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GAVIN PUBLISHERS

Journal of Osteoporosis and Bone Research

Mini-Review

Portier A, et al. J Osteopor Bone Res 2: 103.

DOI: 10.29011/JOBR-103.100103

Implementation of A Fracture Liaison Service: An Effective Initiative to Improve Healthcare after Osteoporotic Hip or Wrist Fracture

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Citation: Portier A, Villoutreix C, Beaussier H, Grin A, Glippa S, et al. (2019) Implementation of A Fracture Liaison Service: An Effective Initiative to Improve Healthcare after Osteoporotic Hip or Wrist Fracture. J Osteopor Bone Res 2: 103. DOI: 10.29011/JOBR-103.100103

Received Date: 13 March, 2019; **Accepted Date:** 02 April, 2019; **Published Date:** 11 April, 2019

Abstract

Background: Fracture Liaison Services (FLS) are healthcare models to manage osteoporosis after fragility fracture. The implementation of these models answered to the observation that current healthcare systems missed a lot of opportunities to diagnose and treat osteoporosis after a sentinel fracture.

Objective: To implement a FLS for diagnosis and treatment of patients with osteoporosis fracture. To improve osteoporosis management after wrist or hip fragility fracture.

Design: Monocentric study: phase 1-observational study, phase 2-quasi-randomized study.

Patients: Patients aged (45-95) years, with osteoporotic wrist or hip fracture, diagnosed in the emergency department.

Intervention: phase 1- Contact by telephone at 6 months to assess osteoporosis management. Phase 2- Randomization into two groups, after consent. Patients in the FLS group were given appointments for a Dual-Energy X-ray Absorptiometry (DXA), osteoporosis treatment was initiated if required, and nurses' visits scheduled at 3 and 6 months. Patients in the control group were managed as usual (without FLS implementation).

Main Measures: Correct osteoporosis management, defined by: 1) prescription of DXA for wrist fracture and (2) instauration or decision to start an anti-osteoporotic treatment for hip fracture.

Phase 1: assessed by a phone-call at month 6. Phase 2- assessed by a blinded evaluation of medical files at month 6.

Key Results: 1/144 patients were included. At 6 months, 12 patients with wrist fracture (15.4%) had a DXA prescribed, and 13 with hip fracture (18.8%) were prescribed osteoporosis medication. 2/323 patients were randomized with similar baseline characteristics in 2 groups. At 6 months after wrist and hip fracture, more patients in the FLS group had appropriate osteoporosis management than those in the control group: respectively 50 (83.3%) vs. 16 (17.4%) and 55 (85.9%) vs. 33 (30.8%); ($p < 0.0001$).

Conclusions: The implementation of a FLS program improved osteoporosis management.

Keywords: Healthcare delivery; Osteoporosis; Performance measurement; Rheumatology

Introduction

In spite of progress in knowledge concerning osteoporosis, this disease remains unrecognized in a majority of patients [1]. Nevertheless, patients with osteoporotic fracture are twice likely to have another fracture compared to other people without [2].

In this context, the International Osteoporosis (IOF) proposed a new model of osteoporosis management, named Fracture Liaison Service (FLS) [3,4]. Benefits of FLS have been reported in terms of increased assessment and treatment of osteoporosis, decreased re-fracture risk, and cost-effectiveness [5-8].

Thus, we decided to quantify the "Care gap" in the management of osteoporosis after frailty hip or wrist fracture, then to implement a FLS program and to compare it with usual care in terms of quality of osteoporosis management. This new FLS is now listed among the 300 IOF FLS world-sites [9].

The objective of FLS implementation was to improve osteoporosis management in patients admitted in Emergency Department (ED) for low kinetic Wrist Fracture (WF) or Hip Fracture (HF). The objective of the intervention was to determine whether osteoporosis assessment and treatment were improved by a FLS program, through a randomized controlled trial: OPTIPOST (Optimization of Osteoporosis management).

Material and Methods

OPTIPOST is an academic-driven single-centre study, consisting of an observational cohort (phase 1) and a quasi-randomized pragmatic trial (phase 2; NCT02060747 clinicaltrials.gov).

Settings

Patients were recruited in HPSJ, a secondary public healthcare establishment including 600 beds, with an ED, an orthopaedic department, a rheumatology department, and a geriatric unit.

