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Hip protectors: recommendations for conducting clinical trials—an international consensus statement (part II)

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Abstract

Introduction—While hip protectors are effective in some clinical trials, many, including all in community settings, have been unable to demonstrate effectiveness. This is due partly to differences in the design and analysis. The aim of this report is to develop recommendations for subsequent clinical research.

Methods—In November of 2007, the International Hip Protector Research Group met to address barriers to the clinical effectiveness of hip protectors. This paper represents a consensus statement from the group on recommended methods for conducting future clinical trials of hip protectors.

Results and conclusions—Consensus recommendations include the following: the use of a hip protector that has undergone adequate biomechanical testing, the use of sham hip protectors, the conduct of clinical trials in populations with annual hip fracture incidence of at least 3%, a run-in period with demonstration of adequate adherence, surveillance of falls and adherence, and the inclusion of economic analyses. Larger and more costly clinical trials are required to definitively investigate effectiveness of hip protectors.

Keywords

Aged; Clinical trial; Hip fractures; Nursing home; Materials testing

Introduction

The worldwide incidence of hip fracture was estimated to be 1.26 million in 1990, with a projected increase to 2.32 million in 2008 and 3.64 million in 2020 [1]. Prevention of hip fracture is a high priority as the world population ages. Current strategies to prevent hip fracture include interventions aimed at preventing falls and prescription of calcium, vitamin D, and antiresorptive medications. Hip protectors have been studied as a method of reducing the risk of hip fracture due to a fall.

The Cochrane Collaboration Review about hip protectors has been progressively modified and draws cautious conclusions. “Accumulating evidence casts some doubt on the effectiveness of the provision of hip protectors in reducing the incidence of hip fracture in older people. Acceptance and adherence by users of the protectors remain poor due to discomfort and practicality” [2]. Economic projections suggest that hip protectors are likely

to be cost–effective [3–6]. However, these economic analyses were performed prior to the more recent and equivocal hip protector clinical trials [7–9]. Therefore, before public policy can be established concerning the use of hip protectors, additional clinical research is needed to determine their effectiveness in preventing hip fracture.

The International Hip Protector Research Group (IHPRG) was convened to develop recommendations for conducting future clinical trials of hip protectors and also to specify methods of testing hip protectors. This paper presents the results of discussions about the clinical trials. A companion paper has been prepared by the IHPRG to examine biomechanical aspects of hip protectors [10].

Materials and methods

The IHPRG was formed in 2007 to address perceived barriers to the clinical value of hip protectors. Funded by the Canadian Institutes for Health Research, the IHPRG consists of international experts in biomechanical engineering, epidemiology, orthopedics, and gerontology. The group met by regular teleconferences throughout 2007 and 2008, had a face-to-face meeting in Copenhagen in November of 2007, and participated in frequent email discussions. This paper is a consensus document from the IHPRG. A similar group met previously in Boston in 2004, and recommendations were published following that meeting [11]. The IHPRG has used the Consolidated Standards of Reporting Trials (CONSORT) statements [12, 13] as a structure for discussion and recommendations for future trials of hip protectors.

Results

Study design

The key issue on which there is considerable debate is the appropriateness of a clinical trial with randomization of participants in the context of hip protectors that have been commercially available and in routine use for over 15 years. It is noted that no randomized studies for use of crash helmets or car safety belts exist, although their use is accepted based on efficacy demonstrated in cohort or case control studies. While a number of researchers believe that randomizing patients to placebo hip protectors cannot be justified, this has not been argued in earnest in the peer-reviewed literature.

The majority of the members of the IHPRG agreed that randomized trials are required because of the conflicting published data regarding hip protector efficacy. It was accepted that randomized clinical trials would be required to better inform clinical decision making.

Key background issues to be resolved prior to undertaking future hip protector clinical trials are establishing (a) an international standard for evaluating the biomechanical efficacy of hip protectors to be used in clinical trials and (b) a robust research design to minimize bias and ensure adequate statistical power taking into account limited adherence with wearing hip protectors in most previous trials. These and other research design issues are discussed in the sections below.

Participants—eligibility and settings

Eligibility issues—To increase statistical power, the population selected should be at high risk of hip fracture and be likely to adhere to the use of hip protectors. We suggest that the annual incidence of hip fracture in the population studied should be at least 3%. Many nursing care facility populations fulfill these criteria. These would also be the populations most likely to benefit from hip protectors.

