Improving safety, efficiency and efficacy of neuraxial blockade through enhanced operator performance

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A thesis submitted to the National University of Ireland, Cork for the degree of Doctor of Philosophy in the Department of Anaesthesia & Intensive Care Medicine, School of Medicine.

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Glossary

AC	Anterior Complex
AMNCH	Adelaide and Meath, incorporating National Children's Hospital
ANOVA	Analysis of Variance
BMI	Body Mass Index
CBME	Competency Based Medical Education
CT	Computed Tomography
CUMH	Cork University Maternity Hospital
ECG	Electro Cardiogram
GA	General Anaesthesia
GRS	Global rating scale
ITT	Intention to treat
IOM	Institute of Medicine
IRR	Inter rater reliability
LF	Ligamentum Flavum
LFD	Ligamentum Flavum Duramater complex
MRI	Magnetic resonance imaging
NMH	National Maternity Hospital
OR	Operating Room
PBP	Proficiency Based Progression
PC	Posterior Complex
PSO	Para Sagittal Oblique

PLL	Posterior Longitudinal Ligament
PC	Posterior complex
SAB	Sub Arachnoid Block
TM	Transverse Median
TOT	Transfer of Training
VAS	Visual Analog Score
VR	Virtual Reality
WRD	Wearable Recording Device

Declaration

The author hereby declares that that this thesis has not been submitted as an exercise for a degree at this or any other University. The work, upon which this thesis is based, was carried out in collaboration with a team of researchers and supervisors who are duly acknowledged in the text of the thesis. The Library may lend or copy this thesis upon request.

Signed: Date:

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Dedication

I dedicate this work to my family which has always been the source of my motivation and will to persist against any odds.

To Arulmozhi, who not only stood by me but supported me at every step of my life, no matter how small or big. You have always pushed me to redefine my limits. Thank you for understanding me when I say “I have go to library to do my write up”, even on the 100th time!!! Thank you for everything.

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Publications/presentations arising from or associated with this work

Presentations

A comparison of conventional midline versus pre-procedure ultrasound guided paramedian techniques in spinal anaesthesia, Srinivasan KK, Loughnane F, Iohom G, Lee P, Awarded Delaney medal in March 2015, presented in International Anaesthesia Research Society meeting, March, 2015, The Hilton Hawaiian Village, Honolulu, Hawaii, USA.

Ultrasound of lumbar neuraxial – an MRI correlation study, Srinivasan KK, Mubarak M, O'leary E, Whitty R, presented in Joint anaesthesia and perioperative medicine conference (UK and Ireland), Oct 2013, Dingle, Ireland (second prize for oral presentation).

Publications

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A comparison of conventional midline versus pre-procedure ultrasound guided L5-S1 techniques in spinal anaesthesia, Srinivasan KK, Loughnane F, Iohom G, Lee P: Submitted to Medical Ultrasound, awaiting review.

Lumbar Neuraxial Ultrasound correlation with MRI, Srinivasan KK, Kok H, Mubarak M, Torregianni W,Whitty R: Submitted to BJA, awaiting review.

Does proficiency based progression training of anesthesiologists reduce failure rate of epidural analgesia during labor? , Srinivasan KK, Gallagher AG, O'Brien, O'Connor R, Holt F, Sudir V, Barrett N, Lee P, Walsh M, O'Donnell B, Shorten G: Submitted to BMJ and awaiting review.

Chapter 1 – Introduction

Original Application

The following application to UCC (university College Cork) for MD by Thesis was approved on March 2014 *(Start date- October 2013 , end date - September 2015).*

Title:

Improving the safety, efficiency and efficacy of neuraxial blockade through enhanced operator performance.

Location:

This study will be based at the Department of Anaesthesia and Intensive Care, Cork University Hospital. It will also utilize the expertise at a number of other locations, namely National Maternity Hospital (NMH,Holles Street,Dublin) and Adelaide and Meath hospital, incorporating National Childrens Hospital (AMNCH,Tallaght).

Supervisors:

Dr.Gabriella Iohom, Consultant Anaesthetist and Lecturer in Anaesthesia and Intensive Care Medicine, University College Cork / Cork University Hospital.

Dr.Peter Lee, Consultant Anaesthetist and Lecturer in Anaesthesia and Intensive Care Medicine, University College Cork / Cork University Hospital.

Prof.George Shorten, Professor of Anaesthesia and Intensive Care Medicine, University College Cork / Cork University Hospital.

Objectives of the proposed work

Successful outcome of a procedural skill depends on three major factors - patient, operator and equipment. Patient factors (especially anatomical) in most cases are non-modifiable. The objective of this thesis is to enhance operator performance by applying the advancements in training methodology and equipments to improve efficiency, safety and efficacy of neuraxial blocks. Specific aims were met with following studies.

Improving efficiency

Study 1 - To develop and validate a metric based assessment tool for epidural catheter placement.

Improving safety

Study 2 - To study a methodology to improve the accuracy of palpated landmarks for administering spinal anaesthesia to reduce risk of entering sub arachnoid space at or above L2-3 interspinous space.

Improving efficacy

Study 3 - To look for anatomical correlation between neuraxial ultrasound images and MRI of lumbar spine.

Study 4 - To compare real-time ultrasound guidance versus conventional landmark guided approach to perform spinal anaesthesia.

Deviations from original thesis

The work carried out differ from that described (above) in the original application in the following ways:

On November 10 th, 2014, the application to change from MD to PhD was approved.

As an extension of study 1, an additional study (study 1a) was performed to examine the effect of performance-based progression training of provision of labour epidural analgesia on clinical outcome.

Study 4 was not undertaken; in its place, a formal comparison (study 4a) was carried out of i. a modified form of real-time, ultrasound-guided vs ii. a pre-procedure ultrasound guided paramedian approach to performance of spinal anaesthesia in parturients.

As an extension of study 4a, an ultrasound guided paramedian approach at the L5-S1 interspace was examined for clinical benefit (study 4b).

The rationale for the changes

After preparatory work for Study 1 and 4, it became clear that there was an opportunity to make a substantially greater research contribution with the potential for a corresponding greater increase in impact. Specifically, the opportunity to conduct the first "end to end" study on proficiency based progression training and possibility of further refining the pre-procedure ultrasound guided paramedian technique. Based on this opportunity and the corresponding greater body of work to be undertaken, I elected to apply for a change from MD to PhD by thesis. This application was approved by UCC on November 10 th, 2014.

Please refer to Chapter 2, 3 4, 5 and 6 in which studies will be described in detail.

The first additional study (study 1a) was be an extension of the metrics based assessment tool that was developed in study 1. The objective was to study the impact of training using a metrics-based tool on clinical performance and patient outcome. The addition of this study meant that each aspect of proficiency based progression (procedure characterisation, validation, training and patient outcome) will be studied for a single procedure in continuity. This makes this the first "end–to–end" study on proficiency based training pathway for a procedural skill. If proven successful, this pathway could form the blueprint for future procedural skills training across all medical specialities.

The planned study on real time ultrasound-guided spinal anaesthesia (study 4) was modified to paramedian ultrasound-guided spinal anaesthesia (study 4a). After the initial pilot cases of real time ultrasound guided spinal anaesthesia, it has trasnspired that this technique was more difficult and cumbersome than anticipated. Hence we decided to study a modification: paramedian real time spinal anaesthesia with pre-procedure ultrasound (study 4a).

The second additional study (study 4b) was an extension to study 4a. During the course of study 4a, we observed a possibility to further improve the efficiency of pre-procedural ultrasound guided paramedian technique. As the study was the first of its kind, we felt it was appropriate to further refine the procedure.

Objectives of the thesis following changes

The overall objective is unchanged, namely to improve safety, efficiency and efficacy of neuraxial blockade through enhanced operator performance. Specific aims were adjusted as follows,

Improving efficiency

Study 1 - To develop and validate a metric based assessment tool for labour epidural catheter placement.

Study 1a - To study the effect of metrics based performance based progression training in provision of labour epidural analgesia on clinical outcome.

Improving safety

Study 2 - To study a methodology to improve the accuracy of palpated landmarks for administering spinal anaesthesia to reduce risk of entering the sub arachnoid space at or above the L2-3 interspinous space.

Improving efficacy

Study 3 - To examine corresponding i. neuraxial ultrasound images and ii. Magnetic Resonance Imaging (MRI) of lumbar spine for clinically relevant association and correlation(s).

Study 4a - To compare conventional landmark-guided midline versus pre-procedure ultrasound guided paramedian techniques in spinal anaesthesia.

Study 4b - Comparison of conventional landmark guided midline versus pre-procedural ultrasound guided paramedian at L5-S1 technique for spinal anaesthesia.

Background and Significance

Neuraxial anaesthesia (spinal and epidural anaesthesia) constitutes an indispensable component of modern anaesthetic practice and is one of the most commonly performed regional anaesthesia techniques. The first recorded case of spinal anaesthesia was performed using cocaine in 1898 by Augustus Bier[1]. Since then it has

been extensively used to facilitate surgery involving lower limbs, pelvis and lower abdomen. Neuraxial blocks are also the preferred anaesthetic technique for caesarean sections[2]. As of 2014, caesarean section constitutes 18.6% of the deliveries conducted worldwide.[3] More than 80% of the caesarean sections worldwide are performed under neuraxial anaesthesia[4-7]. It is also the current gold standard for labour analgesia with 30% - 60% of labouring women receiving epidural analgesia for labour[8] [9,10]. Any advancement in clinical research to improve the safety, efficiency and efficacy of neuraxial techniques will impact millions of patients (parturients and foetuses/neonates) worldwide.

Neuraxial anaesthesia and analgesia offers numerous benefits compared to general anaesthesia which includes (but not limited to): better analgesia,[11] reduction in overall morbidity and mortality (up to 30% in all types of surgery and up to 11% in patients undergoing intermediate to high risk non cardiac surgery),[12-14] reduction in post-operative respirator complications,[15] reduction in the rate of blood transfusion,[16] reduction in post-operative paralytic ileus [17] and reduced surgical site infection.[18] There are early encouraging data on association of epidural analgesia with reduction in cancer recurrence.[19-21]

Numerous advancements have been made in the field of neuraxial blocks since 1900, involving needle design and pharmacology. This thesis focusses on two particular advances – proficiency based progression training of procedural skills and neuraxial ultrasound.

Advancements in procedural skill training – improving efficiency

Deaths due to medical errors is the third leading cause of death in United States. More than 250,000 patients die every year due to medical errors.[22] A significant proportion of medical errors (up to 44%) are related to related to procedural skills .[23] High profile cases such as Bristol[24] and the Bundaberg Hospital cases[25], Institute of medicine (IOM) report[23] on medical errors and medical malpractice claims analysis in the USA[26] and Belgium[27] have all highlighted the fact that a lack of technical competence is a major cause of medical error. In spite of the enormous importance of procedural skills, especially in procedure-rich specialities like anaesthesia and

surgery, training and assessment of procedural skills has been largely underdeveloped. There is no formal system currently for either training in or assessment of procedural skills in Medicine.

Training for procedural skills is largely based on the Halstedian apprenticeship model from the early 1900's. For example, trainees learning to perform epidural anaesthesia do so by "practicing" on patients under the direct supervision of seniors (consultants or senior registrars)[28]. Learning a complex and high risk skill by performing procedures on patients is far from ideal. [29] Furthermore, with a global trend towards reduced working hours for trainee physicians, the number of clinical learning opportunities for trainees is decreasing.

Assessment of procedural skill is still subjective. Robust systems exist to evaluate the knowledge aspects of a trainee's education but no such system exists to objectively evaluate a trainee's procedural skills. Educators rely on self-reported log books and informal supervisor feedback to evaluate these important skills. There is a clear need for a paradigm shift in the way we train and assess our trainees in procedural skills.[30,31]

In a recent review of Irish postgraduate education **(Training 21st Century Clinical Leaders, July 2014)** Prof. Imrie recommended a move away from the current time-based model of medical education to an outcome-based approach organised around competencies. Similar recommendations were made in an Institute of Medicine report on post graduate training in USA - **"Graduate Medical Education That Meets the Nation's Health Needs" (July 2014).**[3] The University of Ottawa has already launched the first competency-based medical education (CBME) for anaesthesia residents in 2015.[32]

Simulation training has been around for many years used extensively in aviation and military and has many advantages compared to conventional training (Table 1.1). Its uptake in medical profession is gradually gaining momentum. We are currently witnessing a paradigm shift from "see one, do one, teach one" approach to "see one, simulate one, do one" approach.[33] Review of simulation studies in anaesthesia over

a decade (2001-2010) has shown that simulation training in anaesthesia is now widely accepted. Although simulation training offers many benefits in procedural skill training, there is still limited evidence to show the transfer of trained skills or positive impact on quality and safety of patient care.[34] There is also insufficient evidence on the effects of simulation training on patient outcomes.[33,35,36]

Table 1.1: Advantages of simulation training [37]

1. Ability for repetitive practise
2. Opportunity for feedback
3. Simulate rare events
4. Simulate events with varying severity
5. No patient risk
6. Learning experience in controlled environment

The thesis aims to address the above limitations by the use of "Proficiency based progression" (PBP) training curriculum. PBP differs from current simulation training methods in that it combines simulation training with proficiency benchmarks. The first study on proficiency based simulation training was performed by Seymour NE [38] which was followed by multiple other studies[39-41]. Studies on acquiring arthroscopic Bankart skill set have shown that it is superior to traditional and simulator enhanced training methods.[42] In PBP, the trainees are not allowed to progress to the next training stage until they demonstrate "proficiency" in a simulated setting on par with experts in the field. This "proficiency" benchmark is derived from mean performance score of experts who are evaluated based on validated metrics that characterise the procedure. This concept has been explored in the last decade and is increasingly gathering recognition. We aim to apply this training methodology to improve efficiency of novices in labour epidural catheter placement and to evaluate its effect on patient outcomes.

The hypothesis of this study is to answer the question "Does development, validation and application of metrics-based proficiency based simulation training improve clinical performance and clinical outcome compared to conventional training in provision of labour epidural analgesia". This hypothesis is based on three assumptions. First, that proficiency based progression training (PBP) is better than conventional training for procedural skills.[41] Second, better performance in virtual reality (VR) simulator will be translated into better operating room (OR) performance (VR to OR).[38] Third, that better procedural skills in the operating room lead to improved patient outcomes.[43] Although these assumptions have been tested individually for various procedures, this will be the first study where we will test the overall hypothesis is tested in an "end-to-end" study that examines the process from training to patient outcome.

The implication of completing such an end-to-end study is demonstration of proof of concept and feasibility of this approach to validation of procedural training generally. We believe this will offer a blueprint for procedural training across all medical specialties and cause a paradigm shift to the approach of training and assessment of procedural skills.

Advances in equipment – improving safety and efficacy

In neuraxial blocks, advancements in equipments was largely in the area of improvement in needle designs.[44] The actual technique of performing a neuraxial block (spinal and epidural) as a landmark guided technique, has changed little from the time of initial description.

Ultrasound guidance has greatly improved and augmented the practice of regional anaesthesia. A recent Cochrane review on ultrasound guidance for peripheral nerve blocks[45] concluded that the use of ultrasound resulted in a superior block success, reduced need for supplementation and lower incidence of vascular punctures compared to a peripheral nerve stimulation technique. The use of ultrasound in neuraxial blocks is a recent development. Although the utility of ultrasound for neuraxial scanning was explored as early as 1980[46], it was not until early 2000 [47-54]that it came to wider use. Neuraxial ultrasound is challenging due the presence of

bony spinal canal and the depth of the target tissue (sub-arachnoid space and epidural space), both of which limit the usefulness of ultrasound beam. This makes it an advanced skill to master relative to superficially situated peripheral nerve blocks. The reasons behind poor neuraxial ultrasound views are not fully elucidated yet. Hence in study 3, we aimed to use MRI data to enhance our understanding of the reasons underlying the inconsistent and limited images obtained when performing ultrasound of neuraxis.

Use of ultrasound to facilitate neuraxial block can be done in many ways. It can be done as a pre-procedural examination to delineate the underlying spine anatomy or it can be used to provide a real time guidance to administering spinal or epidural anaesthesia. Use of real time ultrasound guidance is largely limited to case reports.[55-57] With currently technology, its use is limited by the requirement for wide bore needles and the technical difficulties associated with simultaneous ultrasound scanning and needle advancement.[58] Pre-procedure ultrasound provides information to aid the performance of neuraxial block: interspinous level, midline, depth of the epidural and or sub-arachnoid space, angle of needle insertion, optimal needle point entry etc. Its use improves the precision and efficacy of neuraxial techniques.[59]

The ability of neuraxial ultrasound to identify the interspinous space was used to improve the safety of neuraxial blocks. Interspinous level at which spinal anaesthesia is administered is a surrogate marker for potential spinal cord injury.[60] As neuraxial ultrasound identifies interspinous space more accurately compared to palpation[61-63] (with training up to 90% accuracy can be achieved[61]) we utilised this to improve the accuracy of palpated landmarks for performing spinal anaesthesia in patients undergoing caesarean section. We specifically sought to use ultrasound guidance to improve the accuracy of palpated landmarks (as opposed to using ultrasound solely to identify the landmarks) for several reasons. Firstly, millions of spinal anaesthetics are being performed for caesarean sections across the world, especially in developing and third works countries, where the access to ultrasound for neuraxial scanning is limited. A study designed to improve safety by routine ultrasound, even if it is effective, may not reach everyone. Secondly, as neuraxial ultrasound is an advanced

scanning procedure, even in developed countries, it involves a steep learning curve which might make widespread adoption challenging. Finally, the cost and time involved to facilitate the routine use of ultrasound in a busy obstetric setting might not be practical.

Number of passes and attempts are used as markers to assess the efficacy of administration of neuraxial blocks. Multiple passes and attempts while administering neuraxial anaesthesia are associated with a greater incidence of post dural-puncture headache, paraesthesia and neuraxial hematoma.[64-67] The use of pre-procedural ultrasound increases the first pass success rate for spinal anaesthesia in patients with difficult surface anatomic landmarks[68] but not when routinely used in all patients.[69] Also, studies on pre-procedural ultrasound-guided spinal techniques are limited to a midline approach using a transverse median view (TM). The para-sagittal oblique (PSO) view consistently offers better ultrasound view of the neuraxis compared to TM views. We attempt to address both of these issues by a) routine use of pre-procedure neuraxial ultrasound b) use of para-median approach to performing spinal anaesthesia guided by pre-procedural ultrasound. The aim with both these interventions is to decrease the number of passes and attempts needed to achieve a successful dural puncture, thereby improving the efficacy of the block.

Study Design

Improving efficiency

Although neuraxial blocks are done in wide variety of clinical scenarios, labour epidural catheter placement was chosen to study the impact of training methodology on efficiency. This was due to a couple of reasons. First, trainees learn this in the early part of their training, typically within the first two years. Second, trainees perform large number of epidurals in a relatively short span of time. Both these factors make this an ideal procedure in which to study the effect of a training methodology.

In the initial phase of the study procedure-specific metrics for labour epidural analgesia were developed (study 1). This was carried out in a series of meetings between experts who identified, characterised and defined the procedure. The

metrics developed were then assessed for construct validity (the degree to which the test terms identify the quality, ability or trait it was designed to measure) and concurrent validity (in which the relationship between the test scores and the scores on another instrument purporting to measure the same construct are related). This was done by scoring videos of experts and novices performing labour epidural catheter placement based on metrics developed.

The next phase of the study involved a randomised control study to look at the impact of proficiency based training on patient outcomes (study 1a). This was done by randomly allocating the trainees in to two groups. One group received conventional training and the other group received proficiency based training. Data was collected from the first 10 epidurals performed by the trainees following the training. The primary outcome was pre-defined failure of epidural analgesia.

Improving safety

Direct injury to the spinal cord is a devastating complication of neuraxial blockade. Although rare, the outcome can be debilitating.[60] Spinal anaesthesia administered at or above L2-3 interspinous level can be used as a marker to identify "near miss" cases of spinal cord injury. This is very relevant in pregnant patients who undergo spinal anaesthesia for caesarean section. The incidence of spinal cord injury arising from direct injury by spinal needle is relatively high in this population .[60] Hence this patient population was selected for this particular study.

The aim of this study (study 2) was to improve the accuracy of palpated landmarks to reduce the incidence of spinal anaesthesia done at or above L2-3 interspinous level. In a randomised controlled study, trainees chose two different landmarks to identify the appropriate interspinous space depending on the group to which they were allocated. Once an interspinous space was selected, the use of neuraxial ultrasound enabled identification of the interspinous space. The primary outcome measure was the number of spinal anaesthetics administered at or above the L2-3 interspinous space.

Improving efficacy

Number of attempts and passes has been used to quantify efficacy of neuraxial blocks.[70] Lower limb joint replacement surgeries are usually performed under spinal anaesthetic. Older age profile of this patient population group makes the administration of spinal anaesthesia difficult.[71] Thus they are an ideal cohort in which to study the effect of interventions to improve efficacy of neuraxial blocks.

Ultrasound has been increasingly used to aid neuraxial blocks.[59] The final three studies focuses on application of this technology to reduce the number of passes needed to achieve a successful dural tap.

In study 3, the aim was to look at the anatomical correlation between neuraxial ultrasound image and MRI of lumbar spine. Patients more than 18 years of age, scheduled for MRI lumbar spine were included in the study. The patients had their MRI scan performed following which neuraxial ultrasound imaging of lumbar spine was performed on the same day. The ultrasound images were categorised in to good, intermediate or poor view based on the visibility of ligamentum flavum/ duramater complex. The correlation between the ultrasound images and predetermined anatomical parameters on MRI were then analysed. This study will shed more light on reasons behind poor ultrasound imaging.

Following this, in study 4a, our aim was to look at paramedian approach to spinal anaesthesia aided by pre-procedural ultrasound. In this randomised control study, patients scheduled for elective lower limb joint arthroplasties were randomised into receiving either conventional midline spinal anaesthesia or pre-procedure ultrasound guided paramedian approach guided spinal anaesthesia with the aim to reduce the number of passes needed to achieve successful dural tap. During the course of this study, we observed a trend towards smaller number of passes in L5-S1 interspinous space within the paramedian group. This formed the basis for study 4b in which we looked specifically at pre-procedure ultrasound guided paramedian spinal anaesthesia at L5-S1 interspinous space compared to conventional midline approach. This was done in the same population having lower limb joint arthroplasties performed under spinal anaesthetic. This was done in the same

population group having lower limb joint arthroplasty performed under spinal anaesthetic. Both these studies were designed to improve the efficacy of administering spinal anaesthesia by potentially reducing the number of passes needed to achieve successful dural tap.

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Chapter 2 (study 1, study 1a) - Does proficiency based progression training of anaesthetists reduce failure rate of epidural analgesia during labour?

Abstract

Background

Procedural skills of medical practitioner is closely related to patient outcomes. There is currently no widely accepted approach towards training and assessment of procedural skills. Proficiency based progression methodology (PBP) of training for procedural skill has consistently resulted in reduction of errors during operative performance. We hypothesized that development and validation of a metric based objective assessment tool, followed by its implementation via PBP methodology will decrease the failure rate of epidural analgesia during labour compared to simulation only training methodology.

Methods

Detailed procedure specific metrics for labour epidural catheter placement was developed by based on consensus opinion by three experts. Construct validity and concurrent validity of the assessment tool was established. The assessment tool along with proficiency criteria obtained during the validation phase was then incorporated in to PBP training methodology using simulator. 17 novice anaesthetic trainees were randomised into either group P (PBP methodology) or group S (simulation only methodology). Following training, data from the first ten labour epidural performed was obtained from each trainee. Primary end point was to compare epidural failure rate between the two groups based on pre-defined criteria. Secondary end point was to look at impact of training on clinical performance, patient satisfaction, comparison of proportion of trainees with more than one failure between groups and number of failure per trainee between groups.

Results

A total of 74 metrics were developed and validated. The inter-rater reliability (IRR) metrics based assessment tool was 0.88. A total of seventeen trainees were recruited of which eight trainees were randomised to group S and six trainees to group P. Epidural analgesia failure rates in 140 patients receiving epidural analgesia subsequently administered by these trainees was compared. Baseline characteristics of trainees and demographic variables of the patients were similar between both groups. PBP training reduced the incidence of epidural failure by 46.3% compared to simulation only group (epidural failure in group S= 28.7%, epidural failure in group P = 13.3%, Chi square test, p=0.04). The proportion of patients who experienced pain during uterine contraction at 60 minutes from the time of epidural needle insertion was also greater in Group S (25% , 20/80) than in Group P (10% , 6/60)(Chi square test p = 0.03). Other parameters were similar between the two groups.

Conclusion

Procedure specific metrics developed for labour epidural catheter placement discriminated the performance of experts and novices with IRR of 0.88. PBP training with simulation based on metrics developed reduces epidural failure rates by 46% when compared to simulation only training. This model for evidence based training may be of benefit applied to other procedures.

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Introduction

Medical errors account for as many as 250,000 deaths in the US every year.[1] A significant proportion of such errors (44% by one estimate) are related to procedural skills .[2] Certain procedural skills have been shown to be strongly associated with meaningful patient outcomes.[3] Although it is accepted that training should be based on achievement of specific competencies, no widely accepted approach to the training and assessment of procedural skills exists at present.

Training for procedural skills remains largely based on the apprenticeship model developed during the early 1900's[4]. Educators rely on self-reported log books and informal supervisor feedback to evaluate these skills. Learning a complex and high risk procedural skill on patients is far from ideal.[5] With the global trend towards reduced working hours for trainee physicians, the number of clinical learning opportunities for trainees is decreasing. There is a clear need for a paradigm shift in the way that doctors are trained and assessed in the performance of procedural skills.[6,7]

Currently various techniques exist to assess procedural skills in anaesthesia[8]. For epidural catheter placement, task specific check lists, global rating scales and cumulative sum techniques have been developed and validated.[9,10] These techniques attempt to i. achieve better qualitative outcome (based a subjective assessment) or ii. rely on some form of self-reporting. The resulting limitation in objectivity undermines two critical characteristics of the assessment namely i) inter-rater reliability and ii) facility to provide meaningful feedback to the learner.

We hypothesized that a detailed characterization of a procedural skill (epidural catheter placement for labour analgesia) could inform development of an assessment tool, proficiency standards and an effective training programme which , compared with standard training, would result in superior clinical outcome (effective analgesia). If successful and feasible, this "end to end" approach could provide a model for procedural training generally. We refer to the approach to training employed in this study as proficiency based progression (PBP); it is based on specific unambiguously defined objective metrics and require a learner to achieve proficiency

in each step or phase of the procedure before progressing to the next.[11,12] PBP has been used successfully for procedural skill training in surgery [13] and has begun to be applied to anaesthetic procedures.[14]

Our hypothesis was based on three assumptions. First, proficiency based progression training (PBP) is superior to conventional training for procedural skills.[15] Second, superior performance in a simulated setting will "transfer" to superior performance in a clinical setting.[16] Third, superior procedural skills in the delivery suit will lead to improved patient outcomes (effective epidural analgesia).[3] Although these assumptions have been tested individually for various procedures, this will be the first study in which the overall hypothesis has been tested.

Methodology

With institutional ethical approval (September 2013) and having obtained written informed consent from all participants (anaesthetists and patients), the study was conducted at Cork University Hospital and Cork University Maternity Hospital from September 2013 to September 2016. It was registered with clinicaltrails.gov (study 1 -part 1 &2 -NCT2179879, study 1a - NCT02185079).

Study 1 – part 1: Development of metrics

A group of three experts (MW,BOD,PL) in lumbar epidural catheter placement were selected (an expert was defined as one who has performed more than 500 labour epidural catheter insertions in the preceding 5 year period). They attended five face-to-face meetings (each lasting for 120 -180 minutes). All the meetings were attended by the experts and the same facilitator was present for all the meetings (KKS). During these meetings, the experts identified, characterized and defined the procedure. The expert group then proceeded to identify and define i. metrics or units of behaviour to be measured which together constitute in a step-wise fashion how the procedure is optimally performed and ii. errors or deviations from optimal procedure performance as described previously.[12]

Two video recordings of experts and two video recordings of novices (performing epidural catheter insertion were recorded (see below for technique) for review

during metric development meetings. Novices were defined as anaesthetic trainees with fewer than two years of experience and who have performed fewer than 50 epidural catheter insertions in total.[17]

The experts were requested to define each metric (procedural unit) in the procedure objectively, specifically, and without ambiguity. A metric could be either a step in the procedure or an error. A metric was included only if it they are observable on a head mounted video recording of the procedure. Assessment outcomes were defined dichotomously as "yes or no" answers i.e. that the metric (step or error) as defined either had or had not occurred. For this particular procedure, all metrics were recorded as errors. During this process, the experts were also requested to identify "critical errors" which were defined as errors i) that are likely to result in significant patient harm ii) jeopardize the whole procedure . All discussions during the expert group meetings were audio taped for future reference.

On the completion of the metric development, the expert group independently scored two videos of labour epidural catheter placement (one by a novice and another by an independent expert) using the metrics based assessment tool developed. Scores were compared and any reason for disagreement on rating between experts on a specific metrics (error/critical error in this procedure) was discussed. Further refinement of the individual items was made based on the observations and a final list of metrics (errors and critical errors) was certified by the expert group (appendix 1).

Study 1 – part 2: Validation of metrics

The metrics were then subjected to assessment for construct validity (a set of procedures for evaluating a testing instrument based on the degree to which the test terms identify the quality, ability or trait it was designed to measure) and concurrent validity (the evaluation in which the relationship between the test scores and the scores on the another instrument purporting to measure the same construct are related). Videos of eight experts and eight novices, each performing two lumbar epidural catheter placements for labour were video recorded following written informed consent both from patient and anaesthetist. A wearable camera mounted

glass (1280*720 p, 30fps, Ottera technology ltd, IE) was used for video recording from first person point of view. No third person video recording was used. To be eligible for use in validation, each videos was required to meet the following criteria: i) it should capture the entirety of procedure from the pre-defined start point to end point ii) the procedure should be completed in full by the study participant (novice or expert) iii) it should allow evaluation of all the metrics (including errors).

The eligible videos were then anonymized and submitted to two independent assessors (KH, OOS) who were blinded to the experience of the anaesthetist performing the procedure. The assessors had not participated in the development of the metrics. They were trained in evaluation of performance using the derived metrics, global rating scale (GRS) and task specific checklist (TSCL) in a three hour training session. This training session involved a face to face meeting with the assessors in which detailed description of the metrics, TSCL and GRS were provided. The assessors then scored sample videos independently. Any discrepancies in their scores were discussed in detail. Training was given till inter-rater reliability of 0.8 or above was maintained. Following this training, they reviewed the video recordings and scored the performance based on metrics, GRS and TSCL.[10]

Study 1a: Impact of PBP training on patient outcome

This part of the study comprised a prospective, randomized, single blind control study carried out at Cork University Maternity Hospital. An investigator contacted eligible patients (all pregnant patients of 32 - 38 weeks registered for delivery at Cork University Maternity Hospital) initially by telephone. If the patients were agreeable to receive further information on the study, a detailed patient information sheet and consent forms were provided to them. The patients also were provided with an online link to access the study information via- http://www.ucc.ie/en/assert/aboutthecentre/research/researchproject/. This was hosted in University College Cork website. An investigator subsequently met with patients during one of their antenatal visits, addressed any questions and, if the patient was agreeable, written informed consent to participate in the study was obtained. The participating consented trainees (anaesthesia trainees with fewer than

two years of experience in anaesthesia and performed fewer than 50 epidural catheter insertions in total) were randomly allocated to either group S (simulation training group) or group P (PBP group). Random allocation was done using computer generated random numbers and the allocations were enclosed in sealed envelopes. This was opened prior to randomization of each trainee. The following baseline information was collected from the trainee participants using a questionnaire:

1. Experience in anaesthesia (total experience in months)
2. Total number of epidurals attempted till date (based on estimates and not limited to labour epidurals)
3. Total number of spinal anaesthetics performed till date
4. Use of corrective eye-glasses or contact lenses
5. Presence of colour blindness
6. Date of most recent epidural performed/attempted (whether labour or not)

All participating trainees were required to complete a set of psychometric and visuospatial tests to ensure homogeneity of the trainees namely: card rotation test, cube comparison test, map planning test and Edinburg handedness inventory.[16,18,19]

Trainees in both groups were given access to common study material on labour epidural analgesia prior to attendance at a training workshop (appendix 2, 3). An assessment (MCQ) based on the material provided was done within two weeks of provision of the material to trainees in group P. Trainees in Group P were required to score a predefined pass percentage (80%) before they could proceed to the next phase of training. If the score was not met, additional time was given for the trainees to review the study material provided. No assessments were carried out at this stage in group C. Within four weeks of receiving the study material, participants in both groups attended a workshop consisting of didactic session and a simulation training phase.

In group S, all participants received a didactic face to face presentation (standard content specific to group S delivered by one of the clinical experts from the research group) on performing labour epidural catheter placements which included all the

metrics developed from the part 1 of the study. This didactic session of the workshop was followed by simulation training phase during which the participants were given instructions on how to use the epidural simulator (Manikin KKM43E, Cardiac services 2013, SISK healthcare group, UK). The same epidural simulator manikin was used for both groups .They were allowed to practice in the presence of and with advice from a clinical expert. The trainees were given access to an epidural simulator for a maximum of four hours each day for two consecutive days. The actual duration of simulator use was left to the discretion of the trainees. No assessment was done at the end of their simulation training session.

During the didactic session in group P, all participants received a didactic face to face presentation (standard content specific to group P delivered by one of the clinical experts from the research group) on performing labour epidural catheter placements. During this session every one of the seventy four metrics developed in part 1 of the study was described in detail with the use of specific examples. Relevant video recordings and examples from part 1 of the study was used to highlight how errors happen in “real life” clinical situations. Following this, the trainees proceeded to simulation training phase. In this phase, the trainees were initially given instruction on how to use the simulator and then allowed to practice, hands-on, every metric of epidural catheter placement from pre-defined start to end points (as identified in the metrics based assessment tool in part 1 of the study) on the manikin. At each metric, specific focused feedback was given on how to avoid errors/critical errors. Once the trainee had clear understanding of all the individual metrics involved, they were requested to demonstrate the procedure from the start to finish. Two assessors then independently scored (based on metrics based assessment tool) the procedure performed by the trainee on the manikin. Feedback on errors/critical errors (if any) identified during the procedure were provided. This process was repeated till the trainees were able to attain predetermined level of proficiency consistently. The level of proficiency was based on i) not performing critical errors as identified during development of metrics ii) overall error rate not more than the average (mean) number of error made by experts as identified during validation (part 2 of the study). Trainees in group P were not allowed to proceed to the next phase until they

demonstrate proficiency in the above mentioned steps on two consecutive assessments. The proficiency level was defined as performing no critical errors and a total error count less than or equal to the mean error count of expert group obtained during study 1 part 2. A copy of the list of metrics was provided to all the trainees in group P. The number of attempts needed to achieve proficiency was noted for each trainee.

Following the workshop (consisting of training session and simulation training phase) both groups proceeded as part of the standard training module in obstetric anaesthesia offered at CUMH to perform labour epidural catheter placements. Outcome data were collected from the first 10 labour epidural catheter placements performed by the trainees after the workshop. All participants performed the first of these labour epidurals within two weeks of completion of the workshop or, in the event that two weeks elapsed before the opportunity to do so arose, they underwent re-training by participating in a repeat workshop (including both common training session and simulation training phase) corresponding to the group they were allocated.

The principle outcome of the study was proportionate epidural failure rate between groups. Between group participant failure rates and proportions of groups made up of participants with at least two failures were secondary outcomes. Successful epidural analgesia was defined as one administered unaided by the trainee, without clinical evidence of accidental dural puncture, which resulted in satisfactory analgesia within 60 minutes from the time of first insertion of the epidural needle. The presence of one or more of the following resulted in the attempt being deemed a failure i) accidental dural puncture ii) supervisor takeover iii) patient experiencing no or unsatisfactory pain relief from uterine contractions within 60 minutes form the time of epidural needle insertion iii) the abandonment of the procedure. This was documented by the midwife in the labour ward assigned to the patient. This midwife was unaware of the to the study group to which the participating anaesthetist belonged.

Other secondary outcomes of the study were to assess the impact of training ("VR to OR") clinical performance (in order to assess the degree of transfer of training effect to the clinical setting), patient satisfaction, comparison of proportion of trainees with more than one failure between groups and number of failure per trainee between groups. Transfer of training was assessed by evaluating video recording of placement subset of procedures for which parturients had provided informed consent. Video recordings were acquired using wearable camera mounted glasses (1280*720 p, 30fps, Ottera technology ltd, IE), similar to that used during the validation phase. As for the validation phase, to be eligible for inclusion, i) videos were required to capture the procedure continuously from the pre-defined start and end points ii) the procedure be completed by trainee in full from start to finish iii) the video acquired by the camera should enable evaluation of all the metrics including errors. The eligible videos were then anonymized and submitted to two independent assessors (AR, PC) who were blinded to the identity of the anaesthetist performing the procedure and the group to which they belonged. The assessors who participated in this phase were from different institutions (to that where the study was carried out) and were not involved in the development or validation of the metrics. The assessors were trained as described earlier until the IRR was 0.8 or greater. Patient satisfaction with the quality of their labour analgesia was assessed by telephone calls following delivery within a week. Patients were asked if they were satisfied with labour analgesia received (answer – yes or no).

In addition to demographic data of the patients, the following clinical data were collected: accidental dural puncture, presence of supervisor, requirement to re-site the epidural catheter at any stage during labour, type of delivery, and analgesic efficacy of drugs administered via the epidural catheter if used for instrumental delivery or caesarean section.

Sample size calculation

Labour epidural failure rates according to criteria listed above for year 1 trainees is 25% based on estimates from previous studies.[20] Based on the magnitude of effect of PBP training applied to other procedures[11,15] we sought a decrease in failure rate

in interventional group to 5%. Based on alpha= 0.5 and beta = 0.8, we estimated that a minimum sample size of 48 procedures per group was required. To allow for dropouts and other contingencies, we recruited eight trainees per group, each of whom would perform 10 consecutive procedures (80 procedures /group).

Statistics

All parametric data were analysed for normality of distribution by visual inspection of Q-Q plot and by test of normality (Kolmogorov – Smirinov).

Study 1 – part 2

Each video was scored by two assessors independently. The average of the two scores was used as a final score (metrics, errors and critical errors) for the procedure. Analysis of variance (ANOVA) was used to compare the error score between groups and p value less than 0.05 was considered significant. For inter-rater reliability (IRR), a proportion based on the number of agreements between assessors divided by total number of metrics (i.e. proportionate agreement) was used. The merits of this approach have been extensively discussed elsewhere [21]. IRR > 0.8 was considered acceptable.

Study 1a

Student's t test was used to compare parametric continuous data. Non parametric data were compared using Mann-Whitney U test. Chi-Square tests were was used to compare categorical data. The video assessments were summarized and compared as described above. SPSS v22 was used for statistical calculation (IBM, Armonk, New York, NY, USA).

Results

Study 1(part 1) - Development of metrics

There were 74 finalized metrics. For this particular procedure, all the metrics were represented as either errors or critical errors. A total of 12 metrics were identified as critical errors (appendix 2.7).

Study part 2 – validation of metrics

Demographic and baselines characteristics of participants are summarised in Table 2.1.

Table 2.1: Study part 2- Baseline parameters

Demographic variables	**Novice**	**Expert**
Number of anaesthetist	5	6
Age in years – median (minimum, maximum)	27 (24-32)	53 (44 -57)
Sex (M/F)	5/3	6/2
Anaesthesia experience in years– median (minimum, maximum)	1	22.5 (12-25)

During the validation phase, 32 videos were acquired in total (16 expert, 16 – novice) from which 13 expert videos and 9 novice videos met the criteria for inclusion in the final analysis. Of the 10 videos that were excluded, one patient withdrew consent after the video recording had been obtained; during three procedures the operator removed the recording device prior to completion of the procedure; in six videos, the camera did not capture all the procedural steps (Figure 2.1).

The remaining 22 videos were anonymized and analysed. The construct validity of the different scales are presented in Table 2.2. In the metrics scale, the average number of errors made by the expert group was 16 versus 20 in the trainee group. The difference was statistically significant with $p = 0.02$ by one way ANOVA.

