

REVIEW ARTICLE

Hip Protectors and their Role in Hip Fracture Prevention: A Review

Paul David Cowling*

ABSTRACT Hip fractures cause severe worldwide morbidity and loss of independence, costing national healthcare systems millions of pounds each year. The incidence is increasing with the expanding elderly population common of many Western countries. Hip protectors have been progressively studied in recent years focussing upon their use in hip fracture prevention, and compliance levels. This review aims to determine the effectiveness of protectors, and also investigates compliance levels. A search for English language Randomised Controlled Trials (RCTs) testing effectiveness of hip protectors was performed on Medline and Embase. Nine articles fulfilling the search criteria were found. Each was reviewed for hip protector effectiveness and compliance rates within the study, with results and conclusions critically-appraised. Of the nine articles, six (66.6%) found hip protectors to be effective in preventing hip fractures in selective populations. However, poor compliance rates were found in all reviewed trials. Future research should therefore focus upon improving compliance rates in the studied population.

KEYWORDS: Adherence, compliance, elderly, hip fracture prevention, hip pad, hip protector, protective devices.

INTRODUCTION

In 1992, an estimated 1.7 million hip fractures occurred globally (1). Hip fracture incidence increased exponentially with age in both sexes worldwide (2); the number of admissions from hip and femoral fractures in England in those aged 65 years and older is projected to increase from 40,944 in 2001 to 69,500 by 2021-2022 (3). Therefore, both cost and disease burden will continue to rise, making hip fracture prevention a priority.

Use of mechanical prevention of hip fractures has been progressively studied in recent years. The hip protector's role is to shunt impact energy away from the greater trochanter towards softer tissues anterior, posterior and inferior to the proximal femur, preventing fracture. (Fig. 1)

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The aims of this review are twofold: To determine if hip protectors reduce the risk of a hip fracture, and to determine patient compliance to wearing the hip protector. Other reviews on this topic have attempted to focus upon hip fracture prevention or compliance levels: This review assesses both outcomes.

METHODS

To identify papers for inclusion, a Medline and Embase search was performed, using databases from 1966 to 2004. A keyword search for 'hip protectors' found 99 articles on Medline, and 60 on Embase. From these, articles were included that met the following criteria:

- Randomised controlled trials (RCTs) of hip protectors measuring hip fracture prevention.
- An intervention of allocation to wearing of hip protectors, or to not wearing hip protectors (control group).
- English language articles

Figure 1. Hip protectors for women and men

RESULTS

This process identified eight articles. Another article fulfilling the criteria was identified using reference lists. Therefore, a total of nine articles were included in the review.

Table 1 summarises each article's methods and results. The column entitled 'Outcomes' describes the main variables the articles studied. Authors chose different methods of assessing effectiveness of hip protectors, as well as looking at other variables to consider their use in hip fracture prevention.

The column 'Results' shows each article's statistical results, and where possible, shows the significance of these results. Relative risk is a comparison between the intervention group (given hip protectors) and the control group. For example, Lauritzen et al. (4) found the relative risk of hip fractures among men and women in the intervention group to be 0.44. The control group is given a risk value of 1.0, so the intervention group's risk relative to this is 0.44 i.e. a decrease in risk of getting a hip fracture by 56% ((1.0-0.44) x 100).

Kannus P et al. (5) expressed results as the relative hazard of sustaining a hip fracture. To calculate this, Poisson analysis was used. The rates of hip fracture were then calculated as the number of fractures per 100 falls and expressed as the relative hazard.

This review discusses the specific aspects common to each reviewed article. Each section evaluated articles in chronological order of their publication date.

Effectiveness of hip protectors in prevention of hip fractures

From the nine trials, six (66%) found hip protectors to be effective in preventing hip fractures, with the remaining three finding protectors to be ineffective.

Lauritzen et al. (4) conducted the first large-scale trial of hip protectors, and was often used as a comparison in the other papers reviewed. This Danish study showed that hip protectors reduced risk of hip fracture by 53%, and 9 hip fractures were estimated to have been avoided in the intervention group during the 11-month follow-up period.

