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Original Article

Hip Fracture Prevention Trial Using Hip Protectors in Japanese Nursing Homes

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Abstract. A method to protect the hips during falls could effectively reduce the incidence of hip fractures. We report the results of the first hip protector trial in Japan, performed between July 1996, and September 1999. One hundred and sixty-four elderly female residents of nursing homes, with Activities of Daily Living above the wheelchair level, agreed to participate in this study. Among them, 88 were randomly selected to wear a hip protector and 76 controls did not. All falls and resulting injuries were recorded daily. In anthropometric measurements and ultrasonic bone evaluation, no significant differences were found between the two groups, except in height. During an average of 377 days, the wearers and the non-wearers fell a total of 131 and 90 times, respectively. Among the wearers, there were two non-hip fractures and one hip fracture, so the annual hip fracture rate was calculated at 1.2%, against 8 hip fractures among the non-wearers, or 9.7% per year. The hip fracture rate was significantly lower among the wearers than non-wearers, while the annual number of falls per subject and the distribution of fallers remained the same. According to Cox's proportional hazard regression analysis, the effect of the hip protector on hip fracture prevention was independent of anthropometric data, ultrasonic bone assessment values or number of falls. Moreover, even after limiting the subjects to fallers only, the annual hip fracture rate in non-wearers was higher than in wearers (19.8% vs 2.0%) and the annual hip fracture rate per fall in wearers was lower than that in non-wearers (0.8% vs 8.2%). It was thus concluded that the hip protector is a beneficial device for the prevention of hip fractures.

Keywords: Elderly people; Fall; Hip fracture; Hip protector; Osteoporosis; Prevention

Introduction

Of the many public health problems due to osteoporosis, hip fracture is one of the most serious for the elderly, due not only to the resultant advanced disability and deteriorating quality of life, but also the higher morbidity, mortality and economic costs of hip fracture among this population [1–3].

The number of hip fracture patients has increased yearly throughout the world [1,2,4], although there is international variation in the incidence of hip fractures [5]. Hip fracture rates among persons of Japanese ancestry have been shown to be approximately half that among Caucasians [6]. In Japan, the number of hip fracture patients, which was estimated to be 54 000 in 1987, grew to approximately 92 400 in 1997 [7]; moreover, the age-adjusted incidence rates of hip fracture show a significant increase with increasing age for women [8]. Accordingly, fracture prevention is a major issue in Japan and the world, and of particular significance is the discovery of hip fracture prevention measures for the super-old, who are experiencing an exponential increase in hip fractures.

Although the main cause of hip fracture is obviously the reduction in bone mineral density and weakening of

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bone structure, there are other risk factors. Since it was reported that 90% of hip fracture result from falls [9], the reduction of risk factors for falling is also very important for prevention [10]. There are numerous limitations, however, inherent in identifying and eliminating a multiplicity of risk factors. After all, there is currently no definitive preventive solution for hip fractures of the fall-prone elderly with lower bone mass.

Therefore, reducing the impact on the hip region during falls is another important way of preventing fractures. One such idea is protecting the greater trochanter region with an energy-dispersing material. Lauritzen et al. [11] and Ekman et al. [12] in 1993 and in 1997, respectively, reported studies in nursing homes on the prevention of hip fractures through the use of a hip protector, showing a reduced risk for hip fractures. In the current study, we investigated the effect of the hip protector among Japanese elderly in nursing homes, with an analysis of registered falls, bone mass, and other risk factors relating to falls and fractures.

Subjects and Methods

Study Design

A prospective-randomized study was carried out in which the incidence of hip fractures in residents who wore the hip protector (wearers) was compared with that of residents who did not wear the hip protector (non-wearers) to determine the effectiveness of the hip protector for the prevention of hip fractures.