The GRS scores (but not TSCL) demonstrate construct validity i.e. differentiate between expert and novice performance. The IRR values for the three different scoring systems are summarised in Table 2.3; use of the metrics scale was associated with greatest IRR, 0.88.

Figure 2.1: Study 1 (part 1 & 2) – outline

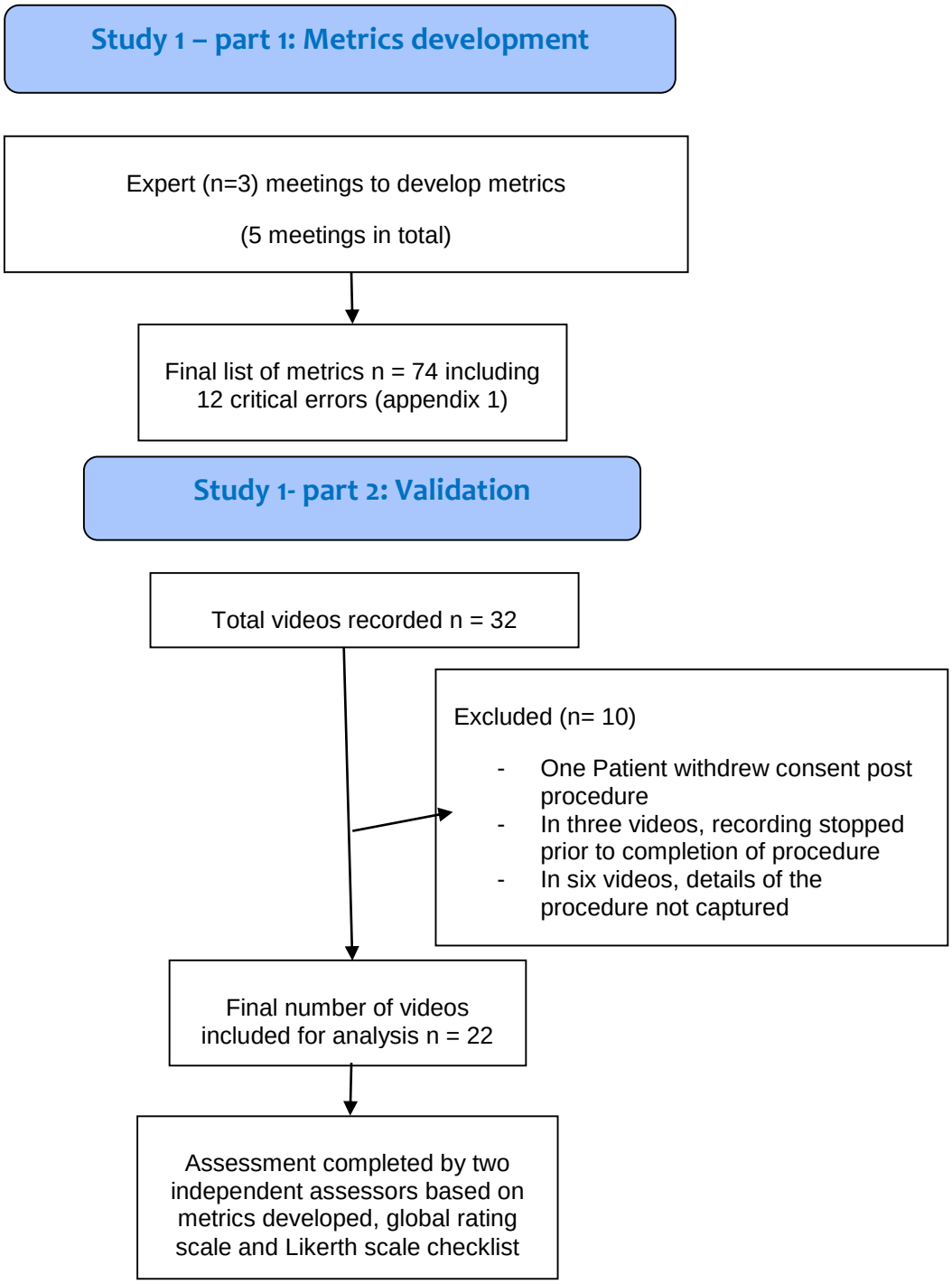


Table 2.2: Study 1 part 2- Assessment scales scoring

Assessment methods	Trainees		Experts		P value
	Mean	SD (CI)	Mean	SD (CI)	
No of errors in Metrics	20	1.59 (18.83- 21.27)	16	4.6 (13.25 – 18.82)	0.02
Task specific check list score	46.9	2.3 (44.1 – 49.8)	48.8	2.7 (46.3 – 51.3)	0.23
Global rating scale score	21.7	2.7 (18.3 – 25)	31.6	1.4 (30.3– 32.9).	<0.001

Metrics – lower is better, TSCL and GRS - higher is better

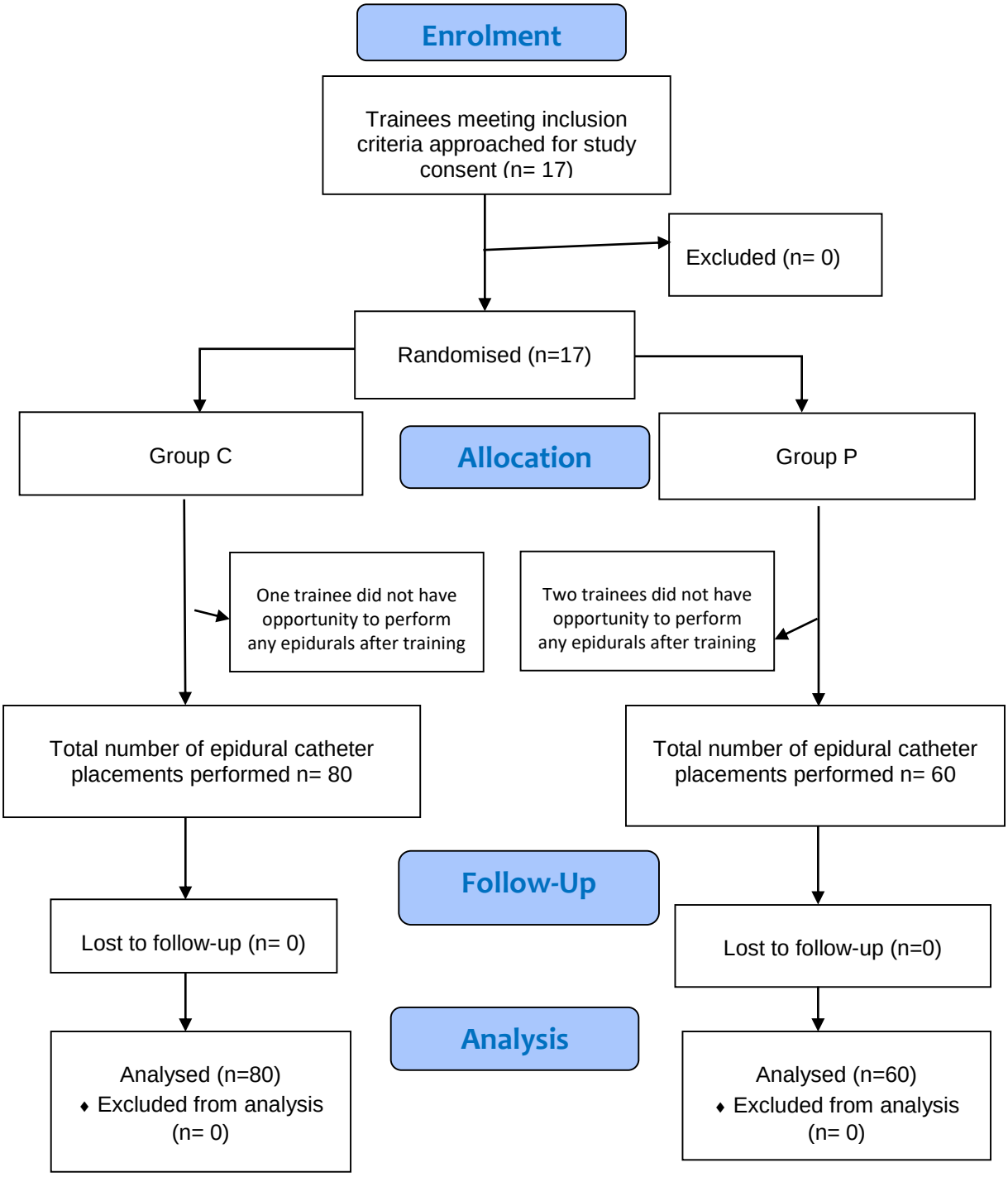
Table 2.3: Study 1 part 2 -Assessment scale IRR

Assessment methods	IRR -Trainees		IRR - Experts		IRR - All procedures combined	
	Mean	SD (CI)	Mean	SD (CI)	Mean	SD (CI)
Metrics	0.86	0.02 (0.83-0.88)	0.88	0.06 (0.85-0.92)		
Task specific check list	0.77	0.08 (0.71-0.83)	0.83	0.05 (0.81-0.87)	0.81	0.07 (0.78-0.84)
Global rating scale	0.15	0.12 (0.06-0.25)	0.46	0.14 (0.37-0.54)	0.33	0.2 (0.25-0.42)

Study 1a – impact of PBP training on patient outcome

A total of 17 trainees were recruited to participate in the study (Figure 2.2, Consort flow chart).

Figure 2.2: Study 1a- Consort flow chart



Of these, one trainee from group S and one trainee from group P did not get an opportunity to perform labour epidural catheter placements within two weeks of participating in the workshop (due to local departmental roster changes) and were not available for re-training. One trainee in group P, who did not get opportunity to perform epidural for more than 2 weeks after the workshop, underwent retraining four weeks after the initial workshop. But he still did not get the opportunity to perform a labour epidural catheter insertion with a second two week window and was not available for re-training. Eight trainees in group S and six trainees in group P proceeded to perform labour epidural catheter insertions.

Baseline characteristics of the trainees were similar in the two groups (Table 2.4, 2.5). Male and female rations were 8:1 in group S versus 3:4 in group P. Only one trainee had colour blindness in group S and none in group P. The demographic parameters, parity of participating parturients and type of delivery were similar in the groups (Table 2.6, 2.7 and 2.8).

Table 2.4: Study 1a- Baseline parameters

Variables	Group S		Group P		P value
	Median	IQR	Median	IQR	
Age	29	5.5	26	3	0.09
Experience in anaesthesia(in months)	17	7	18	6	0.92
Total number of epidurals performed prior to recruitment	16	17.5	10	13	0.29
Total number of spinal anaesthetics performed prior to recruitment	40	30	30	50	0.92
No using glasses/contact lenses	0	1	0	1	0.84
Most recent epidural performed prior to recruitment (days)	7	7	7	7	0.76

Table 2.5: Study 1a - Baseline psychomotor test

Variables	Group S		Group P		P value
	Median	IQR	Median	IQR	
Edinburgh Handedness Inventory scores	90	14.5	90	19	0.29
Card rotation test score	98%	0	95%	0	0.81
Cube comparison test scores	90%	10	90	0	0.81
Map planning test scores	97%	0	97%	0	0.61

Table 2.6: Study 1a- Demographics

Demographics	Group S	Group P	P value
Mean age in years (SD)	31 (5)	31 (5)	0.58
Median weight in Kgs (25 th,75 th percentile)	70 (62,83)	68(62,80)	0.64
Median Height in cms (25 th,75 th percentile)	164 (160,169)	164 (161,169)	0.85
Median BMI (25 th,75 th percentile)	26.7 (23, 29.7)	25.1 (23,28.7)	0.33

All trainees in group P achieved proficiency following three trials on manikin during the workshop. Data were collected during the first 10 procedures each participant performed after completion of training. A total of 80 patients in group S, and 60

patients in group P underwent epidural catheter insertion. Of these in group S, one procedure was abandoned and supervisor take over occurred in eight procedures. In group P, no procedures were abandoned and supervisor taker- over occurred in two procedures.

Table 2.7: Study 1a - Parity

Groups	Para 0 (n)	Para 1 (n)	Para 2 (n)	Para 3 (n)	Para 4 (n)	P value
Group S	39	29	8	3	1	0.21
Group P	35	12	10	3	0	

Table 2.8: Study 1a - Type of delivery

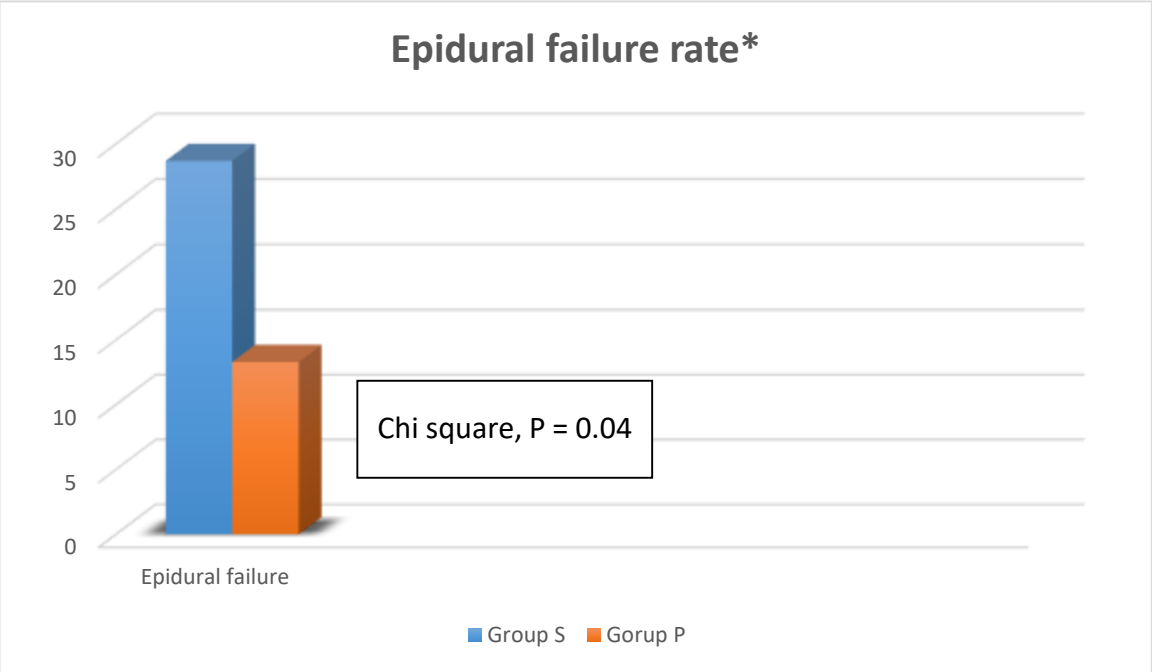
Groups	Normal delivery (n)	Instrumental delivery (n)	Caesarean section (n)	P value
Group S	52	15	13	0.97
Group P	38	12	10	

The principle outcome, proportion of epidural failures - was greater in Group S (23/80, 28.7%) than in Group P (8/60, 13.3 %) (p= 0.04, Chi square test, Figure 2.3). The proportion of patients who experienced pain during uterine contraction at 60 minutes from the time of epidural needle insertion was also greater in Group S (25% , 20/80) than in Group P (10% , 6/60)(Chi square test p = 0.03).

Only 20 of the participating parturients consented to undergo video recording. Of these, 17 were acquired in group P (trainee no 1 = 10 videos, trainee no 7 = 3 videos, trainee no 12 =2 videos, trainee no 13 = 2 videos) and four procedures in group S (trainee no 6 = 3 videos, trainee no 10 = 1 video). Of these 11 acquired from group P and only one video from group S met the criteria for inclusion. The total error score (errors+ critical errors) based on metrics based assessment tool and IRR of the

assessors are summarised in Table 2.9. As there was only a single recording in group S, it was not possible to compare performances between groups. Hence a proposed secondary outcome of the study could not be assessed.

Figure 2.3: Study 1a - Epidural failure rate



*Presence of any one of the following was considered as epidural failure i) accidental dural puncture ii)supervisor takeover iii) patient experiencing no pain relief from uterine contractions at 60 minutes post epidural needle insertion.

Table 2.9: Study 1a - Video assessments

Variables	**Group S**	**Group P**
Number of videos	1	11
Mean number of errors based on metrics	16.5	4.3 (SD 1.8 CI 3.1 -5.5)
IRR	0.96	0.96(SD 0.02 CI 0.95-0.97)

Comparison of proportion of trainees with more than one failure between groups showed no difference (Chi square, p= 0.156) and number of failure per trainee between groups were not different (Wilcoxon rank sum test, p= 0.19). Other epidural analgesia variables were similar in the groups (Table 2.10).

Table 2.10: Study 1a - Labour analgesia variables

Variables	Group S (n=80)	Group P (n=60)	P value
Accidental dural puncture – n (%)	0 (0)	0 (0)	-
Request for senior help - n (%)	10 (12.5)	6 (10)	0.79
Supervisor takeover - n (%)	8 (10)	2 (3.3)	0.19
Procedure abandoned - n (%)	1 (1.2)	0 (0)	0.57
Patient not comfortable at 60 minutes - n (%)	20 (25)	6 (10)	0.03
Reciting epidural at any stage - n (%)	6 (7.5)	5 (8.3)	0.55
Type of delivery - n (%)	Normal – 52 Instrumental – 15 LSCA - 13	Normal – 38 Instrumental – 12 LSCA - 10	0.98
Patient not satisfied with labour analgesia – n(%)	11(13.7)	12 (20)	0.20

Discussion

The development and validation precisely defined metrics and their integration proficiency based progression (PBP) training (when compared to simulation only training) resulted in a decrease in failure rates for provision of labour epidural analgesia. The authors believe that the significance of this finding extends beyond the procedure studied. For the first time three scientifically rigorous training oriented steps have been applied in combination and in sequence to improve a clinical outcome. These are i. procedure characterisation (in the form of unambiguously defined metrics) ii. prospective establishment of construct validity for the resulting characterization and iii. prospective randomized trial of the derived PBP training vs a credible alternative in terms of a clinically meaningful outcome. We suggest that this provides a model which could be applied with benefit to new and existing procedures in medicine.

Assessment tools

TSCL and GRS have been validated for assessment of epidural catheter insertion [10] and other procedural skills in anaesthesia.[22-24] The metrics-based assessment described in this study differ from these in two important ways. First, both TSCL and GRS use Likert scales for assessment. This necessarily introduces an element of subjectivity to the assessment and limits their usefulness to providing detailed, specific feedback to the trainees.[25] The latter underpins effective formative feedback, which is critically important to performance enhancement.

Second, the use of Likert scales tends to decrease the form of inter-rater reliability most relevant to high stakes/risk procedural assessment, namely proportionate agreement (IRR). Certain studies have reported IRR, quantified in the form of correlation coefficients.[26] Correlation coefficients demonstrate association and not agreement.[21] For an assessment tool, especially if used for high stakes assessment, a high level of inter-observer agreement is essential. IRR when calculated as described above proportionate provides an estimate of agreement between the assessors. In this study, although TSCL demonstrated good IRR (score 0.81) but did not differentiate between experts and novices. On the other hand, use of a GRS enabled

differentiation between experts and novices but with a poor IRR score (0.33). Metrics-based assessment was satisfactory both in terms of discriminatory ability (establishing construct validity) and high IRR (score: 0.88).

This combination of objectivity and good IRR appears to support makes metrics-based assessment as a suitable tool for both assessment and training of procedural skills.

Simulation training, PBP and patient outcomes

Patient outcomes are reported in only 0- 5% of medical education studies.[27-30] In a meta-analysis of simulation studies examining patient outcomes, simulation training, when compared to no simulation training, demonstrated a trend towards benefit (OR 0.36, CI -0.06 to 0.78) which was not statistically significant (p= 0.09).[30] A systematic review on simulation training in anaesthesia arrived at a very similar conclusion i.e. that simulation training was, at best, non-inferior to no simulation training.[31] Currently at least, there is limited evidence on the effectiveness of simulation training for regional anaesthesia procedures.[32]

PBP training differs from simulation only training in that the trainees are not allowed to progress to the next training stage (of the procedure) until they demonstrate "proficiency "in a previous stage in a simulated setting. The proficiency benchmark applied (as described in this study) is defined using the quantified performance of experts. This "proficiency" benchmark is derived from mean performance score of experts who are evaluated based on validated metrics that characterize the procedure. The first study on proficiency based simulation training was performed by Seymour NE [16] which was followed by multiple other studies mainly in surgical domain.[11,15,33] In a recent study on acquisition of arthroscopic Bankart skill set by Angelo et al,[13] three groups of trainees were compared. The first group underwent traditional arthroscopy training, the second received training on a shoulder model simulator (using a metrics based curriculum) and the third group underwent PBP training (metrics based curriculum) with a simulator. The metrics used for the study had been developed, stress tested and validated in advance.[34] Participating senior orthopaedic residents surgical skills were assessed on their performance using a

cadaveric shoulder model. The study demonstrated that residents in the PBP group made 56% fewer objective errors compared to those in the traditionally trained group and 41% fewer errors compared to those in the simulation group (both differences statistically significant). Similarly in a RCT on laparoscopic salpingectomy skills acquisition, comparing PBP trained doctors combined with VR simulation versus a control group, Larsen et al[34] demonstrated significant superiority in the PBP group. It is notable that the operative time of the PBP-trained procedures was half of that in the control group in PBP group (12 minutes vs 24 minutes, p <0.001).

The current study differs from others on PBP training in two important ways: first the principle outcome was a meaningful clinical outcome (not just performance quality) and secondly, the derivation of metrics, their validation and their application to training was carried out as part of one continuous process, one we refer to as an "end-to-end" trial. To our knowledge, this is also the first study in anaesthesia to use PBP training methodology. We conclude that that PBP training of anaesthesia trainees can lead to a substantial (46%) decrease in epidural failure rate.

Although no definition of epidural failure is widely accepted, reported failure rates vary between 8 - 23%.[36-38] Thangamuthu et al[20] used a Delphi methodology to standardize the definition of epidural failure and retrospectively reviewed 2169 epidurals performed in the UK over a one year period. Epidural failure was deemed to have occurred if one of the following was present: i) inadequate analgesia reported at 45 minutes after epidural catheter placement ii) accidental dural puncture iii) abandonment of the procedure iv) the epidural catheter needed to be re-sited at any stage during labour v) patient dissatisfaction with the analgesia provided at follow up. Using the standard definition, the incidence of epidural failure rate was reported to be 26.8% in year two trainees and 17.4% in consultants. Patient satisfaction is subjective and can depend on factors other than adequate pain relief. Epidural catheter migration is known to occur either inwards (up to 13.7%) or outwards (up to 22.2%).[39] This might lead to deterioration in analgesia requiring re-siting of an appropriately sited epidural catheter and may not be a consequence of operator error. As our intention in this study was to objectively measure the initial

failure rate associated with deficiencies in the procedure of catheter insertion, both were excluded from the definition of failure rate we employed.

If our study definition of epidural failure was applied to Thangamuthu et al study[20], the incidence of failure would have been 25.3% in year two trainees and 12.6% in consultants (this is an approximation as Thangamuthu et al study[20] recorded abandoned and resiting as a single complication and hence we could not separate them). The incidence of failure rate we report is consistent with that (i.e. 28.7% failure in group S). The prospectively collected data reported in our study versus retrospectively collected data from the previous study might account for the small difference in failure rate. One interpretation of these findings is that the failure rate of those who underwent PBP training (13.3%) was similar to that of consultants as reported from previous study. Also, significantly more patients in group S had inadequate analgesia (25%) compared to group P (10%). This outcome is important as it is clinical and patient centered outcome.

Wearable recording device

This study utilized only wearable recording device (WRD) for the purpose of video recording. No third person video recording was used. Wearable recording devices are increasingly used in medical training.[40,41] The use of devices such as Google Glass[47-49] and GoPro [46-48] have been reported. This study has shown that the use of WRD is feasible in a clinical setting and it has the potential for widespread application in the field of procedural skill training.

One notable strength of this study is the fact that the entirety was conducted in the setting of a busy tertiary referral maternity hospital. We believe that provides support for the contention that PBP training based on carefully defined metrics is not just an useful research methodology but a feasible approach to the training of doctors in “real world” clinical settings.

The study does has certain limitations. First, the study did not succeed in measuring one of its pre-defined secondary outcomes, namely procedure performance in the clinical setting. Another difficulty we encountered was ensuring that the videos

acquired as met the predefined criteria. The videos obtained of trainees in group P demonstrated that the error rates were consistently and uniformly less than (i.e. superior to) the benchmark level set prior to training. With advancement in technology we believe some of the issues can be addressed in future studies. Head mounted cameras from which the captured video can be viewed live on a mobile phone are available and that may enable us to address this issue in the future. Even though we could not evaluate the transfer of training (TOT) in our study, PBP training methodologies previously have consistently reported high TOT using similar training methodology.[11,15,33] Hence we believe this study will not be any different. Further work on this aspect of PBP as a practical training model is required and underway.

Second, this was a single centre study. The PBP training workshops were provided by authors who were involved with development of metrics from development stage. It remains to be seen if similar results can be replicated in other centers. Certain design elements of the study were intended to minimise the potential for institutional or investigator bias, namely: i) the metric definition were required unambiguous descriptions of observable behaviors. This should enable specific feedback to be given during training ii) proficiency benchmark criteria were unambiguous iii) none of the assessors were involved with the development of metrics and they were from different institutions but assessment data demonstrated good IRR. Finally, no attempt was made to measure "skill of optimising epidural analgesia" e.g. timing, dose and selection of agents for top ups etc. This ultimately will influence overall quality of analgesia during labour; our focus was on initial achievement of satisfactory analgesia.

Summary

Procedure specific metrics developed for labour epidural catheter placement discriminated the performance of experts and novices with IRR of 0.88. PBP training with simulation based on metrics developed reduces epidural failure rates by 46% when compared to simulation only training. This model for evidence based training may be of benefit applied to other procedures.

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Appendices

Data corresponding to the appendices (except Appendix 2.7) are provided in the supplementary digital content accompanying this thesis in a folder named Chapter 2.

Appendix 2.1, 2.2, 2.7 are attached in this document below.

Appendix 2.3

Visuospatial and handedness test labelled – Appendix 2.3

Appendix 2.4

Study material for the workshop 1 - PDF document labelled Appendix 2.4

Appendix 2.5

Study material for the workshop 2 – PDF document labelled Appendix 2.5

Appendix 2.6

Multiple choice questions (MCQ's) for group P – PDF document labelled Appendix 2.6

Appendix 2.1

Global rating scale (GRS)

Global-Rating Scale for Epidural Anesthesia

Preparation for procedure	1	2	3	4	5
	Did not organize equipment well. Has to stop procedure frequently to prepare equipment.		Equipment generally organized. Occasionally has to stop and prepare items.		All equipment neatly organized, prepared, and ready for use
Respect for tissue	1	2	3	4	5
	Frequently used unnecessary force on tissue or caused damage		Careful handling of tissue but occasionally caused inadvertent damage		Consistently handled tissues appropriately with minimal damage
Time and motion	1	2	3	4	5
	Many unnecessary moves		Efficient time/motion but some unnecessary moves		Clear economy of movement and maximum efficiency
Instrument handling	1	2	3	4	5
	Repeatedly makes tentative or awkward moves with instruments		Competent use of instruments but occasionally appeared stiff or awkward		Fluid moves with instruments and no awkwardness
Flow of procedure	1	2	3	4	5
	Frequently stopped procedure and seemed unsure of next move		Demonstrated some forward planning with reasonable progression of procedure		Obviously planned course of procedure with effortless flow from one move to the next
Knowledge of procedure	1	2	3	4	5
	Deficient knowledge		Knew all important steps of procedure		Demonstrated familiarity with all aspects of procedure
Overall performance	1	2	3	4	5
	Very poor		Competent		Clearly superior

OVERALL, SHOULD THE CANDIDATE: PASS FAIL

Appendix 2.2

Task specific check list (TSCL)

Task-Specific Checklist for Epidural Anesthesia

Stages Performed	Not Performed	Performed Poorly	Performed Well
1. Ensures patient is positioned comfortably and safely in the middle of the bed			
2. Adjusts height of bed appropriately			
3. Carefully prepares a sterile work surface			
4. Pours antiseptic solution (or has nurse pour it) without contaminating the epidural set			
5. Washes hands and puts on gloves in a sterile fashion			
6. Optimally positions him/herself for the procedure			
7. Prepares the skin at the back widely and aseptically (skin prep _ 3)			
8. Allows solution to dry			
9. Neatly lays out and prepares all necessary equipment (needles, syringes, local anesthetic)			
10. Asks patient to arch her back			
11. Places drape over patient's back in a sterile fashion			
12. Landmarks site of injection after palpating iliac crests			
13. Warns patient of needle insertion			
14. Infiltrates subcutaneous layers with local anesthetic			
15. Places epidural needle with correct positioning of bevel			
16. Inserts epidural needle through skin, subcutaneous tissue, and into ligament before attaching the syringe			
17. Attaches air/saline filled syringe to the needle hub with needle well controlled			
18. Braces hand/s holding the needle against patient's back in complete control of the needle			
19. Slowly advances needle through supraspinous and interspinous ligaments and into ligamentum flavum while applying pressure on the plunger (continuous or intermittent)			
20. Identifies LOR and immediately releases pressure on the plunger			
21. Notes depth of needle insertion before threading catheter			
22. Warns patient about possible paresthesia during catheter threading			
23. Detaches the syringe and threads the catheter to a depth of 4-5 cm			
24. Pulls the needle out while maintaining correct catheter placement			
25. Carefully aspirates from catheter			
26. Injects test dose through flushed filter			
27. Fixes the epidural catheter securely			

Appendix 2.7

Metrics for labor epidural catheter placement (critical errors in red)

Start of procedure: Anaesthetist entering the room

End of procedure: Anaesthetist leaving the room after completion of the procedure

Metrics

I. Initial patient interaction
II. Positioning
III. Maintaining asepsis
IV. Preparation and positioning of equipment
V. Handling sterile epidural preparation field and disinfection of epidural insertion site
VI. Identifying appropriate interspinous space after fenestrated drape
VII. Local infiltration
VIII. Needle insertion /Attachment of loss of resistance (LOR) syringe/identifying LOR
    a) Attachment of LOR syringe and advancement of needle
    b) Attempts in first interspinous space
    c) Subsequent attempts
IX. Catheter insertion
X. Test dose and securing the catheter
XI. Loading dose and assessment of block

No	Metrics and definition (Task/subtask)	Error
I:	**Initial patient interaction**	Error
1	**Does not explain the procedure**	
2	**Does not explain risks involved**	
3	**No verbal consent obtained**	
II:	**Positioning**	Error
4	**Patient not positioned at the edge of the bed**	
5	**Patient not positioned in the middle third of the bed**	
6	**Bed not flat and parallel to floor**	
7	**Does not establish a clear working environment (eg: one or more of the following things not done appropriately- dress taped, CTG monitor belt moved away from field , IV lines and monitor cables away from the working field)**	
III:	**Maintaining asepsis (refer to table at the end please)**	
IV:	**Preparation and positioning of equipment**	Error
8	**Does not position the trolley within 90 degree arc**	
9	**Does not attempt to identify the landmarks (palpates iliac crest with both hands and identifies midline) prior to scrubbing**	
V:	**Handling sterile epidural preparation field and disinfection of epidural insertion site**	Error
10	**Does not check drug name and expiry with midwife**	
11	**Does not use filter needle to draw up local anesthetic for test dose or saline to be used for loss of resistance**	
12	**Does not flush epidural catheter with filter attached(not necessarily removing catheter from pack)**	
13	**Does not prep the back appropriately (Betadine circular motion from center Alcohol horizontal movements)**	
14	**Failure to prep appropriate amount of area (A4 size)**	

15	**Does not give adequate time for antiseptic solution to act (application of antiseptic to insertion of needle – 3 min for betadine and 60 sec for chlorhexidine skin preparation stick)**	
16	**Placing fenestrated drape without removing adhesive tape both from center hole and top**	
17	**Does not get a new drape if position of drape is to be adjusted**	
VI:	**Identifying appropriate interspinous space after fenestrated drape**	Error
18	**Does not request patient to arch the back**	
19	**Does not identify landmarks again(palpates iliac crest and/or palpate midline) prior to local infiltration**	
20	**Landmark reconfirmed > 5 times**	
VII:	**Local infiltration**	Error
21	**Does not dry betadine (after 3 minutes) if still wet prior to infiltration of local anaesthetic**	
22	**Uses more than 5 ml of lignocaine for skin infiltration**	
23	**Does not give adequate time for local anaesthetic to work (90 sec)**	
VIII	**Needle insertion / Attachment of loss of resistance (LOR) syringe / Identifying LOR**	
a)	**Attachment of LOR syringe and advancement of needle**	Error
24	**Direction of insertion downward or? > 45 degree cephalad**	
25	**Stylet of epidural needle not placed in sterile field**	
26	**Connects loss of resistance syringe with more than half barrel of air**	
b)	**Attempts in first interspinous space**	Error
27	**More than 2 passes in the same direction**	
28	**Alteration in direction not limited to single plane in any new pass**	
29	**Second attempt in the same space without change of angulation in either or both planes**	

30	**More than 5 minutes in same attempt**	
c)	**Subsequent attempts**	Error
31	**Does not wait for local anesthetic to work**	
32	**Does not prep again if drape is removed**	
33	**Undertakes an attempt in an unprepared and unsterilized interspace**	
34	**On seeing blood in epidural needle, the anaesthetist proceeds with the same needle without flushing with saline or changing the needle**	
35	**Injects more than 0.5 ml of air**	
36	**Returns syringe to any place other than sterile field***	
IX:	**Catheter insertion**	Error
37	**Threads catheter during contraction**	
38	**Inserts catheter with caudal angulation or direction**	
39	**Does not stabilize needle while passing catheter**	
40	**Pulls catheter back through needle**	
41	**Advances needle over catheter at any point**	
42	**Rotates epidural needle after catheter insertion**	
43	**Inserts epidural catheter without mentioning paresthesia to the patient**	
44	**Does not place epidural needle back in sterile "TRAY"**	
45	**Failure to aspirate catheter "gently" with 2 ml syringe prior to fixing**	
46	**Continues to administer local anaesthetic with blood in the catheter**	
47	**If there is blood in catheter does not perform one of the following options – A) pull back by 1 cm and re aspirate up to 2 times. B)Pulls catheter out C) Flush catheter with saline up to 2 times**	
48	**Injecting local anaesthetic to flush blood in catheter**	
49	**If CSF in catheter is suspected does not perform one of the following actions – A) Take out the catheter. B) Use it as a spinal catheter**	

50	**Proceeds to inject local anaesthetic dose of >5ml despite aspirating clear fluid in the epidural catheter**	
X:	**Test dose and securing catheter**	Error
51	**Does not loop the catheter or use fixating device for taping**	
52	**Tapes less than half way up the back**	
53	**More than 3 ml of Test dose (2% Lidocaine) administered**	
54	**Administers test dose during contraction**	
XI:	**Loading dose and assessment of block**	Error
55	**Does not ask patient for symptoms for intravenous local anesthetic prior to loading dose**	
56	**Failure to assess possibility of inadvertent intrathecal injection of local anaesthetic (failure to ask or identify sensory/motor symptoms prior to loading dose)**	
57	**Does not check blood pressure prior to loading dose**	
58	**Does not check the local anaesthetic solution used for loading dose(name and expiry date)**	
59	**Administers less than 10 ml to more than 20 ml of loading dose**	
60	**Does not communicates with patient during loading dose**	
61	**Fails to disconnect syringe containing local anaesthetic from epidural apparatus following completion of administration of loading/test dose**	
62	**Failure to ensure that filter hub is kept sterile**	
63	**Does not document BP prior to leaving the room**	
64	**Anaesthetist leaves the room without hearing that the patient is getting more comfortable during contractions**	

	Maintaining asepsis	Stage VI	Stage VII	Stage VIII	Stage IX	Stage X	Stage XI
65	**Not bare below elbow except wedding ring (exception – if wearing sterile apron)**						
66	**Hand wash not done as per guidelines (alcohol gel if no visible contamination of hand for 90 sec / scrubbing with antiseptic soap)**						
67	**Not maintaining asepsis during donning of sterile gloves and/or not changing sterile gloves if it is contaminated during the procedure**						
68	**Not observing and changing equipment if it gets contaminated**						
69	**Fenestrated drape contaminated and not replaced**						
70	**Betadine solution cup/ sponge holding forceps/Chlorhexidine stick /gauze used to dry betadine - left in sterile field after use**						
71	**Any equipment placed in patient drape instead of the sterile field***						
72	**Unsheathed needle placed outside sterile "TRAY"****						
73	**Re-sheathing needle any time during the procedure**						
74	**Using sterile gloves in unsterile area after completion of sterile procedure without removing or changing the gloves**						

*Sterile field – area within sterile drape used for epidural preparation

**Sterile plastic tray – plastic cup/tray within epidural preparation field

Appendix 2.8

Data corresponding to the study 1(part 1 and 2) – attached as excel sheet labelled Appendix 2.8

1. Sheet 1 – Metrics scoring
2. Sheet 2 – TSCL scoring
3. Sheet 3 – GRS scoring
4. Sheet 4 - Total TSCL and GRS scores

Appendix 2.9

Data corresponding to the study 1a – attached as excel sheet labelled Appendix 2.9

1. Sheet 1 – Baseline information
2. Sheet 2 – Patient outcome measurements
3. Sheet 3 – Video validation

Chapter 3 (Study 2) - Spinal anaesthesia for caesarean section – an ultrasound comparison of two different landmarks

Abstract

Background

Subarachnoid block (SAB) performed at levels higher than L3-4 interspinous space may result in spinal cord injury. Our aim was to establish a protocol to reduce the chance of SAB performed at or above the L2-3 interspinous space.

Methods

Having each provided written informed consent, one hundred and ten patients at or greater than 32 weeks gestation scheduled for non-emergent caesarean section under SAB were randomly allocated to group A or group B. In group A where the intercristal line intersected an intervertebral space, then that space was selected or, if it intersected a spinous process, the space immediately above was selected for SAB. In group B, where the intercristal line intersected the intervertebral space or a vertebral spinous process, the intervertebral space immediately below was chosen. The level marked for SAB was identified using 2-5 MHz ultrasound probe by one of the four blinded investigators prior to performance of SAB.

Results

In group A, lumbar interspinous space at or above L2-3 was marked in 25 (45.5%) patients compared to 4 (7.3%) in group B ($p<0.001$). Also 5/55 (9.1%) patients in group A had interspace marked at L1-2 versus none in group B. There was no difference between the groups in number of needle passes or attempts, degree of onset of block at 5, 10 and 15 minutes or need for rescue analgesia.

Conclusion

In pregnant patients, if intercristal line intersects an interspinous space, a space below should be chosen for SAB. Where it intersects a spinous process, the

interspace below should be chosen. This significantly reduces the incidence of SAB performed at or above L2-3.

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Introduction

Spinal anaesthesia or sub-arachnoid block (SAB) is the commonest mode of anaesthesia for caesarean section.[1,2] Permanent neurological complications following spinal anaesthesia though uncommon can have devastating consequences.[3,4,5,6-8] Selecting an appropriate interspinous space is one of the important steps to avoid spinal cord damage during SAB.

The intercristal line has been conventionally used to identify the lumbar interspace through which to perform spinal anaesthesia. This may intersect the midline anywhere between from L1-2 to L4-5. [9,10-13,14,15] There are considerable variations (even within various anatomy and anaesthesia textbooks) as to the level at which the intercristal line crosses the midline. [16-20] Currently, there is no consensus on selecting an interspinous space based on intercristal line. Selection of interspace at, above or below the intercristal line has been largely based on individual discretion. It has been shown that experienced anaesthetists were able to correctly identify lumbar interspace in only 29% of the patients.[9] In an obstetric population, 32-48.5% of the attempts, neuraxial blocks were performed at a more cephalad level (a high as L1-2) than originally intended.[21,22] Importance of avoiding SAB at or above L 2-3 cannot be overstated as, based on previous studies on the level of termination of spinal cord and considering the angle of insertion of the needle, it is possible that the needle inserted at L2-3 might reach the conus in 4 to 20% of the people.[7]

Our aim was to develop an objective guide for selecting an appropriate interspinous space based on clinically palpated intercristal line. The hypothesis of the study was that by selecting an interspinous space below the intercristal line, we should be able to significantly decrease the incidence of SAB performed at or above L2-3 without increasing the number of attempts, passes or failure rate of spinal anaesthetics in pregnant patients.

