

Prospective study on Incidence and Functional Impact of Transient Neurologic Symptoms Associated with 1% Versus 5% Hyperbaric Lidocaine in Short Urologic Procedures

Doris Tong, F.R.C.P.C.,* Jean Wong, F.R.C.P.C.,* Frances Chung, F.R.C.P.C.,† Mark Friedlander, M.D.,‡ Joseph Bremang, M.D.,§ Gabor Mezei, M.D.,|| David Streiner, Ph.D.#

Background: The objectives of this study were to compare the incidence, onset, duration and pain scores of transient neurologic symptoms (TNS) with 1% versus 5% hyperbaric lidocaine in spinal anesthesia for short urological procedures in a large prospective study. This study would also evaluate patient satisfaction, and impact of TNS on functional recovery to assess the clinical significance of TNS.

Methods: This was a multicenter, double-blind, randomized controlled trial. Four hundred fifty-three patients undergoing short transurethral procedures were randomized to receive 1% or 5% hyperbaric lidocaine. Eighty milligrams of 1% or 5% hyperbaric lidocaine was administered. During the first 3 days after surgery, the presence of TNS, its intensity and duration, and patient functional level were recorded. An intention-to-treat analysis was used.

Results: There was no difference in the incidence of TNS (21% vs. 18%) between 1% versus 5% lidocaine. Patients with TNS had significantly higher pain scores (5.3 ± 3 vs. 2.3 ± 3) than patients without TNS during the first 24 h. This difference in pain scores persisted until 72 h postoperatively. There was a significant difference in the daily activities functional scores (2.2 ± 1 vs. 1.4 ± 0.8) of TNS versus non-TNS patients during the first 24 h postoperatively.

Conclusions: There was no difference in the incidence of TNS between the 1% versus 5% spinal lidocaine groups. Pain scores were higher in patients with TNS than those who did not have TNS. During the first 48 h postop, a small proportion of patients who had TNS experienced functional impairment of walking, sitting, and sleeping.

SINCE 1993, case series¹⁻⁵ have documented the occurrence of transient radicular irritation syndrome or transient neurologic symptoms (TNS) following spinal anesthesia with hyperbaric 5% lidocaine. These symptoms have been described as pain and dysesthesia in the buttock, thighs or calves, occurring after the recovery from spinal anesthesia, usually within 24 h and resolving within 72 h. The most common factors among these case series were small gauge needles, hyperbaricity,

lithotomy position, and the 5% concentration of lidocaine.¹⁻⁵ A large multicenter observational study found that outpatient status also increased the risk of TNS for patients receiving lidocaine.⁶

Prospective, randomized trials reveal an incidence of TNS with lidocaine spinal anesthesia between 4 and 37%.⁷⁻¹² The etiology of TNS is unclear, and controversy exists regarding the use of lidocaine, particularly, hyperbaric lidocaine.¹³⁻¹⁴ The incidence of TNS was found to be equivalent in two studies comparing 5% and 2% lidocaine^{7,8} in 50 patients undergoing gynecological surgery, and 159 patients undergoing knee arthroscopy or inguinal hernia surgery, respectively. Dilution of lidocaine concentration to 2%, 1%, or 0.5% was found to have no effect on the incidence of TNS in one study of 109 patients having knee arthroscopy.¹² Despite the controversy surrounding this issue, the functional impact of TNS on patients has never been evaluated. This study would evaluate the impact of TNS on different aspects of daily activities in order to shed light on the clinical significance of TNS. We decided to investigate the 1% concentration as this is the highest safe concentration established in animal data, which is most likely to be adequate for surgery.^{15,16}

The objectives of this study were to compare the incidence, onset, duration and pain scores of TNS with 1% versus 5% hyperbaric lidocaine in spinal anesthesia for short urological procedures in a large prospective study. We would also compare the intraoperative and recovery profile of 1% versus 5% hyperbaric lidocaine, patient satisfaction, functional recovery and return to daily activities of TNS versus non-TNS patients.

Materials and Methods

After obtaining approval from the institutional ethics committee and informed consent, 453 patients undergoing short (<1.5 h) urological procedures in the lithotomy position were enrolled in this multicenter, double-blind, randomized controlled trial. The procedures included transurethral resection of bladder tumor, short transurethral resection of prostate, cystoscopic manipulation of bladder or ureteric stones or insertion of ureteric stents.

The exclusion criteria were as follows: ASA classification IV or V, previous failed spinal anesthesia, chronic/recurrent back problems such as severe deformity of the spine, previous back surgery, active neurologic prob-

* Assistant Professor, † Professor, || Clinical Epidemiologist, Department of Anesthesia, Toronto Western Hospital, University Health Network, University of Toronto, Toronto. ‡ Lecturer, Department of Anesthesia, North York General Hospital, Toronto. § Lecturer, Department of Anesthesia, St. Joseph's Health Centre, Toronto. # Professor, Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton.

