The effect of epidural needle type on postdural puncture headache: a randomized trial

[L'effet du type d'aiguille de péridurale sur les céphalées post-ponction durale : une étude randomisée]

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Purpose: A prospective, randomized trial in labouring parturients was undertaken to assess whether the 18G Special Sprotte™ epidural needle is associated with a lower incidence of accidental dural puncture (ADP) in comparison with the 17G Tuohy needle. A secondary purpose was to determine if the incidence of postdural puncture headache (PDPH) differed between groups when ADP occurred.

Methods: Following Institutional Review Board approval 1,077 parturients requesting epidural analgesia at three tertiary obstetrical units were randomized to epidural catheter insertion with a 17G Tuohy or 18G Special Sprotte™ needle. Patients were followed for seven days by a blinded assessor to determine the occurrence of PDPH using standardized criteria. If postural headache or neck ache presented, an ADP was diagnosed even if cerebrospinal fluid (CSF) was not observed at insertion. This subgroup was followed daily to assess headache characteristics and response to blood patch.

Results: Six Tuohy group patients, and two patients in the Sprotte group were excluded. One of the six excluded in the Tuohy group had an ADP. Twenty-eight ADPs occurred, nine unrecognized by CSF visualization (1.8% Tuohy, 3.4% Sprotte, $P = 0.12$). The incidence of unrecognized ADPs was higher in the Sprotte group (40% Sprotte vs 20% Tuohy, $P < 0.05$). If ADP occurred, the incidence of PDPH was lower in the Sprotte group (100% Tuohy vs 55% Sprotte, $P = 0.025$). The ease of use, and user satisfaction were higher in the Tuohy group ($84 \pm 17.3\%$ Tuohy vs $68.2 \pm 25.3\%$ Sprotte, $P < 0.001$).

Conclusion: The incidence of ADP was not reduced with the Special Sprotte™ epidural needle in comparison with the Tuohy needle, but PDPH after ADP occurred less frequently in the Sprotte group.

Objectif : Une étude prospective randomisée a été réalisée chez des parturientes en travail pour évaluer si l'aiguille de péridurale 18G Special Sprotte™ est associée à une plus faible incidence de ponction durale accidentelle (PDA) en comparaison de l'aiguille 17G Tuohy. Un second objectif était de déterminer si l'incidence de céphalées post-ponction durale (CPPD) diffère entre les groupes quand survient une PDA.

Méthode : Suivant l'approbation du Comité d'examen de l'institution, 1 077 parturientes nécessitant une analgésie péridurale dans trois unités obstétricales tertiaires ont été réparties en deux groupes pour l'insertion d'un cathéter péridural avec une aiguille 17G Tuohy ou une 18G Special Sprotte™. Les femmes ont été suivies pendant sept jours par un évaluateur impartial de l'occurrence de CPPD selon des critères normalisés. Si des céphalées posturales ou des douleurs au cou survenaient, une PDA était diagnostiquée même si le liquide céphalo-rachidien (LCR) n'était pas visible à l'insertion. Ce sous-groupe a été suivi quotidiennement pour l'évaluation des caractéristiques des céphalées et la réponse à l'administration épidurale de sang autologue.

Résultats : Six patientes du groupe Tuohy et deux du groupe Sprotte ont été exclues. Une des six exclues du groupe Tuohy présentait une PDA. Il y a eu 28 PDA, dont neuf non reconnues par la visualisation du LCR (1.8 % Tuohy, 3.4 % Sprotte, $P = 0.12$). L'incidence de PDA non reconnues a été plus élevée dans le groupe Sprotte (40 % Sprotte vs 20 % Tuohy, $P < 0.05$). Si une PDA survenait, l'incidence de CPPD était plus faible dans le groupe Sprotte (100 % Tuohy vs 55 % Sprotte, $P = 0.025$). La facilité d'usage et la satisfaction de l'utilisateur ont été plus élevées dans le groupe Tuohy ($84 \pm 17,3\%$ Tuohy vs $68,2 \pm 25,3\%$ Sprotte, $P < 0,001$).

Conclusion : L'incidence de PDA n'a pas été réduite avec l'usage de l'aiguille de péridurale Special Sprotte™ comparée à l'aiguille Tuohy, mais les CPPD suivant une PDA ont été moins fréquentes dans le groupe Sprotte.

