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How effective is an ultrasound-based imaging technique with automated guidance as an aid in performing spinal anesthesia in elective caesarean section patients? A prospective randomized controlled trial

J. Delforche (*), S. Vanderhaeghen (**), M. Coppens (*)

Abstract: *Background*: Ultrasound could potentially aid the procedure of neuraxial anesthesia by obtaining the needle entry site more reliably, thereby lowering the number of needle insertions and thus lowering the rate of complications. This single center prospective randomized trial evaluated the effectiveness of an ultrasound device with automated guidance as an aid in performing spinal anesthesia in pregnant patients undergoing an elective caesarean section (C-section).
Methods: Fifty-eight patients were included and randomized in one of both groups. The needle entry site was identified by a pre-procedure ultrasound in the study group or by a traditional landmark palpation technique in the control group. The primary outcome was first attempt success. Secondary outcomes were: number of needle passes, preparation time (time needed to identify needle insertion point, with or without the use of the device), needle insertion time (time interval from the initial needle insertion until the visualization of cerebrospinal fluid (CSF), total procedure time (sum of the preparation time and needle insertion time) and patient satisfaction. Sub-group analysis was performed on obese patients (body mass index $\geq$ 30 kg/m^2), on cases where residents or attending physicians performed the procedure.
Results: No significant difference in the rate of first attempt success was found among all patients, nor in the sub-group of obese patients, nor in the sub-groups of residents or attending physicians performing neuraxial anesthesia. No significant difference was found in the number of needle passes or patient satisfaction. Use of ultrasound resulted in a significantly longer preparation and total procedure time.
Conclusion: This study could not prove a significant advantage of using a pre-procedure ultrasound device when performing neuraxial anesthesia in elective C-section patients. The post-hoc study power appeared insufficient to draw any conclusions. Additional research is required to evaluate the clinical effectiveness of using a pre-procedure ultrasound when performing neuraxial anesthesia in pregnant patients.

Keywords: Anesthesia; spinal; Cesarean section; ultrasonography.

Introduction

Ever since the epidural nerve block was introduced in the 1920‘s, the technique of epidural anesthesia has steadily been improved upon. Major advances have been achieved in needle design, types of drugs and drug combinations. Identifying the epidural space – the most vital part of the technique – however remained unchanged and relies solely upon anatomical land-marks and a loss of resistance technique. Ultrasound imaging could potentially identify the epidural space, but was unable to produce reliable imaging quality for a long time because of artifacts due to the surrounding bony structures. Luckily over the past few centuries, ultrasound technology has advanced greatly so that today, it can be used (even in a handheld device) to reliably identify the epidural space. The benefit of ultrasound examination prior to the epidural space puncture was established by pioneers some 30 years ago (1, 2). It was also recognized that ultrasound could be of help when identifying anatomical landmarks was challenging because of obesity and/or tissue edema, as frequently seen in pregnant patients (3). Moreover, pregnancy seems to alter the epidural space anatomy (greater skin to epidural space distance, narrower and deformed epidural space, less space in between the spinal processes)

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and hormonal changes during pregnancy result in an alteration in tissue consistency (sometimes causing a false sensation of loss of resistance) (4). These circumstances further strengthened the hypothesis that ultrasound imaging could be of substantial help as opposed to the traditional method when performing epidural or spinal anesthesia in (obese) pregnant patients. Since 2010, multiple studies have found clinical advantages of performing ultrasound examination of the lumbar region prior to the puncture (5). The total procedure time (the time needed to identify the appropriate puncture site and to achieve neuraxial anesthesia) frequently seems to be prolonged, but significantly fewer skin punctures and needle passes are seen when using ultrasound prior to the puncture compared to the traditional anatomical landmark technique (5-9). Interestingly, one study found a reduced total procedure time when using ultrasound (10).

The most pronounced difference in first attempt success rate (the rate at which epidural space or intrathecal space was successfully reached in a first attempt) was seen in obese patients. When comparing between pre-puncture ultrasound and control groups in these patients, a difference in first attempt success rate of up to 48% was observed (10).

Since the rate of complications such as traumatic nerve damage, epidural hematoma and post-dural puncture headache increases with the number of attempts prior to a successful puncture and with attempts on different levels (5, 11, 12), minimizing the number of skin punctures and needle passes might very well be worth the extra total procedure time. Given the very low baseline incidence (1 in 100,000 cases) of serious complications such as epidural hematoma or spinal cord injury due to unintended intracord injection, it is not feasible to design prospective studies to conclusively prove that ultrasound image guidance improves safety. However, evidence strongly suggests that pre-procedure neuraxial ultrasound prevents the occurrence of several well recognized mechanisms of injury, thus minimizing the occurrence of serious complications when administering neuraxial anesthesia.