Methodology

Based on a study by Locks et al[15] we estimated that, if SAB was performed at or above the level of palpated intercristal line, the proportion of blocks performed at or above L2-3 would be 44%. We hypothesized that, by consistently selecting an interspace below the palpated intercristal line, one could decrease the incidence to less than 10%. A study with 55 patients in each arm required at least 80% power to detect a difference between these proportions with a level of significance of 0.05.

Following National Maternity Hospital ethical committee approval, 110 pregnant patients with gestational age more than 32 weeks undergoing category 3 or 4 (Lucas classification) caesarean section under SAB and who consented for the study were included. Patients with previous spinal surgeries, known spinous deformities and in whom the anaesthetist could not palpate the spinous process or interspinous space were excluded from the study.

This was a prospective, randomized, double blind control study with patients randomized based on computer generated random numbers to either group A or group B. The group to which the patients belonged was enclosed in a sealed envelope and was seen only by the anaesthetist performing the SAB. Both the patient and the anaesthetist performing the ultrasound were blinded to the study groups. The anaesthetist who was normally assigned to the theatre performed the SAB. The experience of the staff varied from trainee anaesthetist with more than 1 year of experience to consultant anaesthetist.

In group A at the intercristal line if one encounters an interspinous space, SAB was performed at the same level and if one palpates a spinous process, SAB was performed in the interspinous space above it. In the group B if an interspinous space was palpated at the level of intercristal line SAB was performed one interspace below it and if a spinous process was palpated, the interspace below was chosen for SAB.

In the operating room all patients were positioned sitting up for SAB after applying routine monitors and intravenous access. The patients were seated on the edge of level operating table bed with feet supported by foot rest. The patients were

requested to hug a pillow, flex their neck, back and hips. An assistant supported the patient with the positioning during the performance of the block. The anaesthetist performing the spinal anaesthetic marked the site in the back as per the study group. To identify the intercristal line, a standard protocol of using both hands simultaneously to palpate the iliac crests and using thumb to identify the midline at the same level was used. The anaesthetists were instructed to open the sealed envelope and mark only the selected interspinous space on the back of the patients (as per the group) with a skin marker prior to scrubbing. No other mark was allowed to enable blinding of the investigators performing the ultrasound.

One of the four authors, all of whom have prior experience in neuraxial USG (with each having performed more than 75 neuraxial ultrasound's prior to the study), blinded to the study group, performed ultrasound evaluation of the marked interspinous space. Portable USG equipment with curved 2-5 MHz probe was used (Venue 40, 4C-SC curvilinear probe, General Electric, GE Healthcare, 9900 Innovation Drive, Wauwatosa, WI 53226 U.S.A. 888 526 5144). Initially a paramedian sagittal oblique view was used and sacrum was identified first following which the interlaminar space between L5 and S1 was noted. Subsequent interspinous spaces were identified by counting the interlaminar spaces up from L5-S1. At each interspace the interlaminar space was centred on the ultrasound screen and the corresponding point on the skin at the middle of the long axis of the probe was noted. The interspace corresponding to the skin marking was thus identified and documented. If on scanning the interspace was found to be L1-2 or higher, the anaesthetist performing SAB was advised to perform SAB at two interspaces below it. The patient's data were still included for analysis of primary outcome. The interspinous level identified by the ultrasound was not conveyed to the anaesthetist performing the SAB.

Full aseptic precautions were used for performing the SAB (anaesthetist scrubbed with cap, mask, sterile gown and gloves). Lidocaine was used for skin infiltration. 25 g Whitacre spinal needle was used with introducer. Hyperbaric bupivacaine 0.5% with or without intrathecal fentanyl (15 micrograms) and morphine (100

micrograms) was administered to all patients. If more than one attempt was needed for performing SAB the anaesthetist could choose the same interspace or a different interspace for subsequent attempts which was left to their discretion. At any stage attempts at or above L1-2 were not allowed. In addition to the initial level marked, the final level at which the SAB was done was also noted.

The primary end point was the difference in marked interspace at or above L2-3 between the two groups. In addition to the interspace, demographic variables (age, height, weight, BMI), gestational age, experience of anaesthetist, number of needle passes (number of times the spinal needle was withdrawn to be redirected in the same interspace without exiting the skin) and number of attempts (number of time needle is withdrawn from the skin) were noted.

Also the presence or absence of paresthesia/radicular pain during needle placement and injection ,dose of intrathecal bupivacaine and opioids used, level of block (loss of cold sensation) at 5, 10 and 15 minutes were noted. The need for rescue analgesia and conversion to general anaesthetic were noted as well. All patients who had paresthesia or radicular pain were followed up between 12 to 24 hours post procedure. In cases of persistent radicular symptoms the patients were further evaluated and followed up as per department guidelines.

Statistical analysis

Patients were randomized using computer generated random numbers. Continuous variables were inspected for approximate normal distributions by visualising histograms. The primary analysis set consisted of the intention-to-treat (ITT) population. Age and gestational age were normally distributed and were compared with a 2-independent samples t-test. The distributions for weight, BMI and anaesthetist experience showed some amount of positive skew and they were compared using a Mann-Whitney U test. Categorical variables were compared between groups using a Pearson Chi-square test. In the case where cell counts were low, p-values were checked using Monte Carlo permutation. IBM SPSS v20 software was used.

Results

A total of 128 patients were approached to participate in the study. Ten patients refused consent and 6 patients did not meet the inclusion criteria prior to randomization. Out of the six patients, one patient was less than 32 weeks of gestation, two patients had previous spinal surgeries and, in three patients, the landmarks were not palpable prior to randomization.

The remaining 112 patients were randomized between the two groups. Two patients were excluded from the group A following randomization as, in one patient, the anaesthetist could not palpate spinous process after positioning and, in another patient, the marked interspace could not be utilized as the patient had a tattoo at that level. All the remaining 110 patients received the allocated intervention, were followed up and the results included for analysis (Figure 3.1).

The demographic parameters, anaesthetist experience, parity and gestational age were similar between the two groups (Table 3.1).

The primary end point of the study was the difference in proportions of interspaces marked at or above L2-3. A total of 25/55 (45.5%) patients in group A versus 4/55 (7.3%) patients in group B had the levels marked at or above L2-3. The difference was statistically significant (Chi^2=20.65, $p < 0.001$). Also in group A, 5/55 (9.1%) patients had the L1-2 interspace marked versus none in group B (Table 3.2). It should be noted that, although the interspace marked was L1-2 in these patients, SAB was not performed at that level. In these patients, the SAB was done 2 interspaces below the marked interspace on the advice of the investigating ultra-sonographer.

Figure 3.1: Consort flow diagram

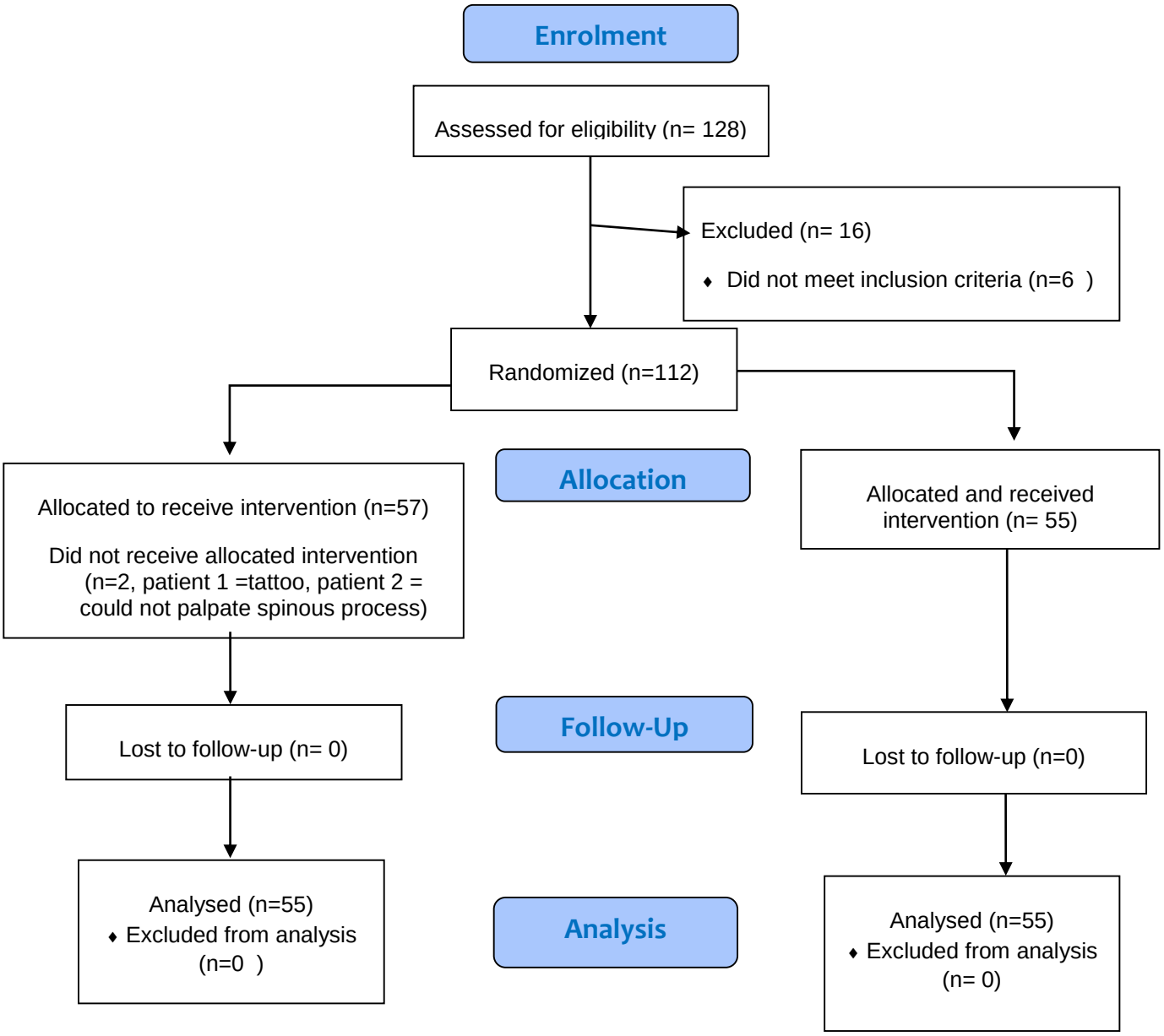

Table 3.1: Comparison of demographic variables, type of caesarean section and experience of the anaesthetist between two groups.

Demographics	Control Group	Intervention group
Age	33.96 (4.99)	33.84 (4.35)
Gestational Age	38.6 (1.5)	38.8 (1.3)
Height	164.3 (6.3)	163.9 (7.3)
Weight	81.8 (15.6)	83.3 (15.5)
BMI	30.4 (5.7)	31.1 (5.7)
Para 0	9 (16.4%)	7 (12.7%)
Para 1	31 (56.4%)	27 (49.1%)
Para 2	9 (16.4%)	16 (29.1%)
Para 3	5 (9.1%)	4 (7.3%)
Para 4	1 (1.8%)	1 (1.8%)
Category 4	50 (90.9%)	53 (96.4%)
Category 3	5 (9.1%)	2 (3.6%)
Experience of anaesthetist	6.8 (5.4)	5.5 (5.2)

Age in years, Gestational Age in weeks, Height in cms, Weight in kgs, BMI (Body Mass Index) in kg/m^2 .Values in mean (SD) or n (%).

Table 3.2: Comparison of interspinous levels marked between the two groups.

Interspinous space marked	Control Group n= 55	Intervention group n=55	P value
L1-2	5 (9.1%)	0 (0%)	
L2-3	20 (36.4%)	4 (7.3%)	
L3-4	27 (49.1%)	31 (56.4%)	< 0.001
L4-5	3 (5.5%)	14 (25.5%)	
L5-S1	0 (0%)	6 (10.9%)	

Values in n(%)

There was no difference between the groups in number of needle passes, number of attempts, paresthesia, radicular pain or onset of block at 5, 10 and 15 minutes, dose of intrathecal opioids or need for rescue analgesia (Table 3.3) . The number of cases in which the anaesthetist was not able to perform a SAB at the marked interspace and had to select a different space was similar between the two groups. One patient in group A was converted to general anaesthesia due to intraoperative bleeding and not due to failure of the SAB (Table 3.3). The structure palpated at the level of intercristal line was similar between the two groups (Table 3.4).

As per the study protocol, 9 patients (16.4%) in the group A and 7 patients (12.7%) in the group B had their SAB performed at a different interspace (above or below at anaesthetist discretion) to that initially marked because of difficulty in performing the block at the marked interspace. When this subgroup of patients were compared with the rest of the study population no difference was noted in their demographics (age, height, weight and BMI) or the experience of anaesthetist involved in the case (Table 3.5).

Table 3.3: Comparison of SAB variable between the groups.

SAB variables	Control Group	Intervention group	P value
Spinous process at intercristal line	36 (65.5%)	29 (52.7%)	NS
Interspinous space at intercristal line	19 (34.5%)	26 (47.3%)	NS
Number of needle passes	2.02 (1.38)	2.13(1.76)	NS
Number of attempts	1.4 (0.71)	1.36(0.73)	NS
SAB done different level	4(7.2%)	7(12.7%)	NS
Paresthesia during SAB	6(10.9%)	4(7.3%)	NS
Radicular pain during SAB	1(1.8%)	0 (0%)	NS
Dose of 0.5% hyperbaric bupivacaine used for SAB	2.13 (0.14)	2.10 (0.14)	NS
Number of patients who received 15 mcg intrathecal Fentanyl	43 (78%)	45(81%)	NS
Number of patients who received 100 microgram intrathecal Morphine	49 (89%)	49 (89%)	NS
Block level above T5 in 5 minutes	47(85%)	48(87%)	NS
Block level above T5 at 10 and 15 minutes	55(100%)	55(100%)	NS
Need for rescue analgesia	3 (5.4%)	3(5.4%)	NS
Conversion to GA	1	0	NS

Values in mean(SD) or n(%) or n, Dose in ml

Table 3.4: Structures palpated at the intercristal line

Structure palpated at intercristal line	Group A	Group B
L1 spinous process	0	0
L12 interspinous space	2	0
L2 spinous process	4	4
L23 interspinous space	14	14
L3 spinous process	5	17
L34 interspinous space	17	11
L4 spinous process	10	3
L45 interspinous space	3	4
L5 spinous process	0	2
L5-S1 interspinous space	0	0

Values in n

There were differences in the marked interspinous space and the interspinous space in which the SAB was actually performed (Table 3.6). Significantly more patients in the group A (n= 22, 40%) when compared to group B (n=8, 14.5%) had their SAB done at L2-3 (Pearson Chi-square test = 8.98, p = 0.003) indicating that the intervention also reduced the proportion of SAB performed at or above the L2-3 level.

Table 3.5: Comparison of patient subgroup with SAB done at selected level versus SAB done at different level.

Parameters	Categories	SAB done at different level	SAB done at selected level	P value
Group	Control	9 (16.4%)	46 (83.6%)	NS
	Intervention	7 (12.7%)	48 (87.3%)	NS
BMI categories	Normal	2 (14.3%)	12 (85.7%)	NS
	Overweight	3 (7.5%)	37 (92.5%)	NS
	Obese	11 (19.6%)	45 (80.4%)	NS
Anaesthetist experience	≤ 5 years	9 (14.1%)	55 (85.9%)	NS
	> 5 & ≤ 12 years	6 (15.5%)	33 (84.6%)	NS
	> 12 years	1 (14.3%)	6 (85.7%)	NS
	Median(IQR)	3.8 (1.5-9.0)	4.0 (1.5-10.0)	NS

Values in n(%)

Table 3.6: Level at which SAB was done

Level at which SAB block was done	Group A	Group B
L2-3	22 (40.0%)	8 (14.5%)
L3-4	30 (54.5%)	27 (49.1%)
L4-5	3 (5.5%)	15 (27.3%)
L5-S1	0 (0%)	5 (9.1%)

Values in n(%)

Discussion

In pregnant patients, selecting an interspinous space below palpated intercristal line significantly decreases the chances of SAB done at or above L2-3 and possibly eliminates the risk of SAB done at L1-2 or above. This is the first study comparing two different landmarks for performing spinal anaesthetic in pregnant patients.

Subarachnoid block (SAB) is preferably performed at or below L3-4 interspace to avoid potential risk of spinal cord injury. In all seven cases of permanent cord injury (6 obstetric and 1 surgical) reported by Reynolds et al[7], SAB was performed at or above L2-3 interspace. The spinal cord has been shown to end lower in women with conus reaching upper part of body of L2 in 48% of women compared to only 27% in men.[23]

Palpated intercristal line and radiological intercristal line (Tuffier's line) are different entities. Palpated intercristal line is the most important landmark used to perform SAB. There is very poor correlation between the interspinous levels at which palpated and radiological intercristal lines cross the midline. In non-pregnant patients, Chakraverty et al[24] compared level of agreement between palpated and imaged intercristal line. They found that 88% of the time palpated intercristal line was one or more interspaces higher than radiological intercristal line. In pregnant patients, the presence of hyper lordosis, exaggerated pelvic rotation, weight gain and decreased ability to flex the spine makes the clinical estimate of interspinous space even higher. So even when Tuffier's line (radiological intercristal line) most commonly intersects at L4 spinous process or L4-5 interspace[25], clinically palpated intercristal line in pregnant patients is most likely to identify a higher interspinous space.

Only three studies to date have been performed to identify the position of palpated intercristal line in pregnant patients.[13,14,15] The selected space corresponded to L2-3 or above in 33% to 51% of patients.[14,15] The results from our study are similar with palpated intercristal line corresponding to L2-3 and above in 45.5 % (25/55) of the group A patients. In the group B only 7.3% (4/55) had levels marked at L2-3. The new landmark is simple and reproducible with the additional strength being that it is

based on palpated iliac crest without using ultrasound which makes the study more applicable in day to day practice.

Ultrasound is not yet routinely used in clinical practice for performing neuraxial blocks.[26] The expertise needed to perform neuraxial ultrasound, the additional time for scanning, cost, the need for equipment at the bedside, and the urgency to perform SAB in certain patients (e.g. emergency caesarean sections) tend to increase the likelihood that clinically palpated landmarks will continue to be used in majority of cases for performing spinal anaesthesia. Hence it is imperative to try to improve the accuracy of palpated landmarks.

It is also important to note that none of the patients in the group B had L1-2 interspace marked for SAB versus 4 in group A. In previous studies, performing SAB at lower interspace has been associated with delay in onset of block height.[27,28] Similar studies in pregnant patients have not been conducted. In our study no difference was noted between the two groups in terms of the time of onset, level of block or quality of analgesia. The need for supplemental analgesia was similar in the two groups.

It is generally perceived that SAB might be difficult to perform at lower lumbar interspinous spaces. No difference was noted in the number of attempts or number of passes needed for SAB between the two groups in this study. Although the time required to perform SAB was not recorded, the authors believe that it is unlikely to show a difference in the absence of any difference in number of attempts or passes.

We did not find identify published studies which compared the position of intercristal line in sitting versus lateral positions. But in a radiological study, Kim et al noted that with full flexion of lumbar spine, the position of intercristal line in relation to spinous process slightly moved caudally from L4 to L4-5.But remained in same level in 58.3% of patients[29]. Clinically, one can assume that the position of intercristal line may not differ significantly between sitting and lateral position. Also the ability of term pregnant patients to achieve adequate flexion at the hips even in lateral position can

be limited. Hence the results of the study can to a great extent extrapolated to lateral position as well.

The study has limitations. Firstly, the new landmark still does not totally eliminate the risk of SAB at L2-3 (7.3% in group B had L2-3 marked) but it reduces the incidence by 38.2%. As discussed later, future studies with further refinement in the landmark could possibly eliminate the risk of SAB done at L2-3 without the use of ultrasound.

Secondly ultrasound accurately identifies a spinous process or interspace in only 68-76% of the time.[30-32] Accuracy rates of 90% or higher is possible with training.[30] All four anaesthetists who performed ultrasound in this study had previous experience in neuraxial ultrasound. Lumbarisation of sacral vertebrae and sacralisation of lumbar vertebrae are likely to be missed by ultrasound of the spine as they can be reliably identified only by X-ray[14,33].

Thirdly the experience of the anesthetist performing SAB varied from one year to greater than 10 years. Due to the prevailing practice at the institution(s) in which the study was performed, the practitioners who performed SAB were not only those with more experience. The variation in experience of the participating anaesthetists was similar in the two groups; therefore we infer that the study reflected “real world” practice.

Finally, there will always be inter-individual variability in terms of identifying what level does the intercristal line crosses the midline. As it does not always cross exactly at spinous process or inter spinous space a certain degree of clinical judgment is needed[14]. The randomization and the total number of patients in the study should help to minimize the variations.

Close observation of the results offers options for future studies to further decrease the risk of SAB done at L2-3. For the 4 patients in the group B in whom the level marked was L2-3, the anaesthetist palpated a spinous process and marked the interspinous space below it. So potentially if one selects 2 interspinous spaces below a palpated spinous process at the intercristal line or selects one interspinous space below if an interspinous space is palpated at the intercristal line it could further

decrease the risk of SAB done at L2-3 or above. If this landmark is used the lowest possible space that one might encounter will be L5-S1 (in all patients who had L5- S1 marked, the anaesthetist palpated an interspinous space and marked one space below it). Also previous studies have shown that the palpated intercristal line was never lower than L4-5 in pregnant patients[14,15] which suggest that in addition to decreased incidence of SAB at L2-3, with the new landmark there is a theoretical possibility of not increasing the failure rates. Future studies with suggested new landmarks could confirm our findings.

There are no studies comparing difference in palpated landmarks to identify interspinous levels between pregnant and non-pregnant patient population. But due to the reasons mentioned earlier (hyper lordosis, exaggerated pelvic rotation, weight gain and decreased ability to flex the spine) clinically palpated intercristal line in pregnant patients is most likely to identify a higher interspinous space and therefore the results of the study might not be applicable in non-pregnant patients. Future studies could also focus on other patient groups in whom SAB is commonly used.

Summary

In summary in pregnant patients if one palpates the intervertebral space at the intercristal line a space below should be chosen for SAB. Where a spinous process is palpated the interspace below should be chosen. Doing so significantly reduces the incidence of SAB performed at or above L2-3. Selection of a lower intervertebral space did not lead to reduced block height or increase in failure rate of the block.

Acknowledgement

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Appendix

Data sheet for Chapter 3 is provided in the supplementary digital content in folder labelled Chapter 3 – Appendix 3.1.exl

Sheet 1 – control group

Sheet 2 – Intervention group

Chapter 4 (Study 3) - Lumbar Neuraxial ultrasound correlation with MRI

Abstract

Background

Ultrasound of neuraxis can be used to identify the best possible inter-spinous space to perform neuraxial block. But the negative predictive value for poor views in transverse median (TM) plane only 30%[1]. The aim of this study was to assess the anatomical correlation between neuraxial ultrasound and magnetic resonance imaging (MRI) at various lumbar interspinous levels and to identify limiting factors to optimal neuraxial imaging by ultrasound.

Methodology

Twenty one patients who underwent MRI of the lumbar spine proceeded to neuraxial ultrasound by an experienced operator. Each lumbar interspinous space was graded on ultrasound as good if both anterior complex (AC) and posterior complex (PC) are visible, intermediate (either AC or PC visible) or poor (both AC and PC not visible) in both the TM and paramedian sagittal oblique (PSO) plane. Pre-determined MRI parameters were measured by readers blinded to sonographic findings at each inter-spinal level: skin to posterior longitudinal ligament (PLL) distance, para-spinal muscle thickness, subcutaneous fat thickness, ligamentum flavum thickness, absence or fusion of ligamentum flavum in the midline, epidural fat thickness, thecal sac diameter and facet joint degeneration. The correlation between neuraxial ultrasound images and these MRI parameters observed were analysed.

Results

Seventy-eight lumbar interspinous spaces were evaluated. Facet join degeneration was significantly greater (p= 0.004) in the TM poor view group. Adjusted logistic regression model for poor view in the TM plane was positively associated with facet joint degeneration and body mass index. The odds of obtaining a poor view in TM plane was 7 times higher (95% CI 1.7-28.9, p=0.007) in the presence of facet joint

degeneration. None of the other variables had significant association with poor neuraxial view in the TM plane. Poor views in PSO plane did not correlate with any of the variables measured on MRI.

Conclusion

Facet joint degeneration is a major contributing factor to poor neuraxial ultrasound views in the TM plane. Poor visualisation of AC and PC on ultrasound might be due to one of the two reasons: i) The ultrasound beam is not able to reach the target or ii) The target structure is absent or defective. Our study has shown that former, rather than the latter is the more plausible explanation in most cases with cause being artefactual rather than structural.

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Introduction

Good visibility of ligamentum flavum-dura complex (Posterior Complex – PC) and posterior longitudinal ligament (Anterior Complex – AC) in neuraxial ultrasound has been shown to be a predictor of successful neuraxial block. The use of ultrasound in neuraxial blocks is also limited by a poor negative predictive value (approximately 30%[1]), limiting its clinical value in patients deemed to be at risk of a technically difficult.

Poor visualisation of ligamentum flavum-dura mater complex may be due to one of the two reasons – attenuation of the sonographic beam by anatomic structures such as ligament calcification, facet joint hypertrophy, narrow interspinous spaces etc and absence or anatomic alteration of the structure such as seen in surgical laminectomies, absence or gaps in ligamentum flavum.

Distinguishing these possible contributors have practical implications depending on the neuraxial procedure performed. If a poor view is obtained because of sonographic attenuation, it might translate to difficulty in performing the neuraxial block. By contrast, if it is due to absence of the target structure, it may still be possible to successfully perform a spinal anaesthetic or dural tap depending on the block intended. Hence, it is relevant to look for anatomical reasons behind poor neuraxial ultrasound views.

The aim of this study is to assess the anatomical correlation between neuraxial ultrasound and magnetic resonance imaging (MRI) of the lumbosacral spine at various lumbar interspinous levels and to identify factors contributing to poor neuraxial ultrasound imaging.

Methodology

A prospective cross-sectional study was performed in a tertiary university hospital. Ethical committee approval was obtained from local ethics committee and informed written consent was obtained from all participants. All patients over the age of 18 years who underwent MRI of the lumbosacral spine were eligible for inclusion. Exclusion criteria included patients with previous spinal surgery, gross spinal

deformities and BMI >40. Both MRI and neuraxial ultrasound were performed sequentially on the same day.

MRI protocol

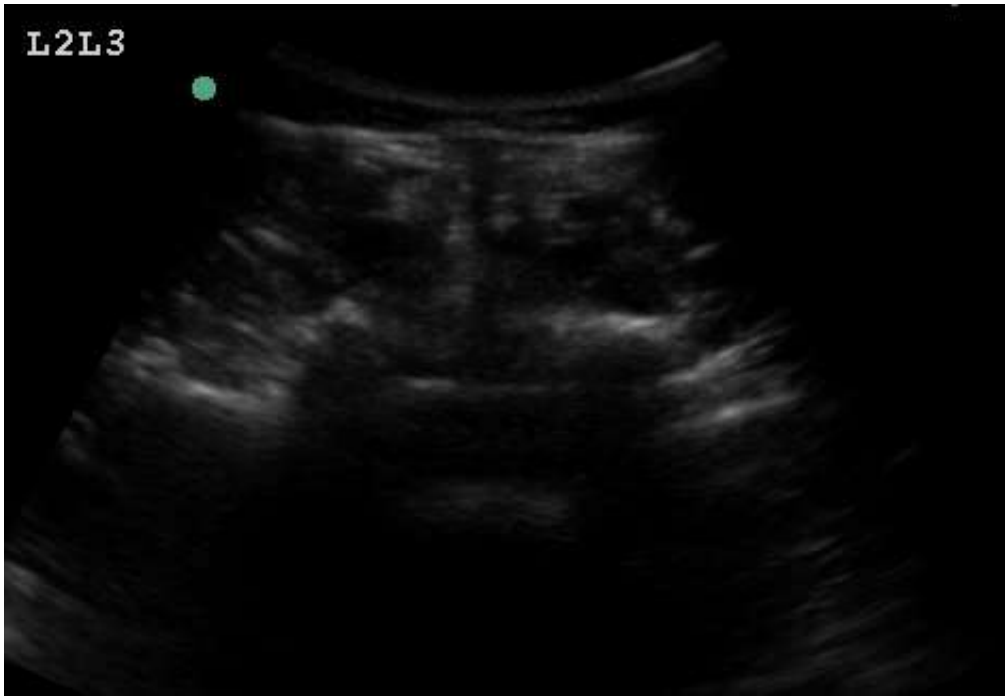
Imaging was performed with patients supine, on a 1.5T MRI system (Symphony, Siemens AG, Erlangen, Germany) using a circularly polarised spinal array coil. T1 and T2-weighted sagittal and selected T2-weighted axial sequences through the lumbosacral spine were obtained. Images were reviewed in consensus by two experienced radiologists (HKK and WCT) on a dedicated PACS workstation (Syngo Studio Advanced V36A, Siemens AG, Erlangen, Germany). Measurements were performed on T2-weighted sagittal sequences (TR 3930.0 ms, TE 99.0 ms, matrix 320 x 288, slice thickness 4.0 mm) and included the oblique subcutaneous fat thickness, interspinous distance, thecal sac diameter and posterior longitudinal ligament thickness. Further measurements were performed on T2-weighted axial sequences (TR 6570.0 ms, TE 95.0 ms, matrix 320 x 165, slice thickness 1.5 mm) at all available levels including epidural fat thickness, distance from the skin surface to the posterior longitudinal ligament, thecal sac diameter, ligamentum flavum thickness, midline fusion of ligamentum flavum and paraspinal muscle thickness. In addition, the presence or absence of facet joint degenerative change was graded. Both readers were blinded to ultrasound findings.

Ultrasound protocol

Ultrasound scanning of the lumbar interspinous spaces was performed on the same day with curvilinear 2-5 MHz probe (P07576, SonoSite Inc, Bothell, WA, 98021, USA). Ultrasound scanning was done by one of the three experienced operators (RW, KKS, MM) each with experience of >100 neuraxial ultrasounds. Scanning was performed with patients in the sitting position with both feet supported by a foot stool. Patients were requested to hug a pillow and arch their back. At each lumbar interspinous level (L1-2 to L5-S1) the best possible transverse median (TM) and paramedian sagittal oblique view (PSO) of AC and PC were obtained. The images were recorded for subsequent review. Two authors (KKS and MM) independently graded the images. They were then graded based on the visibility of AC and PC. When both AC and PC

were clearly visible, it was graded as good (Figure 4.1). If either AC or PC was not clearly visible, it was graded as intermediate (Figure 4.2a, 4.2b). When both AC and PC was not visible, it was graded as poor (Figure 4.3). Readers were blinded to MRI findings. If there was a disagreement in the image grading between the two observers, the third observer (RW) was requested to review the images. Decision on the image grading was made in consensus.

Figure 4.1: Good view in TM plane



Statistical analyses

Neuraxial ultrasound images and MRI parameters were analysed. Continuous data was analysed for normality using the Shapiro-Wilk test. Students t-tests were used to compare normally distributed continuous data. Three variables were normally distributed – skin to posterior longitudinal ligament (PLL) distance, thecal sac diameter and para-spinal muscle thickness. All other variables were not normally distributed. Nonparametric data were compared by Mann-Whitney U test and categorical data were compared using chi-square test. Logistic regression was used to analyse the degree of correlation between the variables that differed significantly between groups. Statistical analyses were performed using SPSS (Version 20, IBM Corporation, Armonk, NY).

Figure 4.2a: Intermediate view TM plane – LF only

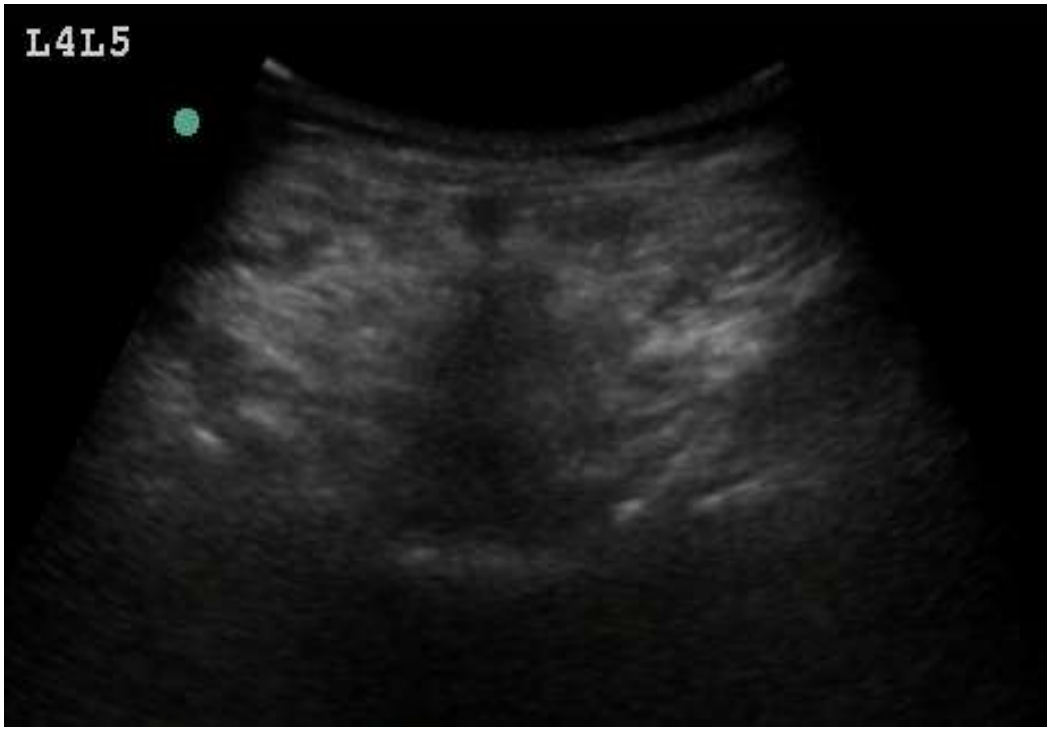


Figure 4.2b: Intermediate view TM plane – PLL only

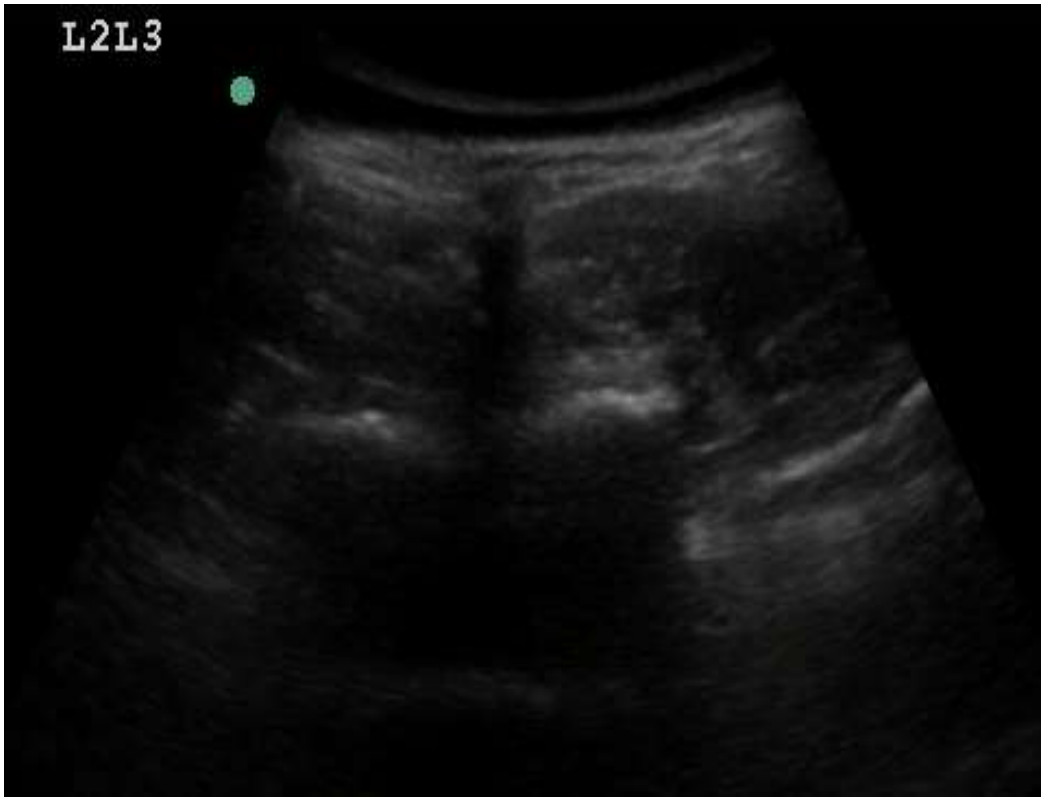
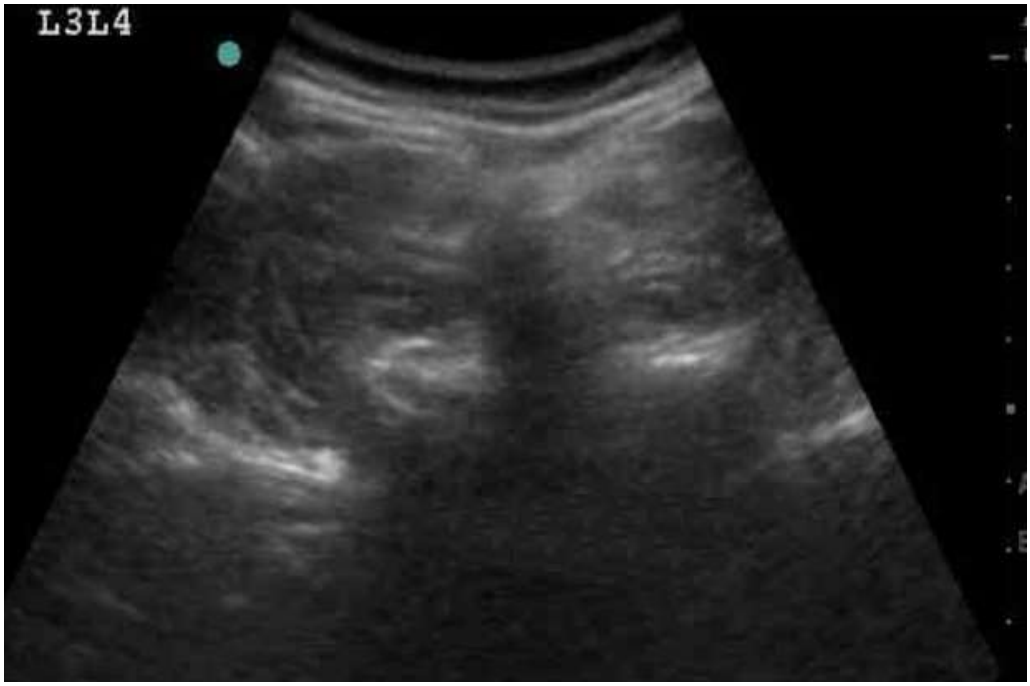


Figure 4.3: Poor view TM plane



Results

Twenty-one patients were included in the study and a total of 78 interspinous spaces were evaluated with ultrasound and MRI. Table 4.1 shows the baseline demographics of study participants.

Table 4.1: Demographics

Parameter	Mean (range: minimum-maximum)	Standard deviation
Age (in years)	52.5 (33-87)	12.4
Height(in cms)	161.6 (149 – 182)	9.6
Weight (in Kilograms)	78.9 (60-110)	11.7
BMI	30.1 (23.5 – 34.6)	3

The female to male ratio in the study population was 1:2. MRI data was not available for all interspinous levels. The L3-4, L4-5 and L5-S1 interspaces were evaluated in all 21 patients, L2-3 was evaluated in seven interspaces and L1-2 in eight interspaces. The distribution of TM and PSO views are shown in Figure 4.4 and Figure 4.5.

