Increased Use of Hip Protectors in Nursing Homes: Economic Analysis of a Cluster Randomized, Controlled Trial

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OBJECTIVES: To assess the cost-efficacy of an intervention program aimed at reducing hip fractures.

DESIGN: Economic evaluation within an 18-month cluster randomized trial.

SETTING: Forty-nine nursing homes in Hamburg, Germany.

PARTICIPANTS: Residents with a high risk of falling (intervention group (IG), n = 459; control group (CG), n = 483).

INTERVENTION: Education session for nurses, who subsequently educated residents, and provision of three hip protectors per resident. CG care was optimized by providing brief information to nurses about hip protectors and providing two protectors per nursing home for demonstration purposes.

MEASUREMENTS: Main outcomes were hip fractures, costs, and incremental cost-effectiveness ratio (ICER).

RESULTS: The intervention was effective in reducing hip fractures (21 in the IG vs 42 in the CG) and resulted in a cost difference of $51 per participant in favor of the CG (95% confidence interval covering cost saving of $242 to cost expense of $325). Costs per additional hip fracture avoided were $1,234. Sensitivity analyses aimed at investigating robustness of the results to a real practice implementation scenario resulted in ICERs varying from $439 to $1,693. Taking into account lower hip protector reimbursement levels, the intervention program would be cost saving (break-even point within the base case analysis = $22 per hip protector).

CONCLUSION: A program consisting of education and provision of hip protectors might produce a slight increase in costs or might even be cost saving if the price of the hip protector could be decreased. **J Am Geriatr Soc 53:2153–2158, 2005.**

Key words: cost-efficacy analysis; program evaluation; hip fractures/prevention and control; orthopedic equipment; nursing homes

The burden of hip fractures in older people is well recognized.[1] In addition to causing substantial health deterioration, hip fractures have a great economic effect due to the requirement of hospital and follow-up care.[2] Fall and fracture prevention programs have been extensively studied.[3] Hip protectors appear to be the only nonpharmacological intervention to effectively prevent hip fractures in high-risk populations,[4] but evidence suggests that hip protectors should be implemented in combination with an education program. This approach has been shown to reduce hip fractures in nursing home residents approximately 40%.[5]

A key outcome of interest is whether the use of hip protectors is cost saving. Economic evaluations based on high-quality data are urgently needed.[4] An economic evaluation was performed alongside a clinically successful cluster randomized, controlled trial to investigate the cost-efficacy of hip protector provision and structured education.[5]

PARTICIPANTS AND METHODS

The design of the trial, methods, and clinical outcomes have been described in full elsewhere.[5–7]

Forty-nine nursing home clusters in Hamburg, Germany, including 942 residents (intervention group (IG), 25 clusters with 459 residents; control group (CG), 24 clusters with 483 residents) participated in an 18-month randomized, controlled trial. A cluster was defined as a nursing home by itself or an independently operating ward of a large nursing home. Each cluster was to select residents according to the following inclusion criteria: aged 70 and older, not bedridden, and living in the nursing home for more than 3 months. After collection of baseline data, a

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researcher not involved in the study allocated clusters using computer-generated randomization lists.

The ethics committee of the Hamburg chamber of physicians approved the study.

Interventions

German health insurance does not cover hip protectors. In the CG, usual care was optimized by providing brief information about the hip protector to the nominated study coordinator of each cluster. Two hip protectors per cluster were provided for demonstration purposes. The program offered to the IG aimed to increase adherence to the use of hip protectors and thereby to reduce hip fractures. Single-session education for nurses of each IG cluster was delivered. Nurses then educated residents. Three free hip protectors (Safehip, Tytex, Denmark) per IG resident were provided.

A description of the education program has been published.[5,7] In short, the education session lasted for approximately 60 minutes, took place in small groups, and was delivered by two investigators. Printed colored flip charts illustrating the main objectives of the education program and leaflets for residents, relatives, and physicians were provided. At least one nurse in each IG cluster was then responsible for delivering the same education program to residents individually or in small groups.

