

High Efficacy for Hip Protectors in the Prevention of Hip Fractures Among Elderly People With Dementia

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Objective: To evaluate the efficacy of hip protectors (HP) in preventing hip fractures (HF) in patients with dementia.

Design: A case-control study.

Setting: Four specialized dementia units.

Participants: 206 physically independent patients with dementia.

Interventions: Beginning in January 2004, following the recommendation of the Israeli Ministry of Health, we recommended the use of HP (Hip Saver-nursing home type) to each family/guardian of all patients in these departments.

Measurements: The rate of falls and HF per falls in patients with and without HP.

Results: We achieved patient compliance of 70% to 80% for wearing the HP 24 hours a day; 106 patients were permanently wearing HP for a total period of 1905 months. Of those, subgroup B of 63 patients had been monitored prior to January 2004, before

HP were introduced. One hundred patients of the same departments have never used HP; together with the months of follow-up before January 2004 in subgroup B, the follow-up period in patients not wearing HP, reached a total of 3136 months. There was no statistical difference between patients with/without HP regarding age, gender, comorbidities, routine laboratory findings, and medications. The rate of falls was not significantly different in patients with and without HP. However, there was a significant difference in the rate of hip fractures (HF): in patients not wearing HP there were 323 falls resulting in 14 HF, and in patients wearing HP, 260 falls but only 2 HF (4.3% versus 0.8%, respectively, $P = .007$, chi-square test, 95% confidence interval 1.3–24.6, NNT = 28).

Conclusions: When appropriately introduced and used, hip protectors have high efficacy in preventing hip fractures in long-term care patients with dementia. The medical, social, and economic beneficial outcomes are substantial. (*J Am Med Dir Assoc* 2008; 9: 313–318)

Keywords: Hip protectors; falls; hip fractures; dementia specialized units

Hip protectors (HP) have been suggested to prevent hip fractures (HF) in elderly people. Parker et al¹ concluded that HP represent an ineffective intervention for elders living at home, whereas their effectiveness in preventing hip fractures (HF) in

an institutional setting is uncertain. We summarize 5 years of follow-up in independent patients in dementia specialized departments (DSD), and our experience with HP in this setting.

PATIENTS, MATERIALS, AND METHODS

The study was conducted in 4 DSD at the Shoham Geriatric Medical Center, Pardes-Hana, Israel. These departments contain at any time 90 to 115 patients with dementia who are all able to walk freely inside the ward.

Preplanning and Interdisciplinary Team Education

Since March 1, 2001, all DSD interdisciplinary team members have undergone a mandatory educational program promoting knowledge on osteoporosis; the severe outcomes of

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The authors have no conflicts of interest pertaining to this article.

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HF; and ways of improving physical, behavioral, and environmental means for preventing falls. A “fall” was defined as actually seeing a patient falling down, or finding a patient on the floor. Each fall in all DSD patients was immediately assessed by a registered nurse (RN) and a physician, all details of the event being recorded and signed by both on a special form. All fractures were reported in detail. The study protocol was approved by the local ethics committee and national health authorities. Throughout 2003, a pilot study was conducted comparing efficacy, compliance, and daily handling of different types of HP (data regarding falls and fractures of patients wearing HP during this pilot study are not included in the present study). Following this pilot study, HP have been approved and recommended for use in long-term care facilities nationally by the Israeli Ministry of Health. During the study (before and after January 2004), there were no changes in our policy regarding the use of bisphosphonates, vitamin D, and calcium supplements.

