Chapter 26. Prevention of Falls in Hospitalized and Institutionalized Older People

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Introduction

A fall is defined as unintentionally coming to rest on the ground, floor, or other lower level, but not as a result of syncope or overwhelming external force. Falling is a common cause of morbidity and the leading cause of nonfatal injuries and trauma-related hospitalizations in the United States.¹ Complications include bone fractures, injury to the soft tissues, increased functional dependence, and fear of falling again, which itself can be debilitating. Each of these complications contributes to increased risk of future falls. Studies in community-dwelling older patients have identified age, gait or balance impairment, sensory or cognitive impairment, musculoskeletal diseases, environmental hazards, and many medications (such as sedative-hypnotic drugs) as risk factors.

One of the strongest predictors of future falls is having previously fallen. There are numerous other risk factors for falls in older persons, which are reviewed in detail elsewhere.^{2,3} The number of risk factors is correlated with the risk of falling. A study by Tinetti and colleagues found the risk of falling increased from 19% when one risk factor was present to 78% in the presence of 4 or more risk factors.⁴ Some of the factors associated with fall risk in the hospital setting, however, may differ from those in community-dwelling or institutional settings. The onset of an acute illness leading to hospitalization may increase fall risk due to immobility and deconditioning. Treatment for an acute condition, such as the addition of new medications or an altered medication regimen, may also increase fall risk.

The hospital environment itself may either be a supportive environment (eg, the presence of handrails and no-slip bathing surfaces) or may contribute to fall risk (eg, unfamiliar rooms, improper bed height). This chapter reviews general evidence regarding multicomponent falls prevention protocols, and 5 specific interventions: identification bracelets, physical restraints, bed alarms, special flooring, and hip protectors.

Prevalence and Severity of the Target Safety Problem

Falls are among the most common incidents reported in institutions,⁵ although incident reports may underestimate their true occurrence.⁶ The incidence of falls among hospitalized patients varies according to the risk factors and case mix of the patient population as well as the presence of falls prevention measures. Rubinstein has reported fall rates of 0.6 to 2.9 falls annually per bed in hospitalized patients and 0.6 to 3.6 falls annually per bed in long-term care institutions, based on published data.⁷ About 50% of the 1.7 million nursing home residents in the United States fall at least once each year, resulting in serious injury in about 10% of residents.⁷⁻⁹ The total cost of falls injuries in 1994 for adults aged 65 years and older was estimated at \$20.2 billion.¹⁰

Hip fractures are the most feared complication of falls. Up to 20% of people sustaining a hip fracture become nonambulatory, and only 14-21% recover their ability to carry out

instrumental activities of daily living.¹¹ The estimated total incremental costs (the difference between costs before and after a hip fracture) of caring for an individual in the year after fracture were estimated to be between \$16,300 and \$18,700.¹² Estimated Medicare expenditures for hip fractures in 1991 were about \$2.9 billion.¹³

Practice Description

Based on the multifactorial etiology of falls, multicomponent interventions have been developed to address patient risk factors and decrease fall rates. However, most studies have not been designed in a way to determine which components of a multicomponent intervention are most effective.

Risk Assessment

A variety of institution-based programs have been implemented to prevent falls. These programs usually begin by identifying individuals at increased risk for falling. This is accomplished by history-taking to elicit past falls history or by using more formal assessment tools.^{4,14-17} Protocols used to perform falls risk assessment in hospitals or nursing homes vary by institution and often have not been validated.¹⁸

Community-Dwelling Elders

An overwhelming majority of the large, prospective, controlled studies have been carried out in the outpatient environment. They deserve mention because many of the interventions could be modified for a hospital-based intervention. Tinetti and colleagues¹⁹ showed that interventions to reduce specific risk factors resulted in a 30% reduction in falls over one year in a prospective community cohort. The targeted risk factors were postural hypotension, use of any benzodiazepine or sedative-hypnotic drug, use of 4 or more prescription medications, environmental hazards, and muscular strength or range of motion impairments. Specific interventions that were part of the multicomponent program included exercise recommendations, behavioral recommendations, medication review, and environmental modifications. A systematic review of predominantly <u>non-hospital</u> based multi-risk factor intervention studies showed significant protection against falling (Peto OR 0.77, 95% CI: 0.64-0.91).²⁰ There was, however, significant heterogeneity across studies.

The large literature on community-based interventions has yielded other insights, some of which may be applicable to the acute care setting. For example, exercise-based interventions²¹⁻²⁵ have been studied as a means to decrease falls in older persons. Results of these trials have not been conclusive. A pre-planned meta-analysis of 7 randomized controlled trials (2 nursing home-based and 5 community-based) that included an exercise component found a 10% decrease in fall risk (adjusted incidence ratio 0.90, 95% CI: 0.81-0.99),²⁶ although a recent systematic review examining the effect of 4 trials of exercise alone found no protection against falling.²⁰ Another important insight from primarily non-hospital settings includes the association between specific medications or classes of medications and falls.^{27,28} Although several studies have used pharmacist- or physician-based medication reviews as part of a multifaceted intervention, the independent effect of medication review and adjustment on fall outcomes has not been reported.