Subjects

Criteria for participants in this trial were that the subject be female with an activity of daily living better than wheelchair-mobile, have the ability to stand unaided, and consent to participate in the study. We performed the trial at six Japanese nursing homes between July 1996 and July 1999. First, the trial proceeded in one nursing home for 2 years from July 1996, and was subsequently performed in the other nursing homes for 1 year from March 1998. The trial duration was preplanned. There were a total of 520 residents in those nursing homes, of whom 322 were ineligible based on our criteria, and 34 were excluded for other reasons. Residents with dementia were included regardless of the degree of the dementia if their family gave consent for the trial. The remaining 164 female subjects who conformed to our criteria were included in the trial, and divided randomly into 88 hip protector wearers and 76 non-wearers (controls) (Fig. 1). Each nursing home had an equal percentage of wearer and non-wearer participants. The mean age of the participants was 83.2 (SD 7.1) years, mean body weight was 42.2 (SD 6.9) kg and mean height was 142.7 (SD 6.6) cm.

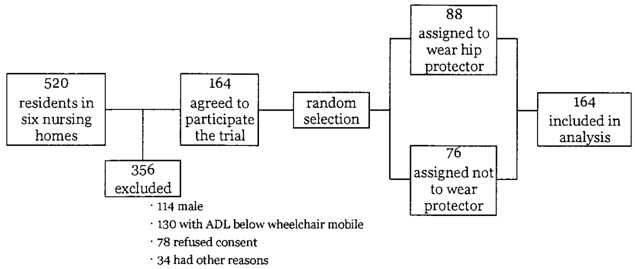

Fig. 1. Profile of the trial. ADL, activities of daily living.

Hip Protector

The hip protector used was a shell-shaped, polypropylene protector that is incorporated into the underwear and covers the trochanter region. Three sets of protectors per year were given to each subject with instructions to wear the protectors 24 h a day, as a rule. Subjects using diapers daily wore their hip protectors over the diapers.

Inspections, Records and Compliance

The care staff observed all participants daily, checked whether and how often they were wearing the hip protector, and recorded all falls and resulting injuries for both wearers and non-wearers. Daily wear status was graded as complete 24 h wear, incomplete wear or not wearing the protector at all. Days when an entry was made in the record were considered part of the observation period. The compliance rate for complete 24 h wear was obtained by the percentage of the complete 24 hour wear periods and the whole observation periods.

Anthropometric Measurement

Before the trial started, all participants were assessed for anthropometric status.

Body weight, height and body mass index were obtained. To examine the differences in muscle function, grip strength and thigh circumference were measured. For a comparison of the amount of soft tissue protecting bone from external forces, the triceps skinfold thickness and trochanter skinfold thickness were measured. Each value was measured three times on the right side. Thigh circumference was measured 10 cm above the upper edge of the patella. A Harpenden skin caliper was used to measure skinfold thickness, 1 cm above the mid-point between the shoulder and elbow for triceps skinfold thickness, and at the area protruding most in the lateral trochanter region for trochanter skinfold thickness. Grip strength values given are the maximum value; otherwise mean values were used for the analysis.

Ultrasonic Bone Assessment

To evaluate the differences in bone strength between the wearers and the non-wearers, we performed an ultrasonic bone evaluation of the right calcaneal bone, at the time of the anthropometric measurement**.** An AOS-100 ultrasound apparatus (Aloka, Japan) was used, which is a dry system measuring the heel through direct contact. We measured two parameters: the speed of sound (SOS, calculated by dividing the heel width by the transit time, expressed in m/s) and the osteosonic index (OSI, calculated using the formula $SOS^2 \times TI$, where TI, the transmission index, is the full width of half the maximum of the highest pulses received from the transmitted ultrasound waves). OSI may reflect the density of the bone [13]. Moreover, the *Z*-score for age- and sex-matched value of each parameter was also used, expressed in standard deviation. The coefficients of variance in vivo were 0.3% for SOS, and 1.6% for OSI [13].

Fractures and Falls

To evaluate the resulting fractures and falls, the annual rate of hip fractures and overall fractures, and the annual number of falls were compared in the two groups. In addition, the same items and the annual hip fracture rate per fall were also analyzed in fallers only. Each annual rate was calculated from each observation period. Subjects who sustained a hip fracture were excluded from the trial at the time of fracture occurrence.