Hip Saver- Nursing Home Type—Characteristics and Handling

Since January 2004, only one type of HP was used in all our patients: the Nursing Home Type Hip Saver, a protector successfully used by other researchers.^{2,3} The Hip Saver contains a firm, elastic, mechanically protective layer worn over the trochanters, thus reducing the intensity of damage resulting from direct blows. It is worn over the underwear (and diaper) and is quite resistant to wear and tear in washing machines. HP of all patients are washed together, separate from the rest of DSD laundry. The optimal way of handling Hip Savers to decrease wear and tear includes washing at temperatures lower than 60°C, light squeezing, and drying at low temperature. For each patient, 2 sets of Hip Savers are personally adjusted after measurement, choosing 1 of 6 sizes. Each set is worn for 2 days while the other is cleaned in the DSD’s washing machine. Hip Savers were purchased by the center and offered to patients free of charge.

Introducing HP—Education, Follow-up, Responsibilities, and Supervision

Beginning in January 2004, all team members (physicians, nurses, certified nurse aids, physical and occupational therapists, social workers) have been obligatory reeducated using the above-mentioned program, concentrating on study objectives, potential adverse effects, and risks and benefits of HP with detailed information regarding their use; the program includes lectures by physicians and nurses, distribution of manufacturer’s material, and individual training regarding the optimal way of dressing patients with HP. Written forms of procedures and guidelines are available in each DSD. Attempts are being made to encourage and motivate teams in order to gain full support and commitment for preventing falls in general, achieving the best compliance for wearing HP, in particular. HP are worn 24 hours a day including while sleeping, and are checked and documented as part of the routine report in each shift. The head nurses have assumed overall responsibility for reducing the rate of falls and HF and achieving high compliance for wearing HP; the educational program

and training are implemented by the head nurses as part of the routine education given to new team members. Monitoring includes a detailed bimonthly head nurse’s report with names of patients wearing/not wearing HP, compliance, wear and tear of HP, and unexpected problems. These reports are evaluated by the project monitor (S.J.) who is responsible for supervision, including ordering and supplying new HP, as well as planned and unexpected visits to DSD during different shifts, to verify that HP are indeed present and adequately worn. The supervisor, physicians, and head nurses are available to answer families’ questions at any time.

Monitoring Patients’ Falls and Hip Fractures

The “fall” reports of all DSD patients who had been institutionalized between March 1, 2001, and September 30, 2006, were evaluated. Since January 2004, we have recommended the use of HP to each family/guardian of DSD patients (intention to treat in all patients present in or admitted after January 2004). We defined compliance as the percentage of DSD patients who were wearing HP permanently, 24 hours a day. The number of falls (independent variable) and HF (dependent variable) were identified in 3 subgroups of patients: Group A, patients admitted after January 1, 2004, who were regularly wearing HP; Group B, patients who had been admitted before HP introduction in January 2004, but were permanently wearing HP after that date; and Group C, patients who never used HP for any of the following reasons: institutionalization period before January 2004, the guardians refused to use HP (a few cases), and “poor compliance” defined as persistent refusal of patients to wear HP despite repeated persuasion attempts by the team for at least 1 week. These “poor compliance” patients may be defined as “intervention failures” and were indeed taken into consideration as such for compliance assessment. However, for efficacy assessments, we disregarded the negligible period of several days when unsuccessfully and inadequately wearing HP, and included data of these patients’ many months of follow-up without HP, as part of group C. Throughout all 5 years of follow-up, patients of all groups were treated at the same departments and mainly by the same interdisciplinary teams.

Exclusion Criteria

Exclusion criteria were based on the fact that the risk of falls in very frail elders and those with short life expectancy is much higher, and in nonambulatory, particularly bedridden, patients risk is significantly lower, than that of robust ambulatory patients with dementia. The following patients were excluded from the final data analysis: (1) patients with life expectancy of less than 6 months; (2) patients who were expected to become nonambulatory in less than 6 months; (3) patients who actually died or became nonambulatory within 6 months of follow-up; (4) patients in whom the use of HP was, for any reason, discontinued after less than 3 months (in groups A and B). Likewise, data of patients followed for less than 3 months in all groups (unless this was due to early HF), were not included in the final data analysis.