Institutionalized Elders

In a nursing home setting, a promising randomized controlled trial incorporating individualized assessment and targeting 4 falls-associated domains has been reported.²⁹ Intervention facilities had 19% fewer recurrent falls (95% CI: 2%-36%) compared with control

facilities and a 31% reduction in mean rate of injurious falls (13.7 vs. 19.9 falls per 100 personyears; p=0.22). Interventions in this study were made in the areas of environmental and personal safety (improvement in room lighting, flooring, footwear), wheelchair use and maintenance (assessment by an occupational therapist), psychotropic drug prescription (assessment and recommendations for change), transfer and ambulation (evaluation and recommendations for change), and facility-wide interventions (eg, in-service educational programs). No analogous study of a multi-intervention standardized protocol has been reported in hospitalized patients.

Hospitalized Elders

In the hospital, interventions have been employed as part of multiple risk factor intervention studies, but many have been poorly described and standardized. In the studies set in acute care environments,³⁰⁻⁴⁵ practices include educational activities for nurse and support staff, patient orientation activities, review of prior falls, and improvement of surrounding environment. Specific environmental components included decreasing ward or room obstacles, adding supplemental lighting and grab bars in bathrooms, and lowering bedrails and bed height. Other studies have attempted to improve transfer and mobility by providing scheduled ambulatory and physical therapy activities and better footwear (eg, non-skid socks). Additionally, studies have incorporated strategies to assist cognitively impaired patients by educating family members to deal with confused patients, minimizing sedating medications, and moving confused patients closer to nursing staff. Because many of these hospital studies use small sample sizes and inadequately describe the precise number and standardization of interventions, their generalizability and reproducibility is limited. However, a recent systematic review of many of these programs concluded that a pooled effect of 25% reduction in the fall rate occurred in the studies that examined prospective interventions compared to fall risk in historical controls.¹⁸

Some interventions with the potential for effectiveness in isolation have been studied. Each of the following hospital- or institution-based individual interventions has been analyzed independently of a multi-component falls prevention program:

- Identification bracelets
- Physical restraints
- Bed alarms
- Special flooring
- Hip protectors

Several generally accepted interventions with high face-validity have not been independently studied, yet are commonly accepted practices. Immobility⁴⁶ is a significant risk factor for several geriatric complications, including falls, pressure ulcers, and functional decline. Minimization of bedrest is a practical, real-world intervention that has implications for prevention of a number of serious hospital-acquired complications.⁴⁷

Comment

There are few hospital or other institution-based randomized controlled trials of standardized falls interventions, although the necessity for well-designed studies is clear. The nursing home-based intervention reported by Ray and colleagues²⁹ provides good evidence that a well-documented intervention can improve falls outcomes in institutionalized patients. No similarly designed trial of a multicomponent intervention in hospitalized patients was identified, although many falls prevention programs incorporate multifactorial interventions. The questions raised by multicomponent falls prevention studies include the generalizability of interventions to

diverse inpatient settings, appropriate targeting of at-risk individuals, analysis of the individual components that provide the best improvement in falls outcomes, and the transportability of interventions between institutions with variable resources for implementation. Evidence for the effectiveness of individual interventions is important, but effectiveness may change (for better or worse) when such interventions are incorporated with others as part of a falls prevention program.

Subchapter 26.1. Identification Bracelets for High-Risk Patients

Background

Some hospitals use colored bracelets to identify patients at high risk for falls. Other identification methods include signs, stickers, or tags placed above the patient's bed, at the nursing station, or on the patient's chart. In theory, these remind staff that the patient is at high risk for falls and trigger interventions that reduce the risk of falls (eg, supervision or assistance with ambulation, minimization of sedative-hypnotic medications, lowering of bed height). Identification bracelets might also impact patients' falls awareness (eg, reminding patients to call for assistance before getting out of bed).

Prevalence and Severity of the Target Safety Problem

See Introduction to Chapter 26.

Opportunities for Impact

We found no published data on the number of hospitals currently using such strategies.

Practice Description and Evidence for Effectiveness

A search of the literature identified many studies that have used identification bracelets, signs, or tags for high-risk patients.^{31-33,35,40-42,44,45,48,49} Most of these involved multiple, simultaneous interventions and were designed such that estimation of the treatment effect due to the identification bracelet, signs or tags component cannot be calculated. The remaining study was a randomized, controlled trial of colored identification bracelets worn by inpatients at high risk for falls (Table 26.1.1).⁵⁰ "High-risk" was defined as history of multiple falls, an episode of incontinence, or an admitting diagnosis of stroke or ataxia. Cox proportional hazards model was used to assess the effect of identification bracelets on time-to-first-fall. The fall rate was 42% (27/65) in the intervention group and 30% (21/69) in the control group, which did not represent a statistically significant difference. After preliminary analysis of the data, the investigators and ethics committee agreed that it was not appropriate to continue for the sole purpose of obtaining statistical power, and the study was terminated.

Potential for Harm

None identified.

Costs and Implementation

Identification tags and similar interventions are associated with minimal costs.

Comment

Use of special bracelets, signs, and stickers to identify patients at high risk for falls is a relatively inexpensive and easy to implement practice. There is currently insufficient information

as to whether identification bracelets, as a isolated intervention, decrease falls. Future studies should assess the effectiveness of similar identification strategies in the context of multicomponent fall prevention programs and, if they are effective, which methods work best.

Table 26.1.1.	Study of identification	bracelets*
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Study	Participants and Setting	Study Design, Outcomes	Results
Mayo, 1994 ⁵⁰	134 high-risk patients in a rehabilitation hospital, 1990-91	Level 1, Level 1	Hazard ratio for fall with intervention: 1.3 (95% CI: 0.8-2.4)

* CI indicates confidence interval.

