Osteosynthetic improvement of osteoporotic bone: prevention surgery

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Summary

A prior osteoporotic femoral neck fracture (FNF) doubles the risk of a second, contralateral hip fracture. Pharmacological prevention of osteoporotic fractures is cost-effective, but medication compliance and persistence rates are suboptimal. The aim of our study was to evaluate the safety and effectiveness of a device developed for the surgical prevention of an additional contralateral FNF in elderly osteoporotic patients. Only patients with a T score ≤ -2.5 were enrolled and randomized either to receive (Group A) or not receive (Group B) surgical prevention. Sixty-seven patients were enrolled. The mean follow-up was 16 months (range 1 to 22). To date, no contralateral FNF has been reported in either group. In Group A, no device-related complications were recorded. Twelve patients reported one or more falls and in four cases a non-thermal fracture occurred. Among the fractures occurring in an osteoporotic patient, those affecting the hip are the most serious. As a matter of fact, hip fractures (HF) are associated with a 20% increase in mortality in the year following fracture (2) and up to 40% of patients do not survive beyond 1 year after fracture (3, 4). Furthermore, a prior femoral fragility fracture doubles the risk for a second, contralateral HF (5). In the literature, there are only a few studies which assess the risk of a second HF occurring in the contralateral hip and the incidence ranges from 7 to 12% (6-15). The risk of a second fragility fracture occurring and, in particular, a HF, appears to be under-recognized and undertreated (16). Thus, strategies for secondary HF prevention should be adopted. Secondary HF prevention can be accomplished in three different ways: pharmacological prevention, non-pharmacological prevention and surgical prevention.

Pharmacological prevention of osteoporotic fractures is cost-effective in inhibiting the occurrence of future fractures (17-20). Unfortunately, compliance and persistence rates to medications are suboptimal (21).

Non-pharmacological strategies include nutrition (22), modification of environmental hazards, and the use of hip protectors. The latter act to either reinforce the strength of the bone and muscles or to prevent falls. A recent review by Gillespie WJ et al. (23) which examined whether external hip protectors reduce the incidence of HF in older people following a fall did not demonstrate a clear effectiveness; although the protectors may reduce the rate of HF if applied to frail older people in nursing care, poor compliance has also been documented.

Surgical prevention is a new preventative strategy, but no clinical studies have been documented as of yet. Finite analysis and pre-clinical studies (24-26) have demonstrated an effectiveness of the device. Secondary HF prevention can be accomplished in three different ways: pharmacological prevention, non-pharmacological prevention and surgical prevention.

The aim of our study is to evaluate the safety and effectiveness of a new device for the surgical prevention of a new fracture in the contralateral hip. This device is a titanium tubular screw with a coated hydroxyapatite thread. We named it the Prevention Nail System (PNS).

Materials and Methods

This prospective randomized clinical trial was approved by the local ethical review board and we obtained special permission from the Italian Ministry of Health to use this new medical device in clinical practice. All patients were admitted to our ward with a radiographic diagnosis of FNF. The inclusion criteria were: low-energy trauma or fall from a standing height, 65 years of age or older, a dual-energy X-ray absorptiometry (DXA) diagnosis of osteoporosis (T-score ≤ -2.5 SD), ability to understand the aim of our study and willingness to sign the informed consent form.

The exclusion criteria were: pathological fractures, trochanteric fractures, non-cooperative patients and a prior FNF. Before surgery, a DXA scan (Norland XR-36, CooperSurgical, Inc. 95 Corporate Drive Trumbull, CT 06611 USA) on the non-injured hip was performed and only patients with a T score ≤ -2.5 were enrolled.

Clinical Cases in Mineral and Bone Metabolism 2011; 8(1): 51-54

Key words:
Femoral neck fractures; osteoporosis; surgical prevention.

Introduction

Bone fragility leads to an increased susceptibility to fractures occurring after minor trauma, and is the clinical end point of this disease (1).
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The injured hip received the standard of care (SOC), which consisted of either bipolar hemiarthroplasty, total hip replacement or internal fixation with cannulated hip screws. The non-injured hip was randomized either to receive (Group A) or not receive (Group B) surgical reinforcement with the PNS.

The American Society of Anaesthesiologists (ASA) score, surgical time and length of hospital stay were recorded (Table 1).

Table 1 - Characteristics of the patients randomized in the two groups. In group A, patients received surgical reinforcement; In group B, patients did not receive surgical reinforcement.

<table>
<thead>
<tr>
<th>Age at surgery</th>
<th>Group A (PNS)</th>
<th>Group B (control)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>83.6 (97-68)</td>
<td>10 M; 24 F</td>
<td>83.2 (93-73) years old</td>
<td>ns p = 0.8</td>
</tr>
<tr>
<td>DXA T-Score</td>
<td>-3.21 (SD±0.68)</td>
<td>-3.47 (SD±0.72)</td>
<td>ns p = 0.62</td>
</tr>
<tr>
<td>Hospital Stay</td>
<td>11.6 ± 3.4 days</td>
<td>12.4 ± 4.7 days</td>
<td>ns p = 0.44</td>
</tr>
<tr>
<td>VAS</td>
<td>0.29</td>
<td>0.53</td>
<td>ns p = 0.66</td>
</tr>
<tr>
<td>ASA score</td>
<td>3 (Median)</td>
<td>3 (Median)</td>
<td>ns p = 0.87</td>
</tr>
<tr>
<td>Falls</td>
<td>8</td>
<td>4</td>
<td>ns p = 0.87</td>
</tr>
<tr>
<td>Second Hip Fracture</td>
<td>0</td>
<td>0</td>
<td>ns p = 0.87</td>
</tr>
<tr>
<td>Second Non Hip Fracture</td>
<td>1 wrist, 1 vertebral</td>
<td>2 vertebrae</td>
<td>ns p = 0.87</td>
</tr>
</tbody>
</table>

