Risk of hip fractures in soft protected, hard protected, and unprotected falls

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Inj. Prev. 2008;14;306-310
doi:10.1136/ip.2007.018275

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Accepted 2 May 2008

ABSTRACT

Objective: To compare hip fracture risk in soft and hard protected falls with the risk in unprotected falls and to compare the incidence of hip fractures in nursing homes providing soft and hard hip protectors.

Methods: An observational study conducted within the framework of a cluster randomized trial in 18 nursing homes. Nursing homes were randomized to offer either soft or hard hip protectors. Individual participants were followed for falls for 18 months.

Results: Of 1236 participating residents, 607 suffered 2926 falls; 590 of the 2926 falls were categorized as soft protected, 852 as hard protected, and 1388 as unprotected falls. Sixty-six verified hip fractures occurred: eight in soft protected falls, 11 in hard protected falls, and 45 in unprotected falls. The hip fracture risk in soft and hard protected falls was almost 60% lower than in unprotected falls (OR (soft) 0.36, 95% CI 0.17 to 0.77; OR (hard) 0.41, 95% CI 0.19 to 0.89). The incidence of hip fracture was 4.6 and 6.2 per 100 person-years in nursing homes providing soft and hard hip protectors, respectively ($p = 0.212$).

Conclusion: Both types of hip protector have the potential, when worn correctly, to reduce the risk of a hip fracture in falls by nearly 60%. Both can be recommended to nursing-home residents as a means of preventing hip fractures.

More than 90% of hip fractures in older people occur as a result of falls and are typically caused by direct impact to the greater trochanter.[1–3] The use of a hard-shelled hip protector during a fall has been shown to protect against the risk of a hip fracture.[4–7] Low rates of uptake and usage limit the effectiveness of offering hip protectors to a high-risk population to reduce the incidence of hip fractures.[8 9] Making hip protectors more comfortable and acceptable to users may facilitate prevention of hip fractures in a population, but it is a challenge to develop an acceptable and comfortable hip protector capable of high force attenuation. Designing hip protectors with soft protective shells rather than hard ones is one way to make hip protectors more acceptable and comfortable, but the efficacy related to protection in a clinical setting is not well documented.[10–13]

Studying the occurrence of hip fracture in protected and unprotected falls is one way to examine the hip protector's performance under realistic impact conditions.[14] The main objective of the present study was to compare hip fracture risk in soft and hard protected falls with the risk in unprotected falls. From a previous study,[5] we expected a reduction in hip fracture risk in hard protected falls compared with unprotected falls. From laboratory tests of the soft hip protectors used in this study[15] (and A C Laing and S N Robinowitch, poster at 5th World Congress of Biomechanics, 2006, Munich, Germany and personal communication from S N Robinowitch), we expected the soft hip protector to be equally or even more effective in reducing the risk of a hip fracture from a fall than the hard-shelled hip protector. We also sought to compare the incidence of hip fractures in nursing homes providing soft hip protectors with that in nursing homes providing hard hip protectors.

MATERIALS AND METHODS

This was an observational study with a prospective design conducted within the framework of a cluster randomized trial in 18 Norwegian nursing homes. The design of the study is presented in full elsewhere.[10] Clinical trials on the risk of hip fractures in protected and unprotected falls have to be observational, but the comparison of incidence is based on the cluster randomized design. The unit for the randomization was each nursing home, with each home randomized to receive either soft or hard hip protectors. The randomization was undertaken by two researcher not further involved in the study.[10]

Participants

Permanent residents in the 18 nursing homes were candidates for inclusion as either a hip protector user or a non-user. Hip protectors were available to all residents, but residents assessed by staff[16] to be at high risk of falling were especially encouraged to take up the offer. Hip protectors used in the study were SAFEHIP hard and SAFEHIP soft (Tytex, Ikast, Denmark). The study design allowed participants both to start and end hip protector use at any time during the intervention period. When a resident died or was transferred, the bed was replaced, and new residents were included continuously during the intervention period. Participants were registered with baseline characteristics and followed-up with fall registration.[10]

Outcomes

A fall was defined as "any event where the resident unintentionally and regardless of cause comes to rest on the floor".[17] When a fall occurred, a member of staff recorded the faller's name, the date, time, and location of the fall, and possible reasons and consequences, including injuries. In addition, hip protector use was recorded (ie, whether the faller had used the hip protector within the previous month, either daily or intermittently), the type of