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Address correspondence to: Dr. Wong, Department of Anesthesia, Toronto Western Hospital, University Health Network, University of Toronto, 399 Bathurst Street, Toronto, Ontario, Canada, M5T 2S8, 416-603-5118, fax: 416-603-6494, jean.wong@uhn.on.ca.

lems such as evolving neurologic deficits in multiple sclerosis, spinal cord lesions, contraindications to spinal anesthesia such as difficult airway, sepsis, coagulopathy, allergy to local anesthetic, morbid obesity (body mass index > 35) and history of analgesic abuse.

A pilot study performed prior to this study determined the dose of 80 mg lidocaine to be optimal for the duration and types of urological procedures in this study.

The sample size calculation was based on a suspected incidence of TNS of 20% for 5% lidocaine, with a 50% reduction of TNS in the 1% lidocaine group, an α of 0.05 (2-tail), β of 0.2 (1-tail), the minimum number of patients required was 213 per group. Anticipating a maximum 5% loss in follow up, 453 patients were recruited.

Patients were randomized to receive either 1% or 5% hyperbaric lidocaine. Randomization was carried out within each of the four participating centers. A block randomization using varying concealed block sizes was used. Random numbers were generated by computer. The randomization schedule was inaccessible throughout the study period and the assignment was kept in opaque sealed envelopes on site. The attending anesthesiologist assessed the patients preoperatively, determined eligibility and executed the assignment. Trial records were kept to review the process of assignment. The patients and research assistants assessing perioperative outcomes were blinded to the randomization. The research assistant entered the operating room after completion of the spinal anesthetic. There were two research assistants involved in the study.

No premedication was given. A complete preanesthetic evaluation was performed. Preoperatively, the research assistant instructed the patients on the use of the verbal rating scale (VRS), and baseline scores were obtained. Intraoperatively, routine monitoring was carried out and baseline values were recorded. An intravenous was established and a preload of 500 ml normal saline was administered. A standard spinal anesthetic technique was performed. The patient was placed in the sitting position. A 25G Whitacre needle (Becton Dickinson, Mississauga, Ontario) was inserted *via* an 18G introducer needle at or lower than L2-3. When the small gauge Whitacre needle posed a technical challenge, 22G Quinke needles (Becton Dickinson) were used. The bevel was pointed cephalad and a median approach was used. Cerebrospinal fluid was aspirated at the start of injection. A rapid injection rate of 1 ml/sec was employed. The patient was then placed in the lithotomy position, and the research assistant was allowed to enter the operating room.

Patients were randomized to receive 80 mg of either 1% (8 ml) or 5% (1.6 ml) hyperbaric lidocaine (Astra Pharma, Mississauga, Ontario). The 1% formulation was prepared by mixing 1.6 ml of 5% hyperbaric lidocaine with 6.4 ml of 10% dextrose to make up 8 ml of 1% hyperbaric lidocaine. No additive was used.

The remainder of the intraoperative management was carried out in a standard manner. The hemodynamic profile was maintained within 20% of the baseline by a combination of ephedrine and fluid administration. One to two mg boluses of midazolam were given for anxiety or a combination of fentanyl and propofol was administered for failure of spinal anesthesia. It was upon the discretion of the attending anesthesiologist to either increase supplementation with intravenous sedation and analgesia or convert to general anesthesia.

Onset of spinal block was defined as a loss of pinprick sensation to T10. The highest dermatomal level of block was defined as the highest level of loss of pinprick sensation. Three variables were defined pertaining to the adequacy of spinal anesthesia: anesthetic failures, technical failures and surgery outlasting the duration of action of the spinal anesthetics when the surgery lasted < 1 h. The number of episodes where blood pressure and pulse rate were beyond 20% of baseline was recorded.

Patients with failure of spinal anesthesia as a result of anesthetic failure, technical failure or prolonged surgery outlasting the effect of a spinal anesthetic were assessed for the occurrence of TNS and these results were included in an intention-to-treat analysis. However, these patients' immediate recovery profile was not assessed.

The assessments of the patient were carried out by the research assistant on arrival in the postanesthesia care unit (PACU) and every 5 min for 30 min, then every 10 min until discharge from the PACU. Patients discharged to the day surgery unit (DSU) were assessed every 15 min until discharge. While in the PACU or DSU, when the patient requested analgesics before the assessment time point, the research assistant reconfirmed the findings of pain, delineated the location and assessed the pain scores before the administration of analgesics.

Immediate recovery was assessed by measuring time to 2 segment regression, plantar flexion, big toe proprioception, forefoot sensation, sustained 5 s leg lift and time to reach the PACU discharge criteria. Late recovery including time to sit, void, ambulate with or without assistance, and reach the DSU discharge criteria were recorded.