Having a precise estimation of the epidural space depth might also help perform the epidural puncture in a safer way. Neuraxial ultrasound could predict epidural space depth within a 95% precision range of 7 mm (5, 7). Whereas without any imaging, the skin to epidural space distance (the area in which we can expect a loss of resistance) is to be expected anywhere from 2 cm depth, up to 9 cm, according to findings of Sutton and Linter (13). This means that ultrasound could reduce the uncertainty of where to expect the ligamentum flavum by a tenfold. It can be assumed that this results in less complications such as puncture of the dura mater with the epidural needle, post dural puncture headache and possibly nerve damage (5, 7, 14).

Ultrasound devices are frequently used in the anesthesiologist's practice. Applications are ample: gaining vascular access, performing peripheral nerve blocks, evaluating gastric content and cardiac function... The use and performance of ultrasound devices has always been subject to inter-individual variation. Experience is the key to success. To minimize this variation and to steepen the learning curve of epidural ultrasound, Accuro, a handheld, battery operated device was created by the American company Rivanna. The main advantage of Accuro is that the device is able to automate image assistance for epidural and spinal puncture. In addition to the raw ultrasound image, the device features an overlay with identification of the midline, bony landmarks and epidural depth and provides an indication of the optimal needle insertion point. To make the interpretation and guidance even more intuitive, a 3D reconstruction of the vertebrae is presented underneath the ultrasound image. The SpinNav3D technology that is featured in the Accuro device automates spinal bone landmark detection and depth measurements and assesses real-time scan plane orientation in 3D. Capogna et al. (15) studied the SpineNav3D technology on pregnant patients. The authors concluded that the epidural depth could be measured with the same accuracy as the standard ultrasound and, in addition, that novices who had previously never used an ultrasound could also obtain measurements rapidly and adequately (15).

The Accuro device is described as an easy-to-use device that delivers superior performance when administering epidural and spinal anesthesia. Multiple case-reports and studies have validated the device both technically and clinically. Technical validation has been made by Tiouririne et al. (16) and Seligman et al. (17) providing a 94% success rate on correct identification of the interlaminar space and an accuracy of epidural depth measurement within 3 mm of manual measurements by expert radiologists or ultrasound users. Carvalho et al. (18) and Capogna et al. (15) also found sufficient technical validation of the Accuro device when compared with traditional ultrasound methods. Clinical validation has been made by Ghisi et al. (9) on obese orthopedic patients and by Singla et al. (19) on parturients planned for a caesarean section

(C-section). Overall a success rate increase of 11% (up to 26% in obese patients) was seen in the group where the Accuro device was used to facilitate the spinal puncture.

Spinal anesthesia is the standard and preferred anesthesia practice in these patients. Because it is often more challenging to perform neuraxial anesthesia in pregnant patients because of obesity, edema (3), altered epidural anatomy and altered tissue consistency (4), this study focused on spinal anesthesia performance in pregnant patients requiring a C-section. Performance of epidural anesthesia in laboring women was not included because spinal needle placement renders an unmistakable result: cerebro-spinal fluid (CSF) return into the spinal needle. This study hypothesized that a pre-procedure ultrasound examination with the Accuro device could augment the first attempt success rate when performing spinal anesthesia in pregnant patients requiring a C-section. Spinal anesthesia was performed by experienced anesthesiologists as well as anesthesiology residents with limited experience to mimic a realistic situation.

Materials and Methods

This single center prospective randomized controlled trial was approved by the University of Ghent (Belgium) ethical committee and by the ethical committee of the general hospital AZ Sint-Lucas Ghent, where the study took place. (Ethical committee approval number BC-07467 E01, approved on 20th July 2020). All subjects provided a written informed consent. This manuscript adheres to the applicable CONSORT guidelines.

Study design

All consecutive patients undergoing a C-section at the 787 bed general hospital AZ Sint-Lucas in Ghent between October 1st 2020 and April 1st 2021 were screened for inclusion. Inclusion criteria were: undergoing an elective C-section under spinal anesthesia and age above 18 years old. Exclusion criteria were: coagulation abnormalities, infection at the spinal punction insertion site, severe cardiac conditions or hypovolemia, anatomical deformities of the back, prior lumbar spine surgery, allergy to ultrasound gel and lack of decision making capacity. Patients who gave informed consent were randomly assigned to either one of two groups: the control group (standard approach using an anatomical landmark technique without the use of ultrasound assistance) or the study group (using the former technique combined with performance of a pre-procedure ultrasound with the Accuro ultrasound device). Randomization sequence was created following simple randomization procedures (computerized random numbers) using Excel 365 (Microsoft, Redmond, WA, USA) with a 1:1 allocation. The group assignment for each patient was concealed from the performing practitioner until right before commencing the procedure.