Statistics

Demographic and baseline characteristics were summarized by two groups through various descriptive statistics. The Mann–Whitney *U*-test was employed to assess the data concerning anthropometric measurements, ultrasonic bone evaluation and the annual number of falls, one-way ANOVA for differences among nursing homes, and Fisher's exact probability test for the annual rate of hip fractures, overall fractures and falls. In order to assess the independent effect of the hip protector on the occurrence of hip fractures, Cox's proportional hazard regression analysis was conducted. Variables used in this analysis were: hip protector wear, age, anthropometric measurement data, ultrasound bone assessment values and the number of falls. All data were analyzed by Statview 5.0 software (SAS Institute, Cary, NC). The significance level was 0.05 (two-sided).

Ethical Issues

This study was undertaken with the approval of the National Chubu Hospital ethics committee.

Results

Study Period and Compliance

The mean whole study period was 377 (SD 250) days, and the range was from 1 to 791 days. The mean observation periods for the hip protector wearers and non-wearers were 360 (SD 255) days and 397 (SD 244) days, respectively. No difference was found between the two groups in the observation periods. Within 6 months, 23 (26%) of the wearers dropped out along with 8 (11%) of the non-wearers. Seventeen initial wearers refused to continue wearing the hip protector within 6 months, and others dropped out of the study due to hospitalization, death or transfer to another facility.

Table 1. Baseline characteristics in all participants with anthropometric measurements and ultrasonic bone assessment

	Wearers (n = 88)		Non-wearers (n = 76)		p value[a]
	Mean	SD	Mean	SD	
Anthropometric measurements					
Age (years)	83.2	7.1	83.1	7	0.763
Body weight (kg)	42.1	6.9	42.2	6.8	0.857
Height (cm)	141.6	6.5	144.3	6.3	0.005
Body mass index (kg/m^2)	21.1	3.4	20.6	3.3	0.468
Grip strength (kg)	8.5	5.6	8.9	5.4	0.680
Thigh circumference (cm)	34.4	4.7	33.7	4.3	0.563
Triceps skinfold thickness (mm)	10.1	4.5	10.1	4.5	0.878
Trochanter skinfold Thickness (mm)	8.6	3.8	8.2	4.2	0.548
Ultrasonic assessment of calcaneal bone					
SOS (m/s)	1497	16	1494	11	0.350
OSI ($\times 10^6$)	1.868	0.164	1.820	0.155	0.093
Z-score of SOS (SD)	−1.228	0.719	−1.340	0.489	0.358
Z-score of OSI (SD)	−0.580	0.637	−0.738	0.505	0.082

SOS, speed of sound (calculated by dividing the heel width by the transit time); OSI, osteosonic index (calculated by the formula $SOS^2 \times$ transmission index). Transmission index is the full width of half the maximum of the highest pulses received from the transitted ultrasound waves.
[a] p value after tied ranks correction in Mann–Whitney *U*-test.

The frequency with which the protector was worn during the trial was also good, with complete 24 h wear for 252 (SD 219) days, incomplete wear for 60 (SD 42) days and no wear for 48 (SD 101) days. Therefore, the compliance rates for complete and incomplete wear of the hip protector were 70% and 17%, respectively. No difference was found among the six nursing homes in the compliance rates.

Mean age was 83.2 years among the wearers and 83.1 years among the non-wearers; the difference was not significant (Table 1).

Anthropometric Measurement and Ultrasonic Bone Assessment

Anthropometric data and ultrasound bone evaluation parameters of the wearers and the non-wearers are shown in Table 1. Excluding the fact that height, which is an important and independent risk factor for hip fracture, was greater in non-wearers ($p = 0.005$ after tied ranks correction), no difference was noted between the groups in relation to muscle, subcutaneous fat, and ultrasonic assessment of calcaneal bone.

Falls

Falls occurring during the trial totaled 131 among the wearers, or 1.37 falls per subject per year. In contrast, there were 90 falls among the non-wearers, or 1.09 falls per subject per year. This was not a significant difference. There were a total of 44 fallers (50%) among the wearers, 23 of whom fell more than two times, and a total of 38 fallers (50%) among the non-wearers, including 23 who fell more than two times. The annual numbers of falls per subject among the fallers who were wearers and non-wearers were 2.98 (95% CI 1.80, 4.15) and 2.37 (95% CI 1.78, 2.95), respectively. We found no significant difference between the groups in the distribution of fallers, or the annual number of falls per subject (Table 2). In addition, there was no significant difference among six nursing homes in the number of falls per subject.