In the PACU, morphine 1-2 mg intravenous boluses were given for pain and dimenhydrinate 25-50 mg intravenous were given for nausea and vomiting. When patients satisfied the PACU discharge criteria,¹⁷ they were discharged to either a hospital floor or the DSU. The pain management in these two locations consisted of acetaminophen with codeine 30 mg, 1-2 tablets every 3-4 h. Outpatients were discharged when they satisfied the modified postanesthetic scoring system.¹⁸ Acetaminophen with codeine was prescribed on discharge. Patients were given a contact phone number if problems arose.

Patients were defined as suffering from TNS if symptoms radiated from the back or buttock down the lower

limb and they had "anything other than zero" on the 0–10 VRS (0 = no pain, 10 = worst pain imaginable).

On the first 3 days postoperatively (postop), the research assistant visited the inpatients and/or contacted the outpatients by phone to conduct a standardized questionnaire (appendix 1) at about 24, 48 and 72 h postop. All patients with neurologic symptoms were followed until they were symptom-free.

The following variables were recorded: the presence or absence of any pain, the intensity of the symptoms as assessed by the VRS, the onset and duration of pain, lower limb paresthesia. The time interval-specific VRS was defined as the higher of the VRS documented at the time of interview at 24, 48, or 72 h, or during the preceding 24 h. The level of function including daily activity, sitting, walking, voiding, bowel movement, sleeping, returning to work, the amount of analgesics consumed, and the reason for consumption were recorded. Functional impairment caused by TNS was assessed by comparing the functional recovery of patients with TNS and without TNS by using a 5-point verbal rating scale, from "not at all affected"¹ to "very strongly affected,"⁵ on overall daily activity, sitting, walking, voiding, bowel movement, and sleeping.

At the end of the third postoperative day, patient satisfaction with the technique was assessed by the patient's willingness to recommend spinal anesthesia to others.

Statistical Analysis

An intention-to-treat and per protocol analysis excluding the anesthesia failures was performed, a *P* value less than 0.05 was considered significant. A chi-square test was used to compare the proportion of TNS between 1% versus 5% hyperbaric lidocaine, patient satisfaction, and the proportion of patients who were employed but not yet returned to work at 72 h postop. The distribution of incidences of TNS between 1% versus 5% lidocaine among the 4 sites was tested by the test of homogeneity (*Q* statistics).

The following secondary analyses were performed, and the *P* value was adjusted for multiple comparisons. The VRS, consumption of analgesics over time, and functional impairment caused by TNS between the two groups were tested by group × time repeated measures ANOVA. A *P* value of less than 0.05 in either comparisons led to comparison across each time interval of the first, second, and third 24 h by rank sum test and repeated measures ANOVA were performed on each of the activities of daily living variables. The highest VRS was tested by rank sum test and the onset of TNS was tested by log-rank test in survival analysis. The VRS across time between 1% versus 5% lidocaine was tested by repeated measures ANOVA for TNS patients and for all patients.

The time to onset of spinal block was tested by log-rank test in survival analysis. The highest dermatomal

Table 1. Comparison of Potential Confounding Factors for 1% versus 5% Lidocaine

Variable	1% Lidocaine (N = 218)	5% Lidocaine (N = 235)
Age, yr	70.0 ± 11.0	71.0 ± 9.2
Sex (M/F), n	208/10	225/10
Body mass index, kg/m ²	27.0 ± 4.7	27.0 ± 4.5
ASA physical status (I/II/III), n	32/139/47	31/157/47
Procedures (TURBT/TURP/other), n	38/167/13	44/174/17
Duration of surgery, min	31 ± 16	34 ± 19

Values are expressed as mean ± SD.

TURBT = transurethral resection of bladder tumor; TURP = transurethral resection of prostate.

level was tested by rank sum test; the adequacy for surgical anesthesia was tested by chi-square. The unpaired *t* test was used where appropriate. The recovery profile was tested by log-rank test in survival analysis, the *P* value was adjusted for multiple comparisons. A *P* value < 0.05 was considered significant.

Results

Four hundred fifty-three patients were recruited. There were no significant differences between the demographics, type of procedure, and duration of surgery between the two groups (table 1). There were no differences between the technical aspects of spinal anesthesia between the two groups.

The time to onset of spinal block was not significantly different between 1% versus 5% lidocaine, 4.3 ± 1.9 versus 4.6 ± 2.4 min (*P* = 0.27); the median highest dermatomal level was T4 for 1% versus T6 for 5% lidocaine (*P* < 0.0001). The number of episodes where blood pressure and pulse rate were beyond 20% of baseline was not significantly different with a median of 0 and a range of 0–8 and 0–7 for 1% versus 5% lidocaine, respectively.

The adequacy for surgical anesthesia (*i.e.*, anesthetic failures) between 1% versus 5% lidocaine was not significantly different 0.9% (95% CI 0–2.2) versus 1.3% (95% CI 0–2.7). As well, the proportion of technical failures and surgery outlasting anesthesia between 1% versus 5%

Table 2. Immediate Recovery Profile for 1% versus 5% Lidocaine

	1% Lidocaine (N = 218)	5% Lidocaine (N = 235)
2 Dermatome regression, min	76 ± 20	77 ± 21
Plantar flexion, min	83 ± 21	89 ± 23*
Big toe proprioception, min	88 ± 21	93 ± 23*
Forefoot sensation, min	85 ± 25	92 ± 25*
Sustained leg lift, min	90 ± 21	95 ± 22†

Values are expressed as mean ± SD.

