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Protocol

Should anaesthesiologists be taught to perform ultrasound-assisted neuraxial access in spinal anaesthesia? – Protocol of a randomised controlled study

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Abstract

Background

Neuraxial blockade, typically guided by manual palpation, can be challenging in certain patient populations. Ultrasound-assisted neuraxial access has the potential to improve success rates, particularly for novice anaesthesiologists, though structured training programs in this technique are limited.

Methods

This multicentre, randomised controlled trial will evaluate the use of ultrasound-assisted neuraxial block, following a simulation-based training programme based on the mastery-learning approach. Participants, consisting of novice and senior anaesthesiologists, will receive training in either ultrasound-assisted or traditional manual palpation techniques. Performance will be assessed in a clinical setting during elective lower limb surgery. Statistical analyses will compare the clinical outcomes of ultrasound-assisted versus manual palpation techniques.

Results

The primary outcome is the success rate of the first spinal block attempt. Secondary outcomes include the number of attempts, needle redirections, time spent, and the need for additional interventions. Patient satisfaction and complications will be evaluated as tertiary outcomes.

Conclusion

This study may present the potential impact of a structured training program on anaesthesiologists' skills in ultrasound-assisted neuraxial access and potentially lead to better patient outcomes. By comparing ultrasound-assisted techniques with traditional manual palpation, the findings may lead to improvements in training methods and ultrasound-assisted approaches for neuraxial access.

Introduction

Neuraxial blockade is traditionally performed using a manual palpation technique to locate the optimal injection site.[1] The procedure can be challenging, especially in patients with a high body mass index (BMI), pregnant patients, and patients with spinal deformities.[2,3] When the manual palpation technique fails, using ultrasound to guide access may prove helpful.[4]

A 2021 guideline presented by the European Society of Anaesthesiology and Intensive Care based on a review of randomised controlled trials and cohort studies recommended the use of preprocedural ultrasound scanning to provide better accuracy in identifying the intended intervertebral space - however, with a weak recommendation due to a sparse amount of evidence.[5] Additionally, the guideline specifically advises physicians in anaesthesia speciality training to use preprocedural ultrasound scanning to reduce skin punctures, suggesting a potential link to improved clinical outcomes, especially for novices.[5] This recommendation aligns with a previous study suggesting that early ultrasound training could be particularly beneficial for novices. As demonstrated in the context of epidural anaesthesia, the incorporation of preprocedural ultrasound imaging may reduce complications and improve success rates.[6] Although ultrasound seems to offer an advantage in patient care, it is sparsely used in clinical practice. A recognised challenge is the lack of structured training in the technique.[7,8] Previous studies focusing on training in traditional neuraxial anaesthesia map out the required amount of training through learning curves. However, this approach may limit optimal use, as significant inter-individual variability in learning curves has been demonstrated.[6,9-16] These training programs, with fixed durations based on time or number of procedures, fail to account for individual differences in skills acquisition.[17] An alternative to this is mastery learning, which aims to ensure a predefined performance standard through repeated practice until a standard level is reached.[18] A final test ensures that every trainee reaches the same level of competency, regardless of their learning pace by ensuring clear objectives for trainees assessed by fixed standards and measurements.[18,19]

However, to the best of our knowledge, no studies have explored the clinical benefits and patient satisfaction for patients of both novice and more experienced anaesthesiologists following a structured training programme in ultrasound-assisted neuraxial access.

Aim

This study aims to investigate whether anaesthesiologists using ultrasound-assisted spinal block have better patient outcomes and satisfaction than anaesthesiologists using the traditional manual palpation technique. Additionally, the study will evaluate the relevance of prior clinical experience.

Methods

Setting

This multicentre randomised controlled trial will take place in simulation centres and clinical departments.

Simulation-based training will be conducted in simulation centres or local departments, where physicians working in anaesthesia will practice ultrasound-assisted or manual palpation neuraxial access under controlled conditions, ensuring a standardised learning environment. Clinical performance will be assessed at hospitals across Denmark during elective lower limb surgery to ensure controlled and comparable conditions.