Ekman A et al. (6) conducted a study in Sweden, and found that four hip fractures occurred in the intervention group (number of residents=302) compared to 17 in the control group (n=442), with a relative risk in the intervention group of 0.33.

Kannus P et al. (5) conducted the largest study reviewed. They followed 1801 participants for 611 person-years (a mean of 0.94 years per each individual) in the intervention group, and 1458 person-years (mean 1.27 years per each individual) in the control group. The study continued until the end of the first full month after 62 hip fractures had occurred in the control group. Rates of hip fracture were 21.3 per 1000 person-yrs in intervention group compared to 46.0 per 1000 person-yrs in control group.

The strength of this study was its sample size. However, there was an enormous dropout rate, and though new subjects entered the trial, only 1148 participants finished the trail (1801 started), some having started partway through. Patients in the protector group were on average 1 year younger, of lower body weight, of lower body mass index, and more likely to have dementia or impaired mental status or a history of previous falls than controls. Therefore, though cluster randomisation occurred, large differences between study groups still occurred.

Chan D et al. (7) tested effectiveness of a locally-made hip protector, consisting of foam pads sown into the inner surfaces of tracksuit pants or trousers. Staff completed a form for each fall, which contained information such as injuries sustained, orientation of the fall and the time of day (as protectors were not worn in bed during this study). This information was deemed important to discover the effectiveness of the protector.

This Australian study found that six hip fractures occurred in the control group (n=31) compared to three in the hip protector group (n=40). The three fractures in the protector-wearing group occurred when the pads were not being worn. As so few subjects were used, and only nine fractures occurred in the 9-month follow-up period, this author believes the power of this study is low.

Harada A et al. (8) specified that though hip fracture rates among Japanese are approximately half that of Caucasians (9), the number of hip fracture patients in Japan grew from 54000 in 1987 to 92400 in 1997 (10). Therefore, hip fracture is a significant problem in Japan. This Japanese study found that only nine hip fractures occurred in the 377 day average follow-up time, with just one occurring in the intervention group (when the participant was not wearing their protectors). Fisher's exact test (p=0.0125) showed a significant difference in annual hip fracture rates between wearers and non-wearers.

Despite a small study sample, it was deemed satisfactory for establishing the reliability of hip fracture data, as calculations showed that at least 120 subjects would be required to detect a difference in annual hip fracture rate (at an alpha level of 0.05 and 80% power). Hip protector wearers had 0.082 times lower risk of hip fracture during follow-up than non-wearers, which this author considers a small decrease in risk for the cost of intervention to the residential home.

Cameron ID et al. (11) conducted sample size calculations, which indicated that 120 participants were required in each group to detect a fall in hip fracture incidence from 15% to 4% over 18 months. This would be possible if 75% adherence rates could be attained. However, due to limited funding this sample size was not achieved. Eight hip fractures occurred in the intervention group (n=86) compared to seven in the control group (n=88). Therefore, this paper concluded that hip protectors were not effective in reducing the incidence of hip fractures.

As the authors admitted, 'the major limitation of the study is that it had low statistical power to detect anything but a very large effect of hip protectors on risk of hip fracture'. A similar study with a larger sample size may show effectiveness of protectors, as this study was too small to form firm conclusions on the effectiveness of protectors.

Van Schoor et al. (12) (The Amsterdam Hip Protector Study) followed participants at high risk of hip fractures. Participants in both groups were also taught about the increased risk for hip fracture among institutionalised elderly and about causes and consequences of hip fractures. Preliminary power calculations found that 700 participants must be followed for 1 year to detect a clinically important reduction in hip fracture incidence from 4% in the control group compared to 1% in the intervention group. Only 561 participants enrolled, so authors extended the follow-up duration, producing a power to detect reduction of 89% (risk reduction of 75%).

The study found differences between the intervention and control groups with regard to time to first hip fracture in univariate analysis, but in multivariable analyses, no effect modification was found. The fracture rate per fall was also calculated: In the intervention group there were 18 hip fractures in 727 falls (fracture rate per fall = 2.5%) and in the control group 20 hip fractures in 1075 falls (fracture rate per fall = 1.9%). Therefore, hip protectors were not effective in preventing hip fractures in this study.