References

- 1. Baker SP, O'Neill B, Ginsburg MJ, Guohua L. *The injury fact book*. 2nd edition. New York: Oxford University Press, 1992.
- 2. Tinetti ME, Speechley M. Prevention of falls among the elderly. *N Engl J Med*. 1989;320:1055-9.
- 3. Myers AH, Young Y, Langlois JA. Prevention of falls in the elderly. *Bone*. 1996;18:87S-101S.
- 4. Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. *N Engl J Med.* 1988;319:1701-1707.
- 5. Sutton J, Standan P, Wallace A. Incidence and documentation of patient accidents in hospital. *Nurs Times*. 1994;90:29-35.
- 6. Kanten DN, Mulrow CD, Gerety MB, Lichtenstein MJ, Aguilar C, Cornell JE. Falls: an examination of three reporting methods in nursing homes. *J Am Geriatr Soc*. 1993;41:662-666.
- 7. Rubenstein LZ, Robbins AS, Schulman BL, Rosado J, Osterweil D, Josephson KR. Falls and instability in the elderly. *J Am Geriatr Soc*.1988;36:266-278.
- 8. Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. *Ann Intern Med.* 1994;121:442-451.
- 9. Tinetti ME. Factors associated with serious injury during falls by ambulatory nursing home residents. *J Am Geriatr Soc.* 1987;35:644-648.
- 10. Englander F, Hodson TJ, Terregrossa RA. Economic dimensions of slip and fall injuries. *J Forensic Sci.* 1996; 41:733-746.
- 11. Zuckerman JD. Hip fracture. *N Engl J Med.* 1996;334:1519-1525.
- 12. Brainsky GA, Lydick E, Epstein R, et al. The economic cost of hip fractures in community-dwelling older adults: a prospective study. *J Am Geriatr Soc*.1997;45:281-287.
- 13. CDC. Incidence and costs to Medicare of fractures among Medicare beneficiaries aged > 65 years: United States, July 1991-June 1992. *MMWR Morbidity & Mortality Weekly Report 1996*;45:877-883.
- 14. Oliver D, Britton M, Seed P, Martin FC, Hopper AH. Development and evaluation of evidence based risk assessment tool (STRATIFY) to predict which elderly inpatients will fall: case-control and cohort studies. *BMJ*. 1997;315:1049-1053.
- 15. Whitney SL, Poole JL, Cass SP. A review of balance instruments for older adults. *Am J Occup Ther*. 1998;52: 666-671.

- 16. Shumway-Cook A, Baldwin M, Polissar NL, Gruber W. Predicting the probability for falls in community-dwelling older adults. *Phys Ther*. 1997;77:812-819.
- 17. Tinetti ME. Performance-oriented assessment of mobility problems in elderly patients. *J Am Geriatr Soc.* 1986;34:119-126.
- 18. Oliver D, Hopper A, Seed P. Do hospital fall prevention programs work? A systematic review. *J Am Geriatr Soc.* 2000;48:1679-1689.
- 19. Tinetti ME, Baker DI, McAvay G, et al. A multifactorial intervention to reduce the risk of falling among elderly people living in the community. *N Engl J Med.* 1994;331:821-827.
- 20. Gillespie LD, Gillespie WJ, Cumming R, Lamb SE, Rowe BH. Interventions for preventing falls in the elderly. In: *The Cochrane Library*, Issue 2, 2000. Oxford: Update Software.
- 21. McMurdo ME, Mole P, Paterson C. Controlled trial of weight-bearing exercise in older women in relation to bone density and falls. *BMJ*. 1997;314:569.
- 22. Wolf SL, Barnhart HX, Kutner NG, McNeely E, Coogler C, Xu T. Reducing frailty and falls in older persons: an investigation of Tai Chi and computerized balance training. Atlanta FICSIT Group. Frailty and Injuries: Cooperative Studies of Intervention Techniques. *J Am Geriatr Soc*.1996;44:489-497.
- 23. Lord SR, Ward JA, Williams P, Strudwick M. The effect of a 12-month exercise trial on balance, strength, and falls in older women: a randomized controlled trial. *J Am Geriatr Soc.* 1995;43:1198-1206.
- 24. Reinsch S, MacRae P, Lachenbruch PA, Tobis JS. Attempts to prevent falls and injury: a prospective community study. *Gerontologist*. 1992;32:450-456.
- 25. Mulrow CD, Gerety MB, Kanten D, et al. A randomized trial of physical rehabilitation for very frail nursing home residents. *JAMA*. 1994;271:519-524.
- 26. Province MA, Hadley EC, Hornbrook MC, et al. The effects of exercise on falls in elderly patients. A preplanned meta-analysis of the FICSIT Trials. Frailty and Injuries: Cooperative Studies of Intervention Techniques. *JAMA*. 1995;273:1341-1347.
- 27. Leipzig RM, Cumming RG, Tinetti ME. Drugs and falls in older people: a systematic review and meta-analysis: I. Psychotropic drugs. *J Am Geriatr Soc*.1999;47:30-39.
- 28. Leipzig RM, Cumming RG, Tinetti ME. Drugs and falls in older people: a systematic review and meta-analysis: II. Cardiac and analgesic drugs. *J Am Geriatr Soc*. 1999;47:40-50.
- 29. Ray WA, Taylor JA, Meador KG, et al. A randomized trial of a consultation service to reduce falls in nursing homes. *JAMA*. 1997;278:557-562.
- 30. Rainville NG. Effect of an implemented fall prevention program on the frequency of patient falls. *Qual Rev Bull*. 1984;10:287-291.
- 31. Fife DD, Solomon P, Stanton M. A risk/falls program: code orange for success...geriatric patients. *Nurs Manage*. 1984;15:50-53.
- 32. Barker SM, O'Brien CN, Carey D, Weisman GK. Quality improvement in action: a falls prevention and management program. *Mt Sinai J Med*. 1993;60:387-90.
- 33. Hendrich AL. An effective unit-based fall prevention plan. *J Nurs Qual Assur.* 1988;3:28-36.
- 34. Craighead J, Fletcher P, Maxwell J. Seven steps for fall prevention. *Dimens Health Serv.* 1991;68:25-26.
- 35. Kilpack V, Boehm J, Smith N, Mudge B. Using research-based nursing interventions to decrease patient falls. *Appl Nurs Res.* 1991;4:50-56.