Spinal puncture technique

Spinal anesthesia was performed with either a 25 gauge needle or a 27 gauge needle (Whitacre needle, brand: BD, Becton Dickinson S.A., Madrid, Spain). Spinal dose regimen was left unchanged between both groups and was determined by the practitioner or by the supervisor when a resident was performing the procedure. The patient was positioned in an upright position with the back rounded as much as possible, shoulders slouched and head flexed. The lumbar region was disinfected, local anesthetic infiltration was performed and successful spinal puncture was acknowledged when CSF was detected. Identification of the assumed correct needle entry site was performed differently in each group according to the study protocol.

Needle entry site identification and ultrasound technique

In the control group, the needle entry site was identified by palpating anatomical reference points. The intercristal line was palpated to identify the L4-L5 intervertebral space and the midline was evaluated by palpating the spinous processes. Anatomical reference points could be palpated again and re-evaluated by the practitioner when the lumbar region was disinfected.

In the study group, the needle entry site was identified by a pre-procedure ultrasound (Fig. 1 to 5.) The practitioner was allowed to also palpate the lumbar region for anatomical reference points while performing the ultrasound examination. The needle entry site was obtained using the Accuro device with SpineNav3D technology. The lower back was scanned in the transverse plane and the device was moved up and down craniocaudally until a fitting needle entry point could be identified. First, the midline was identified by the dashed line and placed in the middle of the display by moving the probe in the transverse plane (Fig. 2). Then, when a spinous process was identified (Fig. 3) the probe was moved craniocaudally along the midline until the spinous

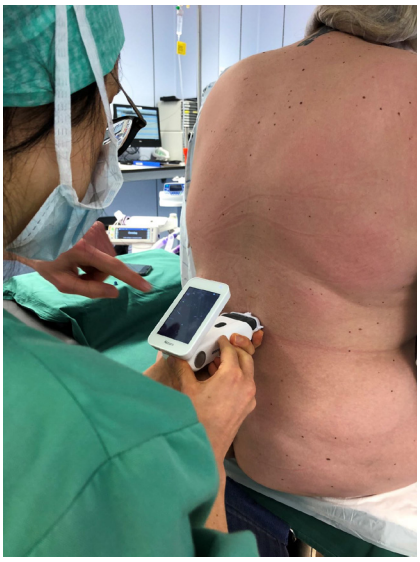
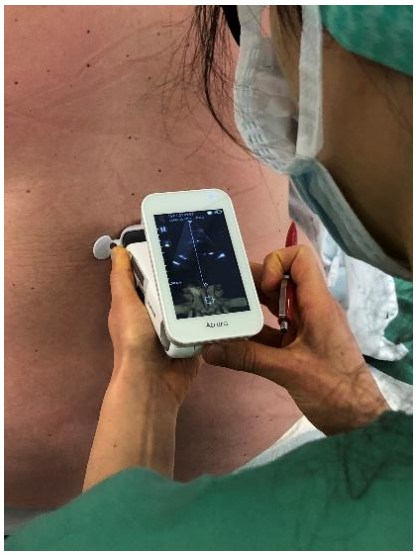


Fig. 1. — Illustration of how the patient is positioned with the Accuro device in use.



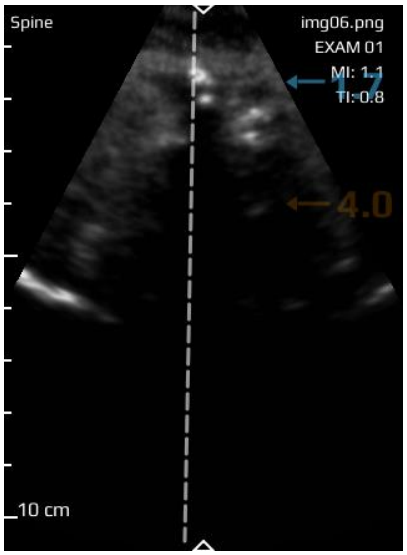
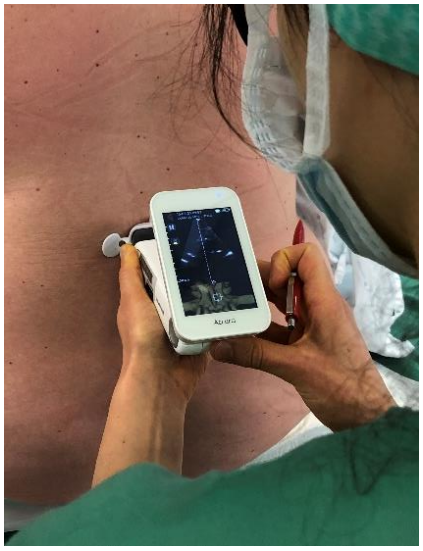


Fig. 2. — Illustration of how the dashed lines on the overlay represent the midline of the lumbar spine. This line is held in the middle of the screen. To the right: screenshot of the Accuro device.