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POSTDURAL puncture headache (PDPH) is a recognized complication of epidural regional analgesia with a frequency of 1–3% in obstetric patients.¹ While improvements in the design of spinal needles with non-cutting tips and smaller gauges have been shown to decrease the incidence of PDPH when compared to standard, earlier designs,^{2–4} there has been little research examining the effect of epidural needle design on the incidence of accidental dural puncture (ADP) and PDPH. The incidence of ADP with a Tuohy epidural needle in parturients varies between 0.04% and 6%.⁵ Postdural puncture headache may occur in up to 80% of these patients and is often debilitating.⁶

The Sprotte spinal needle (Pajunk GmbH, Geisingen, Germany) has been associated with a low incidence of PDPH in parturients.^{7–11} The Special Sprotte™ epidural needle is a modification of the non-cutting Sprotte spinal needle. It has a solid bullet-shaped tip with a lateral opening for passage of an epidural catheter. A recent *in vitro* study suggests that cerebrospinal fluid (CSF) leakage may be lessened with the blunt 18G Special Sprotte™ needle in comparison with the 17G Tuohy needle.¹²

This prospective, randomized trial was designed to test the hypothesis that the incidence of ADP would be lower with the 18G Special Sprotte™ epidural needle compared with the 17G Tuohy needle. The secondary hypothesis was that when ADP occurred, the resultant PDPH would be less severe with the Sprotte design.

Methods

After Institutional Review Board approval of the study protocol and obtaining written informed consent, nulliparous and multiparous parturients requesting epidural analgesia for labour were recruited to participate from three tertiary obstetrical units. All women requesting an epidural for labour analgesia presenting between November, 1998 and November, 2000 were eligible for recruitment if over 18 yr of age, and having an ASA physical status I–III. Patients with recognized contraindications to epidural analgesia, and those who were unable to give informed consent and/or were unable to comply with study protocol were excluded.

At the time of analgesia request, patients were randomized to either the 17G Tuohy or 18G Special Sprotte™ epidural needle for lumbar epidural catheter placement. Randomization was achieved using a computer-generated randomization table prepared for each site by the research pharmacist. Allocation to group assignment was concealed in consecutively

numbered opaque envelopes. The randomization key was maintained in a secure location until study completion. Patient position, level of epidural needle insertion, whether air or saline were used for the loss of resistance (LOR) technique, and the specific medications for labour analgesia were left to the discretion of the anesthesiologist, but were noted in the data collection sheet. The number of attempts required to identify the epidural space and ease of identification of space (poor, fair, good or excellent) were recorded. Visualization of CSF, paresthesia, intravascular placement of needle or catheter, inability to thread catheter, failed block (defined as requiring reinsertion of the epidural catheter), and user satisfaction with the needle were recorded. User satisfaction was measured using a 100-mm visual analogue score scale with 100 indicating complete satisfaction and 0 indicating not at all satisfied. If technical difficulty was encountered with the initially assigned needle, then the anesthesiologist used the epidural needle of his/her choice. Use of epidural needle, other than that assigned, was also recorded.

Patients were informed by the anesthesiologist if an ADP was suspected, but the needle used was not revealed. Patients were followed for the first seven days after epidural catheter placement by daily hospital visit or telephone call for symptoms of PDPH by a research nurse who was blinded to group assignment. Patients with a prior history of headache were questioned to determine if the headache was different from their usual headache. Postdural puncture headache was defined as a postural headache or neck ache lasting more than 24 hr, and occurring within seven days of epidural needle placement. The headache was considered to be a PDPH regardless of whether an ADP was noted at the time of epidural catheter placement, if exacerbated by sitting or standing, and relieved by lying down.¹³

Patients who developed PDPH were followed daily until resolution of their headache. Follow-up daily survey included headache severity (using a verbal numeric rating of 0–100 with 0 = no pain and 100 = worst pain ever), pain location (head only, neck only, both head and neck), associated symptoms (nausea and vomiting, double vision, photophobia, and phonophobia), use of analgesics, and treatment with epidural blood patch (EBP). Treatment of PDPH was not standardized, but was left to the discretion of the attending anesthesiologist. In addition, patient assessment of satisfaction with her analgesia was rated using a verbal numeric satisfaction scale of 0–100 (100 = completely satisfied, 0 = completely unsatisfied).

FIGURE Flow diagram depicting the flow of patients through the study.