* *P* < 0.01. † *P* < 0.05

Table 3. Incidence of TNS Over Time for 1% versus 5% Lidocaine

Time Interval, h	1% Lidocaine (N = 218)	5% Lidocaine (N = 235)
0–24	37 (17)	28 (12)
At 24	16 (7.3)	12 (5.1)
24–48	21 (9.7)	20 (8.3)
At 48	5 (2.4)	8 (3.2)
48–72	5 (2.4)	9 (3.7)
At 72	1 (0.48)	2 (0.93)

Values are expressed as number (percentage).

lidocaine were not significantly different 3.7% (95% CI 2–7) versus 4.3% (95% CI 2–7).

The immediate recovery from 1% versus 5% lidocaine was faster for plantar flexion, big toe proprioception, forefoot sensation and sustained 5 s leg lift (table 2). The time to 2 segment regression was not different between the two groups (table 2). The late recovery variables were not analyzed as there were very few (<10) outpatients in each group.

We were unable to contact ten patients in the 1% lidocaine group, and 14 patients in the 5% lidocaine group for follow-up. There was no difference in the baseline demographics of these patients between the two groups. The distribution of TNS over time between 1% versus 5% lidocaine is shown in table 3. Most TNS subsided over 48–72 h postop, and there was only one patient with TNS lasting more than 72 h until 96 h. The incidence of TNS was 21% (95% CI 16–27) for the 1% lidocaine group versus 18% (95% CI 14–23) for the 5% lidocaine group in the intention to treat analysis. There was no difference in the incidence of TNS between the two groups in both the intention to treat and the per protocol analysis 21% (95% CI 16–26) versus 19% (95% CI 14–24) for the 1% versus 5% lidocaine group. The distribution of the incidence of TNS between 1% versus 5% lidocaine among the 4 sites was not significantly different (Zelen Q = 4.8, $P = 0.19$).

The highest VRS during specific time intervals were higher during all three time intervals tested between TNS versus non-TNS patients across the first, second and third 24 h (table 4). The number of acetaminophen with codeine tablets consumed was higher in the TNS versus

Table 4. Time Interval-specific Highest VRS for TNS versus Non-TNS Patients

Time Interval, h	Highest VRS TNS	Highest VRS Non-TNS
0–24	5.3 ± 3.0	2.3 ± 3.1*
24–48	4.2 ± 2.6	0.5 ± 1.5*
48–72	3.6 ± 2.2	0.2 ± 0.8*

Values are expressed as mean ± SD.

* $P < 0.001$.

TNS = transient neurologic symptoms; VRS = verbal rating scale (0–10, 0 = no pain, 10 = worst pain imaginable).

Table 5. Acetaminophen with Codeine Consumption for TNS versus Non-TNS Patients

Time Interval, h	Number of Acetaminophen with Codeine Tablets for TNS Patients	Number of Acetaminophen with Codeine Tablets for Non-TNS Patients
0–24	2.3 ± 1.9	0.3 ± 1.8*
24–48	1.6 ± 1.5	0.6 ± 1.3*
48–72	1.3 ± 1.4	0.2 ± 0.7*

Values are expressed as mean ± SD.

* $P < 0.0001$.

TNS = transient neurologic symptoms.

non-TNS patients over time during each specific time period during the first, second and third 24 h postop (table 5). The onset time for TNS was 13 ± 11 h for 1% lidocaine and 11 ± 9 h for 5% lidocaine, and the difference was not significant ($P = 0.39$).

Comparison of functional impairment between time interval-specific TNS versus non-TNS patients across each time interval of the first, second, and third 24 h showed significant differences for 24, 48, and 72 h (table 6).

The multiple outcome variables: walking, sitting, voiding, bowel movement, sleeping between TNS versus non-TNS patients as tested by MANOVA showed a P value of 0.0001. Repeated measures ANOVA performed on each of the variables identified walking, sitting and sleeping as the activities accounting for the differences (table 7). A greater proportion of patients with TNS had moderate or severely affected functional impairment with walking during the first 48 h postop (fig. 1), $P < 0.001$. More patients with TNS had severely affected functional impairment of sitting during the first 48 h postop (fig. 2), $P < 0.001$. A greater proportion of patients with TNS had moderate and severely affected functional impairment of sleeping at 0–24 h, and were moderately affected up to 72 h postop compared to patients without TNS (fig. 3), $P < 0.001$. The proportion of patients who were employed but not yet returned to work at 72 h postop between TNS versus non-TNS patients were similar (100% vs. 98%, $P = 0.37$).