Patients with osteoporosis are at increased risk of hip fracture. However, the IHPRG's consensus was that the cost of screening for osteoporosis in an older population at high risk of hip fracture would not be justified [14]. Secondly, more patients without osteoporosis fracture their hips than those with osteoporosis [15]. Even though risk assessment tools are available that do not require bone density testing [16–18], the IHPRG consensus was not to use these tools for determining study inclusion. They might be useful for subgroup analyses.

Screening for fall risk would be another option to enriching the sample for subjects at increased risk of fractures. Postural instability and inability to rise from a chair without hands are significant risk factors for falls and fractures and simple screening assessments for falls risk in nursing care facilities are available [19, 20]. This approach has been recommended [14]. However, there was disagreement whether these screening tools are adequately sensitive and specific to be effective. Also, fall and fracture risk can change rapidly due to change in the environment (for example moving to a nursing care facility), administration of new medications, or the onset of new impairments and diseases.

Age is an easily measured and important risk factor and should be included as a determinant of eligibility. Another factor that can be readily ascertained is likely nonadherence because of behavioral factors, specifically those individuals who, because of dementia, are uncooperative and those who refuse to wear undergarments.

Two exclusion criteria should be considered when conducting trials of hip protectors. The first would be to exclude individuals who are not able to stand or who are confined to bed or a chair, because their risk of falling is low [21]. The second would be individuals with obesity and specifically a hip circumference that exceeds the garment size "extra extra extra large", since such individuals are at lower risk of hip fracture and difficult to fit with hip protector garments.

Hip protectors are optimally effective if the proximal femur is intact (that is without arthroplasty or internal fixation). However, a prior hip fracture with arthroplasty or internal fixation of one proximal femur increases the risk of fracture of the contralateral hip. Secondly, periprosthetic fractures around an arthroplasty may also occur with subsequent falls. Therefore, patients with hip arthroplasty should not be excluded.

The efficacy of hip protectors in the presence of arthroplasty or internal fixation is unknown, but adverse events in this situation have not been reported.

Setting issues—Participant-related factors should also be considered in the context of settings where hip protector research can be conducted. The substantial majority (11/14) of

randomized trials included in the Cochrane Review [2] were conducted in nursing care facilities. Thus, nursing homes and other geriatric long-stay facilities seem suitable settings for hip protector studies. None of the three randomized trials of hip protectors conducted in community settings have shown reduction in hip fractures. The relative risk ratio for these trials shown in the Cochrane Collaboration Review is 1.16 (confidence interval (CI) 0.85–1.59).

Community-based trials were randomized by individuals. Facility-based trials were randomized by facility or nursing unit or individual. Cluster randomization in facilities has multiple potential biases but on the other hand, use of facilities allows for a more comprehensive, efficient monitoring of adherence and falls.

High-risk populations can be defined and could be studied in a community-based setting, for example in people with Parkinson's disease. Thus, future community-based studies can be recommended if targeted to the appropriate high-risk population. This same reasoning applies to people who have recently transferred into a nursing care facility, as a high risk of hip fracture has been demonstrated in this situation [22].

To optimize personnel resources when conducting the research, access to sufficiently large populations at high risk of hip fracture should be considered. One of the issues that will be addressed below is the need to monitor adherence and falls. This can best be achieved in facilities in which professional staff is on duty 24 h a day. In the USA, this condition is met in skilled nursing facilities for older adults. In some countries, the incidence of hip fracture is the highest in intermediate care facilities, and this could be a setting for hip protector research if adequate adherence can be achieved, and falls can be accurately monitored.

In summary, we conclude that people who are not terminally ill or confined to a chair or bed, who are not currently using hip protectors, and who are living in a nursing care facility are the preferred participants in future hip protector studies. However, studies in other settings may also be acceptable provided high-risk groups are targeted.

Interventions

The hip protector selected should have been tested biomechanically and shown to achieve adequate force attenuation and should have met a relevant international testing standard (see our companion paper [10]). It should be emphasized that biomechanical testing should be performed on hip protectors after repeated industrial wash/dry cycles to ensure that biomechanical properties do not deteriorate. Hip protector garments should be shown to position the hip protector over the greater trochanter under normal wearing conditions across sexes and a range of body habitus. In addition, the underwear that is used to hold the hip protector shield or pad in place should have been tested for comfort and durability under industrial laundering conditions. Thus, we recommend that any hip protector selected for an adequately powered efficacy study be pilot tested for force attenuation, adherence, positioning, and durability.

