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Research Paper

Evaluation of short-term efficacy of extraspinal cementoplasty for bone metastasis: A monocenter study of 31 patients

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ABSTRACT

Objective: To study the effect on pain of per-cutaneous cementoplasty for painful extraspinal bone metastasis.
Method: 43 patients with extraspinal bone metastasis were included between April 2006 and October 2014 in this retrospective monocenter study. The primary endpoint was pain level measured on a 0–10 numeric rating scale at week 1 after cementoplasty as compared with pre-cementoplasty. Secondary endpoints were long-term pain level and impact on quality of life and disability.
Results: Mean pain score was 4.2 (SD ± 3.6) before cementoplasty and 1.09 (SD ± 2.4) at week 1 ($p = 0.005$) ($n = 31$ patients). At 22 months after cementoplasty, quality of life and disability improved (according to the patient global assessment) for 47.6% and 52.2% of patients ($n = 21$patients). We did not find a predictor of good response. Cement leakage was the most common adverse event.
Conclusion: Percutaneous cementoplasty of extraspinal bone metastasis is a rapidly efficient treatment with few adverse events. Its efficacy persists over time, with a benefit for disability and quality of life. Although this technique is only palliative, it should be considered in this situation.

1. Introduction

Bone metastasis (BM) may be responsible for pain and fractures, especially if located on long bones but may also induce neurologic complications in a vertebral localization [1]. Regular BM treatments are chemotherapy, radiotherapy [2,3] and administration of bisphosphonates [4] and, more recently, denosumab [5–7]. Analgesics are used alone or associated with these treatments. The disadvantages of these therapies are late or only partial efficacy and side effects.

Cementoplasty has become an important part of palliative care in BM because it can rapidly relieve pain and consolidate the fragile metastatic bone. Cementoplasty refers to the use of a trocar for percutaneous application of cement inside the bone. Percutaneous vertebroplasty (cementoplasty of vertebra) was initially described in the late 1980s by Galibert and Deramond and used to treat a painful and aggressive vertebral hemangioma [8]. Its efficacy to control pain in case of osteoporotic or malignant vertebral fractures and prevent pathological fractures of vertebral metastasis has been described [9,10].

Surprisingly, extraspinal cementoplasty has been less studied [11–13]. Such cementoplasty is palliative treatment and could be very useful for patients with painful bone metastasis. Moreover, it has few major side effects, which is important if used in a frail population. In bone metastasis, pain is intense and severely affects quality of life. Thus, in this study, we retrospectively studied the impact of cementoplasty on short-term pain relief and on quality of life with a more long-term follow-up. We aimed to assess its efficacy on pain, functional disability and quality of life in patients with extraspinal BM.

2. Patients and methods

2.1. Patients

We conducted a monocenter retrospective study of patients with symptomatic BM or myeloma lesions who had undergone one or more extraspinal cementoplasties between April 2006 and October 2014 in Henri Mondor Hospital (Creteil, France). Cementoplasty was proposed to patients with one or more locations of extraspinal painful BM. All cementoplasties were discussed during a multidisciplinary meeting with rheumatologists, neuroradiologists, orthopedic surgeons and oncologists.

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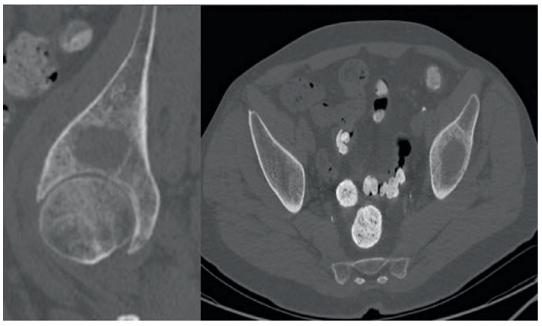