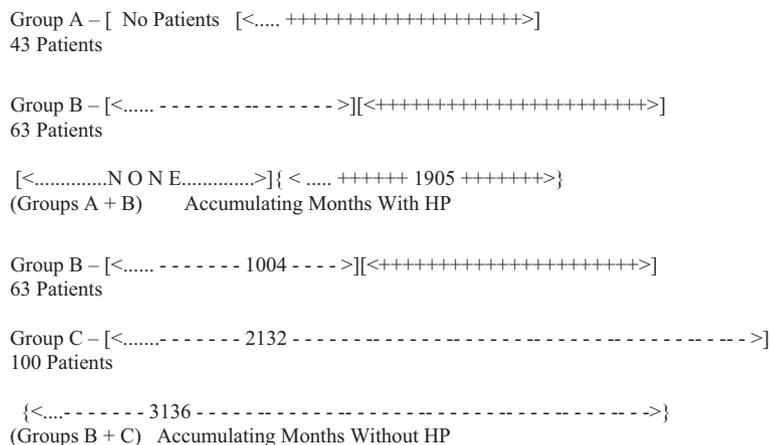


Fig. 1. Subject accrual from the different patient groups and time periods.

Statistical Assessment

Statistical analysis was performed using SPSS 11.5 software (SPSS Inc., Chicago, IL). Chi-square test was used to check the relationship between 2 dichotomous variables. Independent *t* test was used to check differences between the 2 groups for continuous variables (age). Mann-Whitney test was used to check the difference in the rate of falls between the groups.

RESULTS

There were 228 patients (152 women, 76 men) institutionalized at our DSD between March 1, 2001, and September 30, 2006. Of these, 149 (65%) had at least 1 fall during their stay, with no significant gender difference. At the beginning of 2004, compliance of the DSD patients to wear HP varied in different departments (range 56% to 80%). However, with time, the increase in teams' motivation resulted in increased patient compliance, reaching 70% to 80% in all DSD. Hip Savers were proven to be quite resistant to wear and tear. However, with regular use and cleaning in washing machines every 2 days, about 90% have to be replaced each year.

There were 22 individuals who were excluded, most of them because of exclusion criteria 1 and 2.

Only 206 patients fulfilled our rigorous inclusion criteria; 106 patients (43 of group A, 63 of group B) were wearing HP for an average period of 17.96 ± 11.28 months (a total period of 1905 months). One hundred patients (Group C) have actually never used HP, for a total period of 2132 months; together with the accumulating months without HP in group B (before January 2004), the follow-up period of patients without HP averaged 19.24 ± 15.06 months (a total

period of 3136 months). A diagram explaining subject accrual from the different patient groups and time periods is presented in Figure 1.

There was no significant difference in the fall rate between patients wearing/not wearing HP. The monthly fall rate in 106 patients while wearing HP (group A + group B after January 2004) was 0.218, SD = 0.566; the fall rate in 163 patients of group C + group B before January 2004 (while not wearing HP) was 0.168, SD = 0.306 ($P = .64$, Mann-Whitney test).

We compared demographic data and comorbidities between the 106 patients who wore HP during their hospitalization (groups A and B), to the 100 patients who never wore HP (group C). We referred to these 2 groups as independent samples, although 63 patients of group B, included among those who wore HP, had not been wearing HP before January 2004. All data were available for all patients. There was no significant difference between groups A and B and group C regarding age (82.8, SD = 9.6 versus 81.4, SD = 9.6, respectively), female/male ratio (71/35 versus 69/31, respectively) and the incidence of main comorbidities (previous stroke, Parkinson's disease, epilepsy, chronic atrial fibrillation, significant arrhythmia, ischemic heart disease and acute myocardial infarction [MI], congestive heart failure, hypertension, diabetes mellitus, chronic obstructive pulmonary disease, renal failure, hypothyroidism, blindness, deafness, schizophrenia, and previous hip fractures). The incidence of anemia (serum hemoglobin <10 g/dL), hypo albuminemia (serum albumin <3.0 g/dL), and B12 and folic acid deficiency in groups A and B were also comparable to group C. Similarly, no