- 36. Mitchell A, Jones N. Striving to prevent falls in an acute care setting–action to enhance quality. *J Clin Nurs*. 1996;5:213-220.
- 37. Hill BA, Johnson R, Garrett BJ. Reducing the incidence of falls in high risk patients. *J Nurs Adm.* 1988;18:24-28.
- 38. Hernandez M, Miller J. How to reduce falls. *Geriatr Nurs*. 1986;7:97-102.
- 39. Krishna KM, Van Cleave RJ. Decrease in the incidence of patient falls in a geriatric hospital after educational programs [letter]. *J Am Geriatr Soc*.1983;31:187.
- 40. Morton D. Five years of fewer falls. *Am J Nurs*. 1989;89:204-205.
- 41. Sweeting HL. Patient fall prevention–a structured approach. *J Nurs Manag.* 1994;2:187-92.
- 42. Schmid NA. Reducing patient falls: a research-based comprehensive fall prevention program. *Mil Med.* 1990;155:202-207.
- 43. Brady R, Chester FR, Pierce LL, Salter JP, Schreck S, Radziewicz R. Geriatric falls: prevention strategies for the staff. *J Gerontol Nurs*. 1993;19:26-32.
- 44. Cannard G. Falling trend. Nurs Times. 1996;92:36-37.
- 45. Zepp S. "Ban a fall." A nursing innovation to reducing patient falls. *Kans Nurse*. 1991;66:13.
- 46. Mahoney JE. Immobility and falls. *Clin Geriatr Med*. 1998;14:699-726.
- 47. Harper CM, Lyles YM. Physiology and complications of bed rest. *J Am Geriatr Soc.* 1988;36:1047-1054.
- 48. Rogers S. Reducing falls in a rehabilitation setting: a safer environment through team effort. *Rehabil Nurs.* 1994;19:274-276,322.
- 49. Innes E. Maintaining fall prevention. *QRB*. 1985;11:217-221.
- 50. Mayo NE, Gloutney L, Levy AR. A randomized trial of identification bracelets to prevent falls among patients in a rehabilitation hospital. *Arch Phys Med Rehabil*. 1994;75:1302-1308.

Subchapter 26.2. Interventions that Decrease the Use of Physical Restraints

Background

The Health Care Financing Administration (HCFA) defines physical restraints as "any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient that the individual cannot remove easily which restricts freedom of movement or normal access to one's body."¹ Physical restraints have been used in nursing homes and hospitals both as a safety device and as a falls prevention tool. Because restrained patients cannot arise from a chair or transfer out of bed, they theoretically will not fall or, in the case of bedrails, will not roll out of bed. However, the use of physical restraints may lead to substantial adverse outcomes. In fact, serious injuries and even death have been reported with use of these devices.^{2,3} This chapter examines interventions to reduce use of physical restraints and the concomitant effect on fall rates.

Practice Description

Studies examining the use physical restraints have considered 2 types of interventions in hospital or nursing home settings: bedrails and other mechanical restraints designed to restrict mobility. These interventions usually begin with either a physician or nurse making an assessment that a patient is at risk for falls, elopement, or other adverse outcomes. Thereafter,

use of a restraint is initiated, with periodic reassessment of the ongoing need for the device. Safety practices to reduce restraint use in nursing home patients have included nursing education strategies focusing on assessment/reassessment of the need for restraints and the use of alternatives to restraints.

Prevalence and Severity of the Target Safety Problem

See Introduction to Chapter 26.

Opportunities for Impact

Federal guidelines now discourage all but the limited, appropriate use of physical restraints and bedrails. Legislation adopted as part of the Omnibus Budget Reconciliation Act of 1987 directed nursing homes to limit physical restraints, and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) has adopted similar guidelines. Several statewide initiatives (eg, the Pennsylvania Restraint Reduction Initiative, begun in 1996) have been implemented under HCFA's National Restraint Reduction Initiative, resulting in notable reductions in restraint usage.⁴ The Food and Drug Administration's Hospital Bed Safety Work Group has likewise actively raised awareness of the risks and benefits of bedrail use.⁵ Based on an annual HCFA survey, the national restraint rate was approximately 13.5% in 1999, down from approximately 20% in 1996 when HCFA's Restraint Reduction Initiative began.⁶ Nonetheless, data from selected states reveals that the rate was still as high as 26% as of 1998.⁷

Study Designs and Outcomes

Six studies were identified: 2 concerning bedrail interventions^{8,9} and 4 describing mechanical restraints interventions (Table 26.2.1).^{7,10-12} Most studies compare interventions with historical control or baseline rates using a before-after study design. Morbidity data on falls are reported in all studies.

