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

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KEYWORDS
Preventive percutaneous osteosynthesis; Pathological fracture; Cementoplasty; Metastatic bone disease; Interventional radiology

Abstract
Purpose: To retrospectively evaluate the outcome of patients who underwent radiological percutaneous osteosynthesis and cementoplasty (RPOC) for stabilization of malignant pathologic 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 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.
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 ≥ 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 ≥ 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 ± 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, Bjæverskov, Denmark, Fig. 3). During the RPOC procedure, oxymetry was closely monitored. Also, patients received preventive anti-coagulation 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 ≥ 3). All patients but one had invasion of the cortex (average of 27 mm). The mean Mirels score was 9.8 ± 1.1 (SD) (range: 8–12).

No fracture occurred during a follow-up period of 382 days ± 274 (SD) (range: 11–815 days). Three patients died during the follow-up period due to cancer progression. Two
patients died early (11 and 16 days). The first patient with metastatic gastric adenocarcinoma died secondary to a rapid pulmonary metastatic evolution. Pulmonary embolism was excluded on the basis of CT findings. The second one, suffering from lung neoplasm, died 16 days after the procedure when at home. A pulmonary embolism was not eliminated, but there was no clinical orientation for this diagnosis. No major complications such as fracture, infection, hematoma, pulmonary embolism, osteomyelitis, or screw shifting were observed. Minor complication was observed in one patient in the form of hypoesthesia and pain of the lateral thigh in relation to lateral cutaneous nerve
<table>
<thead>
<tr>
<th>Patient#/gender/age (yr)</th>
<th>Mirels score</th>
<th>Primary tumor</th>
<th>VAS score</th>
<th>Operation time (min)</th>
<th>PMMA volume (mL)</th>
<th>Follow-up</th>
<th>Major complications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pretreatment</td>
<td>At 1 month</td>
<td></td>
<td>Fracture</td>
<td>Delay (days)</td>
</tr>
<tr>
<td>1/M/82</td>
<td>11</td>
<td>Lung</td>
<td>7</td>
<td>1</td>
<td>84</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>2/M/35</td>
<td>9</td>
<td>Digestive tract</td>
<td>0</td>
<td>N</td>
<td>121</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>3/F/42</td>
<td>12</td>
<td>Breast</td>
<td>8</td>
<td>1</td>
<td>96</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>4/F/49</td>
<td>10</td>
<td>Sarcoma</td>
<td>7</td>
<td>2</td>
<td>80</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>5/M/55</td>
<td>9</td>
<td>Kidney</td>
<td>0</td>
<td>0</td>
<td>120</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>6/F/62</td>
<td>10</td>
<td>Sarcoma</td>
<td>6</td>
<td>2</td>
<td>105</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>7/M/63</td>
<td>10</td>
<td>Lung</td>
<td>6</td>
<td>N</td>
<td>79</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>8/M/66</td>
<td>9</td>
<td>Lung</td>
<td>0</td>
<td>0</td>
<td>96</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>9/M/52</td>
<td>11</td>
<td>Lung</td>
<td>9</td>
<td>4</td>
<td>93</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>10/M/53</td>
<td>9</td>
<td>Pharynx</td>
<td>5</td>
<td>3</td>
<td>73</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>11/M/66</td>
<td>8</td>
<td>Kidney</td>
<td>0</td>
<td>0</td>
<td>124</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>12/M/41</td>
<td>10</td>
<td>Sarcoma</td>
<td>6</td>
<td>3</td>
<td>82</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

PMMA: polymethylmethacrylate.

* Deceased patient.
of thigh damage that resolves after percutaneous steroid infiltration.

For the 9 patients with painful bone lesions, the pain as evaluated by VAS decreased from 6.8 ± 1.2 (SD) (range: 5–9) before RPOC to 2.3 ± 1.1 (SD) (range: 1–4) one month later.

For all patients RPOC was done successfully. The average procedure duration time was 95 min ± 17 (SD) (range: 79–121 min). The mean volume of PMMA injected was 10 mL ± 2 (SD) (range: 8–15 mL). The mean screw length was 85.3 mm ± 8.1 (SD) (range: 65–100 mm). All patients were able to stand up on the second day after the RPOC procedure, and the mean hospital stay duration was 4 days ± 2 (SD) (range: 2–10 days).

**Discussion**

The results of our study show that preventive RPOC for pathological fracture of the proximal femur due to metastasis is a reliable alternate option for patients who are not candidates for surgical stabilization. Indeed, no fracture occurred in our series despite a population at risk with a Mires score ≥ 8 and a median follow up of 180 days.

RPOC has several advantages, especially in a population of surgery-ineligible patients. RPOC is a less invasive technique than surgery with a percutaneous approach and three incisions of 1 cm, with an effective analgesic effect and a potential reduction of disability after the procedure and the risk of bleeding or infectious complications. Also, bed rest (mean = 2 days) and hospital stay (mean = 4 days) are reduced, with potentially less risk of thromboembolic events. Another advantage is that RPOC can be associated with other complementary therapies such as external beam radiation, thermal ablation and while continuing chemotherapy. Finally, RPOC does not prevent further surgery, should it be needed.

Our results are consistent with those of He et al. [13]. These researchers reported a series of six patients who had percutaneous cementoplasty and interventional internal fixation for stabilization of impending pathological fracture of the proximal femur. The procedure was technically feasible in all patients [13]. No cases of procedural site fractures during a median follow-up of 192 days were noted [13].