The use of "sham" hip protectors was considered. To date, no clinical trial has used placebo hip protectors. Because of the possibility of co-interventions that could accompany hip

protector use (such as increased supervision, or environmental changes), it is recommended that sham hip protectors be used in future clinical trials in institutions. One option for a "sham" hip protector could be a hip protector that has shown only a marginal protective effect in biomechanical laboratory studies. Sham hip protectors should be nearly similar in weight and size to the "active" hip protector under study.

Participants would be told that they will have a 50% chance of wearing one of two hip protectors, one of which tested better than the other in the laboratory. While ethically appropriate to divulge this information, there exists the potential for this knowledge to compromise recruitment, motivation, and adherence of both the patient and nursing staff. Also, if the two pads were easily distinguishable, unblinding could occur. Yet there needs to a label on the garment to identify the two different pads being used in the trial, as well as the name of the participant who is using the pad. This is important for ensuring that participants are receiving the assigned pad and for staff to report which hip protector was worn in the event of a fracture.

Whether hip protectors should be permanently fixed to the undergarment was discussed. Permanent protector fixation has advantages (consistent positioning) and disadvantages (washing problems as some hip protectors are not designed to be laundered). The IHPRG agreed that the strategy to be used will depend on the type of hip protectors being used in the trial.

Ideally, hip protectors should be worn 24 h per day, although the occurrence of hip fractures peaks at times of increased activity [23] and in cold climates during the slippery winter months [24]. However, some risk is present at all times. If the design of the hip protectors is appropriate, users will be able to sleep with the hip protectors in place.

The IHPRG discussed whether soft shell (foam) protectors, which lack a rigid shell, may provide better comfort and adherence. No conclusion was reached and this is also addressed in the companion paper [10]. It was noted that a recent large cluster randomized trial did not demonstrate a clear increase in adherence using a soft shell hip protector [25].

There should be a run-in period with a median compliance of at least 67% required for the study to proceed in that individual or facility. This is applicable for efficacy studies. The optimal duration of the run-in period has not been determined but should be at least 2 weeks, and it should be done before randomization. A run-in period has been successfully used in one study [7]. This involved feedback about adherence to staff and withdrawal of facilities where adequate adherence was not achieved.

Randomization

Of the 13 published randomized trials of hip protectors in nursing care facilities, six have used individual randomization [26–31], seven have used cluster randomization [32–38], and one has used cluster intra-individual randomization [7].

The "active" and "sham" hip protector interventions can be provided using three types of designs. These are intra-individual randomization, individual randomization, and cluster randomization. Each method has advantages and disadvantages (Table 1).

The IHPRG supports intra-individual randomization with the use of a sham hip protector, as this is the strongest design (that is, on a random basis, the same person has an active protector on one hip and a sham protector on the other). If the sham protector is convincing, users and staff of the nursing care facilities are masked to the intervention and concern about the effects of co-interventions and participant confounders are substantially reduced. We do not recommend a comprehensive economic evaluation for this study design because we cannot compare health benefits within an individual. Therefore, we recommend a cost-analysis detailing healthcare resource utilization. It was suggested that in an ideal study design, a randomized comparison group without any protector would also be used to clarify whether the use of hip protectors affect the general risk of hip fracture in a given facility.

Ethical implications of placebo-controlled hip protector studies were considered. It was concluded that it is ethical to conduct placebo-controlled clinical trials of hip protectors because there is not clear evidence for the effectiveness of hip protectors in the clinical setting.

Objectives

The key objective of hip protector studies is to test the hypothesis that hip protectors reduce the incidence of hip fracture. Hip fractures should be defined as proximal femoral fractures and include subtrochanteric fractures. Periprosthetic fractures may also be included but femoral shaft fractures should not. Similarly, there is currently no evidence that hip protectors potentially reduce the incidence of pelvic fractures or any other fracture.

Outcomes

The primary outcome of hip protector studies should be hip fractures (as defined above), and all outcomes should be adjudicated without knowledge of group assignment. Secondary outcomes are adherence with hip protector use, falls (total and injurious), quality of life, adverse effects, and other fractures. Cost–effectiveness and cost–utility analyses should also be conducted. In addition, as hip protectors can only be expected to be effective if they come in contact with the landing surface during a fall, evidence of such impacts should be established. Since reliance on self-report or caregiver report is virtually impossible, it seems feasible that systems can be developed to capture these data. Possibilities are impact piezoelectrical strips or tapes, simple mechanical movement indicators, or pressure sensitive film.