Evidence for Effectiveness of the Practice

The studies reveal no statistically significant difference in falls compared with historical controls when bedrails are removed. In fact, restrained patients appear to have a modest increase in fall risk or fall injuries based on several studies. Weaknesses in study design for some of these studies preclude a final conclusion.

Potential for Harm

The potential for harm with use of bedrails is well-documented, including death from a variety of mechanisms, including death and strangulation.¹³ Mechanical restraints likewise carry a risk of severe injury, strangulation, and mobility limitations that may predispose patients to other adverse outcomes (pressure ulcers, incontinence, acute confusion). Limits to patient freedom, dignity, and quality of life also contribute to the potential for harm. A potential harm of interventions to decrease restraint use is that there may be an increase in other adverse events (eg, elopement) if appropriate alternative preventive measures are not in place.

Costs and Implementation

The costs associated with interventions to reduce the use of restraints have not been described. Nonetheless, reduction in the use of physical restraints will require resources to pay for alternative interventions and rehabilitative measures and will increase labor costs.¹⁴ Compliance with interventions to reduce bedrail rates and to decrease mechanical restraint use

has been good. In fact, given adequate alternatives to the use of these devices, hospital and nursing staffs have decreased their usage significantly. In the Neufeld study,⁷ for example, restraint use fell from 41% to 4%.

Comment

There is growing evidence that physical restraints have a limited role in medical care. Restraints limit mobility, a shared risk factor for a number of adverse geriatric outcomes, and increase the risk of iatrogenic events. They certainly do not eliminate falls, and decreasing their use can be accomplished without increasing fall rates. In some instances reducing the use of restraints may actually decrease the risk of falling. Incorporating changes into physician and staff behavior may be easier if large, multicenter trials are successful in identifying safe alternatives to restraints that effectively limit falls risks for patients.

Study	Participants and Setting	Design, Outcomes	Results
Hanger, 1999 ⁹	1968 hospital patients in New Zealand, 1994; formal bedrail policy and educational program to reduce bedrail use, historical controls	Level 3, Level 1	No significant difference in overall fall rate: 164.8 falls/10,000 bed days before and 191.7 falls/10,000 bed days after the intervention (p=0.18) Fewer serious falls occurred after the intervention (p=0.008)
Si, 1999 ⁸	246 patients in a teaching nursing home, 1993-94; interdisciplinary team assessment and removal of bedrails with provision of bedrail alternatives, historical controls	Level 3, Level 1	No significant difference in fall rates: 2/116 (1.7%) patients before and 2/130 (1.5%) patients after the intervention
Capezuti, 1996 ¹¹	322 nursing home residents; subgroup of confused patients examined for mechanical restraint use	Level 3, Level 1	Confused patients who were restrained had increased odds of falling (OR 1.65, 95% CI: 0.69-3.98) and recurrent falls (OR 2.46, 95% CI: 1.03-5.88)
Capezuti, 1998 ¹²	633 nursing home residents in 3 nursing homes, 1990-1991; restraint education and consultation interventions compared with baseline rates	Level 3, Level 1	No significant increase in fall rates in the restraint-free group Decreased odds of minor injury after restraint removal, adjusted OR 0.3 (95% CI: 0.1-0.9)
Neufeld, 1999 ⁷	2075 nursing home beds in 16 nursing homes, 1991-1993; educational intervention to decrease mechanical restraints compared with baseline rates	Level 3, Level 1	Moderate/severe injuries decreased from 7.4% to 4.4% (p=0.0004) after educational intervention
Tinetti, 1991 ¹⁰	397 elderly patients at 12 skilled nursing facilities; observational cohort study of mechanical restraint use	Level 3, Level 1	 15/275 (5%) of unrestrained patients compared to 21/122 (17%) experienced a serious fall-related injury (p<0.001) Restraint use was significantly associated with a serious fall, adjusted OR 10.2 (95% CI: 2.8-36.9)

 Table 26.2.1. Studies of physical restraints and fall risk*

* CI indicates confidence interval; OR, odds ratio.

References

- 1. Health Care Financing Administration. FY 2001 Annual Performance Plan. Available at: http://www.hcfa.gov/stats/2001.htm. Accessed June 13, 2001.
- 2. FDA Center for Devices and Radiological Health. FDA safety alert: entrapment hazards with hospital bed side rails. August 1995. Available at: http://www.fda.gov/cdrh/bedrails.html. Accessed June 12, 2001.
- 3. Miles SH, Irvine P. Deaths caused by physical restraints. *Gerontologist.* 1992;32:762-766.
- 4. Health Care Financing Administration. National restraint reduction newsletter. Summer 2000. Available at: http://www.hcfa.gov/publications/newsletters/restraint/2000/rr0600.asp. Accessed June 12, 2001.
- 5. FDA Center for Devices and Radiological Health. A guide to bed safety. Available at: http://www.fda.gov/cdrh/beds/bedrail.pdf. Accessed June 12, 2001.
- 6. Health Care Financing Administration. National restraint reduction newsletter. Winter 1999. Available at: http://www.hcfa.gov/publications/newsletters/restraint/1999/ rrwin99.htm. Accessed June 12, 2001.
- 7. Neufeld RR, Libow LS, Foley WJ, Dunbar JM, Cohen C, Breuer B. Restraint reduction reduces serious injuries among nursing home residents. *J Am Geriatr Soc.* 1999;47:1202-1207.
- 8. Si M, Neufeld RR, Dunbar J. Removal of bedrails on a short-term nursing home rehabilitation unit. *Gerontologist.* 1999;39:611-614.
- 9. Hanger HC, Ball MC, Wood LA. An analysis of falls in the hospital: can we do without bedrails? *J Am Geriatr Soc.* 1999;47:529-531.
- 10. Tinetti ME, Liu YB, Ginter S. Mechanical restraint use and fall related injuries among residents of skilled nursing facilities. *Ann Intern Med.* 1992;116:369-374.
- 11. Capezuti E, Evans L, Strumpf N, Maislin G. Physical restraint use and falls in nursing home residents. *J Am Geriatr Soc.* 1996;44:627-633.
- 12. Capezuti E, Strumpf NE, Evans LK, Grisso JA, Maislin G. The relationship between physical restraint removal and falls and injuries among nursing home residents. *J Gerontol A Biol Sci Med Sci*. 1998;53:M47-M52.
- 13. Parker K, Miles SH. Deaths caused by bedrails. J Am Geriatr Soc. 1997;45:797-802.
- 14. Schnelle JF, Smith RL. To use physical restraints or not? [editorial]. *J Am Geriatr Soc*. 1996;44:727-728.

