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ORIGINAL ARTICLE

A comparison of a Neuropen monofilament and ethyl chloride for assessing loss of touch sensation during combined spinal–epidural anaesthesia for caesarean section☆

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ABSTRACT
Background: Before caesarean section is performed under regional anaesthesia the block should be assessed, preferably using a touch stimulus. What constitutes a touch stimulus remains unclear. The aim of this study was to compare a Neuropen monofilament with ethyl chloride in the assessment of touch.
Methods: Forty women undergoing elective caesarean section received combined spinal–epidural anaesthesia. The upper dermatome spread was assessed using touch to a monofilament and ethyl chloride and cold to ethyl chloride at 5, 10, 15 and 20 min after intrathecal injection and again at the end of surgery. Visual analogue pain scores and Apgar scores were collected.
Results: Two one-sided test analysis demonstrated equivalence for Neuropen touch and ethyl chloride touch within one dermatome ($P < 0.0001$). Wilcoxon post tests showed that Neuropen touch was marginally lower than ethyl chloride touch ($P = 0.0056$). The median level of block to touch using both stimuli was below T5 at all time points. Pain scores had a median value of 0 cm and Apgar scores were 10 in all infants at 10 min.
Conclusion: Data from this study suggest that a Neuropen monofilament and ethyl chloride are equivalent when used to assess a block to touch. However, subtle differences in the level of block to touch indicate that sensory level assessments should state the stimulus used. As the block to touch was below T5 at all time points, when opioids are added to local anaesthetics, T5 might no longer represent a necessary goal to ensure the absence of pain during caesarean section.

Keywords: Neuropen; Monofilament; Ethyl chloride; Sensory level; Combined spinal–epidural; Caesarean section

Introduction

The majority of pregnant women undergoing elective caesarean section in the UK receive regional anaesthesia.[1] This is considered to be safer than general anaesthesia but carries the risk of intraoperative discomfort, which is unpleasant for the woman and the leading cause of complaint against obstetric anaesthetists.[2] To minimise this risk, the adequacy of regional anaesthesia must be assessed before surgery, usually by testing the level of block. This assessment can be made using a variety of sensory modalities such as cold, pinprick and touch. Current knowledge favours the use of a touch stimulus and the inclusion of the T5 dermatome as the upper block level to ensure the absence of pain during caesarean section.[3–5]

Although clarity exists in terms of the correct sensory modality and level of block, the correct mechanism of delivering a touch stimulus is less apparent. Comparisons of ethyl chloride, a Neurotip and a Neurotip mounted in a Neuropen have been reported.[6,7] The Neurotip mounted in a Neuropen is a device designed to assess reduced sensation to sharpness and pain in small nerve fibres. We have previously used ethyl chloride to assess level of block to touch after combined spinal–epidural (CSE) anaesthesia. It is administered in an individual droplet fashion from a height of approximately 5 cm above the skin. Maintaining a block to touch at T5 or above using this technique as an assessment tool has been shown to be satisfactory for caesarean section under CSE using bupivacaine and fentanyl.[8] It was decided that a comparison should be made between a Neuropen monofilament, a device which is

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specifically designed to assess touch and pressure sensation in large nerve fibres, and ethyl chloride.

Methods

The study was approved by the Oxfordshire Research Ethics Committee and following this, women booked for elective caesarean section under CSE anaesthesia were invited to participate. Written informed consent was obtained from all subjects. Exclusion criteria included diabetes mellitus, pregnancy-induced hypertension, neurological disease, multiple pregnancy, gestation less than 36 weeks and body mass index greater than 35 kg/m^2.