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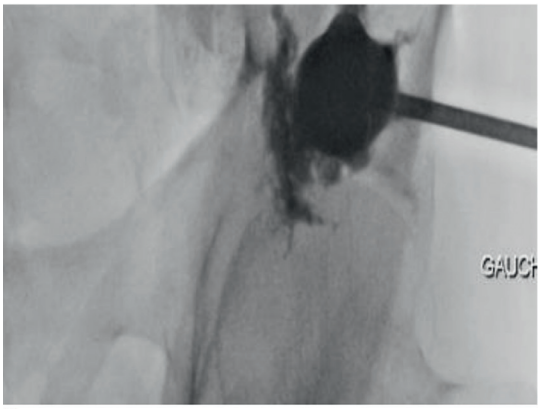

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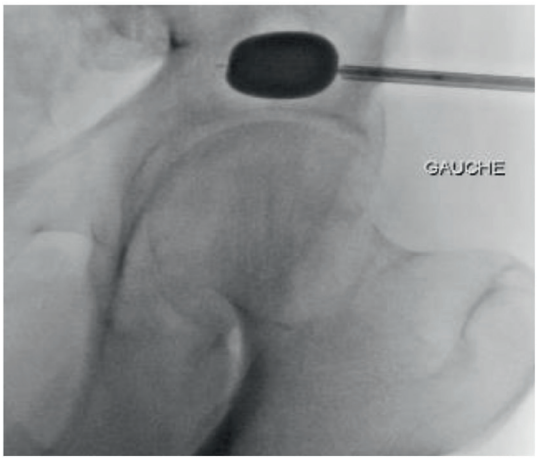

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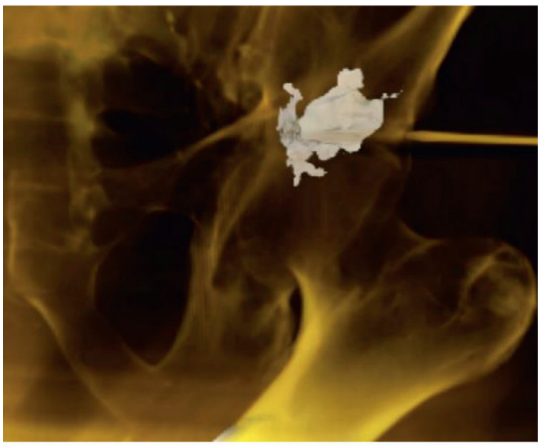

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Fig. 1. (A). Bone metastasis of acetabulum (lung cancer). (B). Inflation of kyphopasty balloon with constrast product. (C). Cement injection after the baloon is deflated. (D). 3D Image.

2.2. Cementoplasty procedure

As often as possible, the procedure was performed under general anesthesia in order to provide comfort for patients, especially during trocar progression, which can be painful. Two experienced neuroradiologists (AG and TT) performed the cementoplasties. The patient's position depended on the BM location (procubitus, decubitus or lateral decubitus). Cementoplasty was performed with use of a scanner (Philips brilliance 64) or a biplane vascular system (BN Philips, or Arti Zee Siemens after 2011), which allows for scanner functions in the choice of the trocar progression assisted by I Guide Software. Cement (methyl methacrylate) was injected with a simple 11-gauge trocar or after inflation of a kyphoplasty balloon in order to “dig” the BM and to limit cement leakage risk. Cement injection was controlled by X-ray radiography. Cement radio-opacity was increased by the addition of 5 g tungsten powder per dose of cement (Fig. 1). Afterward, the patient was transferred to the recovery room and then to a hospital bed for clinical monitoring. All patients were examined the day after the procedure.

2.3. Data collection

Data were collected from systematic analysis of medical files including hospitalization and consultation reports, anesthetic files, cementoplasty procedure reports and the hospitalization management software Actipidos. With Actipidos, we could retrospectively collect data on pain on a 0–10 numeric rating scale (NRS).

Patient characteristics collected were sex, age at cementoplasty, age at diagnosis of primitive cancer and age at diagnosis of BM, and American Society of Anesthesiology Score (ASA score). The following data were collected: primitive cancer type, other BM and/or visceral metastasis, BM type (lytic, mixed or sclerotic), cortical rupture, invasion of adjacent tissues, interval between diagnosis of the BM and the day of cementoplasty, other treatment(s) before and after cementoplasty (radiotherapy and/or bisphosphonate), and analgesic treatment before and after cementoplasty according to the World Health Organisation (WHO) steps. Pain on an NRS (patient self-assessment) was collected the day before cementoplasty and during the week after cementoplasty (week 1). Adverse events were also noted.

