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ORIGINAL ARTICLE

A double blind comparison of the variability of block levels assessed using a hand held Neurotip™ or a Neuropen® at elective caesarean section under spinal anaesthesia

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ABSTRACT

Background: We previously noted that when two experienced anaesthetists assessed the level of spinal block to touch at caesarean section, one with a hand held device (Neurotip™), and the other with a very similar spring loaded device (Neuropen®), the median difference between the assessed levels of block was zero but there were some wide individual paired differences between the anaesthetists. We theorised that differences in the applied pressure of the stimulus may have contributed to this variation. We wished to investigate whether compared to the Neurotip™, the Neuropen® would reduce the variability of assessed block levels between anaesthetists of varying experience.

Methods: The levels of block to touch and sharp pinprick were assessed by paired anaesthetists using both the Neurotip™ and Neuropen®. The anaesthetists were blind to each other's assessments. To ensure comparability of dermatome identification, the patient's torso was marked before surgery.

Results: In 44 cases, managed by 35 different pairs of anaesthetists, there was no statistically significant difference in the variability of differences in assessed levels of block between anaesthetists ($P=0.23$) whether the Neurotip™ or Neuropen® or touch or sharp pinprick were used. The median dermatomal difference [upper quartile, lower quartile] was 0 [1, -1] for both instruments with both touch and sharp pinprick.

Conclusion: Compared to the Neurotip™, the Neuropen® did not result in a reduction of the variability in the differences in spinal block levels when assessed by 35 different pairs of anaesthetists.

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Keywords: Spinal anaesthesia; Sensory block assessment; Caesarean section

Introduction

Spinal anaesthesia is used for the vast majority of caesarean sections in the UK and pain during surgery is a common cause of complaint.¹ While there is general agreement on the height of the block required for caesarean section there is continued controversy as to which sensory modality should be used to assess the level of block. The commonly used modalities are cold, pinprick and touch and it is well recognised that for any individual spinal anaesthetic each of these modalities may indicate a different level of block. Furthermore, even within the same testing modality there are different ways of presenting the stimulus. Touch, for example, can be assessed by such mechanisms as stroking (cotton wool, Von Frey hairs), prodding (blunt needle, Von Frey hairs), or the sensation from the fluid jet of an ethyl

chloride spray or a jet of air from an 18-gauge needle. Whether the use of different mechanisms for testing the same sensation makes a difference to the assessed level of block is unknown.

In a previous study from our unit two experienced anaesthetists, one using a Neurotip™ (Fig. 1a) and the other using a Neuropen® (Fig. 1b) compared their assessments of a spinal block using the touch sensation created by the blunt round needle tip of these instruments.² In that study, although the median dermatomal difference between levels of block obtained by two assessors using two methods was zero, there were frequently disparities of two or more dermatomes between the two assessors and, at times, some short-lived wide disparities of up to seven dermatomes. We postulated that some of the variation in assessed levels of block could be due to differences in the applied pressure by the two assessors. If this hypothesis were correct then, in theory, if all anaesthetists applied the same standardised pressure, variation in block levels assessed by pairs of anaesthetists should be much reduced. We conducted this study

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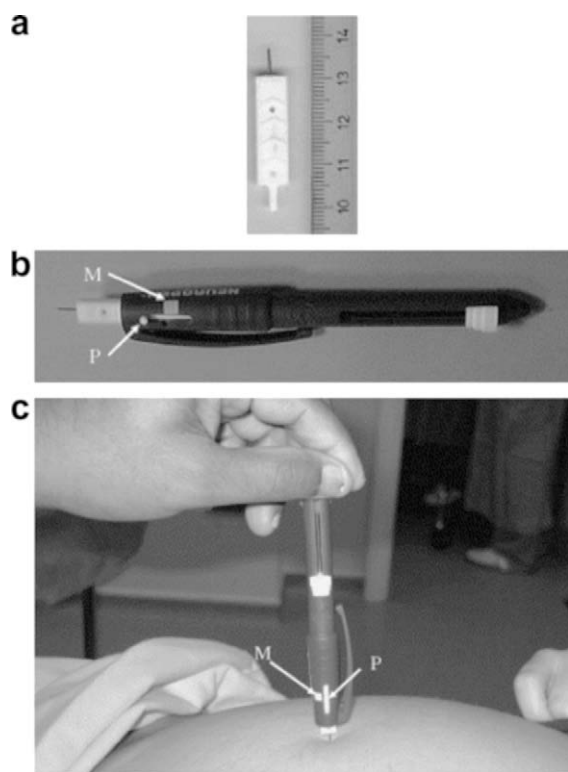