Table 1 Baseline characteristics of users and non-users of hip protectors

Variable	Users (n = 569)	Non-users (n = 664)	p Value
Age	85.3 (7.7)	83.7 (9.19)	0.001*
Gender			
Male	23.5	31.8	0.001*
Female	76.5	68.2	
Weight			
Underweight	18.6	17.7	0.737
Normal weight	61.1	58.3	0.345
Overweight	20.3	23.9	0.146
Barthel ADL score (0–20)			
0–4	10.6	38.0	<0.001*
5–8	23.0	15.4	0.001*
9–11	21.8	9.9	<0.001*
12–20	44.6	36.7	0.006*
Transfer and mobility score of 3 or 4†: Yes	34.7	15.4	<0.001*
Memory 0–4‡	1.57 (1.26)	1.93 (1.40)	<0.001*
Communication 0–4‡	2.41 (1.33)	2.46 (1.41)	0.52
Vitamin D supplementation: Yes	14.7	12.1	0.190
Calcium supplementation: Yes	9.7	5.4	0.005*
Osteoporosis medication: Yes	6.0	3.0	0.012*
Fractures within the last 6 months: Yes	15.6	5.4	<0.001*
Use of walking aids: Yes	76.4	77.7	0.579
Falls within the last 3 months¶: Yes	49.8	15.1	<0.001*
Visual impairment§: Yes	22.6	21.0	0.448
Frequent toileting††: Yes	22.2	13.4	<0.001*
Agitated‡‡: Yes	34.5	18.3	<0.001*

Values are mean (SD) or %.
*Significant at p<0.05.
†A summarized transfer and mobility score in Barthel of 3 or 4.
‡0 = not able to, 1 = large problems, 2 = medium problems, 3 = some problems, 4 = no problems.
¶Has the resident had a fall within the last 3 months?
§Do you think the resident is visually impaired to the extent that everyday function is affected?
††Do you think the resident is in need of especially frequent toileting?
‡‡Do you think the resident is agitated?

hip protector (soft or hard), and whether the hip protector was worn and correctly positioned.

A soft-protected fall was defined as "a fall where a soft hip protector was worn and correctly placed". A hard-protected fall had a corresponding definition. An unprotected fall was defined either as "a fall without any hip protector" or as "a fall where the hip protector was worn but incorrectly placed".

Hip fractures were defined according to the International Classification of Diseases (ICD-10) as either a fracture of the neck of femur or a trochanteric fracture (S72.0 and S72.1). Subtrochanteric femur fractures (S72.2) were not defined as a hip fracture and not included in the analysis. Fractures were confirmed in the participant's medical records.

Sample size

Data from a previous hip protector study were used for sample size calculation.[5 18 19] These data showed that the inclusion of about 900 beds for an intervention period of 18 months would be sufficient to detect a 60% reduction in hip fracture risk between protected and unprotected falls assuming that the use of soft protectors and hard protectors was at the same level. Post hoc analysis of clustering effects revealed a low intracluster correlation (0.01)[20].

Statistical analysis

Statistical analyses were carried out in SPSS V14.0 and Stata V9.0. The difference in baseline characteristics between fallers in nursing homes that provided soft or hard hip protectors were analysed by independent sample t tests and χ^2 tests.

A multivariate binary logistic regression model was used to analyze hip fracture risk in soft and hard protected falls compared with the risk in unprotected falls. We adjusted for clustered observations within faller and nursing homes. All baseline characteristics were checked for potential confounding, and variables showing an independent effect on hip fracture risk in a fall were kept in the final model. The hip fracture risk is presented as an odds ratio (OR) with 95% CI.

For adjustment of the dependency of the falls within each faller, the option in Stata V9.0 "cluster" (id) was used. "Cluster" allows observations that are dependent within clusters. The identity of the faller was defined as the clustering variable (id). The observed falls were assumed to be independent above the level of the clustering variable, namely the level of nursing home. That is, the falls were assumed to be independent between nursing homes. The option "robust" was used to ensure robust estimates of the 95% CI of the OR. The options "cluster" and "robust" affect the estimated standard errors and variance–covariance matrix of the estimators, but not the estimated coefficients. For adjustment of the confounding of nursing homes, we used nursing-home indicators as covariates. The comparison of hip fracture incidence in the two groups of nursing homes was analyzed on an "intention-to-treat" basis.

The study was approved by the regional committee for ethics in medical research. All the participants received written or oral information about the study. Residents with adequate cognitive functions gave written informed consent. For cognitively impaired residents, a member of staff gave consent on their behalf, in accordance with recommendations from the regional committee for ethics in medical research.