Participants

Participants will be either novices (first-year anaesthesia residents recruited early in their training program) or seniors (physicians in their specialist training or specialist-trained anaesthesiologists). Novices will be recruited based on the required sample size, while seniors will be recruited as a convenience sample. Data on participants' demographics will be collected, including age, sex at birth, months of anaesthesia experience, and the number of neuraxial accesses performed with and without ultrasound.

Eligible criteria – Physicians

Physicians will be included using the following inclusion criteria:

1) Physicians working in anaesthesia
2) Opportunity to use the spinal block technique within two weeks of the training session.

Exclusion criteria will be previous structured education in ultrasound-assisted neuraxial access.

Eligible criteria – Patients

Eligible patients will be those scheduled for elective lower limb surgery requiring spinal anaesthesia. Patient demographics, including age, height, weight, history of back surgery, or other known spinal pathologies, will be recorded. Patients will be informed about the study's purpose and

contacted by phone within a week post-procedure to complete a follow-up questionnaire focusing on satisfaction and complications.
Exclusion criteria: Patients under 18 years of age.

Randomisation
For the primary outcome, participants, being novices in anaesthesia, will be randomly assigned to either the intervention group or the control group using block randomisation with randomly selected block sizes. The randomisation list will be created using an integrated random number service offered by the secure platform Research Electronic Data Capture (REDCap) hosted by the Open Patient Data Explorative Network (OPEN).[20] The randomisation will be revealed at the creation of a new participant ID during the inclusion session, and consequently, the randomisation sequence will not be accessible to anyone involved in the study before the inclusion of the participant.
For the secondary outcome, the senior anaesthesiologists will rely on a convenience sample and randomisation to either group.

Structured training intervention
Education and training – intervention group – ultrasound-assisted access
Physicians in the intervention group will receive a video-based theoretical introduction to ultrasound-assisted neuraxial access, focusing on sonographic anatomy, technical aspects, approach to common problems, complications, and contraindications. This video-based theoretical session will be available to participants during the study period.

Following the theoretical curriculum, a simulation-based ultrasound-assisted neuraxial hands-on training on a low-fidelity phantom (CAE Blue Phantom Lumbar Puncture And Spinal And Epidural Ultrasound Training Model (CAE Healthcare, Montréal, Canada) will be conducted. There will be no time limit for completion, adhering to the mastery-learning approach. As a part of the training, participants will complete a post-training test recorded on a tablet, with only their hands and the low-fidelity phantom visible. These tests will be evaluated by an experienced physician. Participants must pass the post-training test to be certified, ensuring a minimum baseline before patient involvement. After training, the participants will be asked to fill out a questionnaire based on the Intrinsic Motivation Inventory (IMI) scale to assess their motivation and engagement with the activity.[21] The

IMI items will consist of six chosen statements. Each statement will be rated on a 7-point Likert Scale, where 1 is “Not true at all”, 4 is “Somewhat true”, and 7 is “Very true”.

Education and training – control group – manual palpation technique

Physicians in the control group will receive a video-based theoretical introduction to neuraxial access using manual palpation. As manual palpation training for spinal blocks is mandatory early in the first year of employment, the video serves as a refresher. The curriculum covers technical aspects, approaches to common challenges, complications, and contraindications. This is followed by simulation-based neuraxial hands-on training on a low-fidelity phantom (CAE Blue Phantom Lumbar Puncture and Spinal and Epidural Ultrasound Training Model, CAE Healthcare, Montréal, Canada). Both the theoretical and practical training are adapted from a well-established simulation-based lumbar puncture curriculum. Participants must pass the post-training test, using the LumPAT assessment tool, which has established validity evidence in a similar simulation-based setting.[22] After training, the participants will be asked to evaluate the training using the Intrinsic Motivation Inventory (IMI) Scale, like in the intervention group.[21]

Clinical testing of groups

After certification, physicians will perform either ultrasound-assisted neuraxial access or traditional manual palpation neuraxial access during their first two planned lower limb surgeries, with live evaluations conducted by a senior specialist-trained anesthesiologist, with experience in the procedures, using clinical metrics. Before clinical performance, participants will receive a short just-in-time brush-up training, where feasible. All participants will have access to a brush-up video and will be strongly encouraged to see it before clinical performance.

