


Combination of Percutaneous Screw Fixation and Cementoplasty for Lytic Bone Metastases: Feasibility, Safety and Clinical Outcomes

Sylvain Bertholon¹ · Rémi Grange¹ · Thierry Thomas² · Marie-Charlotte Tetard³ · Fabrice-Guy Barral¹ · Aurelie Beneton⁴ · Stéphanie Morisson⁴ · Sylvain Grange¹ 

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Abstract

Objective To evaluate feasibility, safety and efficacy of a combination of screw fixation and cementoplasty for pathologic bone fracture.

Methods In this single-center prospective study, all consecutive percutaneous screw fixations under assisted CT guidance for palliation and fracture treatment of pathologic bone fracture were reviewed from July 2019 to February 2021. The primary outcome measure was the procedures' technical success, defined as the correct placement of the screw(s), without any complications. Secondary outcome measures were the safety, the procedures' early analgesic effects and impacts on quality of life at 4 weeks.

Results Technical success was achieved in 11/11 procedures (100%) among 11 patients. No major complications attributable to the procedure were noted. The mean pain scored significantly decreased at the initial follow-up: 8.0 ± 2.7 versus 1.6 ± 2.5 ($p < 0.05$). Opioid doses were statistically lower after procedure: 70.9 ± 37 versus

48.2 ± 46 mg/day ($p < 0.05$). The mean EQ5D score had significantly increased by the early post-procedure consultation: 42.5 ± 13.6 vs 63.6 ± 10.3 ($p < 0.05$).

Conclusion Combination of percutaneous screw fixation and cementoplasty for pathologic bone fracture is feasible and safe. It is efficient to reduce pain, decrease the consumption of opioids and improve the quality of life at 4 weeks after the procedure.

Keywords Screw fixation · Cementoplasty · Interventional radiology · Pain management

Abbreviations

CT	Computed tomography
CBCT	Cone beam CT
NPRS	Numerical pain rate Score
PS	Performance status
EQ5D	EuroQol 5 dimensions

✉ Sylvain Grange
sylvain.grange@chu-st-etienne.fr

¹ Department of Radiology, Hôpital Nord, University Hospital of Saint Etienne, Avenue Albert Raymond, 42055 Saint-Etienne cedex 2, France

² Department of Rheumatology, University Hospital of Saint Etienne, Avenue Albert Raymond, 42055 Saint-Etienne cedex 2, France

³ Department of Neurosurgery, University Hospital of Saint Etienne, Avenue Albert Raymond, 42055 Saint-Etienne cedex 2, France

⁴ Department of Supportive Care in Oncology, Lucien Neuwirth Cancer Institute, 5 Rue Charles de Gaulle, 42055 Saint-Etienne cedex 2, France

Introduction

In oncology, therapeutic progress has allowed a significant increase in life expectancy. A growing number of cancer survivors live to more advanced metastatic stages [1]. Secondary bone lesions are increasing, which are responsible for pain, especially in case of a pathologic fracture [2].

Analgesics, radiotherapy and surgery are widely used in this context, but are not without side effects [3, 4].

Cementoplasty is an interventional radiology procedure that has improved the palliative management of bone lesions [5], providing resistance to compressive stress during weight-bearing activities [6, 7]. However, one of the main disadvantages of cement is its low resistance to torsional stress [8, 9]. Thus, cementoplasty alone is less effective on bones that are subjected to torsional stresses [5, 10–13].

Fixation using a combination of metal screws and cement provides resistance to torsional and compressive stress [14, 15]. In addition, it has been shown that combined use of cement significantly lowers the risk of secondary screw displacement in secondary bone lesions [16–18]. Combination of percutaneous screw fixation and cementoplasty is a mini-invasive procedure; it typically results in early mobilization, almost no blood loss, reduced risk of venous thromboembolism (VTE) [9, 19–24].

The aim of this prospective study was therefore to evaluate feasibility, safety and efficacy of combination of percutaneous screw fixation and cementoplasty for pathologic bone fracture.

Materials and Methods

Study Population

It is a single-center prospective observational study. The inclusion criteria for this study include participants selected for having percutaneous osteosynthesis with cementoplasty on a secondary fractured bone lesion in an oncologic setting. Medical decisions were based on patient pain and quality of life, patient oncology projections, the patients' general conditions and ineligibility for surgical management.

Data Collection

The clinical evaluation included the evaluation of the performance status. The evaluation of the quality of life was conducted with the EQ5D (EuroQol 5 Dimensions) score [25]. The type and intensity of pain according to the Numerical Pain Rating Scale (NPRS) from 0 to 10 were assessed. The consumption of analgesics by step and by dosage was also evaluated. The opioid equivalent dose was calculated with an equianalgesic conversion table [26]. After the procedure, all patients had post-procedure consultations planned (at 1 month) together with systematic CT scans.

