ORIGINAL ARTICLE

Cemented and uncemented stems for displaced femoral neck fracture in the elderly. Retrospective study with a minimum 1-year follow-up

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Abstract. Background and aim: Displaced femoral neck fracture (FNF) is a common and significant health issue especially in older population because of the high rates of mortality and complications. The standard surgical treatment is total or partial hip replacement, including a cemented or uncemented stem. The cemented prosthesis is considered the safer option because of a lower rate of periprosthetic fractures (PPFs) as well as an actually reduced risk of bone cement implantation syndrome (BCIS). This retrospective study aims to assess the efficacy and safety of cemented versus uncemented femoral stem for FNF in patients ≥70 years. Methods: 139 patients affected by displaced FNF underwent hip replacement, receiving 89 cemented (64%) and 50 uncemented (36%) stems. Inclusion criteria were: ≥70 years of age, an ICD-9-CM diagnose code 820.00, 820.01, 820.02, 820.03, 820.10, 820.8, and a minimum 1-year follow-up. A p value <0.05 was considered statistically significant. Results: Surgical time, overall perioperative complication rate with a particular focus on the thromboembolic events, and PPFs incidence were evaluated comparing cemented and uncemented group. No difference in duration of surgery was found. Intraoperative complications were not detected. Pulmonary embolism and deep vein thrombosis were observed each in 1 case of cemented prosthesis. Periprosthetic femoral fractures occurred only in the uncemented group postoperatively, with a statistically significant difference (p<0.05). Conclusions: The low incidence of BCIS and the higher risk of postoperative PPFs in cemented and uncemented stems, respectively, suggest that the use of cementation is a safer procedure. (www.actabiomedica.it)

Key words: femoral neck fracture, hip prosthesis, cemented, uncemented, periprosthetic fracture, elderly

Introduction

Femoral neck fracture (FNF) is a common and significant health issue in patients over the age of 70 years because of the increasing incidence and the high rates of mortality and complications (1-3). Furthermore, severe loss of independence and impaired mobility may occur (4-6), with expensive economic consequences (7). As the world population ages, the incidence has increased from 1.66 million in 1990 to 2.6 million expected in 2025 and 6.2 million in

2050 (8-11). In Europe, 615,000 cases were observed in 2010, and an increase by 32% is expected within 2025 (about 815,000 cases) (12). Well-known risk factors should consider biomechanical and clinical aspects. The biomechanical factors include falls, which are responsible for 90% of FNFs, and are frequently associated with balance, neuromuscular and musculoskeletal disorders. Additional factors, such as muscle weakness and physical inactivity, are more age-related and show a strong correlation with poor bone mineral density, which is typical of the elderly. Chronic

health conditions, impaired cognition and vision, use of medications, alcohol and chemical substances and environmental factors are the most important clinical factors, as they increase the likelihood of falling don (13). Hip replacement is the standard treatment of displaced Garden 3 and 4 FNFs, but the optimal mode of fixation of the femoral component in this patient population remains controversial (14-17). Cemented stems are usually chosen in older subjects with low functional demands. However, frail patients with many comorbidities and cardiovascular and cardiopulmonary instability may suffer of the so-called bone cement implantation syndrome (BCIS), which can lead to thromboembolic events, arrhythmias, and finally to death (18). Press-fit anchorage of the prosthesis may be preferred in younger patients, with the aim to reduce BCIS, although a widely reported disadvantage is the higher risk of intra- or post-operative periprosthetic fractures (PPFs) (14).

Due to the high mortality and complication rates, up to 42% in some series (19), Langslet et al. (20) recommend the use of cemented stems in patients over 70 years. However, comparative studies showed no differences in mortality and complication rate, functional outcomes, and quality of life, although reduced blood loss and duration of surgery were observed for cementless stems (14,15). Anyway, only 30-40% of elderly with FNF undergoing hip replacement are likely to regain full autonomy. Postoperative recovery depends on previous cognitive impairments and comorbidities: 20% lose ability to walk without aid and 25% sustain a PPF (21).