Furthermore, patients will answer a follow-up questionnaire via phone within a week (Appendix 1), and answers will be stored in a secure RedCap database.[20]

Outcomes (Appendix 1)

Participants will be assessed in the clinical setting using predefined metrics, with real-time evaluations from a senior colleague.

The primary outcome will be a successful first spinal block attempt.

Secondary outcomes will include the number of attempts, number of needle redirections, successful block, need for supervisor's verbal or procedural assistance, time spent, additional intervention required intraoperatively, and if the physician expected the access to be difficult, and why.
Patients' satisfaction and complications will be a tertiary outcome.

Sample size calculation

The sample size was calculated to detect a significant difference between two proportions using Stata's power two proportions command. The expected proportions in the two groups were based on a previous study, examining the ultrasound-assisted technique in spinal anesthesia compared to the paramedian manual palpation technique in elderly undergoing orthopaedic surgery.[23] The first pass success rate was 65% in the ultrasound-assisted group compared to 17.5% in the landmark group.[23] The Fisher's exact test was used with a 5% significance level ($\alpha = 0.05$) and 80% statistical power, requiring a total sample size of 36 participants (18 per group) to detect a difference. To account for an anticipated 10% dropout rate, the sample size will be increased to 40 participants (20 per group), ensuring sufficient power to test the null hypothesis that the two proportions are equal, even with dropouts.

Statistical analyses

Demographic data of physicians and patients will be presented, analysed, and summarised using a descriptive approach. Fisher's exact test will be performed to compare outcomes for successful first spinal block attempts between ultrasound-assisted procedures versus manual palpation techniques.
For secondary outcomes of continuous variables, including the number of attempts, number of redirections, and time spent comparisons will be conducted using t-tests for normally distributed data and Mann Whitney test for non-normally distributed data. For binary categorical variables, such as the need for a supervisor's help (verbal or technical), and the need for additional interventions (e.g. general anaesthesia) Fisher's exact test will be used. Patients' perceptions will be summarised in a descriptive form and the complications in the two groups will be compared using Fisher's exact test. McNemar's will be performed to compare the first and second performed procedures. All analyses will be performed using statistical software, and results will be considered at a significance level of $p < .05$.

Ethics

Written informed consent will be obtained from all study physicians and patients. Participation is voluntary and withdrawal from the study may be commenced at any time with no repercussions. MSN and ACB will have access to information about the participants and patients' associated data. All data will be entered and handled in an online database: Research Electronic Data Capture (REDCap). An application will be sent to the Internal Research Register in the Region of Southern Denmark. Likewise, a notification will be sent to the Research Ethics Committee at the University of Southern Denmark.

Discussion

This study aims to add knowledge to the literature, presenting clinical outcomes for anesthesiologists using ultrasound in neuraxial access, following a simulation-based mastery learning programme offering an alternative to traditional apprenticeship.[24-28] Despite a positive consensus of using simulation-based training to enhance patient safety, a limited number of studies have focused on developing curricula in anaesthesia. Most existing research centres on central venous catheter insertion, demonstrating a reduction in complications.[29-31] Studies on neuraxial block skills similarly show positive outcomes from simulation-based training, but the number of studies remains limited.[32]

A central strength of our study is that it is based on the mastery-learning approach. Mastery learning ensures that all trainees achieve a certain level of skills by setting a predefined performance standard.[18] The approach includes a final test that ensures that every trainee reaches the same level of competency, regardless of their learning pace, by providing clear objectives to trainees assessed by fixed standards and measurements.[18,19] Mastery learning has proven valuable in skills training, as it helps reduce errors and improve patient safety. [31,33]

In addition to addressing individual competencies, this study evaluates training outcomes across all four levels of Kirkpatrick's evaluation model (Table 1).[34] Including all four levels is important for understanding not only the immediate subjective reaction of the learner but also whether the training leads to improvement in skills, clinical performance, and ultimately patient outcomes. Measuring across all four levels, provides a more comprehensive understanding of the value of the training and helps identify areas for potential improvement in the curriculum. Furthermore, an essential part of this study is the use of outcome measurements, for which validity evidence has been established, including both the LumPat assessment tool and the IMI.[21,22] Establishing validity is important because

it provides a foundation for interpreting the results accurately, and ensures that the measures are appropriate for the constructs being studied. Additionally, the patient outcome measures used have been applied in previous studies, which supports their relevance in this context.

