# critical appraisal \* éval uation critique

# Do hip pads help prevent hip fractures?

Christine Rivet, MD, CM, CCFP (EM), FCFP

Kannus P, Pakkari J, Niemi S, Pasanen M, Palvanen M, Jarvinen M, Vuori I. Prevention of hip fracture in elderly people with use of a hip **protector.** N Engl J Med **2000**;343:1506-13.

## **Research question**

Are external hip protectors effective at preventing hip fractures in frail elderly people?

# Type of article and design

Community-based, randomized controlled trial.

# Relevance to family physicians

Hip fractures cause substantial morbidity, disability, and death among elderly people. In the United States, 1-year mortality is 20%, and 25% of patients still require care a year after the fracture.<sup>1</sup> Family physicians attempt to prevent hip fractures in various ways (calcium and vitamin D, exercise, hormone replacement therapy, and drugs to prevent or treat osteoporosis) and to prevent falls by assessing and modifying the many factors that make patients susceptible to falls. But physicians have no great success at this.

Just as we wear helmets to protect our heads when cycling, it seems logical to protect hips from injury by reducing the impact on the greater trochanter during falls. This strategy has not been studied extensively until now.

# Overview of study and outcomes

The elderly adults in this study were from 22 communitybased health care centres in Finland. Each centre had treatment units that offered outpatient care or long-stay facilities for those at high risk of hip and other fractures. Men and women in the treatment units were eligible for the study if they were ambulatory, 70 years old or older, and had at least one risk factor for hip fracture: previous fall or fracture, impaired balance or mobility, inability to walk without aids, cognitive impairment, impaired vision,

poor nutrition, or diseases or medications known to predispose people to falls and fractures.

Each participating treatment unit was randomly assigned in a 1:2 ratio as a hip protector unit (HPU) (all subjects would receive protectors) or as a control unit (no subject would use a protector). The study lasted 18 months.

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A hip protector consists of two convex shields, 19.0 cm long, 9.0 cm wide, and 4.5 cm high, inserted into the pockets of a specially designed, stretchy undergarment. The shields fit over the greater trochanter and proximal femur. Subjects in HPU groups were asked to wear the protectors whenever they were standing.

Primary outcomes were fracture of the hip or of the proximal femur (all other fractures were also recorded). Secondary outcomes were number and rate of falls in the HPU group, number of days subjects wore the protectors, and whether protectors were being worn when subjects fell. Follow up was discontinued only because of death, inability to walk, hip fracture, or withdrawal of consent.

## Results

Of 1725 subjects eligible for the study, 204/650 in the HPU group and 94/1075 in control groups refused. At baseline, there were 446 subjects in the HPU group and 981 in the control group. Groups were similar: women made up 77% and 79%, average age was 81 and 82 years, 24% and 15% had had at least four falls in the preceding 12 months, 62% and 59% were residents of long-stay facilities, and 29% and 26% had had fractures since age 50 in the HPU and control groups, respectively.

Thirteen subjects in the HPU group had hip fractures compared with 67 in the control group. Respective rates of hip fracture per 1000 person-years were 21.3 and 46.0; relative risk (RR) of hip fracture in the HPU group was 0.4 (95% confidence interval [CI] 0.2 to 0.8; P = .008). Two subjects in the HPU group had pelvic fractures, compared with 12 in the control group. Rates were 3.3 and 8.2 per 1000 person-years, respectively; RR of pelvic fracture in the HPU group was 0.4 (95% CI 0.1 to 1.8;  $P \ge .05$ ). Hence, there was a significant difference between the groups in terms of hip fractures, but not in terms of pelvic fractures. Risk of other fractures was similar in the two groups.

> In the HPU group, protectors were worn on 48% ( $\pm 29\%$ ) of available days (range < 1 to 100 days). During follow up, there were 1404 falls in this group, 1034 (74%) of which occurred while protectors were being used. The most frequent adverse effect was skin irritation or abrasion (15 subjects).

Dr Rivet practises at the Family Medicine Centre in the Ottawa Hospital, Civic Campus, and teaches in the Department of Family Medicine at the University of Ottawa.