Statistical considerations

An *a priori* sample size calculation revealed that 1,528 patients were required to demonstrate a reduction in the incidence of ADP from 3% to 1% with an alpha of 0.05 and a power of 0.8. Analysis was by intention-to-

treat. A post-hoc secondary efficacy analysis was done excluding those patients who had suffered ADPs with both needles.

Dichotomous data were compared using Chi-square analysis and the Fisher's exact test where appropriate.

TABLE I Baseline characteristics

Group	Tuohy (n = 537)	Sprotte (n = 532)
Age (yr)	30.3 ± 5.2	30.1 ± 5.4
Weight (kg)	79.5 ± 14.9	80.4 ± 15.8
Height (cm)	163.9 ± 7.3	164.4 ± 7.1
Body mass index (kg·m ²)	30 ± 8.2	31 ± 7.3
Previous epidural (%)	46.9	43.5

TABLE II Technical variables

Group	Tuohy (n = 537)	Sprotte (n = 532)
Sitting position (%)	58.3	55.1
Loss of resistance to air (%)	89.1	89.6
Level of training		
Consultant (%)	47.6	49.4
Fellow (%)	5.0	5.6
Resident (%)	47.4	45.0
Level of epidural		
L1/2	1.7	2.5
L2/3	25.1	24.2
L3/4	71.6	71.8
L4/5	1.7	1.5

There were no significant differences between groups.

Unpaired Student's *t* tests were used to compare needles for number of identification attempts and for user satisfaction. To compare ease of identification of the epidural space, a Mantel-Haenszel Chi-square test for linear trends was performed. Ordinal data were analyzed using the Mann-Whitney U test. For PDPH characteristics, the between-group comparisons were made using a Wilcoxon two-sample test. A *P*-value < 0.05 was considered to be significant.

Results

One thousand seventy-seven parturients were recruited, 534 to the Special Sprotte™ epidural needle (Sprotte group) and 543 to the Tuohy epidural needle (Tuohy group). Four patients were lost to telephone follow-up, two in the Sprotte group and two in the Tuohy group. Protocol violations occurred in two Tuohy patients, one due to use of combined spinal/epidural technique and the other was treated by the attending anesthesiologist with a continuous epidural saline infusion immediately following ADP. The decision to perform an epidural was abandoned after randomization due to rapid progression of labour in another two in the Tuohy group. This left 1,069 patients, 532 in the Sprotte group and 537 in the Tuohy group who completed the study (Figure).

The groups were similar with respect to age, weight, height, history of previous epidural anes-

TABLE III Treatment outcomes

Group	Tuohy (n = 537)	Sprotte (n = 532)
User satisfaction	84.7 ± 17.3	68.2 ± 25.3**
(% satisfied)		
Insertion attempts (n)	1.4 ± 0.8	1.4 ± 0.7
Excellent loss of resistance	66.6	36.8**
to air (%)		
Paresthesia	2.2	0.8
(catheter insertion %)		
Blood in needle (%)	8.7	6.3
Failed blocks (%)	2.8	7.0**
Switched needles (%)	03.2**	

***P* < 0.001, different group Tuohy. User satisfaction and ease of identification of the epidural space were higher in the Tuohy group. The number of failed epidural blocks was higher in the Sprotte group. In 17 patients (3.2%) initially assigned to the Sprotte group, the operator switched to the Tuohy after three failed attempts to site the epidural.

TABLE IV Accidental dural punctures (ADP)

GROUP	Tuohy (n = 537)	Sprotte (n = 532)
ADP	10 (1.9%)	18 (3.4%) <i>P</i> = 0.12
Recognized ADP	8 (80%)	11 (61%) <i>P</i> = NS
Unrecognized ADP	2 (20%)	7 (39%) <i>P</i> = 0.417

The total number of ADPs, recognized and unrecognized was 28. The diagnosis of ADP was not made at epidural insertion in nine patients until they reported postdural headaches symptoms at 24 hr. NS = non significant.

TABLE V Characteristics of PDPH

Group	Tuohy (n = 10)	Sprotte (n = 18)
Vaginal delivery (n)	8	8
Cesarean delivery (n)	2	2
Onset (days)	3 ± 2.6	2.2 ± 1.9
Duration (days)	3.3 ± 2.4	5.0 ± 3.4
Average visual analogue scale of pain (mm)	62.7 ± 20.9	58.9 ± 26.9
Nausea (n)	2	2
Use of oral analgesics (n)	9	7
Double vision (n)	1	1
Photophobia (n)	4	1
Phonophobia (n)	4	1
Pain in head (n)	5	6
Pain in neck (n)	2	2
Head and neck (n)	3	2

There were no significant differences between groups with respect to characteristics of postdural puncture headache (PDPH).