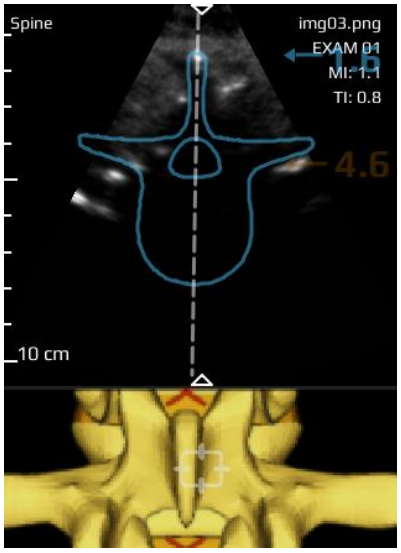
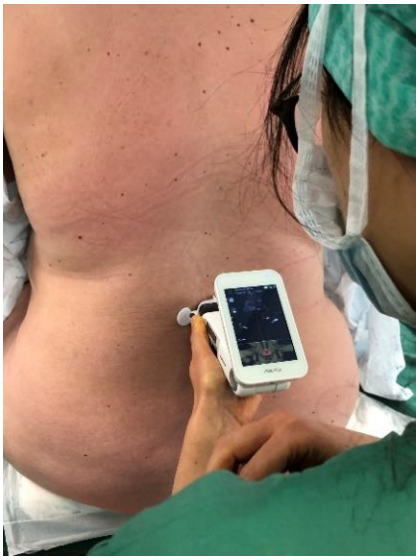


Fig. 3. — Illustration of how a spinous process is identified by the blue overlay on the ultrasound image on the device. To the right: screenshot of the Accuro device. Notice the depth estimation of the spinous process in blue (1.6 cm).



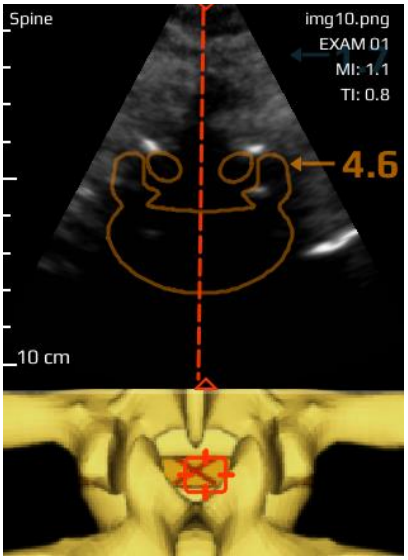


Fig. 4. — Illustration of how an interlaminal space is identified by the red and orange overlay on the ultrasound image on the device. To the right: screenshot of the Accuro device. Notice the depth estimation of the epidural space in orange (4.6 cm). The red dashed line and crosshair represent the proposed needle insertion trajectory.

