

Endoscopic Retrograde Cholangiopancreatography

This report may be used, in whole or in part, as the basis for development of clinical practice guidelines and other quality enhancement tools, or as a basis for reimbursement and coverage policies. Endorsement by the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services (DHHS) of such derivative products may not be stated or implied.

AHRQ is the lead Federal agency charged with supporting research designed to improve the quality of health care, reduce its cost, address patient safety and medical errors, and broaden access to essential services. AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes; quality; and cost, use, and access. The information helps health care decisionmakers—patients and clinicians, health system leaders, and policymakers—make more informed decisions and improve the quality of health care services.

Endoscopic Retrograde Cholangiopancreatography

Prepared for:

Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
2101 East Jefferson Street
Rockville, MD 20852
<http://www.ahrq.gov>

Contract No. 290-97-001-5

Prepared by:

Technology Evaluation Center
Blue Cross and Blue Shield Association
Naomi Aronson, Ph.D.
Program Director
Carole Redding Flamm, M.D., M.P.H.
Project Director

David Mark, M.D., M.P.H.
Frank Lefevre, M.D.
Rhonda L. Bohn, Sc.D., M.P.H.
Beth Finkelstein, Ph.D., M.P.H.
Investigators

Kathleen M. Ziegler, Pharm.D.
Claudia J. Bonnell, B.S.N., M.L.S.
Maurice Carter
Research/Editorial Staff

**AHRQ Publication No. 02-E017
June 2002**

ISBN: 1-58763-102-4
ISSN: 1530-4396

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome written comments on this evidence report. They may be sent to: Director, Center for Practice and Technology Assessment, Agency for Healthcare Research and Quality, 6010 Executive Blvd., Suite 300, Rockville, MD 20852.

Carolyn Clancy, M.D.
Acting Director
Agency for Healthcare Research and Quality

Robert Graham, M.D.
Director, Center for Practice and
Technology Assessment
Agency for Healthcare Research and Quality

The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services of a particular drug, device, test, treatment, or other clinical service.

Structured Abstract

Objectives. Diseases of the pancreas and biliary tree are common in the United States. Prevalence of common bile duct stones is estimated at 6 per 100,000. Incidence of pancreaticobiliary malignancy is approximately 57,400 annually, most with poor prognosis. A variety of diagnostic and therapeutic interventions have been developed to manage these conditions. This systematic review of the evidence on the diagnostic and therapeutic effectiveness of endoscopic retrograde pancreatography (ERCP) addresses four clinical conditions: (1) common bile duct stones; (2) pancreaticobiliary malignancy; (3) pancreatitis; and (4) abdominal pain of possible pancreaticobiliary origin. In addition, the evidence on determinants of complications of ERCP and on the prediction of common bile duct stones are reviewed.

Search Strategy. The PubMed/MEDLINE, BIOSIS, EMBASE, and SCISEARCH databases with a publication date from 1980 through August 13, 2001 were searched for articles indexed to the NLM Medical Subject Heading (MeSH®) “cholangiopancreatography, endoscopic retrograde” and ERCP synonyms and textword combinations. Search was limited to articles on human subjects published in the English language with an online abstract and supplemented by manual searching. Yielded was 5,698 citations.

Selection Criteria. Inclusion was limited to published reports. For diagnostic and therapeutic effectiveness, inclusion was limited to comparative studies prospectively designed or using appropriate retrospective sampling with a prespecified minimum number of subjects. For prediction studies, 100 subjects were required. There were 789 articles retrieved for review, yielding 149 included studies.

Data Collection and Analysis. The protocol was designed prospectively to define: study objectives; search strategy; patient populations; study selection criteria; outcomes; data elements and abstraction; and study quality assessment. One reviewer performed primary data abstraction into evidence tables and a second reviewer checked accuracy. Data synthesis was qualitative.

Main Results.

- Most diagnostic studies were small, did not use common reference standards, and many did not report statistical significance; thus, equivalence and difference among tests cannot be quantified. Qualitative assessment of the available evidence suggests that:
 - Magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasound (EUS) provide similar diagnostic performance as ERCP for detecting common bile duct stones or malignant pancreaticobiliary obstruction.
 - Sensitivity of nonsurgical tissue sampling techniques for detecting malignancy is similar or higher for brush cytology versus bile aspiration cytology, similar for fine-needle aspiration (FNA) cytology versus brush cytology, and similar or higher for forceps biopsy versus brush cytology.