The aim of this retrospective study is to compare the results of cemented *versus* uncemented femoral stem for the treatment of a displaced (Garden 3-4) FNF in patients ≥70 years with regard to the duration of surgery, thromboembolic complication rate, and incidence of PPFs.

Materials and Methods

Study population

This retrospective study includes patients who underwent total hip arthroplasty (THA) or

hemiarthroplasty (HA) between June 2012 and December 2015. All Garden 3 and 4 FNFs, which were assessed with digital X-ray images (anteroposterior and axial views) and identified with the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnose codes 820.00, 820.01, 820.02, 820.03, 820.10, and 820.8 employing the software OrmaWeb were considered. Patients aged 70 years and older were enrolled. Type of prosthesis and surgical technique were verified as well. Moreover, the intraoperative X-ray images were also checked through the PACS Carestream programme. A total of 291 patients who met the inclusion criteria were identified, but 35 were ruled out because of younger age. At a minimum 1-year after surgery, the remaining patients or relatives (in case of dementia or death) were asked to fill in the Barthel Index test, in order to evaluate the level of functional mobility, and the possible postoperative complications, with a particular focus on the need of additional operations, were investigated. The eventual time and causes of death were also registered. Patients who refused to give their informed consent to answer the questionnaire or who were not reached were excluded from the study. 160 of the 256 patients who fulfilled the inclusion criteria were contacted by phone, but only 139 allowed to use answers (Figure 1).

Due to the relatively small number of patients, THA or HA were collected and divided into two groups, cemented (n. 89, 64%) and uncemented (n. 50, 36%) (Table 1). The choice of the mode of fixation depended on the thickness of the cortical bone and on the personal preference of the surgeon. All femoral components had a modular neck. The cemented stem (Profemur® XM - MicroPort, Arlington, TN, USA) has a highly polished, forged cobalt chrome surface, which can reduce friction at the cement-implant interface, and rounded edges promoting radial compressive loading. Fixation was obtained using Cemex (Tecres, Sommacampagna, Italy) bone cement. The uncemented prosthesis (Profemur® E - MicroPort, Arlington, TN, USA) includes a wedge-shaped rectangular stem tapered in the anteroposterior and sagittal planes with proximal anterior and posterior ribs, and a rough titanium surface enabling osseointegration. All surgeries were performed through an anterolateral Watson-Jones approach, with the patient in a supine position

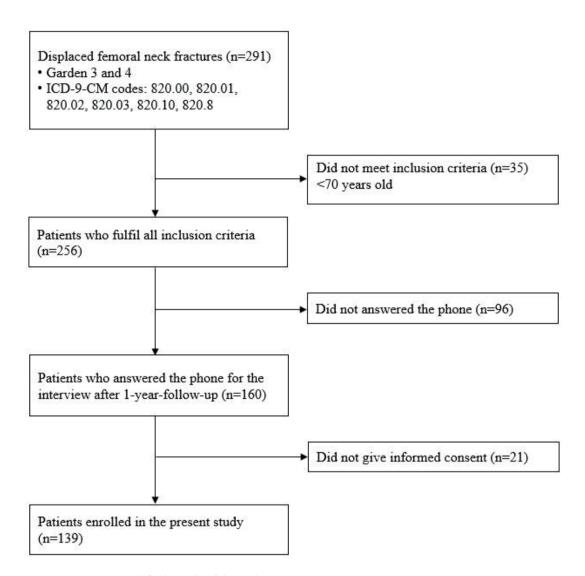


Figure 1 Recruitment process and final sample of the study

under spinal or general anaesthesia. Antibiotics and thromboprophylaxis were administered in all cases.