Economic Evaluation

The economic evaluation was part of the study protocol. A decision-analysis model was used to estimate the cost-efficacy of the intervention program.

Main outcome measures were hip fractures, costs, and incremental cost-effectiveness ratio (ICER: defined as incremental costs per additional hip fracture avoided in the IG compared with the CG). The analysis adopted the viewpoint of the German health and nursing care insurance, adding up all costs and savings relevant from the viewpoint of healthcare insurers and party payers.

In accordance with recent economic evaluations, it was hypothesized that, compared with optimized usual care, the intervention program might incur no increased costs or might even be cost saving.

Assessment included costs for optimization of usual care in the CG and costs for the intervention program, including its implementation and maintenance (education, hip protectors, additional nursing care due to hip protector use) in the IG as well as medical and nursing care costs after hip fracture for both groups. Costs for the interventions were estimated based on information from trial records.

Nurses documented hip fracture and healthcare demand after hip fracture using specially developed documentation sheets. Data were checked every 2 months during personal visits. At the end of the study, one investigator (GM) and the nominated study coordinator from each cluster reviewed all records, including hospital discharge records, to verify the completeness of the clinical and economical outcome data.

All calculations were made on the basis of 1999/2001 retail prices in euro. Results are reported in U.S. dollars (December 2000: 1 euro = approximately US$1). Prices were determined for the time the resource was used. Costs and benefits were not discounted because the time horizon was only 18 months.

Resource Use

Intervention Group

Although there were costs associated with developing the intervention components, these costs were incurred before the trial and were not incremental to this program.

Costs of the educational material covered expenses incurred by printing flip charts and leaflets. Five hours was calculated per education group session, including lead-time, providing the education, and travel time of two investigators (GM). Therefore, the average salary of the investigators per hour was added to the km allowance paid by the public service in 1999, computing 10 km per session per investigator. Costs for the nurses included costs of participation in the education session and time nurses spent to implement and maintain the intervention. The number of nurses who participated in the education sessions was multiplied by their gross salary for 1 working hour. It was estimated that nurses initially spent 15 minutes per resident to deliver the education on hip protectors and that the use of the protector required 20 minutes of work per resident per month over the mean follow-up of the particular cluster.

Costs for three hip protectors per IG resident were added. Under trial conditions, the hip protectors were provided at a particularly low price of $9.20, but the price of $40 per hip protector was used, which would have been the regular market price if 1,000 or more hip protectors had been purchased.

Control Group

Fifteen minutes for the nurse in charge and one investigator were calculated for providing brief information about the hip protector. Ten km and 60 minutes for traveling of a single investigator (GM) who delivered the brief information were computed. The price for two hip protectors per cluster was added.

Both Study Group

For each hip fracture, actual costs of emergency and follow-up treatment were taken into account. The calculation of costs of physicians' emergency consultation after hip fracture included different reimbursement schedules (i.e., family doctor or emergency doctor and time of call-out). Calculation of costs due to transport by ambulance was based on charges of the most popular provider. Because prices of outpatient physiotherapy did not substantially vary between 1999 and 2001, the amount paid in 2000 was used. For wheelchairs, an average charge of available devices was computed. Costs of intensified nursing care due to hip fracture–related premature care dependency were calculated based on degrees of disablement as assessed by expert raters of the medical service of the German statutory health insurance system (grading scale: 0 = none, 1 = considerable, 2 = severe, 3 = most severe).[8] The grading is based on a standardized examination with proven reliability and validity.[9] Degree of disablement was determined at baseline and after hip fracture. From CG data, the mean lead-time of the natural increase of degree of disablement was estimated to be 9 months.