The Neuropen monofilament (Owen Mumford, Oxford, UK) is a retractable, reusable filament mounted in a plastic body (Fig. 1). It is fully deployed and locked in position before use and is then pressed at 90° to the skin with increasing force. The filament begins to bow at which point 10 g of force are exerted on the skin. This test assesses touch and pressure in large nerve fibres and the instrument has been shown to be highly accurate.[9]

All women received oral ranitidine 150 mg on the evening before and on the morning of surgery. With the latter dose they also received oral metoclopramide 10 mg. They wore thromboembolic deterrent stockings throughout the anaesthetic and surgical period. The CSE was performed by a member of the obstetric anaesthetic team (specialist registrar and above). After 16-gauge intravenous access had been obtained, monitoring in the form of automated non-invasive blood pressure, electrocardiography and pulse oximetry was attached. A fluid co-load of 1000 mL warmed compound sodium lactate was administered during the CSE. A needle-through-needle CSE technique was used. The woman was positioned sitting and the L3–4 intervertebral space identified. A 16-gauge Tuohy needle was used to locate the epidural space using loss of resistance to saline in an 8 mL loss of resistance syringe. A 27-gauge atraumatic spinal needle was passed through the Tuohy needle and after confirmation of free flow of cerebrospinal fluid, bupivacaine 12.5 mg in dextrose 8% w/v and fentanyl 15 μg were injected intrathecally. The beginning of the spinal injection was used as time zero. Following this injection an epidural catheter was inserted and the woman was positioned supine with a left lateral tilt and non-invasive blood pressure measurement was taken every minute. The use of vasopressors and further intravenous fluid was left to the discretion of the anaesthetist, as was supplementation of the block by the administration of epidural local anaesthetic.

Fig. 1 The Neuropen, with the monofilament fully deployed from its distal end, shown next to a centimetre rule.

Following positioning an investigator, not involved in siting the block, prepared the woman for assessment. The same investigator was used for all patients to allow consistency. A length of Finepore microporous surgical tape (Premier Healthcare and Hygiene Ltd, Gateshead, UK) was fixed down the midline of the woman's body from symphysis pubis to sternal notch and dermatomes from T12 to T2 were marked on the tape using a dermatomal map as a reference. A screen was erected across the woman's neck to ensure she was unable to see her abdomen and chest.

Block testing was performed at 5, 10, 15 and 20 min after intrathecal injection and again at the end of surgery. At each time point the right side of the body was assessed followed by the left. The woman was asked the question ''tell me when you feel something touch your skin'', a specific question used successfully by Soundararajan et al.[7] The Neuropen monofilament was then applied at 90° to her skin in the mid-clavicular line at L1. This was repeated at approximately 2 cm intervals ascending parallel to the sagittal plane until the woman responded. The dermatome immediately below this level was then documented (the last blocked dermatome). The same procedure was then performed using individual ethyl chloride droplets administered from an aerosol canister held 5 cm above the skin (Ethyl Chloride Fine Spray, Acorus Therapeutics Ltd, Chester, UK). Once ethyl chloride had been detected the woman was asked ''tell me when you feel something cold on your skin'' and the ethyl chloride droplets were administered up her body until she responded. Again, the dermatome immediately below this level was documented. The first assessment was always made by the investigator but subsequently the anaesthetist who sited the block made assessments at their discretion using ethyl chloride. At these points the investigator moved away from the woman so as to be completely blind to the anaesthetist's finding. Surgery was allowed to commence when the anaesthetist had checked the block and was satisfied that the level to touch included T5. The anaesthetists used ethyl chloride to make their final block assessment but their exact technique varied from individual to individual and the length of marked tape was not in place.

The primary end points of the study were the block level to touch for the Neuropen monofilament (NT) and the block level to touch for ethyl chloride (ECT). Secondary end points were the block level to cold (ECC), a 10 cm visual analogue pain score (0 cm representing no pain and 10 cm representing worst possible pain) which was completed by the woman at the end

of the study and Apgar scores of the infant at 1, 5 and 10 min after delivery.

Statistical analysis

To estimate sample size the clinically important difference between NT and ECT was first defined as one or more dermatomes. An equivalence analysis using the two one-sided test (TOST) method was designed to test the null hypothesis that the two modalities differed by one or more dermatomes. Data were taken from a pilot study and the standard deviation of differences between NT and ECT was found to be 1.5 dermatomes. The power was set at 0.90 and, as there were up to five dependent comparisons, the overall alpha error was maintained at <0.05 by using a Bonferroni corrected two-sided P value of <0.0102. A minimum of 35 subjects were required to find a one dermatome difference as significant at an overall two-sided $P < 0.05$ or to conclude equivalence within this margin. It was planned therefore to study 40 women.