Satisfaction was higher among non-TNS patients; 96% (95% CI 93–98) would recommend spinal anesthesia, compared to TNS patients 89% (95% CI 83–92), $P < 0.01$. However, between the 1% versus 5% lidocaine

Table 6. Functional Impairment of Daily Activities Over Time for TNS versus Non-TNS Patients

Time Interval, h	Functional Impairment in TNS Patients	Functional Impairment in Non-TNS Patients
0–24	2.20 ± 1.00	1.40 ± 0.79*
24–48	1.90 ± 1.00	1.10 ± 0.47*
48–72	1.90 ± 0.83	1.00 ± 0.22*

Values are expressed as mean ± SD. Functional impairment scale: 1 = "not at all affected" to 5 = "very strongly affected."

* $P < 0.0001$.

TNS = transient neurologic symptoms.

Table 7. Functional Recovery

Time Interval, h	TNS Patients	Non-TNS Patients
Walking		
0-24	1.500 ± 0.970	1.100 ± 0.460*
24-48	1.500 ± 1.100	1.000 ± 0.280*
48-72	1.300 ± 0.610	1.000 ± 0.067*
Sitting		
0-24	1.400 ± 0.790	1.100 ± 0.490*
24-48	1.400 ± 0.940	1.000 ± 0.260*
48-72	1.100 ± 0.360	1.000 ± 0.095*
Voiding		
0-24	1.000 ± 0.250	1.100 ± 0.410
24-48	1.100 ± 0.230	1.100 ± 0.450
48-72	1.100 ± 0.270	1.000 ± 0.270
Bowel movement		
0-24	1.100 ± 0.480	1.000 ± 0.270
24-48	1.000 ± 0.160	1.000 ± 0.210
48-72	1.000 ± 0.000	1.000 ± 0.110
Sleeping		
0-24	2.400 ± 1.200	1.500 ± 1.000*
24-48	1.500 ± 0.800	1.100 ± 0.410*
48-72	1.500 ± 0.850	1.000 ± 0.150*

Values are expressed as mean ± SD. Functional impairment scale: 1 = "not at all affected" to 5 = "very strongly affected."

* P < 0.001.

TNS = transient neurologic symptoms.

groups, the proportion of patients willing to recommend spinal anesthesia were similar, 95% (95% CI 91-97).

Discussion

The incidence of TNS with 1% *versus* 5% lidocaine was approximately 20% for both groups. This incidence was

similar to the incidence we used in the sample size calculation. Therefore, this study has adequate power to exclude a 50% relative risk reduction associated with the 1% concentration. This is the first negative study in the literature to adequately prove that dilution of lidocaine from 5% to 1% does not affect the incidence of TNS.

This is the first large prospective randomized study that evaluates the functional impact of TNS on patient daily activities. Given the transient nature of TNS and that discomfort from TNS can be effectively treated with potent nonsteroidal antiinflammatory drugs,¹⁹ the clinical significance of TNS has been questioned, and whether TNS warrants the controversy it has generated.^{20,21} Patients with TNS had higher VRS scores and consumed more acetaminophen with codeine compared to patients who did not have TNS. We demonstrated that on a five point scale assessing overall daily activities, there were significant differences between the TNS *versus* non-TNS patients over the first 72 h. Of the five activities we assessed as part of daily activities; walking, sitting, and sleeping showed significant differences between TNS *versus* non-TNS patients. The degree of difference in the mean scores was rarely more than one, this difference in scores implies that the difference ranged only from not at all affected to mildly affected. However, a small percentage of patients with TNS had moderate to severe impairment of walking, sitting, and sleeping suggesting that this subset of patients had clinically significant morbidity with regards to functional recovery during the first 48 h.

