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Percutaneous osteosynthesis and cementoplasty for stabilization of malignant pathologic fractures of the proximal femur

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Preventive percutaneous osteosynthesis;
Pathological fracture;
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Interventional radiology

Abstract
Purpose: To retrospectively evaluate the outcome of patients who underwent radiological percutaneous osteosynthesis and cementoplasty (RPOC) for stabilization of malignant pathological fracture of the proximal femur.
Materials and methods: The clinical files of 12 patients who underwent RPOC for stabilization of malignant pathological fracture of the proximal femur were reviewed. There were 9 men and 3 women with a mean age of 56 years ± 13 (SD) (range: 35—82 years). All patients had metastases of proximal femur and a high fracture risk (Mirels score ≥ 8) and were not eligible for surgical stabilization. The primary endpoint was the occurrence of a fracture after RPOC. Secondary endpoints were the procedure time, early complications of RPOC, pain reduction as assessed using a visual analog scale (VAS) and duration of hospital stay.
Results: No patients treated with RPOC had a fracture during a mean follow-up time of 382 days ± 274 (SD) (range: 11—815 days). RPOC was performed under general ($n = 10$) or locoregional ($n = 2$) anesthesia. The average duration of the procedure was 95 min ± 17 (SD) (range: 73—121 min). The technical success rate was 100%. All patients were able to walk on the day following RPOC. The average duration of hospital stay was 4 days ± 3 (SD) (range: 2—10 days). No major complication occurred. One patient complained of hypoesthesia in the lateral thigh. For symptomatic patients ($n = 7$), VAS score decreased from 6.8 ± 1.2 (SD) (range: 5—9) before treatment, to 2.3 ± 1.1 (SD) (range: 1—4) one month later.
Conclusion: Preventive RPOC for pathological fracture of the proximal femur is a reliable alternative for cancer patients who are not candidates for surgical stabilization. Studies involving more patients are needed to confirm our preliminary experience.

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The femur neck is highly vulnerable to fractures due to bone metastasis [1]. Pathological fractures of the proximal femur due to osteolytic metastases have serious consequences on outcome in patients with cancer and must be prevented. Surgical stabilization by femoroplasty or osteosynthesis remains the gold standard. It improves the quality of life and reduces operative complications especially as it is performed before the occurrence of a pathological fracture [2]. Preventive fixation is indicated in cases of Mirels score $\geq$ 8 [3,4]. However, prophylactic surgical stabilization in patients with metastatic disease is associated with non-negligible surgical morbidity and mortality [5,6]. On-going chemotherapy or external beam radiation therapy may impair healing after standard surgical stabilization. In such situations, cementoplasty alone provides an effective pain relief, but appears insufficient in relation with bone healing and the risk of occurrence of secondary fracture [7,8]. Several studies have shown the added value of radiological percutaneous osteosynthesis with cannulated screws by comparison to cementoplasty alone in patients who are not candidates to surgery [9–11]. However, these studies included various procedures, and the follow-up period was relatively short.

The purpose of this study was to retrospectively evaluate the outcome of patients who underwent radiological percutaneous osteosynthesis and cementoplasty (RPOC) for stabilization of malignant pathological fracture of the proximal femur.

Materials and methods

Patients

Between February 2014 and June 2015, patients with malignant impending pathological fracture of the proximal femur (Mirels score $\geq$8) were considered for inclusion into the study (Fig. 1). RPOC was proposed for prophylactic consolidation to these patients who were not eligible for standard surgical stabilization due to low performance status, refusal of operation or on-going chemotherapy. All cases were discussed and the decision was validated during a multidisciplinary meeting with a consensus decision from interventional radiologists, surgeons, oncologists and radiotherapists. Coagulation and biological parameters needed for the RPOC procedure were a platelet count > 60,000/mL, a prothrombin rate > 60%, an international normalized ratio < 1.5 and a white blood cells count > 4000/mL. Patients were not included if the hip joint was involved or if they had untreatable coagulation disorders or allergy to polymethylmethacrylate (PMMA).

Three patients were not included, two for joint invasion and one with an extensive lesion under the trochanteric line. Twelve patients (nine men, three women) with a mean age of 56 years $\pm$ 13 (SD) (age range: 35–82 years) were thus included in the present study. The study was approved by our institutional review board and informed written consent of all patients was obtained before the procedure.

Technique

RPOC was performed under computed tomography (Emotion 16®, Siemens Healthcare, Erlangen, Germany) and fluoroscopy guidance (Ziehm Vision, Ziehm Imaging, Nuremberg, Germany) by two interventional radiologists in an operating room with an Imactis navigation station (Imactis CT-Navigation®, Imactis, Grenoble, France). This system uses a magnetic field generator placed on the patient near to the puncture site and a detector contained within a needle holder to track the needle trajectory in real time using CT imaging [12]. Antibiotic prophylaxis (cefotaxime, 2 g) was given to the patient 1 h before the procedure. RPOC was performed under general anesthesia in 10 patients and regional anesthesia and spinal anesthesia in one patient each because general anesthesia was contraindicated.

The patient was placed in a supine position on the operating table. Under fluoroscopy guidance, two guide pins were inserted parallel to the inferior cortical part of the femoral neck and one parallel to the upper cortical bone. The correct positioning and measure of the appropriate length for each cannulated screw to be inserted were evaluated after CT data acquisition with further three-dimensional (3D) reconstructions (Fig. 2). Then, a cannulated screwdriver was used to move forward the cannulated screws on the guide pins under fluoroscopy guidance. The percutaneous fixation was performed with cannulated screws of 6.5 mm diameter (Trauma Asnis III™, Stryker, Selzach, Switzerland). The guide pins were removed and cementoplasty was performed under fluoroscopy guidance by injecting PMMA cement (Cohesion®, Vexim SA, Balma, France) through a beveled 11-Gauge bone biopsy needle (Osteo-Site®, Cook Medical, Bjaeverskov, Denmark, Fig. 3). During the RPOC procedure, oximetry was closely monitored. Also, patients received preventive anticoagulation during the period of bed rest. All patients had a consultation at one-month follow-up with the operator who performed RPOC then every 3 months by the oncologist in charge of the patient.

Data analysis

The primary study endpoint was the occurrence of a fracture of the proximal femur after RPOC. Secondary endpoints were duration time of RPOC, procedure complications, volume of PMMA injected, pain (VAS score before and 1 month after the procedure) and the duration of hospital stay.

Results

Patient and bone lesions characteristics are described in Tables 1 and 2. All patients had osteolytic metastases located at the femoral neck (n = 9) or in the trochanter region (n = 3). One patient had received external beam radiation six months before RPOC and three after one month after the procedure because of partial improvement of pain (VAS $\geq$ 3). All patients but one had invasion of the cortex (average of 27 mm). The mean Mirels score was 9.8 $\pm$ 1.1 (SD) (range: 8–12).

No fracture occurred during a follow-up period of 382 days $\pm$ 274 (SD) (range: 11–815 days). Three patients died during the follow-up period due to cancer progression. Two

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