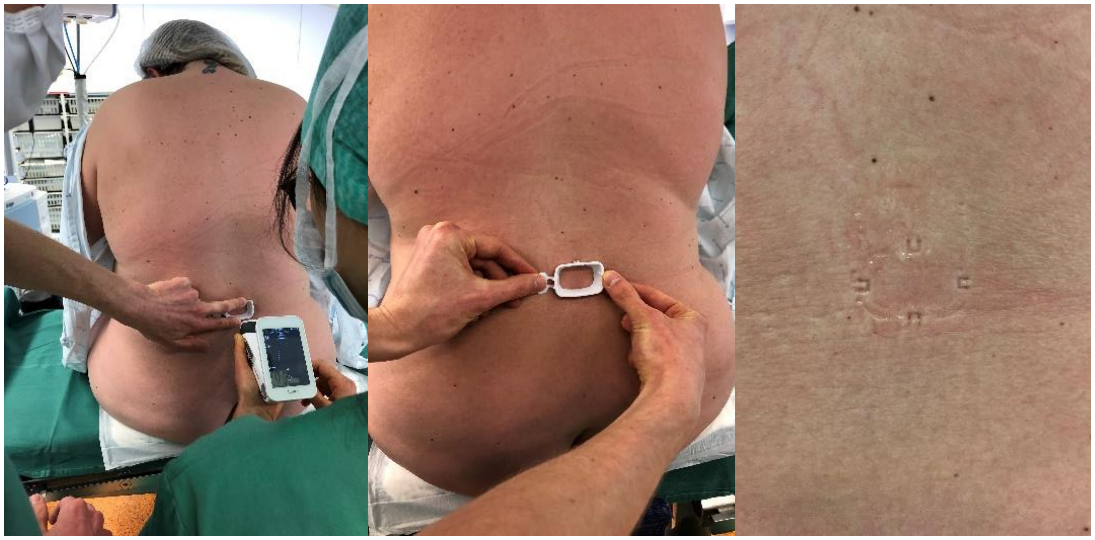


Fig. 5. — Illustration on how skin markings are made by using the Accuro Locator tool. To the right: lumbar region of the patient displaying cutaneous indentations after using the Accuro Locator tool. The proposed needle insertion point is found at the intersection when connecting lines through these indentations.

process disappeared and an interlaminar space (Fig. 4) could be identified. At this time, a red dashed line could be seen on the Accuro device display. While holding the Accuro device in place, noticing the angle at which the probe scanned the lumbar region, cutaneous indentations were made using the Accuro Locator, a detachable skin marking tool that clips onto the Accuro device (Fig. 5). By connecting the cutaneous indentations, the proposed needle entry site is at the intersection of these lines.

The indentation marks were found to be lasting long enough to wipe off any remaining ultrasound gel, have the lumbar region disinfected and have the practitioner prepare everything for the spinal anesthesia. Only after identification of the needle entry site, the lumbar region was disinfected. The spinal anesthesia was then performed as usual, in an upright position, using the same needle and the same spinal dose as in the control group. The proposed needle entry site was used in a first attempt. If this first attempt failed, the performing practitioner could fall back to his/her normal routine by palpation.

Spinal puncture was performed either by attending physicians or by residents under direct supervision of an attending physician. Prior to using the Accuro device, all practitioners watched a 3 minute training video provided by the manufacturing company (20). Residents were expected to have performed at least 10 spinal punctures before. Anesthesiology staff members could give instructions and guidance during the procedure but did not handle the needle. The number of needle insertion attempts by a resident was limited to a maximum of 4, after which the supervising attending physician completed the procedure, for the comfort of the patient. Anesthesiology members of staff in the study consisted of 20 clinicians, residents consisted of 4 clinicians.

Study outcomes

The primary outcome of the study was the rate of successful dural punctures in the first needle insertion attempt. A needle insertion attempt was defined as any advancing movement with the spinal needle. An additional attempt was recorded every time the spinal needle was retracted and redirected. Only 1 attempt with subsequently witnessed cerebrospinal fluid (CSF) in the spinal needle chamber could be recorded as a 'first attempt success' puncture.

Secondary outcomes included: the number of needle passes, the preparation time (the time needed to identify the needle insertion point, with or without the use of the device), the needle insertion time (the time interval from the initial needle insertion until the visualization of CSF, the total procedure time (the sum of the preparation time and the needle insertion time) and patient satisfaction with the anesthesia administration. Patient satisfaction was recorded via a verbal inquiry directly after the dural puncture on a scale of 1 to 5 as follows: 1: very unpleasant; 2: unpleasant; 3: neutral; 4: good; 5: very good. Sub-group analysis was pre-specified for obese patients, cases where residents initiated

the spinal puncture and cases where attending physicians initiated the spinal puncture. All data was measured and recorded by an independent physician observer.

Statistics

Dichotome outcomes such as the primary outcome were assessed using the Fisher's exact test and relative risk scores for categorical data (RR) through a 2x2 contingency table. Continuous variables, such as the time difference between groups and the number of needle passes, were evaluated by an unpaired Wilcoxon or Mann-Whitney-U test. In all cases, a two-tailed P-value of < 0.05 indicated statistical significance. Statistical analysis was performed using the IBM statistics software SPSS, version 26.

Power calculation was performed beforehand (using G*Power software, version 3.1.9.2) assuming a type I error rate of 5% (alpha = 0.05) and a type II error rate of 20% (beta = 0.2) rendering a power of 80% (1-beta = 0.8). A minimum of 68 subjects were required for this study to detect a difference of 40% (effect size = 0.4) in first-pass success rate between the different techniques with a power of 0.8.

Table 1

Demographic and clinical characteristics of subjects. Data are presented as number or mean ± standard deviation (SD), number (% in each group). *Obese patients are defined as having a body mass index (BMI) ≥ 30 kg/m^2.

