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ORIGINAL ARTICLE

A randomised comparison of a hand-held Neurotip and the Neuropen for assessing loss of touch sensation during spinal anaesthesia for caesarean section

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Background: With spinal anaesthesia various methods may be used to assess the block to touch. We wished to compare the levels of block assessed using a non-standardised, assessor-dependent touch stimulus with those assessed when the same stimulus was applied in a standardised manner independent of the assessor.

Methods: In a double-blind, randomised study the levels of block to touch were assessed by two investigators, one using a hand-held Neurotip tester pin and the other using the same tester pin mounted in a spring loaded system (Neuropen). Both the testing device and the order of testing were randomised between the two observers. The dermatomes were marked on patients' torsos before surgery.

Results: Whole group data analysis in a Bland Altman plot demonstrated a median difference of 0 dermatomes between the two methods: the 5th, 25th, 75th, and 95th centiles of agreement being −2, −1, +1, and +2 dermatomes respectively. There were occasional wide differences in levels of block to touch with the Neuropen varying between seven dermatomes rostral to and four dermatomes caudal to the Neurotip. These differences were short-lived and did not affect clinical management.

Conclusion: When comparing two very similar touch stimuli, one standardised and user-independent and one non-standardised, we observed occasional wide but short lived differences in the assessed levels of block to touch. Although these differences did not affect clinical management, whether more dissimilar touch testing methods might affect clinical management remains to be seen.

Keywords: Spinal anaesthesia; Assessing sensory block; Caesarean section

INTRODUCTION

Spinal anaesthesia has become the anaesthetic technique of choice for elective caesarean section. Documentation that an adequate block has been achieved before surgery is now considered an important medico-legal requirement.[1,2] While there seems to be agreement about the dermatome range that should be blocked for caesarean section (T4/5-S5),[3,4] there is disagreement on the best stimulus or the modality to use for assessing sensory loss. Three sensory modalities are commonly used clinically to test adequacy of block: cold, sharp pinprick and touch. Studies in the literature have shown that these three modalities convey very different information and often indicate very different levels of block.[5–9]

In a discussion on the topic one of us (IFR)[10] suggested that loss of touch up to and including T5 is required to prevent pain during regional anaesthesia for caesarean section. However, there are many different ways to test touch sensation. Most of these are unstandardised and their application may be user-dependent. Whether these methods would all indicate a similar level of block in the same patient is unknown. A previous study demonstrated that touch sensation from a continuous ethyl chloride spray was equivalent to a hand-held Neurotip (Fig. 1a).[11] While an ethyl chloride spray is a reasonably controlled stimulus, not dependent on the user, its use is not recommended because of fears about flammability and pollution. A standardised reproducible mechanical stimulus may be applied to the skin with a

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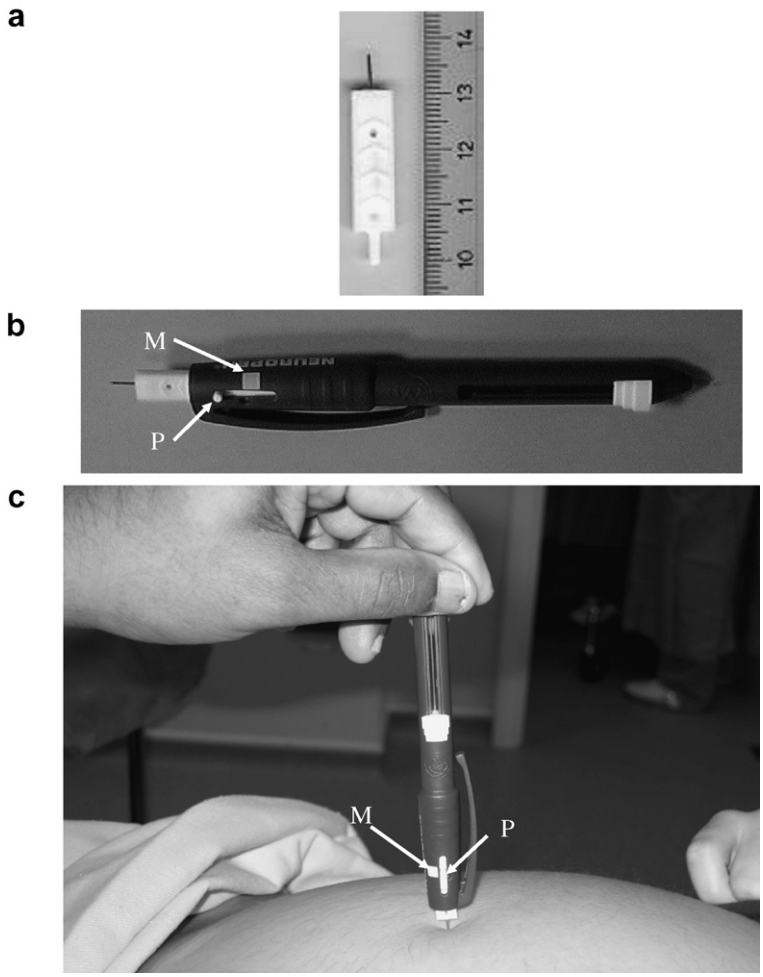

