] Estimated from figure 3.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1238 Fiellau-Nikolajsen 1980			*Continued* 2. Professional tympanometry Dx– : Gradient > .05 ccm Dx+ : Gradient ≤ .05 ccm Myringotomy (sedated) GS– : Fluid absent GS+ : Fluid present 3. Professional tympanometry Dx– : Gradient > .1 ccm Dx+ : Gradient ≤ .1 ccm Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear Comparison 2[a]: sensitivity 78.26% (36/46) specificity 92.86% (39/42) PPV 92.31% (36/39) NPV 79.59% (39/49) accuracy 85.23% (75/88) Comparison 3 [a]: sensitivity 91.30% (42/46) specificity 54.76% (23/42) PPV 68.85% (42/61) NPV 85.19% (23/27) accuracy 73.86% (65/88) prevalence 52.27% (46/88)

[a] These values were calculated from percentages that were provided in the text and thus their accuracy is uncertain.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1241 Fiellau-Nikolajsen 1980	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (Madsen Impedance Meter, type ZO-73, testing tone 220Hz): the author • myringotomies: two otosurgeons * This is the same study as 1238. However, the data are presented slightly differently. Study Cohort: Children who showed abnormal tympanometry and underwent myringotomy. N=44 subjects, 88 ears	Time: 8/1978–2/1979 (tested in August, 1978 – retests in September and November, 1978 and February,1979) Place: Danish urban municipality (Hjoerring munipality: pop. 37,500) Affiliation: Dept's of Otolarygology and Audiology, Hjoerring Hospital, Hjoerring, Denmark Inclusion: • Age: 3 years at study entry (42–54 months by Feb. 1979) • abnormal tympanometric results persisting through 6 months Exclusion: None Patient Characteristics: • mean age 47.2 months, range 42–54 months • male 23, female 21	Comparisons: 1. Professional tympanometry Dx– : Type A and C1 tympanogram Dx+ : Type B and C2 tympanograms Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1[a]: sensitivity 91.30% (42/46) specificity 88.10% (37/42) PPV 89.36% (42/47) NPV 90.24% (37/41) accuracy 89.77% (79/88) prevalence 52.27% (46/88)

[a] Numbers were calculated from percentages and total "n's" presented in Table V.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1245 Fiellau-Nikolajsen 1983	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (Madsen tympanometer, model ZO-73, [Madsen Electronics], 220 Hz testing tone): not specified • myringotomy: ENT surgeon *This is the same study as 1238. However, the data are presented slightly different. Study Cohort: Children who underwent Myringotomy due to persistent abnormal tympanograms across four screens *(Grp 1 was derived from an overall sample of 404 subjects) N=44 subjects, 88 ears	Time: 1978–1979 (four screens: Aug., Sep. & Nov., 1978, Feb. 1979) Place: Subjects identified in municipality of Hjoerring, Denmark, (medium-size urban town with a population of approximately 20,000) Affiliation: ENT Dept., Hjoerring Hospital, Denmark Inclusion: • Age: 3 years (36–48 months) • living in municipality of Hjoerring, Denmark Exclusion: None Patient Characteristics: • age range 36–48 months	Comparisons: 1. Professional tympanometry Dx– : Middle ear pressure >–100 mm H2O or non-flat curve Dx+ : Middle ear pressure ≤–100 mm H2O or flat curve Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry Dx– : Middle ear pressure >–200 mm H2O or non-flat curve Dx+ : Middle ear pressure ≤–200 mm H2O or flat curve Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Professional tympanometry Dx– : Non-flat curve Dx+ : Flat curve Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 95.65% (44/46) specificity 64.29% (27/42) PPV 74.58% (44/59) NPV 93.10% (27/29) accuracy 80.68% (71/88) prevalence 52.27% (46/88) Comparison 2: sensitivity 91.30% (42/46) specificity 88.10% (37/42) PPV 89.36% (42/47) NPV 90.24% (37/41) accuracy 89.77% (79/88) prevalence 52.27% (46/88) Comparison 3: sensitivity 82.61% (38/46) specificity 100.00% (42/42) PPV 100.00% (38/38) NPV 84.00% (42/50) accuracy 90.91% (80/88) prevalence 52.27% (46/88)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1250 Finitzo 1992	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (Maico Screening Immittance Bridge, model No. 610): certified audiologist • pneumatic otoscopy: pediatric otolaryngologist • myringotomy: not specified *No information regarding when tympanometry occurred relative to myringotomy is provided in the methods section. Study Cohort: Children who were to undergo myringotomy for the placement of ventilation tubes for recurrent OM or persistent OME N=88 subjects, 163 ears	Time: not specified Place: Children's Medical Center in Dallas, Texas Affiliation: Methodist Medical Center, Dallas, TX; Callier Center for Communication Disorders and Dept. of Otolaryngology, Univ. of Texas, Dallas, TX Inclusion: • Age: 6 months–9 years • undergoing myringotomy for tube placement to treat recurrent OM or persisitent OME Exclusion: None Patient Characteristics: • mean age 31 months • male 59, female 27	Comparisons: 1. Pneumatic otoscopy[a] – unvalidated examiner Dx– : effusion absent Dx+ : effusion present Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry[a] Dx– : Type A or A' tympanogram Dx+ : Type B tympanogram Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 93.04% (107/115) specificity 58.33% (28/48) PPV 84.25% (107/127) NPV 77.78% (28/36) accuracy 82.82% (135/163) prevalence 70.55% (115/163) Comparison 2: sensitivity 90.28% (65/72) specificity 86.36% (19/22) PPV 98.59% (65/68) NPV 73.08% (19/26) accuracy 89.36% (84/94) prevalence 76.60% (72/94)

[a] Of the 94 ears included the majority underwent myringotomy for recurrent AOM rather than OME; results are not stratified according to rationale for myringotomy. Of 86 children, only 16 had persistent OME; the rest had recurrent OM.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1280 Freyss 1980	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • tympanometry (Madsen ZO 73 impedance bridge): not specified • myringotomy: same investigator for all children Study Cohort: Children undergoing bilateral myringtomy for recurrent otitis media or respiratory tract infection N=50 subjects, 99 ears	Time: not specified Place: Not specified Affiliation: Univ. of Paris VII, Dept. of Oto-laryngology, Hospital Lariboisiere; Dept. of Oto-laryngology, Children's Hosptial Bretonneau, Paris, France Inclusion: • Age: 6 months–8 years • undergoing bilateral myringtomy for recurrent otitis media or respiratory tract infection Exclusion: None Patient Characteristics: • age range 6 months–8 years	Comparisons: 1. Quantitative tympanometry Dx– : ≤115 dB (at 1000Hz) Dx+ : > 115 dB (at 1000Hz) Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Quantitative tympanometry Dx– : < 2 STAR (suprathreshold acoustic reflex) (Madsen units) Dx+ : ≥2 STAR (Madsen units) Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Quantitative tympanometry Dx– : ≤-100 mmH2O Peak Pressure Dx+ : >-100 mmH2O Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 75.00% (57/76) specificity 82.61% (19/23) PPV 93.44% (57/61) NPV 50.00% (19/38) accuracy 76.77% (76/99) prevalence 76.77% (76/99) Comparison 2: sensitivity 93.42% (71/76) specificity 65.22% (15/23) PPV 89.87% (71/79) NPV 75.00% (15/20) accuracy 86.87% (86/99) prevalence 76.77% (76/99) Comparison 3: sensitivity 52.63% (40/76) specificity 82.61% (19/23) PPV 90.91% (40/44) NPV 34.55% (19/55) accuracy 59.60% (59/99) prevalence 76.77% (76/99) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1280 Freyss 1980			*Continued* 4. Quantitative tympanometry Dx– : ≤ 4 Madsen units Maximum Compliance Dx+ : > 4 Madsen Units Maximum Compliance Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 5. Quantitative tympanometry Dx– : <1 Madsen Unit Tympanometric Gradient Dx+ : ≥1 Madsen Unit Tympanometric Gradient Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear Comparison 4: sensitivity 51.32% (39/76) specificity 78.26% (18/23) PPV 88.64% (39/44) NPV 32.73% (18/55) accuracy 57.58% (57/99) prevalence 76.77% (76/99) Comparison 5: sensitivity 61.84% (47/76) specificity 78.26% (18/23) PPV 90.38% (47/52) NPV 38.30% (18/47) accuracy 65.66% (65/99) prevalence 76.77% (76/99)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1282 Fria 1980	Diagnostic study Study Quality Score (0–6): 3 (100101) Examiner(s): • tympanometry (Grason-Stadler, model 1722, 1000Hz at 102 dB SPL): not specified • myringotomy: not specified Study Cohort: OME ~ Children with history of recurrent AOM or otoscopic evidence of persistent OME, or both *(N=40 otoscopically normal children were reported in this article but findings were not relevant to key question four) N=172 subjects, 344 ears	Time: not specified Place: Normal children were from the ambulatory care center. Affiliation: Dept. of Otolaryngology, Univ. of Pittsburgh School of Medicine; Audiology Division, Dept. of Otolaryngology, Children's Hospital of Pittsburgh, Pittsburgh, PA Inclusion: • Age: 3–15 years • history of recurrent AOM or otoscopic evidence of persistent OME, or both Exclusion: None Patient Characteristics: • Grp 1 mean age 8 years, range 3–15 years, Grp 2 mean age 4 years, range 7 months–13 years	Comparisons:[a] 1. Portable tympanometer Dx– : Middle Ear Analyzer Regions 1,2, and 3 Dx+ : MEA region 4 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Portable tympanometer Dx– : acoustic reflex present Dx+ : acoustic reflex absent Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Portable tympanometer Dx– : Pressure Peak Present Dx+ : Pressure Peak Absent Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 96.50% (138/143) specificity 62.28% (71/114) PPV 76.24% (138/181) NPV 93.42% (71/76) accuracy 81.32% (209/257) prevalence 55.64% (143/257) Comparison 2: sensitivity 98.60% (141/143) specificity 44.74% (51/114) PPV 69.12% (141/204) NPV 96.23% (51/53) accuracy 74.71% (192/257) prevalence 55.64% (143/257) Comparison 3: sensitivity 86.71% (124/143) specificity 80.70% (92/114) PPV 84.93% (124/146) NPV 82.88% (92/111) accuracy 84.04% (216/257) prevalence 55.64% (143/257)

[a] Combines children undergoing myringotomy for recurrent AOM and persistent OME. Groups are not separated in the analyses.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
4879 Fried 1985	Diagnostic Study Study Quality Score (0–6): 1 (100000) Examiner(s): • pneumatic otoscopy: three surgeons • acoustic reflectometry (Acoustic Otoscope): not specified Study Cohort: Children undergoing bilateral myringotomy and ventilation tube insertion N=59 subjects, 118 ears	Time: not specified Place: Not specified Affiliation: Joint Center for Otolaryngology, Harvard Medical School, Boston, MA Inclusion: • Age: 1–13 years • undergoing bilateral myringotomy and ventilation tube insertion Exclusion: None Patient Characteristics: • age range 1–13 years	Comparisons: 1. Acoustic reflectometry Dx– : ≤ 4 Reflectivity Units Dx+ : > 4 Reflectivity Units Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1:[a] outcome~(ears – defined by group) sensitivity 70.97% (44/62) specificity 90.00% (36/40) PPV 91.67% (44/48) NPV 66.67% (36/54) accuracy 78.43% (80/102) prevalence 60.78% (62/102)

[a] The results table includes 102 ears. However, this study was of 118 ears. The authors do not discuss why the other 16 ears were excluded from the results table (Table 1 in the article).

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
4878 Gersdorff 1986	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • tympanometry (Grason-Stadler 1723 oto-admittance meter, 220Hz tone): not specified • myringotomy: ENT surgeon Study Cohort: Pathological children with serous and secretory otitis media who underwent myringotomy and ventilating tube insertion (50% of these children received denitrogenization before induction of classic inhalation anesthesia) *(A control group was studied; however, findings were not relevant to key question four.) N=64 subjects, 128 ears	Time: not specified Place: Not specified Affiliation: Dept. of Otorhinolaryngology, Dept. of Anesthesiology, University of Louvain, Belgium Inclusion: • classified as pathological due to presence of serous and secretory OM upon clinical examination Exclusion: None Patient Characteristics: • combined mean age 7.5 years	Comparisons:[a] 1. Professional tympanometry Dx– : Type I tympanogram Dx+ : Type IV tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry Dx– : Typanogram types I, II, III, & V Dx+ : Typanogram type IV Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Professional tympanometry Dx– : Tympanogram Type I Dx+ : Tympanogram types II,III,IV,&V Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 89.71% (61/68) specificity 28.57% (8/28) PPV 75.31% (61/81) NPV 53.33% (8/15) accuracy 71.88% (69/96) prevalence 70.83% (68/96) Comparison 2: sensitivity 75.31% (61/81) specificity 57.45% (27/47) PPV 75.31% (61/81) NPV 57.45% (27/47) accuracy 68.75% (88/128) prevalence 63.28% (81/128) Comparison 3: sensitivity 91.36% (74/81) specificity 17.02% (8/47) PPV 65/49% (74/113) NPV 53.33% (8/15) accuracy 64.06% (82/128) prevalence 63.28% (81/128)

[a] These data are for tympanograms performed before induction of anesthesia only. Tympanogram classifications: Type I~normal; Type II~endotympanic depression; Type III~endotympanic depression and tympanometric curve rounded by weaker compliance; Type IV~flattened curve; Type V~normal endotympanic pressure and rounded tympanometric curve.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1384 Grimaldi 1976	Diagnostic study Study Quality Score (0–6): 2 (100001) Examiner(s): • audiometry (Peters AP 5 audiometer): OME audiologist • tympanometry (Peters AP 61 impedance meter): one audiologist • binocular micro-tympanoscopy: not specified • myringotomy: single surgeon • visual inspection: effusion probably or possible = OME *Although tympanometry and air-conduction audiometry were also assessed in this study, the data cannot be used because they were combined into a diagnostic algorithm rather than being evaluated as individual methods. Study Cohort: Children referred by otologists for presumptive middle ear effusions N=120 subjects, 209 ears	Time: 9-month period (actual dates not specified) Place: Patients from ENT Dept. of King's College Hospital and referred by otologists based on data from a routine outpatient clinic Affiliation: Not specified apart from author being from London Inclusion: • referred by otologists for presumptive middle ear effusions Exclusion: • inadequate audiometric data Patient Characteristics: • age not specified, other than being children	Comparisons: 1. Non-pneumatic otoscopy[a] Dx– : Effusion absent (includes n=47 undecided cases) Dx+ : Effusion present Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Non-pneumatic otoscopy[b] Dx– : Effusion absent Dx+ : Effusion present (includes n=47 undecided cases) Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Binocular micro-tympanoscopy[c] Dx– : no effusion visualized, undecided group Dx+ : effusion visualized Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 85.71% (132/154) specificity 87.27% (48/55) PPV 94.96% (132/139) NPV 68.57% (48/70) accuracy 86.12% (180/209) prevalence 73.68% (154/209) Comparison 2: sensitivity 98.05% (151/154) specificity 36.36% (20/55) PPV 81.18% (151/186) NPV 86.96% (20/23) accuracy 81.82% (171/209) prevalence 73.68% (154/209) Comparison 3: sensitivity 85.71% (132/154) specificity 87.27% (48/55) PPV 94.96% (132/139) NPV 68.57% (48/70) accuracy 86.12% (180/209) prevalence 73.68% (154/209) *Continued on next page*

[a] There were 47 cases where the examiner was undecided; these have been counted as effusion absent (test negative).
[b] There were 47 cases where the examiner was undecided; these have been counted as effusion present (test positive).
[c] This result includes the "undecided" group as normal.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1384 Grimaldi 1976			*Continued* 4. Binocular micro-tympanoscopy[a] Dx– : no effusion visualized Dx+ : effusion visualized; undecided group Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 5. Binocular micro-tympanoscopy[b] Dx– : No effusion visualized Dx+ : Effusion visualized Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear Comparison 4: sensitivity 98.05% (151/154) specificity 36.36% (20/55) PPV 81.18% (151/186) NPV 86.96% (20/23) accuracy 81.82% (171/209) prevalence 73.68% (154/209) Comparison 5: sensitivity 97.78% (132/135) specificity 74.07% (20/27) PPV 94.96% (132/139) NPV 86.96% (20/23) accuracy 93.83% (152/162) prevalence 83.33% (135/162)