Hip Fractures

During the trial, there were a total of 11 fractures in both groups, all of which were caused by falls. In 131 falls, the wearers sustained 1 clavicle fracture, 1 shoulder dislocation-fracture and 1 hip fracture, resulting in an annual overall fracture rate of 3.5%, and an annual hip fracture rate of 1.2%. The one hip fracture occurred when a wearer was not wearing the hip protector. In 90 falls, non-wearers sustained 8 fractures, all of which were hip fractures, for an annual overall fracture rate of 9.7% and the same annual hip fracture rate. The annual hip fracture rate was significantly greater among the non-wearers than among the wearers (Fisher's exact $p = 0.0125$), although there were no differences with regard to the annual overall fracture rate between the two groups (Table 2).

Variables used to assess the effect on hip fractures in Cox's proportional hazard regression analysis are shown in Table 3. From the measured variables of the same kind and having a high correlation with each other, one variable, which was thought to be used more typically, was selected. We compared the subjects with hip fractures with those without them in terms of hip protector wear, age, body weight, height, grip strength from muscle function data, triceps skinfold thickness from soft tissue thickness data, *Z*-score of SOS from ultrasonic bone assessment values, and number of falls per subject. As a result, the number of falls was greater in subjects with hip fractures than in those without

Table 2. Falls and resulting fractures in all participants during the trial

	Wearers (n = 88)	Non-wearers (n = 76)	
Observation period (days)	360 (SD 255)[a]	397 (SD 244)[a]	NS[b]
Number of falls			
1	21	15	
2	7	12	
3	7	4	
4	4	2	
5–9	2	5	
10+	3	0	
Cumulative no. of falls	131	90	
Annual no. of falls per subject[c] (95% CI)	1.51 (0.84, 2.18)	1.09 (0.73, 1.45)	NS[b]
Number and rate of fractures			
No. of overall fractures	3	8	NS[b]
Annual overall fracture rate (%)[c]	3.5	9.7	NS[b]
No. of hip fractures	1	8	p=0.013[d]
Annual hip fracture rate (%)[c]	1.2	9.7	p=0.013[d]

[a] Mean and standard deviation.
[b] No significant differences by Mann–Whitney *U*-test or Fisher's exact probability test.
[c] Annual rate was calculated from the observation period.
[d] Fisher's exact *p*.

Table 3. Variables assessed for effect on hip fractures in all participants

		Subjects with hip fractures (n = 9)		Subjects without hip fractures (n = 155)		p value[a]
Hip protector wear:	Wearers (n = 88)	1 (11.1%)		87 (56.1%)		0.013[a]
	Non-wearers (n = 76)	8 (88.9%)		68 (43.9%)		
		Mean	SD	Mean	SD	
Age (years)		83.1	5.4	83.2	7.2	0.861[b]
Body weight (kg)		41.7	5.2	42.2	6.9	0.811[b]
Height (cm)		145.7	5.4	142.6	6.6	0.113[b]
Grip strength (kg)		9.2	5.4	8.6	5.6	0.733[b]
Triceps skinfold thickness (mm)		8.5	3.5	10.2	4.5	0.298[b]
Z-score of SOS (SD)		−1.346	0.409	−1.273	0.641	0.712[b]
Number of falls per subject		1.56	0.88	1.34	2.62	0.033[b]

SOS, speed of sound (calculated by dividing the heel width by the transit time).
[a] Fisher's exact p.
[b] p value after tied ranks correction in Mann–Whitney U-test.

