Transient Neurological Symptoms After Isobaric Subarachnoid Anesthesia with 2% Lidocaine: The Impact of Needle Type

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BACKGROUND: The reported incidence of transient neurological symptoms (TNS) after subarachnoid lidocaine administration is as high as 40%. We designed this clinical trial to determine the incidence of TNS with two different pencil-point spinal needles: one-orifice (Atraucan) and two-orifice (Eldor) spinal needles.
METHODS: Ninety-nine ASA physical status I or II patients undergoing surgical procedures of the urinary bladder or prostate were prospectively allocated to receive spinal anesthesia with 40 mg, 2% isobaric lidocaine plus fentanyl injected through either a 26-gauge Atraucan ($n = 52$) or a 26-gauge Eldor ($n = 47$) spinal needle. During the first three postoperative days, patients were observed for postoperative complications, including TNS. The primary end-point for this trial was the percentage of TNS in both double- and single-orifice spinal needle procedures.
RESULTS: The incidence of TNS was higher when spinal anesthesia was done through the Atraucan needle (28.8% vs 8.5%, $P = 0.006$). Fifty percent of the patients in the double-orifice group versus 100% of the single-orifice group developed TNS after surgery in the lithotomy position ($P = 0.014$). The relative risk for developing TNS with the Eldor needle was 0.29 (95% CI: 0.07–0.75) compared with the Atraucan needle.
CONCLUSIONS: The use of a double-orifice spinal needle was associated with a lower incidence of TNS, which may have been due to the needle design.
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Transient neurological symptoms (TNS) are characterized by postoperative pain or dysesthesia in the buttocks or lower extremities. The cause of TNS has been investigated in several studies in association with lidocaine concentration (1), osmolarity (2), dextrose concentration (2), lithotomy position (3), ambulatory surgery (3), and early ambulation (4). The only factors found to be associated with increased risk of TNS were lidocaine spinal anesthesia, the lithotomy position, and ambulatory surgery (4). Pooling and maldistribution of local anesthetic encountered with the use of pencil-point spinal needles (5) or spinal microcatheters (6) were suggested to have a causative effect for neurological injury, but not TNS. The Eldor spinal needle (Fig. 1) has two rounded opposing lateral orifices at its pencil-point tip (7) that might affect the dispersion of local anesthetic. However, a single study comparing the block characteristics achieved by this needle versus a single-orifice Sprotte needle found no differences in the quality of the block (8). In this randomized single blinded comparison study using 2% lidocaine in patients undergoing surgical procedure of the urinary bladder or prostate, we evaluated the newly shaped Eldor spinal needle specifically with regard to the incidence of TNS.

METHODS

After obtaining approval of the IRB and written patient informed consent, 99 ASA physical status I and II patients scheduled for suprapubic prostatectomy or transurethral resection of prostate, under spinal anesthesia, were randomized blindly to receive spinal anesthesia with 40 mg, 2% plain preservative-free lidocaine (Rafa Laboratory, Jerusalem,

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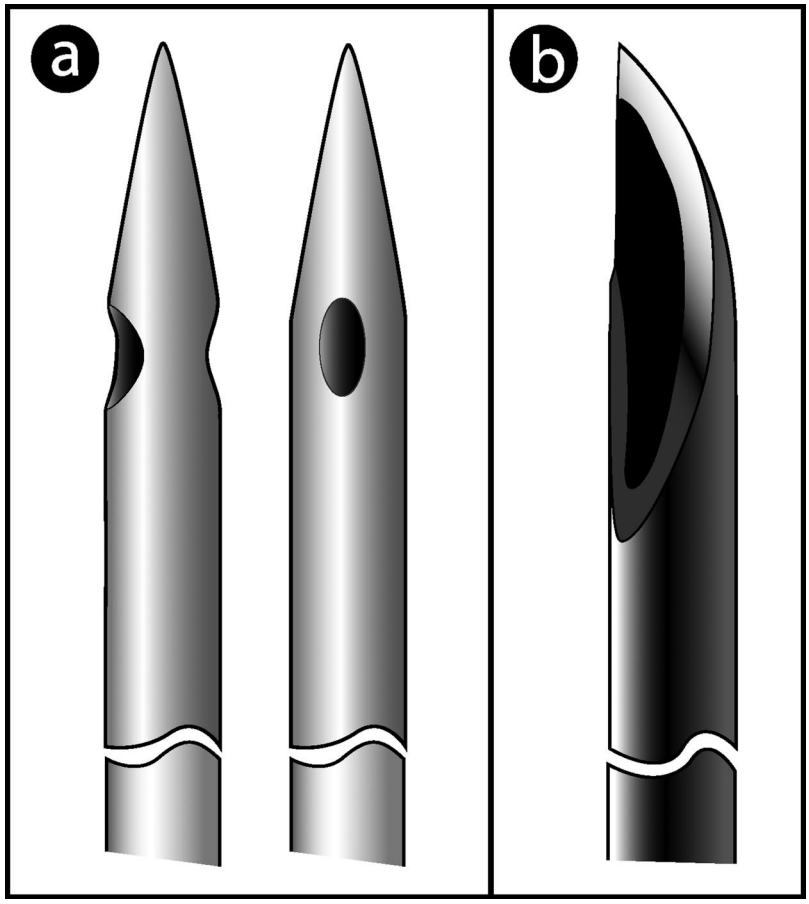