Fig. 1 (a) A Neurotip™ alongside a centimetre scale. (b) The Neuropen® device showing the Neurotip™ loaded. The pointer on the side of the Neuropen is arrowed “P” and the mark with which the pointer should line up during skin testing is arrowed “M.” (c) The Neuropen® showing the Neurotip™ pressed onto the skin and the Neurotip™ depressed into the body of the Neuropen®. The Neuropen® is pressed against the skin until the pointer (“P”) lines up with the white mark on the body of the pen (“M”). This then corresponds to 40 g pressure on the skin.

to investigate whether, compared to the Neurotip™, using the Neuropen® would reduce the variability of assessed block levels between pairs of anaesthetists of varying experience.

Method

The study was approved by the Hull and East Yorkshire Hospitals Local Research Ethics Committee. The study population were ASA I or II women scheduled for elective caesarean section under spinal anaesthesia and who gave informed consent to participate. Women were seen on the morning of surgery by one of the two anaesthetists to be involved in their care and informed consent was obtained. Just before the patient came to the operating theatre, a 5-cm wide strip of low allergenic tape (Micropore, 3M Health Care Ltd, Leicestershire, UK) was applied to the midline of the patient’s body, from sternal notch to umbilicus. Dermatomal levels from T3 to T10 were estimated and marked on the tape.

The Neurotip™ (Owen Mumford, Oxford, UK) consists of a short, round-tipped blunt needle mounted in a plastic body. The Neuropen® (Owen Mumford, Oxford, UK) consists of a Neurotip™ that is spring-mounted into a pen-like body. When using the Neuropen® the end of the blunt needle is pressed against the skin and the force applied by the assessor is standardised by pushing on the pen until a marker on the Neurotip™ aligns with a white mark on the pen body: this is described as the equivalent of 40 g pressure.² When using the Neurotip™ it was pressed momentarily against the patient’s skin according to the assessor’s own interpretation of the required pressure.

The spinal anaesthetic, consisting of 0.5% bupivacaine in 8% w/v dextrose (2.3–2.8 mL) with diamorphine 0.3 mg, was administered at what was estimated to be L3-4 interspace with the patient in a lateral or sitting position depending on her body habitus. Generally, the spinal was performed by the more junior of the two anaesthetists.

The two anaesthetists assigned to each case designated themselves A or B. At 5, 10, and 20 min after spinal injection and again at the end of surgery the block levels on the left were assessed by both anaesthetists. A screen was placed in front of the mother to ensure that she could not see when and how the stimulus was applied to her skin. To minimise the potential for the spinal block levels to have changed between the assessments made by A and B, comparisons were not made until 5 min and only the left side was tested before changing the assessor. It takes about 10–15 s to assess the block to touch and pinprick on one side with one instrument. Before the first of each sensory assessment, a control stimulus with the chosen device was applied to the upper arm to allow the mother to feel what the sharp pinprick felt like. The levels of block to touch and sharp pinprick were checked on the left side first by A using both the Neurotip™ and Neuropen® and then immediately B would do likewise. Anaesthetist A always tested first at each assessment. Each anaesthetist chose for themselves which instrument to use first and this was always used first for any individual patient. Neither anaesthetist was aware of the order of the instruments used by the other, nor the levels of block the other had obtained. The assessed block levels were recorded on separate data-collection sheets so that the anaesthetists remained blind to the block levels obtained by each other. After both A and B had assessed the left-sided block the principal anaesthetist (who may have been either A or B) then checked the right side to ensure there was no major discrepancy in the block levels by his/her assessment. The start of the surgical procedure was determined by the principal anaesthetist, once satisfied with the bilateral block levels.