[a] The results table includes the "undecided" group as abnormal.
[b] There were 47 ears that were not classified as "yes" or "no" pre-operatively; rather they were labeled "undecided." These 47 are not included in the results table.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1397 Haapaniemi 1997	Diagnostic study Study Quality Score (0–6): 2 (100100) Examiner(s): • pure-tone audiometry (Madsen TBN 80 audiometer [Madsen Electronics]): not specified • tympanometry and stapedius reflexes (GSI 28 tympanometer [Grason-Stadler], 226 Hz tone): not specified • otomicroscopy: not specified • paracentesis: not specified Study Cohort: 1st and 4th grade children who underwent a routine ENT investigation at school that included: otomicroscopy, pure-tone audiometry, tympanometry and stapedius reflex measurements * (8th grade children were also studied but their age range was above that specified for key question four) N=426 subjects, 850 ears	Time: not specified Place: Elementary schools of Salo, a small town in Finland Affiliation: Dept. Otolaryngology, Univ. Central Hospital of Turku, Finland Inclusion: • Age represented by grade level: First, fourth and eighth grade • attending an elementary school in Salo, Finland Exclusion: None Patient Characteristics: • 1st grade mean age 7.0 years, range 6–9 years; 4th grade mean age 10.2 years, range 10–12 years	Comparisons: 1. Professional tympanometry Dx– : Tympanometric peak pressure (TPP) ≥ –100 daPa Dx+ : TPP < –100 daPa Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry Dx– : Tympanometric peak pressure (TPP) ≥ –100 daPa Dx+: TPP < –100 daPa Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 3. Professional tympanometry Dx– : Tympanometric peak pressure (TPP) ≥ –150 daPa Dx+ : TPP < –150 daPa Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Values for the “b” and “d” cells in the 2X2 table are not provided in article Unit of measure: Varies Comparison 1: Unit of measure: Subjects sensitivity 93.33% (28/30) specificity 88.00% PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 2: Unit of measure: Ear sensitivity 94.74% (36/38) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 3: Unit of measure: Subjects sensitivity 93.33% (28/30) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1397 Haapaniemi 1997			*Continued* 4. Professional tympanometry Dx– : Tympanometric peak pressure TPP≥ –150 daPa Dx+ : TPP < –150 daPa Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 5. Professional tympanometry Dx– : Tympanometric peak pressure TPP ≥ –200 daPa Dx+ : TPP < –200 daPa Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 6. Professional tympanometry Dx– : Tympanometric peak pressure TPP ≥ –200 daPa Dx+: TPP < –200 daPa Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 7. Professional tympanometry Dx– : non-Type B tympanogram Dx+ : Type B tympanogram Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Comparison 4: Unit of measure: Ear sensitivity 94.74%(36/38) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 5: Unit of measure: Subjects sensitivity 86.67% (26/30) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 6: Unit of measure: Ear sensitivity 89.47%(34/38) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 7: Unit of measure: Subjects sensitivity 53.33% (16/30) specificity 100.00% PPV unknown NPV unknown accuracy unknown prevalence unknown *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1397 Haapaniemi 1997			*Continued* 8. Professional tympanometry Dx– : non-Type B tympanogram Dx+ : Type B tympanogram Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 9. Professional tympanometry[a] Dx– : Cutoff of 0.3 ml is given for admittance (see notes below) Dx+ : Cutoff of 0.3 ml is given for admittance (see notes below) Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 10. Professional tympanometry[a] Dx– : Cutoff of 0.3 ml is given for admittance (see notes below) Dx+ : Cutoff of 0.3 ml is given for Admittance (see notes below) Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Comparison 8: Unit of measure: Ear sensitivity 55.26% (21/38) specificity 100.00% PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 9: Unit of measure: Subjects sensitivity 80.00% (24/30) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 10: Unit of measure: Ear sensitivity 81.58% (31/38) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown *Continued on next page*

[a] For diagnostic cutoffs, an Admittance value of 0.3 ml was given as the cutpoint; however, not sure whether admittance < or = 0.3 ml would be a negative result for MEE OR values > 0.3.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1397 Haapaniemi 1997			*Continued* 11. Professional tympanometry[a] Dx– : Relative gradient > 0.35 Dx+ : Relative gradient ≤ 0.35 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 12. Professional tympanometry[a] Dx– : Relative gradient > 0.35 Dx+ : Relative gradient ≤ 0.35 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 13. Professional tympanometry Dx– : Ipsilateral Stapedius Reflex (at 1000Hz) at 105 dB – present Dx+ : Ipsilateral Stapedius Reflex (at 1000Hz) at 105 dB – absent Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 14. Professional tympanometry Dx– : Ipsilateral Stapedius Reflex (at 1000Hz) at 105 dB – present Dx+ : Ipsilateral Stapedius Reflex (at 1000Hz) at 105 dB – absent Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Comparison 11: Unit of measure: Subject sensitivity 76.67% (23/30) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 12: Unit of measure: Ear sensitivity 73.68% (28/38) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 13: Unit of measure: Subject sensitivity 76.67% (23/30) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 14: Unit of measure: Ear sensitivity 78.95% (30/38) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown *Continued on next page*

[a] For diagnostic cutoffs, a Relative Gradient value of 0.35 was given as the cutpoint; however, not sure whether gradient > 0.35 would be a negative result for MEE (I am assuming it is).

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1397 Haapaniemi 1997			*Continued* 15. Professional tympanometry Dx– : Contralateral Stapedius Reflex (at 1000 Hz) 110dB – present Dx+ : Contralateral Stapedius Reflex (at 1000Hz) at 110 dB – absent Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 16. Professional tympanometry Dx– : Contralateral Stapedius Reflex (at 1000 Hz) 110dB – present Dx+ : Contralateral Stapedius Reflex (at 1000Hz) at 110 dB – absent Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 17. Professional tympanometry[a] Dx– : Tympanogram Types A, C1, and C2 Dx+ : Tympanogram Type B Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Comparison 15: Unit of measure: Subject sensitivity 73.33% (22/30) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 16: Unit of measure: Ear sensitivity 73.68% (28/38) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 17: Unit of measure: Ear sensitivity 55.26% (21/38) specificity 100.00% PPV unknown NPV unknown accuracy unknown prevalence unknown *Continued on next page*

[a] These results examine sensitivity of type B tympanograms in detecting OME in children with either transient or prolonged effusion. Prolonged = effusion still present 4 weeks after myringotomy. Transient = ear healthy 4 weeks after myringotomy.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1397 Haapaniemi 1997			*Continued* 18. Audiometry – air conduction threshold Dx– : ≤ 15 hearing threshold at .25 to 8 kHz Dx+ : > 15 dB hearing threshold (at .25 to 8 kHz) Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 19. Audiometry – air conduction threshold Dx– : ≤ 15 hearing threshold at .25 to 8 kHz Dx+ : > 15 dB hearing threshold (at .25 to 8 kHz) Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 20. Audiometry – air conduction threshold Dx– : ≤ 20 dB hearing threshold (.25 to 8 kHz) Dx+ : > 20 dB hearing threshold (.25 to 8 kHz) Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 21. Audiometry – air conduction threshold Dx– : ≤ 20 dB hearing threshold (.25 to 8 kHz) Dx+ : > 20 dB hearing threshold (.25 to 8 kHz) Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present	*Continued* Comparison 18: Unit of measure: Subject sensitivity 82.76% (24/29) specificity 81.36% (323/397) PPV 24.49% (24/98) NPV 98.48% (323/328) accuracy 81.46% (347/426) prevalence 6.81% (29/426) Comparison 19: Unit of measure: Ear sensitivity 86.49% (32/37) specificity 87.00% PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 20: Unit of measure: Subject sensitivity 68.97% (20/29) specificity 87.91% (349/397) PPV 29.41% (20/68) NPV 97.49% (349/358) accuracy 86.62% (369/426) prevalence 8.38% (29/426) Comparison 21: Unit of measure: Ear sensitivity 72.97% (27/37) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence unknown

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1446 Haughton 1977	Diagnostic study Study Quality Score (0–6): 2 (100001) Examiner(s): • tympanometry (instrument not specified): not specified • tympanocentesis: one of several surgeons Study Cohort: S1~ Ears examined in children admitted for aspiration of the middle ear; Haughton study *(Two additional studies were reported in this article but none reported findings relevant to key question four) N=239 ears, 104 subjects	Time: not specified Place: A typical ear, nose, and throat clinic Affiliation: S1~ Dept. of Otolaryngology and Head and Neck Surgery, Hull Royal Infirmary, Hull, Great Britain Inclusion: • Age: 3 years– >=12 years (max not specified) • admitted for aspiration of the middle ear Exclusion: None Patient Characteristics: • 1% 3 years 6% 4 years 14% 5 years 23% 6 years 10% 7 years 13% 8 years 8% 9 years 10% 10 years 5% 11 years 10% ≥ 12 years	Comparisons: 1. Professional tympanometry Dx– : Compliance > .21 ml Dx+ : Compliance ≤ .21 ml Tympanocentesis (sedation unknown) GS– : Fluid absent GS+ : Fluid present 2. Professional tympanometry Dx– : Compliance > .25 ml Dx+ : Compliance ≤ .25 ml Tympanocentesis (sedation unknown) GS– : Fluid absent GS+ : Fluid present 3. Professional tympanometry Dx– : Compliance > .17 ml Dx+ : Compliance ≤ .17 ml Tympanocentesis (sedation unknown) GS– : Fluid absent GS+ : Fluid present 4. Professional tympanometry Dx– : Gradient > .04 ml/50 mm H2O Dx+ : Gradient ≤ .04 ml/ 50 mm H2O Tympanocentesis (sedation unknown) GS– : Fluid absent GS+ : Fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 75.96% (79/104) specificity 80.74% (109/135) PPV 75.24% (79/105) NPV 81.34% (109/134) accuracy 78.66% (188/239) prevalence 43.51% (104/239) Comparison 2: sensitivity 79.81% (83/104) specificity 74.81% (101/135) PPV 70.94% (83/117) NPV 82.79% (101/122) accuracy 76.99% (184/239) prevalence 43.51% (104/239) Comparison 3: sensitivity 69.23% (72/104) specificity 85.93% (116/135) PPV 79.12% (72/91) NPV 78.38% (116/148) accuracy 78.66% (188/239) prevalence 43.51% (104/239) Comparison 4: sensitivity 76.92% (80/104) specificity 85.19% (115/135) PPV 80.00% (80/100) NPV 82.73% (115/139) accuracy 81.59% (195/239) prevalence 43.51% (104/239) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1446 Haughton 1977			*Continued* 5. Professional tympanometry Dx– : Gradient > .03 ml/50 mm H2O Dx+ : Gradient ≤ .03 ml/ 50 mm H2O Tympanocentesis (sedation unknown) GS– : Fluid absent GS+ : Fluid present 6. Professional tympanometry Dx– : Gradient > .05 ml/50 mm H2O Dx+ : Gradient ≤ .05 ml/ 50 mm H2O Tympanocentesis (sedation unknown) GS– : Fluid absent GS+ : Fluid present 7. Professional tympanometry Dx– : Gradient > .1 ml/50 mm H2O Dx+ : Gradient ≤ .1 ml/ 50 mm H2O Tympanocentesis (sedation unknown) GS– : Fluid absent GS+ : Fluid present	*Continued* Unit of measure: Ear Comparison 5: sensitivity 73.08% (76/104) specificity 87.41% (118/135) PPV 39.18% (76/194) NPV 80.82% (118/146) accuracy 81.17% (194/239) prevalence 43.51% (104/239) Comparison 6: sensitivity 79.81% (83/104) specificity 81.48% (110/135) PPV 76.85% (83/108) NPV 83.97% (110/131) accuracy 80.75% (193/239) prevalence 43.51% (104/239) Comparison 7: sensitivity 87.50% (91/104) specificity 60.00% (81/135) PPV 62.76% (91/145) NPV 86.17% (81/94) accuracy 71.97% (172/239) prevalence 43.51% (104/239)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
3022 Johnson 1980	Cross-sectional Study Quality Score (0–6): 2 (110000) Examiner(s): • tympanometry (impedance bridge): audiologist • myringotomy: not specified *The primary aim of this study was to examine the changes in tympanogram types resulting from anesthesia. This is not a study focused on determining the sensitivity and/or specificity of tympanometry on detecting OME. Study Cohort: Children undergoing myringotomy with placement of ventillation tubes for recurrent AOM or persistent MEE N=61 subjects, 121 ears	Time: not specified Place: Ear, Nose, and Throat Clinic at the University of Utah Medical Center, Salt Lake City, UT Affiliation: Div. of Otolaryngology, Univ. of Utah Inclusion: • Age: 8 months–10 years • recurrent AOM or persistent MEE Exclusion: • perforated tympanic membrane (one ear excluded) Patient Characteristics: • mean age 3.5 years • male 40, female 21	Comparisons: 1. Professional tympanometry[a] Dx– : Normal tympanogram Dx+ : Flat tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 74.32% (55/74) specificity 75.61% (31/41) PPV 84.62% (55/65) NPV 62.00% (31/50) accuracy 74.78% (86/115) prevalence 64.35% (74/115)

[a] Findings excludes 4 ears that were found to have purulent effusion which is consistent with AOM and not OME and 2 where Professional tympanometry result 'unclassified.' According to Table 1 in the article those with Class 1 or 5 changes initially had normal (non-flat) tympanograms.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1600 Jonathan 1989	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • otoscopy (instrument not specified): not specified • tympanometry (instrument not specified): not specified • audiometry (instrument not specified): not specified • myringotomy: not specified *This study focused mainly on sonotubometry. Study Cohort: Children admitted for routine myringotomies (including in some cases adenoidectomy and/or tonsillectomy) *(a control group was studied however findings were not relevant to key question four) N=64 subjects, 126 ears	Time: not specified Place: Grp 1 were operative admissions, and Grp 2 were from a general pediatric ward. Affiliation: St. George's Hospital, Tooting, London Inclusion: • Age: 3–14 years • admitted for myringotomy Exclusion: • pre-existing perforations Patient Characteristics: • mean age 6.2 years, range 3–14 years; Grp 2 mean age 7 years, range 3–14 years • male 35, female 29;	Comparisons: 1. Non-pneumatic otoscopy[a] Dx– : normal appearance of the tympanic membrane Dx+ : abnormal appearance of the tympanic membrane Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry[a] Dx– : Tympanogram has any form other than a flat tracing Dx+ : Tympanogram is flat Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Audiometry – air conduction threshold [a] Dx– : ≤ 15 dB hearing threshold at all frequencies tested Dx+ : > 15 dB hearing threshold at all frequencies tested Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 100.00% specificity 28.00% PPV unknown NPV unknown accuracy 80.36% (90/112) prevalence 100.00% (112/112) Comparison 2: sensitivity 86.00% specificity 86.00% PPV unknown NPV unknown accuracy 85.71% (102/119) prevalence 100.00% (119/119) Comparison 3: sensitivity 90.00% specificity 52.00% PPV unknown NPV unknown accuracy 78.64% (81/103) prevalence 100.00% (103/103)

[a] Data neccesary to complete the results table were not provided.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1632 Karma 1989	Diagnostic study Study Quality Score (0–6): 3 (100101) Examiner(s): • pneumatic otoscopy: otolaryngologist in Tampere or pediatrician in Oulu • myringotomy (only peformed when MEE suspected by pneumatic otoscopy): not specified *OME definition:MEE present without other symptoms/signs of acute infection. Grp 1: Children seen by otolaryngologist in Tampere, Finland Grp 2: Children seen by pediatrician in Oulu, Finland N=2911 subjects, 11804 visits N1=1688 subjects, 5949 visits N2=1223 subjects, 5855 visits	Time: not specified Place: Outpatient Clinics of Otolaryngology at the Tampere or Pediatrics at the Oulu University Central Hospital, Finland Affiliation: Dept. of Clinical Sciences, Univ. of Tampere, Finland; National Public Health Institute, Helsinki, Finland Inclusion: • Age: 0.5–2.5 years • had any ear-related problem or suspicion of them and were brought to either the outpatient clinic in Tampere or Oulu Exclusion: • tympanostomy tubes in one or both ears at a visit • incomplete data Patient Characteristics: • Grp 1 age range 6–11 months 37%, 12–17 m 41%, 18–23 m 18%, 24–29 m 4%, 30–31 m 0.1%; Grp 2 age range 6–11 m 36%, 12–17 m 38%, 18–23 m 20%, 24–29 m 6%, 30–31 m 0.2%	Comparisons: 1. Grp 1 Signs/symptoms Dx– : TM color normal Dx+ : TM haemorrhagic Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Grp 1 Signs/symptoms Dx– : TM color normal Dx+ : TM strongly red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Grp 1 Signs/symptoms Dx– : TM color normal Dx+ : TM moderately red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear–related visits (1–2 years of follow-up) Comparison 1: sensitivity 0.25% (1/408) specificity 100.00% (185/185) PPV 100.00% (1/1) NPV 31.25% (185/592) accuracy 31.37% (186/593) prevalence 68.80% (408/593) Comparison 2: sensitivity 0.74% (3/408) specificity 99.46% (184/185) PPV 75.00% (3/4) NPV 31.24% (184/589) accuracy 31.53% (187/593) prevalence 68.80% (408/593) Comparison 3: sensitivity 2.21% (9/408) specificity 97.84% (181/185) PPV 69.23% (9/13) NPV 31.21% (181/580) accuracy 32.04% (190/593) prevalence 47.30% (408/593) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1632 Karma 1989			*Continued* 4. Grp 1 Signs/symptoms Dx– : TM color normal Dx+ : TM slightly red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 5. Grp 1[a] Non-pneumatic otoscopy Dx– : Tympanic membrane not red Dx+ : Tympanic membrane red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 6. Grp 1[a] Non-pneumatic otoscopy Dx– : Not red Dx+ : Distinctly red – hemorrhagic, strongly or moderately red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear–related visits Comparison 4: sensitivity 1.23% (5/408) specificity 97.84% (181/185) PPV 55.56% (5/9) NPV 30.99% (181/584) accuracy 31.37% (186/593) prevalence 68.80% (408/593) Comparison 5: sensitivity 4.66% (19/408) specificity 94.59% (175/185) PPV 65.52% (19/29) NPV 31.03% (175/564) accuracy 32.72% (194/593) prevalence 68.80% (408/593) LR+: 1.10 LR-: 1.00 Comparison 6: sensitivity 3.43% (14/408) specificity 97.30% (180/185) PPV 73.68% (14/19) NPV 31.36% (180/574) accuracy 32.72% (194/593) prevalence 68.80% (408/593) LR+: .50 LR-: 1.00 *Continued on next page*