Table 1. The Rate of Hip Fractures/Falls, With and Without Hip Protectors

Hip Protector	Hip Fractures		Total Falls
	No	Yes	
No			
Falls, no. (%)	309 (95.7)	14 (4.3)	323 (100%)
Yes			
Falls, no. (%)	258 (99.2)	2 (0.8)	260 (100%)
Total			
Falls, no. (%)	567 (97.3)	16 (2.7)	583 (100%)

significant difference was found between these groups in the incidence of incontinence, the need for assistance during activities of daily living, and the rate of main medications consumed (nitrates; blood pressure-lowering drugs; diuretics; and anti-Parkinsonian, antidepressive, and antipsychotic drugs).

Table 1 shows the rate of HF per falls. It includes only data of patients for whom falls were recorded. There was a significant decrease in the rate of HF in patients wearing HP; in those not wearing HP there were 323 falls resulting in 14 HF (4.3%), and in those wearing HP, 260 falls but only 2 HF (0.8%) ($P = .007$, chi-square test, relative risk [RR] = 5.63, 95% confidence interval 1.3–24.6). The use of HP resulted in a 5.63-fold reduction in the risk of HF (number needed to treat [NNT] = 28).

DISCUSSION

With the increased proportion of the older population surviving with disabling, noncurable diseases, there have been an increasing number of medical, economic, and social age-associated problems.⁴ Instability, osteoporosis, and falls are all age-associated disorders and together contribute to the rapid increase in HF in the elderly. About 1.3 million HF occurred worldwide in 1990⁵ and their total number is predicted to more than quadruple by 2050⁶; HF is the most common reason for admission of elderly people to acute orthopedic wards, and may result in death or permanent disability accounting for an estimated 0.1% of global burden of disease.⁵ This worldwide problem is even more pronounced in nursing homes and particularly in dementia-oriented units in which falls and HF have become leading preventive goals.

Comprehensive multidimensional programs in which all risk factors are addressed represent the best way for preventing HF; they include treatment of osteoporosis, increasing bone mass and muscle strength, and improving gait and balance. However, the effectiveness of all strategies to prevent falls and HF is far from perfect.^{3,7,8} Hip protectors (HP) represent a rational strategy for decreasing the risk of HF when falls do occur. HP consist of padding worn around the hips, specially designed to absorb and shunt energy away from the proximal femur, thus attenuating the force of falls sufficiently to prevent HF. However, several researchers have questioned both their efficacy and their chance of being appropriately used due to compliance problems. Our present research addresses these

2 questions; our results indicate that at least in dementia-oriented long-term care facilities, HP are both effective and of high achievable compliance if appropriately introduced.

In a Cochrane review using a meta-analysis, Parker et al¹ concluded that HP represent an ineffective intervention to prevent HF in the community, and that their effectiveness in institutional settings is uncertain; removal of the data of Kannus et al⁹ from the analysis resulted in a loss of the significant evidence of HP effectiveness, but if the data of O'Halloran et al¹⁰ showing ineffectiveness of HP were also removed, the significant effect of HP in reducing the incidence of HF remained. However, Meyer and Mühlhauser¹¹ point at several major methodological flaws in the large study of O'Halloran et al, and argue that suboptimal implementation of HP in some of the studies assessed by the meta-analysis of Parker et al¹ might have led to low adherence resulting in apparently "ineffectiveness" of the intervention.