Limitations

This study has several limitations. First, the inclusion of senior anaesthesiologists via convenience sampling may introduce selection bias, as participants with either a strong interest in ultrasound may self-select to participate. Additionally, relying on a convenience sample for senior anaesthesiologists may result in an underpowered comparison between novice and senior participants, potentially making it difficult to detect meaningful differences. Clinical performance assessments are based on the judgment of senior anaesthesiologists, whose evaluations may be subject to subjective biases or inconsistencies, potentially affecting the reliability and objectivity of the outcomes.[35] Another limitation is the potential for recall bias in patient-reported outcomes. However, by contacting patients within a week of the procedure, we aim to minimise this issue.

Conclusion

This study presents the potential impact of a structured training program on anaesthesiologists' skills in ultrasound-assisted neuraxial access and potentially lead to better patient outcomes. By comparing ultrasound-assisted techniques with traditional manual palpation, the findings could lead to improvements in training methods and ultrasound-assisted approaches for neuraxial access for novices as well as for experienced anesthesiologists.

Author contribution

MSN, ACB, ABN, LK, and AMG conceived the study. MSN and ACB drafted the manuscript. ABN, AMG, and LK all provided critical revisions to the manuscript. All authors read and approved the final version of the manuscript.

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Conflicts of interest

We wish to confirm there are no conflicts of interest associated with this article.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Tables

Table 1, Kirkpatrick levels and assessment plans. This table outlines the four levels of the Kirkpatrick model used to evaluate the effectiveness of the training program, including how each level is assessed and the methods used to measure outcomes.

Kirkpatrick level	Description	Plan
1: Reaction	Reaction measures the degree to which participants find the program or initiative favourable, engaging and relevant to them.	The Intrinsic Motivation Inventory (IMI) assesses participants' motivation after training, with participants evaluating their experience using a 6-item IMI scale.
2: Learning	Learning measures the degree to which participants acquire the intended knowledge, skills, attitude, confidence, and commitment based on their participation in the program.	The simulation-based training, following the theoretical curriculum, includes a post-training test that is evaluated.
3: Behaviour	Behaviour measures the degree to which participants apply what they learned during the program or initiative when they are back in their environment.	Participants will be assessed in the clinical setting with real-time evaluations from a senior colleague, focusing on the application of skills.
4: Results	Results measure the degree to which targeted organizational outcomes occur as a result of the initiative.	Patients' satisfaction and complications will be measured.

Appendix

Appendix 1 – outcomes

Outcome	Definition
Primary outcome	
Successful first spinal block attempt	Single skin puncture without redirection and with backflow of cerebrospinal fluid
Secondary outcomes – clinical metrics	
Number of attempts	Number of skin punctures
Number of redirections	Number of needle redirections
Successful block for operation	Yes/no
Need for supervisor's verbal help	Verbal guidance
Need for supervisor's technical assistance	Manual procedural assistance
Time spent	Duration to backflow of cerebrospinal fluid from the time of needle insertion
Need for sedation during spinal anaesthesia placement	Yes/no
Additional intervention required intraoperatively - unexpected general anaesthesia	Unexpected general anaesthesia – and if so, the reason o Insufficient block o Longer surgery than expected o Patient comfort o Intraoperative complications (such as bleeding or cardiovascular instability) o Other (if so, what)

Additional intervention required intraoperatively – need for sedation	– and if so, the reason o Pain o Longer surgery than expected o Patient comfort (physical or emotional discomfort e.g. anxiety or distress) o Patient's preferences (request from patient, regardless of any immediate discomfort) Other (if so, what)
Expected difficult access	No Yes – if yes, why: o Patient cooperation difficulties o Spinal deformities o Previous spinal surgeries o High BMI o Other (please elaborate)
Tertiary outcomes – patient related outcomes	
Satisfaction	o Periprocedural pain score (0, no pain; 10, worst pain imaginable) o Periprocedural discomfort (0, no discomfort; 10, worst discomfort imaginable) o Satisfaction in general (very satisfied, satisfied, or dissatisfied)
Complications from procedure day to day 7	Post-dural puncture headache, local infection or paraesthesia