[a] The raw numbers were calculated using a combination of information from tables 2, 3, and 5 in article.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1632 Karma 1989			*Continued* 7. Grp 1[a] Non-pneumatic otoscopy Dx– : TM not cloudy Dx+ : TM cloudy Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 8. Grp 1[a] Non-pneumatic otoscopy Dx– : TM color normal Dx+ : TM color abnormal Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 9. Grp 1[a] Non-pneumatic otoscopy Dx– : TM not bulging Dx+ : TM bulging Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear–related visits Comparison 7: sensitivity 92.89% (379/408) specificity 98.38% (182/185) PPV 99.21% (379/382) NPV 86.26% (182/211) accuracy 94.60% (561/593) prevalence 68.80% (408/593 LR+: 51.60 LR–: .07 Comparison 8: sensitivity 97.55% (398/408) specificity 92.97% (172/185) PPV 96.84% (398/411) NPV 94.51% (172/182) accuracy 96.12% (570/593) prevalence 68.80% (408/593) LR+: 13.90 LR–: .03 Comparison 9: sensitivity 45.10% (184/408) specificity 98.92% (183/185) PPV 98.92% (184/186) NPV 44.96% (183/407) accuracy 61.89% (367/593) prevalence 68.80% (408/593) LR+: 56.50 LR–: .60 *Continued on next page*

[a] The raw numbers were calculated using a combination of information from tables 2, 3, and 5 in article.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1632 Karma 1989			*Continued* 10. Grp 1[a] Non-pneumatic otoscopy Dx– : TM not retracted Dx+ : TM retracted Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 11. Grp 1[a] Non-pneumatic otoscopy Dx– : TM position normal Dx+ : TM position abnormal Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 12. Grp 1 Pneumatic otoscopy – unvalidated examiner Dx– : TM mobility normal Dx+ : TM mobility abnormal Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear–related visits Comparison 10: sensitivity 10.05% (41/408) specificity 95.14% (176/185) PPV 82.00% (41/50) NPV 32.41% (176/543) accuracy 36.59% (217/593) prevalence 68.80% (408/593) LR+: 2.00 LR–: .90 Comparison 11: sensitivity 55.39% (226/408) specificity 94.05% (174/185) PPV 95.36% (226/237) NPV 48.88% (174/356) accuracy 67.45% (400/593) prevalence 68.80% (408/593) LR+: 9.50 LR–: .50 Comparison 12: sensitivity 98.77% (403/408) specificity 90.27% (167/185) PPV 95.72% (403/421) NPV 97.09% (167/172) accuracy 96.12% (570/593) prevalence 68.80% (408/593) *Continued on next page*

[a] The raw numbers were calculated using a combination of information from tables 2, 3, and 5 in article.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1632 Karma 1989			*Continued* 13. Grp 1[a] Pneumatic otoscopy – examiner validation not specified Dx– : TM with normal mobility Dx+ : TM with impaired mobility Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 14. Grp 1 Pneumatic otoscopy – examiner validation not specified Dx– : TM with normal mobility Dx+ : TM mobility distinctly impaired Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 15. Grp 1 Pneumatic otoscopy – examiner validation not specified Dx– : TM mobility normal Dx+ : TM mobility slightly impaired Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear–related visits Comparison 13: sensitivity 98.77% (403/408) specificity 90.27% (167/185) PPV 95.72% (403/421) NPV 97.09% (167/172) accuracy 96.12% (570/593) prevalence 68.80% (408/593) LR+: 10.20 LR–: .01 Comparison 14: sensitivity 76.23% (311/408) specificity 97.30% (180/185) PPV 98.42% (311/316) NPV 64.98% (180/277) accuracy 82.80% (491/593) prevalence 68.80% (408/593) LR+: 30.50 LR–: .20 Comparison 15: sensitivity 22.30% (91/408) specificity 92.97% (172/185) PPV 87.50% (91/104) NPV 35.17% (172/489) accuracy 44.35% (263/593) prevalence 68.80% (408/593) LR+: 3.20 LR–: .80 *Continued on next page*

[a] The raw numbers were calculated using a combination of information from tables 2, 3, and 5 in article.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1632 Karma 1989			*Continued* 16. Grp 2 Signs/symptoms Dx– : TM color normal Dx+ : TM haemorrhagic Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 17. Grp 2 Signs/symptoms Dx– : TM color normal Dx+ : TM strongly red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 18. Grp 2 Signs/symptoms Dx– : TM color normal Dx+ : TM moderately red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear–related visits Comparison 16: sensitivity 5.80% (20/345) specificity 98.05% (151/154) PPV 86.96% (20/23) NPV 31.72% (151/476) accuracy 34.27% (171/499) prevalence 69.14% (345/499) Comparison 17: sensitivity 2.90% (10/345) specificity 99.35% (153/154) PPV 90.91% (10/11) NPV 31.35% (153/488) accuracy 32.67% (163/499) prevalence 29.06% (145/499) Comparison 18: sensitivity 2.90% (10/345) specificity 98.70% (152/154) PPV 83.33% (10/12) NPV 31.21% (152/487) accuracy 32.46% (162/499) prevalence 69.14% (345/499) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1632 Karma 1989			*Continued* 19. Grp 2 Signs/symptoms Dx– : TM color normal Dx+ : TM slightly red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 20. Grp 2 Non-pneumatic otoscopy Dx– : TM color normal Dx+ : Tympanic membrane red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 21. Grp 2[a] Non-pneumatic otoscopy Dx– : TM color normal Dx+ : TM distinctly red – hemorrhagic, strongly or moderately red Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear–related visits Comparison 19: sensitivity 8.99% (31/345) specificity 95.45% (147/154) PPV 81.58% (31/38) NPV 31.89% (147/461) accuracy 35.67% (178/499) prevalence 69.14% (345/499) Comparison 20: sensitivity 12.17% (42/345) specificity 92.21% (142/154) PPV 77.78% (42/54) NPV 31.91% (142/445) accuracy 36.87% (184/499) prevalence 69.14% (345/499) LR+: .20 LR–: 1.00 Comparison 21: sensitivity 11.30% (39/345) specificity 96.75% (149/154) PPV 88.64% (39/44) NPV 32.75% (149/455) accuracy 37.68% (188/499) prevalence 69.14% (345/499) LR+: 3.00 LR–: .90 *Continued on next page*

[a] The raw numbers were calculated using a combination of information from tables 2, 3, and 5 in article.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1632 Karma 1989			*Continued* 22. Grp 2[a] Non-pneumatic otoscopy Dx– : TM color normal Dx+ : TM cloudy Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 23. Grp 2[a] Non-pneumatic otoscopy Dx– : TM color normal Dx+ : TM color abnormal Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 24. Grp 2 [a] Non-pneumatic otoscopy Dx– : TM not bulging Dx+ : TM bulging Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear–related visits Comparison 22: sensitivity 68.99% (238/345) specificity 87.66% (135/154) PPV 92.61% (238/257) NPV 55.79% (135/242) accuracy 74.75% (373/499) prevalence 69.14% (345/499) LR+: 5.60 LR–: .40 Comparison 23: sensitivity 81.16% (280/345) specificity 79.22% (122/154) PPV 89.74% (280/312) NPV 65.24% (122/187) accuracy 80.56% (402/499) prevalence 69.14% (345/499) LR+: 4.00 LR–: .20 Comparison 24: sensitivity 18.26% (63/345) specificity 99.35% (153/154) PPV 98.44% (63/64) NPV 35.17% (153/435) accuracy 43.29% (216/499) prevalence 69.14% (345/499) LR+: 23.00 LR–: .80 *Continued on next page*

[a] The raw numbers were calculated using a combination of information from tables 2, 3, and 5 in article.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1632 Karma 1989			*Continued* 25. Grp 2[a] Non-pneumatic otoscopy Dx- : TM not retracted Dx+ : TM retracted Myringotomy (sedated) GS- : fluid absent GS+ : fluid present 26. Grp 2[a] Non-pneumatic otoscopy Dx– : TM position normal Dx+ : TM position abnormal Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 27. Grp 2 Pneumatic otoscopy – unvalidated examiner Dx– : TM mobility normal Dx+ : TM mobility abnormal Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear–related visits Comparison 25: sensitivity 32.17% (111/345) specificity 90.26% (139/154) PPV 88.10% (111/126) NPV 37.27% (139/373) accuracy 50.10% (250/499) prevalence 69.14% (345/499 LR+: 3.30 LR–: .80 Comparison 26: sensitivity 50.43% (174/345) specificity 90.20% (138/153) PPV 91.58% (174/190) NPV 44.66% (138/309) accuracy 62.53% (312/499) prevalence 69.14% (345/499) LR+: 4.90 LR–: .60 Comparison 27: sensitivity 93.62% (323/345) specificity 71.43% (110/154) PPV 88.01% (323/367) NPV 83.33% (110/132) accuracy 86.77% (433/499) prevalence 69.14% (345/499) *Continued on next page*

[a] The raw numbers were calculated using a combination of information from tables 2, 3, and 5 in article.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1632 Karma 1989			*Continued* 28. Grp 2[a] Pneumatic otoscopy – examiner validation not specified Dx– : TM mobility normal Dx+ : TM mobility impaired Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 29. Grp 2[a] Pneumatic otoscopy – examiner validation not specified Dx– : TM mobility normal Dx+ : TM mobility distinctly impaired Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 30. Grp 2[a] Pneumatic otoscopy – examiner validation not specified Dx– : TM mobility normal Dx+ : TM mobility slightly impaired Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear–related visits Comparison 28: sensitivity 93.62% (323/345) specificity 70.78% (109/154) PPV 87.77% (323/368) NPV 83.21% (109/131) accuracy 86.57% (432/499) prevalence 69.14% (345/499) LR+: 3.30 LR–: .09 Comparison 29: sensitivity 84.35% (291/345) specificity 85.71% (132/154) PPV 92.97% (291/313) NPV 70.97% (132/186) accuracy 84.77% (423/499) prevalence 69.14% (345/499) LR+: 5.90 LR–: .20 Comparison 30: sensitivity 9.28% (32/345) specificity 85.06% (131/154) PPV 58.18% (32/55) NPV 29.50% (131/444) accuracy 32.67% (163/499) prevalence 69.14% (345/499) LR+: .60 LR–: 1.10

[a] The raw numbers were calculated using a combination of information from tables 2, 3, and 5 in article.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1646 Kemaloglu 1999	Diagnostic study Study Quality Score (0–6): 3 (111000) Examiner(s): • otoscopy and pneumatic otoscopy: the first author • tympanometry (AZ7 electroacoustic impedancemeter [Interacoustics]): not specified • acoustic reflectometry (acoustic otoscope [ENT Medical Devices]) • paracentesis: not specified *Potential problem – only children with OME underwent paracentesis which was how the condition was diagnosed. The children without OME (controls) were diagnosed clinically, i.e., they did not undergo paracentesis. Grp 1: Ears with serous otitis media Grp 2: Normal Ears (age matched children who were free of any ENT problem during 3 month follow-up) N=156 subjects, 300 ears N1=81 subjects, 150 ears N2=75 subjects, 150 ears	Time: followed for 3 months (actual dates not specified) Place: Not specified Affiliation: Dept. of ENT, Faculty of Medicine, Gazi Univ., Ankara, Turkey Inclusion: • Grp 1~ears presented retracted TM in stage II or III with vascularization & dullness lasting for at least 3 months (effusion detected on paracentesis.) • Grp 2~free of any ENT problem during follow-up of 3 mos. Exclusion: • Grp 1~ears with tympanosclerosis or pseudomembrane of the TM and those with adhesive OM • Grp 1~subjects with recurrent otitis media who presented normal TM between intervals of AOM) Patient Characteristics: • Grp 1 mean age 6.17 years; Grp 2 mean age 6.42 years	Comparisons: 1. Grps 1 & 2 Professional tympanometry Dx– : A or C tracing on tympanogram Dx+ : B tracing on tympanogram Tympanocentesis (sedation unknown) GS– : fluid absent GS+ : fluid present 2. Grps 1 & 2 Acoustic reflectometry Dx– : Reflectivity < 5 Dx+ : Reflectivity ≥ 5 Tympanocentesis (sedation unknown) GS– : fluid absent GS+ : fluid present 3. Grps 1 & 2 Acoustic reflectometry Dx– : Curve angle > 75 degrees Dx+ : Curve angle ≤ 75 degrees Tympanocentesis (sedation unknown) GS– : fluid absent GS+ : fluid present 4. Grps 1 & 2 Acoustic reflectometry Dx– : Curve angle > 90 degrees Dx+ : Curve angle ≤ 90 degrees Tympanocentesis (sedation unknown) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 96.00% (144/150) specificity 92.00% (138/150) PPV 92.31% (144/156) NPV 95.83% (138/144) accuracy 94.00% (282/300) prevalence 50.00% (150/300) Comparison 2: sensitivity 65.33% (98/150) specificity 99.33% (149/150) PPV 98.99% (98/99) NPV 74.13% (149/201) accuracy 82.33% (247/300) prevalence 50.00% (150/300) Comparison 3: sensitivity 78.00% (117/150) specificity 99.33% (149/150) PPV 99.15% (117/118) NPV 81.87% (149/182) accuracy 88.67% (266/300) prevalence 50.00% (150/300) Comparison 4: sensitivity 97.33% (146/150) specificity 85.33% (128/150) PPV 86.90% (146/168) NPV 96.97% (128/132 accuracy 91.33% (274/300) prevalence 50.00% (150/300)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1650 Kennedy 1982	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • tympanometry (Madsen Z76): audiologist • myringotomy: not specified Study Cohort: Myringotomy or myringtomy with tubes performed on 75 ears suspected of having OME N=75 ears * number of subjects not specified	Time: not specified Place: Not specified Affiliation: Dept. of Otolaryngology, Geisinger Medical Clinic, Danville, PA Inclusion: • Ages: 9 months – 13 years • chronic or recurrent OME Exclusion: None Patient Characteristics: Not specified	Comparisons: 1. Professional tympanometry Dx– : Normal tympanogram Dx+ : Flat, rollover, or peaked negative pressure tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry Dx– : Normal, rollover, or peaked, or negative pressure tympanogram Dx+: Flat, only Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 100.00% (51/51) specificity 45.83% (11/24) PPV 79.69% (51/64) NPV 100.00% (11/11) accuracy 82.67% (62/75) prevalence 68.00% (51/75) Comparison 2: sensitivity 86.27% (44/51) specificity 87.50% (21/24) PPV 93.62% (44/47) NPV 75.00% (21/28) accuracy 86.67% (65/75) prevalence 68.00% (51/75)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1685 Koivunen 1997	Diagnostic study Study Quality Score (0–6): 3 (110001) Examiner(s): • tympanometry (MicroTymp [Welch Allyn]): a trained nurse • myringotomy: operating surgeon *Article does not state when the tympanogram was performed in relation to the myringotomy, thus it is not clear whether this study fits the criterion of the diagnostic test being performed ≤ 24hrs before myringotomy Study Cohort: Children referred for adenoidectomy, tympanostomy tube placement, or both procedures for recurrent otitis media or glue ear *(another group of children were studied but findings were not relevant to key question four) N=162 subjects, 314 ears	Time: Grp 1~8/1992–1/1993; Grp 2~two time periods during 1994 and 1995 (months not specified) Place: Oulu, Finland Affiliation: Depts. of Otolaryngology and Pediatrics, University of Oulu, Finland Inclusion: • referred for adenoidectomy, tympanostomy tube placement, or both procedures in the Dept. of Otolaryngology, in two time periods during 1994–95 Exclusion: • perforation or presence of tympanostomy tubes Patient Characteristics: • mean age 4.7 years, range 1 month-16 years; Grp 2 median age 34 months, range 7 months–8 years • male 130, female 76	Comparisons: 1. Portable tympanometer[a] Dx–: Type A and C tympanograms Dx+:Type B tympanograms Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Portable tympanometer[b] Dx– : Type A and C tympanograms Dx+:Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Portable tympanometer[c] Dx– : Type A and C tympanograms Dx+:Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 80.77% (42/52) specificity 92.97% (119/128) PPV 82.35% (42/51) NPV 92.25% (119/129) accuracy 89.44% (161/180) prevalence 28.89% (52/180) Comparison 2: sensitivity 71.43% (10/14) specificity 38.30% (18/47) PPV 25.64% (10/39) NPV 81.82% (18/22) accuracy 45.90% (28/61) prevalence 22.95% (14/61) Comparison 3: sensitivity 78.79% (52/66) specificity 78.29% (137/175) PPV 57.78% (52/90) NPV 90.73% (137/151) accuracy 78.42% (189/241) prevalence 27.39% (66/241) *Continued on next page*

[a] These results are for the "cooperative" group. These are combined results for children undergoing myringotomy for recurrent AOM and OME; results are not stratified on this variable.
[b] These results are for the "uncooperative" group. These are combined results for children undergoing myringotomy for recurrent AOM and OME; results are not stratified on this variable.
[c] These results are for the "cooperative" and "uncooperative" groups combined. Combined results for children undergoing myringotomy for recurrent AOM & OME; results aren't stratified on this variable.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1685 Koivunen 1997			*Continued* 4. Age: <24 months Portable tympanometer[a] Dx– : Type A and C tympanograms Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 5. Age: >=24 months Portable tympanometer[a] Dx– : Type A and C tympanograms Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear Comparison 4: sensitivity 78.00% specificity 91.00% PPV unknown NPV unknown accuracy unknown prevalence unknown Comparison 5: sensitivity 79.00% specificity 94.00% PPV unknown NPV unknown accuracy unknown prevalence unknown