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Were subjects in the HPU group using their protectors at the time they fractured their hips? Four subjects were wearing hip protectors (0.39 fractures per 100 falls); nine were not (2.43 fractures per 100 falls). Relative risk of hip fracture while wearing a protector was 0.2 (95% CI 0.05 to 0.5; P = .002).

# Analysis of methodology

This well-designed, community-based study had a large enough sample size to show a 50% decrease (if it existed) in the rate of hip fractures with protectors. Relative risk reduction was actually 60%; absolute risk reduction was not given, but can be calculated as 2.5% from the information provided (4.6% fractures in the control group minus 2.1% fractures in the HPU group).

One limitation of the study is that randomization was at the level of the treatment unit and not the individual. Results might be affected by differences between units other than use or non-use of protectors.

Both groups had high drop-out rates: 219/446 and 438/981 in HPU and control groups, respectively. Most drop-outs were for the expected reasons of death, inability to walk, hip fracture, or withdrawal of consent. Built into the study design was the ability to replace subjects who dropped out with new eligible subjects from waiting lists within each treatment unit. This was appropriate, and all subjects who dropped out were included in the analysis for the period during which they participated.

Although the study looked at whether subjects in the HPU group wore the protectors at the time of fracture, the primary analysis was an intention-to-treat analysis. In other words, the analysis was based on randomization to HPU or control group, regardless of whether the HPU group used protectors or not. This reflects real-life conditions.

The study gives the number needed to treat (NNT): 41 people needed to wear protectors for 1 year to prevent one hip fracture (95% CI 25 to 115); eight people is the NNT for 5 years (95% CI 5 to 23). This compares favourably with other preventive maneuvers, such as treating patients with diastolic blood pressures of 90 to 109 mm Hg (128 people need to be treated with antihypertensive medications for 5.5 years to avoid one death, stroke, or myocardial infarction).<sup>2</sup> The low compliance rate  $(48 \pm 29\%)$  was also a limitation.

How easy is it for elderly people to pull the protectors on and off? The authors refer to a previous article about acceptability of the protectors among nursinghome residents,3 but do not give any further information about ease of use in this population.

## Application to clinical practice

This study shows a significant decrease in rate of hip fractures with use of hip protectors. For family physicians,

protectors offer an additional way of preventing hip fractures among patients who are not receiving maximum benefit from other preventive measures. The article does not mention the cost or availability of hip protectors: in response to an e-mail query, the authors gave a price of \$85 (US).

### **Bottom line**

- This large, well-designed, randomized controlled trial found a significant decrease in the rate of hip fractures when elderly adults at risk wore hip protectors. Rates were 21 per 1000 person-years in the HPU group and 46 per 1000 in the control group.
- There were many drop-outs in each group because of death, onset of inability to walk, hip fracture, or withdrawal of consent. Subjects who dropped out were replaced.
- Number needed to treat is 41 people for 1 year or eight people for 5 years to prevent one hip fracture.
- The real bottom line might be whether our elderly patients will wear protective padding that makes them 4 cm wider at each hip!

### **Points saillants**

- Cette étude aléatoire contrôlée de grande envergure et bien conçue a fait valoir un fléchissement significatif dans le taux de fractures de la hanche lorsque les personnes âgées à risque portaient un protecteur. Ces taux étaient de 21 par 1000 années-personnes dans le groupe portant un protecteur et de 46 par 1000 dans le groupe de contrôle.
- Plusieurs des sujets de l'étude s'en sont retirés dans chacun des groupes en raison du décès, de l'apparition d'une incapacité de marcher, d'une fracture de la hanche ou d'un retrait du consentement. On a remplacé par d'autres sujets ceux qui s'étaient retirés de l'étude.
- Le nombre requis à traiter est de 41 personnes pour un an ou huit personnes pendant cinq ans pour prévenir une fracture de la hanche.
- La question, en définitive, est de savoir si nos patients âgés porteront un rembourrage de protection qui les élargit de 4 cm par hanche!

## References

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