Fig. 1 (a) A Neurotip alongside a centimeter scale. (b) The Neuropen device showing the Neurotip loaded. The pointer on the side of the Neuropen is arrowed "P" and the mark with which the pointer should line up during skin testing is arrowed "M." (c) The Neuropen showing the Neurotip pressed onto the 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.

Neuropen.[12] We wished to compare our normal non-standardised testing method, the hand-held Neurotip, against the standard stimulus provided by the Neuropen.

METHODS

The study was approved by the Hull and East Yorkshire Hospitals Local Research Ethics Committee. The study population were 40 ASA I or II women scheduled for elective caesarean section under spinal anaesthesia and who gave informed consent to participate. The women were seen on the morning of surgery by one of the investigators 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 affixed down the midline of her body from the sternal notch to the umbilicus. Dermatomal levels from T3 to T10 were estimated and marked on the tape.

The women were randomly assigned to one of four groups by means of computer generated random numbers. These numbers were used to determine which one of the two devices, hand-held Neurotip or Neuropen (Owen Mumford, Oxford, UK) (Figs. 1a, b, c) was to be used by each investigator and also which investigator (IFR or NS) tested first. The randomisation codes were such that four groups of equal size were created.

1. IFR testing first with Neuropen/NS testing second with Neurotip
2. IFR testing first with Neurotip/NS testing second with Neuropen
3. NS testing first with Neuropen/IFR testing second with Neurotip
4. NS testing first with Neurotip/IFR testing second with Neuropen

The Neurotip (Fig. 1a) consists of a short-round tipped 'blunt' needle mounted in a plastic body. The non-standardised stimulus was the Neurotip, hand-held, pressed momentarily against the patient's skin. The standardised stimulus was a Neurotip mounted in the Neuropen. When ready for use, the Neuropen (Figs. 1b, c) consists of a spring-loaded Neurotip mounted in a 'pen' body so that the Neurotip protrudes from the end of the Neuropen. When the end of the Neurotip is pressed against the skin, the Neurotip is depressed into the 'pen' body (Fig. 1c). The distance the Neurotip is depressed into the Neuropen is indicated by a pointer attached to the spring. When this pointer is opposite a white mark on the body of the pen, this is equivalent to a 40-g 'pressure' (Fig. 1b, c) on the skin.

The spinal anaesthetic, consisting of 0.5% bupivacaine in 8% w/v dextrose 2.5 mL with diamorphine 0.3 mg (total volume 2.8 mL), was administered at what was estimated to be the L3/4 interspace with the woman in the right lateral position. Occasionally the sitting position was used if clinically indicated, for example in obese or scoliotic women.

At predetermined intervals (5, 10, 20, and 30 min after the spinal injection and again at the end of surgery) the block levels were assessed. A towel screen over the mother's chest ensured that she could not see when the stimulus was being applied to her skin. While the first investigator was estimating the block level with the assigned modality, the 2nd investigator was at the other end of theatre out of sight line and thus blinded to the results. The assessments by both investigators were completed in quick succession to minimise any real change in the level of block with time. In a few cases where there were two or more dermatomes difference between the testing methods and the block was below T7, an extra assessment was made at 15 min. The levels of block assessed by each investigator were recorded on separate data sheets so the investigators were blind to the levels of block obtained by each other. The start of surgical preparations was determined by IFR but this was not at any particular predetermined level of block as to do so would have partly unblinded NS and indicated that the block was at or above a certain level.