Participants

All patients between 45 and 95 years, with insurance coverage, attending the ED for low kinetic WF (lower end of radius) or HF (upper end of the femur) were included (inpatients and outpatients). A low kinetic fracture was defined as a fracture caused by a minor trauma (fall from a standing height, sitting or lying position of < 1 meter in height, or down stairs). Fractures in the presence of arthroplasty were not considered. Patients were excluded if they were bedridden, presented serious comorbidities (vital prognosis engaged, according to medical file), were injured in a road accident, or transferred to another hospital.

In phase 2, patients were informed by a letter that a telephone survey would be carried out 12 months after their ED visit and that they could refuse to participate. They were informed about the nurse visits, if concerned. According to French law, no written consent was required. Nevertheless, written information was given to the patient and signed by the doctor. No ethics approval was required for this study

Intervention and Patient Follow Up

Phase 1 ("Real-life" patients)

It was designed to assess current management of osteoporosis after WF or HF, according to French recommendations [10]. Dual-Energy X-Ray Absorptiometry (DXA) and treatment could be prescribed or performed by any doctor (from HPSJ or not).

Phase 2

It was based on a pragmatic experimental design, with implementation of the FLS program. Two new positions were created: a coordinating nurse and a case manager. At baseline, all patients were examined in ED. Emergency care was provided around the clock, 7 days a week. All the eligible patients were provided an information document about osteoporosis with a non-opposition form.

- Outpatients: appointments for both traumatology check-up and DXA, were booked at the moment of their ED visit, planned 15 days after discharge, and confirmed on documents given or sent to patients.
- Inpatients: they were hospitalized in the orthopaedic department and managed by a referent rheumatologist. They underwent biological tests including blood count, serum concentrations of calcium, phosphorus, creatinine, and 25-OH vitamin D. Any vitamin D deficiency was corrected with cholecalciferol (100,000 U) as recommended [11]. DXA was prescribed and performed during hospitalisation, if possible. Prescriptions for DXA (if not performed during hospitalization) and for treatment were present in medical files.

Interventions

The intervention of the nurse and the case manager concerned only patients in the FLS group. Their purpose was to check if DXA or/and anti-osteoporotic treatment were prescribed if required at 4 time points: inclusion, the 15th day traumatology appointment, and specific 3rd (M3) and 6th (M6) months visits. These visits were managed by the nurse with a rheumatologist, and aimed to check the DXA and treatment prescriptions, to complete patient education, to write a letter to the General Practitioner (GP) to assess compliance, and to give advice for preventing falls. If patients were too frail to attend the M3 and M6 visits, they were interviewed by telephone by the nurse at these time points.

For patients in the control group, the nurse and the case manager did not interfere. There was no nurse's visit planned. Prescriptions for DXA and treatment concerning all the patients were in the patient's medical file, with the results of examinations. All participants from both arms were interviewed by a rheumatologist by telephone 12 months after the fracture (M12).

Data Collection

Phase 1

All new records from the ED were reviewed daily to identify eligible patients. Key words sought in the medical records were: hip fracture, wrist fracture, fall, fragility fracture, and osteoporosis fracture. The list of patients was updated in real time. Information was collected by the case manager, with the help of nurses and the senior health manager of the ED. Six months after the fracture, a rheumatologist assessed the management of osteoporosis for each patient by telephone using a standard form.

Phase 2

The FLS was computerized using Dx-Care®, a patient file management program. It was completed by the doctor from ED, by ticking a box in the Dx-Care® in case of fracture, thus creating automatically a specific file, that was completed at M3 and M6 with blood tests, prescriptions of DXA and results if available, prescription of treatment, letter to the GP and dentist opinion for bisphosphonates, if appropriate. Assessment of medical files was performed blindly 6 months after inclusion by one of the rheumatologists. At M12, the questionnaire was assessed by a rheumatologist from HPSJ.

Randomization

Patients were randomized in 2 arms: the FLS group and the control group, depending on the week of the ED consultation. The list of weeks was balanced by a random sequence of blocks of various sizes (2,4 and 6). The ED was not informed of the randomization calendar to prevent possible biases.

Main Outcomes and Measures

The primary outcome was appropriate medical management of osteoporosis, as defined by the French High Authority for Health and the Group of Research and Investigation of Osteoporosis [10-12].