At the time of this investigation, the approval of the local Institutional Review Board was not required

Table 1 Characteristics of the final sample Cemented Uncemented Variable n=89 n=50Mean age at fracture ± SD 80.1 ± 7.3 84.3 ± 6.2 Male (%) 24 (58.5) 17 (41.5) Female (%) 65 (66.3) 33 (33.7) Hemiarthroplasty (%) 68 (76.4) 21 (42) Total hip arthroplasty (%) 21 (23.6) 29 (58)

for retrospective studies, nevertheless, informed verbal consent from individual patients was obtained.

Statistical analysis

The Fisher-test was employed to analyze the differences between the two stem fixation modes as regard postoperative complications and especially PPFs, while the duration of surgery was compared by means of the *t*-test. The IC 95% was calculated for each variable. The statistical analyses were performed using the R programme (R Core Team 2015). A *p* value of <0.05 was considered statistically significant.

Results

Duration of surgery

The implantation of cemented and uncemented prosthesis required an average of 92.7 and 88.4 minutes, respectively, but the difference was not statistically significant (Table 2).

Thromboembolic complications

No intraoperative complications occurred in both groups. The overall complication rate was 11.5%, with a higher, but not significant, incidence with the cementless stem. Pulmonary embolism and deep vein thrombosis

were observed both in 1 case using cemented prosthesis only, with no statistical significance (Table 2).

Periprosthetic fractures

PPFs never occurred intraoperatively, while 3 cases (6%) were observed between 7 and 18 months postoperatively only in the uncemented group. The difference had a p=0.04 (Table 2).

Discussion

Displaced FNF is a common and life-threatening injury in elderly patients (22). The incidence is constantly increasing as the world population ages, and

| Table 2 Main results of the study | | | | |
|------------------------------------|----------------|------------------|-----------------|---------|
| Outcome measure | Total n=139 | Cemented n=89 | Uncemented n=50 | p value |
| Duration of surgery (minutes) ± SD | 91.2 ± 27.3 | 92.7 ± 27.8 | 88.4 ± 26.6 | |
| Complications (%) | 16 (11.5) | 8 (9) | 8 (16) | |
| Pulmonary embolism | 1 (6.3) | 1 (12.5) | - | |
| Deep vein thrombosis | 1 (6.3) | 1 (12.5) | - | |
| Periprosthetic fractures (%) | 3 (2.1) | - | 3 (6) | 0.04 |

| Study | Total sample | Cemented | Uncemented | p value |
|-----------------------|--------------|-------------|------------|---------|
| Current study | 139 | 89 | 50 | |
| • | 91.2 | 92.7 | 88.4 | |
| Li et al. 2020 | 1587 | 798 | 789 | |
| | | 7.30 longer | | 0.01 |
| Veldman et al. 2017 | 950 | 473 | 477 | |
| | | 9.96 longer | | 0.001 |
| Khorami et al. 2016 | 51 | 22 | 29 | |
| | | 95 | 75 | 0.001 |
| Inngul et al. 2015 | 141 | 67 | 74 | |
| | | 82 | 80 | |
| Ng and Krishna 2014 | 207 | 96 | 111 | |
| | | 95 | 81 | 0.017 |
| Annappa et al. 2014 | 100 | 50 | 50 | |
| | | 94 | 81.8 | |
| Li et al. 2013 | 963 | 485 | 478 | |
| | | 7.43 longer | | 0.00001 |
| Yli-Kyyni et al. 2013 | 222 | 122 | 100 | |
| | | 72.6 | 60.1 | 0.005 |
| Parker et al. 2010 | 559 | 280 | 279 | |
| | | 7.24 longer | | 0.00001 |

it is estimated to reach 6,3 million of cases by 2050 (8-11). Hip replacement is the gold standard procedure for Garden 3 and 4 fractures (23), but the type of prosthesis, whether cemented or uncemented, is still controversial. In this investigation, the mean operating time was 91.2 minutes, and it was higher but not statistically different in the cemented stems. A similar outcome was reported in other studies (24,25). Conversely, the shorter duration of surgery in the cementless group was statistically significant in several series (15,16,26-29) (Table 3). A recent meta-analysis including 8 studies for a total of 1587 cases showed reduced operation time using uncemented stems (30).