Figure 4.4: Dstribution of TM view

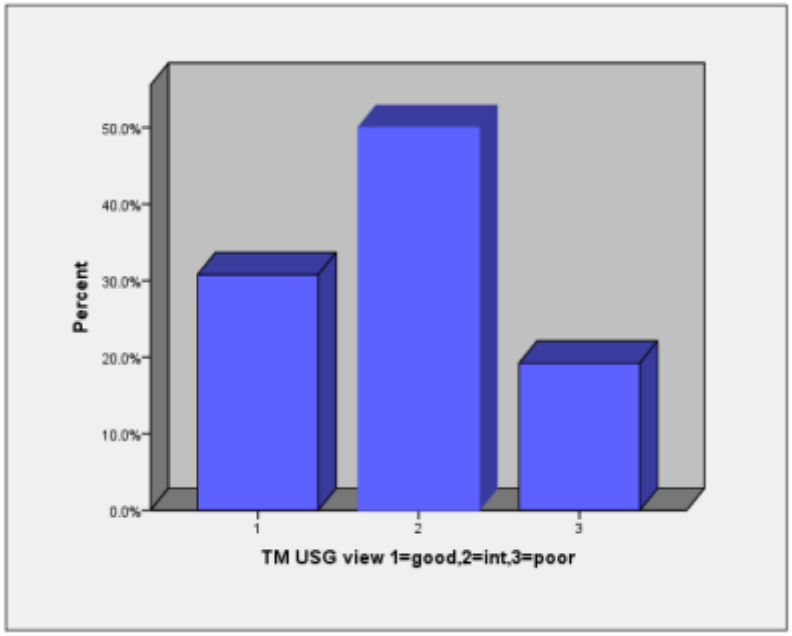
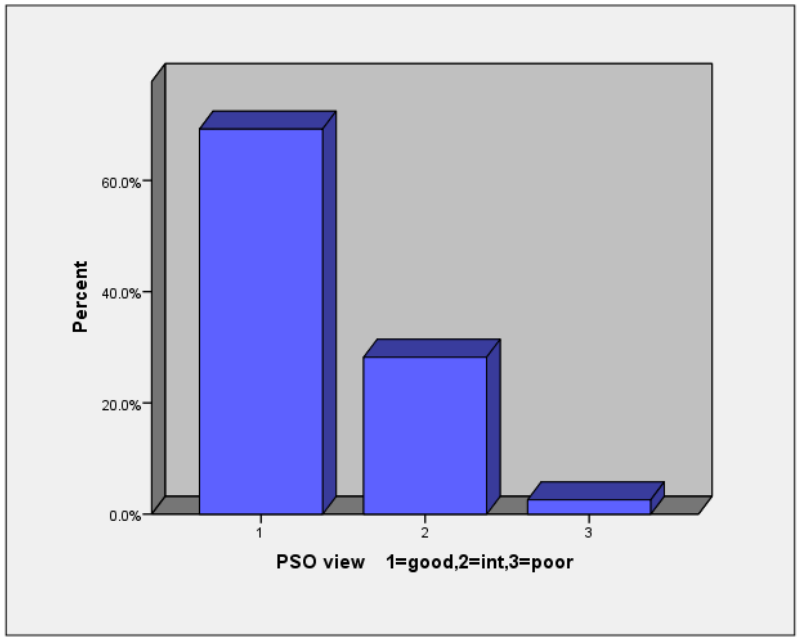


Figure 4.5: Distribution of PSO view



Comparison of continuous variables between poor TM views versus others (good and intermediate views in TM plane) are presented in Tables 4.2 and 4.3. Age (median 47 vs 54 years, p =0.016), weight (median 77 vs 80 kg, p=0.03) and BMI (29.1 vs 32.1 kg/m^2,p = 0.01) were higher in patients with poor ultrasound views.

Table 4.2: Comparison of MRI variables (continuous and parametric) within TM poor view.

Parameters	Poor view in TM orientation (Yes =1,No=0)				P value(student t test)
	0		1		
	Mean	Standard Deviation	Mean	Standard Deviation	
Skin-PLL (mm)	77.2	14.4	78.6	16.6	0.76
Para-spinal muscle thickness (mm)	43.7	13.2	49.1	13.1	0.16
Thecal sac diameter (mm)	13.1	2.3	12.7	2.5	0.55

Facet joint degeneration was significantly greater (p= 0.004) in TM poor view group (Figure 4.6). Failure of midline ligamentum flavum fusion was seen in only 2 of 78 levels (one at L3-4 and L4-5 respectively in one patient). There was no difference (p=0.35) between the two groups (TM poor view versus good/intermediate views). The adjusted logistic regression model for poor view in TM plane was positively associated with facet joint degeneration and BMI (Table 4.4). The odds ratio of obtaining a poor view in TM plane is 7.0 (95% CI 1.7-28.9, p=0.007) in the presence of facet joint degeneration. In contrast poor view in PSO plane did not have any significant correlation with any of the variables identified on MRI.

Table 4.3: Comparison of MRI variables (continuous and nonparametric) within TM poor view

Parameters	Poor view in TM orientation		P value
	No= 0	Yes = 1	
	Median (IQR)	Median (IQR)	
Age (in years)	47 (43-58)	54 (51-68)	0.016
Height (in cms)	160 (154-166)	164 (152- 166)	0.860
Weight (in Kgs)	77 (69-80)	80 (77-89)	0.029
BMI	29.1 (27.6 - 32)	32.1 (29.7 - 33.2)	0.011
Subcutaneous fat (mm)	32 (19.6 - 39.7)	35.6 (18.8 - 39.8)	0.590
Ligamentum flavum thickness (mm)	2.6 (2.1 - 3.1)	3 (2.2- 3.2)	0.320
Epidural fat pad thickness (mm)	5.1 (3-7.1)	4.3 (2.7 - 7.2)	0.550

Figure 4.6: Distribution of facet joint degeneration between TM poor view versus others

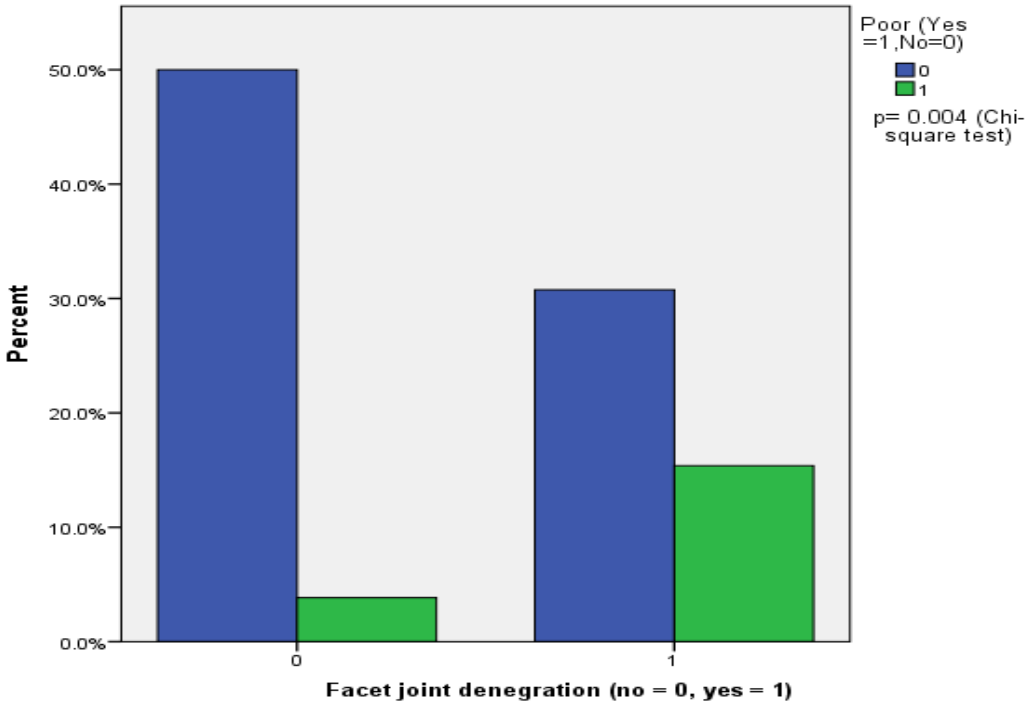


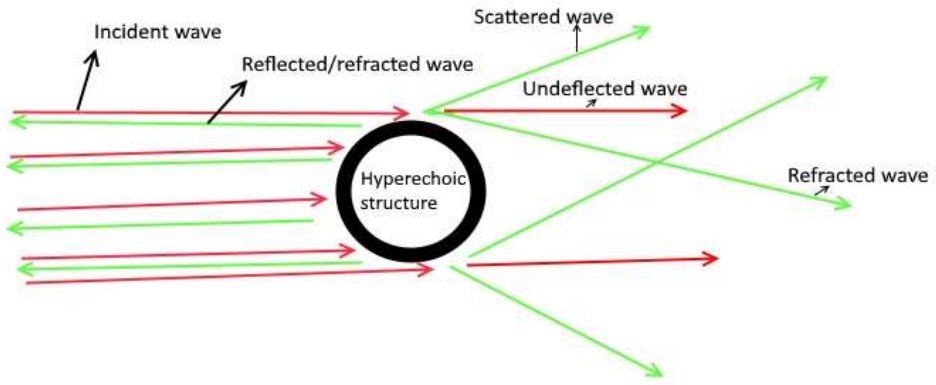
Table 4.4: Logistic regression for predicting poor view in TM plane

Variables in the Equation									
		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	BMI	.275	.113	5.887	1	.015	1.317	1.054	1.645
	Facet degeneration	1.952	.721	7.325	1	.007	7.046	1.713	28.973
	Constant	-10.963	3.585	9.350	1	.002	.000		
a. Variable(s) entered on step 1: BMI, Facet degeneration									

Discussion

Spinal ultrasonography is challenging due to the anatomic nature and layout of the spine. As the ultrasound beam passes through the bony spinal cage, it is subjected to multiple artefacts which significantly limits the ability of ultrasound beam to visualise the structures within the canal. Two such artefacts might be relevant in helping us understand the role played by facet joint degeneration in causing poor ultrasound view: i) refraction shadowing ii) scattering (Figure 4.7).

Figure 4.7: Refraction shadowing and scattering



At the margins of a structure with different acoustic impedance compared to the tissue around it and with a highly curved surface (in this case degenerated facet joint and ligamentum flavum with soft tissues surrounding it) an artefact called lateral shadowing [2,3] (or retraction shadowing[4]) appears. After reflection of the beam, marginal waves get also refracted at the edges of the structure, therefore no sound beam returns to the probe; as a consequence, a shadow near each lateral border of the structure may appear. Sound is refracted as it passes from one medium to another. Thus the direction in which it travels changes when it passes through a boundary at an angle less than 90 degrees. This can lead to subtle misplacement of structures and some degradation of image quality when the angle of incidence is particularly acute.

Another phenomenon is scattering. This occurs when the reflecting surface (degenerated facet joint) is very small compared to the sonographic wavelength, and echoes are reflected through a wide range of angles, consequently reducing their detected intensity. Also the beam are distorted after contact with an irregular surface thereby interfering with the beams reflected from nearby structures.

Both these phenomena result in degradation of image quality from structures deep to the irregular bony surface of degenerated facet joint. This is more relevant to images produced in TM plane where the facet joint is in the same plane as the inter-spinous space (Figures 4.8 and 4.9). Poor neuraxial ultrasound views in our study was strongly associated with facet joint degeneration. However, this does not necessarily mean that there space is so narrow to allow US beam penetration or that the LF is deficient or absent. This might explain the high false negative rates of TM view.[1]

This might also explain the fact that PSO view did not have any correlation with facet degeneration. In PSO view, the ultrasound beam passes through the laminae and is less subjected to the various artefacts described (Figure 4.10).

Figure 4.8: Facet joint position in TM plane

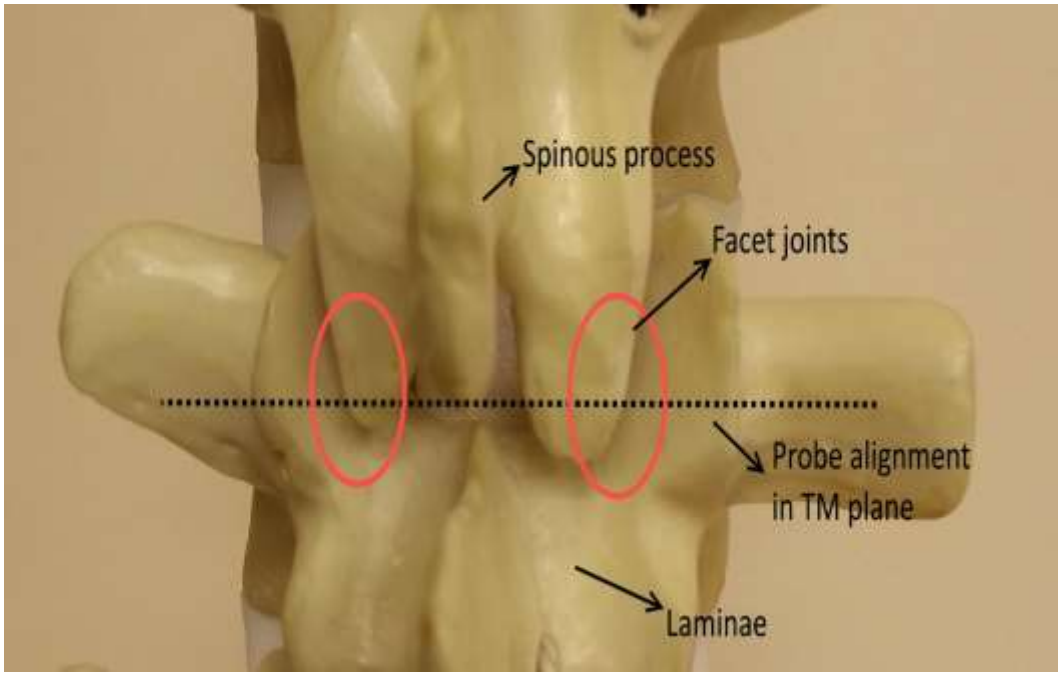


Figure 4.9: Lateral view of Facet joint position in TM plane

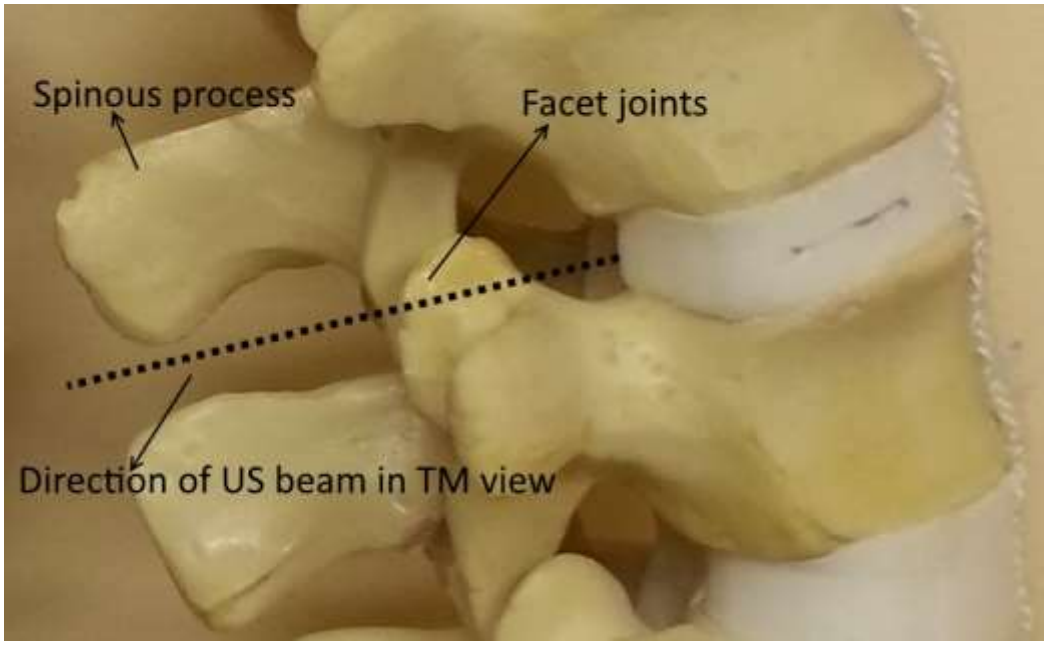
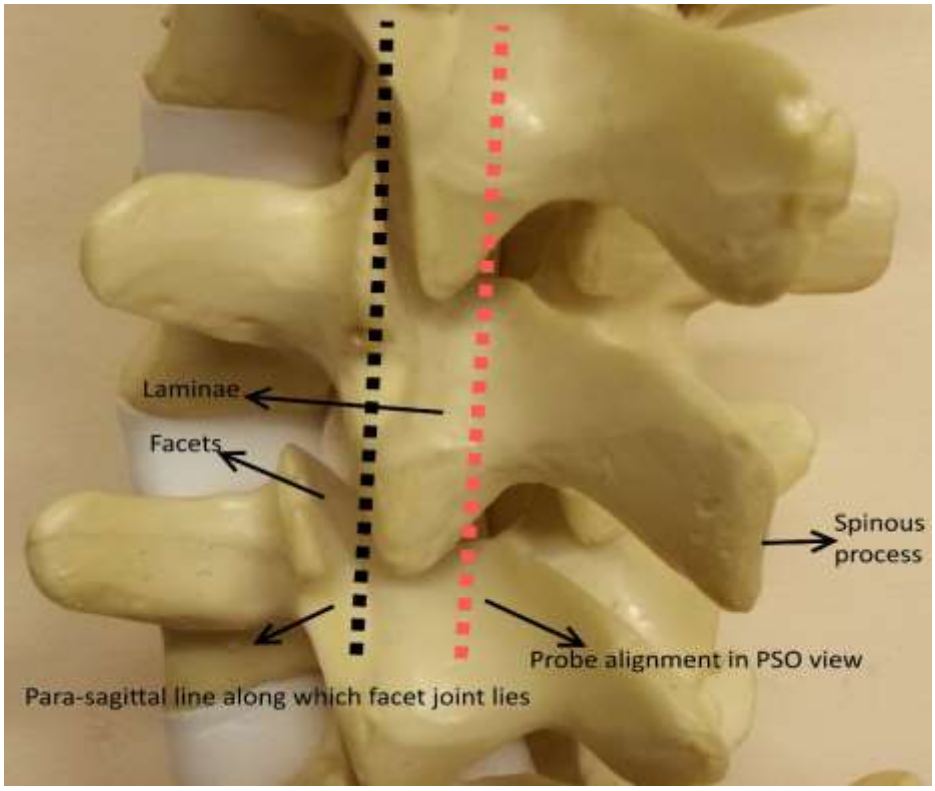


Figure 4.10: PSO plane and facet joint



This study did not find any relation between non fusion of LF in the midline and poor views. The most probable reason was the very low incidence of the gaps detected in this study population. Presence of gaps in the midline due to failure of fusion of LF has been reported previously in the literature. In a cytomicrotome study on 38 cadavers by Hogan et al[5], it was shown that there was a variable incidence of LF gaps in lumbar region. Lirk et al in his study on 45 cadavers documented the incidence of ligamentum flavum gaps in the lumbar region as follows: L1L2 – 22.2%, L2L3 – 11.4%, L3L4 -11.1%, L4L5 – 9.3% and L5-S1 – 0%. In our study the incidence was 0% at L1L2, L2L3, L5-S1 and 4.7 % (1/21) at L3L4 and L4L5 – a lot less than predicted.[6] In this study, on both instances when LF was not fused in midline, ultrasound did not visualise LF-dura complex. In L3-L4 level, the TM view was poor and in the L4-L5 level, the view was intermediate with only PLL visible. This difference may be due to the fact that cadaveric studies might have overestimated its incidence. Integrity of epidural fat, thecal sac and epidural veins cannot be preserved once the tissues are dissected as the delicate balance of pressures between them are disrupted.[2] For

example, the ligamentum flavum is usually held under tension and retracts when cut which might create gaps that might not exists otherwise.[7] [8] Also, the incidence of LF gaps are reported to be higher in cervical and high thoracic regions compared to lumbar regions.[9]

In a previous study in obstetric patients, Lee et al have shown that patients with accidental dural punctures have abnormal ligamentum flavum (LF) on neuraxial ultrasound compared to patients who did not have accidental dural puncture.[10] They described LF as abnormal if the hyperechoic line (LF-dura complex) was either absent or grossly discontinuous. LF gaps was suggested as one of the possible reasons for abnormal appearing LF on ultrasound in the study. Low in-vivo incidence of LF gaps at the lower lumbar levels, as evidence by this study, does not explain the high percentage of abnormal LF in patients with previous unintended dural puncture in their study (71% vs 17%). But facet joint degeneration is strongly associated with asymmetrical thickening of LF which might explain some of their findings.[11] For the reasons described later, facet joint degeneration can make administration of neuraxial block difficult at any given level and difficulty might explain the reason behind accidental dural puncture.

Skin- PLL distance made no difference to the ultrasound views. Similarly anatomical factors such as para-spinal muscle thickness, subcutaneous fat, epidural fat and ligamentum flavum thickness did not have any influence on the quality of view.

The next obvious question is why does presence of facet joint degeneration makes the administration of neuraxial block difficult? In addition to the fact that facet joint degeneration can by itself narrow the window available for the passage of needle between the spinous process, the answer might lie in the factors that are closely associated with facet joint degeneration. Those include: increasing age,[12,13] degenerative disc disease,[14-16] narrowing of intervertebral space, increase in L1-5 lumbar lordosis, pelvic incidence, sacral slope,[17] associated bucking and hypertrophy of LF, LF calcification [18] and spinal canal stenosis.[19] Hence facet joint degeneration can acts as a surrogate marker for a number of structural changes that happen in

spine, almost all of which might make the administration of neuraxial block difficult in a given inter-spinous space.

On the other hand, PSO view do not capture the facet joint degeneration and hence its use in predicting the ease of administration of neuraxial block is limited.[1]

This study has a number of limitations. The small cohort size may have underpowered our ability to detect correlations with the measured parameters. The use of MRI for lumbosacral anatomic assessment also limits detection of ligamentous calcification which is a recognised contributor to difficult neuraxial access. With regards to facet joint degeneration, previous studies have shown that in the presence of MRI, CT is not needed for assessment of degeneration. [13,16] Compared to degeneration of joint, calcification of interspinous ligaments/ supraspinous ligaments/ligamentum flavum cannot be accurately identified by MRI. But the incidences of such calcifications are low ranging between 2.4% to 6.7%.[20] Imaging positions also differed between MRI (supine) and ultrasound (sitting with back arched) which may have limited direct comparability between findings. Measurements in the intervertebral disc height and dural sac diameter changes between supine and sitting position.[21,22] The magnitude of postural changes are small and will have minimal effect on the outcome of this study.

Summary

Facet joint degeneration is a major contributing factor to poor neuraxial ultrasound views in TM plane. As discussed earlier, poor visualisation of ligamentum flavum/duramater complex might be due to one of the two reasons: i) The ultrasound beam is not able to reach the target or ii) The target structure is absent or defective. This study has shown that former, rather than the latter is the more plausible explanation in most cases with cause being artefactual rather than structural. Future studies on improving the neuraxial imaging should focus on postural changes to move the facet joint away from the path of the beam e.g. flexion and lateral rotation. This method has been studied before for neuraxial ultrasound in thoracic regions.[22] In future the role of such manoeuvres to improve the neuraxial ultrasound imaging could be explored in interspinous spaces with poor visibility.

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Appendix

Data corresponding to Chapter 4 is provided in the supplementary digital content in excel file located in folder labelled Chapter 4.

Appendix 4.1.xls - Sheet 1- MRI US data

Chapter 5 (study 4a) - A comparison of conventional landmark guided midline versus pre-procedure ultrasound - guided paramedian techniques in spinal anaesthesia

Abstract

Background

Multiple passes and attempts while administering spinal anaesthesia are associated with a greater incidence of post dural-puncture headache, paraesthesia and spinal hematoma. We hypothesised that the routine use of pre-procedural ultrasound-guided paramedian technique for spinal anaesthesia reduces the number of passes required to achieve enter the subarachnoid space when compared to the conventional landmark-guided midline approach.

Methods

After local ethics approval, 100 consenting patients scheduled for elective total joint replacements (hip and knee) were randomised into group C (conventional) and group P (pre-procedural ultrasound guided paramedian technique) with 50 in each group. The patients were blinded to the study group. All spinal anaesthetics were administered by a consultant anaesthetist. In group C, spinal anaesthetic done via midline approach using clinically palpated landmarks. In group P, pre-procedural ultrasound scan was used to mark the paramedian insertion site and spinal anaesthetic was performed via paramedian approach.

Results

The average number of passes (defined as the number of forward advancements of the spinal needle in a given inter-spinous space, i.e. withdrawal and redirection of spinal needle without exiting the skin) in group P was approximately 0.34 times that of group C and this difference was statistically significant ($p = 0.01$). Similarly, the average number of attempts (defined as the number of times the spinal needle was withdrawn from the skin and reinserted) in group P was approximately 0.25 times

that of group C (p = 0.0021). Group P on an average took 81.5 (99% CI 68.4 to 97 seconds) seconds longer compared to group C to identify the landmarks (p = 0.0002). All other parameters including grading of palpated landmarks, time taken for spinal anaesthetic injection, peri-procedural pain scores, peri-procedural patient discomfort VAS score, conversion to general anaesthetic, paresthesia and radicular pain during needle insertion were similar between the two groups.

Conclusion

Routine use of paramedian spinal anaesthesia in the orthopedic patient population undergoing joint replacement surgery, guided by pre-procedure ultrasound examination, significantly decreases the number of passes and attempts needed to enter the sub-arachnoid space.

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Introduction

Spinal anaesthesia is widely performed using a surface landmark based 'blind' technique. Multiple passes and attempts while administering spinal anaesthesia are associated with a greater incidence of post dural-puncture headache, paraesthesia and spinal hematoma.[1-5]

Real time and pre-procedural neuraxial ultrasound techniques have been used to improve the success rate of spinal anaesthesia. The use of real time ultrasound-guided spinal anaesthesia has to date been limited to case series and case reports.[6-8] Its use may be limited by the requirement for wide bore needles and the technical difficulties associated with simultaneous ultrasound scanning and needle advancement. [9] The use of pre-procedural ultrasound has been shown to increase the first pass success rate for spinal anaesthesia only in patients with difficult surface anatomic landmarks.[10] No technique has been shown to improve the success rate of dural puncture when applied routinely to all patients.[11]

Studies on pre-procedural ultrasound-guided spinal techniques are limited to a midline approach using a transverse median view (TM). The parasagittal oblique (PSO) view consistently offers better ultrasound view of the neuraxis compared to TM views.[12] However no studies have been conducted to assess whether these superior PSO views translate into easier paramedian needle insertion.

We hypothesised that the routine use of pre-procedural ultrasound-guided paramedian spinal technique results in less number of passes required to enter the subarachnoid space when compared to the conventional landmark based midline approach.

Methodology

This was a prospective, randomised, controlled study performed from February 2014 to May 2014. Following approval by the Clinical Research Ethics Committee of Cork Teaching Hospitals (ref no: ECM 4(j) 04/02/14), all consented patients scheduled to undergo elective total knee or total hip arthroplasty under spinal anaesthesia were included in the study. A written informed consent was obtained from all patients

participating in the study. Patients with contraindications to spinal anaesthesia (allergy to local anaesthetic, coagulopathy, local infection and indeterminate neurological disease) were excluded from the study.

The patients were randomised using random number generating software (Research Randomizer Version 4.0) to undergo either conventional landmark-guided spinal anaesthesia (group C) or pre-procedural ultrasound-guided paramedian spinal (group P). Group allocation was concealed by enclosing the codes in a sealed opaque envelope and seen by the attending anaesthetist immediately before performing the procedure. In both groups, spinal anaesthesia was performed by one of three consultant anaesthetists (FL, PL, GI), each having performed more than 75 neuraxial ultrasound scans prior to the study. On arrival to the anaesthesia induction room baseline monitoring (non-invasive blood pressure, pulse oximetry and 3 lead ECG) and intravenous access were established. Patients in both groups were then positioned sitting on a level trolley with feet resting on a foot rest. They were given a pillow to hug and requested to maintain an arched back posture with an assistant holding the patient to aid positioning. No sedation was given prior to or during administration of spinal anaesthesia.

In group C, the anaesthetist palpated the landmarks after positioning and graded the ease of palpation on a 4 point scale (easy, moderate, difficult or impossible) as described in previous studies.[10] The selection of interspinous space was left to the discretion of the anaesthetist. Strict asepsis was followed throughout the procedure with anaesthetist scrubbed prior to procedure, wearing mask and sterile gloves.

The skin was prepped with 2% Chlorhexidine (Chloraprep 3 ml applicator, CareFusion Corporation, San Diego, CA 92130,USA) following which 2-5 mL of 1% lidocaine was used to infiltrate the skin. The anaesthetist performing the spinal technique was allowed to choose the appropriate needle length (90 or 119 mm 25 G –Whitacre needle, Becton, Dickinson and Company, Franklin Lakes, New Jersey, 07417-1880, USA), gauge (25G or 22G), depth and angle of insertion. The type and dose of local anaesthetic injected for spinal anaesthesia was at the discretion of the attending anaesthetist. After completion of spinal anaesthetic injection, and positioning the

patient in the lateral decubitus position, ultrasound was used to identify the interspinous level at which the injection was administered.

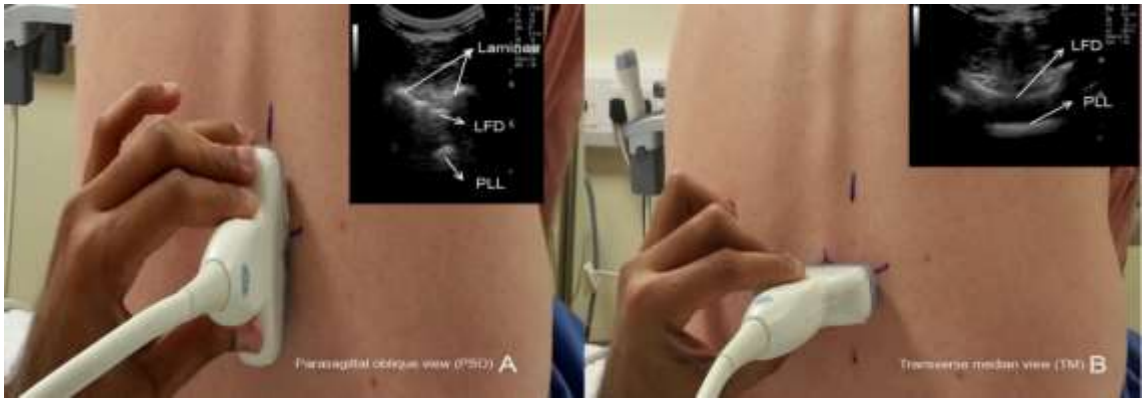
In group P, a portable ultrasound unit (SonixTablet, Peabody, MA, USA) with a curved 2-5 MHz probe was used for initial pre-procedural marking. A paramedian sagittal oblique view of the neuraxis was obtained and the sacrum was identified, following which the interlaminar space between L5 and S1 was noted. Subsequent interspinous spaces were identified by counting the interlaminar spaces in a cranial direction. The interspinous space at which the clearest image of the anterior complex (ligamentum flavum dura complex- LFD) and posterior complex (posterior longitudinal ligament- PLL) was obtained, was selected. At the selected interspace, and with the probe positioned to obtain the clearest ultrasound image, a skin marker was used to mark the midpoint of the long border of the probe and the midpoints of the short borders of the probe (Figure 5.1). The medial angulation of the probe was also noted to guide the insertion of the spinal needle.

At the same horizontal level as the midpoint of the long border of the probe, the midpoint of the line drawn between the two short border midpoints of the probe was used as paramedian insertion point for the spinal needle (Figure 5.2). A transverse median (TM) view at the same level was also obtained and the midline was marked. This marking was used to aid the medial angulation of the spinal needle (Figure 5.2). Both PSO and TM views were graded as good (both LFD and PLL visible), intermediate (either LFD or PLL visible) and poor (both LFD and PLL not visible).[12]

Following skin marking, care was taken to make sure that the needle entry site was free of ultrasound gel prior to needle insertion. In group P, the anaesthetist did not palpate the landmarks for grading until the spinal injection was complete. Spinal anaesthesia was performed in the same aseptic manner as mentioned earlier.

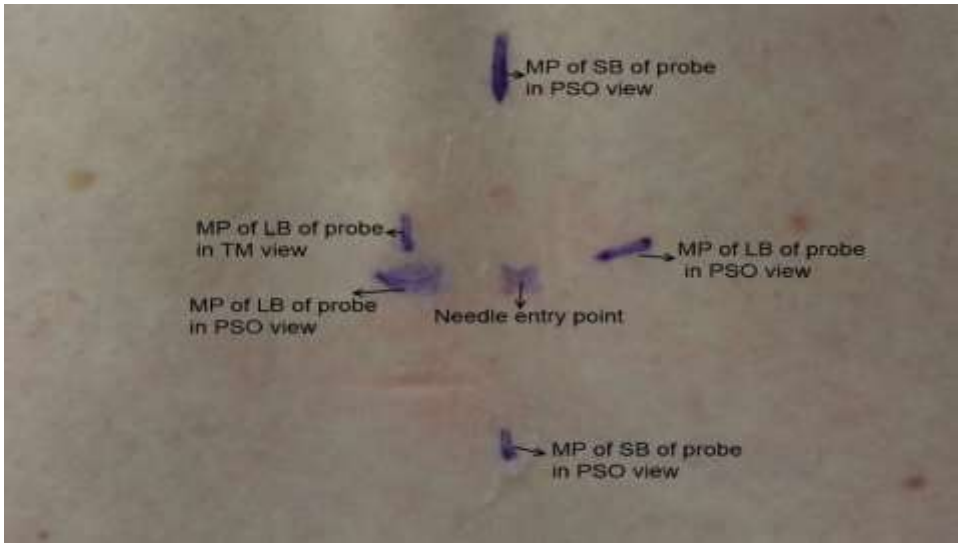
In both groups the anaesthetists were given the option to use alternative methods if unsuccessful after three attempts. For patients in group C, another interspinous space could be used or ultrasound employed. For patients in group P, a midline approach or a conventional landmark palpation technique could be used.

Figure 5.1: Skin marking with probe



A- Skin markings with probe positioned to get the best possible parasagittal oblique view (PSO) of neuraxis B- Midpoint of long border of probe marked in Transverse median view (TM). LFD –Ligamentum flavum dura complex, PLL – Posterior longitudinal ligament.

Figure 5.2: Paramedian skin entry point



Needle entry point shown after skin markings. It is marked at the intersection of the lines joining midpoint of long border of probe and short border of the probe marked during PSO view. The midpoint of long border of probe in TM view was used to aid the medial angulation of the needle in addition to probe angle in PSO view. MP-Midpoint, LB – Long border, SB – Short border.

The outcomes were noted by a single observer (KK) for all patients. Due to the nature of the study, the observer could not be blinded to the groups. In addition to

demographic details from the patients (age, sex and height), type of surgery and history of lumbar spine surgery was recorded. History of difficult neuraxial block was also recorded in both groups. This was obtained from previous anaesthetic records. Our hospital uses a standardized electronic anaesthesia record which requires description of the grade of difficulty of spinal performance as 'Easy', 'Difficult' and 'Failed'. Only previous documented evidence by anaesthetist noting the difficulty in the procedure (spinal, epidural or combined spinal epidural anaesthesia) was included.

A timer was used to record the various time intervals. Time for identifying landmarks in group C was defined as time from which the anaesthetist started palpating to identify the landmarks to completion of the process as declared by the anaesthetist. In group P, it was defined as time from which the ultrasound probe was placed on the skin to the anaesthetist declaring that the markings are completed. Time taken for performing spinal anaesthetic was defined as time taken from insertion of introducer needle to completion of injection. The number of passes (defined as the number of forward advancements of the spinal needle in a given interspinous space i.e. withdrawal and redirection of spinal needle without exiting the skin) and number of spinal needle insertion attempts (defined as the number of times the spinal needle was withdrawn from the skin and reinserted) were noted.[10] The number of passes and attempts were recorded either until the completion of spinal anaesthetic or until the anaesthetist converted to an alternate technique.

Incidence of radicular pain, paraesthesia and blood in the spinal needle was also noted. All patients who experienced paraesthesia or radicular pain were followed over the next 24 hours and any patients with persistent symptoms were further evaluated as per department protocol. The use of long needle i.e. 119 mm 25 G Whitacre needle (Becton, Dickinson and Company, Franklin Lakes, New Jersey, 07417-1880, USA) was also recorded.

In both groups following administration of spinal anaesthesia, patients were positioned on either left or right lateral position depending on the site of surgery and the type of Bupivacaine used (plain or hyperbaric). After positioning and prior to

administration of sedation, patients were asked for their peri-procedural pain scores (patients were specifically asked to rate the pain in their back felt during administration of spinal anaesthesia) measured using an 11 point verbal rating scale (0=no pain, 10=most pain imaginable) and peri-procedural discomfort scores measured using an 11 point verbal rating measured (0=no discomfort, 10=most discomfort imaginable). Level of block (loss of cold sensation tested with ethyl chloride spray) was noted 15 minutes after spinal anaesthetic injection. Type and dose of sedation (midazolam with or without propofol infusion) was left to the discretion of the anaesthetist.

Study Outcomes

The primary outcome was the difference in number of passes between the two groups.

Secondary outcomes included the following,

1. Number of spinal needle insertion attempts

2. Time for identifying landmarks

3. Time taken for performing spinal anaesthetic

4. Level of block

5. Incidence of radicular pain, paraesthesia and blood in the spinal needle.

6. Peri-procedural pain

7. Peri-procedural discomfort score

Statistics

Based on previous study we assumed that the average number of passes per spinal anaesthetic for an experienced anaesthetist would be 3.3 +/- 3.1 (mean +/- SD).[13] We hypothesised that by using pre-procedural paramedian spinal the number of passes could be reduced to 1.3. A total of 38 patients in each group would have been needed to achieve a power of 0.8 and type 1 error of <0.05. We randomised 50 patients per group to allow for dropouts. All data were analysed based on intention to treat. Data

were analysed for normal distribution using the Shapiro–Wilks test. Categorical data were analysed using the Chi-square test or Fisher's exact test as appropriate. Normally distributed parametric data were analysed using Students-t test. All tests were two-tailed.

For non-normally distributed count data (passes and attempts) that cannot have a value of zero and had negative binomial distribution, zero truncated negative binomial regression was used to examine the group effect. For other variables that were non-normally distributed, especially if the data could not be approximated by log-normal distribution, bootstrap independent samples test was applied as it is considered a better approach compared to Z-score procedure [14]. Results for time variables were based on 5000 bootstrap samples. For the variable dose of intrathecal bupivacaine, the 99% confidence interval was based on 5000 bootstrap samples; variances in some samples were zero therefore the p-value was estimated from 1000 bootstrap samples.