Figure 1. Spinal needle types. (a) Double-orifice: Eldor needle. (b) Single-orifice: Atraucan.

Israel) plus 15 μg fentanyl (Janssen Cilag, Kibbutz Shefaim, Israel), injected through either a 26-gauge pencil-point, Eldor needle with two lateral opposing orifices at its tip (TSK Laboratory, Baldoyle Ind, East Dublin, Ireland) or a 26-gauge, single-orifice Atraucan cutting-point double-bevel needle (B. Braun, Melsungen AG, Germany). Randomization was performed using a cluster design, in which patients belonging to a specific session and undergoing a urology procedure of prostate or urinary bladder were given spinal anesthesia with the same type of needle. Patients were randomly allocated to have their spinal anesthesia performed by one of the two types of needles. Needles were kept in sealed envelopes marked with the session number, using random number tables.

Excluded from the study were patients with a history of chronic pain, presence of neurological disease, diabetes mellitus, smoking of more than 10 cigarettes per day for more than 3 yr, chronic use of analgesic medications, and body mass index >30.

Premedication consisted of oral diazepam, 7.5 mg, 1 h before surgery. Intraoperatively, monitors were applied as per ASA guidelines. Before spinal anesthesia was performed, 10 mL/kg of lactated Ringer's solution was administered IV over 20 min. With the patient in the sitting or left lateral decubitus position, the patient's skin was prepped with a 10% solution of povidone iodine in isopropyl alcohol (Fisher Pharmaceutical Labs, Tel Aviv, Israel). After drying the skin at the injection site, 2 mL 2% lidocaine (40 mg) was injected for local anesthesia of skin and subcutaneous tissues using a 21-gauge needle. Spinal anesthesia was performed by two anesthesia providers at the L3–4 or L2–3 interspace with either the Atraucan or the Eldor 26-gauge needle, using the midline approach. Once the correct needle position was identified by free flow of the cerebrospinal fluid, the local anesthetic was injected with the side port of the needle directed cephalad with the Atraucan, and both caudad and cephalad with the two-orifice Eldor needle (Fig. 1). The local anesthetic was injected over 20 s in all patients. Immediately after the intrathecal injection, the patient was turned to the supine or lithotomy position according to the planned surgical procedure, with the operating table in a slight head-up position. The segmental level of anesthesia was assessed bilaterally using cold alcohol swabs at 5 min intervals for 20 min after the block placement and at 15 min intervals thereafter, until complete recovery from the sensory block.

Arterial blood pressure was recorded at 1 min intervals for the first 20 min and at 5 min intervals thereafter, until complete (motor and sensory) recovery from spinal anesthesia. Hypotension was defined as a decrease in systolic blood pressure of >30 mm Hg

or >20% for >5 min and was treated with 5 mg increments of ephedrine and 200 mL boluses of lactated Ringer's solution. Bradycardia <45 bpm was treated with 0.5 mg atropine. The patients and the investigator, but not the anesthesiologist who performed the spinal block, were blinded to the type of the needle used. Data collected prospectively included patient demographics, technical difficulties in performing the block, any paresthesia encountered during the performance of the block, patient position during the block and surgery, and the duration of surgery. During the first three postoperative days, patients were interviewed by an investigator blinded to the patient randomization to identify signs of TNS, according to a protocol (Appendix). TNS was defined as pain and/or dysesthesia in the area of the buttocks, thighs, or lower limbs occurring after recovery from anesthesia. The time from block cessation to the onset of TNS was recorded. Patients with TNS were asked to rate the degree of pain, using a visual analog scale with a score of 0 = no pain to a score of 10 = worst imaginable pain. Neurological examination was performed daily in all TNS patients, until the symptoms subsided completely. Patients with no symptoms of TNS were repeatedly interviewed on the second and third postoperative days by the same investigator, and whenever required, until discharge from the hospital.