The objectives were to evaluate the feasibility, the safety and the efficacy of the procedure. Feasibility was defined as the technical success of the procedure, i.e., the correct placement of the screw or screws, without extrusion; safety

was evaluated by the screening of complications during and at the end of the procedure, as well as during the follow-up period. The efficacy was evaluated by the analgesic effect of the procedure and its impact on quality of life, by comparing patients' self-evaluation of pain (NPRS), quality of life (EQ5D) and consumption of opioids before and after the procedure.

Results

Procedures

From July 2019 to February 2021, 11 procedures were performed 11 patients with cancer and symptomatic bone metastases with pathologic fracture were included.

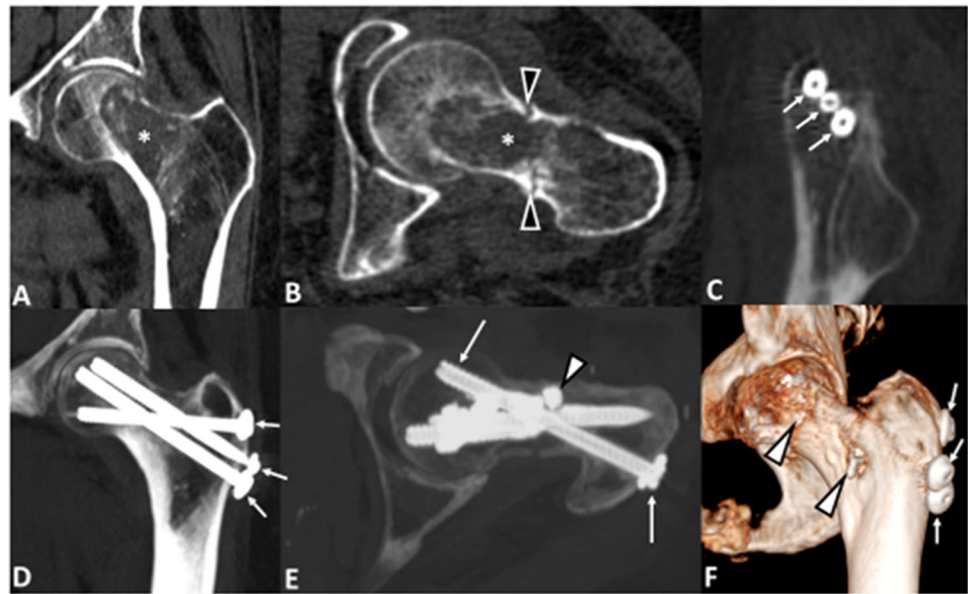
Preoperative clinical data are summarized in Table 1. One procedure example is illustrated in Fig. 1. The percutaneous procedures were performed under the control of a CT scanner and scopy. The aim of the procedure was to place one or several screw(s) across the lesions, through healthy bone on either side. The interventional radiologist positioned under direct control a wire through a coaxial needle, in order to insert titanium cannulated screw(s) of 4 mm or 6.5 mm diameter (*ASNIS Stryker*®). The number and diameter of the screws were defined according to the extent of the fracture, the lytic lesion and the nearby healthy bone. The use of CT guidance during the procedure

Table 1 Patients characteristics

Characteristics	Values
Sex	
Female n (%)	3/11 (27.3)
Age (y)*	72.2 ± 10.3
Cancer type n (%)	
Lung	3/11 (27.3)
Breast	3/11 (27.3)
Prostate	3/11 (27.3)
Bladder	2/11 (18.1)
Lesion characteristic	
Lytic n (%)	8/11 (72.7)
Mixed n (%)	3/11 (27.3)
Size (mm)*	58.8 ± 36.9
Fracture n (%)	11/11 (100.0)
Lesion localization n (%)	
Iliac	8/11 (72.7)
Femur	1/11 (9.1)
Iliopubic ramus	1/11 (9.1)
Odontoid	1/11 (9.1)

*Numbers are mean ± standard deviations

Fig. 1 One example. Sagittal (A) and axial (B) pre-procedure CT scan views: osteolytic lesion of the femoral neck (*) with pathologic fracture (black arrowheads); (C) sagittal CT scan view per procedure: three screws (white arrows) are positioned through the femoral neck lesion in three different orientations); sagittal (D) and axial (E) post-procedure CT scan views: the three screws (white arrows) cross the lesion and the cement (white arrowhead) is positioned around the screws; (F) 3D post-procedure reconstruction CT scan: the screws (white arrows) and cement (white arrowheads) fill the lesion and fracture



allowed to check screw trajectory and to avoid possible complications.