- For wrist fractures: prescription of DXA or, if not, by a letter sent to the GP to prescribe a DXA
- For hip fractures: instauration or the decision to start an anti-osteoporotic treatment (prescription, or a letter sent to the GP to initiate treatment) or, if not prescribed, justification in the record.

This outcome was assessed blindly by one of the rheumatologists 6 months after inclusion by reading the medical file. The secondary outcome consisted of the number of new falls, re-fractures, new hospitalisations, or deaths in the 6 and 12 months after inclusion.

Both phases

Sociodemographic and medical data were collected at baseline (age, sex, weight, fracture location, dementia). For patients with WF and HF, it was noted whether a prescription of DXA or anti-osteoporotic drug respectively was given or sent.

Phase 2 Only

Data concerning new fractures, new falls, new hospitalisations, or death were collected at M12.

Timing

Inclusion in the observational phase was made during a 6 months' period. The duration of participation for an individual patient was 6 months. The interventional phase with FLS program was implemented subsequently after the end of the phase 1.

Sample Size

Based on a previous study in 2008, we hypothesised that the rate of WF for which recommendations were appropriately applied after the ED visit would be 30%, without further intervention, and that this rate would be doubled by FLS implementation. The demonstration of such a difference, with an alpha risk of 5% and a power of 80%, required the inclusion of 42 WF per group. Similarly, for HF, we hypothesised that the rate of appropriate management for patients would increase from 40% to 70%. The demonstration of such a difference, with an alpha risk of 5% and a power of 80%, required the inclusion of 42 patients per group. Stratification was not possible, as randomisation was performed by week of ED attendance rather than patient. Assuming that the incidence of the 2 types of fracture would be roughly equivalent, we decided to include 100 patients per group in the randomised trial, corresponding to 50 patients per fracture type.

Based on the results in phase 1, approximately 25% of the patients included in the FLS arm suffered from dementia. We included these patients in the quasi-randomised study. However, we included an additional 35 subjects per study arm to overcome the potential lack of data and difficulties of follow-up, assuming that the proportion of patients with dementia recruited would be uniform throughout the study, leading to a total sample size of 270 patients.

Statistical Analysis

The results are reported according to the criteria of the Consort Statement, taking the quasi-randomisation into account.

An intention-to-treat analysis was performed. We tested for potential differences using Student's t test for continuous variables and Chi² tests for discrete variables, or their non-parametric equivalents. Relative risks and corresponding 95% confidence intervals were based on the standard Wald asymptotic confidence limits. Agreement between blinded assessment of osteoporosis management at M6 and data collected by the nurse from case reports was assessed using a kappa coefficient. A subgroup analysis for dementia patients was conducted using the same methods. Data analyses were conducted using SAS version 9.4 (SAS Institute) with a threshold of $P \leq 0.05$.

Results

Phase 1: Observational Study

Population

From October 14th 2013 to April 10th 2014, 155 patients were enrolled from ED. After exclusion of bedridden patients, those with another fracture, and those transferred to another hospital, 144 patients were finally assessed. Among them, 123 patients had a complete follow-up (12 died, 5 were lost to follow-up, 4 wanted to stop). Data from all 144 patients were finally analysed.

Baseline characteristics

Of the 144 patients, 78 presented with HF, 69 with WF, 3 patients with both. At baseline, the mean age was 79.7± 11.1 years, 118 (81.94%) patients were women, and the mean body mass index was 23.1 +/- 4.4 kg/m².

Primary outcome

Six months after fracture, 12 (15.4%) patients with WF, and 13 (18.8%) with HF had received appropriate medical management. DXA was performed for six (7.7%) patients with WF.

Phase 2: Quasi-Randomized Study

Population

From April 22nd 2014 to October 7th 2015, 327 patients were assessed for eligibility. After exclusion of 2 patients not meeting the inclusion criteria and 2 patients who declined to participate, 323 patients were randomized: 126 in the FLS group and 197 in the control group. However, 1 patient initially allocated to the control group finally received enhanced care in the FLS group. The flow chart is shown in (Figure 1).