Subchapter 26.3. Bed Alarms

Background

Epidemiologic studies reveal that falls occur commonly in and around bed areas.^{1,2} Decreasing the risk of falls when patients attempt to transfer into and out of bed without assistance is a potentially important target safety goal. This chapter examines the use of a bed alarm system that alerts hospital staff to patient movement out of bed as a strategy to reduce falls. General principles of alarm use in health care settings can be found in Chapter 8.

Practice Description

A sensor device is placed on the bed, under a sitting or reclining patient. When the patient changes position, it detects movement and/or absence of weight. An audible alarm is triggered at the nurses' station and, with some devices, in the patient's room. The alarm alerts nurses when patients attempt to leave the bed without assistance and may alert a patient to remain in bed if the alarm is audible in the patient's room.

Evidence for Effectiveness of the Practice

Several studies have included bed alarms as part of a multifaceted intervention.³⁻⁶ However, the study designs do not allow calculation of the effect attributable to the bed alarm component or were not controlled. A recent, unpublished before-after study was identified in a Web search but the full report could not be obtained before completion of this chapter.⁷ Tideiksaar et al randomized elderly patients at "high risk" for falls to either a group that received an alarm system (the RN+ OnCall bed monitoring system) or to a control group that did not (Table 26.3.1)⁸. The groups were similar in age and gender. No other baseline comparisons were reported. There were fewer falls in the study group but the difference failed to reach statistical significance. However, the total number of falls was low (n=17) and had there been one less fall in the alarm group or one more fall in the control group, the difference would have been statistically significant.

Potential for Harm

No harm was identified. There are theoretical electrical risks if the sensor devices are internally compromised due to bending of the sensor mats and exposure to fluids, but such events have not been reported in the literature.

Costs and Implementation

Costs of the devices vary by manufacturer, the type of bed monitoring system used, and the number of beds to be monitored. Manufacturers' charges range from several hundred to several thousand dollars for the receiving equipment. Individual sensors require replacement after pre-specified periods of use or, in some cases, can be cleaned between patients, which incurs additional hospital costs. Implementation requires adequate staffing to respond in a timely manner to the audible alarms.

Comment

At this time, there is insufficient evidence regarding the effectiveness of bed alarms in preventing falls in elderly patients to recommend the practice. Additional research sufficiently powered to identify meaningful differences, coupled with a formal economic analysis, would be useful.

Study	Participants and Setting	Study Design, Outcomes	Results (95% Confidence Interval)
Tideiksaar, 1993 ⁸	70 patients on a geriatric unit in a university hospital, 1992	Level 1, Level 1	Odds ratio for prevention of falls: 0.32 (0.10-1.03)

 Table 26.3.1. Study of bed alarms for fall prevention

References

- 1. Vassallo M, Amersey RA, Sharma JC, Allen SC. Falls on integrated medical wards. *Gerontology*. 2000;46:158-162.
- 2. Sutton J, Standan P, Wallace A. Incidence and documentation of patient accidents in hospital. *Nurs Times*. 1994;90:29-35.
- 3. Schmid NA. Reducing patient falls: a research-based comprehensive fall prevention program. *Mil Med.* 1990;155:202-207.
- 4. Widder B. A new device to decrease falls. *Geriatr Nurs*. 1985;6:287-288.
- 5. Morton D. Five years of fewer falls. *Am J Nurs*. 1989;89:204-205.
- 6. Innes E. Maintaining fall prevention. *QRB*. 1985;11:217-221.
- 7. Bed-Check Corporation. Fall prevention study: bed alarms, investigating their impact on fall prevention and restraint use. Available at: http://www.bedcheck.com/fall-prevention-study.html. Accessed June 6, 2001.
- 8. Tideiksaar R, Feiner CF, Maby J. Falls prevention: the efficacy of a bed alarm system in an acute-care setting. *Mt Sinai J Med*. 1993;60:522-527.

Subchapter 26.4. Special Hospital Flooring Materials to Reduce Injuries from Patient Falls

Background

One proposed practice to prevent injury due to falls is to alter flooring material on hospital wards or in nursing homes. Carpeting, vinyl, or other biomedically-engineered materials could potentially improve falls outcomes. The use of special flooring materials has been shown to influence specific gait characteristics in hospitalized elders.¹ A recent study described the Penn State Safety Floor, which is designed to remain relatively rigid under normal walking conditions but to deform elastically to absorb impact forces during a fall.² The efficacy of this floor is still being tested outside the laboratory environment among nursing home residents.³

Practice Description

As data on the efficiency of the Penn State Safety Floor² are not yet available, we restrict our review to the use of *hospital-duty carpeting* compared with "usual" vinyl flooring.