[a] These are combined results for children undergoing myringotomy for recurrent AOM & OME; results are not stratified on this variable. Raw numbers were not provided for the results stratified by age.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1785 Lovette 1976	Diagnostic study Study Quality Score (0–6): 2 (100001) Examiner(s): • tympanometry (Model 1720 [Grason-Stadler]): nearly half by a third-year medical student • myringotomy: not specified Study Cohort: children involved in study to assess accuracy of detecting MEE by otoscopic tympanometric data alone * (another study was reported but findings were not relevant to key question four) N=21 subjects, 42 ears	Time: not specified Place: Affiliation: Tufts Univ., School of Engineering, Boston, MA; Dept. of Otolaryngology, Children's Hospital of Pittsburgh, PA Inclusion: • Age: Not specified • recurrent AOM or persistent MEE, or both • candidates for myringotomy and tympanostomy tube insertion Exclusion: None Patient Characteristics: Not Specified	Comparisons: 1. Portable tympanometer[a] Dx– : Admittance ≥ 0.25 mmhos Dx+ : Admittance < 0.25 mmhos Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 90.00% (27/30) specificity 58.33% (7/12) PPV 84.38% (27/32) NPV 70.00% (7/10) accuracy 80.95% (34/42) prevalence 71.43% (30/42)

[a] This study combines children undergoing myringotomy for recurrent AOM and OME. The results are not stratified on this variable.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1804 Macknin 1987	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • acoustic reflectometry: pediatrician • myringotomy: one of the staff otologists * This study was done on children with recurrent otitis media; they do not state whether this means recurrent OME or AOM. Study Cohort: Children who underwent myringotomy and tympanostomy tube placement for recurrent OM and who had reflectometry performed N=100 subjects, 198 ears	Time: not specified Place: Not specified Affiliation: Dept. of Pediatric and Adolescent Medicine and Dept. of Otolaryngology and Communicative Disorders, The Cleveland Clinic Foundation, Cleveland, OH Inclusion: • Age: 1–11 years (one 16 year old female) • underwent myringotomy and tympanostomy tube placement for recurrent OM and had reflectometry performed Exclusion: None Patient Characteristics: • mean age male 3.5 yrs and female 5.6 yrs, range 1–11 yrs except one 16 yr old • male 70, female 30	Comparisons: 1. Acoustic reflectometry[a] Dx– : Zero reflectivity units (RU) Dx+ : ≥ 1RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Acoustic reflectometry[a] Dx– : Zero reflectivity units (RU) Dx+ : ≥ 1 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Acoustic reflectometry[a] Dx– : < 2 reflectivity units (RU) Dx+ : ≥ 2 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 4. Acoustic reflectometry[a] Dx– : < 2 reflectivity units (RU) Dx+ : ≥ 2 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear (comparison specific) Comparison 1: Unit of measure: right ear sensitivity 98.51% (66/67) specificity 0.00% (0/33) PPV 66.67% (66/99) NPV 0.00% (0/1) accuracy 66.00% (66/100) prevalence 67.00% (67/100) Comparison 2: Unit of measure: left ear sensitivity 98.36% (60/61) specificity 2.70% (1/37) PPV 62.50% (60/96) NPV 50.00% (1/2) accuracy 62.24% (61/98) prevalence 62.24% (61/98) Comparison 3: Unit of measure: right ear sensitivity 97.01% (65/67) specificity 12.12% (4/33) PPV 69.15% (65/94) NPV 66.67% (4/6) accuracy 69.00% (69/100) prevalence 67.00% (67/100) Comparison 4: Unit of measure: left ear sensitivity 90.16% (55/61) specificity 5.41% (2/37) PPV 61.11% (55/90) NPV 25.00% (2/8) accuracy 58.16% (57/98) prevalence 62.24% (61/98) *Continued on next page*

[a] The values in the results table were calculated using the sensitivity and specificity provided in Table 2 in article; total "ns" of right and left ears examined (n=100 and n=98 respectively) and percentage of ears with fluid (67% and 62% respectively).

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1804 Macknin 1987			*Continued* 5. Acoustic reflectometry[a] Dx– : < 3 reflectivity units (RU) Dx+ : ≥ 3 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 6. Acoustic reflectometry[a] Dx– : < 3 reflectivity units (RU) Dx+ : ≥ 3 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 7. Acoustic reflectometry[a] Dx– : < 4 reflectivity units (RU) Dx+ : ≥ 4 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear (comparison specific) Comparison 5: Unit of measure: right ear sensitivity 89.55% (60/67) specificity 18.18% (6/33) PPV 68.97% (60/87) NPV 46.15% (6/13) accuracy 66.00% (66/100) prevalence 67.00% (67/100) Comparison 6: Unit of measure: left ear sensitivity 80.33% (49/61) specificity 21.62% (8/37) PPV 62.82% (49/78) NPV 40.00% (8/20) accuracy 58.16% (57/98) prevalence 62.24% (61/98) Comparison 7: Unit of measure: right ear sensitivity 82.09% (55/67) specificity 36.36% (12/33) PPV 72.37% (55/76) NPV 50.00% (12/24) accuracy 67.00% (67/100) prevalence 67.00% (67/100) *Continued on next page*

[a] The values in the results table were calculated using the sensitivity and specificity provided in Table 2 in article; total "ns" of right and left ears examined (n=100 and n=98 respectively) and percentage of ears with fluid (67% and 62% respectively).

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1804 Macknin 1987			*Continued* 8. Acoustic reflectometry[a] Dx– : < 4 reflectivity units (RU) Dx+ : ≥ 4 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 9. Acoustic reflectometry[a] Dx– : < 5 reflectivity units (RU) Dx+ : ≥ 5 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 10. Acoustic reflectometry[a] Dx– : < 5 reflectivity units (RU) Dx+ : ≥ 5 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 11. Acoustic reflectometry[a] Dx– : < 6 reflectivity units (RU) Dx+ : ≥ 6 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Comparison 8: Unit of measure: left ear sensitivity 70.49% (43/61) specificity 48.65% (18/37) PPV 69.35% (43/62) NPV 50.00% (18/36) accuracy 62.24% (61/98) prevalence 62.24% (61/98) Unit of measure: Ear (comparison specific) Comparison 9: right ear sensitivity 76.12% (51/67) specificity 60.61% (20/33) PPV 76.69% (51/64) NPV 55.56% (20/36) accuracy 71.00% (71/100) prevalence 67.00% (67/100) Comparison 10: left ear sensitivity 54.10% (33/61) specificity 62.16% (23/37) PPV 70.21% (33/47) NPV 45.10% (23/51) accuracy 57.14% (56/98) prevalence 62.24% (61/98) Comparison 11: right ear sensitivity 59.70% (40/67) specificity 72.73% (24/33) PPV 81.63% (40/49) NPV 47.06% (24/51) accuracy 64.00% (64/100) prevalence 67.00% (67/100) *Continued on next page*

[a] The values in the results table were calculated using the sensitivity and specificity provided in Table 2 in article; total "ns" of right and left ears examined (n=100 and n=98 respectively) and percentage of ears with fluid (67% and 62% respectively).

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1804 Macknin 1987			*Continued* 12. Acoustic reflectometry[a] Dx– : < 6 reflectivity units (RU) Dx+ : ≥ 6 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 13. Acoustic reflectometry[a] Dx– : < 7 reflectivity units (RU) Dx+ : ≥ 7 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 14. Acoustic reflectometry[a] Dx– : < 7 reflectivity units (RU) Dx+ : ≥ 7 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 15. Acoustic reflectometry[a] Dx– : < 8 reflectivity units (RU) Dx+ : ≥ 8 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear (comparison specific) Comparison 12: left ear sensitivity 36.07% (22/61) specificity 91.89% (34/37) PPV 88.00% (22/25) NPV 46.58% (34/73) accuracy 57.14% (56/98) prevalence 62.24% (61/98) Comparison 13: right ear sensitivity 47.76% (32/67) specificity 90.91% (30/33) PPV 91.43% (32/35) NPV 46.15% (30/65) accuracy 62.00% (62/100) prevalence 67.00% (67/100) Comparison 14: left ear sensitivity 26.23% (16/61) specificity 97.30% (36/37) PPV 94.12% (16/17) NPV 44.44% (36/81) accuracy 53.06% (52/98) prevalence 62.24% (61/98) Comparison 15: right ear sensitivity 17.91% (12/67) specificity 93.94% (31/33) PPV 85.71% (12/14) NPV 36.05% (31/86) accuracy 43.00% (43/100) prevalence 67.00% (67/100) *Continued on next page*

[a] The values in the results table were calculated using the sensitivity and specificity provided in Table 2 in article; total "ns" of right and left ears examined (n=100 and n=98 respectively) and percentage of ears with fluid (67% and 62% respectively).

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 1804 Macknin 1987			*Continued* 16. Acoustic reflectometry[a] Dx– : < 8 reflectivity units (RU) Dx+ : ≥ 8 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 17. Acoustic reflectometry[a] Dx– : < 9 reflectivity units (RU) Dx+ : ≥ 9 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 18. Acoustic reflectometry[a] Dx– : < 9 reflectivity units (RU) Dx+ : ≥ 9 RU Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear (comparison specific) Comparison 16: left ear sensitivity 3.28% (2/61) specificity 100.00% (37/37) PPV 100.00% (2/2) NPV 38.54% (37/96) accuracy 39.80% (39/98) prevalence 62.24% (61/98) Comparison 17: right ear sensitivity 1.50% (1/67) specificity 100.00% (33/33) PPV 100.00% (1/1) NPV 33.33% (33/99) accuracy 34.00% (34/100) prevalence 67.00% (67/100) Comparison 18: left ear sensitivity 0.00% (0/61) specificity 100.00% (37/37) PPV ------- (0/0) NPV 37.76% (37/98) accuracy 37.76% (37/98) prevalence 62.24% (61/98)

[a] The values in the results table were calculated using the sensitivity and specificity provided in Table 2 in article; total "ns" of right and left ears examined (n=100 and n=98 respectively) and percentage of ears with fluid (67% and 62% respectively).

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1817 Mains 1989	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • pneumatic otoscopy: a senior registrar and a senior house officer • myringotomy: not specified Study Cohort: Children admitted to Belfast City Hospital for myringotomy during a consecutive 5 month period N=114 subjects, 209 ears	Time: Patients entered study during a consecutive 5 month period (actual dates not specified) Place: Belfast City Hospital Affiliation: Not specified Inclusion: • admitted for myringotomy to the Belfast City Hospital during a 5-month period Exclusion: None Patient Characteristics: • age range 20 months–12 years • surgery indication primarily persistent middle ear effusion	Comparisons: 1. Examiner type: Observer[a] Pneumatic otoscopy – unvalidated examiner Dx– : TM mobile Dx+ : TM immobile Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Examiner type: Observer[b] Pneumatic otoscopy – unvalidated examiner Dx– : TM mobile Dx+ : TM immobile Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 87.93% (102/116) specificity 90.32% (84/93) PPV 91.89% (102/111) NPV 85.71% (84/98) accuracy 89.00% (186/209) prevalence 55.50% (116/209) Comparison 2: sensitivity 84.48% (98/116) specificity 87.10% (81/93) PPV 89.09% (98/110) NPV 81.82% (81/99) accuracy 85.65% (179/209) prevalence 55.50% (116/209)

[a] Observer described as 'Senior Registrar.'
[b] Observer described as 'Senior House Officer with just several months experience.'

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1837 Marchant 1986	Diagnostic study Study Quality Score (0–6): 2 (100001) Examiner(s): • pneumatic otoscope: one of two experienced otoscopists • tympanometry (otoadmittance meter, model 1723 version II [Grason-Stadler]): not specified • tympanocentesis: not specified *Tympanocentesis was only performed on 21 out of 73 infants. These are the only infants where a gold standard diagnostic procedure was performed. Select group where MD felt OM+ and child would benefit from knowing bug. Study Cohort : Infants 2–18 weeks old who underwent tympanocentesis * (Study Cohort was derived from an overall sample of 73 infants) N=21 subjects, 38 ears	Time: not specified Place: Pediatric Outpatient Clinic at Cleveland Metropolitan General Hospital Affiliation: Dept's of Pediatrics and Communication Services, Case Western Reserve University, OH; Division of Communication Disorders, Cleveland Metropolitan General Hospital, OH Inclusion: • Age: <5 months (all infants were 2–18 weeks of age) • attending well-child visit or otitis media was suspected after otoscopic examination by primary physician or nurse practitioner Exclusion: None Patient Characteristics: • age range 2–18 weeks	Comparisons: 1. Professional tympanometry Dx– : Peak susceptance > 0 mmho Dx+ : Peak susceptance ≤ 0 Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry Dx– : Ipsilateral acoustic reflex threshold ≤ 100 dB HL Dx+ : Ipsilateral acoustic reflex threshold absent or > 110 dB HL Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1[a]: sensitivity 94.29% (33/35) specificity[a] 100.00% (3/3) PPV 100.00% (33/33) NPV 60.00% (3/5) accuracy 94.74% (36/38) prevalence 92.11% (35/38) Comparison 2 [a]: sensitivity 97.14% (34/35) specificity 66.67% (2/3) PPV 97.14% (34/35) NPV 66.67% (2/3) accuracy 94.74% (36/38) prevalence 92.11% (35/38)

[a] The authors state that specificity could not be determined from the small number of ears without middle ear effusion on tympanocentesis.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
1936 Mitchell 1990	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): Unknown • tympanometry (Interacoustics AZ7 tympanometer [PCWerth]): • acoustic reflectometry (Acoustic otoscope [Endeco Medical]): • audiometry (Kamplex AC4 audiometer): • myringotomy: Study Cohort: Children with suspected glue ear were studied over a three-month period pure tone audiometry, tympanometry and acoustic reflectometry were attempted on each ear] N=50 subjects, 100 ears	Time: Three-month period (actual dates not specified) Place: Not specified Affiliation: Dept. of Otolaryngology, St. Thomas' Hospital, London Inclusion: • Age: 6 months–14 yrs • suspected glue ear Exclusion: None Patient Characteristics: • age range 6 months–14 years	Comparisons: 1. Professional tympanometry Dx– : Type A or C tympanogram Dx+ : Type B tympanogram Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present 2. Acoustic reflectometry Dx– : AR value ≤ 2 Dx+ : AR value > 2 Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present 3. Audiometry – air conduction threshold Dx– : Hearing threshold < 20dB Dx+ : Hearing threshold ≥ 20dB Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 87.69% (57/65) specificity 52.63% (10/19) PPV 86.36% (57/66) NPV 55.56% (10/18) accuracy 79.76% (67/84) prevalence 77.38% (65/84) Comparison 2: sensitivity 87.32% (62/71) specificity 59.26% (16/27) PPV 84.93% (62/73) NPV 64.00% (16/25) accuracy 79.59% (78/98) prevalence 72.45% (71/98) Comparison 3: sensitivity 80.39% (41/51) specificity 68.75% (11/16) PPV 89.13% (41/46) NPV 52.38% (11/21) accuracy 77.61% (52/67) prevalence 76.12% (51/67)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2012 Nozza 1992	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (GSI-33 Version I Middle Ear Analyzer [Grason-Stadler], 226 Hz probe tone): Grp 1 audiologist; Grp 2 nurse • myringotomy: surgeon • pneumatic otoscopy: nurse otoscopist validated at sensitivity and specificity >85% * This article includes 2 different studies: (1) examines tympanometry vs. myringotomy and the second examines validated pneumatic otoscopy vs. tympanometry; (2) represents the "general population." Grp 1: Ears in children undergoing myringotomy and tube surgery for treatment of chronic or recurrent OM Grp 2: Norms~Ears in children who were hospital outpatients and unscreened with respect to history of middle ear disease N=138 subjects, 171 ears N1=61 subjects, 111 ears N2=77 subjects, 144 ears	Time: not specified Place: Grp 1 Same-Day Surgery Unit of Children's Hospital of Pittsburgh, PA; Grp 2 children coming to outpatient allergy clinic Affiliation: Children's Hospital of Pittsburgh, PA; Dept.'s of Otolaryngology and Biostatistics, Univ. of Pittsburgh, PA Inclusion: • Age: Grp 1 1–8 years • Grp 1~undergoing myringotomy and tube surgery for treatment of chronic or recurrent OM • Grp 2~hospital outpatients who were unscreened with respect to history of middle ear disease (more representative of children in general population) Exclusion: None Patient Characteristics: • Grp 1 age range 1–8 years; Grp 2 mean age 9 years, range 3–16 years	Comparisons: 1. Grp 1[a] Professional tympanometry (AR alone) Dx– : acoustic reflex present Dx+ : acoustic reflex absent Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Grp 1[a] Professional tympanometry Dx– : Pressure gradient >0.1 Dx+ : Pressure gradient ≤0.1 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Grp 1[a] Professional tympanometry Dx– : Pressure gradient >0.2 Dx+ : Pressure gradient ≤0.2 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 4. Grp 1[a] Professional tympanometry Dx– : Peak compensated admittance >0.1 Dx+ : Peak compensated admittance ≤0.1 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	**Unit of measure: Ear** Comparison 1: sensitivity 88.16% (67/76) specificity 85.19% (23/27) PPV 94.37% (67/71) NPV 71.88% (23/32) accuracy 87.38% (90/103) prevalence 73.79% (76/103) Comparison 2: sensitivity 77.78% (63/81) specificity 90.00% (27/30) PPV 95.45% (63/66) NPV 60.00% (27/45) accuracy 81.08% (90/111) prevalence 72.97% (81/111) Comparison 3: sensitivity 91.36% (74/81) specificity 70.00% (21/30) PPV 89.16% (74/83) NPV 75.00% (21/28) accuracy 85.59% (95/111) prevalence 72.97% (81/111) Comparison 4: sensitivity 30.86% (25/81) specificity 96.67% (29/30) PPV 96.15% (25/26) NPV 34.12% (29/85) accuracy 48.65% (54/111) prevalence 72.97% (81/111) *Continued on next page*