The authors concluded that results from this trial can be generalised to most institutionalised elderly persons and suggested the study's main strength was the number of participants (n=561). The fact that the study's inclusion criteria were specific supports this view, as the authors ensured study of a wide cross-section of elderly people.

Cameron ID et al. (13) concluded that 'hip protectors prevent hip fractures in community dwelling older women if worn at the time of a fall'. This Australian study calculated they required 500 participants per group, with a 5% annual hip fracture incidence in the control group, to ensure the study to have 80% power to detect a 50% reduction in hip fracture risk. However, recruitment ceased with a total sample size of 600 due to lack of funding, leading to the conclusion of limited statistical power.

A 23% non-significant reduction in hip fracture incidence was observed in the intervention group compared to the control group. Using an 'intention-to-treat analysis', no significant difference in hip fracture incidence was found between intervention and control groups. "Intention-to-treat' analysis preserves the baseline comparability between the intervention group and the control group achieved by randomization. It then reflects the performance of hip protectors by ignoring compliance when the data are analyzed.

This study relied upon self-reporting and hospital records to ascertain hip fracture rates, which could have led to inaccurate fracture records. Also, the authors concede the overall effectiveness of hip protectors was not established in this study, because of incomplete adherence, and limited statistical power.

Birks YF et al. (14) studied previous hip fracture sufferers, so participants were at known risk of falls and fractures. Approximately 10% of hip fractures are second fractures (15), and people who sustain one hip fracture are 5-7 times more likely to fracture their second hip compared with age-matched controls (16). Authors calculated 385 participants would be required for a hip fracture rate of 9% in the control group, and 2% in the intervention group. Though they fell short of this figure. Their results showed 6 hip fractures in the intervention group (n=182) compared to 2 in the control (n=184). This study therefore concluded there was no benefit to wearing protectors to prevent hip fractures.

Patient compliance with hip protectors

Table 2 shows compliance definitions and rates for each trial reviewed.

Lauritzen et al. (4) measured compliance as the percentage of residents given hip protectors who wore them regularly. No mention was made of what constituted regular wear, so it is not known how this was calculated. None of the eight participants in the

Table 2. Levels of compliance in RCTs testing effectiveness of hip protectors

Author	Definition of compliance	Compliance
Lauritzen JB (4)	The percentage of residents given hip protectors who wore them regularly.	24%
Ekman A (6)	-	44%
Kannus P (5)	Number of days protector worn as percent of all available follow-up days.	48%
Chan D (7)	The percentage of falls recorded for which the protector was worn in the study	50.3%
Harada A (8)	Percentage of the complete 24hr wear periods and the whole observational period.	70% & 17%*
Cameron ID (11)	Percentage of time for which hip protectors were worn during the day; night use was not considered	57%
Van Schoor (12)	Unannounced visits at 1, 6 &12 months participants were checked to se if he/she was wearing the protector.	37%
Cameron ID (13)	The amount of time that hip protectors were worn during the day.	57%
Birks Y (14)	Participants who only wore protectors occasionally were classed as non-compliant.	34%

-, No mention is made in this paper on the method of measuring compliance
*, Complete 24hr wear compliance rate was 70%, and incomplete wear was 17%.

intervention group who sustained a hip fracture wore the protector at the time of fracture, and authors calculated that protectors conferred 53% protection against hip fractures.

Ekman A et al. (6) gave a compliance rate of 44% without mentioning their method of measurement. No hip fractures occurred to protected hips. Authors concluded that with improved compliance, external hip protectors should be an effective prophylaxis against hip fractures.

Kannus P et al. (5) used a strange method of measuring compliance (see Table 2), giving a compliance rate of 48% (+/-29% range <1 to 100). Thirty-one percent of eligible subjects refused to wear protectors.