Raw data were examined for Gaussian distribution using the D'Agostino omnibus test and frequency histograms and were subjected to parametric and nonparametric analyses as required. Block levels for the Neuropen and ethyl chloride were analysed using repeated measures analysis of variance (RMANOVA) and Friedman repeated measures analysis (FRMA) with Bonferroni corrected post tests as appropriate. Differences in median block levels were estimated using Hodges–Lehmann analysis. To test if the sensory assessments were equivalent, the two one-sided tests (TOST) method and the 90% confidence interval (CI) approach were used. Both TOSTs had to each return $P < 0.05$ to reject the null hypothesis of difference in order to conclude the alternative hypothesis of equivalence within the defined margin. To examine agreement, within-subject or intraclass correlation coefficients were estimated using analysis of covariance (ANCOVA). Differences in block levels were presented in Bland–Altman plots in order to estimate the bias and to demonstrate the within-subject 95% limits of agreement (LA) using the 2.5–97.5 centiles.[10] Data were analysed using Number Cruncher Statistical Systems (NCSS) 2007, NCSS Inc., Kaysville UT and StatXact 8.0, Cytel Inc., Cambridge MA.

Results

A total of 40 women were recruited to the study between January and April 2009. There were no drop outs. All women received a CSE with hyperbaric bupivacaine and fentanyl. In 37 women the CSE was performed in the sitting position but in three women it was performed in the left lateral position due to preference of the anaesthetist and because of patient discomfort in the sitting position. Demographic, obstetric and temporal patient data are shown in Table 1. Significantly the last preoperative study assessment occurred 20 min after intrathecal injection but surgery did not begin until an average of 12.6 min later. This period of time was used by the anaesthetist to re-position the woman and supplement the block with epidural local anaesthetic if warranted. Ten women received epidural local anaesthetic supplementation before the onset of surgery. In nine women this was administered after the 20 min block check and in one woman it was administered immediately before the 20 min block check.

Two one-sided test analysis (Wilcoxon tests) for an equivalence margin of plus or minus one dermatome for NT and ECT was significant ($P < 0.0001$) at both extremes, demonstrating equivalence. In addition, as the more conservative 95% confidence interval (compared to 90% CI) for the median difference of −0.8 to −0.5 was also contained within plus or minus one dermatome range, equivalence for NT and ECT was confirmed.

Agreement was assessed using intraclass correlation (r_i). For NT with ECT, r_i was 0.89 ($P < 0.0001$) and for NT with ECC, r_i was 0.60 ($P < 0.0001$). Agreement was further assessed using Bland–Altman plots (Figs. 2 and 3). As the data did not follow a Gaussian distribution a 2.5–97.5 centile approach was used. The within-subject median bias (95% LA) for NT – ECT was −0.2 (−2.1, 0.7) and for NT – ECC was −4.9 (−7.5, −1.9) dermatomes.

The onset of block, as assessed by different stimuli, is shown in Figs. 4 and 5. Block levels were found to differ significantly from Gaussian distributions, the Neuropen and ethyl chloride touch data were positively skew and the ethyl chloride cold levels were negatively skew.

Table 1 Demographic, obstetric and temporal data

Age (years)	34.2 (4.9)
Height (cm)	163.3 (7.8)
Weight (kg)	65.7 (8.8)
Body mass index (kg/m^2)	25 (3.3)
Gestation (weeks)	39 [37–40]
Indication	
Previous caesarean section	26
Breech	3
Previous traumatic vaginal delivery	3
Previous uterine surgery	2
Fetal macrosomia	1
Dilated aortic root (Marfan's)	1
Transverse lie	1
Placenta praevia	1
Symphysis pubis dysfunction	1
Back pain	1
Start of surgery after spinal (min)	32.6 (6.9)
Duration of surgery (min)	43.5 (12.8)