	Control group (n=29)	**Study group (n=29)**
Age (years)	32.0 ± 6.0	31.6 ± 3.9
BMI (kg/m^2)	29.5 ± 4.9	31.4 ± 5.5
Percentage obese patients* (%)	35	55
First time receiving neuraxial anesthesia	41%	31%
Resident performing neuraxial anesthesia	6 (43%)	8 (57%)
Attending physician performing neuraxial anesthesia	23 (52%)	21 (48%)

Table 2

First attempt success rates, patient satisfaction and mean timings for control group and study group. 1: Good patient satisfaction corresponded with a score of 4 or 5 on a scale of 5. 2: The time needed to identify the needle insertion point, with or without the use of the device. 3: The time interval from the initial needle insertion until the visualization of CSF. 4: the sum of the preparation time and the needle insertion time. * Fisher's exact test; ** Mann-Whitney-U test.

	Control group	**Study group**	**P-value**
First attempt success rates (%)			
All cases (n=58)	31	55	0.11*
Obese cases (BMI ≥ 30 kg/m^2) (n=26)	30	50	0.43*
Residents performing spinal anesthesia (n=14)	25	75	0.58*
Attending physicians performing spinal anesthesia (n=44)	38	62	0.13*
Number of needle passes (mean ± SD)	4.48 ± 4.24	3.5 ± 4.58	0.11**
Patient satisfaction (%)			
Good patient satisfaction[1]	41	59	0.082*
Mean timings (minutes:seconds ± SD)			
Mean preparation time[2]	00:27 ± 00:14	03:53 ± 02:39	< 0.0001**
Mean needle insertion time[3]	02:31 ± 03:13	04:04 ± 05:02	0.473**
Mean total procedure time[4]	03:15 ± 03:30	08:14 ± 05:15	< 0.0001**

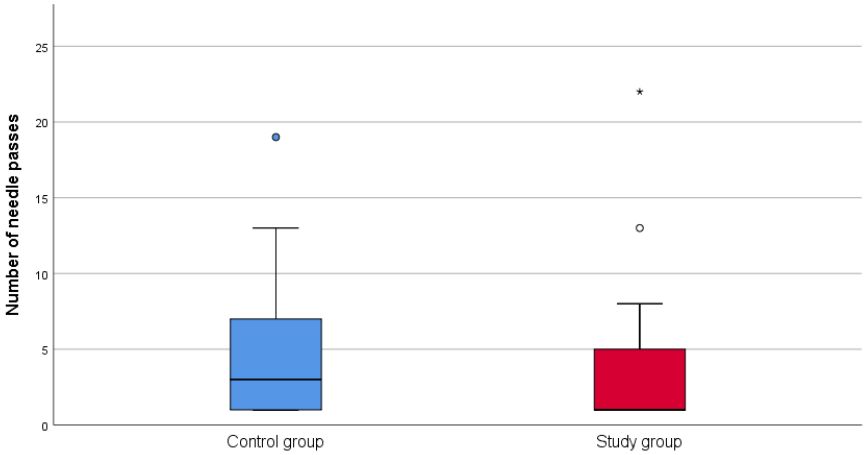


Fig. 6. — Boxplots of the number of needle passes required for spinal placement in each group. In each boxplot, the horizontal line is the median, extends of the boxes are the 25th and 75th percentile, the whiskers reach between 10 and 90 % of the sample values and the dots are outliers beyond the 10th and 90th percentile

Results

Fifty-eight patients were included in the study and the final analysis. No patients were excluded from the study. No major data was missing. There were 29 patients in the control group and 29 patients in the study group. This manuscript adheres to the applicable CONSORT guidelines: see CONSORT addenda: CONSORT_flow diagram and CONSORT_checklist. Patient characteristics are summarized in Table 1.

Twenty-six patients were defined as obese (body mass index (BMI) $\geq$ 30 kg/m2). There were more obese patients in the study group than in the control group. Out of all spinal anesthesias, 24% were initiated by residents and 76% by attending physicians.

Thirty-one percent of cases in the control group were recorded as a 'first attempt success', compared to 55% of cases in the study group. A Fisher's exact test for first attempt success rate between the 2 groups rendered a non-significant P-value of 0.111. No significant difference in first attempt success was observed for the sub-groups of obese patients (BMI $\geq$ 30 kg/m^2), sub-groups where the residents started the procedure or sub-groups where attending physicians started the procedure. No significant difference was observed for the number of needle passes between both groups. Boxplots of the number of needle passes in each group are presented in Figure 6.

Statistical analysis of patient satisfaction between groups was performed using a dichotomized satisfaction score: score 1 up to score 3 was defined as 'poor patient satisfaction', score 4 up to score 5 was defined as 'good patient satisfaction'. No significant difference in patient satisfaction was found between both groups.

The preparation time and total procedure time was found to be significantly longer in the study group. The needle insertion time however, was not found to be significantly different between both groups.