To evaluate the long-term benefit of cementoplasty, patients were followed up by phone call, by using a standardized feedback questionnaire in order to assess patient satisfaction with the cementoplasty. The period between cementoplasty and the phone survey was recorded. During the phone call, data collected were NRS pain level at the site of cementoplasty on the date of the follow-up phone call, improvement or not of this pain after cementoplasty, evaluation of the cementoplasty procedure on a scale of 0–10 points, quality of life improvement (percentage), areas that had improved (walking, movement in daily life etc.), functional recovery and decrease in analgesic treatment. We also asked if patients would be ready to undergo another cementoplasty if it was necessary.

2.4. Endpoints

The primary endpoint was pain level on an NRS at week 1 compared to baseline collected the day before cementoplasty.

Secondary endpoints assessed the long-term efficacy of cementoplasty (i.e., at the time of the follow-up phone call). We chose to use simple questions and not long questionnaires in order to avoid a long phone call for patients who are usually tired because of their disease.

- Functional disability was assessed with a simple question: “Did your functional capacities improve since the cementoplasty?” (answer yes or no).
- Quality of life was assessed by a simple question: “Did your quality of life improve since cementoplasty?” (answer yes or no, percentage).

- Global satisfaction following the cementoplasty (answer yes or no). Clinical success was defined as a ``yes" answer to the question ``Did you feel an improvement after cementoplasty?" Some possible predictive factors of this clinical success were assessed: period between cementoplasty and the diagnosis of the BM of interest, BM type (lytic, mixed or sclerotic), cortical rupture, invasion of adjacent tissues, quality of filling inside the BM by cement (estimated by the operator as satisfactory or not), cement leakage,and other treatment (s) such as radiotherapy or bisphosphonates (before or after cementoplasty).

Finally, adverse events were collected.

2.5. Statistical analysis

Baseline characteristics are described with descriptive statistics. Mann–Whitney–Wilcoxon nonparametric test was used to analyze pain improvement after cementoplasty. $P < 0.05$ was considered statistically significant.

2.6. Role of the funding source

This was a non-funded study.

3. Results

3.1. Number of assessed patients

Overall, 43 patients underwent cementoplasty between April 2006 and October 2014. For the primary endpoint (i.e., pain on an NRS the day before cementoplasty and at week 1), data were available for 31 patients. For secondary endpoints, including functional disability, quality of life and global satisfaction, data were available for 21 patients (68%). The mean delay between cementoplasty and the follow-up phone call was 22 months (range 4–91). The flow of patients is in Fig. 2.

3.2. Clinical characteristics of patients

Mean age at the date of cementoplasty was 61.6 years old (SD ± 11.7) and at the time of diagnosis of cancer was 57.8 years old (SD ± 11.2). There were 20 men (46.5%). The BM locations were mostly in pelvic bones but also in the femur. Other patient clinical characteristics are in Table 1.

Table 1
Clinical characteristics of patients.

Variable	*N* (number of patients whose data is available)	
Age at the date of cementoplasty, *mean ± SD*		61,6 ± 11,7
Age at the date of diagnostic of primitive cancer, *mean ± SD*		57,8 ± 11,2
Sex (male), *n (%)*		20 (45,5)
ASA[a], *n (%)*[b]	23	
ASA[a] 2		12 (54,2)
ASA[a] 3		11 (47,8)
Pain on NRS[c]		4.3
Primitive cancer, *n (%)*	43	43 (100)
Lung		12 (27,9)
Breast		8 (18,6)
Kidney		6 (14)
Myeloma		5 (11,6)
Cervix uteri		3 (7)
Prostate		3 (7)
Hepatocellular carcinoma		1 (2,3)
Colorectal		1 (2,3)
Melanoma		1 (2,3)
Sarcoma		1 (2,3)
Bladder		1 (2,3)
Unknown		1 (2,3)
Visceral metastasis, *n (%)*		34 (77,3)
Lung		11 (25)
Liver		8 (18,2)
Lymph node		7 (15,9)
Brain		5 (11,4)
Adrenal glands		3 (6,8)
Peritoneal carcinomatosis		2 (4,5)
Lymphangitis carcinomatosa		1 (2,3)
Kidney		1 (2,3)

[a] American Society of Anesthesiology score.
[b] Percentages are calculated on the number of patients for whom data were available.
[c] Pain on numeric rating scale.