Table 1. Key Unit Costs in U.S. Dollars Used to Value Resource Use Measured in the Trial (1999–2001 Prices)

Item of Resource	Unit	Unit Cost (US$)	Source
Resource use due to implementation of interventions			
Education material	Item	141	Invoice by the manufacturer
Nurses' salary	Hour	21	Finance department of nursing homes in Hamburg, trade union for the German service industry
Investigators' salary	Hour	31	Finance department of the University of Hamburg
Travel expenses	Kilometer lump sum	0.2	
Hip protector	Item	40	Invoice by the manufacturer
Resource use due to hip fracture–related care:			
Physicians' consultation*	Visit	27–39	Health insurance
Transport by ambulance	Event	283	
Hospital admission, days			
≤20	Lump sum	5,342	
21–36	Lump sum	6,621	
>36†	Day	304	Finance department of corresponding hospital
Inpatient rehabilitation‡	Day	131–220	
Outpatient physiotherapy	Lump sum per visit	24	Health insurance
Walking aid			
Wheel chair	Item	650	Health insurance, manufacturers
Rolling walker	Item	148	
Increased degree of disablement			
From 0 to 1	Day	34	German social security code XI
From 0 to 2	Day	43	
From 1 to 2	Day	8.5	
From 2 to 3	Day	5.1	

* Charges varied depending on reimbursement schedules.
† In one case of hip fracture in the control group, additional costs for 7 further days in the hospital were computed.
‡ Charges varied depending on the corresponding rehabilitation hospital.

Table 1 details the key unit costs, together with their sources.

Time Horizon

Assuming that participants keep up wearing the hip protector, the benefits of the intervention program would extend past the study period, but the extent of this benefit and longer-term compliance rates are uncertain. Because cost data are available for the duration of the trial only, the appropriate effectiveness measure is the one that allows treatment effects during the trial only.

Sensitivity Analysis

Economic evaluation is subject to uncertainty not just because of sample variation but also because of assumptions made and generalizability issues. A sensitivity analysis of the key variables that might influence the result of the economic evaluation was performed. This was done to investigate the robustness of the results to a real practice-implementation scenario. A single nurse rather than the two investigators would educate nurses. Because the educational material set is now commercially available, the purchase price of $70 was used.[10] Because the lead-time estimate of the natural increase of degree of disablement was based on a truncated time interval, an alternate lead-time estimate of 22 months that had been derived from an exponential model was used.

Nursing care related to hip protector use is a major cost component. Therefore, a second sensitivity analysis was performed using 30 minutes of hip protector–related nursing care per trial participant per month rather than the 20 minutes under study conditions.

Effectiveness of the intervention program may vary. Therefore, the effect of changing the absolute risk reduction in hip fractures by ± 10% was tested in a further analysis.

Finally, the costs of hip protectors were varied to break-even. The break-even point is the situation that occurs when intervention costs equal the averted hip fracture–related costs.

Statistical Analysis

The sampling unit of the cluster randomization was nursing home clusters, as was the unit of intervention. Thus, implementation costs and hip fracture–related costs per participant were calculated for each of the clusters. Sample characteristics (mean ± standard deviation (SD), 10th to 90th percentile) were calculated across clusters for each study group separately. For the between-group mean differences, 95% bootstrap confidence intervals (CIs) were calculated using the percentile method, based on 10,000 bootstrap replications.[11] Calculations were performed using APL2000, version 5.0 (APL2000, Princeton, NJ).

RESULTS

Trial Participants and Follow-Up

Mean age of participants was 87; 24% of participants had a history of hip fracture, and more than 70% had at least