The primary end point with each modality was the level of block to touch, defined as the level where the first sensation of touch was appreciated. The question asked of the woman was, "Tell me when you feel something touch your skin" (Hollmén grade 2).[13] By testing from blocked to unblocked dermatomes the patient is "blind" to the stimulus until she feels something and this question identifies the first unblocked dermatome. The data presented in this paper are one dermatome lower, to represent the dermatomes blocked to the stimulus. A clinically significant difference in the assessed block levels was taken to be greater than ±1 dermatome.

Secondary end points were the quality of anaesthesia as defined by the need for any intra-operative supplements and a visual analogue pain score (VAPS) obtained at the end of surgery. The VAPS consisted of an unmarked 10-cm line with "no pain at all"(0) written at the left hand end and "worst pain possible" (10) written at the right hand end. This was shown to the women at the end of surgery and they were asked to mark the line to indicate how much pain they had experienced during surgery.

Forty patients were studied. This number was based on a power analysis using unpublished data and assuming a single assessment on each patient: a difference of one or more segments was taken to be statistically significant. As indicated by the unpublished data, a standard deviation of the difference between testing methods of 0.8 was used; β was set at 0.8 and α at 0.05. This suggested a need for 10 patients per group (4 groups). Since multiple assessments were made on each patient the power is actually higher than 0.8 and for the amalgamated data the power is in excess of 0.99 to detect a difference of 1 dermatome. For statistical analysis the spinal segments were numbered from S5 to C2 as 1 to 29 and these were treated as interval data. Statistical analysis was performed using the software *Statistical Package for the Social Sciences* (SPSS) version 11.5 (SPSS Inc. Headquarters, Chicago, Illinois). Initial data analysis to investigate differences related to who tested with which method (groups 1-4) was performed using the general linear model (GLM) univariate model in SPSS. A Bland Altman plot was used to illustrate the range of differences in block levels between the assessment methods at each time interval.[14,15] The Wilcoxon signed ranks test for pairs of related samples was used to test for any statistically significant difference between the two methods. $P < 0.05$ was taken as indicating significance.

RESULTS

Forty women were recruited into the study but a possible confounding factor occurred a little over half way through the study: due to a fire at the production facility diamorphine supplies ceased and 16 women received fentanyl 25 μg instead of diamorphine 300 μg. However initial analysis of the data did not demonstrate any statistically significant difference between Neuropen levels or hand-held Neurotip levels whether fentanyl or diamorphine had been used or whether IFR or NS tested the block first with the Neurotip or Neuropen. Thus all data were amalgamated for further analysis. Table 1 illustrates some basic demographic and surgical data on the 40 patients studied.

Table 1. Patient data

Age (years)	30.3 (5.7)
Height (cm)	161.6 (7.1)
Weight (kg)	72.3 (15.6)
Gestation (weeks)	38.5 [34, 41]
Start of surgery after spinal (min)	13.8 (4.5)
Duration of surgery (min)	50.8 (9.6)

Data are mean (standard deviation), or median [range].

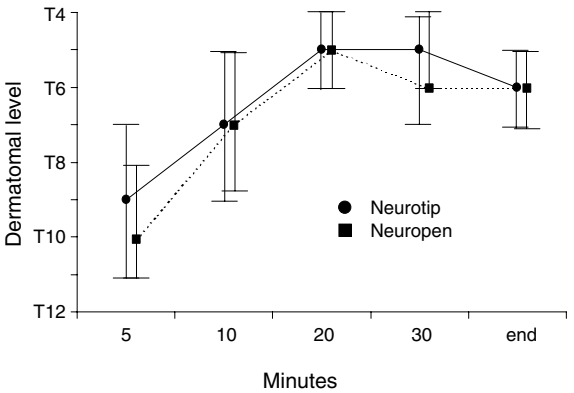

Fig. 2 Onset of block as assessed by the two methods of touch testing. Median values are plotted with upper and lower quartiles represented by the error bars. The levels shown correspond to blocked dermatomes.