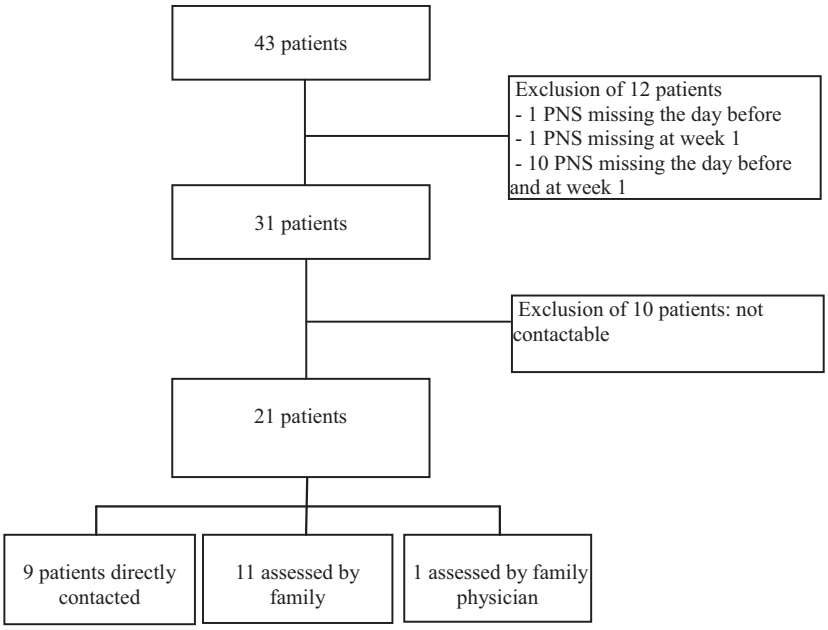

Fig. 2. Flow chart.

Table 2
Characteristics of cemented BM.

Variable	*N* (number of patients whose data is available)	
Site of the bone metastasis, *n (%)*	51	
Acetabulum		20 (39,2)
Iliac crest bone		15 (29,3)
Sacrum		10 (19,5)
Acromion		1 (2)
Iliopubic bone		1 (2)
Ischion		1 (2)
Femoral neck		1 (2)
Lower third of the femur		1 (2)
Tibia		1 (2)
Size (mm), *mean (± DS)*		39 (± 19,6)
Présence of invasion of adjacent tissues, *n (%)*[a]	40	7 (17,5)
Présence of cortical rupture, *n (%)*[a]	41	34 (82,9)
Imaging, *n (%)*	42	
Radiography		2 (4,8)
Scanner		31 (73,8)
MRI		8 (19)
TEP-scanner		1 (2,4)
Type of bone metastasis, *n (%)*[a]	42	
Lytic		32 (76,2)
Mixed		10 (23,8)
Sclerotic		0 (0)
Others treatments of the lesion, *n (%)*		
Radiotherapy	42	19 (45,2)
Period before cementoplasty (month), *mean (± DS)*		5,8 (± 5,7)
Period after cementoplasty (month), *mean (± DS)*		3,9 (± 2,1)
Bisphosphonates	40	15 (37,5)

[a] Percentages are calculated on the number of patients for whom data were available.

3.3. Characteristics of cemented BM

In all, 43 patients underwent 51 cementoplasties; for 6 patients, one procedure was used for two BM locations and for 1 patient three locations. Characteristics of cemented BM are in Table 2. Mean hospitalization duration was 3.4 days and mean general anesthesia duration was 159 min.

3.4. Primary endpoint: efficacy for pain at week 1

Mean pain score on the NRS was 4.2 (SD ± 3.6) the day before cementoplasty and 1.9 (SD ± 2.4) at week 1 ($p = 0.005$). Individual changes in pain score from baseline to week 1 as shown in Table 3: 18 patients improved by ≥ 1 point, 6 patients worsened by ≥ 1 point and 7 patients stayed the same.

