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Original article

Usefulness of a pre-procedure ultrasound scanning of the lumbar spine before epidural injection in patients with a presumed difficult puncture: A randomized controlled trial

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ABSTRACT

Ultrasound (US) is widely used in rheumatology to study and guide injection of peripheral joints. It can also provide useful information about the anatomy of the lumbar spine. Studies have shown that US examination of the spine was a useful tool to help perform epidural anaesthesia. The purpose of the study was to determine if the selection of the optimum puncture level by US may facilitate epidural steroid injection in case of presumed difficult puncture (BMI > 30 kg/m^2, age > 60 years or lumbar scoliosis).

Methods: We performed a prospective randomized controlled study. Eighty patients were randomized in two groups: US group ($n = 40$) which underwent a pre-procedure spinal US to determine the optimal lumbar level for injection or control group ($n = 40$) for which the level of injection was determined by palpation. Primary endpoint was the pain during the procedure assessed using the Visual Analogue Scale (VAS).

Results: We found a positive correlation between depth of the epidural space and BMI ($P < 0.001$) and a negative correlation between size of the interspinous spaces and age ($P < 0.01$). Visibility of the epidural space was not altered by obesity or age. We observed a trend toward a reduction in pain intensity during the procedure in the US group compared to the control group with a mean difference at −0.94 [−1.90; 0.02] but the difference was not significant ($P = 0.054$).

Conclusion: US of the lumbar spine was feasible in patients with lumbar conditions even in obese and old ones and allowed the visualization of the epidural space. However, pre-procedure US examination did not reduce pain during the procedure.

1. Introduction

Epidural injections are one of the most commonly performed interventions in rheumatology practice. They are mainly used to treat radicular pain from herniated discs or spinal stenosis [1]. Three different routes of administration are currently available: interlaminar, transforaminal, and caudal. Although usually easy to perform, steroid epidural injection through the interlaminar space can sometimes be challenging, more particularly in old and obese patients. Indeed, performing this procedure relies primarily on the palpation of anatomical landmarks, which might be obscured in the context of obesity or anatomical variation. Multiple needle insertions and redirections are known to increase pain and discomfort for patients [2]. Finally, accidental dural puncture can occur and lead to post-dural puncture headache [3]. Although X-ray guidance could be an option to guide epidural injection, it delivers a radiation dose to the patient and the physician. Ultrasound (US) has recently demonstrated its ability to produce a reliable and accurate depiction of the lumbar spine anatomy. It has also emerged as one of the new tools to perform guided spine injections. First descriptions of the US spinal anatomy have been reported in the 1980s [4,5]. Although the images were of poor quality by today's standards, the authors were able to define the lamina, ligamentum flavum, spinal canal and vertebral body. These studies have reported a strong relationship between the epidural space depth measured by US and the insertion depth of the needle, confirmed more recently by other authors [6,7]. US can also help to identify

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the interspinous spaces where palpation has been shown to be frequently inaccurate [8]. Pre-procedure US scanning of the lumbar spine is currently widely used to help perform epidural anesthesia or lumbar puncture [9–11]. A recent meta-analysis has confirmed that US could reduce the risk of failed or traumatic procedures and decrease the number of attempts and redirections of the needle [12].

US of peripheral joint is now widely used in rheumatology practice. In contrast, few studies have explored the interest of lumbar spine US in rheumatic diseases. We recently suggested that US could detect changes in the facet joints such as joint space irregularity, osteophytes, and calcifications [13]. It can also show interspinous bursitis or changes in the paravertebral muscles [14,15]. Most studies have focused on the use of US to guide various spine procedures. Ultrasound has been notably used to guide facet joint [16] and peri-radicular injections [17]. We also showed in 30 consecutive patients that real-time US guidance of steroid injections via the sacral hiatus was safe and accurate [18]. As pre-procedure US scanning of the lumbar region has been shown to be useful in obstetric epidural anesthesia or before a lumbar puncture, we asked the question whether it could also be useful before an interlaminar steroid epidural injection. Indeed, patients presenting with low back conditions are older and have a higher risk of degenerative changes in the lumbar spine and the usefulness of this imaging needs to be confirmed in this population. The objective of our study was to determine if a pre-puncture ultrasound examination of the spine may facilitate the injection and thus decrease the pain associated with the procedure.