The most frequent and feared perioperative complications of hip replacements are cardio-pulmonary events. The acrylic bone cement used for the fixation of the prosthesis is likely to be responsible for the so-called BCIS (18), which can occasionally be fatal. However, thanks to modern cementation techniques

and anesthesiological improvements the risk of this complication is actually estimated to be 0.1% (31). In a retrospective study conducted on 1402 patients, Hossain et al. (32) demonstrated a higher mortality rate using cemented implants (p<0.001). Therefore, patients affected by cardio-pulmonary diseases should be preferably treated with uncemented stems. In this series, an overall complication rate of 11.5% (16/139) occurred, most with use of press-fit prostheses (8/50, 16%). A similar, statistically significant outcome was previously reported (26,28-30), although Veldman et al. (27) reached opposite conclusions. We observed only 2 thromboembolic events, both in the cemented group, which occurred intraoperatively and in the first month after surgery. In a cohort of 35 patients, Chammout et al. (33) described 2 pulmonary embolisms during hospitalization and 1 between the 12- and 24-month follow-up. Moreover, 1 deep vein thrombosis was observed at the 3-month follow-up (Table 4).

| Table 4 General and thromboembolic com Study | Total sample | Cemented | Uncemented | p value |
|--|--------------|----------|------------|---------|
| Current study | 139 | 89 | 50 | p varue |
| 3 | | | | |
| Total complications rate | 16 (11.5) | 8 (9) | 8 (16) | |
| Pulmonary embolism | | 1 (12.5) | 0 | |
| Deep vein thrombosis | | 1 (12.5) | 0 | |
| Li et al. 2020 | 626 | 309 | 317 | |
| Pulmonary embolism | | 10 | 1 | 0.02 |
| Mao et al. 2020 | 268 | 132 | 136 | |
| Thrombotic events | | 2 | 0 | |
| Chammout et al. 2017 | 69 | 35 | 34 | |
| Thromboembolic complications | 4 | 4 | 0 | |
| Pulmonary embolism | | 3 | 0 | |
| Deep vein thrombosis | | 1 | 0 | |
| Veldman et al. 2017 | 616 | 311 | 305 | |
| Total complications rate | 175 | 74 | 101 | 0.01 |
| Cardiovascular complications ¹ | | 18 | 10 | |
| Khorami et al. 2016 | 51 | 22 | 29 | |
| Total complications rate | 14 | 5 | 9 | < 0.05 |
| Li et al. 2013 | 963 | 485 | 478 | |
| Cardio- and cerebrovascular complications ² | | 26 | 20 | |
| Yli-Kyyni et al. 2013 | 222 | 122 | 100 | |
| Pulmonary embolism | | 9 | 0 | < 0.005 |

¹ Cardiovascular complications include: intra-operative cardiac arrest, myocardial infarction, cerebral infarction, pulmonary embolism, acute arrhythmia, intra-operative hypotension; ² Cardio- and cerebrovascular complications include: intraoperative cardiac arrest, myocardial infarction, acute cardiac arrhythmia, intraoperative severe blood pressure reduction during preparation of femoral canal, cerebrovascular accidents, pulmonary embolism and deep venous thrombosis.

Although the cementless stems seem safer in regard to thromboembolic events, they show a higher incidence of implant-related complications, such as stem loosening and femoral fractures (22,34,35) (Table 5), with an eight times higher risk of revision within two years (p<0.001) (36). PPFs may occur either intra- or post-operatively, up to 2-5 years after surgery as a consequence of a low energy trauma (90%) (37). The main risk factors are press-fit prosthesis, old age, female gender, poor bone condition, osteoporosis, and previous implants in the same site (37,38). The mortality rate after a second operation for PPF is 7.3% and 11% at 6 and 12 months, respectively. Furthermore, revision surgery involves functional deterioration, limited mobility, and a four times higher risk of readmission to hospital (37). In the present study, a total of 3 (6%) PPFs were observed between 7 and 18 months postoperatively only in the uncemented group (p=0.04). Chammout et al. (33) reported 3 intraoperative fractures and 1 after 18 months, but none occurred in the cemented group. Leonardsson et al.