3.5. Analgesic treatment

The level of analgesic treatment was available before and at week 1 in 26/31 patients. It remained unchanged in 21/26 (80.7%) patients and was decreased in 5/26 (19.2%) patients. No patient had to increase analgesic level. No improvement of pain is related to the increase of analgesic treatments.

3.6. Predictive factors of clinical success

There was no significant difference in size of bone metastasis and efficacy at week 1, which was in mean (± ET) 40 mm (± 16.2), 38 mm (± 10.3) and 43 mm (± 25.7) for patient with decrease NRS ≥ 1 point, stay NRS and increase NRS ≥ 1 point respectively ($p = 0.79$).

During follow-up we found no predictive factors of efficacy among age, period between BM diagnostic and cementoplasty; type of BM; presence or not of cortical rupture and invasion of adjacent tissues; quality of cement filling inside the BM; or radiotherapy or bisphosphonates treatment (Table 4).

Table 3
Individual changes in pain score from baseline to week 1.

Patient number	Pain day before[a]	Pain week 1[a]	Variation
3	3	4	+1
4	3	2	−1
5	4	5	+1
6	2	0	−2
7	0	0	=
8	7	5	−2
9	9	1	−8
10	5	2	−3
11	2	0	−2
12	0	5	+5
13	9	7	−2
14	4	0	−4
15	0	0	=
16	3	0	−3
17	0	3	+3
19	9	0	−9
20	9	0	−9
21	9	0	−9
25	0	2	+2
27	0	0	=
28	8	0	−8
29	0	0	=
30	0	0	=
31	6	6	=
33	3	0	−3
36	3	6	+3
37	10	5	−5
39	8	6	−2
40	2	2	=
41	5	0	−5
44	10	0	−10

[a] On NRS (numeric rating scale).

Table 4
Predictive factors of efficacy.

Factors	Patients who judged cementoplasty as NO effective ($n = 5$)	Patients who judged cementoplasty as effective ($n = 17$)	*p*
Age *(mean ± DS)*	61.6 ± 10.33	65.41 ± 10.34	0.51
Period diagnostic – cimentoplasty[a] *(mean ± DS)*	6.40 ± 6.99	19.5 ± 25.12	0.23
Type of BM *(n, %)*			1
Lytic	3 (75%)	5 (31.3%)	
Mixed	1 (25%)	(68.8%)	
Cortical rupture *(n, %)*			0.54
Yes	4 (100%)	12 (75%)	
No	0 (0%)	4 (25%)	
Invasion of adjacent tissues *(n, %)*			1
Yes	0 (0%)	1 (6.3%)	
No	3 (100%)	15 (93.8%)	
Bisphosphonates *(n, %)*			1
Yes	1 (25%)	4 (26.7%)	
No	3 (75%)	11 (73.3%)	
Radiothérapy *(n, %)*			0.15
Oui	4 (80%)	6 (37.5%)	
Non	1 (20%)	10 (62.5%)	
Quality of filling by cement *(n, %)*			
Incomplete	0 (0%)	4 (50%)	1
Complet	1 (100%)	4 (50%)	

[a] Period between BM diagnostic and cementoplasty (month).

Table 5
Cement leakage: patients' characteristics.

No. patient	Primitive	Site	Type	Cortical rupture	Adjaent tissues invasion	Size of bone metastasis	Cementoplasty effective (yes/non)	Treatment	Commentary
No. 12	Myelomea	Acetabulum	Lytic	Yes	No	35 mm	MD	Pain-killer	Cortical breaking during procedure. Cement lackage inside gluteus maximus. Sciatica pain. Complete improvement.
No. 17	Hepato-cellular carcinoma	Iliac crest bone	Lytic	No	No	34 mm	Yes	Surgery	Cement lackage the length of trocar
No. 21	Kidney	Lower third of the femur	Mixed	Yes	No	38 mm	Yes	Corticosteroid	Pain on walking. Complete improvement.
No. °23	Lung	Iliopubic bone	Lytic	No	Yes	27.8 mm	MD	Pain-killer	Cement lackage the length of trocar. Pain on walking. Complete improvement.
No. 26	Lung	Iliac crest bone	Mixed	MD	MD	MD	MD	Asymptomatic	Small fragment of cement expelled in soft tissues.
No. 29	Colorectal	Acetabulum	Lytic	No	No	29 mm	D	Pain-killer	Rupture for kyphoplasty balloon.