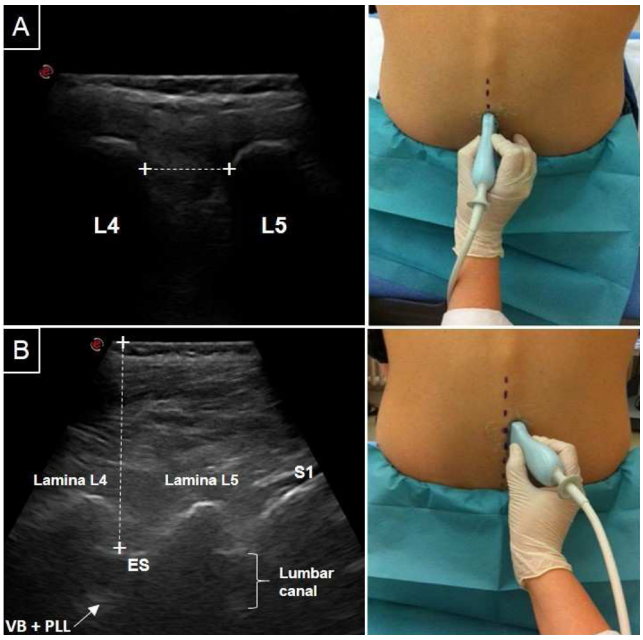

Fig. 1. Technique for measuring the distance between two spinous processes (A) and the depth of the epidural space (B) (ES: epidural space; VB: vertebral body; PLL: posterior longitudinal ligament).

2. Methods

2.1. Design

We conducted a monocentric, prospective, randomized, single-blind, controlled study (NCT01832844). The purpose of the study was to determine if a pre-puncture examination of the lumbar spine with US could reduce the pain during epidural injection when puncture is presumed difficult. The study was conducted between April 2013 and January 2014 in the department of Rheumatology of the Nantes University Hospital. The study was approved by the local ethics committee. Informed consent was obtained from each patient before inclusion in the study. There was no change to the design or protocol during the course of the trial.

2.2. Participants

All patients hospitalized for steroid epidural injection for the treatment of sciatica due to disc herniation or lumbar stenosis were assessed for eligibility. Inclusion criteria used to define a presumed difficult puncture were BMI (Body Mass Index) > 30 kg/m^2, age > 60 years or lumbar scoliosis (Cobb angle > 10°) [19,20]. Patients with a history of spinal surgery or spinal malformation like spina bifida, pregnant women, patients taking anti-platelet drugs and those participating in another study were excluded. Patients were allowed to continue analgesics if previously prescribed. They were also allowed to receive premedication with benzodiazepines in case of anxiety.

2.3. Assessment and interventions

A total of 80 patients were randomized (n = 40 per group). Patients were allocated in 2 groups: US group and control group using a randomization with blocks, online with Capture System software. After randomization, patients remained blinded to their group allocation. Patients of the US group underwent a pre-puncture examination of the lumbar spine by two experimented operators (CDL and BLG) using an ESAOTE MyLab 70x Vision with a linear ultrasound probe (3–11 MHz). In order to have a wider field of view, we used the trapezoid mode of our probe. On a seated patient, ultrasound examination started with a longitudinal median view through the spinous processes. The spinous processes were seen as a series of hyperechoic lines with upward convexity and posterior acoustic shadowing. To identify the vertebral levels, we first located the sacrum, seen as a continuous hyperechoic line and then moved up to its superior edge to identify the L5-S1 interspinous space. The probe was then moved cranially to identify the L4-L5 and L3-L4 interspinous spaces. The minimal distance between two spinous processes was measured on the longitudinal view at the three lower lumbar levels (Fig. 1A). Next, we performed a longitudinal paramedian oblique view to locate the epidural space. The transducer was positioned vertically 1–2 cm lateral to the spinous process and the ultrasound beam was directed obliquely toward the midline. The spinal canal was visible between the interlaminar spaces. The delineating structures were the ligamentum flavum and dura mater posteriorly and the posterior vertebral-body cortex and posterior longitudinal ligament anteriorly. The epidural space was a thin hypoechoic line between the two hyperechoic lines produced by the ligamentum flavum and the posterior dura mater (Fig. 1B). Using this view, we measured, at each lumbar level, the depth of the epidural space. Finally, visibility and accessibility of the epidural space were rated using a semi-quantitative score: 0 for “not”, 1 for “moderate” or 2 for “good” [21]. The score of “2” was the clear appearance of the epidural space as a thin hypoechoic line between the two hyperechoic lines produced by the ligamentum flavum and the posterior dura mater. The score of “0” corresponded to the absence of visibility of the epidural space. The score of “1” corresponded to the intermediate visibility. In this case, the epidural space was located using the hyperechoic structures but the thin hypoechoic line could not be well defined. According to these data, we determined the optimum level to perform the epidural injection. Patients of the control group underwent a ‘fake’ US examination (making the probe touch the skin without recording images) to remain blinded to their group allocation and the level of injection was selected using the traditional landmark technique. An interlaminar