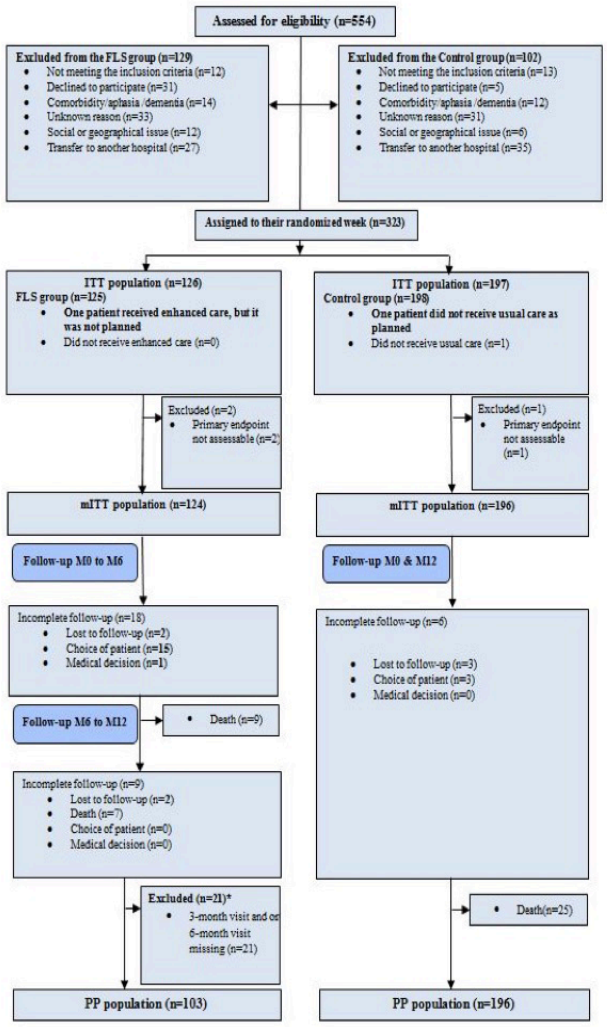

Figure 1: Flow chart of quasi randomized study.

Baseline Characteristics

Most patients were female (272, 84.2%). At baseline, the mean age was 77.5 years. In the FLS group, 66 (52.4%) patients presented with HF and 60 (47.6%) with WF. In the control group, 108 (54.8%) patients presented with HF and 92 (46.7%) with WF. Three (1.5%) patients in the control group and no one in the FLS group presented concomitant WF and HF. Baseline characteristics were comparable between the 2 groups (Table 1).

Characteristics	FLS Group (n= 126)		Control Group (n=197)*	
	Hip (n=66)	Wrist (n=60)	Hip (n=108)	Wrist (n=92)
Sociodemographic data				
Age (years), Mean (SD)	80.74 (10.6)	72.40 (10.6)	82.00 (9.9)	73.11 (11.6)
Female sex N (%)	50 (75.8)	58 (96.7)	87 (80.6)	79 (85.9)
Weight (kg), mean (SD)	60.9 (14.1)	63.0 (11.8)	61.0 (15.4)	65.2 (14.7)
Body mass index (kg/m^2), mean (SD)	22.5 (4.7)	25.1 (4.4)	23.4 (4.7)	24.7 (5.2)
Fracture-related pain: VAS*, mean(SD)	1.89 (1.0)	1.85 (0.7)	2.0 (1.1)	1.86 (0.9)
*3 patients had a wrist and a hip fracture Other location fracture: 24 (19.1%) in FLS group and 32 (16.3%) in Control Group				

Table 1: Quasi-randomized study: Baseline characteristics of the 323 randomized Patients with Hip or Wrist fragility fracture. Values are numbers (percentages) unless stated otherwise.

Primary Outcome

Appropriate osteoporosis management assessed blindly at M6 by physicians was noted for 105 (84.7%) patients in the FLS group and 48 (24.5%) in the control group (RR [95%IC]: 3.46 [2.67-4.47]; $p < 0.001$). This significant difference concerned both fractures: 50 (83.3%) versus 16 (17.4%) patients with WF (RR [95%IC]: 4.80 [3.03-7.59]; $p < 0.001$) and 55 (85.9%) versus 33 (30.8%) patients with HF (RR [95%IC]: 3.46 [2.06-3.76]; $p < 0.001$), for the FLS and control groups, respectively. There was a significantly higher relative risk of appropriate osteoporosis management in the FLS group than the control group (Table 2).