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

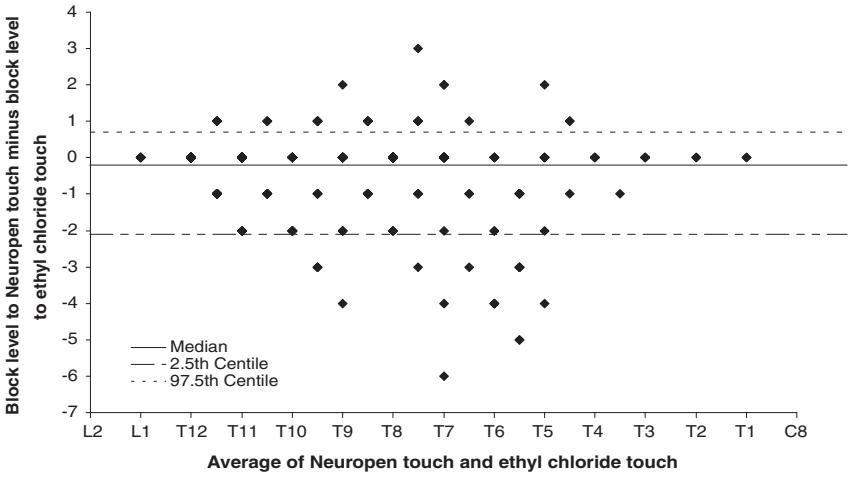

Fig. 2 Bland Altman plot comparing the difference in block level for NT and ECT with the average level of block for the two stimuli. The median difference is shown along with the 2.5th and 97.5th centiles. A positive difference suggests that the level of block for NT is higher than that for ECT. A total of 400 points have been plotted (both sides of the body at each point in time) but due to overlap all the points are not visible. NT = Neuropen monofilament; ECT = block level to touch for ethyl chloride.

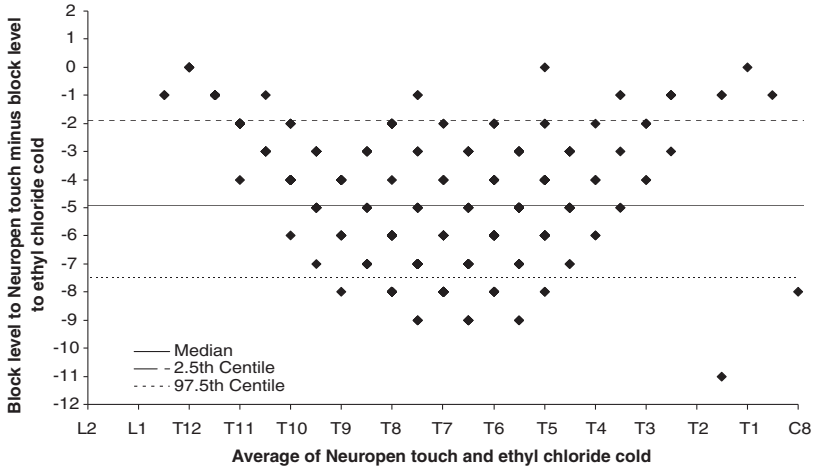

Fig. 3 Bland Altman plot comparing the difference in block level for NT and ECC with the average level of block for the two stimuli. The median difference is shown along with the 2.5th and 97.5th centiles. A positive difference suggests that the level of block for NT is higher than that for ECC. A total of 400 points have been plotted (both sides of the body at each point in time) but due to overlap all the points are not visible. NT = Neuropen monofilament; ECC = block level to cold for ethyl chloride.

There were significant differences (FRMA) for the three stimuli for sensory level ($P < 0.0001$), side of testing ($P = 0.004$) and time ($P < 0.0001$). Wilcoxon (Bonferroni corrected) post tests confirmed that NT and ECT were both significantly lower ($P < 0.001$) than ECC and that NT was marginally and significantly lower ($P = 0.0056$) than ECT (Table 2). Overall, left sided sensory levels were significantly higher ($P = 0.012$) by 0.5 dermatomes (95%CI 0.2, 1.0) than right.

Pain scores collected at the end of surgery had a median value of 0 cm and an interquartile range of 0–0.8 cm. Twenty one women reported a score of 0 cm. In those women with a pain score of 0 cm the median (interquartile range) block level for NT was T11 (T10–T11) and for ECT was T10 (T10–T11) at the end of surgery. Three women received intraoperative epidural local anaesthetic. In two cases surgery was prolonged and the epidural local anaesthetic was given as prophylaxis against discomfort at 72 and 78 min after intrathecal injection. Only one woman complained of intraoperative discomfort. This occurred in prolonged surgery during which the level of block was thought to have fallen. Bupivacaine was administered via the epidural at 69 min after intrathecal injection. This relieved the discomfort and surgery was allowed to continue.