Study Designs and Outcomes

We identified 2 studies of the effect of flooring type (carpet vs. "usual" vinyl flooring) on falls: a randomized controlled trial in an inpatient rehabilitation unit⁴ and a retrospective study of accidents reported in a care of the elderly unit (Table 26.4.1).⁵ Both studies reported Level 1 outcomes. The randomized trial measured the rate of falls. The retrospective analysis studied fall-related injury, defined as any graze, bruise, laceration, fracture or pain.

Evidence for Effectiveness of the Practice

The randomized trial by Donald et al found more falls in the group housed in rooms with carpeted flooring, although the difference barely failed to achieve statistical significance. The earlier retrospective analysis by Healey found that the rate of injury was significantly lower for patients who fell on carpet rather than vinyl flooring.⁵ The severity of injuries was not reported and it was not possible to determine whether the rate of falls differed according to flooring material.

Potential for Harm

No harm was identified, although it is possible that asthmatic patients might react to increased levels of dust-mite allergens in carpeted wards.⁶

Costs and Implementation

No cost estimates for changes in flooring were reported in the literature. Implementation of this practice would require a large expenditure for facilities upgrades nationwide. Likewise, the costs associated with keeping various floor surfaces clean in the hospital or nursing home environment would also be high.

Comment

Advances in biomedical engineering could result in potentially significant redesign of the physical environment in hospitals and nursing facilities. The primary aim of specialized flooring could be either to reduce the risk of falling or to reduce the risk of an injury once a fall has occurred, or both. The two studies analyzed seem to indicate that carpeted floors may increase fall rates but decrease fall injuries; it is possible that other surfaces would yield better results. Further study of this area is warranted.

Study	Participants and Setting	Study Design, Outcomes	Results
Donald, 2000 ⁴	32 patients in an elderly care rehabilitation ward in the United Kingdom in 1996	Level 2, Level 1	Rate of falls: Carpet, 10/16 (63%); vinyl, 1/16 (6%) RR 8.3 (95% CI: 0.95-73; p=0.05)
Healey, 1994 ⁵	Random sample of accident forms (n=213) from care of elderly unit over 4 years	Level 3, Level 1	Falls resulting in injury: Carpet, 15%; vinyl, 91% (p<0.001)

 Table 26.4. Study of special flooring for falls prevention

* CI indicates confidence interval; RR, relative risk.

References

- 1. Wilmott M. The effect of a vinyl floor surface and a carpeted floor surface upon walking in elderly hospital in-patients. *Age Ageing*. 1986;15:119-120.
- 2. Casalena JA, Badre-Alam A, Ovaert TC, Cavanagh PR, Streit DA. The Penn State safety floor. Part II: reduction of fall-related peak impact forces on the femur. *J Biomech Eng*. 1998;120:527-532.
- 3. Stevens JA, Olson S. Reducing falls and resulting hip fractures among older women. *MMWR Morb Mortal Wkly Rep* 2000; 49(RR02):1-12.
- 4. Donald IP, Pitt K, Armstrong E, Shuttleworth H. Preventing falls on an elderly care rehabilitation ward. *Clin Rehabil*. 2000;14:178-185.
- 5. Healey F. Does flooring type affect risk of injury in older patients? *Nurs Times*. 1994;90:40-41.
- 6. Sadler C. Floored thinking. *Nurs Times*. 1993;89:20-21.

Subchapter 26.5. Hip Protectors to Prevent Hip Fracture

Background

Hip fractures are an important cause of morbidity and mortality, resulting in about 340,000 hospitalizations in 1996 in the United States for those aged 65 years and older.¹ Six months after hospitalization for hip fracture, 12.8% of patients require total assistance to ambulate according to a recent prospective study.² New dependency in physical and instrumental activities of daily living is also considerable. For those independent prior to a hip fracture, 20% of patients require assistance putting on pants, 66% require assistance in getting on or off the toilet, and 90% require assistance climbing 5 stairs after a hip fracture.³ Mortality rates range between 18-33% within the first year post-fracture.³ One proposed prevention measure is for a patient to wear a protective pad around the hip to absorb the impact of a fall and to reduce the risk of fracture by "shunting" energy away from the hip region.

Practice Description

External hip protectors are usually made with plastic pads or shields that are padded or constructed with foam-type materials. They fit into specially-designed pockets in undergarments or pants. They are designed to be worn during the day for people who are out of bed, walking or engaged in activities that place them at higher risk for falls. Ideally, they would be worn all the time to protect individuals from nighttime falls.

Prevalence and Severity of the Target Safety Problem

See Introduction to Chapter 26.

Opportunities for Impact

No data on the nationwide use of hip protectors in the hospital or nursing home are available. A small minority of institutions are in the process of evaluating them, and a few may have begun to use them.

Study Designs

Five relevant randomized controlled trials⁴⁻⁸ were identified from a literature search and from a Cochrane systematic review.⁹ The Cochrane review cites 2 additional abstracts^{10,11} not included here. Four of the trials evaluate effectiveness of the devices and one study⁸ examines compliance rates of wearing hip protectors as part of a pilot study. Two studies were cluster-randomized and 2 were randomized by individual patient.