injection of 5 ml of Hydrocortisone was then performed by the same operator, not blinded to US findings, with the patient in seated position. We used an epidural needle (75 or 90 mm, 22 GA) with the "loss-of-resistance" technique to identify the epidural space.

2.4. Outcome measures and baseline variables

For all study patients, we collected sex, age, Body Mass Index (BMI), type of radicular pain (L4, L5, S1 or radicular claudication), presence and angle of a lumbar scoliosis, use of analgesics and premedication.

Our primary outcome measure was the patient-reported pain during the epidural injection assessed by a Visual Analogue Scale (VAS) (0–10 cm). This scale have been shown to be a reliable, valid, fast and responsive instrument for measuring pain and was chosen for its simplicity and acceptability to participants [22]. VAS's were obtained just after the epidural injection. Secondary outcomes included the number of redirections of the needle necessary to reach the epidural space. We considered as redirection each time the direction of the needle needed to be changed without the need to remove it from the skin. A new puncture was defined as the need to withdraw the needle from the skin to change the puncture site. We also assessed the time necessary to perform the injection, i.e. the time between the skin puncture and the end of the injection of hydrocortisone. We collected immediate side effects (bleeding, increase of radicular pain and dural breach) and those occurring 48 hours after the epidural injection (bruise, post-dural puncture headache, pain at the puncture site). Data were also collected during the US scanning. The size of the interspinous spaces in the longitudinal median view and the depth of the epidural space in the longitudinal paramedian oblique view were recorded.

2.5. Statistical analysis

A full intention-to-treat analysis was conducted with each participant included in the original allocation group. Qualitative variables were described as numbers and percentages whereas quantitative variables were described with maximum, minimum, mean and standard deviation.

For primary outcome, we compared the mean VAS pain using a Student *t*-test. To examine the effect of covariate on pain, linear model was extended with covariate adjustment. Tests for interaction were used to assess the effect of age or BMI on pain. We compared the time required for the procedure using a Student *t*-test. The number of attempts was compared by a Khi^2 test. Complications were described in terms of numbers and percentages. Correlation between the US measurements and age or BMI was searched with a Pearson test. Visibility and accessibility of the epidural space at each lumbar level were compared using a Wilcoxon signed-rank test. A *P*-value < 0.05 was deemed to be statistically significant. To determine the sample size, a 2-point difference between groups was designated as clinically important. With a power of 80% and an alpha risk of 5%, we needed 74 patients to detect a between-group effect of 2 on 10 points for the primary outcome. To guarantee sufficient power, we planned to include 80 patients. All analyzes were performed using SAS v.9.3 software.

3. Results

Between April 2013 and January 2014, 171 patients were assessed for eligibility. Eighty-nine did not meet the inclusion criteria and 2 patients declined to participate. Eighty patients were finally randomized (40 per group) and analyzed. No patient was lost of follow-up or discontinued the study. The study flow chart is presented in Fig. 2.

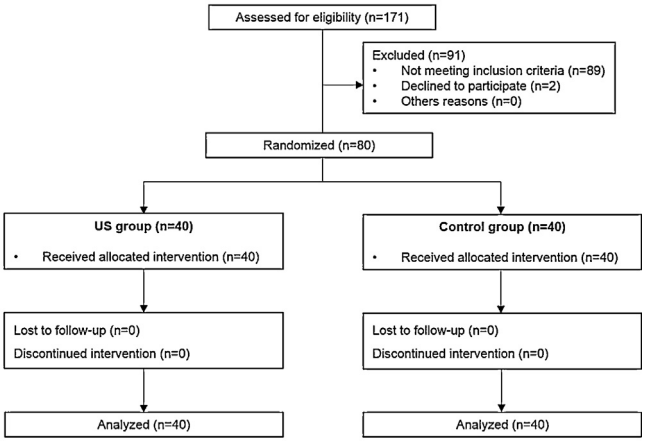

Fig. 2. Study flow chart.

