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Percutaneous image-guided screws meditated osteosynthesis of impeding and pathological/insufficiency fractures of the femoral neck in non-surgical cancer patients

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ABSTRACT

Aim: To present percutaneous image-guided screw-mediated osteosynthesis (PIGSMO) for fixation of impending fractures (ImF) and non-displaced/mildly displaced pathological/insufficient fractures (PF/InF) of the femoral neck in non-surgical cancer patients.

Materials and methods: This is a double-centre single-arm observational study. Retrospective review of electronic records identified all oncologic patients who had undergone femoral neck PIGSMO. Inclusion criteria were: non-displaced or mildly displaced PF/InF, and ImF (Mirels' score ≥8); life expectancy ≥1 month; unsuitability for surgical treatment due to sub-optimal clinical fitness, refusal of consent, or unacceptable delay to systemic therapy.

Results: Eleven patients were treated (mean age 63.7 ± 13.5 years) due to ImF (63.6%, mean Mirels' score 10.1), PF (27.3%) or post-radiation InF (9.1%) under CT/fluoroscopy- (36.4%) or CBCT- (63.6%) guidance.

Thirty-two screws were implanted and cement injection was added in 36.4% cases. Technical success was 90.9%.

No procedure related complications were noted.

At 1-month clinical follow-up (pain/walking impairment), 63.6% and 27.3% patients reported significant and mild improvement, respectively. Imaging follow-up (available in 63.6% cases) showed no signs of secondary fractures, neither of screws loosening at mean 2.8 months. Five patients (45.5%) died after PIGSMO (mean time interval 3.6 months).

Conclusions: PIGSMO is technically feasible and safe in cancer patients with limited life expectancy; it offers good short-term results. Further prospective studies are required to corroborate mid- and to prove long-term efficacy of the technique.

1. Introduction

Bone-seeking tumors account for the 45% of commonly diagnosed cancers [1] and, in the non-vertebral compartment, femur is one of the most common sites [2]. Femoral metastatic disease may significantly impair patients' quality of life and prognosis [3] due to pain and risk of fracture.

Surgical proximal femur arthoplastic replacement represents the first-line treatment [4]. However, surgical management of long bone metastases may deleteriously impair patients' survival [5] and many patients are not deemed good surgical candidates due to sub-optimal fitness, advanced disease, or unacceptable delay to systemic therapy. For this reason, in the last few years, several different minimally invasive interventional treatments have been proposed for the treatment of pathologic/insufficient fractures (PF/InF), and impending fractures (ImF) of the femoral neck, including cementoplasty [6–8], polymethylmethacrylate (PMMA)-augmented metallic materials consolidation [9,10], and percutaneous image-guided screw-

Abbreviations: PF/InF, pathologic/insufficient fractures; ImF, impending fractures; PIGSMO, percutaneous image-guided screw-mediated osteosynthesis; PMMA, polymethylmethacrylate.

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mediated osteosynthesis (PIGSMO) [11,12]. Early reports have demonstrated good technical feasibility and short-term efficacy of proximal femur PIGSMO in cancer patients [11,12]; however, to the best of our knowledge, such experience is still limited [11,12].

The aim of this study is to present our double-centre experience with PIGSMO performed to fix ImF, or non-displaced/mildly displaced PF/InF in non-surgical cancer patients, and to discuss technical aspects, advantages, and limitations of this technique.

2. Materials and methods

This is a double-centre single-arm retrospective observational study, which was conducted with Institutional Review Board approval and a waiver of informed consent at both Centres.

2.1. Study population

Retrospective review of electronic records identified all oncologic patients who had undergone femoral neck PIGSMO across two tertiary referral centres.

A multidisciplinary tumour board including oncologists, orthopaedic surgeons, interventional radiologists, radiotherapists, and anaesthesiologists discussed and selected all cases. Femoral neck PIGSMO was proposed to patients with symptomatic non-displaced or mildly displaced PF/InF, or with ImF (Mirels' score $\geq$8 [13]), <3 cm cortical involvement [7], and absence of trochanteric/sub-trochanteric metastatic involvement [14]; life expectancy $\geq$1 month; unsuitable for surgical treatment due to suboptimal clinical fitness, refusal of consent, or unacceptable delay to systemic therapy. Exclusion criteria were severe and irreversible coagulation disorders and/or local/systemic sepsis.

2.2. Procedures

All procedures were performed in an interventional radiology suite under strict sterile conditions and under general anaesthesia by a senior Interventional Radiologist (minimum 6 years experience) and a resident/fellow (>2 years experience).