Many researchers point at low compliance as a major obstacle in the effective use of HP.^{9,12–14} Meyer and Mühlhauser¹¹ insist that the effectiveness of HP depends on the adherence to wear the device as "they do not work unless they are worn at the time of the fall." It was estimated that the maximum potential preventive effect of HP in older women in the community and in nursing homes is 50%. However, the actual lower preventive effect depends on the acceptance of HP and adherence to wearing them.¹⁵ Obviously, achieving good compliance in the community, particularly in people without significant cognitive decline, depends mainly on the individual's will. To many lay persons, including elders, the risk of future fractures does not seem frightening enough to outweigh the daily inconvenience of permanently wearing HP; compliance is, therefore, unsatisfactory.¹⁶ In our view, because the efficacy of HP in community-dwelling elders has been critically questioned,¹ physicians and nurses are reluctant to recommend HP or persuade elders to wear them, as they do to promote other disease-preventive or health-preserving means.

This view is in line with that of Kannus and Parkkari¹⁷ who concluded that, as compliance represents the most frequent problem with HP, the role of caregiver motivation and involvement becomes crucial. One advantage of our study is that the intervention with HP was carefully planned and properly administered. Unlike some other studies, we investigated a relatively homogeneous population of elderly inpatients suffering from advanced dementia with high risk for falls and HF. Good monitoring and achieving high compliance is more feasible in this setting than it is in the community. Furthermore, all our DSD interdisciplinary team members were specifically educated on the severe outcomes of HF and the importance of preventing falls. When HP were introduced, all team members were repeatedly informed of their importance and how to actually dress the patients and achieve the best compliance possible. Some authors define "compliance" by dividing the number of days wearing HP (only during daytime), by the total number of days. Our definition is more rigorous. All our 106 patients with HP have been wearing HP 24 hours a day including nighttime and this was confirmed and recorded by the teams. We define compliance

as the number of patients permanently wearing HP divided by the total number of patients offered HP. In our patients with high risk for falls, intention to treat was in all patients. Failures to wear HP were mainly due to patients' persistent refusal, and rarely due to guardians' refusal or because of specific clinical problems (eg, huge femoral or inguinal hernia, severe skin disorder). The high compliance rate could be achieved mainly because of the high motivation and a sense of healthy competition between our different DSD teams. Our results prove the statement of Burl et al. who concluded that high HP compliance is both feasible and sustainable in a long-term care population.³

Our study could not be blinded for obvious reasons. The lack of randomization is a real drawback. We were impressed by the effectiveness of HP in our pilot study in 2003; it seemed unethical and even contradictory to the Israeli Ministry of Health recommendations to use HP in all DSD, not to offer HP to all new DSD patients after January 2004 (intention to treat in all patients since January 2004). Randomization was therefore not possible but this fact in itself is not necessarily causing a bias. Our accumulating "control months" data on falls and HF in patients without HP come from 2 sources: patients who had been hospitalized between March 2001 and January 2004; after this date, data of those in whom there was no permission from the guardian, or those with "poor compliance." One may argue that this kind of selection might have caused bias because patients defined as having "poor compliance" may differ in some characteristics from those with good compliance. However, a bias based on differences in demographic, clinical, functional, social, or financial characteristics seems unlikely. This statement is supported by the fact that the groups with/without HP were comparable regarding age, sex, comorbidities, and drugs. We have also decided to disregard the negligible period of a week or less when patients with "poor compliance" were unsuccessfully and inadequately wearing HP, and include their many months of follow-up without HP (before and/or after January 2004) as part of group C (without HP). Again, it seems unlikely that this decision could cause a significant bias.

There may be some potential problems with our control group, but in our belief most of them could not affect the results. Although we found no significant differences between measured parameters in those who wore HP versus controls, there might have been unmeasured differences in the group with poor compliance versus those with good compliance with HP; for example, specific clinical problems that interfered with HP use including those mentioned by us (huge hernia or severe skin disorders). Furthermore, some subjects of the control group were studied before 2004, raising the possibility that other aspects of our program besides HP, may have accounted for some of the reported differences. For example, although there were no changes during the course of the study in the use of vitamin D, calcium, bisphosphonates, or medications that could interfere with protective reflexes during a fall, we did mention the increase in motivation of our team members, eventually resulting in increased compliance during the study; with time, our team's efforts have

resulted in a decrease in the rate of falls in the control group after 2004 versus the period between 2001 and January 2004.