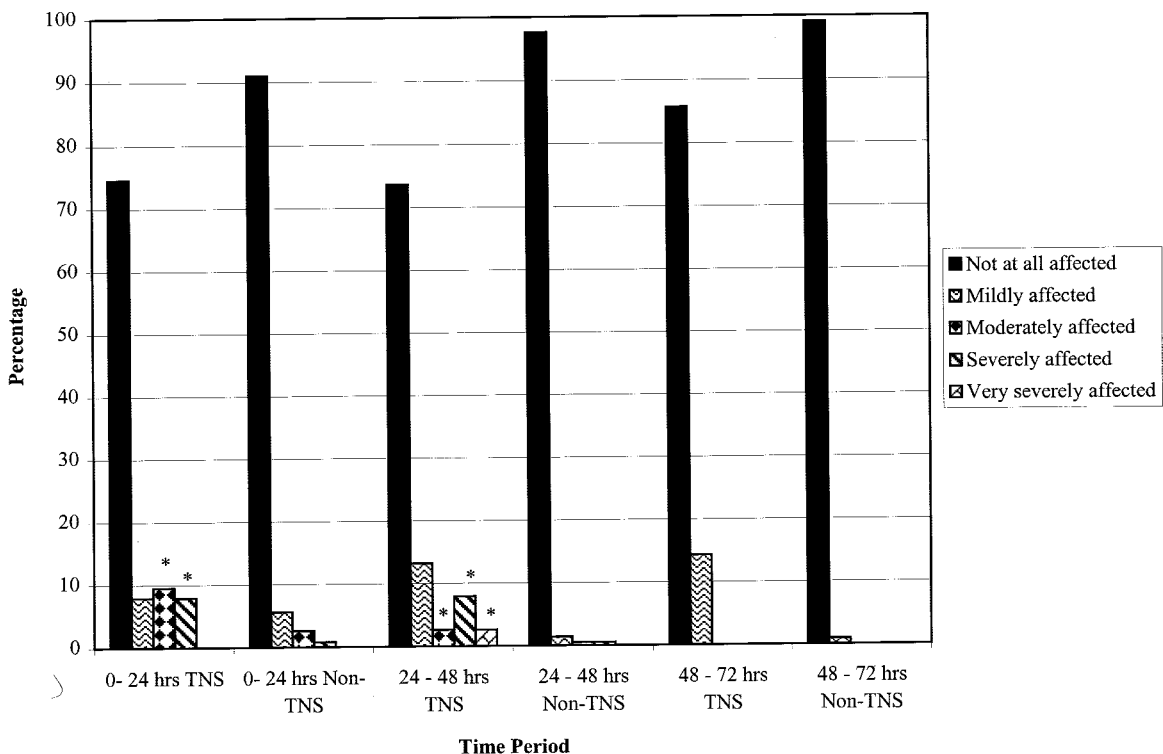


Fig. 1. Functional impairment of walking between TNS and non-TNS patients at 0-24 h, 24-48 h, 48-72 h, *P < 0.001.

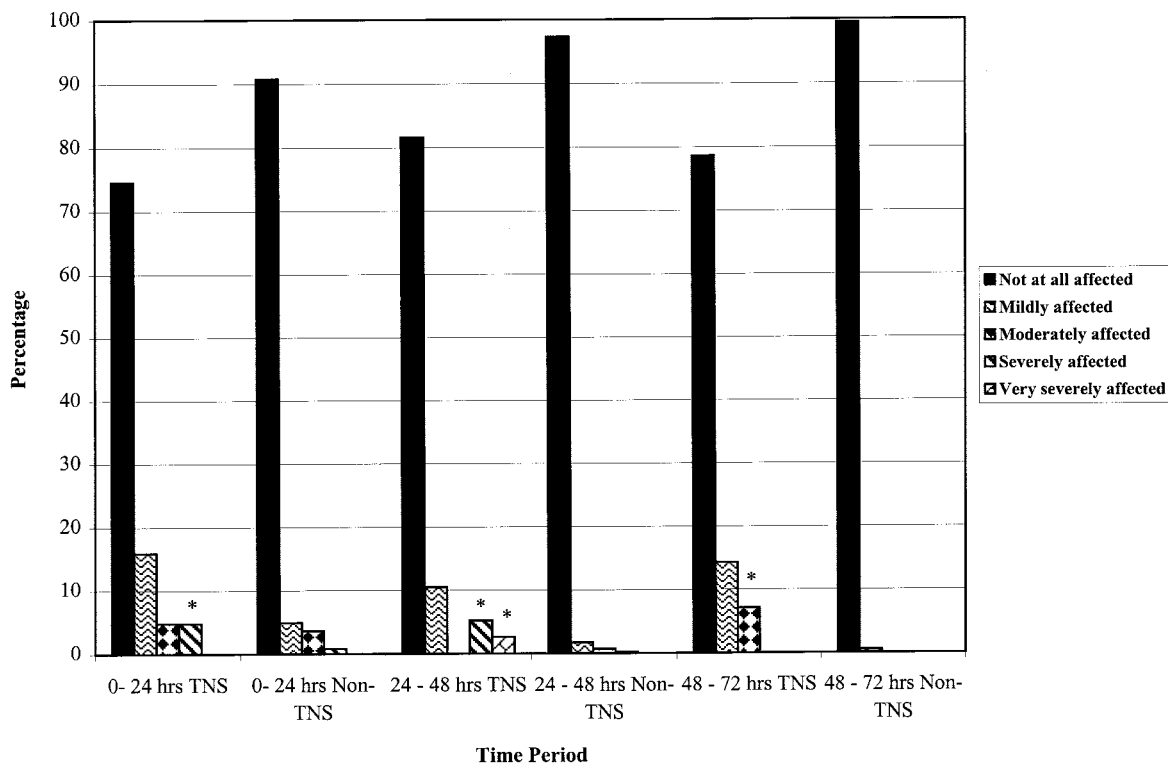


Fig. 2. Functional impairment of sitting between TNS and non-TNS patients at 0–24 h, 24–48 h, 48–72 h, * $P < 0.001$.