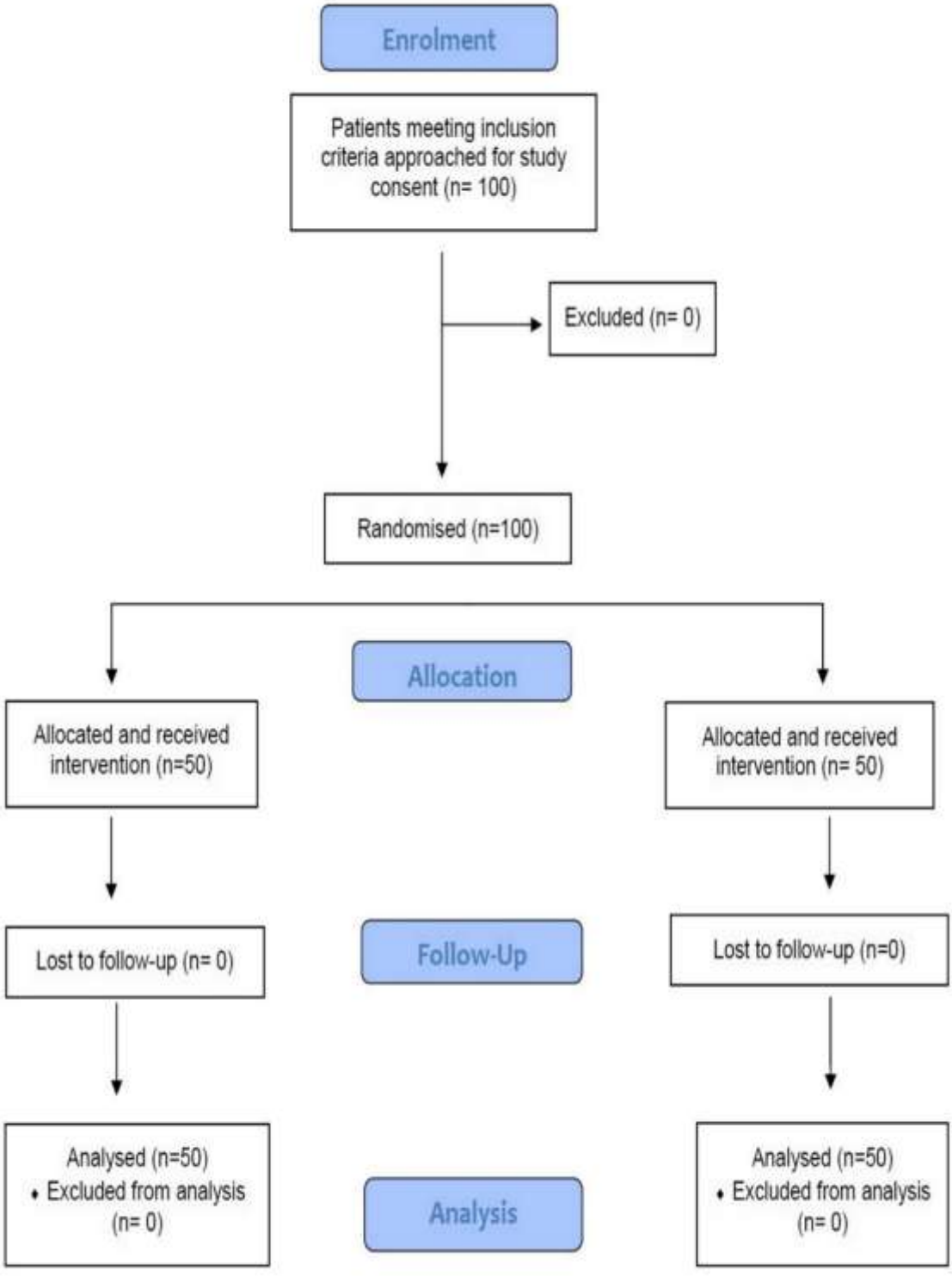
Time variables were reported with 10^{th} and 90^{th} percentile to provide information on the spread. Student t-test for unequal variance (Welch method) gave 99% confidence interval within 1.5 seconds for time taken to identify landmarks and 16.2 seconds for time taken for spinal anaesthetic administration when compared to bootstrap.

For patient characteristic variables and primary outcome variable, a two-tailed p value <0.05 was considered significant and 95% confidence interval (CI) were reported. For all other outcome variables, a two-tailed p value <0.01 was considered statistically significant and 99% CI were reported. SPSS version 20 and STATA 12.1 were used for statistical analysis.

Results

A total of one hundred patients were assessed for suitability. All patients approached gave their consent to take part in the study, and 50 were randomised to each group. All patients received the allocated intervention. No patients were lost to follow up and data acquisition was complete (Figure 5.3). In one patient spinal injection was

Figure 5.3 Consort flow chart



performed in the lateral position due to a vasovagal episode following local anaesthetic infiltration. This patient's data was included in the analysis.

The distribution of demographic data of the patients (age, sex and height), type of surgery, history of lumbar spine surgery, history of difficult dural tap and grading of palpated landmarks was similar between the two groups with the exception of weight (Table 5.1). The mean weight in group C was 84.8 kilograms (SD =14.4) versus 78.1 kilograms (SD= 17.8) in group P (p= 0.04) but there was no difference in BMI between the two groups.

The mean number of passes (the primary outcome variable) in group C was 8.2 (SD 12.3) versus 4 (SD 4) in Group P (Table 5.2). The average number of passes in group P was approximately 0.34 times that of group C and this difference was statistically significant (p = 0.01). The average number of attempts in group P was approximately 0.25 times that of group C (p = 0.0021). Due to the distribution (negative binomial) and type (count) of data, we used a zero truncated, negative binomial regression model and hence one should be mindful of the small sample size (n= 100) when interpreting the results.

On comparing variables for successful dural puncture (Table 5.3) , 84% of patients in group P had successful dural puncture on first attempt compared to 60% in group C (Chi-square test, p = 0.0075). On subgroup analysis of number of passes at each level in group P, L5-S1 had the tendency towards smaller number of passes (mean 2+/-1) compared to L4-5 (mean 4.27+/- 4.1) and L3-4 (Mean 5.15 +/- 5.01) although not statistically significant (p = 0.15).

There were no evidence of differences between the three anaesthetists in terms of number of passes (zero truncated binomial regression, p= 0.97, LR Chi^2 = 0.06) or attempts (zero truncated binomial regression, p= 0.36, LR Chi^2 = 0.83).

Table 5.1: Patient characteristics in Group C and Group P

Variables	**Group C mean (sd) n (%)**	**Group P mean (sd) n (%)**	**Levene's Test for Equality of Variance p-value**	**p-value[#]**
Age (years)[*]	65.2 (11.4)	63.4 (14.1)	0.03	0.48
Weight (kg)[*]	84.8 (14.4)	78.1 (17.8)	0.17	0.04
Height (m)	1.68 (0.08)	1.98 (0.14)	0.08	0.12
BMI (kg m^{-2})	30.14 (4.7)	28.57 (4.5)	0.99	0.09
Male	26 (52)	20 (40)	-	0.23
Type of surgery				
THR	20 (40)	28 (56)	-	
TKR	28 (56)	20 (40)	-	0.29[+]
B/L TKR	2 (4)	2 (4)	-	
Previous lumbar spine surgery	3 (6)	0 (0)	-	-
Previous history of difficult spinal anaesthetic	1 (2)	0 (0)	-	

[#]*P*-values(2-tailed) correct to 2 decimal places had the same value for equal (T-test) and unequal variances (Welch's Test);

[*]Shapiro-Wilks Tests of Normality: Age Group C (p= 0.01), Weight Group P (p=0.04)

[+] Fisher's Exact Test

Table 5.2: Analysis of number of needle passes and number of attempts

Variables	Group C mean (sd)	Group P mean (sd)	*Zero Truncated Negative Binomial Results			
			B	Exp (B)	Confidence Interval Exp (B)	p-value
Number of passes	8.2 (12.3)	4.0 (4.0)	-1.07	0.34	95% C.I.(0.15, 0.79)	0.01
#Number of attempts	1.98 (1.66)	1.28 (0.7)	-1.39	0.25	99% C.I.(0.077, 0.79)	0.0021

Number of attempts (secondary outcome variable), the significance was set at p<.01, and 99% Confidence intervals were calculated

*The distribution of the number of passes and number of attempts was highly skewed and all values exceed 1, therefore the Zero truncated Negative Binomial (STATA) was used to compare the two groups. A patient in the Paramedian Group, has expected Number of Passes equal to exp(-1.07) (i.e. = 0.34) times that of a patient in the Conventional Group (p=0.01), ie fewer passes are expected in the Paramedian Group. Similar analysis applies for attempts.

Table 5.3: Successful dural puncture rates for selected number of attempts and passes in Group C and Group P

Successful Dural puncture	Group C N (%)	Group P N (%)	Confidence Interval	P-value 2-sided
First Pass	20 (40%)	14 (28%)	95% C.I. (-30.4, 6.4)	0.21
Within 2 passes	23 (46%)	25 (50%)	95% C.I. (-15.6,23.6)	0.69
First Attempt	30 (60%)	42 (84%)	99% C.I. (1.7, 46.3)	0.0075
Within 2 attempts	37 (74%)	45 (90%)	99% C.I. (-3.4, 35.4)	0.04

Alternative techniques were employed in six patients in group C (technique used - ultrasound guided paramedian spinal) and two patients in group P (technique used - midline approach by conventional palpation). There was no significant difference between the two groups in requirement for alternative techniques (Fisher's Exact test, p = 0.27). Despite the use of alternative techniques, dural puncture could not be achieved in three out of the six patients in group C. The two patients in group P, in whom alternative technique was used, successful dual puncture was achieved in both the patients.

It took the operator on average 81.5 seconds longer (99% CI 68.4 to 97 seconds) to identify the landmarks in group P than in group C (p = 0.0002). The dose range of intra-thecal bupivacaine was between 14 mg to 18 mg. Other parameters were comparable between the groups (Table 5.4, 5.5). All five patients in the study who had radicular pain or paraesthesia during needle placement were followed up for 24 hours post-surgery and none of them had persistent symptoms.

Of the five patients in group C who required general anaesthesia (GA), failure to perform spinal anaesthesia was the reason in three patients. Of the other two

patients who required GA, one had pain on incision and one developed abdominal pain during the surgery. Of the four patients in group P who needed GA, three patients reported pain on incision, and one patient became difficult to sedate 30 minutes into the surgery. The interspinous level at which the spinal was performed was significantly different between the two groups with p = 0.0025 (Table 5.6). Four patients in group C had their spinal performed at L2-3 versus none in group P (Fisher's exact test; p=0.05). There was no difference within the quality of ultrasound views (Table 5.7) and number of passes or attempts for both TM (p = 0.49, p= 0.19) and PSO (p= 0.43, p = 0.32) views.

Table 5.4: Spinal anaesthesia variables 1

Variables		**Group C n (%)**	**Group P n (%)**	**p value**
Grading of palpated landmarks	Easy	30 (60)	30 (60)	0.78*
	Moderate	15 (30)	17 (34)	
	Difficult	5 (10)	3 (6)	
	Impossible	0 (0)	0 (0)	
Type of Bupivacaine	Heavy	20 (43)	19 (38)	0.65
	Plain	27 (57)	31 (62)	
Paresthesia during insertion of spinal needle (n)		1	3	-
Radicular pain during insertion of spinal needle (n)		1	0	-
Blood in spinal needle (n)		2	0	-
Long spinal needle used (n)		3	2	-
Failure to perform spinal anaesthetic (n)		3	0	-
Conversion to GA (n)		5	4	-

*Fisher's exact test

Table 5.5: Spinal anaesthesia variables 2

Variable	Group C mean (10^{th},90^{th}) N=50	Group P mean (10^{th},90^{th}) N=50	Bootstrap Independent Samples Test*		
			P – C Mean Difference (se)	99% Confidence Interval Lower, Upper	p-value 2-taild
Time taken for identifying landmarks (seconds)	14.6 (9.1, 24.8)	96.1 (58.1, 133.9)	81.5 (5.21)	68.4, 97.1	0.0002
Time taken for spinal injection (seconds)	169.9 (46.1, 558.7)	97.8 (41.1, 189.4)	-66.0 (35.31)	-161.5, 11.0	0.09
Dose of intrathecal Bupivacaine (mg)	N=47 16.34 (15.0, 17.7)	N=50 16.40 (15.0, 17.5)	0.06 (0.22)	-0.50, 0.62	0.78+
Variable	**Group C** **Median (Q1,Q3)**	**Group P** **Median (Q1,Q3)**	**Mann-Whitney U Test** **p-value**		
Peri-procedural Vas scores of pain at injection site	3.0 (1.8, 5.0)	3.0 (1.0, 4.3)	0.59		
Peri-procedural patient discomfort VAS score	10.0 (8.0,10.0)	10.0 (8.0, 10.0)	0.28		

*For time variables, 5000 bootstrap samples taken.+ For variable Dose of intrathecal bupivacaine 5000 bootstrap samples were taken and variances in some samples were zero therefore the p-value was estimated from 1000 bootstrap samples.

Table 5.6: Interspinous level at which dural puncture was done and block height

Variables		Group C	Group P	p value
Interspinous level at which dural puncture was done (n)	L2-3	4	0	0.0025*
	L3-4	22	13	
	L4-5	19	26	
	L5-S1	2	11	
Dermatome level of loss of cold sensation 15 minutes post spinal anaesthetic injection (N)	T5	2	2	0.69*
	T6	4	3	
	T7	2	2	
	T8	12	14	
	T9	1	2	
	T10	14	10	
	T12	10	11	
	L1	1	6	

*Fisher's Exact test

Table 5.7: Distribution of quality of ultrasound views (PSO and TM views) in group P

Group P US views		Number of views – n (%)
PSO view	Grade 1	30 (60%)
	Grade 2	20 (40%)
	Grade 3	0 (0%)
TM view	Grade 1	10 (20%)
	Grade 2	24(48%)
	Grade 3	16 (32%)

Discussion

The use of pre-procedural ultrasound-guided paramedian spinal technique resulted in a greater than 50% reduction in the number of passes required for success compared to a conventional landmark-based midline approach in patients undergoing total hip or total knee arthroplasty. In addition, a pre-procedural

ultrasound-guided paramedian spinal technique significantly reduced the number of attempts, and increased the first attempt success rate in achieving dural puncture. The number of passes was greater in our control group compared to the referenced study.[13] This might be due to a number of reasons. First, the patient population was different. Mean age and BMI in our study was 65.2 years and 30 respectively versus 56.2 years and 23.8 in the referenced study. Second, in the study by Kim et al, the number of passes was self-reported whereas in our study it was recorded by an independent observer. This is important as it has been shown that the self-reported number of passes is always lower than the actual number of passes.[16]

To date, routine use of pre-procedure ultrasound in the general adult or obstetric populations has not been shown to improve the number of passes or attempts needed to achieve successful dural puncture.[11, 17] We observed a reduction in number of passes required to enter the sub-arachnoid space due to the following probable reasons.

First, our population group had an average age of 64.3 years (SD = 12.8). Spinal anaesthesia has been shown to be more difficult in an older population compared to a general adult population.[18]

Second, we used a paramedian approach to the neuraxis (guided by ultrasound) which has not been studied so far. In the presence of interspinous ligament calcification and an inability to achieve adequate flexion (both of which are common in elderly), this paramedian approach might be valuable. It has also been shown that both the length and width of the lumbar spinous process increases significantly with ageing which further narrows the interspinous space available for midline approach.[19] The interlaminar space is least affected by changes due to ageing and offers a potential window for spinal anaesthesia. The same reasons explain why the PSO view consistently yields a clearer image of LFD and PLL compared to TM view.[12, 20, 21] Although a paramedian approach for epidural catheter placement has been shown to have technical advantages compared to the midline approach,[22] previous studies on landmark guided paramedian versus midline approach to spinal anaesthetic have yielded mixed results.[23 24, 25] It is conceivable that the advantages

of the paramedian approach were more pronounced in our orthopedic population group.

Third, we used both the probe angle and midline marking to aid paramedian insertion of the spinal needle. Using a midline approach the needle angle is only guided by the operator remembering the angle of the probe. As even small changes in angle of insertion of needle and entry point can cause significant changes to where the tip of the needle finally ends up, we believe the addition of another skin marking at the midline to guide the angle of the needle might have played an important role.

Finally, the studies that showed no difference on routine scanning looked at first pass success rates between the two groups (success at first attempt and first pass). We chose to look specifically at the number of passes required in each group. We believe using only first pass success rates may potentially miss important differences between the groups.

Establishing landmarks took on average 81.5 (99% CI 68.4 to 97.1) seconds longer in group P. In a study by Chin et al using similar end points, the ultrasound group took 240 seconds longer.[10] The difference might be due to the fact that in their study scanning was done in patients with difficult surface landmarks and it involved marking three interspinous spaces. Our study population included all patients and we marked only one interspinous space as we wanted it to reflect real time practice. In the same manner we did not find a difference in the time taken to perform spinal anaesthetic probably reflecting the routine use in all patients.

The study does have limitations. First, neither the observer nor the attending anaesthetists were blinded to the study group. The fact that the ultrasound group would have skin markings and the difference in the direction of needle insertion would make the blinding very difficult. A potential for bias cannot be excluded. Second, the procedure is heterogeneous with multiple factors affecting the number of passes including individual anaesthetist preference and style of practice, and the number of attempts and/or time taken before using alternate methods. This reflects daily clinical practice. Having a single anaesthetist perform all procedures might limit

the differences due to the aforementioned reasons but it might be subjected to individual bias and lack of validation. Third, neuraxial ultrasound has limitations. TM views for a midline approach to dural puncture have a positive predictive value of up to 85% but a negative predictive value of just 30%.[12] Also ultrasound views are generally more difficult to acquire in elderly due to anatomical changes (facet hypertrophy, interspinous and supraspinous ligament calcification). [28] In addition, the necessity to remember the angle of approach of the needle and the inaccuracies of skin markings can further decrease its utility in patients with a longer distance between skin and dura mater.

Summary

Use of paramedian spinal anaesthesia in an elderly orthopaedic population, guided by pre-procedure ultrasound examination, significantly decreases the number of passes and attempts needed to reach sub-arachnoid space.

Spinal anaesthesia is still largely a blind procedure. An ultrasound beam may prove a better tool compared to a needle in locating the target.

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Appendix

Data corresponding to Chapter 5 is provided in a excel sheet in the supplementary digital content located in the folder Chapter 5.

Appendix 5.1.xls – sheet 1 – PM spinal US study

Chapter 6 (study 4b) - A comparison of conventional landmark-guided midline versus ultrasound-guided L5-S1 paramedian techniques in spinal anaesthesia – a randomized control study

Abstract

Introduction

Ultrasound guided paramedian approach to performing spinal anaesthesia has only recently been explored. We hypothesised that the routine use of pre-procedural ultrasound-guided paramedian spinals at L5-S1 interspace could reduce the number of passes required to enter the subarachnoid space when compared to the conventional landmark-guided midline approach.

Methods

After local ethics approval, 120 consenting patients scheduled for elective total joint replacements (Hip and Knee) were randomised into either group C (conventional) or group P (pre-procedural ultrasound guided paramedian L5-S1 technique) with 60 in each group. The patients were blinded to the study group. Midline approach with palpated landmarks was used in group C whereas in group P, L5-S1 paramedian approach was facilitated by pre-procedure ultrasound.

Results

The distribution of demographic data of the patients (age, sex, weight and height), type of surgery, history of lumbar spine surgery and history of difficult dural tap were similar between the two groups. A patient in the paramedian group L5/S1 had an expected number of passes equal to 1.195 times (95% CI 0.57, 2.47) that of a patient in the conventional group (P = 0.63), i.e., similar number of passes were expected in both groups. A patient in the paramedian group L5/S1 had an expected number of attempts equal to 1.079 times (99% CI 0.41, 2.8) that of a patient in the conventional group (P = 0.84), i.e., a similar number of attempts were expected in both groups. The first pass success rates (1 attempt and 1 pass) was significantly greater in group

C compared to group P (43% vs 22%, p = 0.02, table 3). Patients in group P had difficult surface landmarks compared to group C (P = 0.04).

Conclusion

Routine use of paramedian spinal anaesthesia at L5-S1 interspace, guided by pre-procedure ultrasound, in patients undergoing lower limb joint arthroplasties did not reduce the number of passes or attempts needed to achieve successful spinal anaesthesia.

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Introduction

Spinal anaesthesia is conventionally performed using a landmark-guided midline approach. Various modifications have been described to reduce the morbidity [1-5] related to repeated attempts and passes. These include a pre-procedure ultrasound-guided midline approach[6], real-time ultrasound-guided approach[7,8], landmark-guided paramedian approach[9-13] and pre-procedure ultrasound-guided paramedian approach[14,15]. Ultrasound is beneficial only in patients administered a single shot spinal anaesthetic who have difficult surface landmarks or abnormal anatomy. There is insufficient data to support the routine use of ultrasound in all patients [16,17].

In our previous study on patients undergoing lower limb joint replacement surgery, pre-procedural ultrasound-guided paramedian approach, performed routinely in all patients, significantly reduced the number of passes and attempts required for success.[14]. On sub group analysis, we observed a non-significant trend towards a lower number of passes in the L5/S1 interspace compared to other inter-vertebral spaces, using a paramedian approach. L5-S1 had the least number of passes (mean 2+/-1) compared to L4-5 (mean 4.27+/- 4.1) and L3-4 (Mean 5.15 +/- 5.01).

Anatomically the L5/S1 interspace is the widest interlaminar space and is least affected by a patient's inability to flex. [18-20] . Previous case reports on landmark-guided techniques have suggested high success rate with the paramedian approach at L5/S1 level (Taylor's approach) [12,13].

Hence we hypothesised that by selective targeting of the L5/S1 interspinous space with ultrasound, we should be able to further refine the paramedian approach. The aim of the study was to compare conventional midline approach at any interspinous level to a pre-procedure ultrasound-guided L5/S1 paramedian approach.

Methodology

This was a prospective, randomised, controlled study conducted in a university teaching hospital in Ireland between July 2014 and June 2015. The trial was registered with clinicaltrials.gov (ID – NCT02189681) following approval by the clinical research ethics committee of Cork teaching hospitals. All consented patients

scheduled to undergo elective total knee or total hip arthroplasty under spinal anaesthesia during the study period were included. A written informed consent was obtained from all patients in the study. Patients with contraindications to spinal anaesthesia (allergy to local anaesthetic, coagulopathy, local infection and indeterminate neurological disease) were excluded from the study.

The patients were randomised using random number generating software (Research Randomizer Version 4.0) to undergo either conventional landmark-guided spinal anaesthesia (Group C) or pre-procedural ultrasound-guided L5/S1 paramedian spinal (Group P). Opaque sealed envelopes were used to conceal the allocation. The envelope was opened by the attending anesthetist immediately before performing the procedure. Patients were not informed about their group allocation.

In both groups, spinal anaesthesia was performed by one of three consultant anesthetists (FL, PL, GI), each having performed more than 100 neuraxial ultrasound scans prior to the study. After application of standard monitoring (non-invasive blood pressure, pulse oximetry and three-lead ECG) and obtaining intravenous access, the patients were positioned sitting on a level trolley with feet resting on a foot rest. An assistant supported the patient to aid positioning and the patients were asked to maintain an arched back position during scanning and during performance of spinal anaesthesia.

In group C, the anaesthetist selected the preferred interspace and graded the ease of palpation after positioning on a 4 point scale (easy, moderate, difficult or impossible) as described in previous studies[6]. There was no restriction on the interspace selected for this group. Asepsis was maintained and the anaesthetist scrubbed prior to procedure, wearing mask and sterile gloves. The skin was prepared with 0.5% Chlorhexidine spray (CareFusion Corporation, San Diego, CA 92130,USA) following which 1% lidocaine (2-5 ml) was used for skin infiltration. A 25G Whitacre spinal needle (Becton, Dickinson and Company, Franklin Lakes, New Jersey, 07417-1880, USA) was used initially in all patients. The procedural anaesthetist chose the length (90 mm length or 119mm). Patients in each group received 3.5 ml of 0.5% hyperbaric bupivacaine for spinal anaesthesia. After completion of spinal anaesthetic

injection the patient was placed in lateral decubitus (with operating side in dependant position). Ultrasound scan was then done to identify the level at which dural tap was performed.

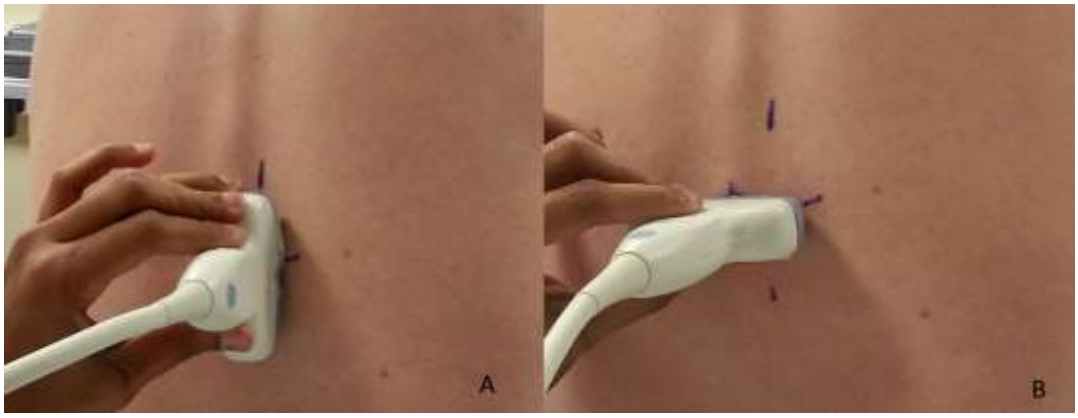
In group P, a 2-5 MHz curvilinear probe (SonixTablet, Peabody, MA, USA) was used for initial pre-procedural marking. The sacrum was identified first in parasagittal oblique view following which the interlaminar space between L5 and S1 was noted. This space was selected for all patients. At this interspace, and with the probe positioned to obtain the clearest ultrasound image with the interspace in the middle of the screen, a skin marker was used to mark the midpoint of the long and short borders of the probe. The medial angulation of the probe was also noted to guide the insertion of the spinal needle. At the same horizontal level as the midpoint of the long border of the probe, the midpoint of the line drawn between the two short border midpoints of the probe was used as paramedian insertion point for the spinal needle. A transverse median (TM) view at the same level was also obtained and the midline was marked. This marking was used to aid the medial angulation of the spinal needle (Figure 6.1and 6.2).

Following skin marking, the injection site was cleared of any residual ultrasound gel prior to needle insertion. The spinal anaesthesia was performed as described for the control group. In group P, the anaesthetist palpated and graded the landmarks immediately after the administration of spinal anaesthetic in sitting position. This was done to minimise bias if palpation were to occur prior to scanning.

In both groups, after three unsuccessful attempts, the anaesthetists were allowed to use alternative methods when felt necessary. For patients in group C, another interspinous space could be used or ultrasound employed. For patients in group P, a midline approach or a conventional landmark palpation technique could be used. Outcomes were measured by two observers (KK, AML) for all patients. Due to the nature of the study, these observers were not blinded to the groups. Time for identifying landmarks in group C was defined as time from which the anaesthetist started palpating to identify the landmarks to completion of the process as declared by the anaesthetist. In group P, it was defined as time from which the ultrasound

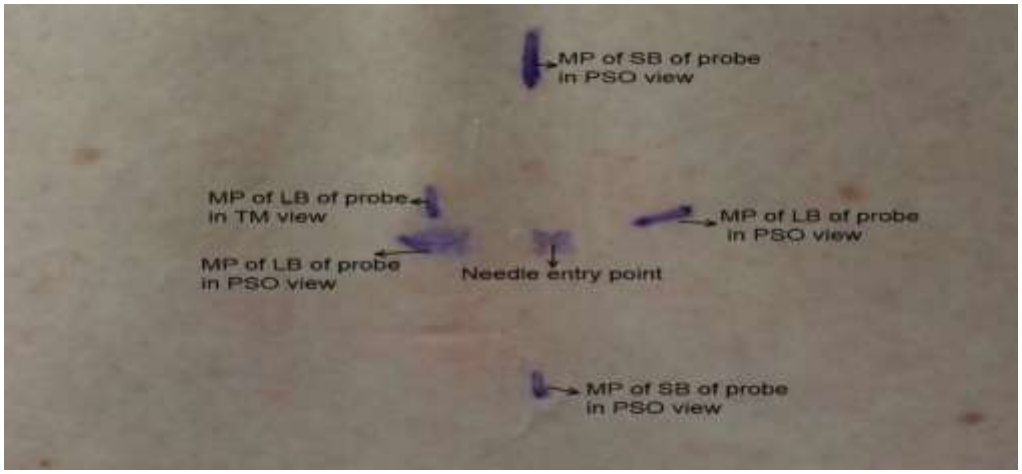
probe was placed on the skin to the anaesthetist declaring that the skin markings were completed.

Figure 6.1: Skin markings with probe



A- Skin markings Probe positioned to get the best possible parasagittal oblique view (PSO) of neuraxis B- Midpoint of long border of probe marked in Transverse median view (TM).

Figure 6.2: Paramedian skin entry point shown after skin markings



It is marked at the intersection of the lines joining midpoint of long border of probe and midpoint of short border of the probe marked during PSO view. The midpoint of long border of probe in TM view was used to aid the medial angulation of the needle in addition to probe angle in PSO view. MP-Midpoint, LB – Long border, SB – Short border.

Time taken to perform spinal anaesthesia was defined as the time from insertion of introducer needle to completion of injection. The number of passes, defined as the

number of forward advancements of the spinal needle in a given interspinous space (i.e. withdrawal and redirection of spinal needle without exiting the skin) and the number of needle insertion attempts (defined as the number of times the spinal needle was withdrawn from the skin and reinserted) were noted. The number of passes and attempts were recorded either until the completion of spinal anaesthetic or until the anaesthetist converted to an alternate technique.

Incidence of radicular pain, paraesthesia and blood in the spinal needle hub was also noted. All patients who experienced paraesthesia or radicular pain were followed over the next 24 hours and patients with persistent symptoms were managed as per local department protocol.

In both groups following administration of spinal anaesthesia, patients were positioned on either left or right lateral position depending on the site of surgery. After positioning and prior to administration of sedation, patients were asked for their peri-procedural pain scores measured using an 11 point verbal rating scale (0=no pain, 10=most pain imaginable) and peri-procedural discomfort scores measured using an 11 point verbal rating measured (0= no discomfort, 10=most discomfort imaginable). Level of block (loss of cold sensation to ethyl chloride spray) was noted 30 minutes after the local anaesthetic injection. Type and dose of sedation (Midazolam +/- Propofol infusion) was left to the discretion of the anaesthetist.

The primary outcome was the number of passes in the two groups. Secondary outcomes included the number of spinal needle insertion attempts, first pass success rates (1 attempt and 1 pass), time for identifying landmarks, time taken to administer spinal anaesthetic, level of block at 30 minutes, incidence of radicular pain, paraesthesia and blood in the spinal needle, peri-procedural pain, and peri-procedural discomfort.

Statistical analysis

In a pilot observational study done in our department, the average number of passes per spinal anaesthetic for an experienced anaesthetist was noted to be 6.4 +/- 8.6 (mean +/- SD). We hypothesised that by using pre-procedural paramedian spinal at

L5-S1 level, the number of passes could be reduced to two. A minimum of 60 patients in each group would therefore be needed to achieve 80% power to detect a difference with a less than 0.05 chance of type 1 error. We randomised 60 patients to each group. All data were analysed on an intention-to-treat basis.

Data were visually inspected for normality and Shapiro-Wilks test was done to check for normal distribution. Categorical data were analysed using the Chi-square test/ Fisher exact test as appropriate. Normally distributed parametric data were analysed using two-tailed Students t- test. Non-parametric data were analysed using the Mann Whitney U test. Zero truncated negative binomial regression was used for count data (passes and attempts). P value of <0.05 was considered significant. For primary outcome variables 95% CI was reported and for other variables 99% CI was reported. SPSS version 20 (Property of IBM © Copyright IBM Corporation 2000, 2013) and STATA (1996 – 2016 Statacorp LP) were used during statistical analysis.

Results

One hundred and twenty patients consented to take part in the study and 60 patients were randomised to each group (Figure 6.3). In one patient in group P, spinal anaesthetic was not attempted due to poor visualisation of anatomy in ultrasound and palpated landmarks were impossible to locate. This patient received a general anaesthetic. Sixty patients in group C and 59 patients in group P were included in the final analysis. No dropouts or incomplete data acquisition was noted. No patients were lost for follow up (Figure 6.3). The distribution of demographic data (Table 6.1) was similar between the groups.

The average number of passes and attempts were similar between the groups (Table 6.2). The distribution of the number of passes and number of attempts was highly skewed and all values exceeded 1 (Figure 6.4 and 6.5); therefore, the zero truncated negative binomial (STATA) was used to compare the 2 groups. A patient in the paramedian group L5/S1 had an expected number of passes equal to 1.195 times (95% CI 0.57, 2.47) that of a patient in the conventional group (P = 0.63), i.e., similar number of passes were expected in both groups. A patient in the paramedian group

L5-S1 had an expected number of attempts equal to 1.079 times (99% CI 0.41, 2.8) that of a patient in the conventional group (P = 0.84), i.e., a similar number of attempts were expected in both groups. The first pass success rates (1 attempt and 1 pass) was significantly greater in group C compared to group P (43% vs 22%, p = 0.02, Table 6.3).

Figure 6.3: Consort flow sheet

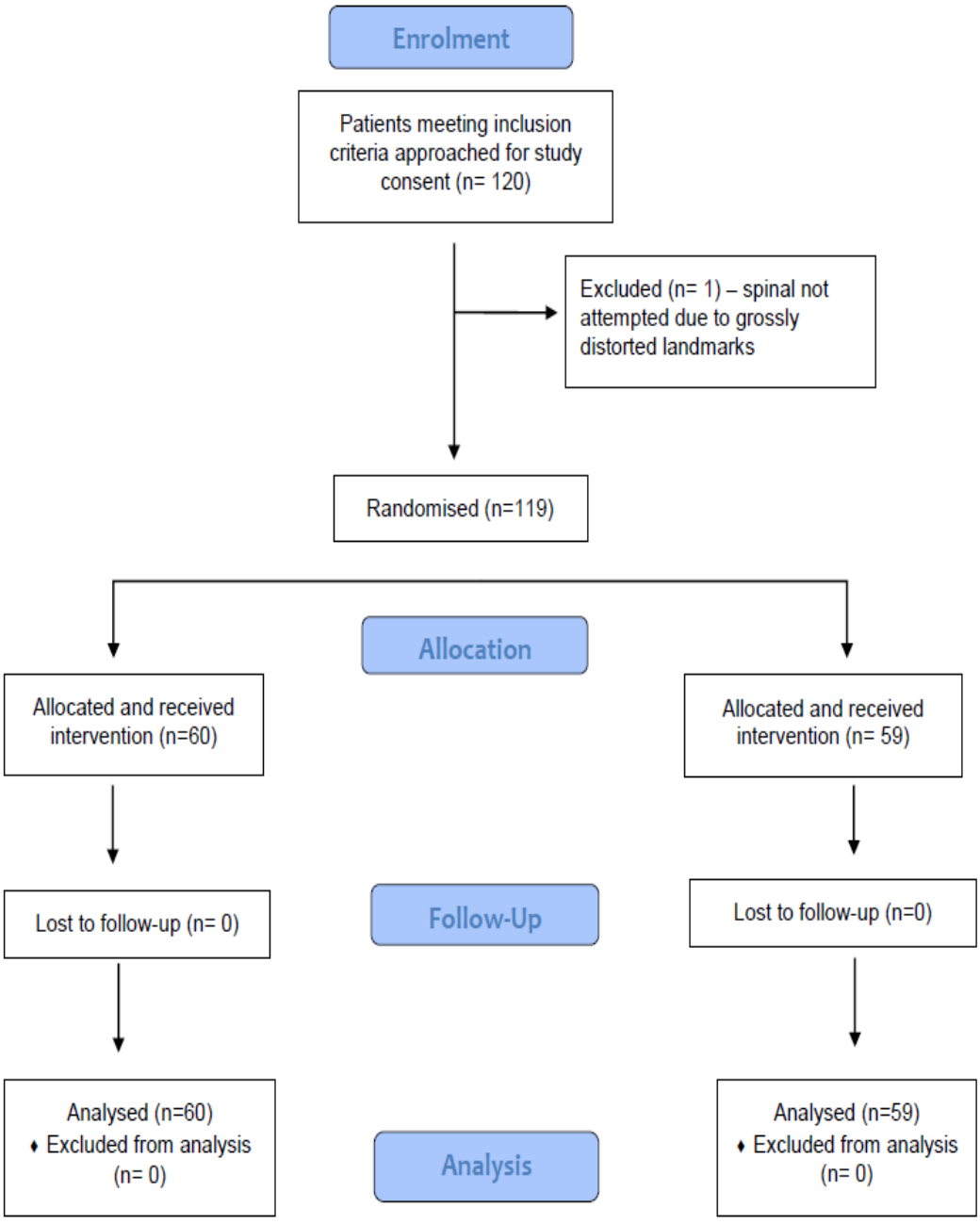


Table 6.1: Patient characteristics in Group C and Group P

Variables		Group C mean (sd)	Group P-L5-S1 mean (sd)	Levene Test for Equality of Variance p-value	T-Test p-value ((2-tailed)[a]
Age (years)		68.2 (10.3)	65.3 (9.7)	0.76	0.11
Weight (kg)		86.1 (13.9)	82.8 (18.9)	0.02[c]	0.15[c]
Height (m)		1.67 (0.09)	1.66 (0.10)	0.20	0.80
BMI (kg m^{-2})		30.6 (4.7)	30.1 (6.4)	0.02[c]	0.42[c]
Variables		**Group C n (%)**	**Group P n (%)**		**Chi-Square Test p-value**
Male		30 (50)	28 (48)		0.72
Type of surgery	**THR**	38 (63)	29 (48)		0.14[d]
	TKR	22 (37)	30 (30)		
	B/L TKR	0 (0)	1 (2)		
Previous lumbar spine surgery		2 (3)	1 (2)		—
Previous history of difficult spinal anaesthetic (n)		1 (2)	1 (2)		—

BMI = body mass index; THR = total hip replacement; TKR = total knee replacement; B/L = bilateral. [a]P values (2-tailed) correct to 2 decimal places had the same value for equal (t test) and unequal variances (Welch test). [b]Shapiro-Wilk tests of normality: age group C (P = 0.02), LnWeight group C (P = 0.03). [c]Test base on natural log transformed data. [d]Fisher exact test.

Table 6.2: Analysis of number of needle passes and number of attempts

Variables	**Group C** **n, mean (sd)**	**Group P – L5-S1** **n, mean (sd)**	**Zero Truncated Negative Binomial Results**		
Number of needle passes until spinal anaesthesia or decision to use alternate method **(min,max)**	n=60 6.13 (8.76) (1, 43)	n=59 6.95 (7.46) (1, 31)	B Exp (B) 0.178 1.195	Confidence Interval Exp (B) 95% C.I.(0.577, 2.477)	p-value 0.63
[#]Number of attempts until spinal anaesthesia or decision to use alternate method **(min,max)**	n=60 2.00 (2.15) (1, 15)	n=59 2.07 (2.06) (1, 11)	0.076 1.079	99% C.I.(0.416, 2.797)	0.84

[#] Number of attempts (secondary outcome variable), the significance was set at p<.01, and 99% Confidence intervals were calculated (CI = confidence interval).