The onset of the block to touch as assessed with the two testing methods is illustrated in Fig. 2. There was no statistically significant difference between the levels of block assessed with the two methods at any of the assessment times and the median difference was 0 dermatomes (Fig. 3).

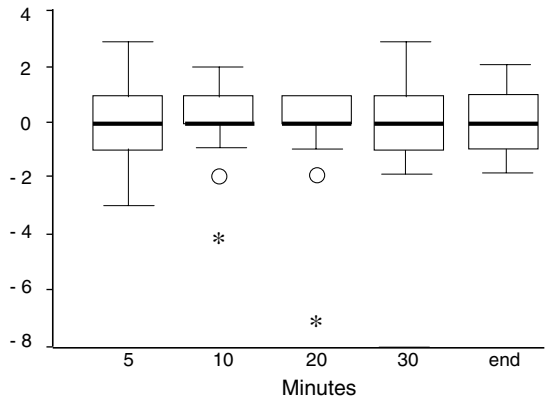

Fig. 3 Box plots showing the number of dermatomes difference between levels of block to touch assessed by the hand-held Neurotip and the Neuropen at each of the time intervals. A negative value indicates that the Neuropen block was higher than the Neurotip block. Thick line: median value; upper and lower edges of the box: upper and lower quartiles; whiskers: defined within SPSS as the most distant point which does not meet the definition of an outlying point. If there are no outliers or extreme values the whiskers represent the range. O: outlying points, defined as cases with values between 1.5 and 3 box lengths from the upper or lower edge of the box. *Extreme points, defined as cases with values more than three box lengths from the upper or lower edge of the box.

A Bland Altman plot (Fig. 4) was constructed for the data amalgamated from all assessment times. Since the data are not normally distributed, the median difference is shown along with the limits of agreement as the 5th and 95th centiles.[15] There were occasional wide differences in the assessment of block to touch with the Neuropen varying between seven dermatomes rostral to and four dermatomes caudal to the Neurotip. These differences were short lived and did not affect clinical management.

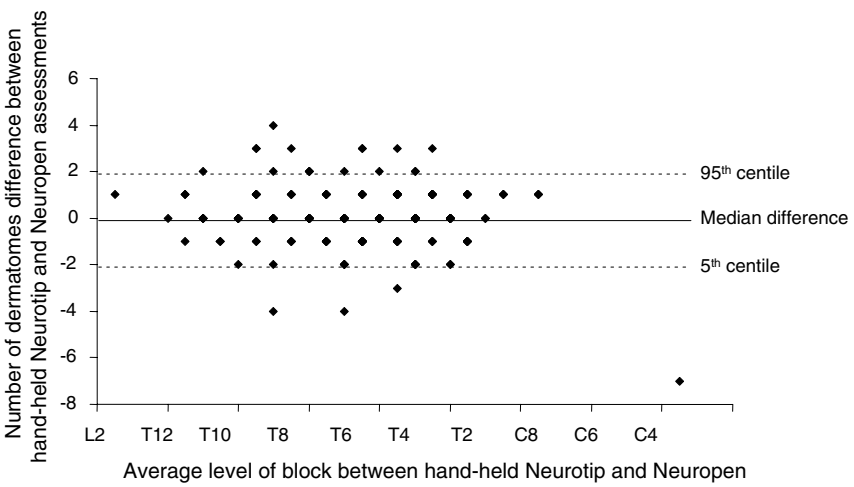

Fig. 4 Bland Altman plot showing the number of segments difference between the block assessed by the hand-held Neurotip and the Neuropen plotted against the average of the levels of block to touch assessed by the hand-held Neurotip and the Neuropen. The 5th and 95th centiles for limits of agreement are shown. The 25th and 75th centiles for limits of agreement were −1 and +1. A negative difference indicates that the Neuropen block was higher than the Neurotip block. Because of superimposition of data points not all the individual plotted points are visible.