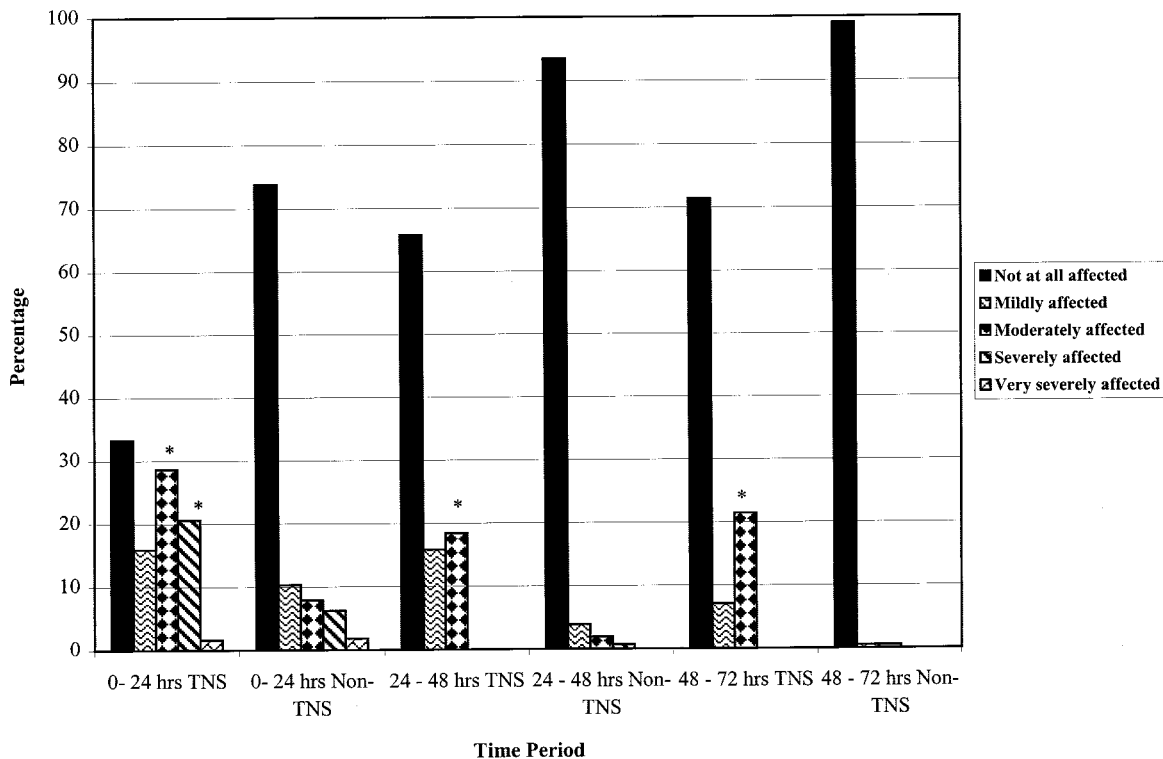


Fig. 3. Functional impairment of sleeping between TNS and non-TNS patients at 0–24 h, 24–48 h, 48–72 h, * $P < 0.001$.

The TNS did not influence the proportion of patients who returned to work; however, we did not specifically examine factors such as sick time available to employees, which may have influenced when patients returned to work.

Patients who did not experience TNS were more willing to recommend spinal anesthesia to their acquaintances than patients who experienced TNS, suggesting patients who did experience TNS were less satisfied. Interestingly, 89% of the patients who did have TNS still recommended spinal anesthesia.

A large prospective observational study found the risk of TNS was higher with lidocaine, odds ratio (OR) 5.1 (CI 2.5–10.2) compared to bupivacaine, ambulatory anesthesia OR 3.6 (CI 1.9–6.8), and the lithotomy position OR 2.6 (CI 1.5–4.5). The dose of lidocaine was not a risk factor for TNS, however, the investigators did not examine whether concentration of lidocaine was a risk factor.⁶ Our results are consistent with two previous smaller prospective studies which found a similar incidence of TNS with 2% and 5% lidocaine.^{7,8} Although this study is limited to short urological procedures, our results confirm the findings of a randomized study comparing 0.5%, 1% and 2% lidocaine in 109 patients undergoing ambulatory knee arthroscopy; dilution of lidocaine did not reduce the incidence of TNS.¹²

The etiology of TNS remains unclear. Our hypothesis that 1% lidocaine may be associated with a decrease in the incidence of TNS was based on *in vitro* data on isolated animal nerves suggesting a dose-dependent relationship with conduction and histologic changes starting with 1% lidocaine.^{15,16} The reduction of lidocaine concentration to 1% in our study did not affect the incidence of TNS. However, even very dilute lidocaine concentrations (0.5%) have been found to be associated with a similar incidence of TNS,¹² thus clinical trials do not confirm experimental laboratory toxicity data about lidocaine concentration.

Neurotoxic causes for TNS remain speculative; other potential causes for TNS include muscle spasm, needle trauma, myofascial trigger points, and early mobilization.¹⁹ Rowlingson has suggested that TNS be renamed “postspinal musculoskeletal symptoms” (PSMS).²¹ The etiology of TNS remains to be determined.