In the intervention group, nine participants had a hip fracture (among 370 falls) while not wearing the hip protector (relative hazard 0.2; 95% CI, 0.05-0.5; p=0.002). Results showed 13 participants in the protector group sustained a hip fracture, compared with 67 in the control group. Only 4 of these fractures occurred while the participant was wearing the protector. Therefore, the authors concluded that risk of hip fracture could be reduced in frail elderly adults by using hip protectors.

Chan D et al. (7) rated their study's compliance rate as 'low'. However, due to the methods used to assess compliance, the rate would be higher if nighttime falls were excluded. The low fracture rate coupled with poor compliance led to the study's low power. More specifically, in a staff survey, dementia was indicated as the reason for non-compliance. Of the 71 participants in this study, 64.8% were identified as having dementia.

The authors concluded that the data supported the value of pads to prevent hip fractures, as none occurred while pads were in place.

Harada A et al. (8) graded 'daily wear status' as complete 24hr wear, incomplete wear, or not wearing the protector at all. The frequency with which the protector was worn was rated as 'good' by authors, with complete 24hr wear for 252 (SD219) days, incomplete wear for 60 (SD 42) days, and no wear for 48 (SD 101) days. Therefore, compliance rates for complete and incomplete wear of the hip protector were 70% and 17% respectively. The authors concluded that their good compliance rates were attributable to good understanding and sufficient motivation by institutional staff.

This method of publishing compliance rates is confusing. Unlike other papers, compliance rates were not reported as a percentage of the participants wearing protectors for the 24hr period, but as the percentage of the complete 24hr period the protectors were worn.

Cameron ID et al (11) recorded adherence with protectors on four occasions throughout the study and rated it as 'satisfactory' for several months, with 70% of participants wearing the protectors for at least half a day. However, at 12 and 18-month follow-up assessments, the rate fell to 45-50%with a mean longitudinal adherence of 57% (SD 40%). Eight hip fractures occurred in the intervention group, all occurring as a result of fall, and none wore properly applied protectors at the time. Participants in the intervention group wore hip protectors for 54% of falls.

The authors surmise a possible reason for low adherence is the small number of residents in each hostel wearing protectors (2% of residents at each facility), leading to a dilution effect on staff commitment to the project.

Van Schoor et al (12) measured compliance at unannounced visits throughout the trial (after one month, compliance = 61%, after 6 months = 45%, after 12 months =37%). Authors rated overall compliance as 'moderate to good', yet only four of the eighteen participants from the intervention group who sustained hip fractures were wearing hip protectors at the time (22%).

In this study, newsletters emphasizing points such as importance of wearing protectors at night encouraged compliance. However, fewer than 16% were found to be using the protector at night. Four participants in the intervention group sustained hip fractures during the late evening/early morning, and one from falling out of bed. This was a sizeable proportion of the total number of hip fractures in the intervention group (n=18), so nighttime hip protection continues to be an important issue.

Cameron ID et al (13) measured compliance by self-reporting, which could be untruthful. The authors rated this study's compliance rate as 'satisfactory' for approximately one year, with 57% of participants reporting that they wore the protectors for at least half of every day. However, in the follow-up assessments at 18 and 24 months, this fell to 50% and 42% of surviving participants. The mean (SD) longitudinal adherence was 53%.

Hip protectors were worn in 51% of falls occurring in the intervention group. Three hip fractures occurred while participants were wearing protectors, though the cause of these fractures were a road traffic accident and two cases of falling backwards, for which the protector seemed an ineffective shield. Due to low compliance, the authors concluded that 'it is reasonable to provide hip protectors to those older women living in the community who are at high risk of hip fracture, and are strongly motivated to wear them'.

Birks YF et al (14) did not mention how compliance was defined, other than that a non-compliant participant 'only wore the protector occasionally'. A final compliance rate of 34% was calculated after stating that 60% of participants reported wearing protectors at least occasionally. Only 5 participants wore them during the night and day, and 35 in the daytime only, from a total of 182 participants.