Table 2. Base Case Analysis Results on Resource Use per Participant

Cost Item	Intervention Group* (n = 459)	Control Group† (n = 483)	Difference‡ (95% Confidence Interval)*
	Mean ± Standard Deviation (10th to 90th percentile) $		
Implementation of interventions			
Educational material	8 ± 1.6 (5.6–10)	NA	8 (7.4–8.7)
Education§/brief information‖	30 ± 17 (15–40)	2.5 ± 0.6 (1.4–3)	28 (22–35)
Hip protectors	121¶	4.4 ± 1.1 (2.5–5.4)	117 (116–117)
Hip protector-related nursing care#	108 ± 11 (94–122)	NA	108 (104–113)
Sum	268 ± 20 (247–299)	6.8 ± 1.7 (3.9–8.4)	261 (254–269)
Hip fracture–related care			
Consultation of a physician	0.7 ± 1.1 (0–2.4)	1.1 ± 2.8 (0–2.8)	– 0.4 (– 1.7–0.6)
Transport by ambulance	13 ± 13 (0–35)	21 ± 21 (0–50)	– 8.6 (– 19–0.5)
Hospital treatment	260 ± 268 (0–668)	430 ± 411 (0–966)	– 170 (– 372–15)
Inpatient rehabilitation	54 ± 157 (0–295)	47 ± 133 (0–189)	7.5 (– 72–92)
Outpatient physiotherapy	4.2 ± 7.2 (0–16)	18 ± 33 (0–58)	– 14 (– 29 to – 2.7)
Walking aid	4.6 ± 14 (0–26)	12 ± 19 (0–46)	– 7.1 (– 17–2)
Increase of degree of disablement	30 ± 99 (0–128)	48 ± 119 (0–252)	– 18 (– 80–42)
Sum	366 ± 445 (0–939)	576 ± 571 (0–1,389)	– 210 (– 504–65)
Total costs	634 ± 439 (257–1,213)	583 ± 570 (7.7–1,396)	51 (– 242–325)

* Mean follow-up = 14.7 ± 5.7 months.
† Mean follow-up = 13.7 ± 6.1 months.
‡ Intervention minus control.
§ Travel expenses and salaries incurred by single session of education of nurses.
‖ Travel expenses and salaries incurred by brief information of nurses.
¶ Each participant in the intervention group received three hip protectors ($40.40 per hip protector), which resulted in costs of $121 per participant. Therefore, this cost figure is constant.
# Costs of initial information of residents about the hip protector and additional care due to hip protector use.
NA = not applicable.

one fall during the preceding 12 months. For 167 IG subjects and 207 CG subjects, the study was terminated because of death (91%) or moving ($P > .3$). Data from all participants were included in the analysis. Mean follow-up ± SD was 14.7 ± 5.7 months for the IG and 13.7 ± 6.1 months for the CG, a difference also not statistically significant.[5,6]

Clinical Outcome

There were 21 hip fractures in 21 intervention group residents and 42 hip fractures in 39 control group residents (absolute risk reduction 4.1%). Further study results are reported elsewhere.[5,6,12,13]

Costs and Cost Efficacy

Table 2 shows the costs per participant by category of cost and allocation as calculated in the base case analysis. Implementing and maintaining the intervention program yielded costs (mean ± SD (10th to 90th percentile)) of $268 ± $20 ($247 to $299) per IG participant, whereas optimization of usual care produced costs of $6.8 ± $1.7 ($3.9 to $8.4) per CG participant. Reduced costs of hip fracture–related healthcare demand counterbalanced the increased costs of the combined intervention in IG participants. Resource use after hip fracture yielded $366 ± $445 ($0 to $939) per participant in the IG, compared with $576 ± $571 ($0 to $1,389) per participant in the CG.

In total, the mean difference in costs between the study groups was $51 per participant in favor of the CG, with a 95% CI covering cost saving of $242 to cost expense of $325. ICER would be $1,234.

Sensitivity Analysis

A multiway sensitivity analysis was conducted to explore costs and ICER under realistic practice-setting conditions. Varying the costs of educational staff and education material and extending the time horizon of the expected increase of degree of disablement to 22 months produced a mean cost difference in favor of the CG of $18 (95% CI = – $334–351) per participant. ICER would be $439. Considering additional costs for nursing care related to hip protector use within a second sensitivity analysis produced a mean cost difference of $70 per participant in favor of the CG (95% CI = – $283–403). ICER would be $1,693.

Varying the absolute risk reduction by ± 10% did not substantially alter the results of the base case analysis (ICER $1,122 and $1,371, respectively).

Break-even analysis indicated hip protector reimbursement thresholds of $22 within the base case analysis and $34 and $16 within the first and second sensitivity analyses, respectively.

DISCUSSION

This analysis suggests that an intervention program comprising structured education of nurses, encouragement of residents to use the hip protector, and provision of free hip protectors might be only slightly more cost consuming than optimized usual care or might even be cost saving by decreasing the hip protector price.