One of the limitations of this study is that the attending anesthesiologist was not blinded, however, the research assistants assessing the perioperative outcomes were blinded to the randomization. The research assistants were allowed to enter the operating room, only after the spinal anesthetic was completed.

Another limitation of this study is that patient satisfaction was only assessed by a yes-no question, and this can be improved by using a 5–7 point scale. As yet, there has not been a tested and validated patient satisfaction scale for use in regional anesthesia.²² For the measurement of pain, a yes-no question on the presence of pain was

included in the questionnaire in order to guide the flow for the following questions. However, even when the patients denied the presence of pain on the yes-no question, the research assistant proceeded to administer the VRS. This is due to the fact that a yes-no question has only two steps and any measurement instrument with less than 5–7 categories has been shown to be unreliable for assessing subjective outcomes.²³

We did not investigate whether the incidence of TNS is dose-dependent. Recently, the dose of lidocaine has been reduced often in combination with other agents, particularly fentanyl in other studies.

In conclusion, compared with 5% lidocaine, 1% lidocaine did not show a reduction in the incidence of TNS or a decrease in severity, or duration of TNS. We have shown that patients with TNS had higher VRS and consumed more acetaminophen with codeine than patients without TNS. As well, during the first 48 h postoperatively, a small proportion of patients who had TNS experienced clinically significant functional impairment of some of the activities of daily living.

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Appendix I

Postoperative questionnaire- postop (circle one) 24h/ 48h/ 72 h

Inpatient *Outpatient-phone questionnaire*

1. Do you have any pain right now? Yes No

2. Administer 0-10 VRS

VRS 0-10

If yes on 1, or any positive value on 2,

1) Where is the pain?

Lower abdomen/ backpain/ perineal/ back + the back of legs

2) How intense is the pain?

mild discomforting distressing horrible excruciating

3) When did it start?

4) Has anything made the pain better or worse?

5) Do you have any numbness down your legs? Yes No

6) Do you have any headache? Yes No

If no to the above section,

1. Did you have any pain in the last 24 hrs? Yes No

2. Administer 0-10 VRS

VRS 0-10

If yes on 1, or any positive value on 2,

1) Where is the pain?

Lower abdomen/ backpain/ perineal/ back + the back of legs

2) How intense is the pain?

mild discomforting distressing horrible excruciating

3) When did it start?

4) How long did it last?

5) Has anything made the pain better or worse?

6) Do you have any numbness down your legs? Yes No

7) Do you have any headache? Yes No

Continue the following sections regardless of the answers to the previous sections.

- a) Are your daily activities affected by pain?
 Not at all mild mod severe very severe
- b) Is your walking affected by pain?
 Not at all mild mod severe very severe
- c) Is your sitting affected by pain?
 Not at all mild mod severe very severe
- d) Is your voiding affected by pain?
 Not at all mild mod severe very severe
- e) Is your bowel activity affected by pain?
 Not at all mild mod severe very severe
- f) Is your sleep affected by pain?
 Not at all mild mod severe very severe
- g) Are there other reasons that are affecting your above activities?

- h) Are you currently employed? Yes No
 If *yes*, have you returned to work? Yes No

If *no*, indicate how much do you agree with the following statements.

Pain is the main reason for not returning to work?

- Strongly disagree disagree no opinion agree Strongly agree

Headache is the main reason for not returning to work?

- Strongly disagree disagree no opinion agree Strongly agree

Numbness is the main reason for not returning to work?

- Strongly disagree disagree no opinion agree Strongly agree

Fatigue is the main reason for not returning to work?

- Strongly disagree disagree no opinion agree Strongly agree

There are other reasons for not returning to work?

- Strongly disagree disagree no opinion agree Strongly agree

What are the other reasons? _____

- 1) Are you taking pain killers? Yes No
 If *yes*, indicate how much do you agree with the following statements.
Nerve Pain that is at the back and going down the legs is the main reason for taking pain killers?
 Strongly disagree disagree no opinion agree Strongly agree
Wound pain is the main reason for taking pain killers?
 Strongly disagree disagree no opinion agree Strongly agree
Headache is the main reason for taking pain killers?
 Strongly disagree disagree no opinion agree Strongly agree
There are other reasons for taking pain killers?
 Strongly disagree disagree no opinion agree Strongly agree
What are the other reasons? _____
- 2) Are you taking the prescribed Tylenol #3? Yes No
 How many tablets have you taken _____
- 3) Are you taking any other pain killers? Yes No
 If *yes*, what kind _____
- 4) Have you tried to contact your physician? Yes No
Is pain the main reason for contacting your physician?
 Strongly disagree disagree no opinion agree Strongly agree
Are there other reasons for contacting your physician? Yes No
 If *yes*, what reason _____

- IV. Would you recommend this anesthetic technique to people you know?
 Yes No
 What is the reason for recommending or not recommending? _____