Post-hoc (a posteriori) power calculation rendered a power (1-β) of 45.3%.

Discussion

This single center prospective randomized trial could not show a significant difference in first attempt success rate when performing spinal anesthesia with a pre-procedure ultrasound of the spine by means of the Accuro device compared with the traditional landmark palpation technique in pregnant patients undergoing an elective C-section.

The primary outcome was chosen as the rate of 'first attempt success' because it was hypothesized that needing only a single puncture for performing neuraxial anesthesia could augment patient satisfaction and safety of the procedure. Nevertheless, to further evaluate possible advantages of ultrasound assistance, the absolute number of needle passes was compared between both groups. No significant difference could be found either. The greatest advantage of using the ultrasound-assisted technique is to be expected in obese patients (as described in the introduction), while our population consisted of all patients in need of a C-section. A sub-group analysis was made for obese patients which still showed no significant difference in first attempt success rate. Also, patient satisfaction did not seem to differ significantly between both groups. There was no significant difference in first attempt success

rate in either sub-group of residents or attending physicians when using a pre-procedure ultrasound. Lastly, when comparing time measurements in both techniques, the needle insertion time was not significantly different, but the preparation time and the total procedure time were significantly larger when a pre-procedure ultrasound was used.

Only 31% of cases in the control group were recorded as a 'first attempt success', compared to 55% of cases in the study group. This corresponds poorly to literature stating first attempt success rates in traditional landmark palpation technique to be around 61-64% (11, 21, 22). However, these first attempt success rates are among all patients receiving neuraxial anesthesia. In pregnant patients presenting for elective C-section in the study of Singla et al. (19), first attempt success rates in the control group were reported to be 59%. The lower first attempt success rates in our study could not be explained by having a larger number of obese patients. A possible explanation for this phenomenon could be the preparation and training of the residents who performed the spinal anesthesia in the study of Singla et al. was more thorough, or possibly the definition of a 'first attempt success' was slightly different.

Residents performing spinal anesthesia

Out of all spinal anesthesia procedures, 24% was initiated by a resident. Experience varied, but in order to enter the study, residents were expected to have performed at least 10 spinal punctures before. Sub-group analysis of these cases revealed no significant benefit of using a pre-procedure ultrasound. Recent literature provides conflicting data on this topic. Unexperienced practitioners that received training, including a 2 hour hands-on workshop and successful completion of at least 20 supervised ultrasound-guided epidurals were able to effectively and independently use the ultrasound-guided technique, with the majority able to complete the pre-procedure scan within 2 minutes and reach the epidural space with just one needle pass (23). Another study focused on 3 junior trainees who were randomized to perform spinal anesthesia in 20 parturients with impalpable spinous processes using either an ultrasound-assisted or landmark-based technique. Again, training was provided and 10 successful supervised ultrasound-guided spinal punctions were performed before the actual study was started. Fewer needle passes and a shorter needling time was needed in the ultrasound-assisted group (24). However, another randomized controlled trial (RCT) is interesting because it found no added benefit of a pre-procedure ultrasound performed by junior trainees when patients were not obese and when the conventional landmark technique was closely supervised and guided (25). It seems that the residents who participated in our trial could have benefitted of a more extensive training, for example by including a hands-on workshop and successful completion of more than 10 supervised ultrasound-assisted neuraxial anesthesia procedures.

Definition of the primary outcome

Results of our study could be influenced by the definition of the primary outcome. Singla et al. (19) defined a 'first pass success' as a successful dural puncture on the first insertion attempt. Only a complete withdrawal of the spinal or introducer needle from the patient's skin counted as an additional insertion attempt. In our study, an additional attempt was recorded every time the spinal needle was retracted and redirected, even when it did not exit the patient's skin. This is an important distinction in terminology and should be considered when comparing results.

Obese patients

Our trial included all patients undergoing an elective C-section. Other studies have also failed to demonstrate superiority of the pre-procedure ultrasound technique, especially when it is used in patients with easily identifiable anatomical landmarks, and also when it is performed by experienced anesthesiologists (26, 27). However, in patients with difficult spinal anatomy or high BMI, the evidence is much more compelling. A significantly lower number of attempts (up to a 48% reduction) (9) was needed to perform epidural or spinal anesthesia in patients with a high BMI and impalpable spinous processes when using an ultrasound-assisted technique (6, 10, 28). These results could not be reproduced in our trial. Possibly, the small amount of cases within these sub-groups accounted for finding no evidence of added benefit in obese patients in our trial. Of note, in one case, an extra-long spinal needle (27G, 120mm) was apparently needed after an initial failed attempt with a normal 90mm needle. This directly resulted in a failure of first attempt success, even while the correct needle insertion point was identified by the pre-procedure ultrasound. Study protocol could have included these events to possibly make a better interpretation of the potential benefit of using ultrasound.