Patients' baseline characteristics are summarized in Table 1. Twenty-four patients (60%) in the US group and 23 (57%) in the control group were over 60 years, 22 patients (55%) in the US group versus 19 (47%) in the control group had a BMI > 30 kg/m^2. Lumbar scoliosis with a Cobb angle > 10° was present in 8 patients (20%) of the US group and in 6 (15%) of the control group. 13 patients of the US group versus 8 of the control group met more than one criterion defining a difficult puncture. The majority of patients were taking analgesics (82% in the US group and 75% in the control group) and only a few received premedication (5 patients in the US group and 3 in the control group).

The epidural space was not visible at the L3-L4 and L4-L5 levels in two cases, whereas the visibility was sufficient for all patients at the L5-S1 level. The average depth of the epidural space was 49.9 mm (± 13.4) at the L3-L4 level, 49.6 mm (± 13.6) at the L4-L5 level and 48.4 mm (± 14.8) at the L5-S1 level. The average distance between spinous processes was 13.4 mm (± 5.5), 14.3 mm (± 5) and 14.9 mm (± 4.8) at the L3-L4, L4-L5 and L5-S1 levels respectively. We found a positive correlation between the depth of the epidural space and BMI (Fig. 3A). The distance between spinous processes was reduced in older patients at each lumbar level (Fig. 3B). The visibility and accessibility of the epidural space were assessed using a semi-quantitative score from 0 to 2 as described in the method section. There was no difference of visibility between the three lumbar levels. Interestingly, the visibility of the lumbar epidural space was not altered by weight or age. We found a lower accessibility at the L3-L4 level compared to the L4-L5 level (*P* = 0.008). After US scanning, the optimum level to perform the injection was L4-L5 in 22

Table 1
Baseline demographic and clinical characteristics of study patients.

	US group, *n* = 40	Control group, *n* = 40	*P*
Age, Mean ± SD (years)	61.3 ± 17.8	63.8 ± 15.1	ns
Men, *n* (%)	14 (35)	13 (32)	ns
BMI (kg/m^2)	30.1 ± 6.9	29.8 ± 6.2	ns
L4 crural neuralgia, *n* (%)	4 (10)	5 (13)	ns
L5 sciatica, *n* (%)	16 (40)	21 (52)	ns
S1 sciatica, *n* (%)	11 (27)	9 (22)	ns
Radicular claudication, *n* (%)	9 (23)	5 (13)	ns
Age > 60, *n* (%)	24 (60)	23 (57)	ns
BMI > 30, *n* (%)	22 (55)	19 (47)	ns
Lumbar scoliosis, *n* (%)	8 (20)	6 (15)	ns
> 1 criteria of presumed difficult puncture, *n* (%)	13 (32)	8 (20)	ns
Analgesic treatment, *n* (%)	33 (82)	30 (75)	ns
Premedication, *n* (%)	5 (13)	3 (7)	ns

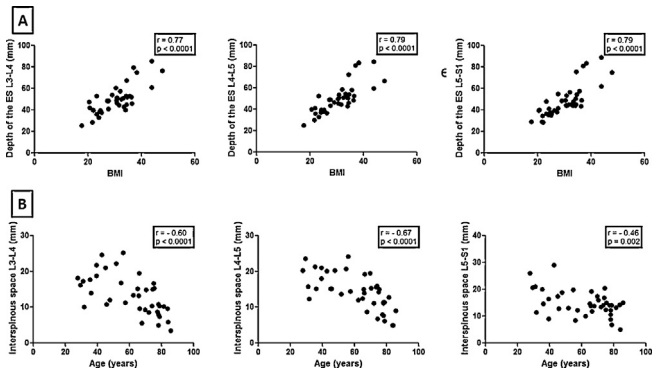

Fig. 3. Correlation between interspinous spaces and patient age (A) and between the depth of the epidural space (ES) and patient BMI (B), at each lumbar level.

cases (55%) ($n = 22$), L5-S1 in 17 cases (42.5%) and L3-L4 in only 1 case (2.5%).