Figure 6.4: Comparison of number of passes between the groups

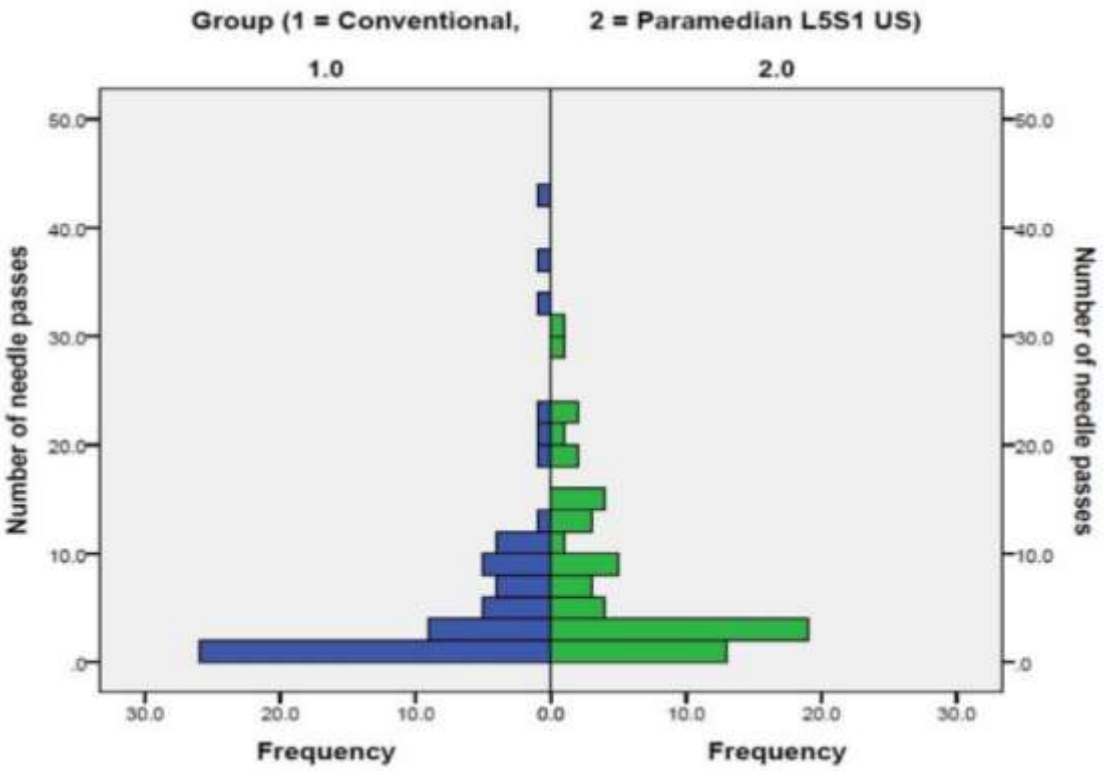


Figure 6.5: Comparison of number of attempts between the groups

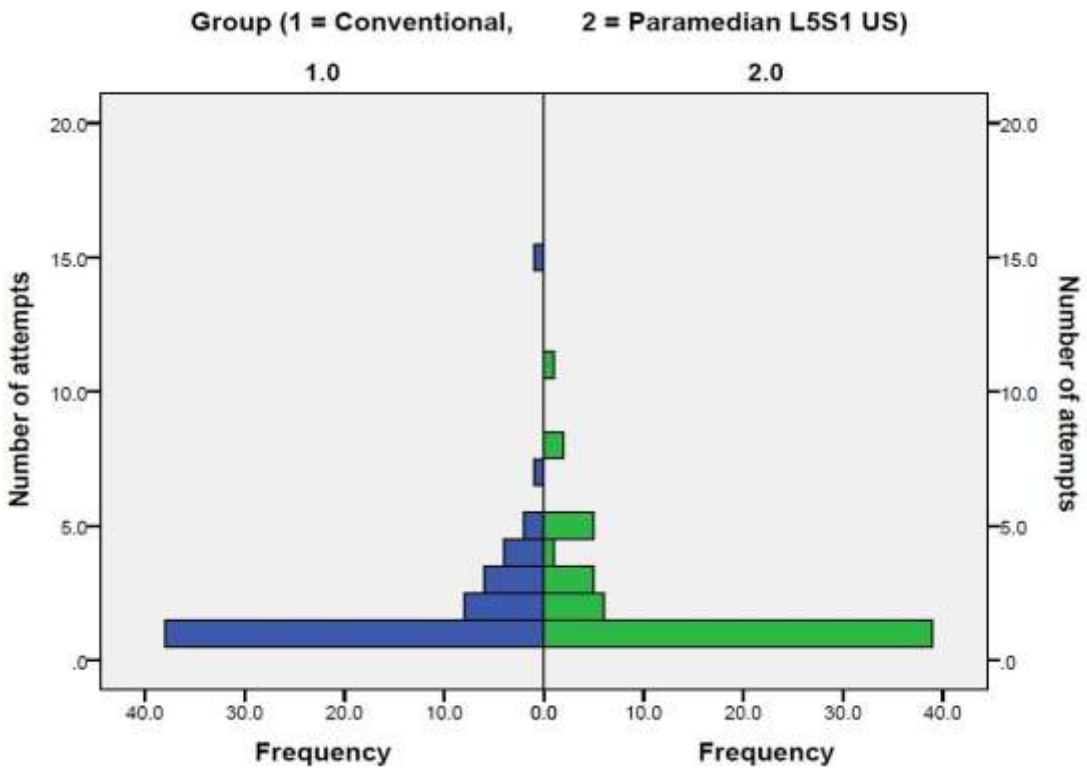


Table 6.3: Successful dural puncture rates

	Group C n (%)	Group P L5-S1 n (%)	Difference C(%) - P(%)	Confidence Interval Lower %, Upper %	p-value
Spinal Anaesthesia on:	n=60	n=59			
First pass	26 (43)	13 (22)	21	95% C.I. (4.9, 37.7)	0.02
Within 2 passes	31 (52)	23 (39)	13	95% C.I. (-5.1, 30.4)	0.16
First attempt	38 (63)	39 (66)	-3	99% C.I. (-25.3, 19.8)	0.75
Within 2 attempt	46 (77)	45 (76)	1	99% C.I. (-19.6, 20.4)	0.96

It took an average of 93 seconds longer (99% CI 79.5, 106.7p <0.0002) for landmarks to be established in group P compared to group C (Table 6.4). Other parameters were comparable between the groups (Table 6.4, 6.5 and 6.6) with the exception of grading palpated landmarks.

Alternative techniques were employed in three patients in group C (technique used - ultrasound guided paramedian spinal) and five patients in group P (technique used - midline approach by conventional palpation). Despite the use of alternative techniques, dural puncture could not be achieved in two patients in group C and one patient in group P. All nine patients in the study who had radicular pain or paraesthesia during needle placement were followed up for 24 hours post-surgery and no patient had persistent symptoms.

Of the two patients in group C who required general anaesthesia (GA), spinal anaesthesia could not be performed in one patients and the second patient did not have any measurable block post administration of spinal anaesthetic. Of the three

patients in group P who needed general anaesthesia, in one patient the spinal could not be performed and in two patients the block level was inadequate. A non-parametric Mann-Whitney U test (U=1890.5, P=0.32) showed that the distributions of sensory block level at 30 minutes were similar (U=1890.5, P=0.32) in Group C and Group P, with a median of T6 (Q1=T5;Q2=T8) in both groups.

A significantly greater number of patients had the spinal needle inserted at or above L2-3 (n=10) in group C versus group P (n=0) with $p < 0.001$ (chi square test). Of note, none of the patients in conventional group had spinal administered at L5-S1 level.

Table 6.4: Spinal anaesthesia variables 1

Variable	**Group C mean (10^{th},90^{th}) N=60**	**Group P LS51 mean (10^{th},90^{th}) N=59**	Bootstrap Independent Samples Test[a]		
			P – C Mean Difference (sec)	**99% Confidence Interval Lower, Upper**	**p-value 2-tailed**
Time taken for identifying landmarks (seconds)	12.3 (8.0, 15.9)	105.1 (67.0, 156.0)	92.7 (5.28)	79.5, 106.7	0.0002
Time taken for spinal injection or decision to use alternate method (seconds)	127.4 (40.0, 229.9)	137.2 (42.0, 296.0)	9.8 (28.98)	-68.9, 86.3	0.73

Table 6.5: Spinal anaesthesia variables 2

Variable	**Group C** **Median (Q1,Q3)**	**Group P** **Median (Q1,Q3)**	**Mann-Whitney U Test** **p-value**
Peri-procedural Vas scores of pain at injection site	2 (1, 3)	2.0 (1, 4)	0.99
Peri-procedural patient discomfort VAS score	9 (8, 10)	9 (8, 10)	0.96

[a]For time variables, 5000 bootstrap samples taken, [b]Sample size is show where there were missing cases for a variable

Table 6.6: Spinal anaesthesia variables 3

Variables		Group C n (%)	Group P n (%)	p value
Grading of palpated landmarks	Easy	34 (57)	32 (54)	0.04[#]
	Moderate	23 (38)	15 (25)	
	Difficult	3 (5)	11 (19)	
	Impossible	0 (0)	1 (2)	
Paresthesia during insertion of spinal needle (n)		3	4	–
Radicular pain during insertion of spinal needle (n)		2	7	–
Blood in spinal needle (n)		2	6	-
Long spinal needle used (n)		5	3	-
Failure to perform spinal anaesthetic (n)		2	1	–
Conversion to GA (n)		2	3	–

[#] Fisher's exact test

Discussion

In patients undergoing elective hip or knee joint replacements, routine use of pre-procedure ultrasound-guided paramedian spinal performed at the L5-S1 level did not reduce the number of passes or attempts required to achieve a successful spinal anaesthetic when compared to a conventional landmark guided midline approach.

Four randomised controlled studies and two cohort studies have been published on pre-procedural ultrasound to facilitate spinal anaesthesia in non-obstetric patients[6,14,16,21-23]. Of these, three studies looked at the routine use of ultrasound[14,16,21] and others were done in patients in whom the procedure was anticipated to be difficult. While the use of ultrasound in patients with difficult anatomy has been largely positive, the data on its routine use is conflicting[14,16,21].

Abdelhamid et al[21] studied 90 patients undergoing spinal anaesthesia by midline approach. The nature of surgery was not mentioned and the study population was relatively young (mean age 34.7 years). Lim et al [16] on the other hand looked at 170 patients undergoing various procedures under spinal anaesthesia (paramedian approach) with an older population (mean age 62.2 years). The former study reported a significantly improved success rate and the latter showed no difference.

The study by Lim et al was different to this study in many ways. First, the population group was different. Second, spinal anaesthesia was attempted by trainee anaesthetist with zero to three years of experience whereas in this study it was done by experienced consultant anaesthetist. Third, the neuraxial scanning was done by a different operator and the results were communicated to the person performing the procedure. In this study it was done by the same person performing spinal anaesthesia. Fourth, both groups received paramedian spinal anaesthesia. In this study it was compared with midline conventional spinal anaesthesia as it is still considered as the default technique. Finally, Lim et al used one of the three interspinous spaces L2-3, L3-4 or L4-5 and did not use L5-S1. We only used L5-S1 in our study for paramedian approach. In spite of the differences, the outcomes were similar as there was no difference in the number of passes between the groups.

Studies using a paramedian approach to spinal anaesthesia utilising ultrasound are a recent development[14-16]. The earlier study using this approach [14] in 100 patients undergoing elective knee and hip replacement (mean age 63.4 years) showed significant reduction in the number of passes and attempts to achieve successful dural tap. Our study attempted to further refine the paramedian approach by using only the L5-S1 interspace. In spite of L5-S1 being the widest interlaminar space that is least affected by flexion or extension in a patient, we still found no difference between the two groups. In addition, the L5-S1 group had lower first pass success rates (one attempt and one pass) compared to the conventional midline group. We can only speculate on possible reasons for this outcome.

1. In spite of being the widest interlaminar space, the L5-S1 interspace has a very high incidence of facet joint osteoarthritis and spondylolisthesis [24-26].
2. Anatomical variations such as sacralisation of lumbar vertebrae and lumbarisation of sacral vertebrae can occur in up to 12% of general population[27].
3. L5/S1 is the most commonly misidentified interspace when using neuraxial ultrasound due to a combination of these factors [28].
4. In our previous study using a paramedian approach, the interspace with best views of anterior and posterior complexes was used [14] whereas in this study L5/S1 was used in all patients irrespective of their visibility.
5. Although the study population was older, it only included elective joint replacements. Positioning them in sitting position was not challenging. On the other hand, the use of L5-S1 inter-spinous space might be more appropriate in elderly patients needing trauma surgery e.g. surgery for hip fracture, where it can be challenging to obtain good positioning for administration of spinal anaesthesia.

This study also showed (a significantly lesser number of spinals) that no spinal was performed at or above L2-3 level (compared to a landmark-guided approach) in the ultrasound group. This is clinically important as a needle inserted at or above L2-3 level has a 4% to 20% possibility of reaching the conus[29].

The negative results of the study further help delineate the role of "routine" pre-procedure neuraxial scanning in patients receiving spinal anaesthetic. Routine pre-procedure scanning guided paramedian spinal, by selecting the interspace with the best ultrasound image of the anterior and posterior complexes, reduces the number of passes and attempts[14]. Limiting the paramedian spinal to L5-S1 interspace does not offer any benefit compared to conventional midline approach. In any case, the use of ultrasound significantly reduced the incidence of needle insertion at or above L2-3 inter-spinous space.

This study has its limitations. Firstly although the patients were unaware of their group allocation it is still possible that by the use of ultrasound before versus after spinal injection might make the blinding less robust. In addition it was difficult to blind the observers due to the use of paramedian approach and skin markings in the ultrasound group. Secondly, the number of attempts and passes prior to the use of an alternate technique was left to the discretion of the anaesthetist. This does reflect day to day practise but introduces the possibility of bias. This might be countered to a certain degree by having three different experienced anaesthetists administer spinal anaesthesia. Thirdly, as discussed earlier, neuraxial ultrasound has its own limitations in correctly identifying the L5-S1 interspinous space. However, all three anaesthetist performing the procedure were experienced in neuraxial ultrasound, having performed more than 100 neuraxial scans in this patient population prior to the study. Finally, this was a study looking at paramedian approach involving only L5-S1 interspinous space. Care should be taken to not extrapolate the results to compare the utility of neuraxial ultrasound against conventional approach for lumbar puncture.

Summary

The routine use of paramedian spinal anaesthesia performed at the L5-S1 level guided by pre-procedure ultrasound does not reduce the number of passes or attempts in achieving successful dural tap.

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Appendix

Data corresponding to Chapter 6 is provided in a excel sheet in the supplementary digital content located in the folder Chapter 6.

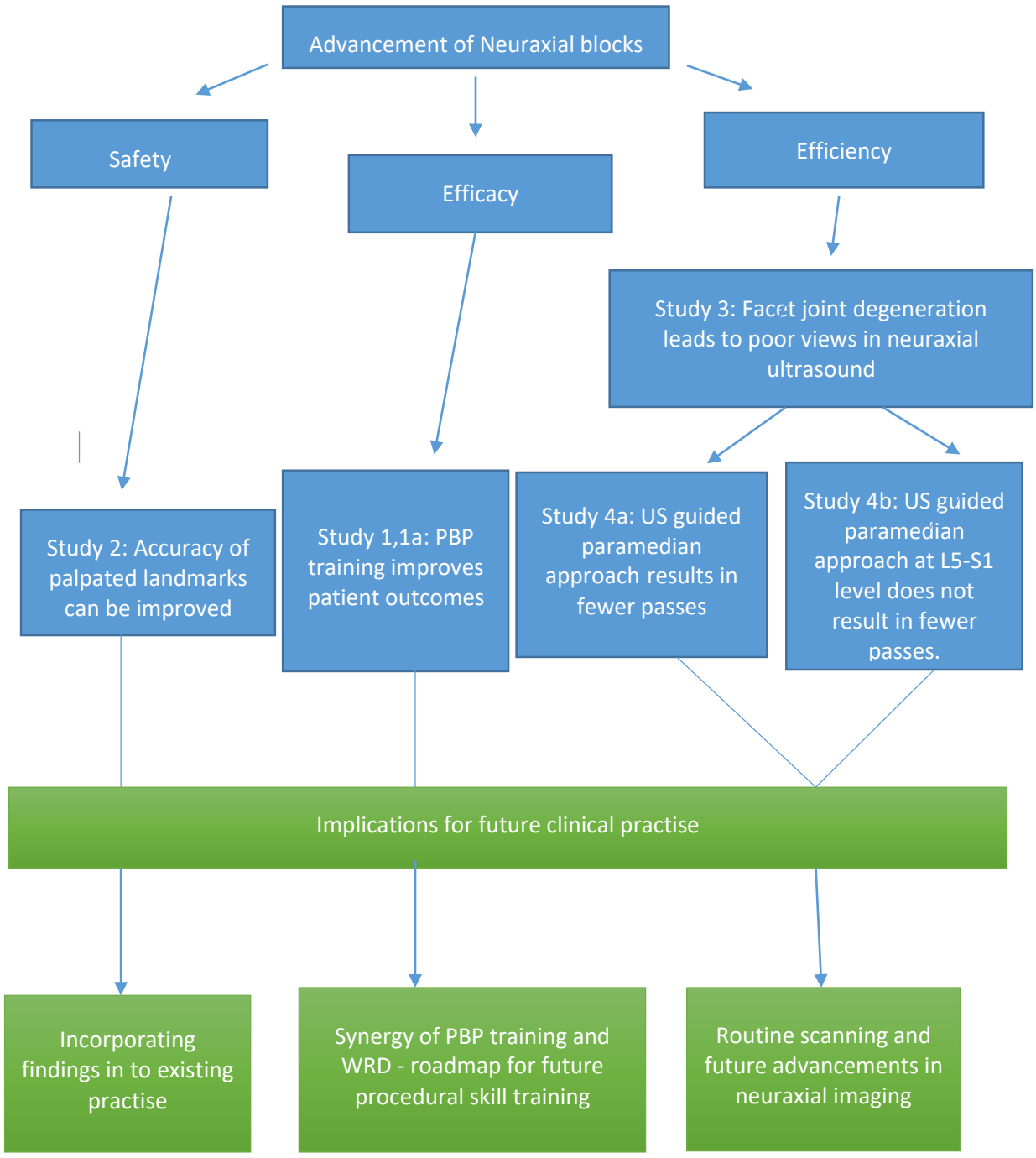
Appendix 6.1.xls – sheet 1 – L5-S1 PM spinal US study

Chapter 7 – Conclusion

Principle Findings

We endeavored to answer three questions. Can we improve safety, efficiency and efficacy of neuraxial blockade through enhanced operator performance? (Figure 7.1).

Figure 7.1: Thesis findings outline



Can we improve the safety of neuraxial blocks by increasing the accuracy of needle insertion?

Study 2, conducted in 112 pregnant patients scheduled for caesarean section, showed that inserting the spinal needle below the intercristal line significantly reduces the incidence of spinal anaesthesia performed at or above L2-3 interspace compared to at or above intercristal line (absolute risk reduction of 38.2%, $p<0.001$), thereby potentially improving the safety of neuraxial block administration by decreasing the risk of direct spinal cord injury.

Does training using proficiency-based progression with specific metrics improve skill acquisition and thus patient outcome?

We developed and validated metrics for use as an objective assessment tool for labour epidural catheter placement. This assessment tool was then used to provide training on labour epidural catheter placement with a proficiency-based progression (PBP) method using a simulator. This form of training was then compared to a simulation-only training method in 17 novice anaesthetic trainees. Epidural analgesia failure rates in 140 patients receiving epidural analgesia subsequently administered by these trainees was then compared. PBP reduced the incidence of epidural failure by 46.3% compared to simulation only group (epidural failure in simulation only group = 28.7%, epidural failure in PBP group = 13.3%, $p=0.04$). This study, conducted between September 2013 and September 2016, is the first “end to end” study of its kind to show benefit in terms of patient outcome.

Can we improve the efficacy of neuraxial block using ultrasound?

To improve the efficacy of neuraxial block we conducted three research projects. In study 3 we sought to better understand neuraxial ultrasound imaging, by comparing lumbar MRI imaging and neuraxial ultrasound in 21 patients, a total of 79 interspinous levels. It was observed that facet joint degeneration correlated significantly with poor neuraxial ultrasound views. The odds of obtaining a poor view in neuraxial ultrasound was seven times higher in the presence of facet joint degeneration (95% CI 1.7-28.9, $p=0.007$).

In study 4a, we endeavored to improve the efficacy of spinal anaesthesia administration by comparing a pre-procedure ultrasound-guided paramedian approach with a conventional midline approach in 100 patients scheduled to undergo lower limb joint arthroplasties. It was observed that the number of passes to achieve successful dural tap was significantly lower in the ultrasound group (mean 4, SD 4) compared to the conventional group (mean 8.2, SD 12.3). The number of passes and attempts in ultrasound group was 0.34 (p= 0.01) and 0.25 (p=0.002) times respectively compared to the conventional group.

We attempted to further refine the pre-procedure ultrasound-guided paramedian technique for spinal anaesthesia. In study 4b, in 120 patients, we compared a conventional landmark-guided midline technique with a pre-procedure ultrasound-guided paramedian technique at the L5-S1 interspace. We found no difference between groups in the number of passes or attempts to achieve successful dural puncture.

Thesis implications

The aim of the thesis was not to comprehensively address all aspects of neuraxial blocks but to focus on three clinical areas where neuraxial blocks are a preferred anaesthetic modality: Caesarean section, labour epidural analgesia and lower limb joint arthroplasty. We demonstrated significant potential improvements in all three aspects of neuraxial blocks – safety, efficiency and efficacy.

Incorporating findings in clinical practise – towards safer spinal anaesthetic for caesarean sections

Caesarean section constitutes 18.6% of the deliveries conducted worldwide [1] and 80% of Caesarean sections are performed under neuraxial anaesthesia[2-5]. In the editorial accompanying our study [6] the importance of avoiding L2-L3 interspinous space in administering spinal anaesthesia for caesarean section was stressed and based on our study findings[7], the editorial suggested “In the meantime, or until something better comes along, the best chance of avoiding L2–L3 with surface

anatomy palpation might be to follow the maxim: ‘‘Feel a space, down one place: bone pokes through, go down two’’.

The ideal solution is to perform neuraxial ultrasound in every patient receiving spinal anaesthesia for caesarean section. But ultrasound is not yet in routine clinical practice for performing neuraxial blocks.[8] In low income countries, where neuraxial blocks are increasingly utilized for caesarean sections[9], the opportunities to perform pre-procedure neuraxial ultrasound scanning are very limited, at least at present. As our study suggests, a simple modification of the surface landmark palpation technique significantly improves the safety of spinal anaesthesia, without the routine use of neuraxial ultrasound. Widespread implementation of this study has the potential to improve safety of a commonly performed anaesthetic technique worldwide.

Synergy of PBP and WRD – a roadmap for future procedural skill training

The successful outcome of the “end to end “ study on PBP training methodology is a demonstration of proof of concept for this approach to procedural skill training in the medical profession. This could potentially form the blueprint for future procedural skill training and assessment, not only in the field of anaesthesia but in medicine as a whole. One of the other important components of our study design was the exclusive use of wearable recording devices (WRD) for video recording.

We believe these two independent advances, one technical (WRD) and the other methodological (PBP)[10] may act synergistically to enable consistently effective training in procedural skills in future.

Video recording has traditionally been linked to the training of procedural skills largely in the form of instructional “how to” segments. Recognition of the value of video recording in the detailed, “analytical” assessment of such skills is relatively recent.[11] Advancements in digital technology, and in particular, wearable recording devices have made feasible the integration of such technology into routine or standardized training of medical procedural skills. In recent years, head-mounted, high resolution audio-visual recording devices (such as Google glass and GoPro) have been studied in the setting of medical training.[12-16] These WRD’s offer some

additional benefits over traditional teaching methods and video recordings in the acquisition and maintenance of technical skills. First, with improvements in wearable technology – in particular the decreasing footprint of such devices – WRDs have become truly non-distracting to the operator and as a result they may influence operator performance to a lesser degree. Importantly this distinguishing feature of WRDs has the potential to decrease the Hawthorne effect and observer bias that may be associated with more traditional methods of direct assessment.[17] Second, WRD's facilitate true deliberate practice by allowing operators to repeatedly and objectively self-assess against both procedure-specific validated metrics and their individual performances, removing some of the limitations of perceived self-efficacy to estimate competency or expertise. The wearable recording device alone will not be sufficient (as it simply enables acquisition of more data) but these devices can be central to acquiring digital recordings without consuming the learner's attention.

The success of PBP is dependent on the definition and recognition of specific observable behaviors. In addition to defining procedure-specific metrics and errors, PBP requires the establishment of performance benchmarks based on a mean of expert performance. Trainees are instructed specifically and practise *to achieve those benchmarks*, at first in a simulated setting. Having achieved proficiency in a simulated setting, we propose that each trainee uses i) the characterised reference procedure (in the form of a set of metrics/errors) and ii) a WRD and mobile device for download and review, in the clinical setting. These tools together enable the trainee to recurrently review and update versions of their own performance of particular procedural skills. They are thus enabled to continue deliberate practice and self-assessment on a daily basis whilst the degree of "real time" clinical supervision is unchanged.

Our proposed approach is that each procedure the trainee subsequently performs in the clinical setting is recorded using a WRD; and that they perform a formal self-assessment of each procedure. The trainee is generally motivated to self-improvement and so performs self-assessment diligently; he or she should also bring a detailed and developing knowledge of their own performance to each successive

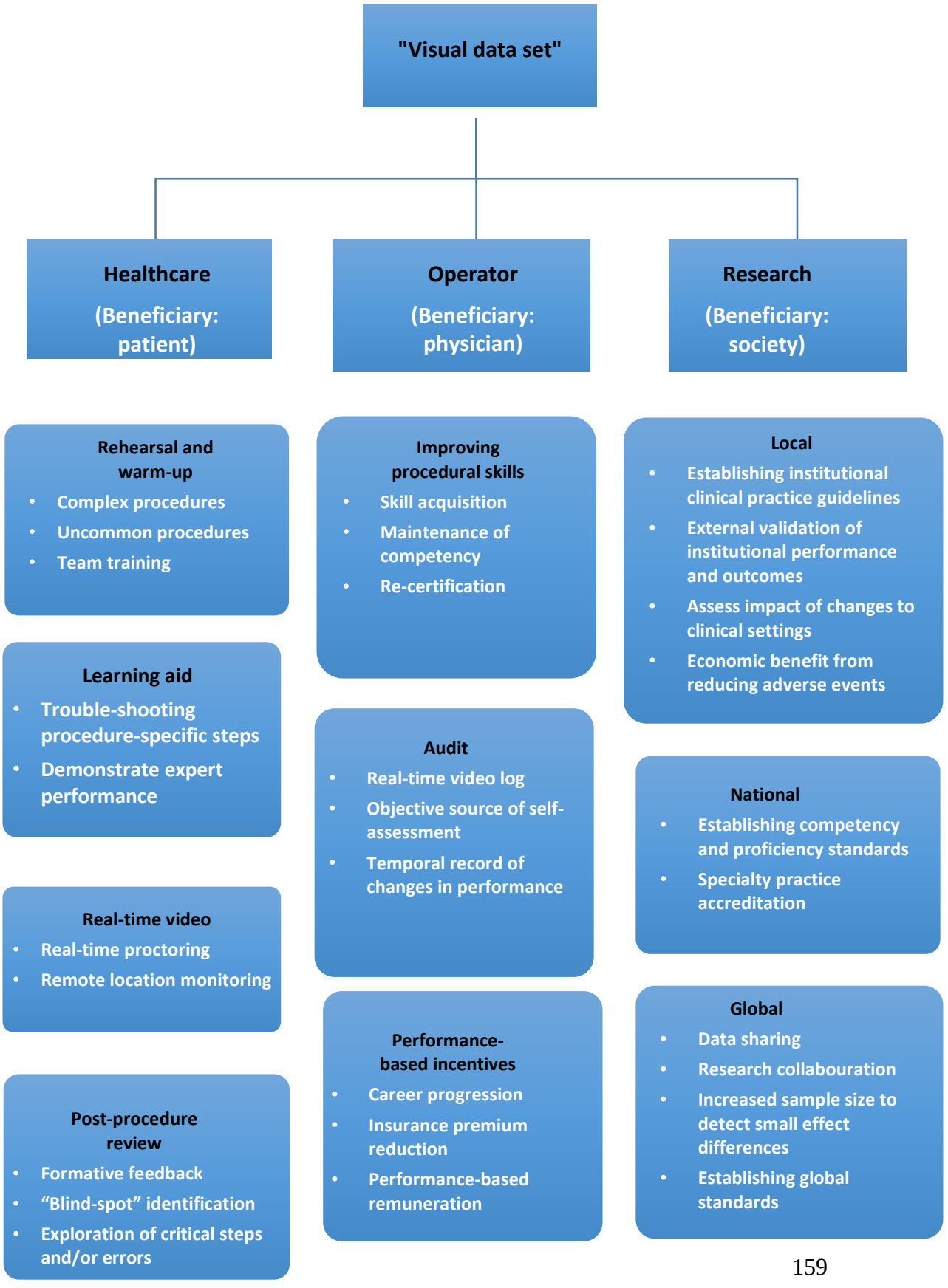
review. The clinical supervisor will review a sample of video recordings of performance and score them against the benchmarks, independently of the trainee. This review will supplement the supervisor's memory of live observation in determining feedback and allow "sign off" for a particular skill. The selection of performances for review as well as the timing of the review(s) may be dictated by trainee or trainer or by the duration of a training module. The paradigm shift in procedural skill training which we describe here may address the deep misgivings that many trainers and trainees have regarding current practices for supervision and especially "sign off". However, this process is completely new to procedural skill training and we do not underestimate the cultural shift required to successfully integrate this suggested approach into "real world" training.

In the longer term, this synergy also offers an ideal opportunity to evaluate the association between physician performance and clinical outcomes. To achieve this, a useful adjunct is the current emphasis in clinical outcomes research on the creation of digital repositories and patient registries to standardize data collection and promote collaboration among researchers. This development will promote the effective use of digital data derived from WRDs and will ensure high-quality large databases are used to inform decision-making. If we label the data acquired by WRD from a procedure as a "visual dataset", the potential applications, beneficiaries, and implications of using WRDs in conjunction with objective procedure characterization in healthcare are summarized in the Figure 7.2.

Routine scanning and future advancements in neuraxial imaging

Routine pre-procedure neuraxial scanning has not been shown to improve the number of passes or attempts needed to achieve successful dural puncture in previous studies.[18,19] In our study (4 and 4a) we were able to show that routine pre-procedure scanning is beneficial and feasible in a routine clinical setting provided equipment and expertise are available. We discussed the limitations of routine use of neuraxial ultrasound earlier in this thesis. We believe however, it will become

Figure 7.2: Potential applications and beneficiaries of data obtained from WRD in conjunction with objective procedure characterization



the standard of care in future. While study 1 attempts to improve safety of neuraxial block even without the routine use of ultrasound (reflecting current practice), study 4a and 4b focuses on the best possible use of neuraxial ultrasound when expertise and equipment are available (future scope of practice).

The future of neuraxial imaging is constantly evolving. Emerging technologies such as GPS guidance[20], real time ultrasound guided techniques[21], 3D and 4D ultrasound [22] are being actively explored to facilitate performance of neuraxial blocks.

Currently rapid integration of technology into clinical practice is happening across various domains. We demonstrated that enhanced operator performance using technological advancements resulted in improved safety, efficacy and efficiency of neuraxial blocks. As clinicians and researchers, it is our responsibility to facilitate this integration in a scientific manner with advancement in patient safety and quality of care as the guiding principles.

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Publications Arising

Spinal Anaesthesia for Caesarean section: an ultrasound comparison of two different landmark techniques

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ORIGINAL ARTICLE

Spinal anaesthesia for caesarean section: an ultrasound comparison of two different landmark techniques

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ABSTRACT

Background: Spinal anaesthesia performed at levels higher than the L3–4 intervertebral space may result in spinal cord injury. Our aim was to establish a protocol to reduce the chance of spinal anaesthesia performed at or above L2–3.

Methods: One hundred and ten consenting patients at 32 weeks of gestation or greater scheduled for non-emergency caesarean section under spinal anaesthesia were randomly allocated to have needle insertion performed at an intervertebral space determined by one of two landmark techniques. In Group A, if the intercristal line intersected an intervertebral space, this space was selected or if the intercristal line intersected a spinous process the space immediately above was selected. In Group B, if the intercristal line intersected an intervertebral space or a spinous process, the intervertebral space immediately below was chosen. The actual intervertebral space chosen was identified using ultrasound by a blinded investigator.

Results: In Group A, an intervertebral space at or above L2–3 was marked in 25 (45.5%) patients compared with 4 (7.3%) in Group B ($P < 0.001$). In 5/55 (9.1%) patients in Group A, the intervertebral space initially chosen was L1–2 whereas this occurred in no patient in Group B. There was no difference between groups in number of needle passes or attempts, onset of block at 5, 10 and 15 min or need for rescue analgesia.

Conclusion: Our data suggest that when performing spinal anaesthesia in pregnant patients, if the intercristal line intersects an intervertebral space then the space below should be chosen and if the intercristal line intersects a spinous process then the interspace below should be chosen. This will reduce the incidence of spinal anaesthesia performed at or above L2–3.

Keywords: Spinal anaesthesia; Intercristal line; Ultrasound

Introduction

Spinal anaesthesia is the commonest mode of anaesthesia for caesarean section.[1,2] Permanent neurological complications following spinal anaesthesia, although rare, can have devastating consequences.[3–8] Selecting an appropriate intervertebral space is important to avoid spinal cord damage during needle insertion.

The intercristal line is conventionally used to identify the vertebral interspace used for spinal anaesthesia. This may intersect the midline anywhere from L1–2 to L4–5.[9–15] There is considerable variation within anatomy and anaesthesia textbooks regarding the level at which the intercristal line crosses the midline.[16–20] Currently, there is no consensus for selecting an intervertebral space based on the intercristal line; selection of an interspace at, above or below the intercristal line is largely based on individual discretion. It has been shown previously that experienced anaesthetists were able to correctly identify the lumbar intervertebral space in only 29% of patients.[9] In the obstetric population, 32–48.5% of neuraxial blocks are performed at a more cephalad level (as high as L1–2) than originally intended.[21,22] The importance of avoiding spinal anaesthesia at or above L2–3 cannot be overstated as, based on previous studies on the level of termination of spinal cord and considering the angle of insertion of the needle, it is possible that a needle inserted at L2–3 might reach the conus medullaris in 4–20% of occasions.[7]

Our aim was to develop an objective guide for selecting the appropriate intervertebral space based on the palpated intercristal line. The hypothesis was that by selecting an intervertebral space below the intercristal line, the incidence of spinal anaesthesia performed at or above L2–3 would be decreased without increasing the number of attempts, number of passes or the failure rate.

Methods

Following approval by the Ethical Committee of National Maternity Hospital, Dublin, Ireland, 110 pregnant patients with gestational age of 32 weeks or greater

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undergoing non-emergency caesarean section under spinal anaesthesia who consented for the study were included. Patients with previous spinal surgery, known spinal deformity or in whom the anaesthetist could not palpate spinous processes or intervertebral spaces were excluded.

This was a prospective, randomized, double-blind study with patients randomised using computer-generated random numbers to one of two groups. Group codes were enclosed in sealed envelopes and were seen only by the anaesthetist performing the block. The patient and the anaesthetist performing ultrasound were blinded to the study group. The anaesthetist who was normally assigned to the theatre performed the spinal anaesthetic. The experience of the staff varied from trainee anaesthetists with >1 year of experience to consultant anaesthetists.

In Group A, if the intercristal line intersected an intervertebral space, this space was selected or if the intercristal line intersected a spinous process the space immediately above was selected. In Group B, if the intercristal line intersected an intervertebral space or a spinous process, the intervertebral space immediately below was chosen.

In the operating room, all patients were positioned sitting for spinal anaesthesia after applying routine monitors and securing intravenous access. Patients were seated on the edge of a level operating table with their feet supported by a footrest. They were requested to hug a pillow and flex their neck, back and hips. An assistant supported the patient during performance of the block. The anaesthetist marked the level on the back as per the study group. To identify the intercristal line, a standard protocol using both hands simultaneously to palpate the iliac crests and using the thumb to identify the midline at the same level was employed. Anaesthetists were instructed to open the sealed envelope and mark only the selected intervertebral space on the back with a skin marker before scrubbing. No other mark was allowed to ensure blinding of the investigator performing ultrasound.

One of the four authors, each of whom had prior experience with neuraxial ultrasound (>75 neuraxial ultrasound examinations before the study) and were blinded to the study group, performed ultrasound evaluation of the marked intervertebral space. Portable ultrasound equipment with a curved 2–5 MHz probe was used (Venue 40, 4C-SC curvilinear probe, GE Healthcare, Wauwatosa, WI, USA). Initially, a paramedian sagittal oblique view was used and the sacrum identified after which the interlaminar space between L5 and S1 was noted. Subsequent intervertebral spaces were identified by counting the interlaminar spaces up from L5–S1. At each interspace the interlaminar space was centred on the ultrasound screen and the corresponding point on the skin at the middle of the long axis of the probe was noted. The interspace corresponding to the skin marking was thus identified and documented. If on scanning the interspace was found to be L1–2 or higher, the anaesthetist performing the block was advised to perform needle insertion two interspaces lower; these patients' data were included for analysis of the primary outcome. The intervertebral level identified by the ultrasound was not conveyed to the anaesthetist performing the block.

Full aseptic precautions were used for performing the spinal anaesthesia (anaesthetist scrubbed with cap, mask, sterile gown and gloves). Lidocaine was used for skin infiltration. A 25-gauge Whitacre spinal needle was used with an introducer. Hyperbaric bupivacaine 10–12 mg with or without fentanyl 15 μg and morphine 100 μg was used for all patients. If more than one attempt was needed for performing spinal anaesthesia, the anaesthetist could choose the same interspace or a different interspace for subsequent attempts which was left to their discretion. Attempts at or above L1–2 were not allowed at any stage. In addition to the initial level marked, the final level at which the spinal anaesthesia was performed was noted.

The primary endpoint was the difference between groups in the proportion of interspaces marked at or above L2–3. In addition, demographic variables, gestational age, the experience of the anaesthetist, the number of needle passes (number of times the spinal needle was withdrawn and redirected in the same interspace without exiting the skin) and the number of attempts (number of times the spinal needle was withdrawn from the skin) were noted. Additionally, the presence or absence of paraesthesia or radicular pain during needle placement and injection, dose of bupivacaine and opioid, level of block (loss-of-cold sensation) at 5, 10 and 15 min and need for rescue analgesia and conversion to general anaesthesia were noted. All patients who had paraesthesia or radicular pain were followed up between 12 to 24 h post-procedure. In cases of persistent radicular symptoms, the patients were further evaluated and followed-up as per department guidelines.

Statistical analysis

Based on a previous study by Locks et al.[15] we estimated that if spinal anaesthesia were performed at or above the level of the palpated intercristal line, the incidence of needle insertion at or above L2–3 would be approximately 44%. We hypothesized that, by consistently selecting an interspace below the palpated intercristal line, we could decrease the incidence to <10%. A study with 55 patients in each arm would have at least 80% power to detect a difference between these proportions with a level of significance of 0.05.

Continuous variables were inspected for approximate normal distribution by visualising histograms. The primary analysis set consisted of the intention-to-treat (ITT) population. Age and gestational age were

normally distributed and were compared with a two-independent samples t test. The distributions for weight, body mass index and anaesthetist's experience showed positive skew and were compared using the Mann-Whitney U test. Categorical variables were compared with the Pearson chi-square test. In cases where cell counts were low, *P* values were checked using Monte Carlo permutation. Analyses were performed using IBM SPSS Statistics version 20 (IBM SPSS Inc., Chicago, IL, USA).

Results

A total of 128 patients were approached for the study. Ten patients refused consent and six did not meet the inclusion criteria before randomization (1 <32 weeks of gestation, 2 previous spinal surgery, 3 landmarks not palpable). The remaining 112 patients were randomized to the two study groups. Two patients were excluded from Group A following randomization (1 spinous processes not palpable after positioning, 1 marked interspace could not be utilized as the patient had a tattoo at that level). The remaining 110 patients received the allocated intervention, were followed-up and had results included for analysis (Fig. 1).

Patient characteristics, parity, gestational age and anaesthetist experience were similar between the two groups (Table 1). The proportion of patients in whom the intervertebral space was marked at or above L2-3, was significantly different between groups: 25/55 (45.5%, 95% CI 32.3 to 58.7%) in Group A versus 4/55 (7.3%, 95% CI 0.4 to 14.2%) in Group B (*P* <0.001). In Group A, 5/55 (9.1%) patients had the L1-2 vertebral interspace marked versus no patient in Group B (Table 2).

There was no difference between groups in the number of needle passes, number of attempts, incidence of paraesthesia or radicular pain, onset of block at 5, 10 and 15 min, dose of intrathecal opioid or need for rescue analgesia (Table 3). The number of cases where the anaesthetist was not able to perform spinal anaesthesia at the marked intervertebral space and had to select a different space was similar between the two groups. One patient in Group A was converted to general anaesthesia because of intraoperative bleeding (Table 3). The structure palpated at the level of the intercristal line was similar between the two groups (Table 4).