	FLS* group,		Control group		RR†	95% CI	P-value‡
	124		196				
	N	n (%) with appropriate management	N	n (%) with appropriate management			
wrist fractures	60	50 (83.3)	92	16 (17.4)	4.8	3.03-7.59	<.001
hip fractures	64	55 (85.9)	107	33 (30.8)	2.79	2.06-3.76	<.001
wrist or hip fractures	124	105 (84.7)	196	48 (24.5)	3.46	2.67-4.47	<.001
*FLS: Fracture Liaison Service †RR: Relative Risk ‡Chi-square test							

Table 2: Appropriate medical osteoporosis management assessed retrospectively by two physicians, blinded to group, by medical record review at M6 of m-Intention-To-Treat (m-ITT) population.

Secondary Outcomes

We observed more appropriate osteoporosis management, assessed by nurse at M3 and M6 visits and at telephone call at M12, for more patients in the FLS group than the control group, using case report forms. Concerning WF, we observed correct osteoporosis management (prescription of DXA, or not if justified) during the period from inclusion to 12 months through case report forms for 55 (91.7%) patients in the FLS group versus 23 (25.0%) in the control group ($p < 0.0001$). Concerning HF, we observed correct management for 49 (76.6%) patients in the FLS group versus 29 (27.1%) in the control group ($p < 0.0001$). For most patients with WF, the prescription was recorded at M0, whereas it was made after 6 months for patients with HF (Table 3).

Patients with hip Fracture	FLS* group	Control group	P-value
N=171	N=64	N=107	
Prescription for antiosteoporotic drug, if required‡, including visits at M0, M3, M6, and M12	49 (76.6)	29 (27.1)	<.001
M0 visit	14 (21.9)	17 (15.9)	0.3
M3 visit	29 (45.3)	-	-
M6 visit	6 (9.4)	-	-
M12 phone call	0 (0.0)	12 (11.2)	<.001

*FLS group: Fracture Liaison Service Group.
†Prescription of Bone Mineral Density measurement with Dual-Energy X-Ray Absorptiometry (DXA).
‡Including prescription by physicians from St Joseph Hospital and prescriptions by other physicians
Three patients had a hip and a wrist fracture.

Table 3: Appropriate osteoporosis management assessed by specific nurse visits at M3 and M6 for patients with wrist and/or hip fracture.

There was good agreement between blinded assessment by the doctor and assessment from case report forms by the nurse for both WF and HF with kappa values of 0.73 [0.69-0.89] and 0.76 [0.61-0.91], respectively. Zoledronate was the most often prescribed treatment (49.2%) for patients with HF, followed by Alendronate (40.3 %). Risedronate was the most current treatment (44.0 %) for patients with WF, followed by Alendronate (20 %) (Table 4).

Anti-osteoporotic drug	Patients with Wrist Fracture and prescription of anti-osteoporotic drug	Patients with Hip Fracture and prescription of anti-osteoporotic drug
	N (%) n=25	N (%) n=67*
Alendronate N (%)	5 (20.0)	27 (40.3)
Risedronate N (%)	11 (44.0)	3 (4.5)
Zoledronate N (%)	4 (16.0)	33 (49.2)
Teriparatide N (%)	0 (0.0)	1 (1.5)
Raloxifene N (%)	3 (12.0)	0 (0.0)
Strontium N (%)	0 (0.0)	0 (0.0)
Denosumab N (%)	2 (8.0)	3 (4.5)

Table 4: Characteristics of anti-osteoporotic drug prescription (m-ITT).

During the 12-month period after fracture, 91 patients experienced new falls: 40 (32.3%) in the FLS group and 51 (26.0%) in the control group (p=0.16). Amongst them, 20 patients presented with a new fracture: 6 (4.8%) in the FLS group and 14 (7.1%) in the control group (p=0.43) (Table 5).

	FLS* group	Control group	RR†	SE	P-value
	N=124	N=196			
Refracture N(%)	6 (4.8)	14 (7.1)	0.69	0.28-1.75	0.43
New fall N(%)	40 (32.3)	51 (26.0)	1.27	0.91-1.77	0.16
New hospitalisation N(%)	27 (21.8)	47 (24.00)	0.93	0.62-1.39	0.72
Death N(%)	15 (12.1)	25 (12.8)	0.95	0.52-1.73	0.86

*FLS group: Fracture Liaison Service Group
*†RR: FLS vs Control Group

Table 5: Re-fracture rate, new falls, new hospitalisations or death assessed at the M6 visit with the nurse and M12 telephone call for the m-ITT population (n=320), from M0 to M12.