The primary endpoint of our study was to assess if a pre-procedure US scanning could decrease pain during the procedure. We found a trend toward a reduction in pain during the epidural injection in the US group compared to the control group. Indeed, pain was 2.01 ± 1.6 in the US group versus 2.95 ± 2.5 in the control group, mean difference of -0.94 [-1.90; 0.02] ($P = 0.054$). To examine the effect of covariate on pain, linear model was extended with covariate adjustments. Tests for interaction were used to assess the effect of age or BMI on pain. Model with covariate adjustment were not significant for BMI (P for interaction = 0.59). For patients over 60 years old, mean VAS was 1.86 ± 1.61 in the US group versus 3.50 ± 2.58 in the control group with a mean difference of -1.64 [-2.88; -0.40] (P for interaction = 0.08) (Fig. 4).

We found no significant difference between the 2 groups in the secondary outcomes (Table 2). Epidural injection was performed in a single attempt in 55% for the US group compared to 40% for the control group (P = ns). The average time necessary to perform the injection was 65.9 ± 31.8 seconds in the US group versus 77.3 ± 39.2 seconds in the control group (P = ns). The number of immediate or late complications was not different in the 2 groups (Table 2).

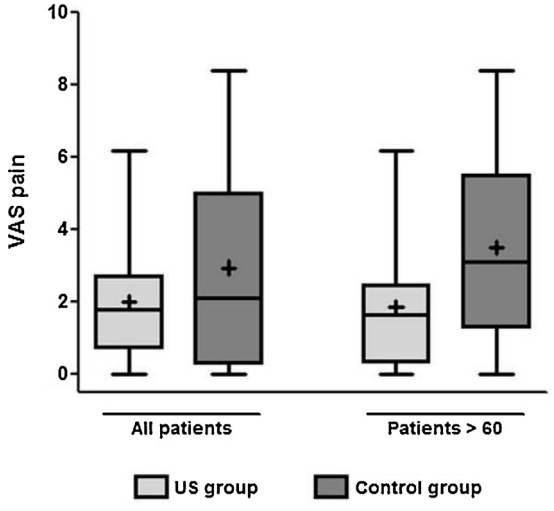

Fig. 4. Comparison of VAS pain between the two groups and in the subgroup of patients over 60 years. Data are represented in minimum, maximum, median, mean (+) and standard deviation.

Table 2
Secondary outcomes and complications of epidural steroid injections in the US group and the control group.

	US group, $n = 40$	Control group, $n = 40$	P
VAS pain/10, mean ± SD	2.01 ± 1.6	2.95 ± 2.5	0.054
Number of redirections, mean ± SD	1.6 ± 2.7	2 ± 2.7	0.53
Injection in a single attempt, *n* (%)	22 (55)	16 (40)	0.17
Redirection ≥ 1, *n* (%)	18 (45)	24 (60)	ns
Time, mean ± SD (s)	65.9 ± 31.8	77.3 ± 39.2	0.15
Number of site puncture > 1, *n* (%)	0	2 (5)	ns
Procedure immediate complication			
Bleeding, *n*	1	1	ns
Dural breach, *n*	2	2	ns
Increase of radicular pain, *n*	4	5	ns
Procedure complication after 48 h			
Ecchymosis, *n*	1	2	ns
Post-lumbar puncture headache, *n*	0	0	ns
Pain at the puncture site, *n*	1	0	ns

4. Discussion

US of the lumbar spine is currently widely used in the field of anesthesiology to help perform epidural anesthesia [12]. This technique is also useful to help perform lumbar puncture in the context of emergency care [23]. Epidural steroid injection remains one of the most common treatments for sciatica or radicular claudication. In this study, we asked the question whether US could also be useful in rheumatology practice to help perform epidural injection. Our study is the first to evaluate the feasibility of a US pre-procedure scanning in a population of patients with sciatica or lumbar stenosis. Until now, the feasibility of this imaging procedure has been mainly studied in the context of epidural anesthesia. Most of the studies were in the setting of obstetric anesthesia, and thus included a population composed of young and healthy women [24]. Here, we show that although more than 60% of our patients were over 60 years old, the epidural space was visible in all patients. This is in accordance with the results of Chin et al. who performed US of the lumbar spine in 50 patients with a mean age of 67 years old, undergoing total joint arthroplasty [25]. They showed that the epidural space was visible at one or more inter-vertebral levels in all their patients. US of the lumbar spine is thought to be technically challenging because of the depth of the anatomical structures studied. It is even truer in obese patients where subcutaneous adipose tissues can hamper the propagation of the US beam. In our study, visibility of the epidural space was good even in obese patients. In this population, we observed a good correlation between BMI and the depth of the epidural space at each lumbar level. Moreover, US localization of the epidural space can also be challenging in older patient due to the frequency of degenerative changes of the spine. Elderly patients may have degenerative spinal diseases with narrowed interspinous and interlaminar spaces as a result of ossification of the interspinous ligaments and hypertrophy of the facet joints. We confirmed this hypothesis and found a negative correlation between age and distance between interspinous processes. However, despite these changes, visualization of the epidural space was still possible in all patients. This confirms that the oblique paramedian longitudinal view is the optimum window for ultrasound imaging of the epidural space [26].