1 = One Way Anova; 2 = Pearson’s chi-square test

Results

Since September 2008, we have enrolled 67 patients in our trial (49 females and 18 males, mean age of 84, range 68 to 97). Fifteen patients with an osteopenic DXA T-score were excluded. Group A consisted of 34 patients: 15 have reached the 12 months FU, 15 have reached the three months FU, and 4 the one month FU. Five patients did not return for FU but they were contacted by phone.

The mean DXA T-score was -3.21 (SD±0.68); Group B consisted of 33 patients: 17 have reached the 12 months FU, 11 have reached the three months FU, and five the one month FU. Four patients in Group B died and were therefore excluded from our analysis; the mean T-score was -3.47 (SD±0.72).

The surgical time in Group A was longer by an average of 20 minutes (SD±5 min).

To date, the mean FU is 16 months (range 1 to 22); No contra-lateral FNF occurred in either group. In Group A, no device-related complications were recorded.

Twelve patients reported one or more falls and in four cases a new non-femoral fragility fracture occurred: two in Group A (one wrist and one vertebral) and two in Group B (2 vertebral fractures). The ASA scores recorded ranged from 1 to 4 and the median was 3 in both groups.

CT scans of the reinforced hips performed at 3 and 12 months FU were analyzed in axial, coronal, and sagittal planes and showed no radiolucencies or PNS loosening. X-rays were analyzed to check for atrophy or hypertrophy around the hydroxyapatite-coated thread. No differences were found at the various FU time-points (Fig. 1).
Clinically, in Group A, only one patient reported slight pain in the reinforced hip, with a score of 10mm on the Visual Analogue Scale (VAS) (range 0 to 100 mm). Comparing the HHS, in patients with the reinforced hips (Group A) or the intact hips (Group B), no statistical difference (p = 0.08) was found: (mean HHS: Group A = 76±13.8; Group B = 71±12.5). The average hospital stay was 11.6 days ± 3.4 in Group A and 12.4 ± 4.7 in Group B with no statistically significant difference (p = 0.1).

**Discussion**

Reducing a future fracture in frail elderly patients requires a sequence of interventions, including the identification of risk factors for falls, bone density measurements, and the initiation of pharmacological therapies for osteoporosis. Unfortunately, pharmacological and non-pharmacological strategies are very difficult to achieve. The main problem with pharmacological prevention is therapy adherence (27) and the long period needed for only a slight improvement in bone strength.

Surgical prevention is a possible solution to prevent a second contralateral hip fracture in elderly osteoporotic patients. In the present study, which is still ongoing, we analyzed a device developed for the secondary surgical prevention of hip fractures. The PNS was well tolerated by patients; only one patient in Group A had a VAS of 10/100 and was affected by osteoarthritis, which was radiographically evident on the X-rays performed on the reinforced hip.

The PNS is a safe device exhibiting good osteointegration. Osteointegration was radiographically confirmed, even at 3 months postoperatively. The surgical technique is simple and fast (only an additional 20 minutes of surgical time was needed for the procedure). The rehabilitation protocol was the same in the two groups, with total weight bearing on the non-fractured hip from the second day after surgery.

No further hospitalization was necessary for the PNS group. No contralateral FNFs occurred in either group. Nevertheless, only 31% of patients returned to their pre-injury walking ability. 69% percent of patients lost their self-sufficiency and were impaired in one or more of their daily activities. 10% of these patients completely lost their walking ability.

We believe that a longer FU and a larger cohort of patients is necessary in order to verify the real effectiveness of the PNS in preventing FNFs in elderly osteoporotic patients. In the future we aim to identify the patient population which could truly benefit from the surgical prevention of FNF, in order to focus on this specific, high risk group of patients. Considering the high mortality and morbidity rate of FNFs in elderly patients, we may surgically prevent hip fractures even before the first fracture has occurred.

<table>
<thead>
<tr>
<th>WALKING ABILITY</th>
<th>Group A % (PNS)</th>
<th>Group B % (control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without aids</td>
<td>25.7</td>
<td>21.1</td>
</tr>
<tr>
<td>One cane</td>
<td>14.3</td>
<td>15.8</td>
</tr>
<tr>
<td>One crutch</td>
<td>5.7</td>
<td>26.8</td>
</tr>
<tr>
<td>Two crutches</td>
<td>5.7</td>
<td>0</td>
</tr>
<tr>
<td>Walking frame</td>
<td>14.3</td>
<td>21.1</td>
</tr>
<tr>
<td>Walking with a Caregiver</td>
<td>20</td>
<td>15.8</td>
</tr>
<tr>
<td>Bed only</td>
<td>14.3</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 2 - Walking ability at the latest FU expressed as a percentage of the total number of patients in each group.

Clinical Cases in Mineral and Bone Metabolism 2011; 8(1): 51-54
References