[a] Values in the results table were determined by using the values provided in the text of this article which state no MEE group = 30 and MEE group = 81. Combining this information with the provided sensitivity and specificity allowed calculation of the numbers.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2012 Nozza 1992	*Continued*		*Continued* 5. Grp 1[a] Professional tympanometry Dx– : Peak compensated admittance > 0.2 Dx+ : Peak compensated admittance ≤ 0.2 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 6. Grp 1[a] Professional tympanometry Dx– : Peak compensated admittance > 0.3 Dx+ : Peak compensated admittance ≤ 0.3 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 7. Grp 1[a] Professional tympanometry Dx– : Peak compensated admittance > 0.4 Dx+ : Peak compensated admittance ≤ 0.4 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 5: sensitivity 55.56% (45/81) specificity 93.33% (28/30) PPV 95.74% (45/47) NPV 43.75% (28/64) accuracy 65.77% (73/111) prevalence 72.97% (81/111) Comparison 6: sensitivity 72.84% (59/81) specificity 80.00% (24/30) PPV 90.77% (59/65) NPV 52.17% (24/46) accuracy 74.77% (83/111) prevalence 72.97% (81/111) Comparison 7: sensitivity 81.48% (66/81) specificity 63.33% (19/30) PPV 85.71% (66/77) NPV 55.88% (19/34) accuracy 76.58% (85/111) prevalence 72.97% (81/111) *Continued on next page*

[a] Values in the above results table were determined by using the values provided in the text of this article which state no MEE group = 30 and MEE group = 81. Combining this information with the provided sensitivity and specificity allowed calculation of the numbers.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2012 Nozza 1992			*Continued* 8. Grp 2[a] Professional tympanometry Dx– : acoustic reflex present Dx+ : acoustic reflex absent Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 9. Grp 2[a] Professional tympanometry Dx– : Pressure gradient >0.1 Dx+ : Pressure gradient ≤ 0.1 Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 10. Grp 2[a] Professional tympanometry Dx– : Pressure gradient >0.2 Dx+ : Pressure gradient ≤ 0.2 Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 11. Grp 2[a] Professional tympanometry Dx– : Peak compensated admittance > 0.1 Dx+ : Peak compensated admittance ≤ 0.1 Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 8: sensitivity 87.50% (7/8) specificity 81.98% (91/111) PPV 25.93% (7/27) NPV 98.91% (91/92) accuracy 82.35% (98/119) prevalence 6.72% (8/119) Comparison 9: sensitivity 67.67% (6/9) specificity 100.00% (135/135) PPV 100.00% (6/6) NPV 97.83% (135/138) accuracy 97.92% (141/144) prevalence 6.25% (9/144) Comparison 10: sensitivity 77.78% (7/9) specificity 99.26% (134/135) PPV 87.50% (7/8) NPV 98.53% (134/136) accuracy 97.92% (141/144) prevalence 6.25% (9/144) Comparison 11: sensitivity 67.67% (6/9) specificity 100.00% (135/135) PPV 100.00% (6/6) NPV 97.83% (135/138) accuracy 97.92% (141/144) prevalence 6.25% (9/144) *Continued on next page*

[a] Values in the above results table were determined by using the values provided in the text of this article which state no MEE group = 135 and MEE group = 9. Combining this information with the provided sensitivity and specificity allowed calculation of the numbers.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2012 Nozza 1992			*Continued* 12. Grp 2[a] Professional tympanometry Dx– : Peak compensated admittance > 0.2 Dx+ : Peak compensated admittance ≤ 0.2 Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 13. Grp 2 [a] Professional tympanometry Dx– : Peak compensated admittance > 0.3 Dx+ : Peak compensated admittance ≤ 0.3 Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 14. Grp 2[a] Professional tympanometry Dx– : Peak compensated admittance > 0.4 Dx+ : Peak compensated admittance ≤ 0.4 Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present	*Continued* Unit of measure: Ear Comparison 12: sensitivity 77.78% (7/9) specificity 100.00% (135/135) PPV 100.00% (7/7) NPV 98.54% (135/137) accuracy 98.61% (142/144) prevalence 6.25% (9/144) Comparison 13: sensitivity 77.78% (7/9) specificity 97.78% (132/135) PPV 70.00% (7/10) NPV 98.51% (132/134) accuracy 96.53% (139/144) prevalence 6.25% (9/144) Comparison 14: sensitivity 77.78% (7/9) specificity 88.89% (120/135) PPV 31.82% (7/22) NPV 98.36% (120/122) accuracy 88.19% (127/144) prevalence 6.25% (9/144)

[a] Values in the above results table were calculated based on numbers provided under results on pg. 312 in article.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2013 Nozza 1994	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (GSI-33 Version I Middle Ear Analyzer [Grason-Stadler], 226 Hz probe tone): clinically certified and licensed audiologist • pneumatic otoscopy: Pediatric Nurse Practitioner validated at sensitivity 85% and specificity 71% • myringotomy: several surgeons This study combines results for children with chronic OM and recurrent otitis media; they do not state which of these categories represents OME or if either of them represents AOM. Grp 1: Myringotomy and Tympanostomy Group~Ears in children brought to operating room at Children's Hospital of Pittsburgh for M&T surgery Grp 2: Norms1~Ears studied by Nozza et al. N1=171 subjects, 249 ears N2=(subjects?), 130 ears	Time: not specified Place: Grp 1~Same-Day Surgery Unit of Children's Hospital of Pittsburgh, PA Affiliation: Children's Hospital of Pittsburgh, PA; Dept's of Otolaryngology and Biostatistics, Univ. of Pittsburgh, PA Inclusion: • Grp 1~Age: 1–12 years • Grp 1~chronic or recurrent OM • Grp 1~brought to operating room at Children's Hospital of Pittsburgh for M&T surgery Exclusion: None Patient Characteristics: • median age 3.8 years, range 1–12 years	Comparisons: 1. Grp 1 Diagnostic Method: unknown Dx– : tympanometric gradient > 0.2 Dx+ : tympanometric gradient ≤ 0.2 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Grp 1 Diagnostic Method: unknown Dx– : Tymp. Width ≤ 250 daPa Dx+ : Tymp. Width > 250 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 3. Grp 1[a] Pneumatic otoscopy – validated examiner Dx– : MEE absent Dx+ : MEE present Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 4. Grp 1 Professional tympanometry Dx– : Acoustic reflex present Dx+ : Acoustic reflex absent Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear (comp. 1–40) Unit of measure: Subject (comp. 41–43) Comparison 1: sensitivity 84.67% (116/137) specificity 61.61% (69/112) PPV 72.96% (116/159) NPV 76.67% (69/90) accuracy 74.30% (185/249) prevalence 55.02% (137/249) Comparison 2: sensitivity 84.67% (116/137) specificity 73.21% (82/112) PPV 79.45% (116/146) NPV 79.61% (82/103) accuracy 79.52% (198/249) prevalence 55.02% (137/249) Comparison 3: sensitivity 84.67% (116/137) specificity 71.43% (80/112) PPV 78.38% (116/148) NPV 79.21% (80/101) accuracy 78.71% (196/249) prevalence 55.02% (137/249) Comparison 4: sensitivity 85.48% (106/124) specificity 64.89% (61/94) PPV 76.26% (106/139) NPV 77.22% (61/79) accuracy 76.61% (167/218) prevalence 56.88% (124/218) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2013 Nozza 1994	*Continued*		*Continued* 5. Grp 1 Professional tympanometry Dx– : tympanometric gradient >0 Dx+ : tympanometric gradient ≤ 0 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 6. Grp 1 Professional tympanometry Dx– : tympanometric gradient >.1 Dx+ : tympanometric gradient ≤ 0.1 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 7. Grp 1 Professional tympanometry Dx– : tympanometric gradient >0.3 Dx+ : tympanometric gradient ≤0.3 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 8. Grp 1 Professional tympanometry Dx– : Peak admittance > 0 Dx+ : Peak admittance ≤ 0 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 5: sensitivity 23.36% (32/137) specificity 98.21% (110/112) PPV 94.12% (32/34) NPV 95.65% (110/115) accuracy 57.03% (142/249) prevalence 55.02% (137/249) Comparison 6: sensitivity 65.69% (90/137) specificity 91.07% (102/112) PPV 90.00% (90/100) NPV 68.46% (102/149) accuracy 77.11% (192/249) prevalence 55.02% (137/249) Comparison 7: sensitivity 92.70% (127/137) specificity 38.39% (43/112) PPV 64.80% (127/196) NPV 81.13% (43/53) accuracy 68.27% (170/249) prevalence 55.02% (137/249) Comparison 8: sensitivity 10.95% (15/137) specificity 98.21% (110/112) PPV 88.24% (15/17) NPV 47.41% (110/232) accuracy 50.20% (125/249) prevalence 55.02% (137/249) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2013 Nozza 1994			*Continued* 9. Grp 1 Professional tympanometry Dx– : Peak admittance >0.1 Dx+ : Peak admittance ≤0.1 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 10. Grp 1 Professional tympanometry Dx– : Peak admittance >0.2 Dx+ : Peak admittance ≤0.2 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 11. Grp 1 Professional tympanometry Dx– : Peak admittance >0.3 Dx+ : Peak admittance ≤0.3 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 12. Grp 1 Professional tympanometry Dx– : Peak admittance >0.4 Dx+ : Peak admittance ≤0.4 Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 9: sensitivity 27.01% (37/137) specificity 97.32% (109/112) PPV 92.50% (37/40) NPV 52.15% (109/209) accuracy 58.63% (146/249) prevalence 55.02% (137/249) Comparison 10: sensitivity 45.99% (63/137) specificity 91.96% (103/112) PPV 87.50% (63/72) NPV 58.19% (103/177) accuracy 66.67% (166/249) prevalence 55.02% (137/249) Comparison 11: sensitivity 70.07% (96/137) specificity 80.36% (90/112) PPV 81.36% (96/118) NPV 68.70% (90/131) accuracy 74.70% (186/249) prevalence 55.02% (137/249) Comparison 12: sensitivity 83.21% (114/137) specificity 68.75% (77/112) PPV 76.51% (114/149) NPV 77.00% (77/100) accuracy 76.71% (191/249) prevalence 55.02% (137/249) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2013 Nozza 1994			*Continued* 17. Grp 1 Professional tympanometry Dx– : tympanometric Width ≤300 daPa Dx+ : tympanometric Width >300daPa Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 18. Grp 1 Professional tympanometry Dx– : tympanometric Width ≤325 daPa Dx+ : tympanometric Width >325 daPa Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 19. Grp 1 Professional tympanometry Dx– : tympanometric Width ≤350 daPa Dx+ : tympanometric Width >350 daPa Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 20. Grp 1 Professional tympanometry Dx– : tympanometric Width ≤400 daPa Dx+ : tympanometric Width >400 daPa Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 17: sensitivity 76.64% (105/137) specificity 84.82% (95/112) PPV 86.07% (105/122) NPV 74.80% (95/127) accuracy 80.32% (200/249) prevalence 55.02% (137/249) Comparison 18: sensitivity 70.07% (96/137) specificity 88.39% (99/112) PPV 88.07% (96/109) NPV 70.71% (99/140) accuracy 78.31% (195/249) prevalence 55.02% (137/249) Comparison 19: sensitivity 61.31% (84/137) specificity 89.29% (100/112) PPV 87.50% (84/96) NPV 65.36% (100/153) accuracy 73.90% (184/249) prevalence 55.02% (137/249) Comparison 20: sensitivity 48.91% (67/137) specificity 96.43% (108/112) PPV 94.37% (67/71) NPV 60.67% (108/178) accuracy 70.28% (175/249) prevalence 55.02% (137/249) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2013 Nozza 1994			*Continued* 21. Grp 1 Professional tympanometry Dx– : Acoustic reflex present Dx+ : Acoustic reflex absent Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 22. Grp 1 Professional tympanometry Dx– : Tympanometric gradient >0 Dx+ : Tympanometric gradient ≤0 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 23. Grp 1 Professional tympanometry Dx– : Tympanometric gradient >0.1 Dx+ : Tympanometric gradient ≤0.1 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 24. Grp 1 Professional tympanometry Dx– : Tympanometric gradient >0.2 Dx+ : Tympanometric gradient ≤0.2 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 21: sensitivity 76.61% (95/124) specificity 76.60% (72/94) PPV 81.20% (95/117) NPV 71.29% (72/101) accuracy 76.61% (167/218) prevalence 56.88% (124/218) Comparison 22: sensitivity 23.36% (32/137) specificity 100.00% (112/112) PPV 100.00% (32/32) NPV 95.73% (112/117) accuracy 57.83% (144/249) prevalence 55.02% (137/249) Comparison 23: sensitivity 64.23% (88/137) specificity 93.75% (105/112) PPV 92.63% (88/95) NPV 68.18% (105/154) accuracy 77.51% (193/249) prevalence 55.02% (137/249) Comparison 24: sensitivity 84.67% (116/137) specificity 65.18% (73/112) PPV 74.84% (116/155) NPV 77.66% (73/94) accuracy 75.90% (189/249)) prevalence 55.02% (137/249) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2013 Nozza 1994			*Continued* 25. Grp 1 Professional tympanometry Dx– : Tympanometric gradient >0.3 Dx+ : Tympanometric gradient ≤0.3 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 26. Grp 1 Professional tympanometry Dx– : Peak admittance >0 Dx+ : Peak admittance ≤0 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 27. Grp 1 Professional tympanometry Dx– : Peak admittance > 0.1 Dx+ : Peak admittance ≤0.1 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 28. Grp 1 Professional tympanometry Dx– : Peak admittance >0.2 Dx+ : Peak admittance ≤0.2 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 25: sensitivity 92.70% (127/137) specificity 32.14% (36/112) PPV 62.56% (127/203) NPV 78.26% (36/46) accuracy 65.46% (163/249) prevalence 55.02% (137/249) Comparison 26: sensitivity 10.95% (15/137) specificity 100.00% (112/112) PPV 100.00% (15/15) NPV 47.86% (112/234) accuracy 51.00% (127/249) prevalence 55.02% (137/249) Comparison 27: sensitivity 26.28% (36/137) specificity 100.00% (112/112) PPV 100.00% (36/36) NPV 99.12% (112/113) accuracy 59.44% (148/249) prevalence 55.02% (137/249) Comparison 28: sensitivity 46.72% (64/137) specificity 97.32% (109/112) PPV 95.52% (64/67) NPV 59.89% (109/182) accuracy 69.48% (173/249) prevalence 55.02% (137/249) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2013 Nozza 1994			*Continued* 29. Grp 1 Professional tympanometry Dx– : Peak admittance >0.3 Dx+ : Peak admittance ≤0.3 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 30. Grp 1 Professional tympanometry Dx– : Peak admittance >0.4 Dx+ : Peak admittance ≤0.4 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 31. Grp 1 Professional tympanometry Dx– : Tympanometric Width ≤150 daPa Dx+ : Tympanometric Width >150 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 32. Grp 1 Professional tympanometry Dx– : Tympanometric Width ≤200 daPa Dx+ : Tympanometric Width >200 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 29: sensitivity 70.07% (96/137) specificity 84.82% (95/112) PPV 84.96% (96/113) NPV 69.85% (95/136) accuracy 76.71% (191/249) prevalence 55.02% (137/249) Comparison 30: sensitivity 76.74% (105/137) specificity 66.07% (74/112) PPV 73.43% (105/143) NPV 69.81% (74/106) accuracy 71.89% (179/249) prevalence 55.02% (137/249) Comparison 31: sensitivity 94.89% (130/137) specificity 28.57% (32/112) PPV 61.90% (130/210) NPV 82.05% (32/39) accuracy 65.06% (162/249) prevalence 55.02% (137/249) Comparison 32: sensitivity 89.05% (122/137) specificity 50.89% (57/112) PPV 68.93% (122/177) NPV 79.17% (57/72) accuracy 71.89% (179/249) prevalence 55.02% (137/249) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2013 Nozza 1994			*Continued* 33. Grp 1 Professional tympanometry Dx– : Tymp. Width ≤225 daPa Dx+ : Tymp. Width >225 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 34. Grp 1 Professional tympanometry Dx– : Tymp. Width ≤275 daPa Dx+ : Tymp. Width >275 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 35. Grp 1 Professional tympanometry Dx– : Tymp. Width ≤300 daPa Dx+ : Tymp Width >300 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 36. Grp 1 Professional tympanometry Dx– : Tymp. Width ≤325 daPa Dx+ : Tymp. Width >325 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 33: sensitivity 86.13% (118/137) specificity 61.61% (69/112) PPV 73.29% (118/161) NPV 78.41% (69/88) accuracy 75.10% (187/249) prevalence 55.02% (137/249) Comparison 34: sensitivity 78.83% (108/137) specificity 85.71% (96/112) PPV 87.10% (108/124) NPV 76.80% (96/125) accuracy 81.93% (204/249) prevalence 55.02% (137/249) Comparison 35: sensitivity 78.83% (103/137) specificity 86.61% (97/112) PPV 87.29% (103/118) NPV 74.05% (97/131) accuracy 80.32% (200/249) prevalence 55.02% (137/249) Comparison 36: sensitivity 70.07% (96/137) specificity 93.75% (105/112) PPV 93.20% (96/103) NPV 71.92% (105/146) accuracy 80.72% (201/249) prevalence 55.02% (137/249) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2013 Nozza 1994			*Continued* 37. Grp 1 Professional tympanometry Dx– : Tymp. Width ≤350 daPa Dx+ : Tymp. Width >350 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 38. Grp 2 Professional tympanometry Dx– : Tymp. Width ≤150 daPa Dx+ : Tymp. Width >150 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 39. Grp 2 Professional tympanometry Dx– : Tymp. Width ≤200 daPa Dx+ : Tymp. Width >200 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 40. Grp 2 Professional tympanometry Dx– : Tymp. Width ≤250 daPa Dx+ : Tymp. Width >250 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 37: sensitivity 62.04% (85/137) specificity 94.64% (106/112) PPV 93.41% (85/91) NPV 67.09% (106/158) accuracy 76.71% (191/249) prevalence 55.02% (137/249) Comparison 38: sensitivity 88.89% (8/9) specificity 91.97% (126/137) PPV 47.06% (8/17) NPV 99.21% (126/127) accuracy 93.06% (134/144) prevalence 6.25% (9/144) Comparison 39: sensitivity 77.78% (7/9) specificity 99.26% (134/135) PPV 87.50% (7/8) NPV 98.53% (134/136) accuracy 97.92% (141/144) prevalence 6.25% (9/144) Comparison 40: sensitivity 77.78% (7/9) specificity 100.00% (135/135) PPV 100.00% (7/7) NPV 98.54% (135/137) accuracy 98.61% (142/144) prevalence 6.25% (9/144) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2013 Nozza 1994			*Continued* 41. Grp 2 Professional tympanometry Dx– : Tymp. Width ≤150 daPa Dx+ : Tymp. Width >150 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 42. Grp 2 Professional tympanometry Dx– : Tymp. Width ≤ 200 daPa Dx+ : Tymp. Width >200 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 43. Grp 2 Professional tympanometry Dx– : Tymp. Width ≤250 daPa Dx+ : Tymp. Width >250 daPa Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present	*Continued* Unit of measure: Subjects Comparison 41: sensitivity 88.89% (8/9) specificity 79.41% (54/68) PPV 36.36% (8/22) NPV 98.18% (54/55) accuracy 80.52% (62/77) prevalence 11.69% (9/77) Comparison 42: sensitivity 88.89% (8/9) specificity 89.71% (61/68) PPV 53.33% (8/15) NPV 98.39% (61/62) accuracy 89.61% (69/77) prevalence 11.69% (9/77) Comparison 43: sensitivity 88.89% (8/9) specificity 92.65% (63/68) PPV 61.54% (8/13) NPV 98.44% (63/64) accuracy 92.21% (71/77) prevalence 11.69% (9/77)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2048 Orchik 1978	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (electroacoustic impedance bridge, Madsen 70–72): performer not specified • myringotomy: surgeon Study Cohort: Ears of patients who underwent myringotomy for suspected serous otitis media N=76 ears * number of subjects not specified	Time: not specified Place: Not specified Affiliation: Dept. of Audiology and Speech Pathology, Memphis State Univ., TN; East Texas Rehabilitation Center Inclusion: • Age: 6 months–14 years • underwent myringotomy for suspected serous otitis media Exclusion: None Patient Characteristics: • mean age 4.5 years, range 6 months–14 years	Comparisons: 1. Portable tympanometer[a] Dx– : Type A and C tympanograms Dx+ : Type B tympanogram Myringotomy (sedation unknown) GS– : fluid absent or minimal GS+ : fluid present in moderate or large amounts 2. Professional tympanometry[b] Dx– : Acoustic reflex present Dx+ : Acoustic reflex absent Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present 3. not included 4. Professional tympanometry Dx– : Type A & C1&C3 tympanogram Dx+ : Types B & C2 tympanograms Myringotomy (sedation unknown) GS– : fluid absent or minimal GS+ : fluid present in moderate or large amounts *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 53.85% (21/39) specificity 94.59% (35/37) PPV 91.30% (21/23) NPV 66.04% (35/53) accuracy 73.68% (56/76) prevalence 51.32% (39/76) Comparison 2: sensitivity 89.74% (35/39) specificity 78.38% (29/37) PPV 81.40% (35/43) NPV 87.88% (29/33) accuracy 84.21% (64/76) prevalence 51.32% (39/76) Comparison 3: (not included-same as C1) Comparison 4: sensitivity 79.49% (31/39) specificity 86.49% (32/37) PPV 86.11% (31/36) NPV 80.00% (32/40) accuracy 82.89% (63/76) prevalence 51.32% (39/76) *Continued on next page*