Imaging guidance consisted of combined CT (Somatom Definition AS, Siemens, Erlangen, Germany) and Fluoroscopy (Arcadis Orbit; Siemens, Erlangen, Germany) in Centre 1 (Strasbourg); and Cone-Beam CT (CBCT) equipped with XPerCT and X-PerGuide tools (Allura, Philips Healthcare, Amsterdam, Netherlands) in Centre 2 (Bordeaux). Anticoagulants and blood coagulation parameters were arranged according to Society of Interventional Radiology guidelines [15]. Broad-spectrum intravenous antibiotic cover (2 g cefazolin) was administered pre-procedurally in all cases.

Patients were positioned supine and initial CT or CBCT was acquired to plan screws trajectory and cutaneous entry-points. Multi-planar reconstructed images were used to measure screws length from cortical surface to the intended distal intra-osseous anchor point. Cannulated self-drilling screws were used (6.5 mm AsnisTM III Cannulated Screw System, Kalamazoo, Michigan, USA). Under intermittent fluoroscopy, each screw was advanced coaxially and manually over a k-wire using a driver, until the distal tip was anchored in healthy distal bone in the femoral head, and the head of the screw abutted the external cortical bone of the proximal femoral epiphysis.

Successful placement was confirmed on final CT/CBCT. For PF/InF, screws were placed perpendicularly across the fracture-line; for ImF across the lytic area. Screws were deployed in order to obtain an inverted triangle construct (Fig. 1).

Additional PMMA injection was performed at the discretion of the attending senior radiologist, on the basis of substantial femoral osteolysis/osteopaenia, which might compromise screws stability. In these cases, injection was performed through a dedicated 10G co-axial trocar (Gangi Special Vertebroplasty Needle, Optimed, Ettlingen, Germany) inserted adjacent to the screws. PMMA (Osteopal V, Heraeus Medical GmbH, Wehrheim, Germany) was injected under continuous fluoroscopy until adequate filling or leakage, were noted.

2.3. Follow-Up

All patients were clinically reviewed in an outpatient basis before and 1 month after PIGSMO by the treating interventional radiologist. Pre- and post- PIGSMO consultation records were reviewed in order to assess post-PIGSMO global status in terms of pain/walking ability according to a simple 4-point scale (1 = worse; 2 = unchanged; 3 = improved; 4 = significantly improved).

After the first clinical follow-up, patients were not followed-up systematically neither clinically neither with dedicated imaging, unless suspicion of complication including secondary fracture, was doubted. However, all patients underwent routine imaging follow-up every 3–6 months for systemic disease monitoring, and their electronic records were reviewed to find out the last imaging follow-up available, including the area of PIGSMO in the field of view, in order to investigate local evolution of the treated focus.

In the end, any patients' decease following PIGSMO and related to systemic disease evolution was censored.

2.4. Data collection

Patients' demographics, tumour type, prior treatments, lesion location, symptomatic status, and Mirels' score for ImF were recorded.

Number of screws, technical success, complications ([15]), short-term clinical outcomes, and local evolution of the treated focus on latest follow-up imaging were assessed.

Technical success was accorded when imaging obtained at the end of the procedure showed: (a) screws parallel (less than 5° deviation); (b) screws tips within 5 mm form the subchondral bone but not penetrating the joint; (c) not all screws in the cranial half of the femoral head and (d) not all screws in the anterior half of the femoral head. Moreover, if PMMA was injected to increase screws stability, any PMMA leakage was carefully searched on imaging obtained just at the end of the procedure; and if leakage was noted, the procedure did not account for technical success.

Local evolution of screws was assessed on the most recent imaging (CT or X-ray) covering the treated lesion in order to identify loosening (i.e. $\geq$2 mm peri-screw lucency).

3. Results

Between March 2014 and October 2016, 11 patients were treated (6 male, 5 female, mean age 63.7 $\pm$ 3.5 years, range 37–81). Disease spectrum ranged from solitary bone lesions to poly-metastatic involvement. All patients had been treated with systemic chemotherapy, and over 50% had undergone prior local treatment (Table 1).

Eleven PIGSMO sessions were performed in 11 femoral necks (4 left-sided, 7 right-sided) to treat seven ImF (63.6%, mean Mirels' score 10.1), three PF (27.3%) and one post-radiation InF (9.1%).

Interventional sessions were guided by a combination of CT/fluoroscopy (4/11 sessions; 36.4%) or CBCT (7/11 sessions; 63.6%).

Thirty-two screws were implanted (screws length 88.1 $\pm$ 11.9 mm; range 65–115). All patients but one were treated with 3 screws. Adjunctive PMMA injection was performed in 4/11 (36.4%) femoral necks. One (9.1%) PIGSMO was performed