TABLE VI Incidence of PDPH and EBP after ADP

Group	Tuohy (n = 10)	Sprotte (n = 18)
PDPH	10 (100%)	10 (55.5%) <i>P</i> = 0.025*
PDPH after CSF seen	8 (100%)	3 (27.2%) <i>P</i> = 0.003*
EBP	7 (70%)	3 (16.6%) <i>P</i> = 0.18
> 1 EBP	3 (30%)	1 (5.5%) <i>P</i> = NS

**P* < 0.05, different from group Tuohy. PDPH = postdural puncture headache; CSF = cerebrospinal fluid; EBP = epidural blood patch; ADP = accidental dural puncture. NS = non significant.

sia, and level of anesthesiologist's training (Table I). Groups did not differ with respect to level of epidural needle placement, patient positioning during catheter insertion, or LOR method (Table II). Mode of delivery was similar in both groups.

Treatment outcomes are summarized in Table III. User satisfaction was found to be significantly higher with the Tuohy needle ($84.7 \pm 17.3\%$ Tuohy *vs* $68.2 \pm 25.3\%$ Sprotte, $P < 0.001$). Although the number of attempts required to identify the epidural space did not differ between groups, recognition of LOR was rated to be excellent by a significantly higher percentage of operators in the Tuohy group (66.6% in group Tuohy *vs* 36.8% in group Sprotte, $P < 0.001$).

The incidence of paresthesia or intravascular needle insertion was similar between groups. The anesthesiologist chose to switch from the assigned Sprotte to Tuohy needle due to technical difficulty in 17 (3.2%) patients in the Sprotte group. No patient assigned to the Tuohy group was switched to the Sprotte needle. The number of patients having failed blocks requiring epidural catheter reinsertion was significantly higher in the Sprotte group. Thirty-seven (7.1%) patients in the Sprotte group experienced a failed epidural block while only 15 (2.8%) patients did so in the Tuohy group ($P < 0.001$). Of the 28 patients who developed PDPH, two had a history of chronic migraines. Both patients reported that this headache was different in that it was much worse on assuming an upright position, but alleviated by lying down.

The total number of ADPs was 28 (Table IV). The onset of ADPs occurred at the time of epidural needle insertion in 19 patients. In nine patients, an ADP was recognized only after post-dural headache symptoms were reported on follow-up (20% in group Tuohy *vs* 39% in group Sprotte, $P = 0.417$). All patients in the Tuohy group in whom CSF was observed at needle placement developed a PDPH (Table VI), whereas only three patients (27.2%) with recognized ADP did so in the Sprotte group ($P < 0.05$).

Of those patients who did develop PDPH symptoms, there were no significant differences with respect to severity, onset, duration, location of pain, or associated symptoms between groups. Three patients with PDPH in the Sprotte group received EBP compared to seven patients in the Tuohy group (30% *vs* 70%, respectively, $P = 0.18$). Three patients with PDPH in the Tuohy group had more than one EBP. One patient in the Sprotte group was offered EBP but refused. One patient with PDPH assigned to the Sprotte group required multiple EBPs but had initial ADP with the Sprotte, followed by ADP with the Tuohy needle (Table VI).

Four patients initially assigned to the Sprotte group were switched to the Tuohy group because of technical difficulty, but later developed PDPH. It was impossible to determine which needle caused the dural puncture. A secondary efficacy analysis excluded these four patients, and included only patients in whom it could be ascertained which needle had caused the dural puncture. This analysis showed that the Sprotte needle was associated with a reduced frequency of PDPH compared with the Tuohy (42.9% *vs* 100%, $P < 0.05$).

Discussion

This is the first prospective, randomized multicentre trial to compare the effect of epidural needle design on the incidence of ADP and PDPH in obstetric patients after labour epidural analgesia. We failed to confirm our hypothesis that the blunt 18G Special Sprotte needle™ is associated with a lower incidence of ADP when compared to the sharper tip design of the Tuohy epidural needle.

It is well-recognized that CSF loss is a potent stimulus for development of PDPH, with symptom severity increasing with larger needle diameter, and possibly, as a function of needle tip design. One accepted etiology of PDPH is CSF leakage allowing the brain to sag, thereby causing traction on pain-sensitive meninges, especially in the upright position. Loss of CSF also leads to compensatory venodilation, causing headache.¹⁴ By decreasing the CSF leak, it should be possible to decrease the incidence of PDPH.