- Robust evidence is lacking to compare strategies for treatment of common bile duct stones.
- The absence of any risk factors for common bile duct stones (i.e., clinical jaundice or elevated bilirubin, elevated liver function tests, dilation on ultrasound) is a strong predictor of the absence of stones.
- For palliation of biliary obstruction of malignancy, outcomes of surgical bypass and ERCP stenting are similar, but major complications are greater for surgery and stent replacement occurs with ERCP. Total resource utilization was reported to be lower with metal than plastic stents. Pre-operative stenting has greater overall complications than surgery alone and does not appear to improve surgical outcomes.
- Evidence on treatment of chronic pancreatitis and relapsing or recurrent pancreatitis is sparse.
- Endoscopic sphincterotomy appears to relieve pain in patients with pancreaticobiliary pain, sphincter of Oddi dysfunction, and elevated basal sphincter of Oddi pressure on manometry.
- Factors associated with complications of ERCP were age 60 years or less, suspected sphincter of Oddi dysfunction, precut endoscopic sphincterotomy, difficulty in cannulation, multiple pancreatic contrast injections, and case volume.

Conclusions. Rigorous studies are required in order to reliably quantify the relative performance of diagnostic ERCP compared to alternatives. Comparative studies of alternative diagnostic and treatment strategies for common bile duct stones are urgently needed. Interventions intended to reduce complications of ERCP should incorporate prospectively defined studies to evaluate results.

This document is in the public domain and may be used and reprinted without permission except those copyrighted materials noted for which further reproduction is prohibited without the specific permission of copyright holders.

Suggested Citation:

Flamm CR, Aronson N, Mark D, et al. Endoscopic Retrograde Cholangiopancreatography. Evidence Report/Technology Assessment Number 50. (Prepared by Blue Cross and Blue Shield Association under Contract No. 290-97-001-5.) AHRQ Publication No. 02-E017 Rockville, MD: Agency for Healthcare Research and Quality. June 2002.

Contents

Summary	1
EVIDENCE REPORT	
Chapter 1. Introduction	17
Chapter 2. Methodology	21
Chapter 3. Results and Conclusions	
Part I: Common Bile Duct Stones.....	31
Part I, Section 1: Diagnostic Performance of ERCP in Detecting Common Bile Duct Stones—Comparison with Alternatives	31
Part I, Section 2: Outcomes of Treatment Using ERCP for Common Bile Duct Stones—Comparison of Strategies Using ERCP, Surgery, or Medical Management.....	46
Part I, Section 3: Diagnostic Value of Individual Risk Factors or Predictive Models for Assessing the Likelihood of Having a Common Bile Duct Stone	70
Part II: Pancreaticobiliary Malignancy.....	81
Part II, Section 1: Diagnostic Performance of Nonsurgical Tissue Sampling Techniques in Pancreaticobiliary Malignancy—Comparison of Strategies Using ERCP, EUS, or Percutaneous Approach.....	81
Part II, Section 2: Diagnostic Performance of ERCP in Pancreaticobiliary Malignant Obstruction—Comparison to Alternatives	96
Part II, Section 3: Outcomes of Treatment Using ERCP for Palliation of Pancreaticobiliary Malignancy—Comparison of Strategies Using ERCP, Surgery, or Interventional Radiology	105
A. Comparison of ERCP Stent Versus Surgical Bypass	105
B. Comparison of Metal vs. Plastic Stents During ERCP	117
C. Additional Comparisons of ERCP Strategies).....	125
Part II, Section 4: Outcomes of Treatment Using Preoperative ERCP Drainage for Relief of Malignant Obstructive Jaundice).....	141
Part III. Pancreatitis	157
Part III, Section 1: Diagnostic Performance of ERCP in Detecting Underlying Causes or Complications of Pancreatitis Amenable to Treatment— Comparison to Alternatives	157
Part III, Section 2: Outcomes of Treatment Using ERCP for Pancreatitis— Comparison of Strategies Using ERCP, Surgery, or Medical Management	163
Part IV. Abdominal Pain of Possible Pancreaticobiliary Origin	187
Part IV, Section 1: Diagnostic Performance of ERCP Manometry In Evaluation of Abdominal Pain of Possible Pancreaticobiliary Origin—Comparison With Alternatives	187

Part IV, Section 2: Outcomes of Treatment Using ERCP for Abdominal Pain of Possible Pancreaticobiliary Origin	191
Part V. Patient, Procedure or Operator Determinants of ERCP Complications	201
Part V, Section 1: Multivariable Analyses.....	201
Part V, Section 2: Randomized, Controlled Comparison Trials.....	230
Chapter 4. Future Research.....	249
References.....	251
Evidence Tables	267
Bibliography	297
Appendix A. Excluded Publications	343
Appendix B. TAG Members and Reviewers	365
Appendix C. Abbreviations	367