RESULTS

During the intervention period, 1236 residents were enrolled in the study. Of these, 660 (54%) were registered in nursing homes provided with soft hip protectors, and 576 (47%) in nursing homes provided with hard hip protectors. During the intervention period, 440 residents died, and 13 moved to another municipality or back to their own home.

Mean (SD) total observation time was 361 (201) days in nursing homes provided with soft hip protectors and 365 (198) days in those provided with hard ones (p = 0.759). A total of 604 (49%) participants started to use a hip protector during the intervention period; 314 (48%) used soft hip protectors and 290 (50%) used hard ones. Table 1 presents the baseline characteristics of users and non-users.

Falls

During the follow-up period, 2926 falls were registered among 607 (49%) of the 1236 participants. Table 2 presents the baseline characteristics of fallers in the two groups of nursing homes. The two groups of fallers were quite similar other than transfer and mobility scores, visual impairment, and frequent toileting. These variables did not have an independent effect on hip fracture risk in our data.

Table 3 shows the characteristics of falls that occurred in the two groups of nursing homes. Ninety-six falls (42 and 54 in nursing homes providing soft and hard hip protectors, respectively) were not categorized because of missing information about hip protector use during the fall or missing information about the positioning of the hip protector. These

Table 2 Baseline characteristics of fallers (one or more falls) in nursing homes provided with soft and hard hip protectors

Variable	Soft hip protectors (n = 298)	Hard hip protectors (n = 309)	p Value
Age	85.9 (8.3)	85.1 (7.6)	0.239
Gender			
Male	26.5	31.7	0.159
Female	73.5	68.3	
Weight			
Underweight	15.5	17.3	0.626
Normal weight	63.0	59.6	0.439
Overweight	21.5	23.1	0.708
Barthel ADL score (0–20)			
0–4	9.6	11.6	0.511
5–8	20.9	22.3	0.753
9–11	18.8	21.3	0.511
12–20	50.7	44.9	0.183
Transfer and mobility score of 3 or 4†: Yes	27.9	35.9	0.037*
Memory 0–4‡	1.6 (1.3)	1.7 (1.3)	0.523
Communication 0–4‡	2.4 (1.3)	2.5 (1.3)	0.312
Vitamin D supplementation: Yes	13.2	14.4	0.669
Calcium supplementation: Yes	7.8	8.5	0.772
Osteoporosis medication: Yes	6.1	4.3	0.304
Fractures within last 6 months: Yes	11.4	15.4	0.159
Use of walking aids: Yes	72.6	74.5	0.602
Falls within last 3 months¶: Yes	43.8	50.2	0.124
Visual impairment§: Yes	17.4	28.1	0.002*
Frequent toileting††: Yes	17.5	24.0	0.049*
Agitated‡‡: Yes	35.5	36.5	0.801

Values are mean (SD) or %.
*Significant at $p<0.05$.
†A summarized transfer and mobility score in Barthel of 3 or 4.
‡0 = not able to, 1 = large problems, 2 = medium problems, 3 = some problems, 4 = no problems.
¶Has the resident had a fall within the last 3 months?
§Do you think the resident is visually impaired to the extent that everyday function is affected?
††Do you think the resident is in need of especially frequent toileting?
‡‡Do you think the resident is agitated?

falls were excluded from the analysis, but included in sensitivity analysis (table 4).

Injuries

Sixty-six verified hip fractures (30 in nursing homes providing soft hip protectors and 36 in nursing homes providing hard hip protectors) occurred in 61 participants (five experienced a second hip fracture). Eight of the 66 verified hip fractures occurred in soft-protected falls, 11 in hard-protected falls, and 45 in unprotected falls. Two of the 66 fractures occurred in falls not categorized and consequently not included in the main analysis for protected and unprotected falls, but included in the sensitivity analysis (table 4).

In addition, three hip fractures and one pelvic fracture occurred in four participants without any observed or reported fall. These fractures were not included in the analysis.

Risk of a hip fracture in falls

The hip fracture rate pr 100 falls was 2.4 and 2.1 in nursing homes providing soft and hard hip protectors, respectively. Related to falls that were categorized as soft, hard and unprotected, the hip fracture rates were 1.35, 1.29 and 3.24. Table 4 shows the OR of a hip fracture in soft and hard protected falls compared with the risk in unprotected falls, unadjusted and adjusted for the dependency within each faller, nursing home, and other potential confounders. Using a soft or a hard hip protector during a fall lowers the risk of a hip fracture by nearly 60% compared with the risk in unprotected falls.