Table 4. Hazard ratios of variables for hip fracture in all participants

	Hazard ratio (95% CI)	p value
Hip protector wear	0.082 (0.009, 0.746)	0.026
Age	1.012 (0.917, 1.116)	0.819
Body weight	0.991 (0.861, 1.142)	0.906
Height	1.038 (0.914, 1.180)	0.564
Grip strength	1.043 (0.901, 1.206)	0.574
Triceps skinfold thickness	0.856 (0.668, 1.096)	0.218
Z-score of SOS	1.106 (0.305, 4.003)	0.878
Number of falls per subject	1.053 (0.809, 1.372)	0.700

them, while no differences were found in anthropometric and ultrasonic bone assessment data (Table 3). According to the results of Cox's proportional hazard regression analysis shown in Table 4, the hip protector wear proved to have a significant independent effect on hip fracture prevention, indicating that wearers had 0.082 times lower risk of hip fracture during follow-up than non-wearers, after controlling for anthropometric data, ultrasonic bone assessment value or the number of falls.

Analysis in Fallers Only

Moreover, the results were the same even after comparison of the fallers only in both groups (Table 5). The hip fracture rate in the fallers among the non-wearers was noticeably higher than among the wearers (Fisher's exact $p = 0.010$), while no differences were found in terms of overall fractures. In addition, as a result of the analysis for hip fracture rate per fall in both groups, it was found that the annual hip fracture rate per fall in the wearers, which was 0.8%, was lower than that in the non-wearers, at 8.2% (Fisher's exact $p = 0.004$) (Table 5).

Table 5. Falls and resulting fractures in fallers only

	Wearers (n = 44)	Non-wearers (n = 38)	
Observation period (days)[a]	406 (SD 217)[b]	389 (SD 242)[b]	NS[a]
Annual number of falls per subject[c] (95% CI)	3.02 (1.62, 3.73)	2.18 (1.67, 2.77)	NS[a]
Annual hip fracture rate (%)[c]	2.0	19.8	p=0.010[d]
Annual hip fracture rate per fall (%)[c]	0.8	8.2	p=0.004[d]

[a] No significant differences by Mann–Whitney U-test or Fisher's exact probability test.
[b] Mean and standard deviation.
[c] Annual rate was calculated from the observation period.
[d] Fisher's exact p.

Discussion

This study was conducted in order to investigate the effectiveness of hip protectors in preventing hip fractures among the elderly in Japan. In order to obtain more accurate results, participants were randomly divided into two groups of hip protector wearers and non-wearers, and factors related to the risk of falling and fracture such as physique indices, muscle and bone strength were examined.

Although Tinetti et al. [14] reported a low 1% hip fracture rate due to falls among elderly people living in the community, it was also reported that individuals living in institutions were almost 4 times more likely to sustain a hip fracture than those living in private homes [15]. Therefore, we also conducted the present study in nursing homes to improve the efficiency of the trial, as has been done in previous studies [11,12].

Nursing homes in Japan are divided into two types according to the level of care provided. This trial was carried out in high-level care facilities.

Concerning the measurements we made among the participants, past investigations have found increased risk of hip fractures with lower body weight and body mass index [16–18]; conversely, patients with hip fracture were significantly taller than controls, although increased height was not associated with a change in fracture risk [19]. Triceps skinfold thickness has also been found to be related to subsequent hip fracture risk [16,20]. Diminished grip strength and quadriceps femoris muscle strength were noted to be closely correlated to an increased risk of falls [20–22]. Although quadriceps femoris muscle strength was not measured, thigh circumference, which reflects this value well, was measured. We measured skinfold thickness not only in the triceps region but also in the lateral trochanter region, which is commonly hit in hip fractures. Ultrasonic evaluation of calcaneal bone was substituted in the present study for evaluation of femoral bone strength, although bone mineral density measurement of the proximal femur is most accurate, since it has been reported that ultrasonic bone evaluation of the calcaneal bone can aptly discriminate hip fracture [23,24]. As a result, we thought that, except for height, wearers and non-wearers could be compared as identical groups with regard to indices of physique, muscle strength and bone strength. Moreover, we considered the two groups the same with regard to a fall situation from the fall rate and the distribution of fallers.

There was no difference in the rate of all fractures between the two groups. However, the rate of hip fracture was significantly lower in the hip protector wearing group; moreover, it was still lower among the wearers even after limiting the subjects to fallers. In addition, Cox's hazard regression analysis showed that wearing a hip protector had an independent effect on the occurrence of hip fractures, after controlling for anthropometric data, ultrasonic bone assessment data or number of falls. Thus, the hip protector was considered to have effectively prevented hip fracture due to falls among the nursing home residents in our study.