When a treatment raises costs, there is no explicit agreement of the acceptable cost-effectiveness ratio. One study[14] suggested that $1,500 (converting to cited £1,000 at 2002 exchange rates) per hip fracture avoided would be conventionally accepted, because this amount easily falls within the implicit threshold for a quality-adjusted life year or life year gained considered by the National Institute for Clinical Excellence.[15] However, this estimate is based on expert opinion rather than on a scientific study of the quality-adjusted life years associated with hip fracture.

The present evaluation is based on prospective economic data collection alongside a methodologically rigorous trial.[5,6] The economic evaluation was a predefined outcome parameter of the study.

There have been previous efforts to evaluate the cost effects of hip protectors. One[16] used a Finnish study[17] as its main source of data. Because this trial has methodological limitations, the estimates of the economic evaluation may not be reliable. The Finnish study excluded 31% of participants who were assigned to wear the hip protector but who declined to participate after randomization. Individuals from a waiting list replaced participants who dropped out. In addition, statistical analyses did not adjust for cluster allocation.[17] Another study[18] derived effectiveness data for its economic evaluation from a meta-analysis that was outdated at the time of publication. Furthermore, an individual patient meta-analysis on cluster randomized, controlled trials was conducted, which resulted in unit of analysis bias.[19] The economic evaluations by other studies[20–22] are based on broad syntheses in modeling studies of trial and other evidence. The last study[22] also used effectiveness data from the Finnish study[17] for base case analysis.

Irrespective of methodological shortcomings, these economic evaluations consistently suggest that using hip protectors in institutional-dwelling older people might be cost saving. In contrast, a recently published economic analysis alongside a randomized, controlled trial could not demonstrate a reduction in costs through the use of hip protectors in institutionalized older people,[23] but this result was not surprising, because the intervention under investigation did not reduce hip fractures. The clinical trial was substantially underpowered, and hip protectors were distributed to cognitively impaired persons without systematic involvement of the caregivers. Consequently, adherence to the use of hip protectors was poor.

In comparison with former studies, the present trial investigated the effects of a combined intervention comprising education and free hip protectors. Optimized usual care was used as comparator instead of no intervention. The hip protector had been available in the control group, which represents current practice. Another study[24] did not include the costs of hip protectors for participants who did not adhere to wearing them. In contrast, in the present evaluation, a conservative estimate, including costs of hip protectors and related nursing care for all participants, was used irrespective of whether the hip protector was worn.

Because published data are inevitably specific to a context and will need some reinterpretation by decision-makers across countries and health systems, transparency in reporting can help decision-makers generalize results from one setting to another.[25] Therefore, quantities of resources are reported separately from the unit costs, and details of cost ascertainment are displayed.

The study has several limitations. Similar to some other economic evaluations of interventions to prevent hip fracture,[24,26] an intermediate outcome on costs per additional hip fracture avoided was used. Although some economic studies[16,20,21] considered quality of life, the present analysis did not include the quality-of-life effect of wearing hip protectors. In a pilot phase study, the measurement of health-related quality of life was unfeasible in this population of frequently cognitively impaired and frail elderly.[13] Because life expectancy did not significantly differ between the study groups,[5,6] calculation of costs per life years saved was not performed. Thus, the ICER presented in this study has limited comparability with other healthcare interventions.

The trial was powered not on costs but on the primary outcome measure, which was hip fracture. The 95% CI surrounding the cost difference is wide. It is well known that economic evaluations require larger sample sizes than clinical comparisons, because cost variables generally have higher variance than clinical outcomes.[27] The problem of sample size and statistical power relating to piggyback evaluations has not been resolved.[28]

There is some uncertainty concerning the determination of cost parameters, which may lead to some inaccuracy. Expense of hip protector–related nursing care was based on investigators' estimates. Therefore, it is particularly important to consider the results of the sensitivity analysis.

In conclusion, the program examined deserves consideration of implementation, not only for its medical benefits but also for its incremental costs per additional hip fracture avoided, which are likely to suit the amount that has been suggested as economically acceptable.[14] Cost savings of the intervention program could be achieved by lowering the reimbursement level for hip protectors.

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