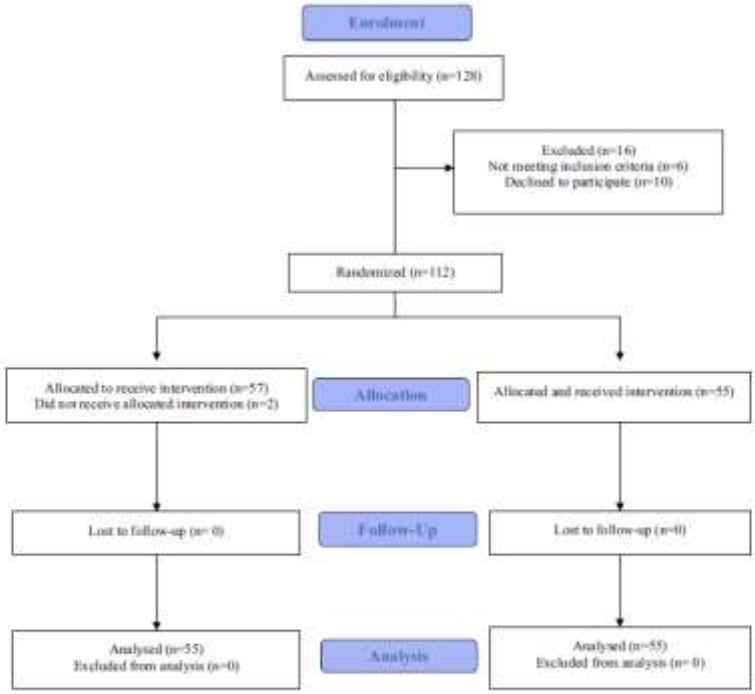

Fig. 1 Consort flow diagram

Table 1 Patient characteristics and experience of the anaesthetist

	Group A ($n = 55$)	Group B ($n = 55$)
Age (years)	34.0 ± 5.0	33.8 ± 4.4
Gestational age (weeks)	38.6 ± 1.5	38.8 ± 1.3
Height (cm)	164.3 ± 6.3	163.9 ± 7.3
Weight (kg)	81.8 ± 15.6	83.3 ± 15.5
Body mass index (kg/m^2)	30.4 ± 5.7	31.1 ± 5.7
Parity		
0	9 (16.4%)	7 (12.7%)
1	31 (56.4%)	27 (49.1%)
2	9 (16.4%)	16 (29.1%)
3	5 (9.1%)	4 (7.3%)
4	1 (1.8%)	1 (1.8%)
Experience of anaesthetist (years)	6.8 ± 5.4	5.5 ± 5.2

Data are mean ± SD or number (%). No significant differences between groups.

Table 2 Intervertebral space marked

	Group A ($n = 55$)	Group B ($n = 55$)	P value
L1–2	5 (9.1%)	0 (0%)	<0.001
L2–3	20 (36.4%)	4 (7.3%)	<0.001
L3–4	27 (49.1%)	31 (56.4%)	<0.001
L4–5	3 (5.5%)	14 (25.5%)	<0.001
L5–S1	0 (0%)	6 (10.9%)	<0.001

Data are number (%).

According to the study protocol, nine patients (16.4%) in Group A and seven (12.7%) in Group B had spinal anaesthesia performed at an intervertebral space that was different (above or below at the anaesthetist's discretion) to that initially marked because of difficulty in performing the block at the marked interspace. When this subgroup of patients was compared with the rest of the study population, no difference was noted in patient demographics or the experience of anaesthetist (Table 5).

Table 4 Structure palpated at the intercristal line

	Group A ($n = 55$)	Group B ($n = 55$)
L1 spinous process	0	0
L1–2 intervertebral space	2	0
L2 spinous process	4	4
L2–3 intervertebral space	14	14
L3 spinous process	5	17
L3–4 intervertebral space	17	11
L4 spinous process	10	3
L4–5 intervertebral space	3	4
L5 spinous process	0	2
L5–S1 intervertebral space	0	0

Data are number.

As the anaesthetist could choose a different intervertebral space if they were unsuccessful in their initial attempt, there were differences in the marked intervertebral space and the intervertebral space at which spinal anaesthesia was actually performed (Table 6). On analysing these data, significantly more patients in Group A ($n = 22$, 40%, 95% CI 27.1 to 52.9%) compared with Group B ($n = 8$, 14.5%, 95% CI 5.2 to 23.8%) had their spinal anaesthesia performed at L2–3 ($P = 0.003$) indicating that the intervention also reduced the proportion of blocks performed at or above the L2–3 level.

Discussion

Our study showed that in pregnant patients, selecting an intervertebral space below the palpated intercristal line significantly decreases the chances of spinal anaesthesia

Table 3 Details of subarachnoid block

	Group A ($n = 55$)	Group B ($n = 55$)
Spinous process at intercristal line	36 (65.5%)	29 (52.7%)
Intervertebral space at intercristal line	19 (34.5%)	26 (47.3%)
Number of needle passes	2.02 (1.38)	2.13 (1.76)
Number of attempts	1.4 ± 0.7	1.4 ± 0.7
Block performed at different level	4 (7.2%)	7 (12.7%)
Paraesthesia	6 (10.9%)	4 (7.3%)
Radicular pain	1 (1.8%)	0 (0%)
Volume of 0.5% hyperbaric bupivacaine (mL)	2.1 ± 0.1	2.1 ± 0.1
Patients receiving intrathecal fentanyl	43 (78%)	45(81%)
Patients receiving intrathecal morphine	49 (89%)	49 (89%)
Block level above T5 at 5 min	47 (85%)	48 (87%)
Block level above T5 at 10 and 15 min	55 (100%)	55 (100%)
Rescue analgesia required	3 (5.4%)	3 (5.4%)
Conversion to general anaesthesia	1 (1.8%)	0

Data are mean ± SD or number (%). No significant differences between groups.

Table 5 Comparison of patient subgroup with spinal performed at the selected level versus patients with spinal performed at a different level

	Spinal performed at different level	Spinal performed at selected level
Group A	9 (16.4%)	46 (83.6%)
Group B	7 (12.7%)	48 (87.3%)
All patients		
Age (years)	34.5 ± 5.6	33.8 ± 4.5
Height (cm)	163.2 ± 6.9	164.2 ± 6.8
Weight (kg)	83.7 ± 12.0	82.4 ± 16.0
Body mass index (kg/m^2)	31.6 ± 5.1	30.6 ± 5.8
Experience of anaesthetist (years)	3.8 [1.5–9.0]	4.0 [1.5–10.0]

Data are number (%), mean ± SD or median [interquartile range].

Table 6 Level at which spinal anaesthesia was performed

	Group A ($n = 55$)	Group B ($n = 55$)
L2–3	22 (40.0%)	8 (14.5%)
L3–4	30 (54.5%)	27 (49.1%)
L4–5	3 (5.5%)	15 (27.3%)
L5–S1	0 (0%)	5 (9.1%)

Data are number (%).

being performed at or above L2–3 and possibly eliminates the risk of it being performed at L1–2 or above. To our knowledge, this is the first study comparing two different landmark techniques for performing spinal anaesthesia in pregnant patients.

Spinal anaesthesia is preferably performed at or below L3–4 to avoid the potential risk of spinal cord injury as the conus medullaris reaches the upper part of the body of L2 in 48% of women.[23] In all seven cases of permanent cord injury (6 obstetric and 1 surgical) reported by Reynolds,[7] spinal (or combined spinal-epidural) anaesthesia was performed at or above the L2–3 intervertebral space.

The palpated intercristal line and the radiological intercristal line (Tuffier's line) are distinct entities. The former is the most important landmark used during performance of spinal anaesthesia. There is poor correlation between the intervertebral levels at which the palpated and radiological intercristal lines cross the midline. In non-pregnant patients, Chakraverty et al.[24] compared the level of agreement between palpated and imaged intercristal lines. They found that in 88% of cases, the palpated intercristal line was one or more intervertebral spaces higher than the radiological intercristal line. In pregnant patients, the presence of hyperlordosis, exaggerated pelvic rotation, weight gain and decreased ability to flex the spine, makes the clinical estimate of the intervertebral space even higher. So although Tuffier's line most commonly intersects the L4 spinous process or the L4–5 interspace,[25] the palpated intercristal line is likely to identify a higher intervertebral space in pregnant patients.

Only three studies have been performed to identify the position of palpated intercristal line in pregnant patients.[13–15] It corresponded to L2–3 and above in 33–51% of patients.[14,15] The results from our study are similar, with the palpated intercristal line corresponding to L2–3 and above in 45.5% of patients in Group A. In Group B, only 7.3% had levels marked at L2–3. Our landmark technique is simple and reproducible with the additional strength that it is based on palpation of the iliac crests without using ultrasound which makes it easily applicable in daily practice.

Ultrasound is not yet routinely used in clinical practice for performing neuraxial blocks in all units.[26] The expertise needed for neuraxial ultrasound, the additional time required for scanning, cost, the need for equipment at the bedside, and urgency to perform spinal anaesthesia in some patients mean that clinically palpated landmarks are still used in the majority of cases. Hence, it is imperative to try to improve the accuracy of palpated landmarks. It is also important to note that no patient in Group B in our study had the L1–2 vertebral interspace marked versus four patients in Group A. In previous studies, performing spinal anaesthesia at lower intervertebral spaces has been associated with delay in onset of block height.[27,28] Similar studies in pregnant patients have not been conducted. In our study no difference was noted between the two groups in terms of the time of onset, level of block or quality of analgesia. The need for supplemental analgesia was similar between the two groups. It is often perceived that spinal anaesthesia might be difficult to perform at lower lumbar interverebral spaces. In our study, no difference between groups was noted in the number of attempts or the number of passes required, although we did not record the time required to perform spinal anaesthesia.

We could not find any direct studies comparing the position of the intercristal line in the sitting versus the lateral position. In a radiological study, Kim et al. noted that with full flexion of the lumbar spine, the position of the intercristal line in relation to the spinous process slightly moved caudally from L4 to L4–5, but it remained at the same level in 58% of patients.[29] Thus,

we suggest that the position of intercristal line may not differ significantly between the sitting and lateral positions. Also the ability of term pregnant patients to achieve adequate flexion at the hips even in the lateral position can be limited. Hence, we believe that it is reasonable to extrapolate the results of our study to the lateral position.

Our study has limitations. Firstly, although the landmark technique used in Group B reduced the incidence of marking an intervertebral space at or above L2–3 compared with the technique in Group A, it may not totally eliminate the risk of needle insertion at L2–3. Future studies with further refinement in the landmark technique could possibly eliminate the risk of spinal anaesthesia performed at L2–3 without the use of ultrasound. Secondly, ultrasound accurately identifies a spinous process or interspace in only 68–76% of cases.[30–32] Accuracy of 90% or higher is possible with training.[30] In our study, all four anaesthetists had previous experience with neuraxial ultrasound. Of note, lumbarisation of sacral vertebrae and sacralisation of lumbar vertebrae are likely to be missed by ultrasound as they can be reliably identified only by X-ray.[14,33] Thirdly, the experience of the anaesthetist performing spinal anaesthesia varied from 1 year to >10 years in our study. Because of the nature of our staffing, it was difficult to restrict spinal anaesthesia to more experienced anaesthetists. However, as there was no significant difference between the two groups in terms of experience of anaesthetist, our study should reflect a real-life situation. Finally, there is likely to be inter-individual variability in identifying the level where the intercristal line crosses the midline. As it does not always cross exactly at a spinous process or intervertebral space a certain degree of clinical judgment is needed.[14]

Close inspection of our results offers options for future studies to further decrease the risk of needle insertion at L2–3. In the four patients in Group B in whom the level marked was L2–3, the anaesthetist palpated a spinous process and marked the intervertebral space below it. So potentially, if one selects two intervertebral spaces below a palpated spinous process at the intercristal line or selects one intervertebral space below if an intervertebral space is palpated, the risk of needle insertion at L2–3 or above could be further decreased. If this technique were used, the lowest possible space that one might encounter would be L5–S1: in all patients who had L5–S1 marked, the anaesthetist palpated an intervertebral space and marked one space below it. Also, previous studies have shown that the palpated intercristal line was never lower than L4-5 in pregnant patients[14,15] which suggests that in addition to a decreased incidence of needle insertion at L2–3, with the revised technique there is a theoretical possibility of not increasing the failure rate. Future studies with suggested new landmark techniques could confirm our findings. Future studies could also focus on other patient groups in whom spinal anaesthesia is commonly used.

In summary in pregnant patients, if one palpates the intervertebral space at the intercristal line a space below should be chosen for needle insertion. When a spinous process is palpated, the space below should be chosen.

Disclosure

This study was supported by departmental funds only and the authors have no conflicts of interest to declare.

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Conventional landmark-guided midline versus pre-procedure ultrasound guided paramedian techniques in spinal anaesthesia

Regional Anesthesia

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Conventional Landmark-Guided Midline Versus Preprocedure Ultrasound-Guided Paramedian Techniques in Spinal Anesthesia

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BACKGROUND: Multiple passes and attempts while administering spinal anesthesia are associated with a greater incidence of postdural puncture headache, paraesthesia, and spinal hematoma. We hypothesized that the routine use of a preprocedural ultrasound-guided paramedian technique for spinal anesthesia would reduce the number of passes required to achieve entry into the subarachnoid space when compared with the conventional landmark-guided midline approach.

METHODS: One hundred consenting patients scheduled for elective total joint replacements (hip and knee) were randomized into group C (conventional) and group P (preprocedural ultrasound-guided paramedian technique) with 50 in each group. The patients were blinded to the study group. All spinal anesthetics were administered by a consultant anesthesiologist. In group C, spinal anesthetic was done via the midline approach using clinically palpated landmarks. In group P, a preprocedural ultrasound scan was used to mark the paramedian insertion site, and spinal anesthetic was performed via the paramedian approach.

RESULTS: The average number of passes (defined as the number of forward advancements of the spinal needle in a given interspinous space, i.e., withdrawal and redirection of spinal needle without exiting the skin) in group P was approximately 0.34 times that in group C, a difference that was statistically significant ($P = 0.01$). Similarly, the average number of attempts (defined as the number of times the spinal needle was withdrawn from the skin and reinserted) in group P was approximately 0.25 times that of group C ($P = 0.0021$). In group P, on an average, it took 81.5 (99% confidence interval, 68.4–97 seconds) seconds longer to identify the landmarks than in group C ($P = 0.0002$). All other parameters, including grading of palpated landmarks, time taken for spinal anesthetic injection, periprocedural pain scores, periprocedural patient discomfort visual analog scale score, conversion to general anesthetic, paresthesia, and radicular pain during needle insertion, were similar between the 2 groups.

CONCLUSIONS: Routine use of paramedian spinal anesthesia in the orthopedic patient population undergoing joint replacement surgery, guided by preprocedure ultrasound examination, significantly decreases the number of passes and attempts needed to enter the subarachnoid space. (Anesth Analg 2015;121:1089–96)

Spinal anesthesia is widely performed using a surface landmark-based "blind" technique. Multiple passes and attempts while administering spinal anesthesia are associated with a greater incidence of postdural puncture headache, paraesthesia, and spinal hematoma.[1–3]

Real-time and preprocedural neuraxial ultrasound techniques have been used to improve the success rate of spinal anesthesia. Information on the use of real-time ultrasound-guided spinal anesthesia has, to date, been limited to case series and case reports.[4–8] Its use may be limited by the requirement for wide-bore needles and the technical difficulties associated with simultaneous ultrasound scanning and needle advancement.[9] The use of preprocedural ultrasound has been shown to increase the first-pass success rate for spinal anesthesia only in patients with difficult surface anatomic landmarks.[10] No technique has been shown to improve the success rate of dural puncture when applied routinely to all patients.[11]

Studies on preprocedural ultrasound-guided spinal techniques have focused on a midline approach using a transverse median (TM) view. The parasagittal oblique (PSO) view consistently offers a better ultrasound view of the neuraxis compared with TM views.[12] However, no studies have been conducted to assess whether these superior PSO views translate into easier paramedian needle insertion.

We hypothesized that the routine use of preprocedural the ultrasound-guided paramedian spinal technique results in fewer passes required to enter the subarachnoid space when compared with the conventional landmark-based midline approach.

METHODS

This was a prospective, randomized, controlled study performed from February 2014 to May 2014. After approval by

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the Clinical Research Ethics Committee of Cork Teaching Hospitals (ref no. ECM 4[j] 04/02/14), all consented patients scheduled to undergo elective total knee or total hip arthroplasty with spinal anesthesia were included in the study. A written informed consent was obtained from all patients. Those with contraindications to spinal anesthesia (allergy to local anesthetic, coagulopathy, local infection, and indeterminate neurological disease) were excluded from the study.

The patients were randomized using random number-generating software (Research Randomizer version 4.0) to undergo either conventional landmark-guided spinal anesthesia (group C) or preprocedural ultrasound-guided paramedian spinal anesthesia (group P). Group allocation was concealed by enclosing the codes in a sealed opaque envelope seen by the attending anesthesiologist immediately before performing the procedure. In both groups, spinal anesthesia was performed by 1 of 3 consultant anesthesiologists, each having performed >75 neuraxial ultrasound scans before the study. On arrival to the anesthesia induction room, baseline monitoring (noninvasive blood pressure, pulse oximetry, and 3-lead electrocardiography) and IV access were established. Patients in both groups were then positioned sitting on a level trolley with feet resting on a foot rest. They were given a pillow to hug and were requested to maintain an arched back posture with an assistant holding the patient to aid positioning. No sedation was given before or during the administration of spinal anesthesia.

In group C, the anesthesiologist palpated the landmarks after positioning and graded the ease of palpation on a 4-point scale (easy, moderate, difficult, or impossible) as described in previous studies.[10] The selection of interspinous space was left to the discretion of the anesthesiologist. Strict asepsis was observed throughout the procedure with the anesthesiologist, scrubbed before the procedure, wearing a mask and sterile gloves. The skin was prepared with 2% chlorhexidine (ChloraPrep 3 mL applicator; CareFusion Corporation, San Diego, CA) after which 2 to 5 mL of 1% lidocaine was used to infiltrate the skin. The anesthesiologist performing the spinal technique was allowed to choose the appropriate needle length (90- or 119-mm 25-G Whitacre needle), gauge (25-G or 22-G), depth, and angle of insertion. The type and dose of local anesthetic injected for spinal anesthesia were at the discretion of the attending anesthesiologist. After completion of spinal anesthetic injection, and positioning the patient in the lateral decubitus position, ultrasound was used to identify the interspinous level at which the injection was administered.

In group P, a portable ultrasound unit (SonixTablet, Peabody, MA) with a curved 2- to 5-MHz probe was used for initial preprocedural marking. A paramedian sagittal oblique view of the neuraxis was obtained, and the sacrum was identified, after which the interlaminar space between L5 and S1 was noted. Subsequent interspinous spaces were identified by counting the interlaminar spaces in a cranial direction. The interspinous space at which the clearest image of the anterior complex (ligamentum flavum dura complex [LFD]) and posterior complex (posterior longitudinal ligament [PLL]) was obtained was selected. At the selected interspace, and with the probe positioned to obtain the clearest ultrasound image, a skin marker was used to mark the midpoint of the long border of the probe and the midpoints of the short borders of the probe (Fig. 1). The medial angulation of the probe was also noted to facilitate guiding the insertion of the spinal needle. At the same horizontal level as the midpoint of the long border of the probe, the midpoint of the line drawn between the 2 short border midpoints of the probe was used as paramedian insertion point for the spinal needle (Fig. 2). A TM view at the same level was also obtained, and the midline was marked. This marking was used to aid the medial angulation of the spinal needle (Fig. 1). Both PSO and TM views were graded as good (both LFD and PLL visible), intermediate (either LFD or PLL visible), and poor (both LFD and PLL not visible).[12] After skin marking, care was taken to make sure that the needle entry site was free of ultrasound gel before needle

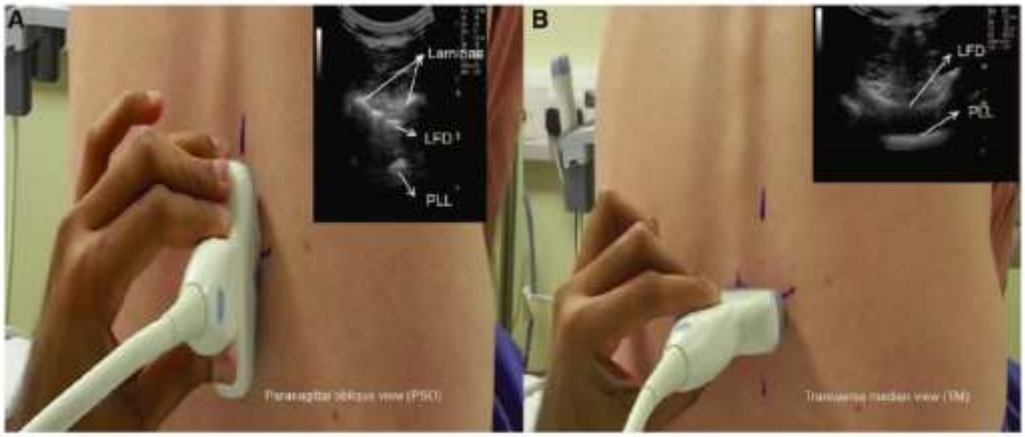

Figure 1. A, Skin markings with the probe positioned to get the best possible parasagittal oblique (PSO) view of neuraxis. B, Midpoint of the long border of the probe marked in transverse median (TM) view. LFD = ligamentum flavum dura complex; PLL = posterior longitudinal ligament.

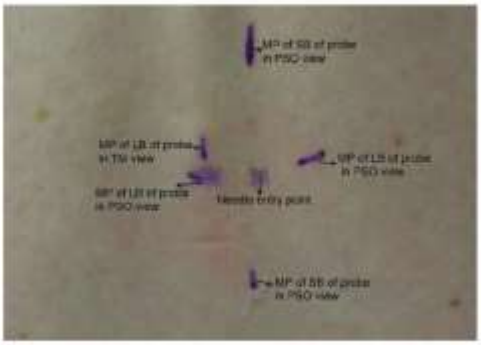

Figure 2. Paramedian skin entry point shown after skin markings. It is marked at the intersection of the lines joining midpoint of the long border of the probe and midpoint of the short border of the probe marked during parasagittal oblique (PSO) view. The midpoint of the long border of the probe in transverse median (TM) view was used to aid the medial angulation of the needle in addition to probe angle in PSO view. MP = midpoint; LB = long border; SB = short border.

insertion. In group P, the anesthesiologist did not palpate the landmarks for grading until the spinal injection was complete. Spinal anesthesia was performed in the same aseptic manner as mentioned earlier.

In both groups, the anesthesiologists were given the option to use alternative methods if 3 attempts were unsuccessful. For patients in group C, another interspinous space could be used or ultrasound used. For patients in group P, a midline approach or a conventional landmark palpation technique could be used.

The outcomes were noted by a single observer for all patients. Because of the nature of the study, the observer could not be blinded to the groups. In addition to demographic details from the patients (age, sex, and height), type of surgery and history of lumbar spine surgery were recorded. History of a difficult neuraxial block was also recorded in both groups. This was obtained from previous anesthetic records. Our hospital uses a standardized electronic anesthesia record that requires description of the grade of difficulty of spinal performance as "easy," "difficult," or "failed." Only evidence previously documented by the anesthesiologist noting the difficulty of the procedure (spinal, epidural, or combined spinal epidural anesthesia) was included.

A timer was used to record the various time intervals. Time for identifying landmarks in group C was defined as time from which the anesthesiologist started palpating to identify the landmarks for the completion of the process, as declared by the anesthesiologist. In group P, it was defined as time from which the ultrasound probe was placed on the skin to the anesthesiologist declaring that the markings were completed. Time taken for performing spinal anesthetic was defined as time taken from insertion of the introducer needle to the completion of injection. The number of passes (defined as the number of forward advancements of the spinal needle in a given interspinous space, i.e., withdrawal and redirection of spinal needle without exiting the skin) and number of spinal needle insertion attempts (defined as the number of times the spinal needle was withdrawn from the skin and reinserted) were noted.[10] The number of passes and attempts were recorded either until the completion of spinal anesthetic or until the anesthesiologist converted to an alternate technique.

Any radicular pain, paraesthesia, or blood in the spinal needle was also noted. All patients who experienced paraesthesia or radicular pain were followed over the next 24 hours, and any patients with persistent symptoms were further evaluated as per department protocol. The use of a long needle, that is, 119-mm 25-G Whitacre needle, was also recorded.

In both groups after administration of spinal anesthesia, patients were positioned on either left or right lateral position, depending on the site of surgery and the type of bupivacaine used (plain or hyperbaric). After positioning, and before administration of sedation, patients were asked for their periprocedural pain scores (patients were specifically asked to rate the pain in their back during administration of spinal anesthesia) measured using an 11-point verbal rating scale (0 = no pain, 10 = most pain imaginable) and periprocedural discomfort scores measured using an 11-point verbal rating measured (0 = no discomfort, 10 = most discomfort imaginable). Level of block (loss of cold sensation tested with ethyl chloride spray) was noted 15 minutes after spinal anesthetic injection. Type and dose of sedation (midazolam with or without propofol infusion) were left to the discretion of the anesthesiologist.

Study Outcomes

The primary outcome was the difference in number of passes between the 2 groups. Secondary outcomes included the following:

1. Number of spinal needle insertion attempts
2. Time for identifying landmarks
3. Time taken for performing spinal anesthetic
4. Level of block
5. Incidence of radicular pain, paraesthesia, and blood in the spinal needle
6. Periprocedural pain
7. Periprocedural discomfort score

Statistical Analysis

Based on a previous study, we assumed that the average number of passes per spinal anesthetic for an experienced anesthesiologist would be 3.3 ± 3.1 (mean ± SD).[13] We hypothesized that by using a preprocedural paramedian spinal, the number of passes could be reduced to 1.3. A total of 38 patients in each group would have been needed to achieve a power of 0.8 and type 1 error of <0.05. We randomized 50 patients per group to allow for dropouts. All data were analyzed based on intention to treat. Data were analyzed for normal distribution using the Shapiro-Wilk test. Categorical data were analyzed using the χ^2 test or Fisher exact test as appropriate. Normally distributed parametric data were analyzed using Student *t* test. All tests were 2-tailed.

For nonnormally distributed count data (passes and attempts) that cannot have a value of zero and had negative binomial distribution, zero truncated negative binomial

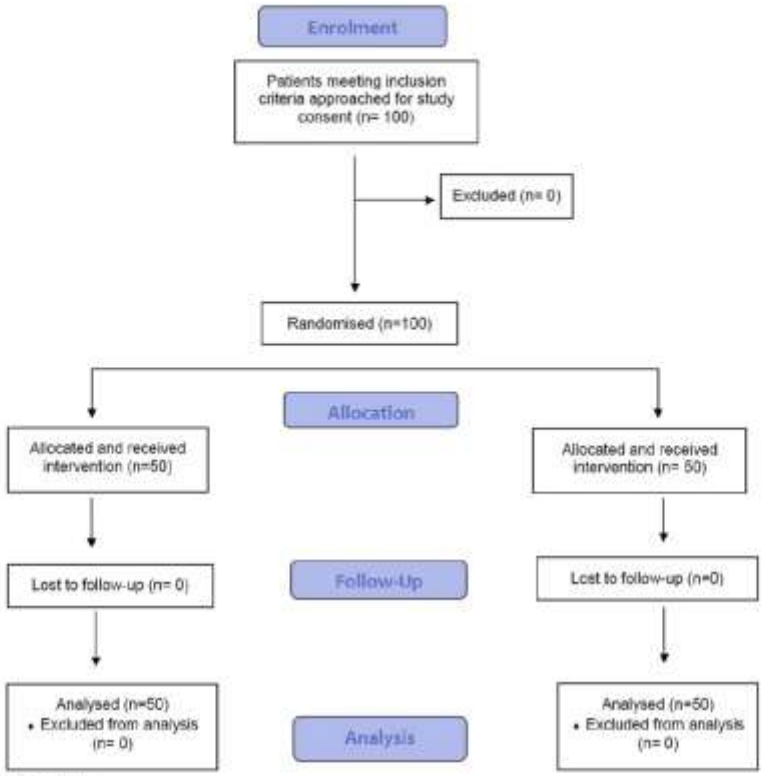

Figure 3. Consort flow sheet.

regression was used to examine the group effect. For other variables that were nonnormally distributed, especially if the data could not be approximated by log-normal distribution, a bootstrap independent samples test was applied, because it is considered a better approach compared with the Z-score procedure.[14] Results for time variables were based on 5000 bootstrap samples. For the variable dose of intrathecal bupivacaine, the 99% confidence interval (CI) was based on 5000 bootstrap samples; variances in some samples were zero; therefore, the *P* value was estimated from 1000 bootstrap samples.

Time variables were reported with 10th and 90th percentile to provide information on the spread. Student *t* test for unequal variance (Welch method) gave 99% CI within 1.5 seconds for time taken to identify landmarks and 16.2 seconds for time taken for spinal anesthetic administration when compared with bootstrap.

For patient characteristic variables and primary outcome variable, a 2-tailed $P < 0.05$ was considered significant and 95% CIs were reported. For all other outcome variables, a 2-tailed *P* value <0.01 was considered statistically significant and 99% CIs were reported. SPSS (IBM SPSS Statistics for Windows, Version 21.0, Armonk, NY) and STATA 12.1 (StataCorp LP, College Station, TX) were used for statistical analysis.

RESULTS

One hundred patients were assessed for suitability. All patients gave their consent to take part in the study, and 50 were randomized to each group. All patients received the allocated intervention. No patients were lost to follow-up, and data acquisition was complete (Fig. 3). In one patient, spinal injection was performed in the lateral position because of a vasovagal episode after local anesthetic infiltration. This patient's data were included in the analysis.

The distribution of demographic data of the patients (age, sex, and height), type of surgery, history of lumbar spine surgery, history of difficult dural tap, and grading of palpated landmarks was similar between the 2 groups with the exception of weight (Table 1). The mean weight in group C was 84.8 kg (SD = 14.4) vs 78.1 kg (SD = 17.8) in group P ($P = 0.04$), but there was no difference in body mass index between the 2 groups.

The mean number of passes (the primary outcome variable) in group C was 8.2 (SD 12.3) vs 4 (SD 4) in group P (Table 2). The average number of passes in group P was approximately 0.34 times that of group C, and this difference was statistically significant ($P = 0.01$). The average number of attempts in group P was approximately 0.25 times that of group C ($P = 0.0021$; Table 2). Because of the

Table 1. Patient Characteristics in Group C and Group P

Variables	Group C, mean (SD)/*n* (%)	Group P, mean (SD)/*n* (%)	Levene test for equality of variance, *P* value	*P* value[a]
Age (y)[b]	65.2 (11.4)	63.4 (14.1)	0.03	0.48
Weight (kg)[b]	84.8 (14.4)	78.1 (17.8)	0.17	0.04
Height (m)	1.68 (0.08)	1.98 (0.14)	0.08	0.12
BMI (kg/m^2)	30.14 (4.7)	28.57 (4.5)	0.99	0.09
Male	26 (52)	20 (40)	—	0.23
Type of surgery				
THR	20 (40)	28 (56)	—	0.29[c]
TKR	28 (56)	20 (40)	—	
B/L TKR	2 (4)	2 (4)	—	
Previous lumbar spine surgery	3 (6)	0 (0)	—	—
History of difficult spinal anesthetic	1 (2)	0 (0)	—	

BMI = body mass index; THR = total hip replacement; TKR = total knee replacement; B/L = bilateral.
[a]*P* values (2-tailed) correct to 2 decimal places had the same value for equal (*t* test) and unequal variances (Welch test).
[b]Shapiro-Wilk tests of normality: age group C (*P* = 0.01), weight group P (*P* = 0.04).
[c]Fisher exact test.

Table 2. Analysis of Number of Needle Passes and Number of Attempts

	Group C	Group P	Zero truncated negative binomial results[a]			
Variables	Mean (SD)	Mean (SD)	B	Exp (B)	CI Exp (B)	*P* value
Number of passes	8.2 (12.3)	4.0 (4.0)	−1.07	0.34	95% CI (0.15–0.79)	0.01
Number of attempts[b]	1.98 (1.68)	1.28 (0.7)	−1.39	0.25	99% CI (0.077–0.79)	0.0021

CI = confidence interval.
[a]The distribution of the number of passes and number of attempts was highly skewed and all values exceed 1; therefore, the zero truncated negative binomial (STATA) was used to compare the 2 groups. A patient in the paramedian group has an expected number of passes equal to exp(−1.07) (i.e., = 0.34) times that of a patient in the conventional group (*P* = 0.01), i.e., fewer passes are expected in the paramedian group. Similar analysis applies for attempts.
[b]Number of attempts (secondary outcome variable), the significance was set at *P* = 0.01, and 99% confidence intervals were calculated.

Table 3. Successful Dural Puncture Rates for Selected Number of Attempts and Passes in Group C and Group P

Successful dural puncture	Group C *n* (%)	Group P *n* (%)	CI	*P* value 2-sided
First pass	20 (40)	14 (28)	95% CI (−30.4, 6.4)	0.21
Within 2 passes	23 (46)	25 (50)	95% CI (−15.6, 23.6)	0.69
First attempt	30 (60)	42 (84)	99% CI (1.7, 46.3)	0.0075
Within 2 attempts	37 (74)	45 (90)	99% CI (−3.4, 35.4)	0.04

CI = confidence interval.

distribution (negative binomial) and type (count) of data, we used a zero truncated, negative binomial regression model and hence one should be mindful of the small sample size (n = 100) when interpreting the results. On comparing variables for successful dural puncture (Table 3), 84% of patients in group P had a successful dural puncture on the first attempt compared with 60% in group C (χ^2 test, P = 0.0075). On subgroup analysis of number of passes at each level in group P, L5 to S1 had a tendency toward a smaller number of passes (mean 2 ± 1) compared with L4 to L5 (mean 4.27 ± 4.1) and L3 to L4 (mean 5.15 ± 5.01) although not statistically significant (P = 0.15). There was no evidence of differences among the 3 anesthesiologists in terms of number of passes (zero truncated binomial regression, P = 0.97, likelihood ratio χ^2 = 0.06) or attempts (zero truncated binomial regression, P = 0.36, likelihood ratio χ^2 = 0.83).

Alternative techniques were used in 6 patients in group C (technique used—ultrasound-guided paramedian spinal) and 2 patients in group P (technique used—midline approach by conventional palpation). There was no significant difference between the 2 groups in requirement for alternative techniques (Fisher exact test, P = 0.27). Despite the use of alternative techniques, dural puncture could not be achieved in 3 of the 6 patients in group C. Successful dual puncture was achieved in both patients in group P in whom an alternative technique was used.

It took the operator on average 81.5 seconds longer (99% CI, 68.4–97 seconds) to identify the landmarks in group P than in group C (P = 0.0002). The dose range of intrathecal bupivacaine was between 14 and 18 mg. Other parameters were comparable between the groups (Tables 4 and 5). All 5 patients in the study who had radicular pain or paraesthesia during needle placement were followed up for 24 hours postsurgery, and none of them had persistent symptoms.

Of the 5 patients in group C who required general anesthesia (GA), failure to perform spinal anesthesia was the reason in 3 patients. Of the other 2 patients who required GA, 1 had pain on incision and 1 developed abdominal pain during the surgery. Of the 4 patients in group P who needed GA, 3 patients reported pain on incision and 1 patient became difficult to sedate 30 minutes into the surgery.

Table 4. Spinal Anesthesia Variables 1

Variable	Group C Mean (10th, 90th) n = 50	Group P Mean (10th, 90th) n = 50	Bootstrap independent samples test[a] P – C mean difference (SE)	99% confidence interval Lower, Upper	P value 2-tailed
Time taken for identifying landmarks (s)	14.6 (9.1, 24.8)	96.1 (58.1, 133.9)	81.5 (5.21)	68.4, 97.1	0.0002
Time taken for spinal injection (s)	169.9 (46.1, 558.7)	97.8 (41.1, 189.4)	−66.0 (35.31)	−161.5, 11.0	0.09
Dose of intrathecal bupivacaine (mg)	n = 47 16.34 (15.0, 17.7)	n = 50 16.40 (15.0, 17.5)	0.06 (0.22)	−0.50, 0.62	0.78[b]
Variable	**Group C Median (Q1, Q3)**	**Group P Median (Q1, Q3)**	**Mann-Whitney *U* test *P* value**		
Periprocedural VAS scores of pain at injection site	3.0 (1.8, 5.0)	3.0 (1.0, 4.3)	0.59		
Periprocedural patient discomfort VAS score	10.0 (8.0, 10.0)	10.0 (8.0, 10.0)	0.28		

Q = quartile; VAS = visual analog scale.
[a]For time variables, 5000 bootstrap samples taken.
[b]For variable dose of intrathecal bupivacaine, 5000 bootstrap samples were taken and variances in some samples were zero; therefore, the *P* value was estimated from 1000 bootstrap samples.

Table 5. Spinal Anesthesia Variables 2

Variables	Group C n (%)	Group P n (%)	P value
Grading of palpated landmarks			
Easy	30 (60)	30 (60)	0.78[a]
Moderate	15 (30)	17 (34)	
Difficult	5 (10)	3 (6)	
Impossible	0 (0)	0 (0)	
Type of bupivacaine			
Heavy	20 (43)	19 (38)	0.65
Plain	27 (57)	31 (62)	
Paresthesia during insertion of spinal needle (n)	1	3	–
Radicular pain during insertion of spinal needle (n)	1	0	–
Blood in spinal needle (n)	2	0	–
Long spinal needle used (n)	3	2	–
Failure to perform spinal anesthetic (n)	3	0	–
Conversion to GA (n)	5	4	–

GA = general anesthesia.
[a]Fisher exact test.

Table 6. Interspinous Level at Which Dural Puncture Was Done and Block Height

Variables		Group C	Group P	P value
Interspinous level at which dural puncture was done (n)	L2–3	4	0	0.0025[a]
	L3–4	22	13	
	L4–5	19	26	
	L5–S1	2	11	
Dermatome level of loss of cold sensation 15 minutes after spinal anesthetic injection (n)	T5	2	2	0.69[a]
	T6	4	3	
	T7	2	2	
	T8	12	14	
	T9	1	2	
	T10	14	10	
	T12	10	11	
	L1	1	6	

[a]Fisher exact test.

The interspinous level at which the spinal was performed was significantly different between the 2 groups with $P = 0.0025$ (Table 6). Four patients in group C had their spinal performed at L2 to L3 versus none in group P (Fisher exact test; $P = 0.05$).

There was no difference within the quality of ultrasound views (Table 7) and number of passes or attempts for both TM ($P = 0.49$, $P = 0.19$) and PSO ($P = 0.43$, $P = 0.32$) views.

DISCUSSION

The use of a preprocedural ultrasound-guided paramedian spinal technique resulted in a >50% reduction in the number of passes required for success compared with a conventional landmark-based midline approach in patients undergoing total hip or total knee arthroplasty. In addition, a preprocedural ultrasound-guided paramedian spinal technique

Table 7. Distribution of Quality of Ultrasound Views (PSO and TM Views) in Group P

Group P US views		Number of views, n (%)
PSO view	Grade 1	30 (60)
	Grade 2	20 (40)
	Grade 3	0 (0)
TM view	Grade 1	10 (20)
	Grade 2	24 (48)
	Grade 3	16 (32)

PSO = parasagittal oblique; TM = transverse median; US = ultrasound.

significantly reduced the number of attempts and increased the first attempt success rate in achieving dural puncture. The number of passes was greater in our control group compared with the referenced study.[13] This might be because of a number of reasons. First, the patient population was different. Mean age and body mass index in our study were 65.2 years and 30 kg/m^2, respectively, versus 56.2 years and 23.8 kg/m^2 in the referenced study. Second, in the study by Kim et al.,[13] the number of passes was self-reported, whereas in our study, it was recorded by an independent observer. This is important, because it has been shown that the self-reported number of passes is always lower than the actual number of passes.

To date, the routine use of preprocedure ultrasound in the general adult or obstetric populations has not been shown to improve the number of passes or attempts needed to achieve successful dural puncture.[11,13] We note a reduction in number of passes required to enter the subarachnoid space because of the following probable reasons. First, the age of our population group was, on average, 64.3 years (SD = 12.8), and spinal anesthesia has been shown to be more difficult in an older population compared with a general adult population.[16] Second, we used a paramedian approach to the neuraxis (guided by ultrasound), which has not been studied so far. In the presence of interspinous ligament calcification and an inability to achieve adequate flexion (both of which are common in the elderly), this paramedian approach might be valuable. It has also been shown that both the length and the width of the lumbar spinous process increase significantly with aging, which further narrows the interspinous space available for a midline approach.[17] The interlaminar space is least affected by changes attributable to aging and offers a potential window for spinal anesthesia. The same reasons explain why the PSO view consistently yields a clearer image of LFD and PLL compared with TM view.[12,18,19] Although a paramedian approach for epidural catheter placement has technical advantages compared with the midline approach,[20] previous studies on the landmark-guided paramedian versus midline approach to spinal anesthetic have yielded mixed results.[21–23] It is conceivable that the advantages of the paramedian approach were more pronounced in our orthopedic population. Third, we used both the probe angle and the midline marking to aid paramedian insertion of the spinal needle. Using a midline approach, the needle angle is only guided by the operator remembering the angle of the probe. Because even small changes in angle of needle insertion and entry point can cause significant changes to where the tip of the needle finally ends up, we believe the addition of another skin marking at the midline to guide the angle of the needle might have played an important role.