The touch level was defined as the first level where touch was appreciated. The question asked of the

mother was “tell me when you first feel something touch your skin” (Hollmén grade 2).³ The testing stimulus moved from blocked to unblocked dermatomes to ensure that the mother was ‘blind’ to the stimulus until she felt something. The testing continued in a cranial direction until the mother indicated that the stimulus was as sharp as the control stimulus (Hollmén grade 0).³ This was noted as the level of block for sharp pinprick. The question asked of the mother for pinprick was “tell me when this feels as sharp as it did on your arm.” Since these block levels identify the first unblocked dermatome the data presented are one dermatome lower to represent the dermatomes blocked to the stimulus.

The primary end points were the variations observed between the two anaesthetists (A and B) in their assessments of the level of block to both touch and pinprick with the two testing methods. Secondary end points were the dermatomal differences between the anaesthetists and the comfort of the women during surgery. Intraoperative comfort was assessed at the end of surgery when the women were asked to complete two visual analogue scale (VAS) scores. The first VAS was for actual pain, and consisted of an unmarked 10-cm line with “no pain” marked at one end and “worst pain possible” at the other. The second VAS was for non-painful pulling and tugging sensations: this line was marked “no pulling or tugging at all” at one end, and “pulling and tugging very uncomfortable” at the other.

Statistical analysis

The number of subjects recruited was based on a power analysis using raw data from a previous study² and assuming a single assessment on each patient: a difference in the variation of one or more dermatomes between the assessors was taken to be clinically and statistically significant. As indicated by previous findings,² a standard deviation for the variation of 1.66 was used; β was set at 0.8 and α at 0.05. Since multiple assessments were made on each patient the power of the study is in excess of 0.9 to detect a difference of 1 dermatome.

For statistical analysis the spinal segments were numbered from S5 to C2 as 1 to 29 and were treated as interval data. The data were analysed using the software Statistical Package for the Social Sciences (SPSS) version 14.0.0 (SPSS Inc. Headquarters, Chicago, Illinois). The degree of variability in the assessed levels of block to pinprick or touch sensation between anaesthetists A and B, when using either the Neurotip™ or the Neuropen®, was assessed using the absolute deviations of the individual differences between A and B from the whole group medians. These absolute deviations from the group median were examined graphically with notched box plots, drawn with an on-line interactive programme.⁴ This latter method of comparing variability

is simple and effective.⁵ In addition, all data from each of the four assessment times were amalgamated and the overall mean bias between anaesthetists and the 95% limits of agreement were calculated, with allowance for repeated testing.⁶ Differences between anaesthetists in the assessed levels of block, and the absolute deviations from the group median were also compared with the general linear model (GLM) repeated measures test in SPSS. $P < 0.05$ was considered statistically significant. If a statistically significant difference occurred, this was to be adjusted using the Bonferroni correction for multiple significance tests and, where this correction was used, it was indicated in the results.

Results

Forty-four women were recruited to the study. Demographic and surgical details are reported in Table 1. Twenty-five anaesthetists took part in the study: three consultants, 4 staff grades, 10 specialist registrars and 8 senior house officers. Levels of experience in obstetric anaesthesia ranged from trainees with one year total anaesthetic experience in their first obstetric attachment, to a consultant with more than 25 years obstetric anaesthesia practice. These anaesthetists made up 35 different pairs, with 5 pairs being repeated once, and 2 pairs being repeated twice.

Fig. 2 illustrates the onset of the block as assessed by anaesthetists A and B with the Neurotip™ and the Neuropen®. There was no statistically significant difference in variation of block levels between the two anaesthetists for whole group data or at any time interval, using either the Neuropen® or the Neurotip™ for either sharp pinprick or touch sensations (Table 2, Figs. 3a, 3b). The median dermatomal difference between anaesthetists A and B was zero at all time intervals for both instruments and both modalities.