The primary outcome for this trial was the percentage of TNS in both double- and single-orifice spinal needle procedures. Initially, the sample size was based on one planned analysis at the end of the study. A sample size of 150 patients in each group was calculated to achieve 80% power and a two-sided [*alpha*] of 0.05, assuming a 12.5% and 25% incidence of TNS in the double- and single-orifice groups, respectively. After 99 patients were enrolled in the study, a safety concern was raised by the physicians who were involved in data collection due to the clinical impression of frequent TNS. Although the overall incidence of TNS was not increased, the possibility of a large group disparity raised ethical concerns that led to the decision of data unblinding. Before unblinding the data, the statistician and the IRB were informed regarding our clinical suspicion of frequent TNS. The course of action decided at that stage was to terminate the study in case of verification of a significantly frequent incidence of TNS in the interim analysis. Interim analysis at that point revealed a 19% overall incidence of TNS with 8.5% and 28.8% in the double- and single-orifice groups, respectively. Because of ethical concerns, a decision was then made to terminate the study.

The difference in TNS rates in the collected data was then analyzed by group sequential (interim) analysis methods, and results were found to be consistent with a statistically significant difference of >17.8% between the two groups. The interim analysis was performed by a statistician who decided on the criteria by which the study would be discontinued. This boundary was calculated based on the previously specified power, significance level, and effect sizes. The boundary shape (determined after data unblinding) was set according to Pocock (9). Such an approach requires a predetermined number of interim analyses. Because such a judgment had not been determined at the study design phase, the number of analyses was *ad hoc* set to four. These calculations led to a maximal sample size of 200 patients in each group, with four interim analyses, after enrollment of 50 patients per group. The number of patients in each group at time of study termination matched the number of patients needed for first data analysis (50 in each group).

The boundaries for achieving a two-sided statistical significance of 0.05 were a difference in TNS rate of 17.8%, 12.6%, 10.3%, and 8.9% in each interim analysis, respectively. For further details, see Jennison and Turnbull (10). Adjustments to the *P* value and the confidence interval, comparing TNS rates, were done using analysis time ordering.

Univariate comparisons of the patients' characteristics were performed using unpaired *t*-test, χ^2, or Fisher's exact test. The Fisher's exact test was used when the expected values in a cell were less than five. Stratified analysis and Mantel-Haenszel relative risk and 95% confidence intervals were used to examine potential confounders. For variables significantly different between groups in the univariate analysis, odds ratios and 95% confidence intervals were obtained from multiple logistic regression analysis to estimate their independent contribution to TNS. The module used for statistical analysis was Seq Trial 2 (2002) in 5-Plus 6, 2 ©, 2003, Insightful Corp.

RESULTS

During the 6-mo study period, 152 patients underwent urology procedures under spinal anesthesia. Of them, 99 (65.1%) fulfilled the inclusion criteria and agreed to participate in the study. Excluded from the study were patients with diabetes mellitus (14.5%), obesity (8.6%), technical difficulties in performing spinal anesthesia (4.6%), refusal to participate (3.3%), neurological problems (2%), and other reasons (2%). There were no differences in the patients' demographics, surgery characteristics and quality, and duration of spinal anesthesia (Table 1). There were 47 procedures performed with the Eldor needle and 52 in the Atraucan group. During performance of anesthesia, sitting position was used in 72% of patients with the Eldor and 94% with the Atraucan needle ($P = 0.003$). The incidence of TNS was significantly higher with the Atraucan than with the Eldor needle (Table 2) (adjusted *P* value = 0.006, with adjusted 95% CI of the difference in TNS rate of 5.6%–35%). The relative risk of TNS development with Eldor versus Atraucan needle was 0.29 (95% CI: 0.07–0.75). After considering the confounding factors (type of surgery and patient's position during performance of anesthesia and surgery) (using the Mantel- Haenszel method), the incidence of TNS was

Table 1. Demographic and Clinical Characteristics of Patients According to the Type of Needle Used for Spinal Anesthesia