Among the 15 patients with dementia with WF, DXA was prescribed for 6 in the FLS group (100%) and 1 patient in the control group (11.1%), p=0.001. Among the 33 patients with dementia with HF, 11 in the FLS group (73.3%) and 5 patients in the control group (27.8%) received a prescription for anti-osteoporotic drug, p=0.01. There was no difference in the rates of mortality, re-fracture, or new falls for dementia patients. Among patients receiving a prescription for DXA, DXA was performed for 42 (76.4%) in the FLS group and 7 in the control group (46.7%) (p=0.02).

Discussion

The implementation of a FLS program was an effective method to improve osteoporosis management. The rates of baseline osteoporosis investigation and treatment were very low before implementation of the FLS, suggesting a lot of "Missed opportunities", that the FLS can capture.

Rigorous management was essential for FLS, in terms of human capital, with dedicated actors, material support in the form of computerized medical records, and coordination between medical departments. The central role of the nurse has to be underlined. The age of patients, their associated comorbidities and the complex care pathways after fracture were difficulties for FLS implementation. Then, telephone follow-up could be complicated by hearing loss, poor comprehension, language impairment.

One of the strengths of the study was to prove that the management of osteoporosis was inadequate in the absence of systematic intervention. Another strength was the efficient recruitment of subjects, due to systematic identification of low energy fracture in the ED. The benefits of a FLS were also proven in the subgroup of people with dementia; these patients are often excluded from trials, because of difficulties to investigate and treat this subgroup. Finally, systematic blinded assessment avoided measurement biases.

A 1st limitation was the difference between the number of patients in the 2 groups, despite randomisation. This occurred due to 4 main factors: 1/ we used quasi-randomisation for reasons of feasibility, 2/ patients allocated to the FLS group often refused to be included because they had to go to the hospital for appointments at M3 and M6, 3/ patients were transferred to another hospital for organizational reasons, and 4/ patients had medical issues that made it difficult to manage their osteoporosis at the time of the study. There was globally good agreement between blinded assessment by doctors at M6 and the results from case report forms reported by the nurse at the M6 visit. However, some cases of disagreement could be explained by a lack of coordination between the orthopaedic department, in which the prescription of the anti-osteoporotic drug was given to the patient, but not always described or entered into medical files. Discrepancies also occurred due to difficulties in finding all prescriptions, at a time when all medical data were not yet completely integrated into electronic files. There was a trend towards a lower incidence of re-fracture and new falls in the FLS group relative to the control at 12 months, but the result was not statistically significant. Another limit of this study concerned the absence of formal assessment of falls risk, although benefits of falls assessment in IOF programs have been reported [13,14]. Fall prevention can optimize global patient health and preserve autonomy. We aim to subsequently create a specific collaboration between a fall-related unit and our FLS in HPSJ. Finally, we did not assess adherence to anti-osteoporotic treatment.

The "Gap" in osteoporosis management after fracture was already reported [15-17]. Thus, FLS programs were implemented to care "Missed opportunities". Majumdar, et al. found that patients with osteoporotic hip fracture were more likely to receive osteoporosis drugs in the interventional group (with a specific case manager) than patients in the control group (51 versus 22%, $p < 0.001$) [19]. As in our study, the intervention of a case manager and/or dedicated nurse was also beneficial in other models of FLS [19-23]. In contrast with other studies, we

did not observe an improvement in fall incidence and mortality with the implementation of FLS, probably due to the short period of assessment (12 months) [22,23]. Dementia patients need to be included in FLS, because dementia was associated with a lower probability of using anti-osteoporotic drugs in spite of worse consequence after fracture in those frail patients [24-25].

Finally, FLS implementation answers to the "Gap" of osteoporosis management after frailty fracture. In France, osteoporosis was recently defined as a national priority, in the same status as cardiovascular disease; we hope that FLS programs will be developed and improved.

Acknowledgements

The authors acknowledge the doctors of the emergency and the orthopaedic departments who were involved in the study, particularly Dr Olivier Ganansia, Dr Abdelslam Mohamed-Hadj, and Dr Pomme Jouffroy. Finally, we acknowledge all the people who participated in our study and all the providers involved who remained committed and supportive.

Conflicts of interests

All authors: A. Portier, C. Villoutreix, H. Beaussier, A. Grine, S Glippal, A. Vilfaillot, K. Camaret, D. Llop, G. Chatellier, G. Rajzbaum declare that they have no competing interest.

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