Finally, studies that showed no difference on routine scanning investigated first-pass success rates between the 2 groups (success at first attempt and first pass). We chose to look specifically at the number of passes required in each group. We believe that using only first-pass success rates may risk overlooking important between-group differences.

Establishing landmarks took on average 81.5 (99% CI, 68.4–97.1) seconds longer in group P. In a study by Chin et al.,[10] using similar endpoints, this process in the ultrasound group took 240 seconds longer. The difference might be because of the fact that in their study, scanning was done in patients with difficult surface landmarks, and it involved marking 3 interspinous spaces. Our study population included all patients, and we marked only one interspinous space, because we wanted it to reflect real-time practice. Likewise, we found no difference in the time taken to perform spinal anesthetic, probably reflecting its routine use in all patients.

The study does have limitations. First, neither the observer nor the attending anesthesiologists were blinded to the study group. The fact that the ultrasound group would have skin markings and the difference in the direction of needle insertion would have made blinding very difficult. A potential for bias cannot be excluded. Second, the procedure is heterogeneous with multiple factors affecting the number of passes, including individual anesthesiologist preference and style of practice and the number of attempts and/or time taken before using alternate methods. This reflects daily clinical practice. Having a single anesthesiologist perform all procedures might limit the differences because of the aforementioned reasons, but it might also be more apt to reflect individual bias and lack of validation. Third, neuraxial ultrasound has limitations. TM views for a midline approach to dural puncture have a positive predictive value of up to 85% but a negative predictive value of just 30%.[12] Also, ultrasound views are generally more difficult to acquire in the elderly because of anatomical changes (facet hypertrophy, interspinous, and supraspinous ligament calcification).[24] In addition, the necessity to remember the angle of approach of the needle and the inaccuracies of skin markings can further decrease the utility of ultrasound views in patients with a longer distance between skin and dura mater.

CONCLUSIONS

The use of paramedian spinal anesthesia in an elderly orthopedic population, guided by preprocedure ultrasound examination, significantly decreases the number of passes and attempts needed to reach the subarachnoid space.

Spinal anesthesia is still largely a blind procedure. An ultrasound beam may prove better than a needle for locating the target. ■

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Key words: Proficiency based progression, wearable recording devices, competence based training

The move from time-based to competence-based training has been limited by practical (often resource) issues and by the variability of effect offered by different training methodologies. Two independent advances, one technical (wearable recording devices) and the other methodological (proficiency based progression - PBP)[1] may act synergistically to enable consistently effective training in procedural skills. In this article, we describe our ongoing work in which both are integrated in "real world" training and the potential for these together to transform training in procedural skills.

A potential synergy

Although the proficiency of physicians undertaking procedural skills directly influences patient outcome,[2] valid assessment of doctors' procedural skills are is yet a reality. The wearable recording device alone will not be sufficient (as it simply enables acquisition of more data) but these devices can be central to acquiring digital recordings without consuming the learner's attention. Gallagher et al have described PBP for training in procedural skills. This approach consistently achieves greatly superior training effect –including clinical performance– compared with other methods of competency assessment approaches[3], but requires the development of unambiguously defined and detailed procedure-specific metrics and errors, so called "procedure characterization".[1] The success of PBP is dependent on the definition and recognition of specific observable behaviors. In practice this requires direct (and resource-consuming) expert observation or video acquisition and analysis. The emergence low cost, high quality wearable recording devices may address this impediment to widespread introduction of PBP. This synergy may enable doctors to acquire a cumulative personal "visual dataset" suitable for routine highly focused, deliberate practice as well as providing a practical means of quality assured training overseen by a clinical supervisor.

Wearable recording devices (WRD)

For the purposes of this article, we define WRDs as any electronic device carried on the person that records aspects of performance while not impeding or distracting from task completion. In recent years, head-mounted, high resolution audio-visual recording devices such as Google glass and Go-pro have been studied in the setting of medical training.[4] These WRDs appear to be non-distracting to the operator, and also have the potential to decrease any Hawthorne effect or

observer bias.[5] In our experience of developing carefully defined metrics and errors, most are amenable to detection from a first person view, such as that acquired using a WRD (Table 1).

Table 1

No	Metrics (Errors)	Error
1	**Patient not positioned at the edge of the bed**	
2	**Patient not positioned in the middle third (lengthwise) of the bed**	
3	**Bed not horizontal and parallel to the floor**	
4	***A clear working environment not established (eg: one or more of the following actions not completed - dress/gown taped, CTG monitor belt moved away from field , IV lines and monitor cables away from the working field)***	
5	**Adequate time not allowed for antiseptic solution to act (interval from application of antiseptic to insertion of needle : 3 min for betadine and 60 sec for chlorhexidine)**	
6	**Stylet of epidural needle not replaced in the sterile field, once withdrawn form needle**	
7	**Loss of resistance syringe connected with less than half barrel (5 mL) of air**	
8	**More than two needle passes made in the same direction**	
9	**Alteration in direction of needle advancement not limited to a single plane in any new pass**	
10	**Second attempt made in the same interspace without a change in angulation in one or both planes**	
11	**More than five minutes expended in same attempt**	
12	***Insertion attempt made in an unprepared and unsterilized interspace***	

Integrating WRDs in procedural skill training

In addition to defining procedure specific metrics and errors, PBP requires establishment of performance benchmarks based on a mean of expert performance. The trainee practices and is instructed specifically *to those benchmarks*, at first in a simulated setting. Having achieved proficiency in a simulated setting, we propose that each trainee uses i. the characterized reference procedure (in the form of a set of metrics/errors) and ii. a WRD and mobile device for download and review, into the clinical setting. These tools together enable them to recurrently review and update versions of their own performance of particular procedural skills. They are thus enabled to continue deliberate practice and self-assessment on a daily basis whilst the degree of "real time" clinical supervision is unchanged.

Our proposed approach is that each procedure the trainee subsequently performs in the clinical setting is recorded using a WRD; and that he/ she performs formal self-assessment of each. The trainee is generally motivated to self-improvement and so performs self-assessment diligently;

he or she should also bring a detailed and developing knowledge of their own performance to each successive review. The clinical supervisor will review a sample of video recordings of performance and score them against the benchmarks, independently of the trainee. This review will supplement the supervisor's memory of live observation in determining feedback and "sign off" for a particular skill. The selection of performances for review as well as the timing of the review(s) may be dictated by trainee or trainer or by the duration of a training module. The paradigm shift in procedural skill training which we describe here may address the deep misgivings that many trainers and trainees have regarding current practices for supervision and especially "sign off", and do so in a an efficient way. However, this process is completely new to procedural skill training and we do not underestimate the cultural shift required to successfully integrate this suggested approach into "real world" training.

At our institution, the use of WRDs has been successfully piloted for this purpose. Since February 2015 we have utilized WRDs to record the stabilization of preterm (<32 weeks gestational age) infants in the delivery room by trainees and consultant physicians in neonatology. Metrics specific to this period of complex care and procedures have been developed and validated for WRDs. In addition to using traditional education methods for newborn stabilization and demonstrating competency using low fidelity mannequin models in the simulation lab, trainee neonatologists also use WRDs to monitor maintenance of technical skills when performing these preterm stabilizations. We compared learning and clinical outcomes before-and-after the implementation of a new metric-based training incorporating WRD-assisted learning at our institution. There were 38 pre-intervention video recordings compared to 29 post-intervention video recordings. Our (previously unpublished) findings indicate that trainee neonatologists find this mode of learning useful, that WRDs improve skill acquisition, and that the use of WRDs correlates with improvements in patient safety, as supported by an improvement in many aspects of newborn stabilization, including a reduction in the average time to the placement of an electrocardiogram leads (60secs versus 26 secs, p=0.013), and a better utilization of team members during the stabilization process (47% versus 16%, p value 0.016).

In the longer term, this technology also offers an ideal opportunity to evaluate the association between physician performance and clinical outcomes.

Challenges

One potential limitation of WRDs, is that the first-person perspective of an operator may not capture all important or relevant information to allow the accurate assessment of specific procedural skills or the surrounding environment (e.g. team communication). The recording and storage of patient and physician data raises certain medico-legal, ethical, and logistical concerns, none of which is insurmountable.

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Continuing education

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Ultrasound for neuraxial blockade

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Abstract

Neuraxial blockade is still largely performed as a blind procedure. Despite of developments in the type of needles used and drugs administered, the process of locating the epidural or intra-thecal space is still limited to identification of landmarks by palpation and reliance on tactile feedback of the operator. Ultrasound has provided the long needed "eye" to the procedure and has already shown promise of improving the safety and efficacy or neuraxial blocks. This review focuses on understanding the sonoanatomy of the neuraxial space, performing a systematic pre-procedural ultrasound scan, and reviewing the available evidence.

Keywords: neuraxial blockade, spinal, epidural, ultrasound, pre-procedure scanning

Introduction

There is a recent increase in the use of ultrasound (US) to facilitate spinal and epidural anesthesia. A combination of factors conspire to produce a poor US image of the neuraxis: the bony enclosure of the vertebral arches, target structures lying deep to the skin and ultrasound technology poorly suited to the task. These issues hindered the widespread use of US imaging of the neuraxis until the last decade. Rapid advancements in US imaging have addressed some of these limitations. In addition, the use of US for peripheral anaesthesia techniques has created a generation of US -proficient anaesthetists. Millions of neuraxial blocks are performed across the world, traditionally as a blind, tactile procedure. Permanent neurological injury occurs when spinal anaesthesia is administered at or above the L2-3 inter-spinous space [1]. Multiple attempts at achieving a successful neuraxial block are associated with an increased incidence of post dural puncture headache, paraesthesia and spinal hematoma [2-6].

Neuraxial US could potentially address these limitations thereby improving the safety of these procedures. Rapid progress has been made to the extent that routine use of pre-procedural US examination has been recommended to avoid the risk of dural puncture performed at or above the L2-3 inter-spinous space in pregnant patients [7].

Both pre-procedure and real-time US guidance have been used. This review focuses on the current use of pre-procedure US guidance for neuraxial block.

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History

The earliest documented use of neuraxial US dates back to 1971 by Bogin et al [8]. The authors used US to examine the anatomy of the vertebral column to aid lumbar puncture. Grau et al subsequently published a series of articles, mostly in obstetric populations, examining the role of neuraxial US, which paved the way for current research [9-15].

Real-time visualisation for para-median insertion of combined spinal-epidural needle was described by Karmakar et al in 2009 [16]. In this case series, real-time visualisation of needle was successfully used in 14/15 patients studied. Since then multiple case studies and case

series have been published on real time needle guidance in performing neuraxial blocks [17,18]. Recently the use of GPS guidance for spinal needle placement was studied by Brinkman et al in human cadavers and attracted much research in this area [19-27].

Anatomy of neuraxial structures relevant to ultrasound

Each vertebra consists of a vertebral body and arch. The arch is composed of pedicles, superior and inferior articular process, transverse processes and spinous process. In the lumbar region, the spinous processes are broader and less steep than in the thoracic region. Lumbar laminae are also less tilted with no overlap. In contrast, thoracic laminae are broader and they overlap. Fig 1a shows the broad and short spinous process of lumbar vertebrae compared to the long and narrow spinous process of thoracic vertebrae. In fig 1b the difference in inter-laminar spaces is obvious. The thoracic inter-spinous space has steep angulation in addition to being narrow compared to the lumbar inter-spinous space. Thus the size of the window for US beam penetration is lesser in the thoracic region compared to the lumbar region. The needle trajectory for neuraxial blockade passes through the inter-spinous and inter-laminar spaces. A transverse cross section image at the level of the spinous process will not include articular or transverse processes. A transverse cross section at the level of inter-spinous space will include facet joints and transverse process but will not show laminae (fig 2).

The ligamentum flavum extends from the posterior surface of the lamina below to the anterior surface of the lamina above. It consists of elastic cartilage. The dura mater is closely related to the ligamentum flavum with the epidural space separating the two. The epidural space is a potential space and both the dura mater and ligamentum flavum are frequently seen as a single hyper-echoic structure, often called the posterior complex (PC).

The posterior surfaces of the vertebral bodies are connected by the posterior longitudinal ligament. Under US the two structures appear as the anterior complex (AC). The posterior longitudinal ligament is narrow at the level of vertebral bodies and broader at the level of intervertebral discs. The fibres of this ligament are denser and stronger compared to the anterior longitudinal ligament. It should be noted that the PC by definition should lie anterior to the transverse processes.

Various anatomical factors can impede the visualisation of neuraxial structures: a narrow inter-spinous space, thickening and calcification of inter-spinous ligaments, facet joint hypertrophy, and the absence of fusion of ligamentum flavum in the midline.

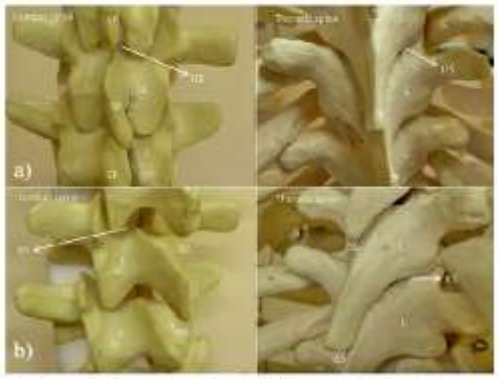

Fig 1. Lumbar and thoracic vertebrae, anatomical aspect: a) posterior view; b) lateral view. SP – spinous process, L – lamina, ILS – interlaminar space, ISS – interspinous space.

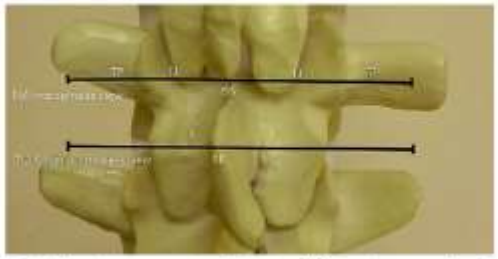

Fig 2. Structures encountered at two different cross sectional levels: ISS – inter-spinous space, L – lamina, SP – spinous process, FJ – facet joint, TP – transverse process.

Clinical sonoanatomy

Equipment

A low frequency (2 to 5 MHz) curvilinear probe is preferred to visualise the neuraxial structures due to the depth at which they are located. Depth (8 cm to start with), focus point and gain are adjusted as appropriate. Because of the limitations of the bony window, it is essential that ideal conditions for scanning are maintained including plenty of US gel, dimming the room lights and positioning of the operator. Higher frequency linear and hockey stick (7-13 MHz) probes may be used in the paediatric population because of the lesser distance from skin to neuraxis and limited ossification, especially in infants less than 6 months.

Sonoanatomy

Neuraxial US scanning is done in two planes - sagittal and transverse. Due to the broader bony window, lumbar neuraxial structures are visualised better compared to the

thoracic region. Bony structures (spinous process, laminae, transverse processes and vertebral body) are hyper-echoic and are seen as bright white structures. Ligamentous structures (inter-spinous ligament, posterior longitudinal ligament and ligamentum flavum) and membranes (dura mater) are less hyper-echoic compared to bone. Fat, muscle and fluid are progressively hypo-echoic and seen as darker structures. Pattern recognition plays a very important role in identification of structures. The following description refers to pre-procedure neuraxial ultrasound examination of the lumbar region unless specified otherwise.

Sagittal views

In this view the long axis of the probe is placed in the sagittal plane lateral to midline (fig 3a). Different views may be obtained, depending on the position of the probe (fig 3b).

When the probe is placed approximately 3 cm lateral to midline the transverse processes are seen as hyper-echoic lines (fig 4a). These are short white lines with a slight curve. Superficial to the transverse process one can see the erector spinae muscles. Psoas muscles and peritoneum can be seen deeper to the transverse process. It is important to note the depth at which the transverse processes are seen. As one moves the probe medially, the structures encountered such as facet joints and laminae will be more superficial.

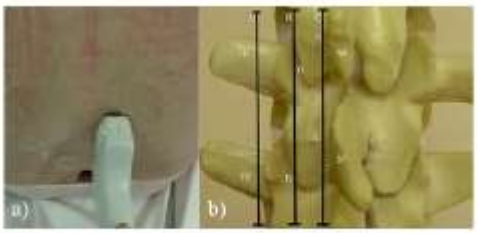

Fig 3. Para-sagittal (PS) a) probe position on a patient; b) anatomical planes of interest. SP – spinous process, L – lamina, FJ – facet joint, TP – transverse process; line A – PS transverse process view, line B – PS facet joint view, line C – PS laminar view.

As the probe is moved medially the facet joints are brought into view (fig 4b). It is important to note that all these structures are visualised within a few centimetres and hence movement of the probe medially should be slow and deliberate to carefully observe pattern changes. The facet joints are seen as near-continuous wavy white structures with humps (described as the "camel hump sign"). The gap between the lines is the facet joint between the superior and inferior articular processes. On further slight medial movement of the probe, the laminae are seen as slanting white lines with the alignment resembling saw teeth or horse heads arranged one after the other (fig 4c). With a slight medial tilt of the probe (towards the median sagittal plane), the inter-laminar window allows visualisation of neuraxial structures. Medial angulation in this position, described as the para-sagittal oblique view (PSO), is important as it gives the best chance to visualise the neuraxial structures (fig 5a). Structures thus visualized include lamina, posterior complex (ligamentum flavum and dura mater), hypo-echoic spinal canal and the anterior complex (posterior longitudinal ligament and posterior surface of the vertebral body). In some individuals the epidural space may be seen as a small gap between the ligamentum flavum and the dura mater within the PC. This PSO view consistently provides better visualisation of neuraxial structures compared to transverse median view due to a better bony window (fig 5b,c).

In addition to visualising the structures, the PSO view is also used to identify the level of the inter-laminar space. The sacrum is identified by placing the probe at the level of posterior superior iliac spine in PSO view orientation. The sacrum is identified as a continuous convex hyper-echoic line (fig 5d). Due to the dorsal tilt of the sacrum, the caudal portion is superficial and the cranial portion is deeper. If a convex hyper-echoic line is seen with cranial portion superficial and caudal portion deeper, it means that either the probe orientation is incorrect or that the probe position is too caudal in the vertebral column. The lumbo-sacral junction may then be identified as the first

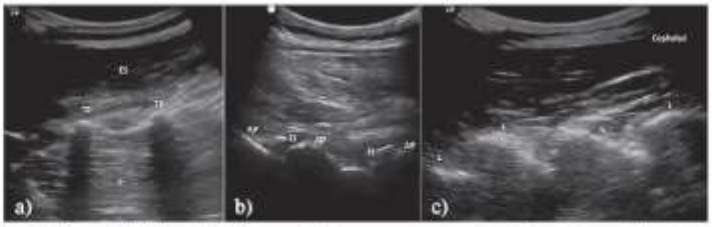

Fig 4. Para-sagittal longitudinal view of a) transverse processes; b) facet joints; c) laminae. ES – erector spinae muscle, TP – transverse process, P – psoas muscle, FJ – facet joint, AP –

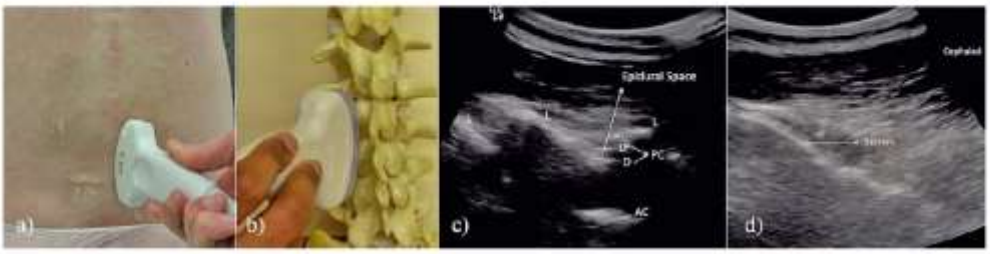

Fig 5. Para-sagittal oblique (PSO) a) probe position on a patient; b) probe position on a spine model; c) ultrasound view of lumbar spine; d) ultrasound view of sacrum. L – lamina, LF – ligamentum flavum, D – dura mater, PC – posterior complex, AC – anterior complex, S – sacrum.

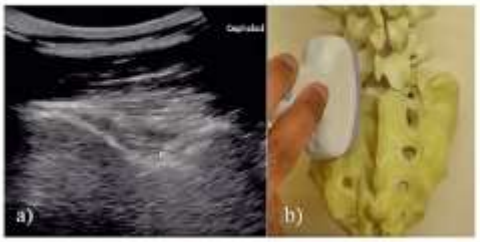

Fig 6. Para-sagittal oblique (PSO) a) ultrasound view of L5S1; b) probe position on a spine model. S – sacrum, L – lamina, PC – posterior complex

Fig 7. Transverse median (TM) a) probe position on a patient; b) cephalad angulation of the probe; c) probe position on a spine model.

inter-laminar space between the sacrum and L5 lamina by sliding the probe cephalad (fig 6a, b). It is important to make sure that the structures visualised cephalad to the sacrum are the laminae of the lumbar vertebral body and not facets or transverse process. The key is slow and deliberate medio-lateral movement of the probe and pattern recognition. Once the L5-S1 inter-laminar space is identified, further spaces are identified by sliding the probe cephalad. Alternatively, the vertebral level may be determined by identifying the twelfth thoracic vertebra based on its articulation with the last rib, and thereafter moving the probe in a caudal direction. Note that while the probe is in the para-median sagittal position, the hyper-echoic structures seen are the laminae. The inexperienced practitioner may confuse these with the spinous processes.

From the PSO view, if one eliminates the medial tilt and moves the probe medially, it places the probe directly above the spinous process. In this view the visibility of neuraxial structures are almost impossible due to the dense hyper-echoic shadows underlying the spinous process. This view has minimal utility in identifying neuraxial structures but can be used to mark the tip of the spinous process which may be useful in patients with scoliosis.

Transverse median views

To obtain transverse views, the long border of the probe is placed in the transverse plane (fig 7a) and angulated cephalad to replicate the direction of the spinous processes (fig 7b,c). In TM view, it is important for the operator to memorise the cephalad tilt of the probe needed to get the best view of PC and AC. This will aid the direction of advancement of the spinal or epidural needle. Depending on the position of the probe two images may be obtained.

On placing the probe directly above the spinous process (fig 8a), they are seen as hyper-echoic structures with laminae on either side (fig 8b). Due to high echogenicity of bone, structures beneath the spinous process are not seen. On moving the probe slightly cephalad or caudad, one can see the inter-spinous ligaments (fig 9a). As the echogenicity of these structures are less than spinous process it allows us to visualise other neuraxial structures. Due to the way the spinous processes and the vertebrae are arranged, scanning at this level does not show the laminae but instead the facet joints and transverse processes are seen on either side of the midline as hyper-echoic structures (fig 9b). Once this view is obtained, due to the angulation of the spinous processes,

Fig 8. Transverse median cross section at the level of a lumbar spinous process a) beam path on a spine model; b) ultrasound view. SP – spinous process, L – lamina.

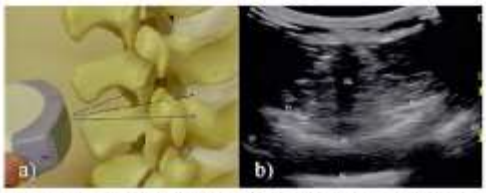

Fig 9. Transverse median cross section at the level of a lumbar inter-spinous space a) beam path on a spine model; b) ultrasound view. ISL – inter-spinous ligament, FJ – facet joint, TP – transverse process, PC – posterior complex, AC – anterior complex.

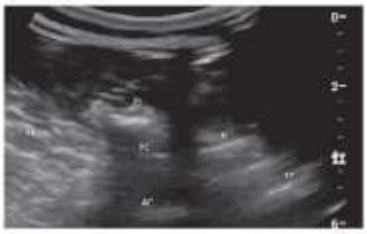

Fig 10. Transverse median view in a scoliotic spine. FJ – facet joint, PC – posterior complex, TP – transverse process, AC – anterior chamber. Note that neither the facet joints nor the transverse processes are symmetrical. In these cases one should adjust the medio-lateral probe angulation till they are symmetrical to obtain the orientation of the vertebrae.

a slight cephalad tilt of the probe might be necessary to bring the PC and AC into view. These are seen typically as two hyper-echoic lines with the intervening spinal canal seen sometimes as a hypo-echoic structure. Their visibility may not be as good as in PSO view due to the limitations of the bony window and scattering of the ultrasound beam by the irregular surface of the bone, especially in the presence of facet joint hypertrophy. In some cases one can either visualise the PC or AC. The fact that the AC lies anterior to the transverse processes should help in identifying the structures seen.

In scoliotic individuals the neuraxial structures may not be aligned symmetrically (fig 10). Hence, in addition to the cephalad tilt, the probe has to be tilted medio-laterally to identify the direction in which vertebrae are oriented. This is done by rotating the probe medio-laterally until the facet joints and transverse processes are placed symmetrically on the screen. In such cases both the cephalad and medio-lateral angulation of the probe should be recalled when advancing the needle.

Positioning

The patient can be positioned in either sitting or lateral position. It is preferable to scan and mark the back in the exact position that neuraxial blockade will be administered i.e. arched back position. Due to the depth of the epidural and intra-thecal space, any deviation in the skin markings, even by few millimetres can lead to failure in locating the space. Inaccuracy of skin markings has been shown to be the most common mistake made by novices while learning neuraxial ultrasound [28].

Skin markings for needle entry site

This is done in a systematic manner to improve the accuracy.

Step 1: Identification of sacrum and inter-laminar spaces in PSO view

The ultrasound probe is placed in a sagittal plane medial to the posterior superior iliac spine. Once the sacrum is identified, the probe is moved cephalad to identify other inter-laminar spaces. In each inter-laminar space, the best possible view of anterior and posterior complex is obtained. With the inter-laminar space in the middle of the screen, the middle of the medial side of the long border of the probe is marked (fig 11a). Two to three spaces are thus marked.

Step 2: Selecting the best inter-spinous space on TM view

At each selected inter-laminar space, the probe is turned 90 degrees to obtain a transverse median view of AC and PC. Once the appropriate inter-laminar space is in the middle of the ultrasound screen, the midpoint of the long border of the probe and the midpoint of the short border of the probe is marked. As the ultrasound beam emanates from the middle of the probe, the intersection of the two markings should correspond to the needle entry point (fig 11b). Good visualisation of both AC and PC in transverse median view corresponds to successful administration of spinal anaesthetic in that level. However this has not been the case with PSO views [29]. Hence the inter-spinous space at which the best views of AC and PC is obtained in TM view should be selected.

Fig 11. Skin markings prior to the neuraxial anaesthetic technique once the best image of the target has been obtained and centred in a) para-sagittal oblique view; b) transverse median view

Step 3: Angle and depth of insertion of spinal needle

During skin markings for transverse median view, the cephalad angulation of the probe needed to obtain the best view of ligamentum flavum and dura mater is noted. Also the medio-lateral angle is adjusted till the facet joint and transverse processes are symmetrical on the screen (as described earlier). Both angles will have to be remembered by the operator.

The depth of the ligamentum flavum-dura mater complex (PC) from skin on ultrasound measurement has been shown to be accurate in multiple studies [18,30-32].

Advantages of neuraxial ultrasound

Pre-procedure neuraxial US scanning done by experts has been shown to increase success rates in trainee anaesthetist [33] . In patients with difficult surface landmarks (BMI >35, poorly palpable surface landmarks, moderate to severe lumbar scoliosis and previous lumbar spinal surgery) US has been shown to improve the success rates of spinal anaesthesia [30].

Landmark based estimation of inter-spinous space, even in experienced practitioners, has been shown to be accurate in only 39% of the time [34]. Ultrasound helps to improve accuracy. Compared with other standard modalities (MRI [35], CT [25] or plain X-rays [36]), US has been shown to be accurate up to 76% of the time. With modern US machines and adequate training, accuracy rates of up to 90% have been described [25]. Certain congenital anomalies such as sacralisation of lumbar vertebrae and lumbarisation of sacral vertebrae (which occur in up to 12% of general population [37]) can only be reliably identified by plain films.

A difference of 5 to 15 mm in the depth has been observed between US estimation and actual depth [18,32,38]. This can be attributed to tissue compression by the US probe, or an US beam angle different to that used for insertion of the spinal or epidural needle. Estimation of depth can allow one to choose appropriate needle length prior to the procedure. It may also help to avoid dural tap during epidural insertion.

Pre-procedure scanning has also shown to have an 85% positive predictive value for successful dural puncture [29]. If one can see both AC and PC in TM view, it indicates that there is a clear path for the US beam to pass, and hence the likelihood of inserting a spinal or epidural needle into the intended space is higher. Multiple scoring systems have been developed to assess the degree of difficulty in any given inter-spinous space [39] but the bottom line is to select the inter-spinous space with the best possible TM view of AC and PC.

Limitations

The technique of neuraxial US is a relatively new development. Due to the limited bony window, the learning curve is steep [28]. Another limitation of neuraxial US is that images are difficult to obtain in patients with difficult anatomy, in whom one might expect US to offer most benefit. Although imaging can be challenging in this group of patients, it has been shown that in experienced hands, neuraxial US is beneficial [30].

The neurotoxicity of US gel is unclear [40,41]. The gel must be cleaned away from the site of needle insertion and strict asepsis maintained. This can be difficult if real time imaging is used.

If meticulous care is not taken during the skin markings, it can lead to unsuccessful block. Factors such as a change in patient position between skin marking and needle placement, mis-estimation of the middle of the probe, movement of skin and subcutaneous tissues during probe placement (especially in elderly and obese patients), the necessity to remember cephalad and medio-lateral angles of the probe can all lead to minor inaccuracies. Due to the depth of the neuraxial structures, any minor change in skin markings or changes in angle of insertion can lead to exaggerated changes to the final position of the needle tip.

Future trends

The use of real time US-guided spinal anaesthesia has been advocated to improve the success rates. To date, this has been only demonstrated in case series and case reports [17,21,42]. Its use may be limited by the requirement for wide bore needles and the technical difficulties associated with simultaneous US scanning and needle advancement [23]. Studies comparing real-time with pre-procedure scanning are needed to confirm the utility of this technique.

Real time volumetric three dimensional imaging of the spine using a hand held device has been shown to

be a feasible technique in a recent study [43]. The utility of this in performing neuraxial blocks has yet to be ascertained.

Conclusion

The use of US to guide performance of neuraxial blocks is a relatively new development, yet much research is currently underway on the topic. Advances in technology have greatly helped to turn the shadows of the bony vertebral column into internal landmarks. Although some limitations remain, there is promise of improvements in the safety and efficacy of neuraxial blocks using US. Technically, the importance of pattern recognition and meticulous skin markings cannot be overstated. Neuraxial scanning, even if not performed routinely on all patients, may soon be considered the standard of care in certain patient populations.

Conflict of interest: none

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Cumsum cannot define competency

Declaration of interest

None declared.

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CUMSUM cannot define competency

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Editor—Drake and colleagues[1] have addressed the drawbacks of CUMSUM analysis, namely self-reporting and small sample size. They have also broadened the definition of failure to increase the sensitivity. We would like to highlight some related issues. Procedural skill proficiency can lead to better patient outcomes.[2] However, substandard performance does not invariably lead to poor patient outcome. For example, poor aseptic technique during a procedure such as placement of an epidural catheter does not necessarily affect the (analgesic) success of the procedure, at least in the short term. Nonetheless, it is clearly unacceptable.

Hence, the concept of defining competency based only on failure rates is inherently flawed. We suggest that ascertaining competency for a particular procedure first requires establishment of a benchmark of proficiency for that procedure. This should be based on unambiguous, objective, and validated metrics. Each procedure (performed by each trainee or not) can then be assessed based on these benchmarks. A practitioner can then be deemed competent once he or she meets the benchmarks consistently. This concept of proficiency training has been described in detail elsewhere.[3] This approach should enable trainees to receive prompt, specific, and objective feedback on their performances. The ability to give feedback on performance is one of the key factors in deliberate practice and is absent in CUMSUM.[4]

We disagree with the authors' conclusion that 'CUMSUM is an effective tool in charting the development of competence for trainees'; efficacy requires that meaningful change in performance standard is captured, which is a condition not met if success or failure alone is measured.

Declaration of interest

None declared.

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New assessment tool for remote simulation based ultrasound guided regional anaesthesia – A call for further refinement

anatomy of the nerve. He hypothesizes that the amount of nerve swelling after intraneural injection may depend on the position of the needle within the nerve, that is, intrafascicular or interfascicular. We believe that this could be the case and that the hypothesis warrants further investigation. Other factors that, in our opinion, could potentially be of influence are the compliance of the tissue surrounding the nerve, the size of the nerve in relationship to the volume of injectate, and the speed and pressure of the injection.

Secondly, Dr Orebaugh wonders whether the previously mentioned signs of intraneural injection apply only to solitary nerves. In fact, these criteria are based on our previous (cadaver) study of the supraclavicular brachial plexus and at the sciatic nerve.[2] We are therefore confident that these signs are present in complex nerve structures, provided that the ultrasound image quality is sufficient and that the injection is placed within the epineurium of at least one of the nerves at the anatomical location. However, we have not assessed the ultrasound characteristics of injections placed outside the epineurium, but within the enveloping fascial sheath. Rather, our control "extraneural" injections were targeted outside epineurium and sheath entirely. Given the tendency to position the needle tip ever closer to the nerve, we agree that future studies may want to differentiate between extraneural, intraneural (subepineural), and "paraneural" (inside sheath, outside epineurium) injections. However, we believe that precise positioning of the needle tip between sheath and epineurium may be quite difficult. Andersen et al[6] could visualize the paraneural sheath of the sciatic nerve on ultrasound but only after the layers had been separated by the injection of fluid. On histological images, one cannot always clearly discriminate surrounding fascial layers from the epineurium because they are both very thin (≤0.2 mm) and often in close vicinity.[7]

As a last remark, we want to point out that we do not a priori consider an intraneural injection as harmful to the patient. However, we believe that accurate detection is important so that the practitioner can make a conscious decision on this matter.

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New Assessment Tool for Remote Simulation-Based Ultrasound-Guided Regional Anesthesia
A Call for Further Refinement

Accepted for publication: January 14, 2015.

To the Editor:

We read with interest the article "A valid and reliable assessment tool for remote simulation-based ultrasound-guided regional anesthesia" by Laurent et al.[1] We believe it is a useful contribution to the literature on procedural skills training but wish to highlight certain methodological issues.

1. The Checklist and GRS used in the study contain definitions which are subjective. For example, such terms as "carefully handles tissue but occasionally causes unintentional damage" (in GRS) and "needling technique" (in the Checklist) are vague and subjective. Although these tools may be adequate for assessment, particularly when applied in narrow contexts such as when institutional or regional norms apply, their external validity is questionable. More importantly, when used for training, their use does not allow one to provide detailed and specific feedback to trainees.
2. The Likert system of grading (applied to GRS and Checklist in this study) is also inherently subjective. In general, this leads to poor interrater reliability (IRR). Although the authors report "good" reliability based on intraclass correlation (ICC) values, this may be misleading (see point 3).
3. For validation of any assessment tool, agreement (and not association) between assessors should be calculated. Correlation coefficients reflect the degree of association, inferring some relationship between observations. What is required in estimating reliability of an assessment tool is quantification of agreement (ie, sameness or equal value). This is particularly relevant to a tool which could be used for high stakes assessment in the future. The appropriate method to quantify agreement is to calculate IR (ie, a proportion based on the number of agreements between assessors divided by the total number of metrics). The merits of this approach have been extensively discussed elsewhere.[2–4]
4. For the purpose of achieving a superior IRR and to provide detailed specific feedback to trainees, stringently defined objective metrics with dichotomous variables should be preferred (eg, the modified Cheung checklist used by Wong et al[5]).

Although this study purports to demonstrate construct and concurrent validity for the tool studied, methodological considerations previously mentioned should be addressed before it is adopted more widely.

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Reply to Drs Srinivasan and Shorten

Accepted for publication: February 6, 2015.

To the Editor:

We thank Drs Srinivasan and Shorten for their letter[1] calling for further refinement of the assessment tool validated for evaluation of remote simulation-based ultrasound-guided regional anesthesia training.[2] We address their concerns, in order, below:

1) Cheung et al[3] developed the Global Rating Scale (GRS) and Checklist as a global assessment tool for ultrasound-guided peripheral nerve blocks. The process of development included the Delphi method where 18 ultrasound-guided nerve block specialists provided their expert opinion on what was to be included in the GRS and Checklist. Our study was designed simply to validate these assessment tools. Discussion and training among the raters were completed to determine the most appropriate interpretation of the definitions that are questioned. We believe that external validity is not compromised if raters agree on how to use these tools in evaluating a particular ultrasound-guided block. We would argue that these descriptions would be an objective assessment of the operator if end points for these values were decided on between raters. The Checklist and GRS were developed as a global assessment tool for all types of nerve blocks, and we believe that some wording choices were intentionally more subjective. "Carefully handles tissue but occasionally causes unintentional damage" in the GRS was decided as the inappropriate use of the needle as an instrument. Actions that cause damage include an undue number of needle insertions, inaccurate angle of insertion, and multiple attempts of trying to achieve the target. In the Checklist, "needling technique" was used to assess any mistakes commonly made by novice operators. Lastly, training does not take place in isolation from the instructor; detailed and specific feedback can always be provided to trainees—these tools are guideposts and do not substitute teaching.
2) A Likert scale system of grading may be less objective but allows the assessment to be more qualitative.[4] The comment suggesting poor inter-rater reliability does indeed seem to be a generalization, without reference to the literature. A tool's reliability is dependent on a number of factors, including the training of the assessors. A combination of a Checklist and GRS has been suggested as a complementary pair for comprehensive evaluation in education research.[4]
3) We agree that what is required in estimating reliability of an assessment tool is quantification of agreement. Intraclass correlation coefficients calculated using an absolute agreement definition can be used for this purpose, the principles of which are discussed in McGraw and Wong.[5]
4) Explicit dichotomous variables may be preferred for usability; however, this study aimed to validate the Checklist and GRS developed by Cheung et al.[3] Rater training and discussion on the use of these tools were conducted to improve the reliability of ratings. The ability of evaluators to provide detailed specific feedback directly to participants was not limited by these tools.

To conclude, we will quote Reznick et al[6] and remember that "validity cannot be proven in any one experiment. Rather, over time and experimentation, one accrues evidence for the validity of a test."

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Sonographic Localization of the Piriformis Muscle Using a Caudal-to-Cranial Approach

Accepted for publication: January 20, 2015.

To the Editor:

Piriformis syndrome is a clinical condition associated with irritation to piriformis muscles or compression to sciatic nerves at the buttock level. In a recently published randomized controlled trial, ultrasound-guided corticosteroid injection with local anesthesia was proven to provide similar efficacy in pain relief and procedural time compared with fluoroscopically guided injections.[1] However, because the piriformis muscle is deeply situated in the gluteal region, precise recognition of this muscle is never an easy task, especially in obese patients.

There are 2 common methods to visualize piriformis muscles by ultrasound. The first is through placing the probe at the level of the posterior superior iliac spine and then moving it caudally until the sacrum and ilium are seen.[1] The main concern of using the posterior superior iliac spine as the initial bony landmark is that the investigators may be puzzled by similar structures such as the posterior

Missing link

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Dear Editor,

Beard et al have described their use of wearable cameras to augment training of surgical residents by creating a "point of view surgical education library".[1] Their clearly articulated argument for such use is convincing, innovative and achievable in a healthcare setting. We suggest that one critical aspect of the practice of using wearable recording devices for procedural training in medicine has been overlooked or understated. A "metrics"- driven approach to surgical training has consistently been shown to be effective in decreasing errors and improving efficiency both in the simulated and clinical environment.[2-4] These performance metrics and errors are observable behaviours, most or all of which can be captured by first person view videos. Metrics are the fundamental materials on which deliberate practice, feedback and assessment are based. In effect, the first person surgical video is an invaluable training resource when viewed as a digital dataset, best interpreted through the filter of unambiguously defined metrics. Over the past three years, our experience in enabling trainees to use wearable recording devices in clinical settings (e.g. peripheral nerve blockade[5], epidural anaesthesia, and neonatal tracheal intubation and PICC line insertion) has reaffirmed the value of combining two complementary innovations

namely, metrics based training and wearable recording devices. One facilitates acquisition, the other interpretation and exploitation of critical visual data.

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