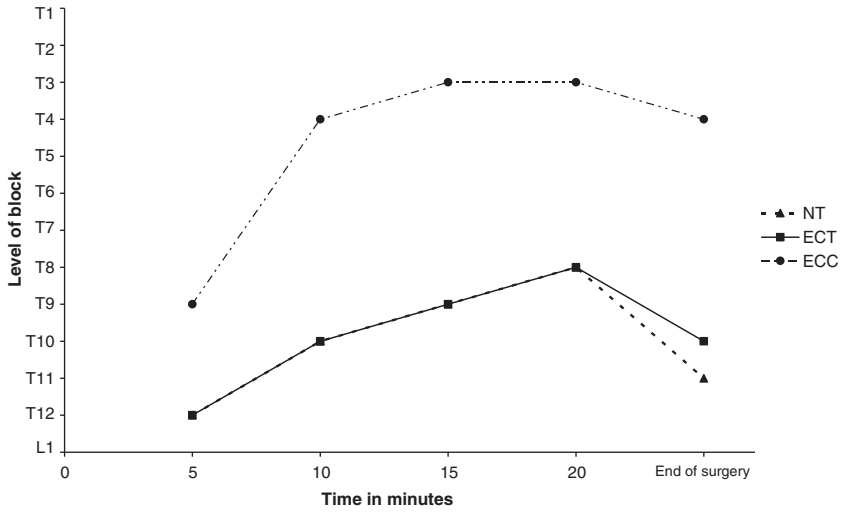

Fig. 4 Onset of the block on the right side. The points represent median values.

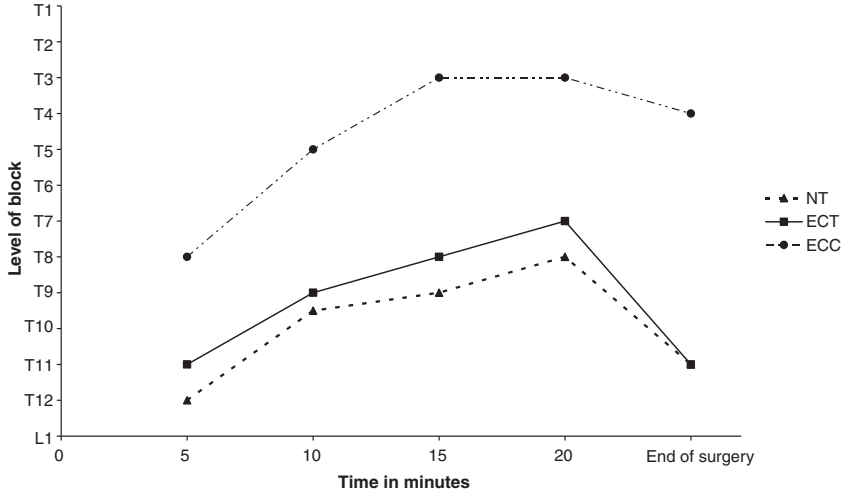

Fig. 5 Onset of the block on the left side. The points represent median values.

Table 2 Wilcoxon (Bonferroni corrected) post tests comparing NT and ECT, NT and ECC and right and left sides

	Median	Interquartile range	Difference	95% CI	*P* value
NT	T10	T11–T9			
ECT	T9	T11–T8	−0.5	−0.8, −0.5	0.0056
NT	T10	T11–T9			
ECC	T4	T5–T3	−5.5	−6.0, −5.0	<0.001
Right	T8	T9–T6			
Left	T8	T9–T6	−0.5	−0.2, −1.0	0.012

NT = Neuropen monofilament; ECT = block level to touch for ethyl chloride; ECC = block level to cold for ethyl chloride; T = thoracic dermatome.

At 1 and 5 min, Apgar scores had a median value of 10 with a range of 6–10. At 10 min all the infants had an Apgar score of 10. There were no admissions to the special care baby unit.