(39) described a twenty-fold increased risk of PPFs for press-fit implants, with a peak of incidence 2 years after surgery. These findings have been confirmed by a recent study including 7/141 PPFs between 1 and 4 years postoperatively. As the difference was not statistically significant, the authors speculated that the rate of PPFs could be related to the patients' ageing and the increased risk of falls (22). In a randomized trial comparing 112 cemented and 108 cementless bipolar HAs at five years, Langslet et al. (20) found 1% and 7.4% PPFs, respectively (p=0.035). However, only 3 out of 8 fractures in the press-fit group occurred after one year. Highly significant results, suggesting the use of cement in order to reduce the incidence of PPFs were reported in a meta-analysis by Li et al. (30). Although most of the studies highlights an increased and significantly higher risk of periprosthetic fracture using uncemented stems (26,27,29,40), a randomised controlled trial at 12-month follow-up including 130 patients undergoing HA reported no difference in stem-specific complications (41).

| Study | Total sample | Cemented | Uncemented | p value |
|--|--------------|----------|------------|---------|
| Current study | 139 | 89 | 50 | |
| Postop (7-18 months) | | 0 | 3 (6) | 0.04 |
| Li et al. 2020 | 1093 | 543 | 550 | |
| Not specified intra- or postop | | 7 | 57 | 0.00001 |
| Mao et al. 2020 | 268 | 132 | 136 | |
| Not specified intra- or postop | | 7 | 18 | 0.026 |
| Barenius B et al. 2018 | 141 | 67 | 74 | |
| Postop (12-48 months) | | 2 | 5 | |
| Chammout et al. 2017 | 69 | 35 | 34 | |
| Total | | 0 | 4 | 0.03 |
| Intraop | | 0 | 3 | |
| Postop (after 18 months) | | 0 | 1 | |
| Veldman et al. 2017 | 486 | 245 | 241 | |
| Implant-related complications ¹ | | 11 | 31 | 0.002 |
| Langslet et al. 2014 | 220 | 112 | 108 | |
| Postop (after 5 years) | | 1 | 8 | 0.035 |
| Yli-Kyyni et al. 2013 | 222 | 122 | 100 | |
| Total | | 3 | 9 | |
| Periop | | 1 | 7 | < 0.05 |
| Postop | | 2 | 2 | |
| Taylor et al. 2012 | 160 | 80 | 80 | |
| Intraop | | 0 | 6 | 0.028 |
| Postop | | 1 | 12 | 0.0023 |

¹ Implant-related complications include: intra- and post-operative periprosthetic fractures, aseptic loosening and dislocation

Undoubtedly, our study involves some important limitations. In particular, a minimum 1-year follow-up can be too short for detecting the true incidence of postoperative complications. Furthermore, the small final sample of patients might have affected the statistical power of the outcomes. Finally, this is a retrospective and non-randomised study. However, all the operations have been carried out using the same surgical approach and comparable cemented and uncemented femoral stems, as they were all manufactured with modular necks.

Conclusion

Due to similar intraoperative complication rates, cemented and uncemented stems can be both safely used in the management of displaced FNF in the elderly, with unremarkable difference in length of surgery. However, press-fit fixation is associated with a higher risk of PPFs in the postoperative time. Further studies including a larger sample of patients and a longer follow-up period are required to definitely confirm these findings.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Ethics Approval and Consent to Participate: All procedures were performed following written informed patient consent and in accordance with the ethical standards of the institutional research committee and the 1964 Declaration of Helsinki and its subsequent amendments or comparable ethical standards.

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