MD: missing data.

3.7. Secondary endpoints: functional disability, quality of life and patient's global satisfaction

Concerning the 21 patients evaluated by phone, mean improvement in quality of life was 47.6% and functional improvement 52.2%. The mean rating of the cementoplasty procedure was 8.3 of 10 points. In response to the question Would you do another cementoplasty?, 4 (18%) patients replied No and 17 (81%) Yes.

3.8. Adverse events

Considering the 51 cementoplasties, adverse events were:

- 6 cement leakages: 1 asymptomatic, 4 responsible for pain, which quickly resolved, and 1 needing surgery (Table 5).
- 1 hematoma in spinalis and gluteus maximus muscles (without decrease in haemoglobin range, 24 h after cementoplasty).
- 1 acute respiratory distress because of an infection of pulmonary tumor necrosis Embolism of cement in pulmonary arteries was excluded with use of the scanner. The direct link between this complication and cementoplasty is not clear, but tracheal intubation during general anesthesia could be responsible for the infection.

4. Discussion

In agreement with the literature (4, 67, 68), extraspinal BM cementoplasty is quickly effective for relief pain. Moreover, it seems to have long-term efficacy on pain and is also effective to improve functional disability and quality of life. The level of pain must be decreased in these severely ill patients in order to limit bed rest and its complications. Thus, this therapy should be considered, even in patients with short-term life expectancy. Our study confirms that this procedure is useful in BM, especially in flat bones and the pelvis and sacrum. We also included patients with long–weight-bearing bone localizations, where the shear forces do not always allow good resistance of the cemented bones. One may argue the relatively low level of pain the day before cementoplasty. This level is probably underestimated because it was evaluated in patients at rest and patients take numerous pain-killers such as opioids, before cementoplasty.

Our results are consistent with the literature [11–13]. In the Cazzato et al. study [13], the largest study, 66 lesions were treated (51 patients), with local pain relief at 1 month for 59/66 lesions (89.4%). In this study, cement leakage was minor and asymptomatic in 26/66 cases (39.4%). In one case (1/66, 1.5%), a symptomatic minor amount of intra-articular cement leakage occurred. The important and immediate pain reduction after cementoplasty advocates for its own efficacy beyond analgesic treatments.

In our study, some patients were lost to follow-up for several reasons: death or unable to contact. We are aware that questions we used to evaluate the functional impairment and the quality life are too general, but they may reflect the general condition of those severely ill patients. Among the different conditions associated with the cementoplasty success, we could not find any relevant predictive factor. Ianessi et al. [12] could not demonstrate an association between quality of cement filling inside the BM and pain decrease.

As compared with other BM metastasis treatments, cementoplasty has several advantages. First, it can be proposed to fragile patients for whom surgery is too dangerous. Technical feasibility was 100% in skilled hands. Its efficacy is immediate and lasts for a long time, unlike the delayed efficacy of radiotherapy. In addition to its analgesic effect, cementoplasty provides bone consolidation [14]. Local complications included cement leakage (6 in our study), which is the same proportion as in the literature. One patient died of acute respiratory distress because of an infection of pulmonary tumor necrosis. Tracheal intubation during general anesthesia could be responsible for tumor necrosis infection. Most cementoplasties were performed under general anesthesia

Table 6
Mirels' score (17).

	Score 1	Score 2	Score 3
Site	Upper limb	Lower limb	Peritrochanteric
Pain	Mild (< 4 on a 0–10 PS)	Moderate (≥ 4 on a 0–10 PS)	Functional impairment
Lesion radiological aspect	Blastic	Mixed	Lytic
Cortical bone involvement	<1/3	1/3–2/3	≥2/3

Score ≤ 7: < 5% risk of fracture.
Score 8: 15% risk of fracture.
Score ≥ 9: High risk of fracture; stabilization should be considered.