Discussion

The aim of this study was to compare ethyl chloride and a Neuropen monofilament in the assessment of touch

sensation before caesarean section. Four hundred assessments were made in 40 women and equivalence was confirmed within one dermatome. This suggests that a Neuropen monofilament could be used as an alternative to ethyl chloride in assessing loss of touch sensation after central neuraxial blockade. This is an attractive proposition as the Neuropen monofilament is neither flammable nor polluting, unlike ethyl chloride and, being reusable, it might prove to be financially less costly. The Neuropen monofilament is also a standardised stimulus, as it accurately delivers a single point 10 g force each time it is used.[9] Ethyl chloride, on the other hand, is a stimulus that may be a single point if it is administered carefully from the aerosol but can easily become a multiple point stimulus if increased pressure is inadvertently applied to the aerosol top. Also, the force applied by an ethyl chloride droplet is not standardised. It varies depending on the pressure used to drive it from the canister and the height from which the droplet falls. In addition the area of skin over which the ethyl chloride droplet covers will vary with droplet volume, unlike the Neuropen monofilament which has a distal end of fixed area.

Although TOST analysis confirmed that Neuropen touch and ethyl chloride touch were equivalent within one dermatome, there were some individual wide differences. On occasions the Neuropen detected the level of block to touch as up to 3 dermatomes higher and 6 dermatomes lower than ethyl chloride. The fact that a total of 13 women received supplementation of their block with epidural local anaesthetic might be suggested as a cause for this. However, on closer examination of the data, individual wide differences began to appear as early as 10 min post intrathecal injection, long before any epidural supplementation. This finding is very similar to that seen in a study comparing two different methods of assessing touch after spinal anaesthesia; a hand-held Neurotip and a Neurotip mounted in a Neuropen.[7] It was suggested that the individual wide differences might be related to differences in receptor density and therefore the probability of stimulating a receptor with a single point. If this were the case in our study then one might expect ethyl chloride to detect a level of block lower than the monofilament because ethyl chloride droplets, although administered individually, occasionally appeared as multiple droplets or individual droplets in quick succession. There would be a greater probability of stimulating a receptor and the level of block would be lower than with the single point monofilament. In fact the analysis of bias suggested that the block tended to be slightly lower with the monofilament. Alternatively, individual wide differences could exist because of difficulties in standardising the force of stimulus provided by the ethyl chloride droplets or distraction of the woman during block assessment. It is also possible that individual block assessments were influenced by testing of the block by the anaesthetist within the study period.

The bias toward the level of block with the monofilament being slightly lower than with ethyl chloride suggests that there are subtle differences between these two stimuli in their assessment of touch. This finding might represent a spectrum within the modality of touch whereby an increasing force of touch stimulus applied to the skin recruits increasing numbers of touch fibres. As the number of recruited fibres increases, the likelihood of a nerve impulse being propagated by an unblocked nerve fibre increases. It could be suggested that the Neuropen monofilament is slightly more 'forceful' than ethyl chloride and therefore detects slightly lower block levels to touch. Differences in levels of block to touch using different stimuli have been seen in other studies and therefore when assessing a block we should state exactly what stimulus was used to elicit touch.[11]

It is known that after both spinal and epidural anaesthesia there exists a zone of differential block at the cranial limits with loss of cold sensation lying several dermatomes higher than touch sensation.[12,13] It has also been shown that the relationship between these levels is not always constant and therefore one cannot predict the level of block to touch from that of cold.[6] In making a comparison between the Neuropen monofilament and ethyl chloride it was felt important to assess the relationship between the level of block to touch, as detected by the monofilament, and the level of block to cold. We found a significant difference between these two levels with the level of block to the monofilament, being significantly lower than that to cold. This finding was evident as early as 5 min post intrathecal injection, with a difference of up to nine dermatomes at this time point. Epidural local anaesthetic was therefore unlikely to be the sole cause of the differential block, as this was administered immediately before or after the 20 min time point. Although the Neuropen detected lower levels than ethyl chloride cold, the relationship was quite variable adding further to evidence that one cannot predict the level of block to touch from the level of block to cold. The behaviour of the Neuropen monofilament with respect to ethyl chloride cold was very similar to that found by Russell when he compared a Neurotip touch stimulus with ethyl chloride cold.[6] However, Russell found a median difference of 2 dermatomes between the Neurotip and ethyl chloride whereas we found a difference of almost 5 dermatomes between the monofilament and ethyl chloride cold. This possibly represents a difference between the Neuropen monofilament and the Neurotip in terms of intensity of stimulation of receptors or it might reflect a difference in the methods of testing for cold used in the two studies. It is also possible that the difference in level of block between the two stimuli was accentuated in our study by epidural supplementation.