[a] In this results table the type "c" tympanograms are included as normals.
[b] Values derived from false positive % and false negative % reported in Table VI for acoustic reflex and total numbers of normal and abnormal ears as reported in Table 2.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2048 Orchik 1978			*Continued* 5. Professional tympanometry[a] Dx– : acoustic reflex present at 500, 2,000, or 4,000 Hz Dx+ : acoustic reflex absent at 500, 2000, or 4000 Hz Myringotomy (sedation unknown) GS– : fluid absent or minimal GS+ : fluid moderate/large amounts 6. Professional tympanometry [a] Dx– : acoustic reflex present at 1000Hz Dx+ : acoustic reflex absent at 1000 Hz Myringotomy (sedation unknown) GS– : fluid absent or minimal GS+ : fluid moderate/large amounts 7. Quantitative tympanometry Dx– : Static compliance ≥.28cc Dx+ : Static compliance <.28 Myringotomy (sedation unknown) GS– : fluid absent or minimal GS+ : fluid present in moderate or large amounts	*Continued* Unit of measure: Ear Comparison 5: sensitivity 87.18% (34/39) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence 51.32% (39/76) Comparison 6: sensitivity 89.74% (35/39) specificity unknown PPV unknown NPV unknown accuracy unknown prevalence 51.32% (39/76) Comparison 7: sensitivity 89.74% (35/39) specificity 40.54% (15/37) PPV 61.40% (35/57) NPV 78.95% (15/19) accuracy 65.79% (50/76) prevalence 51.32% (39/76)

[a] Specificity data might be abstractable from this article for these cutpoints.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2049 Orchik 1978	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (electroacoustic impedance bridge): not specified • myringotomy: surgeon Study Cohort: Patients who were undergoing myringotomy for suspected serous otitis media N=75 subjects, 142 ears	Time: not specified Place: not specified Affiliation: Div. of Communication Disorder, North Texas State Univ.; J.W. Dunn, MD, and Associates, Denton TX Inclusion: • Age: Not specified • undergoing myringotomy for suspected serous otitis media Exclusion: None Patient Characteristics: Not Specified	Comparisons: 1. Professional tympanometry[a] Dx– : Type A and As tympanograms Dx+ : Type B tympanograms Myringotomy (sedation unknown) GS– : fluid absent or minimal GS+ : fluid present in moderate or large amounts 2. Professional tympanometry[b] Dx– : Type A, As, C, and Cs tympanograms Dx+ : Type B tympanograms Myringotomy (sedation unknown) GS– : fluid absent or minimal GS+ : fluid present in moderate or large amounts 3. Professional tympanometry[c] Dx– : Types A and As Dx+ : Types B, C, and Cs Myringotomy (sedation unknown) GS– : fluid absent or minimal GS+ : fluid moderate/large amounts	Unit of measure: Ear Comparison 1: sensitivity 75.41% (46/61) specificity 81.25% (26/32) PPV 88.46% (46/52) NPV 63.41% (26/41) accuracy 77.42% (72/93) prevalence 65.59% (61/93) Comparison 2: sensitivity 54.76% (46/84) specificity 89.66% (52/58) PPV 88.46% (46/52) NPV 57.78% (52/90) accuracy 69.01% (98/142) prevalence 59.15% (84/142) Comparison 3: sensitivity 82.14% (69/84) specificity 44.83% (26/58) PPV 68.32% (69/101) NPV 63.41% (26/41) accuracy 66.90% (95/142) prevalence 59.15% (84/142)

[a] Excluded data presented for type “c” tympanograms. Classified ears with “none” and “minimal” effusion as = no effusion. Classified ears with “moderate” or “impacted” as = +effusion.
[b] Type “c” and “cs” tympanograms are included as “normals.” Classified ears with “none” and “minimal” effusion as = no effusion. Classified ears with “moderate” or “impacted” as = +effusion.
[c] Type “c” and “cs” tympanograms are included as “abnormals.” Classified ears with “none” and “minimal” effusion as = no effusion. Classified ears with “moderate” or “impacted” as = +effusion.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2050 Orchik 1980	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (electroacoustic impedance bridge, Madsen ZO-72): not specified • myringotomy: surgeon Study Cohort: Ears of patients undergoing myringotomy for suspected serous otitis media N=76 ears * number of subjects not specified	Time: not specified Place: not specified Affiliation: Memphis State Univ, TN; J.W. Dunn, MD, and Associates, TX Inclusion: • Age: 6 months–14 years • undergoing myringotomy for suspected serous otitis media, usually for recurrent OM or failure of single OM episode to respond to medical treatment Exclusion: None Patient Characteristics: • mean age 4.5 years, range 6 months–14 years	Comparisons: 1. Professional tympanometry[a] Dx– : Type A tympanogram Dx+ : Type B tympanpgram Myringotomy (sedation unknown) GS– : Fluid absent or minimal GS+ : Fluid present in moderate or large amounts 2. Professional tympanometry[b] Dx– : Type A and C tympanograms Dx+ : Type B tympanograms Myringotomy (sedation unknown) GS– : Fluid absent or minimal GS+ : Fluid present in moderate or large amounts 3. Professional tympanometry[b] Dx– : Type A tympanograms Dx+ : Type B and C tympanograms Myringotomy (sedation unknown) GS– : Fluid absent or minimal GS+ : Fluid present in moderate or large amounts *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 87.50% (21/24) specificity 92.31% (24/26) PPV 91.30% (21/23) NPV 88.89% (24/27) accuracy 90.00% (45/50) prevalence 48.00% (24/50) Comparison 2: sensitivity 53.85% (21/39) specificity 94.59% (35/37) PPV 91.30% (21/23) NPV 66.04% (35/53) accuracy 73.68% (56/76) prevalence 51.32% (39/76) Comparison 3: sensitivity 92.31% (36/39) specificity 64.86% (24/37) PPV 73.47% (36/49) NPV 88.89% (24/27) accuracy 78.95% (60/76) prevalence 51.32% (39/76) *Continued on next page*

[a] Excluded data presented for type “c” tympanograms. Ears with “none” and “minimal” effusion classified as = no effusion; ears with “moderate” or “impacted” as = +effusion.
[b] Type “c” tympanograms are included as “normals.” Ears with “none” and “minimal” effusion classified as = no effusion; ears with “moderate” or “impacted” as = +effusion.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2050 Orchik 1980			*Continued* 4. Professional tympanometry Dx– : Acoustic refl. present @500 Hz Dx+ : Acoustic refl. absent @500 Hz Myringotomy (sedation unknown) GS– : Fluid absent or minimal GS+ : Fluid present in moderate or large amounts 5. Professional tympanometry Dx– : Acoustic reflex present at 1000 Hz Dx+ : Acoustic reflex absent at 1000 Hz Myringotomy (sedation unknown) GS– : Fluid absent or minimal GS+ : Fluid present in moderate or large amounts 6. Professional tympanometry Dx– : Acoustic reflex present at 2000 Hz Dx+ : Acoustic reflex absent at 2000 Hz Myringotomy (sedation unknown) GS– : Fluid absent or minimal GS+ : Fluid present in moderate or large amounts *Continued on next page*	*Continued* Unit of measure: Ear Comparison 4: sensitivity 87.18% (34/39) specificity 70.27% (26/37) PPV 75.56% (34/45) NPV 83.87% (26/31) accuracy 78.95% (60/76) prevalence 51.32% (39/76) Comparison 5: sensitivity 89.74% (35/39) specificity 72.97% (27/37) PPV 77.78% (35/45) NPV 87.10% (27/31) accuracy 81.58% (62/76) prevalence 51.32% (39/76) Comparison 6: sensitivity 87.18% (34/39) specificity 75.68% (28/37) PPV 79.07% (34/43) NPV 84.85% (28/33) accuracy 81.58% (62/76) prevalence 51.32% (39/76) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2050 Orchik 1980			*Continued* 7. Professional tympanometry Dx– : Acoustic reflex present at 4000 Hz Dx+ : Acoustic reflex absent at 4000 Hz Myringotomy (sedation unknown) GS– : Fluid absent or minimal GS+ : Fluid present in moderate or large amounts 8. Quantitative tympanometry Dx– : Static compliance ≥ .28 cc Dx+ : Static compliance < .28 cc Myringotomy (sedation unknown) GS– : Fluid absent or minimal GS+ : Fluid present in moderate or large amounts	*Continued* Unit of measure: Ear Comparison 7: sensitivity 87.18% (34/39) specificity 75.68% (28/37) PPV 79.07% (34/43) NPV 84.85% (28/33) accuracy 81.58% (62/76) prevalence 51.32% (39/76) Comparison 8: sensitivity 89.74% (35/39) specificity 40.54% (15/37) PPV 61.40% (35/57) NPV 78.95% (15/19) accuracy 65.79% (50/76) prevalence 51.32% (39/76)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2055 Ovesen 1993	N/A Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (Tympan-O-scope model zs 330 [Madsen Electronics]): ENT physician • otomicroscopy: not specified • myringotomy: two other ENT specialists Study Cohort: Children with unilateral or bilateral SOM N=222 subjects, 440 ears	Time: not specified Place: Not specified Affiliation: Ear Nose and Throat Dept., Aarhus Univ. Hospital, Aarhus C, Denmark Inclusion: • Age: 0.8–14.8 years • two of the following three criteria: otomicroscopical findings consistent with SOM during 3 months, >20 dB hearing impairment, and/or adenoid symptoms Exclusion: None Patient Characteristics: • mean age 4.1 years, 0.8–14.8 years • male 132, female 88	Comparisons: 1. Professional tympanometry[a] Dx– : Type A tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry[b] Dx– : Type A/C1/C2 tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Professional tympanometry[c] Dx– : Type A or C1 tympanogram Dx+ : Type B or C2 tympanogram Myringotomy (sedated) GS– : Fluid absent GS+ : Fluid present 4. Professional tympanometry[d] Dx– : Type A tympanogram Dx+ : Types B/C1/C2 tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 99.36% (310/312) specificity 48.15% (13/27) PPV 95.68% (310/324) NPV 86.67% (13/15) accuracy 95.28% (323/339) prevalence 92.04% (312/339) Comparison 2: sensitivity 90.64% (310/342) specificity 72.55% (37/51) PPV 95.68% (310/324) NPV 53.62% (37/69) accuracy 88.30% (347/393) prevalence 87.02% (342/393) Comparison 3: sensitivity 94.44% (323/342) specificity 52.94% (27/51) PPV 93.08% (323/347) NPV 58.70% (27/46) accuracy 89.06% (350/393) prevalence 87.02% (342/393) Comparison 4: sensitivity 99.42% (340/342) specificity 25.49% (13/51) PPV 89.95% (340/378) NPV 86.67% (13/15) accuracy 89.82% (353/393) prevalence 87.02% (342/393)

[a] Excludes cases where no operation was performed. It also excludes cases where an operation was performed and the tympanogram was type C1 or C2.
[b] Excludes cases where no operation was performed. Type C1 and C2 are classified as “normal” in the above results table.
[c] Excludes cases where no operation was performed. Type A and C1 are classified as “normal”and type B and C2 are classified as “abnormal” in the above results table.
[d] Excludes cases where no operation was performed. Type A is classified as “normal”and types B, C1, and C2 are classified as “abnormal” in the above results table.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2058 Oyiborhoro 1987	Diagnostic study Study Quality Score (0–6): 3 (100101) Examiner(s): • acoustic reflectometry (acoustic otoscope [Endeco Medical]): not specified • pneumatic otoscopy: otolaryngologist validated with sensitivity 97.73% and specificity 90.90% • tympanometry diagnostic impedance audiometer Madsen ZS 77 MB): not specified • audiometry (Beltone clinical audiotry model 200-C): not specified • myringotomy Grp 1: Children who did not have MEE Grp 2: Children who had MEE Grp 3: Subgroup of children in group2 who underwent myringotomy (44 pathologic ears) N1=100 subjects, 200 ears N2=100 subjects, 175 ears N3=23 subjects, 44 ears	Time: Referred over a 10-month period (actual dates not specified) Place: Subjects drawn from the ENT clinic at the Dr. Martin Luther King, Jr. Health Center, Bronx, NY Affiliation: Columbia Univ., NY; VA Medical Center, Cleveland, OH; as above Inclusion: • Age: 3–12 years • Grp 1: normal hearing and middle ear function based upon results from otoscopy, tympanometry and pure tone audiometry) • Grp 2: pure tone thresholds ≥20dB HL (250–8000 Hz); air-bone gaps of at least 15 dB HL (250–4000 Hz); type B tympanograms in the ears studied w/no sensorineural components; or demonstrated hearing and immittance abnormalities at least two times in ears studied during the 10-month period of investigation. Exclusion: • Grp 1~history suggested the existence of any known middle ear pathology Patient Characteristics: • mean age 8.7 years, range 3–12 years • male 90, female 110	Comparisons: 1. Grps 1 & 2 combined Acoustic reflectometry Dx– : Acoustic otoscope reflectivity<4 Dx+ : Acoustic otoscope reflect. ≥4 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 2. Grps 1 & 2 combined Acoustic reflectometry Dx– : Acoustic otoscope reflectivity<3 Dx+ : Acoustic otoscope reflect. ≥3 Validated pneumatic otoscopy GS– : MEE absent GS+ : MEE present 3. Grp 3[a] Acoustic reflectometry Dx– : Acoustic otoscope reflectivity<4 Dx+ : Acoustic otoscope reflect. ≥4 Myringotomy (sedation unknown) GS– : Fluid absent GS+ : Fluid present	Unit of measure: Ear Comparison 1: sensitivity 93.14% (163/175) specificity 83.00% (166/200) PPV 82.74% (163/197) NPV 93.26% (166/178) accuracy 87.73% (329/375) prevalence 46.67% (175/375) Comparison 2: sensitivity 97.71% (171/175) specificity 65.50% (131/200) PPV 71.25% (171/240) NPV 97.04% (131/135) accuracy 80.53% (302/375) prevalence 46.67% (175/375) Comparison 3: sensitivity 95.45% (42/44) specificity - (0/0) PPV 100.00% (42/42) NPV - (0/2) accuracy 95.45% (42/44) prevalence 100.00% (44/44)