There were occasional wide differences between the block levels assessed by A and B with both instruments and both modalities. At the time of surgery, these wide differences were unknown and did not effect clinical management since the principle anaesthetist was not aware of the levels found by the other assessor. In retrospect, had these differences been known at the time of surgery they would have had minimal impact. In our unit touch is used to assess when the block is sufficient for surgery, so differences in pinprick levels would not affect any decision regarding the adequacy of the block.

Table 1 Patient data

Age (years)	31.5 ± 5.6
Height (cm)	162.5 ± 7.5
Booking weight (kg)	72.7 ± 15.0
Booking body mass index (kg/m ²)	26.3 ± 7.8
Gestation (weeks)	39 [35, 42]

Data are mean ± standard deviation or median [range].

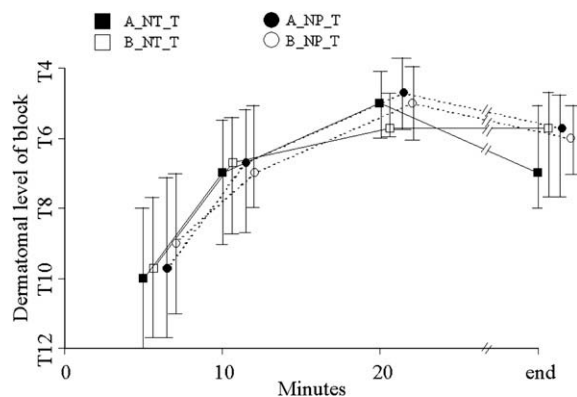


Fig. 2 Onset of block to touch as assessed by the two anaesthetists (A and B) using the Neuropen® and the Neurotip™. Median values are plotted with upper and lower quartiles represented by the error bars. The levels plotted correspond to blocked dermatomes. A_NT_T = Neurotip™ touch sensation assessed by anaesthetist A. B_NT_T = Neurotip™ touch sensation assessed by anaesthetist B. A_NP_T = Neuropen® touch sensation assessed by anaesthetist A. B_NP_T = Neuropen® touch sensation assessed by anaesthetist B.

Table 2 Mean bias and 95% limits of agreement for assessments of block level at all times by anaesthetists A and B

	Mean bias*	95% limits of agreement**
Neurotip touch	0.1	-3.1 to 3.0
Neuropen touch	0.2	-2.5 to 2.0
Neurotip sharp	-0.1	-3.1 to 3.0
Neuropen sharp	-0.2	-2.6 to 2.2

A negative value indicates that the assessment of block level by B was higher than that by A. Bias and the 95% limits of agreement are both categorised in terms of dermatomal levels.

* "Bias" is mean difference between all the pairs of measurements made by two methods.⁶

** "95% limits of agreement" are upper and lower limits of the range within which 95% of the differences between two measurement techniques are found.⁶

With touch sensation, the blocks levels were either both higher than required for surgery with both instruments, or both lower than required for surgery, or the difference had disappeared at the next assessment, or the surgery had already started and the patient was comfortable before the discrepancy arose.

The median [lower quartile, upper quartile] VAS pain scores and VAS pulling/tugging scores were 0 [0, 0.5] and 2.0 [0, 3.0] cm respectively. No patient required intra-operative analgesic supplements.

Discussion

Compared to the Neurotip™ the standardised spring loaded Neuropen® did not reduce the variability in as-