Characteristic	Double-orifice, Eldor needle (n = 47)	Single-orifice, Atraucan needle (n = 52)	P
Age	72 (9.6)	71 (11.1)	0.65
BMI	25.1 (2.6)	25.7 (2.2)	0.19
Previous surgery (%)	76	88	0.12
Previous anesthesia (%)	57	61	0.68
Type of surgery (%)			
TURP or SPP	68	45	0.02
Other	32	55	
Duration of surgery (min)	54 (23)	62 (32)	0.17
Position during anesthesia (%)			0.003
Sitting	72	94	
Lateral decubitus	28	6	
Position during surgery (%)			0.60
Lithotomy (n)	17 (8)	23 (12)	
Supine (n)	83 (39)	77 (40)	
Maximum sensory level (%)			0.54
T6–T8	34	38	
T9–T12	59	52	
Paresthesia during performance of the block (%)	1 (2)	1 (1.9)	0.52
Bleeding during performance of the block	1 (2)	1 (1.9)	0.52

Data are presented as means (±SD) or percentages.

TURP = transurethral resection of prostate; SPP = suprapubic prostatectomy; BMI = body mass index; (n) = number of patients.

Table 2. Symptoms Reported Within 72 h of Surgery by Type of Needle Used for Spinal Anesthesia

Symptoms	Double-orifice, Eldor needle (n = 47)	Single-orifice, Atraucan needle (n = 52)	P
TNS (%)	8.5	28.8	Adjusted P = 0.006
In lithotomy position (n)	50[a] (4)	100[a] (12)	0.014
In supine position (n)	0[b]	7.5[b] (3)	<0.001
Nausea/vomiting	12.8	17.3	0.67
Pain after recovery	57.4	67.3	0.31
Time of TNS diagnosis from the end of surgery			
<24 h	8.5	19.2	0.53
24 h and later	—	9.6	
Site of pain			
Surgical area	46.8	52.0	0.61
Spinal puncture area	14.9	15.4	0.95
Thigh area affected			
Anterior	2.1	7.6	0.21
Posterior	4.2	11.5	0.18
Sides affected			
Bilateral	2.1	5.7	0.12
Unilateral	6.4	13.4	0.15
Intensity of pain			0.35
None	42.6	32.7	
Mild to moderate	48.9	50.0	
Intense	8.5	17.3	

All data are presented as percentages, except for n = number of patients.

[a] Percentage of patients with transient neurological symptoms (TNS) in lithotomy position.

[b] Percentage of patients with TNS in sitting position.

found to be lower with the Eldor needle (when controlling the type of surgery—P = 0.018, 0.24 [0.071–0.78] and when controlling patient's position—P = 0.23, 0.36 [0.06–1.92]), when compared with the Atraucan needle. The incidence of TNS within the Atraucan group was not influenced by the type of surgery and patient's position during performance of anesthesia or surgery. Half of the patients in the double-orifice group versus all the patients in the single-orifice group developed TNS after surgery in the lithotomy position (P = 0.014). The effect of surgery type and patient's position on the incidence of TNS was further analyzed by multivariable logistic regression (Table 3), which showed that the types of needle and surgery, but not patient's position during the operation, were associated with the development of TNS. Furthermore, in the multivariate logistic regression analysis, no interaction between the primary variables was found to be statistically significant. The duration of

Table 3. Odds Ratio (95% Confidence Interval) of the Association Between the Type of Needle, Type of Surgery, and Positioning During Spinal Anesthesia, and Transient Neurological Symptoms

Factor		*P*
Type of needle (double versus single orifice)	0.24 (0.065–0.90)	0.034
Type of surgery (prostate versus other urological)	0.24 (0.071–0.78)	0.018
Positioning during surgery	0.36 (0.06–1.92)	0.230

TNS was 24–48 h. There was no difference in severity of TNS in both study groups, and no patient was discharged home with TNS.