[a] All children in this group had fluid on myringotomy, thus specificity cannot be determined for this group.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2118 Paradise 1976	Diagnostic study This ID number includes two separate studies Study Quality Score (0–6): STUDY 1: 4 (111001) STUDY 2: 5 (111101) Examiner(s): • tympanometry (Madsen Electroacoustic Impedance Meter, Model ZO 70 [Madsen Electronics]): audiologist • pneumatic otoscopy: pediatrician • myringotomy: by or under supervision of one of two otolaryngologists Study Cohort: infants and children who had been scheduled for myringotomy and insertion of tympanostomy tubes because of recurrent AOM or persistent MEE, or both * (group of infants and children not receiving myringotomy were studied but findings were not relevant to key question four) N=107 subjects, 214 ears	Time: 5/25/1972–5/9/1974 Place: Grp 1 not specified: Grp 2 various outpatient waiting areas at Children's Hospital of Pittsburgh, PA Affiliation: Dept. of Pediatrics, Community Med., and Otolaryngology, and Speech and Theatre Arts Cleft Palate Center, Univ. of Pittsburgh; Ambulatory Care Center, Children's Hospital of Pittsburgh Inclusion: • Age: 10 days–5 years Grp 1: • scheduled for myringotomy and insertion of tubes due to recurrent AOM or persistent MEE or both Grp 2: • not scheduled for myringotomy • in various outpatient waiting areas of the Children's Hospital of Pittsburgh; available and parents willing to allow participation in study Exclusion: None Patient Characteristics: • age range 10 days–5 years 11 months • Grp 1 male 62, female 45; Grp 2 male 103, female 70 • black 66, white 214	Comparisons: 1. Pneumatic otoscopy[a] – unvalidated examiner Dx– : MEE absent Dx+ : MEE present Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Pneumatic otoscopy[b] – unvalidated examiner Dx– : MEE absent Dx+ : MEE present Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Pneumatic otoscopy[c] – unvalidated examiner Dx– : MEE absent Dx+ : MEE present Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 91.37% (127/139) specificity 74.67% (56/75) PPV 86.99% (127/146) NPV 82.35% (56/68) accuracy 85.51% (183/214) prevalence 64.95% (139/214) Comparison 2: sensitivity 98.55% (136/138) specificity 74.67% (56/75) PPV 87.74% (136/155) NPV 96.55% (56/58) accuracy 90.14% (192/213) prevalence 64.79% (138/213) Comparison 3: sensitivity 98.45% (127/129) specificity 81.16% (56/69) PPV 90.71% (127/140) NPV 96.55% (56/58) accuracy 92.42% (183/198) prevalence 65.15% (129/198)

[a] Ears with fluid "suspected" as having effusion are included as false negatives. Fluid-free ears "suspected" as having effusion included as false positives. "Not examined" ear included as false negatives.
[b] Ears with fluid "suspected" as having effusion are included as true positives. Effusion free ears "suspected" as having effusion included as false positives. The one ear "not examined" is not included.
[c] Ears in the "suspect" category are not included. The one ear that was not examined is not included.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
4790 Paradise 1996	Diagnostic study Study Quality Score (0–6): 5 (111110) Examiner(s): • tympanometry (Grason-Stadler GSI 33): two audiologists • pneumatic otoscopy: tested otoscopists which we interpreted as validated otoscopists Grp 1: Ears in infants during their first year of Grp 2: Ears in infants during their second year of life (Note: these ears are not necessarily independent.) N=362 subjects, 1296 ears N1=701 ears N2=595 ears * (did not specify how many children in each group)	Time: not specified Place: Children's Hospital outpatient department Affiliation: Not specified but authors recognized as being from Children's Hospital of Pittsburgh, PA Inclusion: • Age: 2–23 months • healthy infants Exclusion: None Patient Characteristics: Not specified	Comparisons: 1. Grp 1– 1st year of life Examiner type (Audiologist #1) Professional tympanometry Dx– : Normal tympanogram Dx+ : Questionable or Flat Tymp. Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 2. Grp 1– 1st year of life Examiner type (Audiologist #1) Professional tympanometry Dx– : Normal/questionable tymp. Dx+ : Flat tympanograms Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 3. Grp 1– 1st year of life Examiner type (Audiologist #2) Professional tympanometry Dx– : Normal tympanograms Dx+ : Questionable or Flat Tymp. Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 4. Grp 1– 1st year of life Examiner type (Audiologist #2) Professional tympanometry Dx– : Normal/questionable tymp. Dx+ : Flat tympanograms Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 85.71% (120/140) specificity 47.95% (269/561) PPV 29.13% (120/412) NPV 93.08% (269/289) accuracy 55.49% (389/701) prevalence 19.97% (140/701) Comparison 2: sensitivity 47.86% (67/140) specificity 90.91% (510/561) PPV 56.78% (67/118) NPV 87.48% (510/583) accuracy 82.31% (577/701) prevalence 19.97% (140/701) Comparison 3: sensitivity 42.86% (60/140) specificity 90.02% (505/561) PPV 51.72% (60/116) NPV 86.32% (505/585) accuracy 80.60% (565/701) prevalence 19.97% (140/701) Comparison 4: sensitivity 32.14% (45/140) specificity 96.08% (539/561) PPV 67.16% (45/67) NPV 85.02% (539/634) accuracy 83.31% (584/701) prevalence 19.97% (140/701) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 4790 Paradise 1996			*Continued* 5. Grp 2– 2nd year of life Examiner type (Audiologist #1) Professional tympanometry Dx– : Normal tympanograms Dx+ : Questionable/Flat tymp. Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 6. Grp 2– 2nd year of life Examiner type (Audiologist #1) Professional tympanometry Dx– : Normal/questionable tymp. Dx+ : Flat tympanograms Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 7. Grp 2– 2nd year of life Examiner type (Audiologist #2) Professional tympanometry Dx– : Normal tympanograms Dx+ : Questionable/Flat tymp. Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present 8. Grp 2– 2nd year of life Examiner type (Audiologist #2) Professional tympanometry Dx– : Normal/questionable tymp. Dx+ : Flat tympanograms Validated pneumatic otoscopy GS– : effusion absent GS+ : effusion present	*Continued* Unit of measure: Ear Comparison 5: sensitivity 90.36% (75/83) specificity 69.92% (358/512) PPV 32.75% (75/229) NPV 97.81% (358/366) accuracy 72.77% (433/595) prevalence 13.95% (83/595) Comparison 6: sensitivity 65.06% (54/83) specificity 94.92% (486/512) PPV 67.50% (54/80) NPV 94.37% (486/515) accuracy 90.76% (540/595) prevalence 13.95% (83/595) Comparison 7: sensitivity 68.67% (57/83) specificity 92.00% (471/512) PPV 58.16% (57/98) NPV 94.77% (471/497) accuracy 88.74% (528/595) prevalence 13.95% (83/595) Comparison 8: sensitivity 65.06% (54/83) specificity 94.92% (486/512) PPV 67.50% (54/80) NPV 94.37% (486/515) accuracy 90.76% (540/595) prevalence 13.95% (83/595)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
4793 Park 1988	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • tympanometry (Teledyne Avionics instrument type TA-3D and Grason-Stadler instrument 1723 middle ear analyzer): not specified • myringotomy: not specified Study Cohort: Children diagnosed as having OME who received myringotomies with and w/out ventilation tubes *(a group of 79 healthy children were also studied but findings were not relevant to key question four) N=290 subjects, 528 ears	Time: Grp 1~not specified; Grp 2~1981–1986 Place: Korea (specifics not provided) Affiliation: not specified Inclusion: • Grp 1~Age: Not specified • Grp 2~Age: 2–15 years • Grp 1~healthy children, who showed <10 db air-bone gap and in whom physical exams were normal • Grp 2~OME diagnosed by physical exam and impedance audiometry • Korean pediatric population Exclusion: None Patient Characteristics: • Grp 2 age range 2–15 years	Comparisons: 1. Male Children Professional tympanometry Dx– : Type A tympanogram Dx+ : Type B or C tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Male Children Professional tympanometry Dx– : Type A or C tympanograms Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Female Children Professional tympanometry Dx– : Type A tympanogram Dx+ : Type B or C tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 4. Female Children Professional tympanometry Dx– : Type A or C tympanograms Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 91.94% (228/248) specificity 13.16% (5/38) PPV 87.36% (228/261) NPV 20.00% (5/25) accuracy 81.47% (233/286) prevalence 86.71% (248/286) Comparison 2: sensitivity 73.39% (182/248) specificity 39.47% (15/38) PPV 88.78% (182/205) NPV 18.52% (15/81) accuracy 68.88% (197/286) prevalence 86.71% (248/286) Comparison 3: sensitivity 94.82% (183/193) specificity 16.13% (5/31) PPV 87.56% (183/209) NPV 33.33% (5/15) accuracy 83.93% (188/224) prevalence 86.16% (193/224) Comparison 4: sensitivity 78.76% 152/193) specificity 54.84% 17/31) PPV 91.57% (152/166) NPV 29.31% (17/58) accuracy 75.45% (169/224) prevalence 86.16% (193/224) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 4793 Park 1988			*Continued* 5. Male Children Professional tympanometry Dx– : Type A tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 6. Female Children Professional tympanometry Dx– : Type A tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear Comparison 5: sensitivity 90.10% (182/202) specificity 17.86% (5/28) PPV 88.78% (182/205) NPV 20.00% (5/25) accuracy 81.30% (187/230) prevalence 87.83% (202/230) Comparison 6: sensitivity 93.83% (152/162) specificity 26.32% (5/19) PPV 91.57% (152/166) NPV 33.33% (5/15) accuracy 86.74% (157/181) prevalence 89.50% (162/181)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2236 Rees 1992	Cross-sectional Study Quality Score (0–6): 1 (100000) Examiner(s): • tympanometry (Rexton tympanometer): not specified • myringotomy: not specified *This study focuses on changes in tympanometry resulting from general anesthesia, not on the sensitivity/specificity of tympanometry for identifying fluid filled ears. Study Cohort: Children admitted to ENT Dept. for myringtomy and possible grommet insertion N=155 subjects, 310 ears	Time: 6-month period (actual dates not specified) Place: ENT Department of the Radcliffe Infirmary, Oxford, UK Affiliation: Dept. of Otolaryngology, Radcliffe Infirmary, Oxford, UK Inclusion: • Age: 18 months–11 years • admitted to the ENT Dept. of the Radcliffe Infirmary over a 6-month period • seen by an otologist within 3 months of admission • with clinically persistent middle ear effusion • able to tolerate examination and tympanometry Exclusion: None Patient Characteristics: • age range 18 months–11 years	Comparisons: 1. Portable tympanometer[a] Dx– : Type A or C tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Portable tympanometer[b] Dx– : Type A or C tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 100.00% (260/260) specificity 18.00% (9/50) PPV 86.38% (260/301) NPV 100.00% (9/9) accuracy 86.77% (269/310) prevalence 83.87% (260/310) Comparison 2: sensitivity 100.00% (260/260) specificity 100.00% (50/50) PPV 100.00% (260/260) NPV 100.00% (50/50) accuracy 100.00% (310/310) prevalence 83.87% (260/310)

[a] Results are based on the tympanogram readings 1 hour before myringotomy.
[b] Results are based on the tympanograms obtained immediately before myringotomy.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
4804 Renvall 1996	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • tympanometry (Model 85AR [American Electromedics Corporation]): not specified • myringotomy: not specified Study Cohort: Children who underwent tympanometry and were candidates for ventilation tube insertion N=73 subjects, 127 ears	Time: not specified Place: not specified Affiliation: Inclusion: • Age: 3–12 years • suffered from longstanding serous otitis media • candidate for tympanocentesis and ventilation tube insertion under general anesthesia Exclusion: None Patient Characteristics: • age range 3–12 years	Comparisons: 1. Professional tympanometry Dx– : Peaked tympanogram Dx+ : Flat tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present\	Unit of measure: Ear Comparison 1: sensitivity 86.14% (87/101) specificity 96.15% (25/26) PPV 98.86% (87/88) NPV 64.10% (25/39) accuracy 88.19% (112/127) prevalence 79.53% (101/127)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2344 Sassen 1994	Diagnostic study Study Quality Score (0–6): 3 (111000) Examiner(s): • tympanometry (type GSI-27A and type Tymp-85TT, 226 Hz probe tone, used six weeks in each group and then interchanged): not specified • otomicroscopy: three ENT surgeons • myringotomy: three ENT surgeons *This study combines children undergoing myringotomy because of recurrent AOM or chronic OME but does not stratify the results according to type of OM. Grp 1: Hospital A ~ Ears in children with middle ear problems who were only undergoing insertion of tympanostomy tubes [not (adeno)-tonsillectomy with myringotomy] Grp 2: Hospital B ~ Ears in children with URIs who were undergoing (adeno)-tonsillectomy with myringotomy *Continued on next page*	Time: not specified Place: Study performed in two hospital: Hospital A~ Gemini-Hospital in Den Helder and Hospital B~ St. Elisabeth-Hospital in Leiderdorp, The Netherlands Affiliation: Dept. of Otorhinolaryngology, Univ. Hospital Leiden, The Netherlands Inclusion: • Age: 5 months–11 years & 5 months • candidate for insertion of ventilation tubes, or adenoidectomy and/or tonsillectomy w/myringotomy • Grp 1~middle ear problems (not URIs) and undergoing insertion of tympanostomy tubes only • Grp 2~URIs and undergoing (adeno)-tonsillectomy with myringotomy *Continued on next page*	Comparisons: 1. Grp 1 and Grp 2 Binocular micro-tympanoscopy Dx– : Tympanic membrane~normal Dx+ : Tympanic membrane~abnormal Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Grp 1 and Grp 2 Professional tympanometry–both types Dx– : Type (A,C1,C2,O) Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Grp 1 and Grp 2 Professional tympanometry–both types Dx– : Type (A, C1, O) tympanogram Dx+ : Type B or C2) tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 4. Grp 1 and Grp 2 Age (5 months–2 years) Professional tympanometry–both types Dx– : Type (A,C1,C2) tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 96.77% (270/279) specificity 13.86% (14/101) PPV 75.63% (270/357) NPV 60.87% (14/23) accuracy 74.74% (284/380) prevalence 73.42% (279/380) Comparison 2: sensitivity 80.65% (225/279) specificity 58.42% (59/101) PPV 84.27% (225/267) NPV 52.21% (59/113) accuracy 74.74% (284/380) prevalence 73.42% (279/380) Comparison 3: sensitivity 90.68% (253/279) specificity 32.67% (33/101) PPV 78.82% (253/321) NPV 55.93% (33/59) accuracy 75.26% (286/380) prevalence 73.42% (279/380) Comparison 4: sensitivity 90.38% (47/52) specificity 66.67% (10/15) PPV 90.38% (47/52) NPV 66.67% (10/15) accuracy 85.07% (57/67) prevalence 77.61% (52/67) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2344 Sassen 1994	*Continued* N=266 subjects, 515 ears N1=273 ears N2=242 ears * (did not specify how many children in each group)	*Continued* Exclusion: • Grp 1~ URIs • perforation of the tympanic membrane • history of >6 myringotomies and/or >3 insertions of middle ear ventilation tubes Patient Characteristics: • age range 5 months–11 years 5 months • male 143, female 123	*Continued* 5. Grp 1 and Grp 2 Age (5 months–2 years) Professional tympanometry–both types Dx– : Type (A, C1) tympanogram Dx+ : Type (B or C2) tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 6. Grp 1 and Grp 2 Age (2–12 years) Professional tympanometry–both types Dx– : Type (A,C1,C2) tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 7. Grp 1 and Grp 2 Age (2–12 years) Professional tympanometry–both types Dx– : Type (A, C1) tympanogram Dx+ : Type (B or C2) tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 8. Grp 1 Professional tympanometry–both types Dx– : Type (A,C1,C2) tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	*Continued* Unit of measure: Ear Comparison 5: sensitivity 92.31% (48/52) specificity 53.33% (8/15) PPV 87.27% (48/55) NPV 66.67% (8/12) accuracy 83.58% (56/67) prevalence 77.61% (52/67) Comparison 6: sensitivity 81.38% (236/290) specificity 62.60% (82/131) PPV 82.81% (236/285) NPV 60.29% (82/136) accuracy 75.53% (318/421) prevalence 68.88% (290/421) Comparison 7: sensitivity 94.83% (275/290) specificity 35.11% (46/131) PPV 76.39% (275/360) NPV 75.41% (46/61) accuracy 76.01% (320/421) prevalence 68.88% (290/421) Comparison 8: sensitivity 75.42% (135/179) specificity 74.65% (53/71) PPV 88.24% (135/153) NPV 54.64% (53/97) accuracy 75.20% (188/250) prevalence 71.60% (179/250) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2344 Sassen 1994			*Continued* 9. Grp 1 Professional tympanometry–both types Dx– : Type (A, C1, O) tympanogram Dx+ : Type (B or C2) tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 10. Grp 2 Professional tympanometry–both types Dx– : Type (A,C1,C2) tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 11. Grp 2 Professional tympanometry–both types Dx– : Type (A, C1) tympanogram Dx+ : Type (B or C2) tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear Comparison 9: sensitivity 91.62% (164/179) specificity 43.66% (31/71) PPV 80.39% (164/204) NPV 67.39% (31/46) accuracy 78.00% (195/250) prevalence 71.60% (179/250) Comparison 10: sensitivity 90.80% (148/163) specificity 52.00% (39/75) PPV 80.43% (148/184) NPV 70.37% (38/54) accuracy 78.57% (187/238) prevalence 68.49% (163/238) Comparison 11: sensitivity 97.55% (159/163) specificity 30.67% (23/75) PPV 75.36% (159/211) NPV 85.19% (23/27) accuracy 76.47% (182/238) prevalence 68.49% (163/238)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2412 Shaw 1978	Cross-sectional Study Quality Score (0–6): 1 (100000) Examiner(s): • tympanometry (Grason-Stadler 1720 otoadmittance meter, 220 and 660 Hz probe tones): not specified • myringotomy; not specified *This is a pre-, post-anesthesia study looking at the effects on tympanometry. Study Cohort: Ears in children who underwent myringotomy surgery N=59 ears * Sample size =39 patients and 68 ears with probable middle-ear fluid. Only 59 ears received surgery but the authors did not state whether all patients in the sample received surgery or if some were excluded when number of ears was reduced from 68 to 59.	Time: not specified Place: Not specified Affiliation: Univ. of Illinois, Hearing Clinic, Champaign, IL Inclusion: • Age: 2–11 years • probable middle-ear fluid unilaterally or bilaterally based on otologic and audiologic exam • underwent myringotomy surgery Exclusion: • ears that did not undergo myringotomy surgery Patient Characteristics: • age range 2–11 years	Comparisons: 1. Professional tympanometry[a] Dx– : Type A tympanogram Dx+ : Type B and C tympanograms Myringotomy (sedated) GS– : Fluid absent GS+ : Fluid present 2. Professional tympanometry[a] Dx– : Type A and C tympanogram Dx+ : Type B tympanograms Myringotomy (sedated) GS– : Fluid absent GS+ : Fluid present	Unit of measure: Ear Comparison 1: sensitivity 100.00% (49/49) specificity 10.00% (1/10) PPV 84.48% (49/58) NPV 100.00% (1/1) accuracy 84.75% (50/59) prevalence 83.05% (49/59) Comparison 2: sensitivity 97.96% (48/49) specificity 30.00% (3/10) PPV 87.27% (48/55) NPV 75.00% (3/4) accuracy 86.44% (51/59) prevalence 83.05% (49/59)