Although the Special Sprotte™ needle failed to reduce ADP, it appeared to offer some protection against the development of PDPH. Patients who had ADPs with Special Sprotte™ needles were less likely to experience PDPH than patients who had ADPs with Tuohy needles. A cadaveric study conducted in an *in vitro* model by Angle *et al.* showed that epidural needle gauge is the most important predictor of CSF leak.¹² In the same study, CSF leakage tended to be less with a non-cutting epidural needle compared with a cutting needle of the same gauge, although the results did not reach statistical significance.

The rate of EBP was 16.6% in the Sprotte group *vs* 70% in the Tuohy group, although the number of patients who experienced ADP was too small to establish statistical significance. Since there was no difference in mean visual analogue scale pain scores between groups, it is not possible to determine which factors influenced the clinical decision to offer the patient an EBP. The observed difference may have been affected, in part, by the differing indications for administering EBP. Criteria were not standardized, since clinical indications were similar (moderate to

severe postural headache persisting beyond 48 hr after epidural insertion in the afebrile patient) within each of the three obstetrical units.

One of the major limitations of this study is that the sample size estimates required 764 patients per group. Unfortunately, the study was terminated prior to achieving the target sample size due to limited funding and change of study personnel. The reduced sample size prevented us from obtaining sufficient statistical power to determine whether or not there is a true difference in the incidence of ADPs between groups. However, with over 1,000 patients recruited, we were able to demonstrate a lower incidence of PDPH symptoms after ADP with the Sprotte epidural needle, which is a clinically important observation.

There appears to be a higher incidence of unrecognized ADPs at the time of epidural insertion with the Sprotte *vs* the Tuohy needle (2/10 *vs* 7/10 respectively, Fischer's exact probability $P = 0.035$). This may have been due to the location of the lateral hole in the Sprotte needle, which is sited 1.3 mm proximal to the tip. This location could allow the needle tip to breach the dura, without CSF backflow occurring.

The difference in user satisfaction rates was a tertiary study outcome, but nevertheless could present a barrier to more widespread use of the Special Sprotte™ needle. Only 36.8% of anesthesiologists described the loss of resistance to air (LORTA) as being excellent with the Sprotte needle, in comparison to 66.6% of anesthesiologists using the Tuohy needle. No operator switched from the Tuohy to the Sprotte needle after experiencing difficulty locating the epidural space, in contrast to 3.2% of anesthesiologists who were initially assigned to the Sprotte group. There is a learning curve in developing familiarity with the more subtle LOR of the Sprotte needle. Could this have affected the rate of ADP and PDPH? Certainly, lack of familiarity with this needle may have contributed to the lower satisfaction scores, difficulty in identification of the epidural space, and higher incidence of failed epidural blocks in the Sprotte group. Greater efforts to increase skill level with the Sprotte needle, including formal training sessions or mandating a minimal number of Sprotte procedures before participation of the anesthesiologists into the study protocol, might have influenced the observed frequency of ADP. Almost 90% of the anesthesiologists were using LORTA at the time of this study. Hence, the numbers were too small to determine whether user satisfaction was increased with LOR to saline in the Sprotte group.

Other limitations of this study included lack of standardization of the epidural technique, such as use of opioids, hourly volume of epidural infusate,

and orientation of needle bevel. However, none of these factors was likely to have significantly influenced headache severity. The type of 17G Tuohy needle also varied between study sites; and included both disposable and reusable Tuohy needles. Finally, application of conservative management techniques of suspected PDPH, including duration of bed rest, state of hydration, and use of analgesic medications, were not specifically controlled by study protocol.

In conclusion, the blunt 18G Special Sprotte™ epidural needle does not result in a decreased incidence of ADP in labouring parturients when compared to the 17G Tuohy needle. However, the Special Sprotte™ needle was associated with a significantly lower incidence of PDPH after ADP. The trend towards more unrecognized ADP in the Sprotte group suggests that follow-up for PDPH is warranted. The theoretical benefits of the Sprotte epidural needle design in reduction of CSF leakage may have been overshadowed by the lack of familiarity with a different technique required to identify the epidural space. Overall, user acceptance of the needle must be taken into account in further studies investigating the influence of epidural needle design on ADP and PDPH.

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