Study limitations

The following weaknesses of our study were identified:

– Unfortunately, but inherent to the nature of the ultrasound technique, the study could not incorporate blinding in patients, nor in practitioners.

– The patient is possibly biased as soon as an introduction is made to the 'novel' ultrasound machine. This could have influenced patient satisfaction.

– The spinal puncture technique can differ between anesthesiologists. Some anesthesiologists tend to make far more advancing needle maneuvers than others, even when a pre-procedure ultrasound was performed. This renders the 'number of needle passes' less useful as a measure on how uncomfortable the performance of the spinal anesthesia was. This probably has no effect on the prevalence of complications (such as the occurrence of traumatic nerve damage, epidural hematoma and post-dural puncture headache) (5, 11, 12), since the multiple needle advances are frequently made to identify spinal processes in an effort to get in between them and not so much as multiple deeper punctures of the epidural and spinal space. However, whenever the spinal needle was retracted, a first attempt success was abolished, influencing our primary outcome.

– Some (experienced) anesthesiologists are reluctant to use an ultrasound-assisted technique and rely on their experience, even when spinal puncture is presumed to be difficult.

– The number of attending physicians was rather large: this could have resulted in a bias, since ultrasound is known to have a large interindividual performance difference. Ideally, a sub-group analysis for each clinician could abolish this bias. Although this would render our power well below the threshold of 0.8, requiring a much larger population.

– Although a power analysis was performed beforehand, stating that 68 patients were needed in order to detect a clinically significant effect size of 40% with a power of 80%, there were only 58 patients included in the final analysis. Because of time constraints and the ongoing COVID 19 pandemic which posed various other challenges to the anesthesiology staff in the hospital environment, this created a less than ideal situation in which to perform a prospective randomized controlled trial. The inclusion period was interrupted twice for a month because the main researcher was temporarily needed at the COVID intensive care unit. Also, a lower-than-expected number of elective C-sections presented themselves during the study period. In an ideal setting, this study would have continued up until a minimum of 68 patients were recruited. Perhaps even more patients should have been recruited, since the effect size seemed to be less than expected. Namely, the a priori power was calculated using an estimated and clinically significant effect size of 40%. Clinical validation was made by Ghisi et al. (9) on obese orthopedic patients and by Singla et al. (19) on parturients planned for C-section. Overall a success rate increase of 11% (up to 26% in obese patients) was seen in the group where the Accuro device was used prior to the spinal puncture. This was less than the proposed 40% increase in first attempt success rate. The lower number of inclusions and the difference in effect size explain a much lower post-hoc (a posteriori) study power of 45.3%.

Application of ultrasound in neuraxial anesthesia

Acquisition and preservation of neuraxial ultrasonography skills represent a major impediment to its widespread use for bedside procedures (29). With the Accuro device, this could be diminished. While studies investigating a learning curve of using the Accuro device are not yet available, it seems that in select cases (especially in patients where neuraxial anesthesia is presumed difficult, patients with difficult spinal anatomy and patients with high BMI), the Accuro device could augment first attempt success rates and result in significantly fewer needle insertion attempts, even when used by those who are not skilled in ultrasound-assisted neuraxial blocks.

Further studies could shed some light on the learning curve and investigate new techniques that could aid the practitioner further when performing neuraxial anesthesia. Although real-time ultrasound-guided spinal and epidural techniques have been described, they are distinctly different from the ultrasound-assisted approach used in this study. Real-time ultrasound-guided neuraxial blockade (as described in a review by Chin et al. in 2018 (14)) can be useful, but is technically challenging. In a recent update, the Rivanna company has adapted the Accuro device to enable the practitioner to perform a real-time guided thoracic epidural by means of a paramedian approach.

Conclusion

Our prospective trial could not prove a significant advantage of using a pre-procedure

ultrasound device when performing neuraxial anesthesia in elective C-section patients. However, since ultrasound is not painful, might possibly lower some risks and complications of the procedure, is constantly evolving and might improve over time, is relatively inexpensive and widely available in anesthesiology practice, we believe the ultrasound technology can take a place where neuraxial anesthesia performance is (presumed) difficult. Even when ultrasound can only slightly reduce the number of needle passes, patients might benefit from less painful procedures and possibly less complications when receiving neuraxial anesthesia. Further studies with larger study populations could evaluate if ultrasound will become as important to the anesthesiologist when performing neuraxial anesthesia as in gaining vascular access or performing peripheral nerve blocks over time.

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