As only eight fractures occurred in total (2.9% of participants rather than the 9% anticipated), the study's power was reduced. Authors described the compliance rate as 'low', when coupled with the low hip fracture rate did not produce significant conclusions. Consequently, the authors stated that larger RCTs among high-risk individuals are required.

Issues of comfort and supply of hip protectors

Major reasons for non-compliance with hip protectors were skin irritation and being bedridden (6). Common adverse effects also noticed include: leg swelling and bowel irritation (5), and infection due to wearing protectors (13).

Problems with supply also occurred, as shortages occurred when protectors were washed (12).

Chan D et al (7) found that one resident and one staff member noted concern about comfort of the protectors used. Fifty-seven percent of staff described appearance as a concern, yet no residents indicated that as an issue. Residents gave 'perceived lack of personal risk' as a reason for non-compliance.

DISCUSSION

From the 9 trials, 6 (66%) found hip protectors to be effective in preventing hip fractures with the remaining 3 finding protectors to be ineffective. This shows that hip protectors are of use in preventing hip fractures.

The three trials that found protectors to be ineffective (11, 12, 14) all had longer follow-up periods than the trials that found hip protectors to be effective in preventing hip fractures. These three trials (11, 12, 14) studied over periods of two years, 18 months, and 14 months respectively. Only one other trial (13) had a comparable follow-up period (2 years); all other trials followed participants for less than one year. This could indicate that hip protectors are effective for the first year of use, but after that, compliance falls thus decreasing their effectiveness. However, more trials are required with a longer follow-up period to fully assess this outcome.

The nine RCTs had varying sizes, ranging from 71 participants (7) to 1801 (5). Trials with fewer participants often lead to low power results, especially when coupled with a poor compliance rate. However, only one trial (7) of the three (7, 8, 11) with the lowest number of participants alluded to this having a bearing on their conclusions. The other two trials (7, 8) had calculated the minimum number of participants they felt was required, and deemed themselves to have fulfilled this criterion.

Inclusion criteria between these studies also varied. Some trials studied males and females (4, 5, 6, 7, 12, 14) while others only females (8, 11, 13). In industrialised countries, the lifetime risk of hip fracture is about 18% in women and 6% in men (17). Hip fracture prevalence increases from about 3/100 women aged 65-74 years to 12.6/100 women aged 85 and above

Table 1. RCT which examined the effectiveness of hip protectors

Author	Participants	Follow-up	Design	Outcomes	Results	Effective*
Lauritzen JB (4)	665M+F (30% M) >69yrs	11 months	Cluster RCT. Ten of the 28 wards of a nursing home were randomised to the intervention group. Nursing-home staff kept record of age, sex, type of impact & trauma.	Hip #, falls, compliance mortality	RR = 0.44 95% CI = 0.21-0.94)	EFFECTIVE
Ekman A (6)	744M+F living in 4 nursing homes (mean age 84yrs)	11 months	Cluster RCT. One nursing home from the four was selected & offered protectors.	Falls, hip #, compliance mortality	RR = 0.33 (CI = 0.11-1.00)	EFFECTIVE
Kannus P (5)	1801 M+F (21% M) =70yrs living in health-care centres (ambulatory, at least one identifiable risk factor for fracture)	All # until 1st month after 62 hip # in control	Cluster RCT. The subjects asked to wear protector whenever they were on their feet & especially when at high risk of falling e.g. slippery roads in the winter	Hip #, falls, compliance adverse effects	HR =0.4 (CI=0.2-0.8; p=0.008)	EFFECTIVE
Chan D (7)	71 M+F residents of 9 nursing homes at high risk	9 months	RCT. Locally made protector.	Hip #, falls, compliance	RR = 0.264 (95% CI = 0.073-0.959)	EFFECTIVE
Harada A (8)	164 F (mean age 83.2yrs) nursing home residents.	1 year	RCT. Care staff observed daily compliance & falls.	Falls, fall injury, bone density evaluation, compliance	Annual hip # rate in non-wearers was higher than in wearers (19.8% vs. 2.0%, p=0.0125	EFFECTIVE
Cameron ID (11)	174 F=75yrs (mean age 85.6yrs) in residential care, had 2 or 1 fall requiring admission in past 3 mths	2 yrs	RCT. A nurse supplied & fitted protectors, & encouraged adherence. Followed up at 2 weeks, then 2,10,18 months	Falls, injury hip #, incidence adherence	HR = 1.46 (95% CI 0.53-4.51)	NOT EFFECTIVE
Van Schoor NM (12)	561 M+F(11% M) =70yrs (mean age 84.8yrs) living apartment houses & nursing homes, with low bone density &/or high risk of falling	18 months	RCT. Participants in intervention & control groups were taught about increased risk for hip fracture among institutionalised elderly and about causes and consequences of hip fractures Every 3 months, Participants in intervention group were asked whether they were wearing protectors at the time of falling.	Time to 1st #, number of #, falls, compliance, adverse effects of protection mortality	HR=1.05, (CI=0.55-2.03)	NOT EFFECTIVE
Cameron ID (13)	600 F =74yrs (mean 83yrs) community residents who had 2 or 1 fall(s) requiring hospital admission in past yr	2 yrs	RCT. Three visits were made by adherence nurses, & 2 telephone contacts. Further visits if not adhering. Fractures self-reported & secondary check using hospital records.	Adherence, falls #, incidence, adverse effects of protectors, mortality.	RR = 0.23 (CI = 0.08-0.67)	EFFECTIVE
Birks Y (14)	366 M+F (12.6% M) community residents =70yrs (mean 80.1yrs) who sustained 1 hip # and 1 hip intact.	14 months	RCT. Intervention group received protectors & general advice in form of leaflet on how to reduce fracture risk. The control group just received leaflet on how to reduce fracture risk.	2nd hip #, other #, compliance adverse effects of protectors	OR = 3.10 (95% CI 0.62-15.58)	NOT EFFECTIVE