A standard definition of adherence with hip protectors should be used, and it is suggested that the published definition “Adherence is the wearing of hip protectors in accordance with the recommendations of the study protocol, and is measured as the amount of time hip protectors are worn” [39] is used. This method requires unannounced checking by a research staff member to achieve optimal accuracy. Checking should occur during the day and night and should be undertaken at least twice a month during follow-up. It is also reasonable to assess adherence using the concept of “protected falls” which means whether the hip protector was worn at the time of a fall [39]. There are risks of reporting bias using this method. To reduce this bias, ideally, all falls should be reported on a 24-h “hot line” so that the observer can document the use of the pad and side of fall.

Falls should be measured as an outcome because it is possible that these could be increased if users feel more confident and hence expose themselves to greater risk. Conversely, a significant reduction of falls in people using hip protectors may be a marker of co-interventions in addition to hip protectors. While almost all hip fractures occur as a result of a fall [40, 41], it is important to record falls accurately because a few hip fractures will occur without a fall and because of the possibility that the rate of falls could change when hip protectors are used. A standard definition of a fall should be used [42]. The direction of the fall should also be reported if clearly apparent (sideways, forward, backward) because efficacy analysis will benefit from fall direction and because backward falls may also be associated with hip fracture. Logistically, this is difficult because most falls are not observed.

Registration of nonhip fractures and other fall-induced injuries in both groups is also relevant as differences in these variables may reflect a co-intervention effect. The hip protector in itself is not expected to influence the rate of nonhip fractures or other fall-induced injuries.

Economic evaluations of effective hip protector interventions should be conducted where protector effectiveness is characterized as number of hip fractures prevented or quality adjusted life years (QALYs) saved. The QALYs statistic is able to simultaneously capture the gains from reduced morbidity and mortality by assigning quality weights to health states that are based on preferences, anchored on perfect health and death, and measured on an interval scale. Health states that are more preferred (or desirable) are assigned higher preference weights and will be favored in the analysis. QALYs also provide a common metric to characterize effectiveness across different interventions and disease states.

A number of generic and disease specific instruments exist in the form of questionnaires that are an indirect method of estimating individual's preferences. The Euro-Qol5D (EQ5D) is a generic preference-based utility instrument developed by the EuroQol Group [43]. The EQ5D includes five attributes: mobility, self-care, usually activity, pain/discomfort, and anxiety/depression with each attribute having three possible options: (1) no problems, (2) some problems, and (3) major problems. In total, these options combine for a total possible 243 health states identified. The EQ5D has been tested and validated among specific populations. Measurement of health-related quality of life in people living in nursing care facilities who have significant cognitive impairment is methodologically challenging but is likely to be feasible using a simple measure such as the EQ5D. Among people with dementia, it is suggested that collection of individual's preferences is possible using this instrument [44].

Cost–effectiveness analyses conducted alongside clinical trials of hip protectors should be designed in tandem with clinical trials. A comprehensive list of healthcare resource utilization and cost items relevant to implementing the trial intervention in a real-world setting should be included.

The cost–effectiveness of use of hip protectors compared with usual care should also be assessed as the incremental cost per hip fracture prevented. For the cost items collected, the costs of the hip protectors and the probable increase in staff time for their use should be

documented including the need for extra garments because of losses in the laundering process or delivery back to users. Because older people have fewer years of life to live than other populations and these years are often lived with some reduction in quality of life, the cost–effectiveness of hip protectors could be considered in relation to hip fractures prevented.

While it is not expected that it will be feasible to detect changes in the mortality of hip protector users, it is important to accurately ascertain the date and cause of death. This is relevant for monitoring adverse events, assessing statistical power of the study and for cost–effectiveness analyses.

Adverse effects of hip protectors have been reported in most hip protector studies, and we recommend their measurement in future clinical trials. They include local problems (pressure ulceration and skin infections and irritations) as well as serious adverse effects, for example falling and fracturing the hip while donning hip protectors. Hip protector discomfort can influence adherence with hip protector use (e.g., in hot weather [2]).

Sample size

This is a complex topic that depends on the background risk of hip fracture in the population, the rate of attrition of participants due to death, loss of mobility, transfer to other facilities, adherence with the use of the hip protector, the effectiveness of the hip protector itself, the method of randomization (individual or cluster), and the method of analysis. Some current designs of hip protectors have been estimated to reduce the risk of hip fracture by approximately 80% if worn at the time of a fall [9, 33]. Other assumptions are shown in the footnote of Table 2.