Whilst examining data for differences in block level between different stimuli, it was noted that there were also differences between sides of the body. Levels were slightly higher on the left than on the right and it is possible that this was as a result of positioning women supine with left tilt after intrathecal injection of hyperbaric bupivacaine and that three women received their anaesthetic in the left lateral position. Also the right side of the body was always assessed before the left meaning that there was time for the block to rise on the left whilst the right side was being assessed.

Although levels of block to cold were relatively high after 20 min, high enough to be acceptable to many UK anaesthetists,[14] median levels of block to touch with both stimuli were still low, below T5. This might be explained by the fact that we positioned the women sitting and used hyperbaric bupivacaine which spreads under the effect of gravity and therefore pools when patients are sitting.[15,16] However, a recent study showed that block levels reached a maximum of T5 after 10.6 min when CSEs were performed in the sitting position using only 9 mg hyperbaric bupivacaine 0.5% and fentanyl 10 μg.[17] It should be noted that the participants in this study were on average 10 cm shorter in stature than in our study. It has also been shown that the ED50 to achieve a block to T5 using hyperbaric bupivacaine 0.5% in a spinal anaesthetic performed in the sitting position is 9.95 mg.[18] The discrepancy in level of block to touch between these studies and our study after an appropriate intrathecal dose of local anaesthetic delivered in the sitting position probably represents differences in the exact method used to assess the block. For example in the work by Tyagi et al., blocks were assessed by complete loss of sensation to pinprick.[17] It is unclear whether these assessments represented loss of sharp sensation or a complete loss of touch sensation and as such makes it difficult to draw comparisons. This highlights the importance of giving a very clear description of how a block is assessed when a study is performed.

Sometimes anaesthetists have difficulty correctly identifying dermatomes and this could represent another reason for the low block levels found in our study.[19] However, this issue was addressed by the use of a dermatomal map to improve accuracy and a length of tape to improve precision of dermatome identification. This simple method has been used by other authors in studies involving block assessment.[7] Another explanation could be the exact method of recording the block. It has been shown that different anaesthetists, if testing the same block, will record different levels.[20] Some might identify the level where sensation is first detected while others might identify the level where sensation reaches peak intensity. Yentis described a level where as one ascends, sensation no longer changes.[21] This level is likely to be several dermatomes higher than the level of the last blocked segment to touch. We recorded the level of the last blocked segment to touch because it can be objectively identified, the patient either responds or they do not, and it has been used in other studies of block assessment therefore allowing comparison.[6,7]

Although median levels of block to touch appeared relatively low before surgery and were even lower after surgery, only one woman complained of intraoperative discomfort. An explanation might lie in the fact that the intrathecal component of the CSE comprised local anaesthetic and opioid in combination. When these agents are used together, the level of block required to ensure pain-free surgery might not need to be as high as T5. Although this has been suggested by other authors,[22] in our study there was a period of time between the 20 min block assessment and the start of surgery when several women received epidural local anaesthetic and some were repositioned by the anaesthetist. The level of block may have risen during this time. This might have meant that when uterine manipulation took place, the period of time when the block needs to be particularly dense, levels might have been much higher than those documented at 20 min.

In conclusion, data from this study show that a Neuropen monofilament and ethyl chloride are equivalent, within one dermatome, when used to assess a block to touch. However, on closer examination of the data, there were occasional large differences in the level of block to touch and the Neuropen monofilament tended to indicate slightly lower levels than ethyl chloride. It is therefore important to state exactly what stimulus was used to elicit touch when a block is assessed. Using both methods to detect touch, at all times median block levels were lower than T5. Only one woman complained of intraoperative discomfort therefore when opioids are added to local anaesthetics, T5 might no longer represent a necessary goal to ensure the absence of pain during caesarean section. Further work would need to be done to validate this claim.

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