DISCUSSION

Our study suggests that TNS is more common after spinal anesthesia with 2% isobaric lidocaine, plus fentanyl, when a single-orifice cutting point (Atraucan) needle is used in patients undergoing urology procedures. Our report on the incidence of TNS is similar to the previously reported incidence with lidocaine (14.2%) and prilocaine (4%) for the same type of surgery with spinal anesthesia performed through 25-gauge to 29-gauge Quincke needles (11). Other studies report an incidence of TNS ranging from 4% to 37% (12–17). Although most local anesthetics are associated with TNS (12,18–23), it occurs most frequently with lidocaine. The type and duration of surgery and patient position during surgery may also add to the variability of the factors implicated with the TNS (3,12,14,17). All these variables were assessed in our study and were not found to be confounding for the association between the needle type and incidence of TNS. The precise etiology of TNS has not been elucidated, with previous theories having postulated local anesthetic toxicity (17,24–26), needle trauma or neuronal ischemia as a result of sciatic stretching (27).

Pooling and maldistribution of local anesthetic, encountered with the use of pencil-point needles, was also suggested to cause transient neurologic deficit, but not TNS (5). This was suggested to occur after slow injection rates of 5% hyperbaric lidocaine with sacrally directed Whitacre needles, or when using spinal microbore catheters (6). Freedman et al. (3), in a large epidemiologic study of needle types (Quinke versus Whitacre), found no difference in the rate of TNS, although both were single-orifice needles with different distributions of local anesthetic. We undertook our study with the hypothesis that the type of the needle may affect the incidence of TNS and that, specifically, the two-orifice needle may produce a more uniform distribution of the local anesthetic. However, when comparing the two-orifice, 26-gauge Eldor spinal needle, with the 27-gauge Pencan (Sprotte) needle (8), there were no differences in the quality of the block consistent with our results. Although neural injury is clearly linked to anesthetic maldistribution, there was no evidence supporting the link with TNS in previous studies or the current study. For example, in our study, the maximum sensory level was similar between the groups, implying that the maldistribution of local anesthetics does not seem to be the cause of the different incidence of TNS between the groups.

A limitation of our study is the lack of homogeneity of the groups in regard to type of surgery and patient's position during the spinal administration. The difference in operative procedures stems from the nonhomogeneity of the patients in the cluster. However, despite the statistical significance of these differences when reported as univariate variables, the multivariable analysis did not identify these two variables (type of surgery and patient's position) as confounding factors when comparing the type of needle and the incidence of TNS. Also, methodology bias cannot be excluded by early termination of our study and the performance of interim analysis of the results.

The interim analysis was not planned at the study design, but was decided upon due to concerns regarding a potentially high disparity in the incidence of TNS. This necessitated the interim analysis. Statistically, it has not been determined how to address the problem of unplanned interim analysis (10). After unblinding the data, we constructed a group sequential study (interim analysis design) to match the enrolled patients' status with the previously specific study parameters. This approach allowed us to conduct an *ad hoc* interim analysis as if it were initially planned. We believed that this approach was suboptimal, but it yielded lesser bias than disregarding the fact of early study termination. As for the *P* value, the boundaries were 17% when comparing the TNS incidence for a significance level of 0.05. The adjusted *P* value comparing TNS incidence was P value = 0.006 with adjusted 95% CI of the difference in TNS rate of 5.6%–35%. Finally, our study was not double-blind. However, although the anesthesiologist performing spinal anesthesia was not blinded, both the investigator and the patient were unaware of the needle type used for spinal anesthesia. Therefore, it is unlikely that an investigator bias affected the results of the study. In our study, we used two types of needles: the pencil-point needle has been shown to be associated with maldistribution of photalocyanine blue dye in a spinal model, whereas the Quincke needle was not (5).

The results of our study show that the use of a single-orifice Atraucan spinal needle for the administration of 40 mg of 2% spinal lidocaine in urology surgeries was associated more frequently with TNS when compared with the use of the two-orifice Eldor needle. The reduced incidence of TNS with the use of two-orifice spinal needle may be attributable to the needle design.

APPENDIX*

Patient Questionnaire for Postoperative Follow-up for Diagnosis of Transient Neurological Symptoms
(Please encircle or fill-in any relevant finding.)

Do you suffer from?	- Nausea or vomiting	Yes	No
	- Difficulty with urination or defecation	Yes	No
	- Any muscle weakness	Yes	No
	- Pain at site of spinal injection	Yes	No
	- Pain or strange sensation at site of surgery	Yes	No
	- Unusual sensations	Yes	No
	- If yes, where do you have unusual sensation		

Characteristics of the unusual symptoms	- Burning	- Tingling	- Dull
	- Aching	- Numbness	- Hypesthesia
	- Other sites:		

Have you experienced such symptoms before?	Yes	No

* Adopted with changes from Hampl et al. (2).

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