Because of the two possible study designs (unmatched case-control designs and matched case-control designs), two estimates of sample sizes are shown in Table 2. In each case, the estimates assume an absolute risk as indicated with reductions in hip fracture percentage of 80% and 50%, a two-sided test at alpha=0.05, and power=80%. Using the unmatched design, the sample size for an 80% reduction in the control fracture percentage of 6% is 439 in each treatment group while it is 408 for a matched design, adjusted for 80% adherence, and for a combined 40% rate of deaths and dropouts. If the reduction is only 50% rather than 80%, the sample sizes per group would have to increase to 1,395 and 1,425, respectively. Table 2 shows that the required sample size is highly dependent on the incidence of hip fracture in the control group and the effect size if the protector is worn at the time of the fall.

Previous hip protector trials have chosen to “replace” participants who “drop out” due to death or immobility or for other reasons because of the high attrition rate expected in nursing facilities [7, 33]. This allows “person-months” of observation to be used. This is equivalent to continuing recruitment, and the additional participants are enrolled and randomized using the same procedures as initially enrolled participants. Replacement due to nonadherence is not acceptable, and ideally, replacement only due to death should occur.

Randomization sequence and blinding

The randomization sequence should be computer generated and managed centrally by a clinical trials center. There are multiple aspects of blinding to be considered. Real and sham protectors should neither be easily distinguishable by the researchers, caregivers, nor the participants. This has been discussed above.

Outcome assessment should be performed by masked observers. All study participants who sustain hip fractures should have their X-rays assessed centrally by an adjudication panel including a radiologist and clinicians blinded to hip protector use. All hip fractures, whether or not accompanied by death, should undergo adjudication.

In cluster randomized trials, the allocation of the cluster should be concealed until participants from that cluster have been recruited. Ideally, outcome assessors should be also masked to the allocation of the cluster but in practice, this is very difficult to achieve. These issues do not arise if the preferred intra-individual method of randomization is adopted.

Statistical methods

The method of analysis for the primary outcome (hip fracture) should be McNemar's test for binomial proportions for matched-pair data (intra-individual randomization). For this test, each hip should be classified as protected or unprotected and fractured or not.

The design that we have proposed is not clustered by nursing home, but the participation of multiple nursing homes may introduce factors that are not balanced at a facility or unit level, such as flooring or other physical features, or staff to resident ratio, or other factors. Adjustments for these factors should be made to McNemar's test. These issues are discussed in more detail in the recent methods paper from the Hip Impact Protection Program study [45].

Generalizability

The nursing care facilities participating in the clinical trial should be characterized carefully. The staffing and environment of the facilities as well as details of participant's demographics and comorbidities should be recorded. This will aid an assessment of generalizability of the trial results. It appears that there are substantial differences in staffing of facilities in different countries, and this may influence the feasibility of implementation and use of hip protectors.

The Cochrane Hip Protector Review authors have suggested that comparisons of hip protectors with alternative fracture prevention strategies should be encouraged [2]. While this can be considered, the study group concluded that it is necessary to establish the effectiveness of hip protectors before comparison with other strategies is attempted.

Registration and reporting methods

Future hip protector clinical trials must be registered, and the protocol should be publicly available. In addition, it is important that trial reports conform to the requirements of the recently published CONSORT statement for nonpharmacological treatment studies [46].

Complying with this version of CONSORT will mean that important elements of trial design are consistently reported. These elements include unit of randomization, sample size calculations with assumptions, unit of analysis, whether the sample size calculations and final analyses were subject to any adjustment because of cluster randomization, how missing data were handled, and a statement about intention-to-treat analyses.

Ethical and other issues

Many potential participants in future hip protector studies will be cognitively impaired and unable to provide informed consent. The investigators have enrolled participants with cognitive impairment in past studies following the provision of consent from a person legally entitled to give consent on the older person's behalf. This is generally a family member. This method should be used in future studies.

In keeping with good research reporting practice, sources of trial funding as well as any competing financial interests of investigators should be declared in any publications.

Conclusions

The proposed criteria for designing future hip protector clinical trials will provide further data about the efficacy, effectiveness, and cost-related factors of hip protectors in nursing care facilities and possibly in other very high risk groups. These recommendations will also be useful to funding bodies who are considering proposals. Key recommendations are shown in Table 3.

The major new development proposed for future clinical trials is the use of sham hip protectors with intra-individual randomization. The feasibility of this strategy should be assessed through a systematic review of currently available hip protectors to identify similar protectors (in terms of size, shape, mass, and ability to fit into the same underwear) with markedly different biomechanical performance as assessed by the methods suggested in the companion paper to this [10].