Incidence of hip fractures in the two groups of nursing homes

The incidence rate of hip fractures occurring in falls was 4.6 and 6.2 per 100 person-years in nursing homes providing soft and hard hip protectors, respectively ($p = 0.212$). The rate ratio was 0.74 in favor of the soft hip protector (95% CI 0.46 to 1.19). Excluding those who never used a hip protector, the incidence rate among those using a soft or a hard hip protector was 6.8 and 9.6 per 100 person-years, respectively ($p = 0.209$), with a rate ratio of 0.71 (95% CI 0.42 to 1.21).

DISCUSSION

The study suggests that both types of hip protector have the potential, when worn correctly, to reduce the risk of a hip fracture in a fall by nearly 60%. The intention-to-treat analysis did not show any significant difference in hip fracture incidence between the two groups of nursing homes, which suggests that the two types of hip protector offer the same protection. Our result is consistent with previous published data for the hard-shelled hip protector[5] and with the laboratory data for the soft-shelled hip protector.[15] Nevertheless, we cannot draw strong conclusions about SafeHip's potential to reduce the incidence of hip fractures when delivered as an intervention in nursing homes.

A large number of unprotected falls occurred in both groups of nursing homes (table 3). This emphasizes the challenge of uptake and adherence with the use of both soft and hard shelled hip protectors.[10] It is difficult to identify residents prone to falling in a nursing home setting.[16] Even though hip protectors were available to all residents, residents assessed by "staff judgment" to be at high risk of falling were especially encouraged. A large number of unprotected falls may be explained by a low precision of "staff judgment" to predict fallers as well as difficulties with persuading people at high risk to take up the offer and stay adherent. We have previously shown that more than 20% of those refusing the offer were assessed to be in need of hip protectors.[10]

Kannus *et al*[7] and Cameron *et al*[4] showed a stronger preventive effect of the hip protector in their study groups than in the present study. The fact that all the participants in the present study were nursing-home residents may explain the smaller risk reduction. An alternative explanation may be that Kannus *et al* used a different type of hard hip protector, which, according to van Schoor *et al*[21] and Kannus *et al*,[22] has a force attenuation capacity superior to SAFEHIP hard. SAFEHIP soft was not tested in the studies referred to here. The type of hip protector used is not stated in the study of Cameron *et al*.[4]

Neither the soft nor the hard hip protectors used in the present study offered complete elimination of hip fracture risk. Some investigators have reported hip fractures from falls on the buttocks.[4 23] This may be why some hip fractures occurred even while hip protectors were being worn. A different explanation may be the hip protector's ability to reduce the force of impact to the proximal femur during a fall. This ability can be further improved, eg, by increasing the thickness of the protective shells. However, this may negatively affect compliance.

There is no indication that fall mechanisms differed in the two groups of nursing homes (table 3). The observed difference in the localization of the falls may influence hip fracture risk in

Table 3 Fall characteristics in nursing homes provided with soft hip protectors and in nursing homes provided with hard hip protectors

	Soft hip protectors (n = 660)	Hard hip protectors (n = 576)	Total	p Value
No of fallers	298/660 (45%)	309/576 (54%)	607	0.002*
Median no and range of falls/faller	2 (1–45)	3 (1–86)		
Total no of falls	1232/2926 (42%)	1694/2926 (58%)	2926	<0.001*
No of falls among regular users at the time of the fall (% of these falls where a hip protector was used)	764 (84.9†)	141 (82.1‡)	1855 (83.2)	0.129
No of protected falls	590/1190 (50%)	852/1640 (52%)	1442	0.311
No of unprotected falls¶	600/1190 (50%)	788/1640 (48%)	1388	0.311
Time of the fall (n = 2759§)				
7 am –10 pm	847 (74%)	1199 (75%)	2046	0.582
10 pm –7 am	304 (26%	409 (25%)	713	
Fall position (n = 2771††)				
From walking or standing position	690 (59%)	930 (58%)	1620	0.625
Falling out of bed or a chair	322 (28%)	433 (27%)	755	0.590
Other	156 (13%)	240 (15%)	396	0.151
Location of the fall (n = 2903‡‡)				
Private room	734 (60%)	818 (49%)	1552	<0.001*
Bathroom	127 (10%)	182 (11%)	309	0.421
Day rooms	322 (26%)	616 (37%)	938	<0.001*
Stairway	2 (0.2%)	2 (0.1%)	4	0.835
Outdoors	30 (2.5%)	53 (3.2%)	83	0.319
Other	7 (0.6%)	10 (0.6%)	17	<0.000*