The main objective of our study was to assess if US could decrease the pain during the epidural injection procedure. We

included patients older than 60 years old or with spinal deformities (lumbar scoliosis) or altered anatomical landmarks (obesity, BMI > 30 kg/m^2). We found a trend toward a reduction in the VAS pain during the injection in the US group compared to the control group but the difference was not statistically significant. However, the mean level of pain in our study was lower than what we had expected. Indeed, we assessed in a preliminary study the level of pain experienced during epidural injection in a sample of patient and found a mean VAS pain of 5/10. We therefore established as clinically relevant a reduction in pain of 2 points. We finally observed a mean VAS pain of 2.95 in the control group, making the clinically 2-point difference difficult to achieve. The Hawthorne effect, which influences evaluations made by physicians especially during clinical trials and most notably when the evaluation criterion is subjective, might explain this result. In clinical trials, this effect can result in a marked decrease in pain scores [27].

Our study is the first to evaluate the pain during the procedure as a primary outcome. Indeed, studies performed in anesthesiology have usually focused on the efficacy of anesthesia or the number of attempts to reach the epidural space. Nevertheless, some studies have assessed the comfort of the patient as a secondary outcome. Chin et al. did not find that US improved the comfort of the patients during epidural anesthesia before a prosthesis surgery [19]. On the opposite, Grau et al. showed in two studies that patient satisfaction was better with than without US [20,24]. However, the intensity of pain associated with epidural catheterization and steroid injection procedure is probably different. Moreover, in these studies, patients were not blinded to their allocation group, making changes in subjective evaluation such as comfort or satisfaction difficult to interpret.

Our criteria defining a presumed difficult puncture included patients older than 60 years old and/or with BMI > 30. These two criteria do not correspond to the same cause of difficulty. The former population has a reduced space between spinous processes whereas the latter is younger but has difficult palpation landmarks and a deeper localization of the epidural space. To determine if the type of inclusion criteria could change our results, we performed tests for interaction. The difference between the 2 groups seemed to be greater with a decrease of 1.64 point [−2.61; −0.67] in patients over 60 years old. However, the difference was not either statistically significant. Moreover, we did not find any impact of the BMI on the change of VAS. Regarding our secondary outcomes, the selection of the level with the larger distance between the spinous processes could prevent multiple tries or redirections of the needle. Indeed, repeated needle insertions and redirections increase the pain and discomfort experienced by the patient [2]. In a previous study involving 300 pregnant women, ultrasonography has been shown to decrease the number of needle placement attempts from 2.2 ± 1.1 to 1.3 ± 0.6 [24] and it ensured proper catheter placement without redirection in 67.4% of cases in obese parturient [6]. However, in patients with easily palpable anatomical landmarks, the use of pre-procedural spinal ultrasound did not improve the ease of insertion of labour epidural catheters as compared with the traditional palpation technique [28]. Finally, in 120 orthopedic patients undergoing lower limb surgery, US was associated with both a significantly higher number of successful epidural puncture on the first needle insertion attempt (65% vs. 32%) and a significantly smaller number of needle passes (6 [1–10] vs. 13 [5–21]) [19]. In our study, number of redirections and number of injections performed in a single attempt were not different between the two groups, which probably explain why we did not find any difference in VAS pain.

Our study has several limitations. First, the physician was not blinded to the group allocation as he performed both the US and the epidural injection. Blinding the operator in US imaging trial is always challenging. In our study, this would imply a lack of helpful information on the spine anatomy such as the depth of the epidural space or the best direction for the needle. Most importantly, patients were blinded to their group allocation as we performed a fake US in the control group. This allowed a better assessment of a subjective criterion such as pain. Second, neither the efficacy of the epidural injections nor the confirmation of proper placement of the needle were included as outcomes. A previous study has already shown that the use of the "loss-of-resistance" technique led to a successful needle placement in 75% of the injections [29]. Thus, for adequate power, the number of patients needed to perform a randomised controlled study assessing efficacy should have been greater.

Disclosure of interest

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

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