Feasibility work could also usefully be performed in evaluating screening methods to identify potential hip protector users whose absolute risk of hip fracture is more than 3% annually and to assess their likely adherence with hip protectors and ability to provide data for the health utility analyses. The ability to identify clinical populations at very high risk of hip fracture who do not live in nursing care facilities is also a priority for future hip protector research.

Further work should be undertaken to fine tune the statistical methods to be used in future trials. A computer simulation study could be performed to guide the statistical analysis of a proposed trial of hip protectors. The simulation could compare the properties (such as bias, precision, coverage, efficiency) of different methods of analysis based on different units of randomization and units of analysis. It is also important to find out how misspecification of the method of analysis (based on unit of randomization) could affect these properties.

Because adherence is such a key factor in all hip protector clinical trials, it may be necessary to wait for the development of hip protectors and hip protector underwear that are more

acceptable to hip protector users. A step along this path may be the trend to greater use of "soft" hip protectors observed by some of the IHPRG. A soft pad design seeks increased user compliance, but depending on design, this may be achieved at the cost of reduced force attenuation, efficacy, and safety [47].

Feasibility testing for the use of hip protectors during the night as well as the day and evening prior to the selection of the hip protectors to be used in the clinical trial may assist with maximizing adherence. Increasing the rigor of the design of future clinical trials of hip protectors will increase the cost of future trials. This development is essential due to the legitimate questions that are increasingly asked about the effectiveness of hip protectors in the research and day-to-day clinical contexts.

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Table 1

Advantages and disadvantages of three methods of randomization for future hip protector clinical trials

	Intra-individual randomization	Individual randomization	Cluster randomization
Advantages	Smaller sample size	Less complicated design, implementation, and analysis	Less chance of contamination among the control participants
	Masking to treatment if “sham” protector is convincing	Relatively smaller sample size	
	Every participant has the opportunity to receive the intervention		
Disadvantages	Each participant should have two intact hips (if sample size is large this problem if obviated)	Substantial risk of contamination/co-intervention	Greater risk of co-intervention[a]
	Difficult to keep real and sham pads on assigned side	50% of the participants will not benefit from intervention	Care needed with inclusion criteria and falls risk as participants may vary between clusters
	50% of the hips are not protected	Motivation and adherence adversely affected	More complex analysis
	Findings may not be fully generalizable as the device is not utilized in clinical practice		Relatively larger sample size

[a] Avoided if cluster randomization to side on which the hip protector is placed (see Kiel et al. 2007)

Table 2

Estimated sample sizes for future hip protector clinical trials, with varying annual incidence of hip fracture (based on the assumptions listed in the text—24-month study, adherence of 67%, using the definition of the hip protector being worn at the time of the fall, a 40% combined dropout and death rate. Calculations performed using nQuery Advisor software (Statistical Solutions, Saugus, MA, USA))

Hip fracture percentage during study (%)	Estimated sample size in each group by percent reduction and study design			
	80% Reduction		50% Reduction	
	Unmatched[a]	Matched[b]	Unmatched[a]	Matched[b]
2	1,352	1,444[c]	4,318	4,274
4	656	708[c]	2,125	2,134
6	439	408	1,395	1,425
8	324	306	1,030	1,069
10	257	244	843	855
12	210	203	663	711

[a] Assuming a chi-square (uncorrected) test of proportions

[b] Assuming a McNemar's test of paired proportions

[c] Fisher's exact test used when McNemar's test fails due to proportion <0.01

Table 3

Key recommendations of the international hip protector study group for future clinical trials of hip protectors

Further randomized trials should be conducted in nursing care facilities and possibly community settings for high risk groups
Participants in clinical trials of hip protectors should be at high risk (annual incidence >3%) of proximal femoral fracture—suggested indicators are history of bone fragility fracture, low weight, functional impairment, increased fall risk, and older age
Hip protectors used in clinical trials should have been assessed using agreed international testing methods
“Sham” hip protectors should be used with intra-individual randomization (i.e., on random basis the same person has an “active” protector on one hip and a “sham” protector on the other), and, in an ideal study design, a randomized comparison group without any protector should be used to clarify whether the use of hip protectors affects the general risk of hip fracture
A “run-in” period prior to the clinical trial should occur with adequate adherence to be demonstrated
Falls and, ideally, fall directionality should be monitored
Adherence should be monitored by research staff across day- and nighttime hours
Economic analyses should be included in future clinical trials of hip protectors