Deschamps et al. presented a series of 12 patients treated with preventive RPOC of the proximal femur [14]. No fracture occurred during a median follow-up of 145 days. As in our study, procedures were fully completed and well tolerated. All patients walked the second day after RPOC and for symptomatic patients VAS was improved to 1 month. The median duration of the procedures was lower in our study (95 min ± 17) that in the study by Deschamps et al. (110 min ± 43). This can be explained by the use of a real-time guidance system requiring prior CT examination. This system allows a real-time path planning of the needle by double-skew, reducing the number of necessary controls and therefore the time of placement of the guide pins. Moreover, we report a longer follow-up period (382 days versus 145 days on average).

Patients at risk of pathological fracture of the proximal femur caused by metastatic lesions should undergo a preventative stabilization, for which surgical treatment is the gold standard. Patients who undergo prophylactic surgical stabilization have better overall survival rate at all points, during the time after the intervention [15]. However, the decision to operate patients with cancer is difficult because the indication is based on life expectancy and prognosis of the disease, the general condition of the patient and the risk of fracture. To date, no specific risk factor has been identified to predict the occurrence of a pathological fracture of the femur, but surgical stabilization is highly indicated for a lesion with a Mires score ≥ 8 [3,4].

Ristevski et al. reported in a retrospective study on the prophylactic surgical stabilization for femoral metastatic lesions in 201 patients a hospital stay of 19.3 days; an 8% rate of surgical and medical complications during hospitalization and a 3% rate of deep vein thrombosis within 3 months after surgery. Death rate during the procedure was 1%, 9% during the hospital stay, and 13.9% at three months [15].

Apart from the surgical approach several alternative techniques have been described for percutaneous treatment of oncologic bone lesions including cementoplasty alone.

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**Table 2** Lesion characteristics in 12 patients who underwent radiological percutaneous osteosynthesis and cementoplasty.

<table>
<thead>
<tr>
<th>Patient#</th>
<th>Primary tumor</th>
<th>Lesion characteristics</th>
<th>Cortical involvement (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Size (mm)</td>
<td>Location</td>
</tr>
<tr>
<td>1</td>
<td>Lung</td>
<td>39</td>
<td>Right FN</td>
</tr>
<tr>
<td>2</td>
<td>Digestive tract</td>
<td>37</td>
<td>Left FN</td>
</tr>
<tr>
<td>3</td>
<td>Breast</td>
<td>30</td>
<td>Left FN</td>
</tr>
<tr>
<td>4</td>
<td>Sarcoma</td>
<td>45</td>
<td>Left GT</td>
</tr>
<tr>
<td>5</td>
<td>Kidney</td>
<td>36</td>
<td>Right FN</td>
</tr>
<tr>
<td>6</td>
<td>Sarcoma</td>
<td>45</td>
<td>Right FN</td>
</tr>
<tr>
<td>7</td>
<td>Lung</td>
<td>39</td>
<td>Right FN</td>
</tr>
<tr>
<td>8</td>
<td>Lung</td>
<td>32</td>
<td>Left FN</td>
</tr>
<tr>
<td>9</td>
<td>Lung</td>
<td>41</td>
<td>Left FN/GT</td>
</tr>
<tr>
<td>10</td>
<td>Pharynx</td>
<td>42</td>
<td>Right GT</td>
</tr>
<tr>
<td>11</td>
<td>Kidney</td>
<td>33</td>
<td>Right FN</td>
</tr>
<tr>
<td>12</td>
<td>Sarcoma</td>
<td>45</td>
<td>Right GT</td>
</tr>
</tbody>
</table>

FN: femoral neck; GT: great trochanter.
Deschamps et al. reported a 1-year pathologic fracture rate of 40.6% for impending fracture of the proximal femur treated with cementoplasty alone [11]. Tian et al. in a non-randomized prospective study reported that the treatment of impending pathological fracture of the proximal femur using combined cementoplasty and internal fixation resulted in greater bone consolidation and also reduced the risk of pathologic fracture than cementoplasty alone did [9]. In line with those results, several reports have concluded that even if pain relief is acceptable after cementoplasty, there is a risk of fracture due to insufficient consolidation of the femur [8,9,16—18].

Studies have described other percutaneous techniques that included internal fixation with modified trocars, bone marrow nails, Kirschner wires, cement-filled catheters and augmentation using micro-needles mesh and cement [19—22]. However, clinical evidence is lacking. Furthermore, inclusion criteria in these studies were not always in relation to an impending fracture with a high risk for fracture. Conversely, screw fixation is used by orthopedic surgeons and biomechanical studies have shown its effectiveness in bone consolidation [23,24].

Our study has several limitations because of the limited number of patients and a retrospective design. Another limitation is that we did not make comparisons with other therapeutic options such as cementoplasty alone. Another limitation is the lack of control group. Nevertheless cementoplasty alone does not provide adequate mechanical stability. Unlike spiral fractures that occur on compressive strength, the femur is subjected to more complex twisting mechanisms. According to the results of previous studies, cementoplasty alone has biomechanical limitations. On the other hand, comparison with a control group was ethically hardly conceivable because of the major risk of fracture in our patients.

In conclusion our results show that RPOC provides prophylactic consolidation for impending metastatic lesion of proximal femur. This is a minimally invasive procedure that can be considered as an alternative option for fragile patients who are not candidates for surgical stabilization. Future multi institutional studies on involving larger population are needed to confirm our experience.

Disclosure of interest
The authors declare that they have no competing interest.

References