The first hip fracture prevention trial using hip protectors, by Wortberg in 1988, reported no hip fractures in 16 falls in a wearer group [25], and 4 cases of hip fracture in 7 falls in a non-wearer group. In 1993, Lauritzen et al. [11] conducted a large-scale, randomized hip protector study of 11 months duration for 665 male and female participants, and reported 8 hip fractures in the wearer group and 31 fractures in the non-wearer group. They calculated a relative risk of 0.44 for hip fracture in the wearer group, and found the hip protector to be effective for hip fracture prevention [11]. A later study by Ekman et al. [12] in 1997 involved 744 nursing home residents and lasted 11 months, and reported 4 cases of hip fracture in the wearer group and 17 cases of hip fracture in the non-wearer group. They determined a relative risk of 0.33 for hip fracture in the wearer group [12]. However, factors of physique and bone strength were not measured in these studies, so it is not known whether the compared groups had baseline differences for hip fracture risk. In the present study, this aspect was analyzed and effectively verified.

In our previous study using human femora, the hip fracture threshold for the elderly of an average 2100 N agreed with the finding of Lotz et al. [26,27], and this value is a far smaller force than the 5600 N estimated to be delivered to the trochanter in a fall [28]. These results clearly suggest that if an elderly person falls and strikes the trochanter side directly without breaking the fall with use of hands or the like, the rate of hip fracture will be high [29,30]. This led theoretically to the suggestion that not only bone mass maintenance and fall prevention but also force attenuation were important in preventing hip fracture in the elderly, who have markedly low bone mass and a high risk of falling [31].

Problems with protectors include compliance. In the study by Lauritzen et al. [11], the fall registration study indicated that only 24% of residents given hip protectors wore them regularly. In the study by Ekman et al. [12] compliance was 44%, and Parkkari's study had a compliance rate of 63% [32]. Compliance regarding hip protector wear was exceptionally high at 70% for complete 24 h wearing and 17% for incomplete wear in our study. This was a result of the good understanding and sufficient motivation by the institution staff, who were deeply concerned about the frequent fall injuries among residents in the past. Their firm belief in the importance of preventing hip fractures was a large factor in the high compliance in our trial, as mentioned by Parkkari [32]. Unexpectedly, once dementia residents acquired the habit of wearing the hip protector, they continued to wear it more habitually. Even in our study, which had a high compliance, a hip fracture occurred when the subject was not wearing the protector, and it is thought that the goal of improving the hip protector should be intensified to achieve continuous wear of the protector while maintaining biomechanical performance.

The present study has several limitations. Firstly, our sample size was small. However, it was deemed satisfactory for establishing the reliability of the hip fracture data, based on the calculation that at least 120 subjects would be required to detect a difference in the annual hip fracture rate (1.2% for the wearers and 9.7% for the non-wearers) at an alpha level of 0.05 and 80% power.

Secondly, we could not obtain sufficient information regarding fall severity, for example, the fall direction, which is an independent risk factor for hip fracture [18,33], height of the fall, floor conditions, breaking the fall with the arms, or the ultimate site of impact. Therefore, we did not examine the efficacy of the hip protector specifically in falls under the highest risk conditions for hip fracture.

Thirdly, since this study was conducted in nursing homes providing a high level of care, the results are not directly applicable to the elderly living in the community at large. It is thought that the independent elderly have little awareness of the necessity of wearing a hip protector, or perceive it as an added burden – attitudes which produce a high probability of low compliance. The sense of wearing and biomechanical efficacy of the protector tend to be reciprocal, and they are thought to be important for a device suited to the physical and psychological condition of the subject rather than offering a standardized produce balancing the two factors.

In conclusion, we have demonstrated the preventive effect of hip protectors for hip fracture in 164 elderly residents of high-level care nursing homes in Japan. Hip protector wearers had a lower hip fracture rate compared with non-wearers. Thus, hip protectors can be expected to play a significant role in preventing hip fractures in the frail elderly who are at high risk of falling and have low bone strength.

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