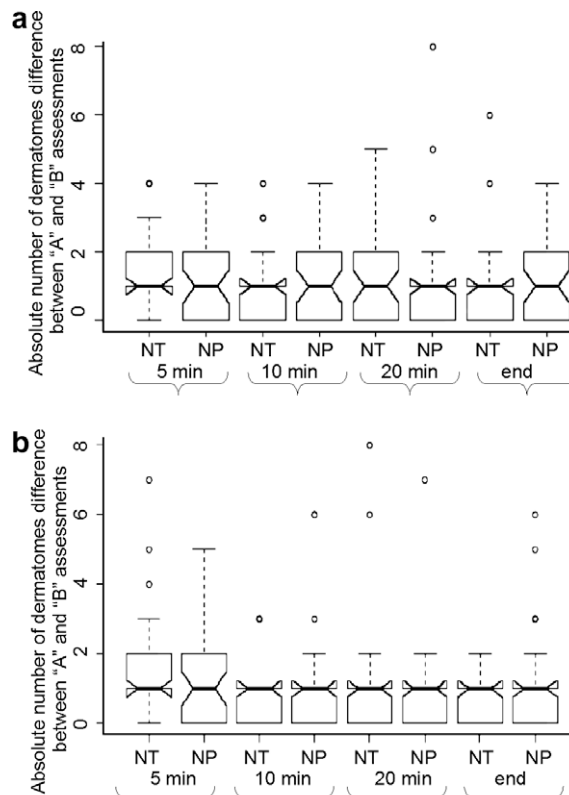


Fig. 3 (a) Notched box plots showing the absolute number of dermatomes difference at each time interval between levels of block to touch (anaesthetist A vs. anaesthetist B) using either the hand held Neurotip™ (NT) or the Neuropen® (NP). (b) Notched box plots showing the absolute number of dermatomes difference at each time interval between levels of block to pinprick (anaesthetist A vs. anaesthetist B) using either the hand held Neurotip™ (NT) or the Neuropen® (NP). The thick line is the median, the upper and lower ends of the box are the upper and lower quartiles; whiskers represent the range of values which does not meet the definition of an outlying value. If there are no outlying (or extreme) values the whiskers represent the range. The notches in the box represent the 95% confidence interval for the median.⁴ If notches overlap then there is no statistically significant difference between medians for the data sets. \circ represents extreme points, defined as cases with values greater than 3 box lengths from the upper or lower edge of the box.

sessed block levels between the two anaesthetists and there were similar wide inter-observer differences in the assessed levels of block with both instruments.

A potential limitation of our study was the non randomisation of order of use of the Neurotip™ and Neuropen® by anaesthetists A and B. While randomisation is usually an important part of a study, fortuitously, on asking later, virtually all the anaesthetists used the Neurotip™ first. This had the effect of ensuring that for the vast majority of assessments the time delay between A and B using the Neurotip™ was the same as the time delay between them using the Neuropen®. Had these

instruments been randomised by A and B it would have added the confounding factor of different time delays between the relevant assessments. One could also argue that the A and B order of the anaesthetists should have been randomised for each of the four assessments on any one patient. Randomising the anaesthetist order at each time interval would be important to avoid bias if there was some kind of interaction whereby the second assessor's levels were affected by the first. There was no evidence of such an interaction in our first study,² where the order of testing was rigidly controlled. In this current study, had this been an important factor then there would have been a difference between A with the Neurotip™ and B with the Neurotip™ and between A with the Neuropen® and B with the Neuropen®. The anaesthetists themselves were not randomised to be A or B and chose for themselves but with 25 anaesthetists and 35 different pairs, we do not feel that this is an important issue. We decided not to randomise A or B to be the principle anaesthetist as there were a number of completely new trainees, and at this very early stage of their training, this would not have been ethically sound. Thus only consultants or trainees who had been deemed competent for distant supervision (i.e. were on the resident on-call rota) took the role of principle anaesthetist.

Despite the possible limitations to our study, it is difficult to understand why two observers using the same instrument should obtain levels of block two or more dermatomes different. It is known that anaesthetists do not always interpret the distribution of dermatomes in a consistent manner,⁷ but this source of variation was eliminated in the current study by having dermatomes clearly marked on tape fixed to the midline of the patient's torso. While it is theoretically possible that an interaction between the earlier and later block assessments could sensitise or desensitise the patient to stimuli, our previous study demonstrated no consistency in the observed differences.² We had initially postulated that a possible reason for the variation might be related to different pressures being applied by different anaesthetists using the Neurotip™. Perhaps a greater pressure applied by one anaesthetist might be able to stimulate receptors in dermatomes that were blocked to a lighter pressure applied by another anaesthetist. The results of this study do not support such a conjecture. The standardised pressure stimulus from the Neuropen® did not reduce the variability between the anaesthetists in their block assessments and there were still some wide inter-observer differences in the levels of block with both instruments and both modalities. It may be that the pressures applied by all the anaesthetists with and without the Neuropen® were similar but this seems unlikely.