Group B patients contributed 60% of the months in the HP group and about 30% of the months in the control group. One may argue that if this group had greater longevity and length of stay on the DSD, they could have a different disease profile that was not balanced between the HP versus control groups. However, we think that none of the above-mentioned potential problems could significantly affect our main findings.

Our results indicate that at least in institutional settings, independent elderly people with dementia do benefit from HP. Wearing HP is not associated with a reduction in the rate of falls, but is effective in significantly reducing the risk of HF. Our results are comparable with other researchers who claim that if HP were worn at the time of a fall, the chance of HF is reduced by about 80%.^{2,18,19}

The economic burden to health services imposed by falls and HF in elders is steadily increasing globally. The annual rate of falls in DSD is about 1.5 per patient, 1% to 5% of them result in HF.^{3,13,20,21} Using an average figure of 3%, 4.5% of DSD patients are expected to have HF yearly. If HP were used in all DSD patients, assuming good compliance of 80% and risk reduction of 80% in HF (as achieved by our strictly regulated project), we may prevent 2.9 HF per 100 DSD patients yearly. In Israel, there are about 506 DSD patients per million population and the estimated cost of short-term treatment of one HF is \$18,000. As the educational programs including lectures, distribution of manufacturer's material, and individual training of all team members were performed during working hours as part of the routine patient care, there were not many direct costs to be taken into account to counterbalance the possible savings. If we subtract the average yearly cost of 2 HP per person (~ \$130) in 80% of all DSD patients, implementing the decision of the Israeli Ministry of Health to use HP in DSD nationwide would probably result in an annual net saving of \$211,000 per million population, only in DSD and for short-term treatment only.

Obviously, DSD patients represent just the tip of the iceberg; in Israel, elders represent 10% of the general population, an estimated 19% of them have dementia and 84% of those live in the community.²² Expanding our project to elders living in the community, with and without dementia, while adding the costs of long term care, the extent of HF prevention and cost reduction would increase significantly. This statement is in line with the work of Honkanen et al,²³ indicating that HP use saved costs and improved quality-adjusted-life-years (QALY) in community-dwelling elders. In response to of Honkanen et al, Drinka²⁴ stresses that data regarding efficacy of HP are conflicting mainly because of nonadherence. He warns of a bias that may result from the fact that patients wearing HP may have higher functional ability with fewer incontinent episodes and less resistance to care to allow staff to apply the HP. This was not the case in our study because most of our patients were incontinent with no significant difference in the rate of incontinence or in the level of functional ability between those wearing and not wearing HP.

Our results are in agreement with 2 recent research projects in elders in long-term care facilities. In a systematic review

and meta-analysis, Oliver et al²⁵ concluded that the use of HP in care homes prevents HF. Sawka et al,²⁶ using a Bayesian meta-analysis, found that HP decrease HF risk in elderly nursing home residents. On the other hand, in a well-designed study in nursing home residents, Kiel et al²⁷ were not able to detect protective effect of HP on the risk of HF, despite good adherence to the protocol; however, the incidence of HF in their nursing home residents (3.1%, with and without HP) was much higher than that achieved in our DSD patients.

It would be fair to conclude that data supporting a general policy of providing HP are still conflicting, particularly in community dwellers and nursing home residents. At least in long-term care institutional settings, the grave outcomes of HF outweigh the inconvenience of wearing HP and their relatively low cost, making HP cost effective both clinically and economically. This goal however, is difficult to achieve in dementia and nondementia community-dwelling elders because of significant problems of compliance. Patients and guardians should be informed of the pros and cons of wearing hip protectors in noninstitutionalized settings as well.

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