Study Outcomes

Studies reported hip fractures as an outcome, although compliance with the intervention was the primary outcome in one study. Additional outcomes reported were mortality, falls, and non-hip fractures.

Evidence for Effectiveness of the Practice

External hip protectors appear to be an effective means to reduce the risk of a hip fracture in older persons aged 65 and over who fall. Table 26.5.1 lists the abstracted studies and outlines their pertinent features. The generalizability of these results to wider audiences and to lower risk populations has not been demonstrated, nor has the potential benefit for hospitalized patients been reported. Concerns with compliance could hinder their effectiveness on a population-wide level.

Potential for Harm

Discomfort from wearing the device, difficulty managing the garment while dealing with continence, and the potential for skin irritation and breakdown are causes for concern if fragile older people were to wear hip protectors. Because long-term compliance is low, it is unclear how many people would experience such problems if the devices were worn for longer periods during the day or for long-term use.

Costs and Implementation

An Australian study published in 2000 quoted a cost of A\$10 per pair (approximately \$5.25US).⁴ The retail price quoted by one US manufacturer of a different hip protector is approximately \$90 per pair. The lycra-containing undergarment used by some manufacturers to keep the hip pads in place requires special laundering and would require a tracking system similar to that used for other specialized garments or medical devices assigned to patients within a facility. Once provided, if devices can be put on and taken off by individual users, implementation is straightforward. The cost-effectiveness of the devices has not been formally reported.

Comment

One of the main philosophical concerns raised by these studies is the change in emphasis from primary prevention of the underlying cause of hip fractures (ie, falls) to an emphasis on methods of protecting patients from the deleterious consequences of falls. However, a strategy for addressing the multiple risk factor model for falls is still warranted for primary falls prevention. With this caveat in mind, there is strong evidence to support the ability of hip protectors to prevent hip fractures. This evidence, in addition to their high face validity, may encourage their rapid adoption. Further evaluation of their costs, acceptability to patients, and effectiveness in hospitalized patients (versus nursing home residents) is needed.

Study	Participants and Setting	Design, Outcomes	Results
Parker, 2000 ⁹	1752 nursing home or rest home residents in 5 countries	Level 1A, Level 1	Peto OR 0.44 (95% CI: 0.26-0.75) of hip fracture in the intervention group in cluster-randomized studies;
			Peto OR 0.22 (95% CI: 0.09-0.57) in patient- randomized studies
Chan, 2000 ⁴	71 nursing home residents in Australia, year not stated	Level 1, Level 1	RR of hip fracture in the intervention group 0.264 (95% CI: 0.073-0.959)
Ekman, 1992 ⁵	746 nursing home residents in Sweden, year not stated	Level 1, Level 1	RR of hip fracture in the intervention group 0.33 (95% CI: 0.11-1.00)
Kannus, 2000 ⁶	1801 community based elderly in Finland, 1996-1997	Level 1, Level 1	RR of hip fracture in the intervention group 0.4 (95% CI: 0.2-0.8; p=0.008)
Lauritzen, 1993 ⁷	665 nursing home residents in Denmark, 1991-1992	Level 1, Level 1	RR of hip fracture in the intervention group 0.44 (95% CI: 0.21-0.94)
Villar, 1998 ⁸	141 rest home residents in the UK, year not stated	Level 1, Level 3	30% compliance over 3 months (hip fracture outcomes not assessed)

 Table 26.5.1. Hip protectors to prevent hip fracture*

* CI indicates confidence interval; OR, odds ratio; and RR, relative risk.

References

- 1. Stevens JA, Olson S. Reducing falls and resulting hip fractures among older women. *MMWR Morb Mortal Wkly Rep.* 2000;49:1-12.
- 2. Hannan EL, Magaziner J, Wang JJ, et al. Mortality and locomotion 6 months after hospitalization for hip fracture. *JAMA*. 2001;285:2736-2742.
- 3. Magaziner J, Hawkes W, Hebel JR, et al. Recovery from hip fracture in eight areas of function. *J Gerontol*. Medical Sciences 2000;55A:M498-M507.
- 4. Chan DK, Hillier G, Coore M, et al. Effectiveness and acceptability of a newly designed hip protector: a pilot study. *Arch Gerontol Geriatr*. 2000;30:25-34.
- 5. Ekman A, Mallmin H, Michaelsson K, Ljunghall S. External hip protectors to prevent osteoporotic hip fractures. *Lancet*. 1997;350:563-564.
- 6. Kannus P, Parkkari J, Niemi S, et al. Prevention of hip fracture in elderly people with use of a hip protector. *N Engl J Med.* 2000;343:1506-1513.

- 7. Lauritzen JB, Petersen MM, Lund B. Effect of external hip protectors on hip fractures. *Lancet* 1993;341:11-13.
- 8. Villar MTA, Hill P, Inskip H, Thompson P, Cooper C. Will elderly rest home residents wear hip protectors? *Age Ageing*. 1998;27:195-198.
- 9. Parker MJ, Gillespie LD, Gillespie WJ. Hip protectors for preventing hip fractures in the elderly. In: *The Cochrane Library*, Issue 2, 2001. Oxford: Update Software.
- 10. Harada A, Okulzumi H. Hip fracture prevention trial using hip protector in Japanese elderly. *Osteoporos Int*. 1998;8(Suppl 3):121.
- 11. Heikinheimo R, Jantti PL, Aho HJ, Maki-Jokela PL. To fall but not to break safety pants. *Proceedings of the Third International Conference on Injury Prevention and Control*, Melborne 1996;1996:576-578.