In all patients, 11-Gauge trocars were inserted (*OnControl*®, *Teleflex*; *TCD*®, *Thiebaud*), and then, the injection of polymethylmethacrylate cement (*Palacos*®-Heraeus Medical) was performed after screw insertion. In order to obtain optimal stabilization, cement was injected both into the lesion, at the end of the screws (in the healthy bone) and surrounding the screw. Potential adverse events and complications were also recorded with CIRSE and Clavien-Dindo classifications [27, 28]. The technical success of the procedure was defined as the correct placement of the screw(s), without any complications.

Technical success was achieved in 11/11(100%) procedures. In total, 16 screws were inserted (1.45 ± 0.7 per procedure). Iliac bone was the most frequent treated area.

Patients were able to get up within 24 h of the procedure in 90.9% of cases (10/11).

Adverse Events

Minimal cement leaks (small volume, leakage into the soft tissues) were noted in 3 procedures, which did not result in any consequences. In 2/11(18.2%) procedures, patients had complications: 1/11(9.1%) with a minor complication in the form of subcutaneous hematoma following screw insertion and 1/11(9.1%) with an asymptomatic pulmonary cruciate embolism (Clavien-Dindo 2 and CIRSE 3). The pulmonary embolism was discovered incidentally after the procedure during a usual oncological CT follow-up, and it was possibly unrelated to the procedure.

Clinical Outcomes at Initial Follow-up (4 weeks)

Clinical outcomes are summarized in Table 2. No displacement of material occurred during the follow-up. One patient died before completing the 4-week follow-up, of rapidly progressing metastatic disease. This death was unexpected and was considered to be unrelated to the procedure. All fractures were stabilized. The mean Pain Numerical Rating Scale (NPRS) dropped from 8 ± 2.7 to 1.6 ± 2.5 ($p < 0.01$) at the initial follow-up (4 weeks). Opioid use reduced significantly after procedure from 70.9 ± 37 to 48.2 ± 46 mg/d ($p < 0.05$) at 4 weeks.±

The mean EQ5D score significantly increased at the early post-procedure consultation from 42.5 ± 13.6 to 63.6 ± 10.3 ($p < 0.01$). One patient died before evaluation of quality of life.

Discussion

The present study showed excellent technical outcomes (100%) and a high rate of fracture stabilization (100%: 11/11). These findings are consistent with previous studies [24].

Surgical treatment exposes them to a risk of morbidity [29] and longer hospitalization [4]. Thus, for patients with comorbidities and limited life expectancy, surgical options are not suitable. The procedure was accompanied by a short period of hospitalization and early standing-up. These findings are consistent with previous studies [18]. These elements are a definite advantage for these fragile patients. Moreover, our results demonstrate a significant and rapid improvement in pain and quality of life at 4 weeks. Findings also show a significant and rapid decrease in opioid.

Table 2 Clinical outcomes

	Pre-procedure	Post-procedure	<i>P</i> value
Mean pain score*	8.0 ± 2.7	1.6 ± 2.5	<i>p</i> < 0.01
Mean EQ5D score*	42.5 ± 13.6	63.6 ± 10.3	<i>p</i> < 0.01
Mean opioid dose (mg)*	70.9 ± 37	48.2 ± 46	<i>p</i> < 0.05

*Numbers are mean ± standard deviations

Opioid use is common in patients with bone metastases and represents a risk of side effects [30].

The development of percutaneous osteosynthesis associated with cementoplasty has made it possible to safely and effectively treat patients who previously could not benefit from any effective surgical or interventional treatment.

This study is a prospective study to evaluate the analgesic efficacy of this intervention. Analgesic consumption was closely monitored, no patients were lost to follow-up, and there were no missing data. Quality of life was evaluated with the EQ5D scale, which is appropriate for prospective follow-up of quality of life in cancer patients [25].

The main limitations of our study include the single-center nature and the absence of a randomized control group. Furthermore, the evaluation of pain may have been affected due to other events and comorbidities related to age and treatments. Other therapies may confound pain scores in longer follow-up assessments.

Conclusions

This prospective study confirms that combination of percutaneous screw fixation and cementoplasty for pathologic bone fracture is feasible and safe. The novelty of the study results from its meticulous documentation of indicators of pain, quality of life, medication use and scan monitoring. Furthermore, it provides evidence about the procedures' abilities to drastically reduce pain, consumption of analgesics and increase the quality of life at 4 weeks post-procedure.

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Author's Contribution SG, SB, SM and RG elaborated the project. SG, SB and SM collected the data. SB, SG and RG performed the procedure and wrote the manuscript. All authors managed the patients, corrected and validated the manuscript.

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Declarations

Conflict of interest No potential conflict of interest was reported by the authors.

Ethical approval This study has obtained approval from local research committee ("terre d'éthique" CHU Saint-Etienne IRBN942019/CHUSTE). The "clinical trial" document has been completed (NCT05191264).

Informed consent Informed consent was obtained from all individual participants included.

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