Outside the practice of anaesthesia, the Neuropen® is viewed as a useful, user independent, standardised assessment tool when evaluating peripheral nerve func-

tion.⁸ However, the scientific basis for such a view seems minimal. When assessing peripheral neuropathy by sharp pinprick or touch sensations, the specificity of the Neuropen® was poor at only 39%. In other words, the Neuropen® frequently indicated a lack of sensation when no neuropathy was present.⁸ This implies that the Neuropen® tip is able to make contact with the skin without being appreciated by the patient. In addition, the κ coefficient for inter-observer agreement was only 0.35 for both individual sensations, indicating poor agreement between observers.⁸ The fact that patients with intact nervous systems may not feel either stimulus from the Neuropen® suggests an alternative hypothesis accounts for the differences between observers.

It is known that skin receptor density is at its lowest on the trunk and thus the probability of stimulating a receptor with a small, single-point stimulus will be lower on the trunk than elsewhere on the body. This leads to the possibility that wide differences in block levels between anaesthetists could be the result of single point skin stimulation missing appropriate receptors. Jacobs adds further interesting observations on sensory testing by pointing out that a patient's perception of tactile sensation is idiosyncratic and influenced by a number of factors that include levels of anxiety and/or relaxation, fatigue and ambient temperature.⁹ Consequently, as a result of this idiosyncratic response the same patient is likely to provide two or three different responses to the same test over as many occasions simply due to "variation in personal circumstance".⁹ He goes on to suggest that to overcome such patient factors a more "extreme stimulus" may be required to ensure that patients recognise the stimulus as "uniform".⁹ In both this current study and the study of Paisley and colleagues⁸ touch and sharp sensations were assessed by a single prod of the skin whereas Jacobs emphasises that several such stimuli should be presented repeatedly over a small area.⁹ Such repetitious applications ensure that minor variations in application pressure are evened out and the chances of not stimulating an appropriate receptor are minimised. Data from the current study and the previous study⁸ would support the proposal that a stimulus created by a single prod of the skin, whether using touch or sharp sensation, may not always be appreciated by patients despite an intact sensory nervous system.

If skin receptor density is a factor then, as well as multiple stimuli from a single point, more continuous testing methods such as stroking, using a moving ethyl chloride spray jet or even using a wider stimulating probe, might be expected to have a greater consistency. These possibilities have never been studied in detail and the limited data presented in three separate abstracts are mixed.¹⁰⁻¹² Kocarev and colleagues,¹² using several different touch stimuli, found no difference in block levels, whether using continuous stroking or a single point stimulus. Another investigation demonstrated no differ-

ences between similar paired touch stimuli (intermittent versus continuous) but there was a significant difference between the two different touch modalities used (cotton wool, von Frey Hair).¹¹ The third study found that cotton wool stroking indicated a significantly lower level of block than the touch sensation of ethyl chloride spray or a Neurotip[®]: the latter two were not significantly different from each other.¹⁰ All three of these studies appear to have used a single investigator to make all assessments on any one patient, so these data are subject to conscious or unconscious bias that could affect the independence of the observations.

As before,² detailed analysis of individual differences in block levels revealed occasions when up to eight dermatomes difference in the block to touch or pinprick occurred. These differences were unknown at the time of surgery and so did not affect clinical management. In retrospect they would have had minimal impact because either the differences were short-lived, or both levels were at T7 and above, or surgery was already ongoing and the patient was comfortable.

In conclusion, the results of the current study suggest that there is no statistically significant difference in the variability of the levels of block assessed by two anaesthetists using the hand held Neurotip[™] or the user-independent Neuropen[®] as described.

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