Annex 1
Standardised questionnaire used during calling.

Who is asked? Patient – Family – Family physician
Date of calling:
Date of cementoplasty:
Pain (PNS /10 points):
Did you felt an improvement after cementoplasty?: yes / no
Percentage of improvement between before and after cementoplasty?
Have you decreased analgesic treatments after cementoplasty?: yes / no
Was it easier for you to do things in everyday life (walking, other activities) after cementoplasty?
Percentage of improvement of functional disability?
Functional recovery: no / mild / moderate / normal
Percentage of improvement of quality of life?
Would you do a cementoplasty again if necessary? yes / no
Mark on 10 points the cementoplasty procedure?

(except one local anesthesia with sedation and one local anesthesia switched to general anesthesia because of intense pain during the procedure). In our experience, we prefer general anesthesia for the patient's comfort, although in fragile patients, local anesthetic block would be better. The major drawback of cementoplasty is that it is a palliative technique that must be considered only as an analgesic and consolidative treatment [14].

In our study, no fracture post-cementoplasty procedure occurred. However, the risk of sencondary fracture post-cementoplasty has been reported, especially when treating lesions in long bones [15]. Cazzato et al. showed that secondary fractures occurred in 16 cases (8%, $r = 2.5$) after cementoplasty, but in the same review, no subsequent fracture was observed after percutaneous stabilization coupled with cementoplasty (in 17% of cases) [15]. Therefore, percutaneous osteosynthesis is more effective (with or without cementoplasty) than cementoplasty alone for consolidation of BM of long bones [15]. The indication for cementoplasty should be discussed regarding other possibilities of consolidation. Actually, cementoplasty does not completely achieve effective consolidation. Therefore, it should not be proposed as first-line treatment of dyaphiseal BM. Surgical management (such as endomedullary nailing or other forms of consolidation) should always be considered in patients who are not bedridden and/or have a sufficient life term expectancy [16]. For Cazzato et al., patients with a Mirels score ≥ 9 (Table 6) (considered at high risk of fracture) should be offered dedicated consolidative therapies other than cementoplasty [16,17].

Regarding the consolidation of the femoral neck, our study should be interpreted with caution because of only one lesion on the femoral neck in our patients. BM localization at the pelvic ring and especially the femoral neck is associated with high risk of fracture. In those localizations, surgical options should always be preferred to percutaneous cementoplasty, especially in case of an incident femoral neck fracture, for which cementoplasty is not indicated. In the therapeutic arsenal, percutaneous osteosynthesis (under CT-scan guidance) is an option that offers several advantages over classical surgery (Cazzato and coworkers, published in 2016 [19] and 2017 [20]). Indeed, Deschamps et al. reported successful results with this technique in terms of pain relief, fracture palliation and bone consolidation [18].

The strength of this study is the relatively large number of patients similar to other studies: 50 patients for Anselmetti et al. [11], 20 patients for Iannessi et al. [12] and 51 patients for Cazzato et al. [13]. Another strength is the different localizations of BM: lower limbs and pelvic bones. However, several limitations should be noted. The long-term follow-up was difficult. We decided not to examine patients in person (because of the many recurrent visits and hospitalizations) and considered that a phone call would be more appropriate. Quality of life assessment was not formal assessment but simple binary questions (Annex 1) and it was collected 22 month after procedure; therefore, caution must be exercised when interpreting this efficacy parameter. Some patients were lost to follow-up because of death, refusal, and not able to contact. Finally, we assessed the cementoplasty efficacy for BM and myeloma but we cannot ascertain its efficacy for other bone pathologies.

To conclude, extraspinal cementoplasty is a palliative treatment for BM with an immediate and long-lasting efficacy. The benefit/risk balance seems to favour frail patients. A rigorous clinical examination is paramount before cementoplasty to ensure that the BM is responsible for pain. Other studies with more patients and a prospective design are required.

5. Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

Conflict of interest

There is no financial support or other benefits and no commercial sources for the work, nor any other financial interest for any of the authors that could create a potential conflict of interest or the appearance of a conflict of interest with regard to the work.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jbo.2018.09.004.

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