[a] This is a pre-, post-anesthesia study looking at the effects on tympanometry. Pre-operative results were used.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2545 Szucs 1995	Diagnostic study Study Quality Score (0–6): 1 (100000) Examiner(s): • tympanometry (Amplaid 720 type impedance meter): not specified • myringotomy: ENT surgeon Study Cohort: Children w/ chronic OME and recurrent otitis media N=40 subjects, 78 ears	Time: 6 month period between 5/1992–12/1992 Place: Ear-Nose and Throat Department of Brussels Free University, Brussels, Belgium Affiliation: Dept. of Otorhinolaryngology, Brussels Free Univ., Belgium Inclusion: • Age: 1 year 3 months–11 years 4 months • chronic OME and/or recurrent OM Exclusion: • although not stated specifically to be a criteria none of the children had any accompanying disease Patient Characteristics: • mean age 5 years 8 months, range 1 year 3 months–11 years 4 months • male 27, female 13	Comparisons: 1. Professional tympanometry[a] Dx– : Type A tympanograms Dx+ : Type B tympanograms Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry[b] Dx– : Type A and C tympanograms Dx+ : Type B tympanograms Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 3.Professional tympanometry[c] Dx– : Type A tympanogram Dx+ : Type B and C tympanograms Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 94.74% (36/38) specificity 57.14% (8/14) PPV 85.71% (36/42) NPV 80.00% (8/10) accuracy 84.62% (44/52) prevalence 73.08% (38/52) Comparison 2: sensitivity 73.47% (36/49) specificity 79.31% (23/29) PPV 85.71% (36/42) NPV 63.89% (23/36) accuracy 75.64% (59/78) prevalence 62.82% (49/78) Comparison 3: sensitivity 95.92% (47/49) specificity 27.59% (8/29) PPV 69.12% (47/68) NPV 80.00% (8/10) accuracy 70.51% (55/78) prevalence 62.82% (49/78) *Continued on next page*

[a] The above results table excludes type “C” tympanograms.
[b] The above results table includes type “C” tympanograms as normal.
[c] The above results table includes type “C” tympanograms.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2545 Szucs 1995			*Continued* 4. Professional tympanometry[a] Dx– : Type A and C tympanograms Dx+ : Type B tympanogram Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present 5. Professional tympanometry[b] Dx– : Type A and C tympanograms Dx+ : Type B tympanogram Tympanocentesis (non-sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear Comparison 4: sensitivity 82.61% (19/23) specificity 90.00% (9/10) PPV 95.00% (19/20) NPV 69.23% (9/13) accuracy 84.85% (28/33) prevalence 69.70% (23/33) Comparison 5: sensitivity 57.89% (11/19) specificity 70.59% (12/17) PPV 68.75% (11/16) NPV 60.00% (12/20) accuracy 63.89% (23/36) prevalence 52.78% (19/36)

[a] Adenoid hypertrophy present in this group.
[b] Adenoid hypertrophy absent in this group.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2601 Tom 1994	Diagnostic study Study Quality Score (0–6): 4 (111001) Examiner(s): • tympanometry (Teledyne Screening Meter model no. TA-7A): certified audiologists • myringotomy: surgeon *This study combines data for persistent OME and recurrent AOM but does not stratify the results based on this variable. Study Cohort: Children scheduled to undergo myringotomy with pressure equalization tube insertion for either OME refractory to medical management or recurrent OM N=109 subjects, 213 ears	Time: not specified Place: Not specified Affiliation: Div. of Otolaryngology, Children's Hospital of Philadelphia, PA; Div. of Medical Audiology, Children's Seashore House, PA; Dept. of Otolaryngology, Univ. of Pennsylvania Inclusion: • Age: 5 months–11 years • scheduled to undergo myringotomies w/ pressure equalization tube insertion for either OME refractory to medical management or recurrent OM Exclusion: • ears discovered either at tympanometry or surgery to have small perforations (n=5 ears excluded) Patient Characteristics: • mean age 3 years 8 months, range 5 months–11 years 5 months • male 62, female 47	Comparisons: 1. Professional tympanometry[a] Dx– : Type A tympanogram Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry[b] Dx– : Type A and C tympanograms Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Professional tympanometry[c] Dx– : Type A tympanogram Dx+ : Types B and C tympanograms Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 92.59% (100/108) specificity 51.85% (14/27) PPV 88.50% (100/113) NPV 63.64% (14/22) accuracy 84.44% (114/135) prevalence 80.00% (108/135) Comparison 2: sensitivity 65.36% (100/153) specificity 78.33% (47/60) PPV 88.50% (100/113) NPV 47.00% (47/100) accuracy 69.01% (147/213) prevalence 71.83% (153/213) Comparison 3: sensitivity 94.77% (145/153) specificity 23.33% (14/60) PPV 75.92% (145/191) NPV 63.64% (14/22) accuracy 74.65% (159/213) prevalence 71.83% (153/213)

[a] The above results table excludes all ears with type "C" tympanograms.
[b] The above results table includes type "C" tympanograms as normal.
[c] The above results table includes type "C" tympanograms as abnormal.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2607 Toner 1990	Diagnostic study Study Quality Score (0–6): 2 (100001) Examiner(s): • pneumatic otoscopy: one of the authors • tympanometry (REXTON TYMP82): not specified • myringotomy: not specified Study Cohort: Children undergoing myringotomy due to indication of MEE N=121 subjects, 222 ears	Time: Consecutive 5-month period (actual dates not specified) Place: ENT Department of the Belfast City Hospital, Belfast, UK Affiliation: as above Inclusion: • Age: 18 months–12 years • indication of need for myringotomy (in the majority ~ due to clinically persistent MEE) Exclusion: • pneumatic otoscopy and tympanometry could not be performed • lack of cooperation during test procedure or in allowing removal of excessive wax Patient Characteristics: • age range 18 months–12 years	Comparisons: 1. Pneumatic otoscopy – unvalidated examiner Dx– : mobile Dx+ : immobile Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry[a] Dx– : Type A and C tympanograms Dx+ : Type B tympanogram Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Professional tympanometry[b] Dx– : Type A tympanogram Dx+ : Type B and C tympanograms Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 4. Professional tympanometry[c] Dx– : Type A tympanograms Dx+ : Type B tympanograms Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 87.10% (108/124) specificity 88.78% (87/98) PPV 90.76% (108/119) NPV 84.47% (87/103) accuracy 87.84% (195/222) prevalence 55.86% (124/222) Comparison 2: sensitivity 86.29% (107/124) specificity 92.86% (91/98) PPV 93.86% (107/114) NPV 84.26% (91/108) accuracy 89.19% (198/222) prevalence 55.86% (124/222) Comparison 3: sensitivity 96.77% (120/124) specificity 76.53% (75/98) PPV 83.92% (120/143) NPV 94.94% (75/79) accuracy 87.84% (195/222) prevalence 55.86% (124/222) Comparison 4: sensitivity 96.40% (107/111) specificity 91.46% (75/82) PPV 93.86% (107/114) NPV 94.94% (75/79) accuracy 94.30% (182/193) prevalence 57.51% (111/193)

[a] The above results table includes type “C” tympanograms as normal.
[b] The above results table includes type “C” tympanograms as abnormal.
[c] The above results table excludes all ears with type “C“ tympanograms.

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2675 van Balen 1994	Diagnostic study Study Quality Score (0–6): 4 (111010) Examiner(s): • tympanometry (AR 85 [American Electromedics], 226 Hz probe tone, and microtymp [Welch Allyn], 226 Hz probe tone): general practitioner with special training from ENT department with classification problems discussed with Ear, Nose, and Throat surgeons • myringotomy: Ear, Nose, and Throat surgeon Study Cohort: Children selected by the Ear, Nose and Throat surgeon for uni- or bilateral myringotomy and/or tympanostomy tube insertion N=142 subjects, 284 ears	Time: 9/1990–8/1991 Place: Day-care department, University Children's Hospital, Utrecht and the General Hospital, Overvecht, Utrecht, Netherlands Affiliation: Dept. of General Practice, Univ. of Utrecht, Netherlands Inclusion: • Age: 6 months–12 years • undergoing uni- or bilateral myringtomy and/or tympanostomy tube insertion after referral by General Practitioner Exclusion: • craniofacial malformations and those w/trisomy 21 Patient Characteristics: • age range 6 months–12 years	Comparisons: 1. Portable tympanometer Dx– : Type A and C1 tympanogram curves Dx+ : Type B and C2 tympanogram curves Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 94.23% (147/156) specificity 48.05% (37/77) PPV 78.61% (147/187) NPV 80.43% (37/46) accuracy 78.97% (184/233) prevalence 66.95% (156/233)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2713 Vaughan-Jones 1992	Diagnostic study Study Quality Score (0–6): 2 (100001) Examiner(s): • pneumatic otoscopy: not specified • audiometry (Audioscope [Welch Allyn] and Madsen OB822 audiometer): not specified • tympanometry (Microtymp [Welch Allyn], 226 Hz probe tone, and American Electric Model 85, 256 Hz probe tone): not specified • myringotomy: not specified *For pneumatic otoscopy, the authors do not define a negative or positive test result. Study Cohort: Children undergoing myringotomy N=100 subjects, 200 ears	Time: not specified Place: Audiology Department at Ninewells Hospital, Dundee Affiliation: Dept. of Otolaryngology, Ninewells Hospital, Dundee Inclusion: • admitted with a diagnosis of OME and scheduled to undergo myringotomy Exclusion: • inadequate view of the tympanic membrane or variable audiometric responses Patient Characteristics: • mean age male 6.3 years, female 6.2 years • male 56, female 44	Comparisons: 1. Pneumatic otoscopy – unvalidated examiner Dx– : not defined Dx+ : not defined Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 2. Professional tympanometer Dx– : Type A,C1 & C2 curves Dx+ : Type B curves Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 3. Portable tympanometer Dx– : Type A and C1 curves Dx+ : Type B and C2 curves Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 4. Professional tympanometry Dx– : Type A and C1 tympanograms Dx+ : Type B and C2 tympanograms Myringotomy (sedated) GS– : fluid absent GS+ : fluid present *Continued on next page*	Unit of measure: Ear Comparison 1: sensitivity 89.63% (121/135) specificity 75.38% (49/65) PPV 88.32% (121/137) NPV 77.78% (49/63) accuracy 85.00% (170/200) prevalence 67.50% (135/200) Comparison 2: sensitivity 67.41% (91/135) specificity 93.85% (61/65) PPV 95.79% (91/95) NPV 58.10% (61/105) accuracy 76.00% (152/200) prevalence 67.50% (135/200) Comparison 3: sensitivity 88.89% (120/135) specificity 63.08% (41/65) PPV 83.33% (120/144) NPV 73.21% (41/56) accuracy 80.50% (161/200) prevalence 67.50% (135/200) Comparison 4: sensitivity 88.15% (119/135) specificity 70.77% (46/65) PPV 86.23% (119/138) NPV 74.19% (46/62) accuracy 82.50% (165/200) prevalence 67.50% (135/200) *Continued on next page*

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
Continued 2713 Vaughan-Jones 1992			*Continued* 5. Audiometry – air conduction threshold Dx– : ≤26 dB at 500Hz Dx+ : >26 dB at 500 Hz Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 6. Audiometry – air conduction threshold Dx– : ≤26 dB at 1000Hz Dx+ : >26 dB at 1000 Hz Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 7. Audiometry – air conduction threshold Dx– : ≤26 dB at 2000Hz Dx+ : >26 dB at 2000 Hz Myringotomy (sedated) GS– : fluid absent GS+ : fluid present 8. Audiometry – air conduction threshold Dx– : ≤26 dB at 4000Hz Dx+ : > 26 dB at 4000 Hz Myringotomy (sedated) GS– : fluid absent GS+ : fluid present	*Continued* Unit of measure: Ear Comparison 5: sensitivity 68.15% (92/135) specificity 84.62% (55/65) PPV 90.20% (92/102) NPV 56.12% (55/98) accuracy 73.50% (147/200) prevalence 67.50% (135/200) Comparison 6: sensitivity 59.26% (80/135) specificity 93.85% (61/65) PPV 95.24% (80/84) NPV 52.59% (61/116) accuracy 70.50% (141/200) prevalence 67.50% (135/200) Comparison 7: sensitivity 32.59% (44/135) specificity 95.38% (62/65) PPV 93.62% (44/47) NPV 40.52% (62/153) accuracy 53.00% (106/200) prevalence 67.50% (135/200) Comparison 8: sensitivity 46.67% (63/135) specificity 93.85% (61/65) PPV 94.03% (63/67) NPV 45.86% (61/133) accuracy 62.00% (124/200) prevalence 67.50% (135/200)

Evidence Table 4. Diagnostic Methods (Continued)

Record# Author Year	Study Quality Examiner(s) Group(s) and Sample Size	Time/Place/Affiliation Inclusion/Exclusion Criteria Patient Characteristics	Comparison(s) Influencing Factors Diagnostic Methods (Dx), Cutpoints Gold Standards (GS), Cutpoints	Findings
2758 Watters 1997	Diagnostic study Study Quality Score (0–6): 2 (110000) Examiner(s): • tympanometry (Grayson-Stadler [sic] GS133 Tympanometer): pediatric audiologist • myringotomy: not specified Study Cohort: Children who underwent surgery (grommet insertion) for possible MEE N=501 subjects, 955 ears	Time: 12 month period (11/1/1993–10/1994) Place: Affiliation: Dept's of Otolaryngology and Paediatric Audiology, Radcliffe Infirmary, Oxford, UK Inclusion: • Age: 11 months–15 years • undergoing surgery (insertion of grommets) for possible MEE Exclusion: • children with a 'normal' tympanogram in one or both ears and had surgery cancelled Patient Characteristics: • age range 11 months–15 years	Comparisons: 1. Professional tympanometry[a] Dx– : Type A or C tympanogram Dx+ : Type B tympanogram Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present 2. Professional tympanometry[b] Dx– : Type A tympanogram Dx+ : Type B or C tympanograms Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present 3. Professional tympanometry Dx– : Type A tympanogram Dx+ : Type B tympanogram Myringotomy (sedation unknown) GS– : fluid absent GS+ : fluid present	Unit of measure: Ear Comparison 1: sensitivity 91.14% (679/745) specificity 79.05% (166/210) PPV 93.91% (679/723) NPV 71.55% (166/232) accuracy 88.48% (845/955) prevalence 78.01% (745/955) Comparison 2: sensitivity 99.06% (738/745) specificity 33.81% (71/210) PPV 84.15% (738/877) NPV 91.03% (71/78) accuracy 84.71% (809/955) prevalence 78.01% (745/955) Comparison 3: sensitivity 98.98% (679/686) specificity 61.74% (71/115) PPV 93.91% (679/723) NPV 91.03% (71/78) accuracy 93.63% (750/801) prevalence 85.64% (686/801)

[a] This results table includes type "C" tympanograms as normal.
[b] This results table includes type "C" tympanograms as abnormal.