On closure of the rectus sheath (at 63 min in a 70-min procedure) one patient suddenly developed pain (VAPS score 77) with sweating, retching, and vomiting. This was successfully treated with a 100-μg i.v. bolus of fentanyl along with nitrous oxide in oxygen and air (F_IN_2O 60%). The levels of touch at this time were T10 to both Neurotip and Neuropen. No other patient had any pain.

DISCUSSION

Our whole group data, comparing the level of block as assessed by a standardised touch stimulus (Neuropen) with that assessed by a non-standardised touch stimulus (hand-held Neurotip), demonstrated no statistically significant difference between the two methods. However, although the group median difference between the assessment methods at all time intervals was zero dermatomes (Fig. 3), a more detailed analysis revealed some wide differences between the levels of block assessed by the two methods (Fig. 4). At first sight such wide differences (up to 7 dermatomes) might be expected to have had some impact on clinical management, but in reality, this was not so. The differences were short-lived and had disappeared by the time of the next assessment.

It is not clear why two closely related assessment methods should indicate levels of block several dermatomes apart. One possibility is inter-investigator differences in the interpretation of the dermatomal levels. This problem was clearly demonstrated by Congreve and colleagues.[16] However, this was not the case in the current study. Our methodology was specifically chosen to ensure that both investigators could relate accurately their observed level of block to the same dermatomes, as marked on the tape. Another possibility is that after having her block level assessed by one method the patient became sensitised (or desensitised) to the testing and responded differently to the second method. There was no evidence of any such effect whether based on which testing method was used first, or which investigator tested first. The observed differences were inconsistent.

We feel there are two possible explanations for the intermittent differences in block levels. First, it is possible that the observed differences are related to receptor density and the probability of stimulating an individual touch receptor with a single point. If this were to be the case then, theoretically, one would expect continuous touching methods such as stroking, or methods that involve a larger stimulus area to have a greater inter-method consistency, but this has never been the subject of detailed investigation. Three studies, presented as abstracts, have observed a variable relationship between different methods of touch assessment including stroking and single point touch.[17–19] Kocarev and colleagues found that it was impossible to distinguish between various touch methods (Neuropen: a single point, Neurotip stroking, cotton wool stroking, von Frey hair: a single point, von Frey hair stroking).[19] Lewis and colleagues observed a significant difference between levels of block assessed by cotton wool or a von Frey hair, but there was no difference between cotton wool stroking and intermittent touch, or between the von Frey hair stroking and single point touch.[18] Mukherjee and colleagues had mixed findings with no difference observed between the touch sensations of ethyl chloride spray (continuous) or Neurotip (single point touch) but cotton wool stroking was significantly different from both the ethyl chloride and the Neurotip.[17] The limited data available in these three abstracts do not enable us to understand the methodology or allow us to interpret the data in detail. Different endpoints were used in the assessment of the blocks and all three studies present only whole group data, so differences between the methods at individual assessment times are unknown. Finally, all three studies appear to have used a single investigator to make all the assessments on any one patient: the data are thus subject to conscious or unconscious bias which could affect the independence of the observations.

The second possible explanation for the intermittent differences in block levels may be that the hand-held Neurotip was applied with widely varying pressure, resulting in over- or under-stimulation of receptors compared to the standardised Neurotip. The Neuropen has been found to be a sensitive device compared to the standard quantitative sensory threshold measures for assessing peripheral nerve function in diabetic patients.[12] If inter-investigator variability in applied pressure to a hand-held Neurotip is an important factor resulting in different interpretations of block levels then the Neuropen, with its standardised pressure, should reduce variation in block assessment between investigators. A standardised touch stimulus such as the Neuropen would be of value only if more consistent than the other user-dependent methods of assessing block to touch sensation. A study to compare the consistency of block assessments between investigators when using either the hand-held Neurotip or the Neuropen is currently under way.

In conclusion, the group data of the current study suggest that there is no statistically significant difference between the levels of block assessed by the hand-held Neurotip and the Neuropen. However, detailed analysis of the differences in block levels at individual assessment times reveals occasions when up to seven dermatomes difference in the block to touch may occur. In this study, these differences did not affect clinical management because either the differences were short-lived, or both levels were T7 and above, or surgery was ongoing and the patient was comfortable.

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