(18). Elderly women are the most susceptible cohort to hip fractures and therefore, this population should be of greater research focus.

The biggest problem with all studies was a low compliance rate. Compliance was generally found to be poor and this was a major reason for a study's results to fall short of its pre-trial power calculations. Two of the three RCTs that found hip protectors to be ineffective suggested the reason was the trial's low power due to poor compliance (11, 14). Another (13) study stated that a reason for the lack of effectiveness of the protectors could be due to compliance. However, the definition of compliance or adherence used in the studies was not uniform and so comparison between these studies was difficult.

Trials finding protectors to be effective also had problems with compliance. Despite various definitions, not one RCT showed a good compliance rate. Reasons for low compliance included discomfort, skin irritation, nighttime non-adherence, and protectors being washed. The number of fractures in intervention groups whilst not wearing protectors was very high. Many occurred in the evening/early morning, emphasizing the risks of non-compliance at nighttime. Improvement of compliance levels is a necessity if hip protectors are to be used alongside the proven use of other prophylactic measures such as Vitamin D and calcium (19), and bisphosphonates (20).

Future trials in this area should focus upon:

- Studying hip protectors' effectiveness for a period of at least twelve months
- Improving compliance levels
- Development of hip protectors than can be worn in bed/at night time
- Developing a standard method of measuring compliance, ensuring comparison between trials easier.

The search strategy and inclusion criteria attempted to ensure all relevant papers were reviewed. The limitations of this review are that a formal meta-analysis of data has not been performed. However, varying methods and compliance definitions make this difficult.

Other reviews on this topic attempted to focus upon hip fracture prevention or compliance levels (21). This review is assessing both outcomes, as well as considering very recently published papers not available to past reviewers.

CONCLUSION

Six of the nine articles studied found hip protectors to be effective at preventing hip fractures. However, the three articles that found their protectors to be ineffective also had the longest follow-up periods, which implicates the diminishing effectiveness of protectors after the first year of use. This could be due to the compliance rate decreasing as a study continued for a longer period of time. In spite of this, all trials reviewed found compliance was a prominent issue. The lower than expected participant numbers of many studies was also problematic, as it decreased the power of these studies.

However, from the evidence presented in this review, hip protectors continue to play a role preventing hip fractures.

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