*Significant.
†20 falls with missing information about hip protector use during the fall.
‡30 falls with missing information about hip protector use during the fall.
¶96 falls were not categorized.
§167 falls with missing information.
††155 falls with missing information.
‡‡23 falls with missing information.

a given fall, but the direction of the influence is uncertain. The construction of the building is another important determinant of hip fracture risk in any given fall. Unfortunately, there is no information about the construction of each nursing home, eg, the flooring material.[24]

Estimates of hip fracture risk in a fall are based on fall registration by the staff in each nursing home. The accuracy of the data about hip protector use depends on the accuracy of the staff reports on falls. This potential bias cannot be excluded.

The protective shells in the soft hip protector changed shape and were easily destroyed if the washing and drying instructions were not followed. The protective shells sometimes became thicker and smaller. These changes may have been overlooked. How these changes influenced the protective quality of the soft hip protector is uncertain.

The different baseline characteristics between fallers in the two groups of nursing homes shown in table 1 were not associated with a higher risk of hip fracture in a fall and consequently not assessed as confounders.

A strength of this study was the high number of participants, the high number of recorded falls, and the precision of fall ascertainment. This gave the study a high probability of finding a true effect on the risk of a hip fracture. Using each fall rather than the faller as a unit for the analysis may overstate significance. The fact that only five participants had fractures twice, and that we adjusted for the dependency of falls within each faller, and for relevant baseline characteristics justifies using falls as the unit for the analysis. Adjustment for the clusters of individuals and nursing homes did not influence the estimate markedly, which indicates that the cluster effect was small.

The study population is probably representative of residents in Norwegian nursing homes with respect to age and gender.[25 26] General conclusions must be drawn with caution, and no conclusions about risk reduction should be drawn outside a nursing home setting.

IMPLICATIONS FOR PREVENTION

Hip protectors may be very effective in groups at high risk of falls and fractures who both accept and actually wear the device. Both soft and hard hip protectors reduce the risk of a hip fracture by nearly 60% and can be recommended to

Table 4 Risk of hip fracture in soft and hard protected falls compared with the risk in unprotected falls

	Unadjusted			Adjusted*†		
Variable	OR	p Value	95% CI	OR	p Value	95% CI
Soft-protected falls‡	0.41	0.021	0.19 to 0.88	0.36	0.009	0.17 to 0.77
Hard-protected falls‡	0.39	0.006	0.20 to 0.76	0.41	0.022	0.19 to 0.89

*Adjusted for the dependency within each faller, nursing home, and other potential confounders having an independent influence on fracture risk in falls (gender, fracture within the last 6 months, fall within the last 3 months, weight and Barthel ADL index).
†Sensitivity analysis including falls not included in the main analysis did not influence the effect significantly.
‡Reference category: unprotected falls.

What is already known on this topic

- Hard-shelled hip protectors have been shown to reduce the occurrence of hip fractures when worn during a fall.
- Low rates of uptake and usage limit the effectiveness of offering hip protectors to a high-risk population to reduce the incidence of hip fractures.

What this study adds

- Both soft and hard hip protectors are capable of reducing the risk of a hip fracture by nearly 60% when used correctly during a fall.
- The result is consistent with the laboratory data for the soft hip protectors.
- Adherence seems to be a challenge for both types of hip protector.

nursing-home residents as a means of preventing a hip fracture. However, persuading more residents to both accept and wear the device is a challenge of great importance if the full protective benefit of hip protectors is to be realized.

Acknowledgements: We thank the residents and staff at the participating nursing homes. Special thanks go to the study coordinators for their support and help in collecting the data. Appreciation is also extended to the Norwegian Institute for Health and Rehabilitation for funding this study. Finally, sincere thanks are offered to Tytex and ALPHA Med for providing the hip protectors.

HB managed and directed the project and the data gathering, analyzed and interpreted the data, wrote the paper as a part of her PhD project, and acts as guarantor for the paper. AB is the sub-supervisor for the PhD project and participated in the planning of the data collection, contributed critically to the revising of the paper, and approved the final version to be published. LF is the head supervisor for the PhD project, made the application for the grant, contributed substantially to the analysis and interpretation of the data in close collaboration with HB, contributed critically to the revising of the paper, and approved the final version to be published.

Competing interests: None.

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