Original Article
2022, 12(2): 41-50
DOI: 10.22038/EBCJ.2022.63511.2648

Received: 06/02/2022
Accept & ePublished: 28/05/2022

Evidence Based Care Journal
http://ebcj.mums.ac.ir
Online ISSN: 2008-370X

Sprotte versus Quincke Spinal Needles on the Frequency of Spinal Anesthesia Success in Patients undergoing Cesarean Section Delivery

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Abstract

Background: In previous studies, the anesthesia technique was performed by different people and different results were reported, which makes comparisons difficult.

Aim: This study aimed to compare Sprotte (Non-cutting) and Quincke (Cutting) spinal needles on the frequency of spinal anesthesia success in patients undergoing cesarean delivery.

Method: This double-blind randomized clinical trial study was performed in 2019 on 100 pregnant women in ASA class I or II with term and single pregnancies who were candidates for elective cesarean section with spinal anesthesiain Tabriz Al-Zahra Hospital. Spinal anesthesia was performed using Sprotte spinal needle 25G in the intervention group (n=50) and with Quincke's spinal needle 25G in the control group (n=50). The frequency of spinal anesthesia failure was recorded as complete and partial failure. Data were analyzed using SPSS.16 software. P<0.05 was considered statistically significant.

Results: In the Sprotte group, there was one patient with incomplete failure and two with complete failure; in the Quincke group, there were 2 patients with incomplete failure and 3 with complete failure; the two groups were not significantly different (P=0.749). Three patients in the Quincke group required repeated spinal block. The frequency of sensory (P=0.002) and motor (P=0.001) block for surgery was significantly higher in the Sprotte group. The Post-Dural puncture headache (PDPH) was significantly higher in the Quincke group (P=0.006).

Implications for Practice: The Post-Dural puncture headache (PDPH) using Sprotte spinal needle was lower than using Quincke needle in patients with spinal anesthesia for cesarean delivery.

Keywords: Cesarean Delivery, Spinal anesthesia, Sprotte, Success, Quincke

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Introduction

Spinal anesthesia was introduced in 1899 by Bier for clinical use in anesthesia. Reduction of morbidity and mortality with regional anesthesia techniques led to the widespread use of these methods in anesthesia for surgery of lower umbilical regions (1-3). In recent years, the use of regional anesthesia for cesarean delivery has been increasing due to the improvement of maternal and fetal outcomes compared to general anesthesia. In the United States, more than 95% of cesarean deliveries are performed under regional anesthesia. Most women prefer to be awake during labor to hear their baby's crying sound for the first time at birth (4-7).

Spinal anesthesia is also the preferred regional anesthesia technique (in comparison with epidural anesthesia) for cesarean delivery. The procedure is an easy technique to perform and train, non-expensive for the patient, and has a quick onset of action. This procedure provides effective, reliable and predictable sensory and motor block even in cases of emergency cesarean section and good surgical conditions with excellent analgesia during surgery. It has a high success rate and almost no systemic toxicity in mother and fetus due to the use of lower doses of the drug compared to epidural block. However, there is a possibility of failure for unknown reasons (5, 8-11).

Incidence, causes and subsequent management of failed spinal anesthesia were less defined in recent studies. The term, block failure is defined as when spinal anesthesia has been performed, but the block does not exist and/or is insufficient for the surgery (12,13). The prevalence of failure in educational centers was 17% (up to 25% in some training centers) and the prevalence was reported as 0.7%-16% in the recent published articles (1, 9, 14-17). The rate of failure of spinal anesthesia has been reported as 15 to 19% in several studies conducted in Iran in recent years (18-20). In single-shot spinal anesthesia, it is not possible to extend the block in cases of insufficient anesthesia. On the other hand, in cases of unsuccessful spinal anesthesia, it is needed to convert spinal anesthesia to general anesthesia, and the risk of aspiration and difficult endotracheal intubation persist that may lead to drug interventions. In addition, the most common complications of patients in obstetric practice is anxiety during surgery after unsuccessful spinal anesthesia for cesarean section (4, 8, 21, 22).

Studies have shown that spinal needle tip design is very important in complications of spinal anesthesia. Various studies have reported that pencil-point needles cause less damage to the meninges compared to other needles and reduce the incidence of PDPH (23-26). Today, the use of non-cutting needles is recommended to reduce the incidence of PDPH (27-30). In the previous study, spinal needles with different numbers were used which can be effective in the success rate of spinal anesthesia technique; also only one type of needle was used (31). On the other hand, in order to achieve accurate results, the anesthesia technique must be performed by one person, while in previous studies, it has been performed by different people with different methods (median and paramedian) (32). Several studies (26, 31, 33) have been performed with high sample sizes, all of which had the following problems, and finally, due to the vacuum of their studies, this study was performed. Therefore, this study was performed to eliminate the weaknesses of previous studies. On the other hand, in recent years, there is a program to prevent elective cesarean section in public and educational hospitals; moreover, the satisfaction of patients has become more important than before; so it is essential to choose the appropriate method to achieve maximum satisfaction of women who are candidates for cesarean section delivery.

Currently, single-shot spinal anesthesia was performed using a Quincke cutting-point needle with 0.5% bupivacaine for cesarean delivery in our medical center (Tabriz Al-Zahra Hospital). Due to the lower complications of Pencil-point spinal needles and the lack of a similar study, this study was performed to compare Sprotte (non-cutting) and Quincke (cutting) spinal needles in the frequency of spinal anesthesia failure rates for cesarean delivery.

Methods

Patients

This double-blind randomized clinical trial study was performed in 2019 on women in Class I or II of the American Society of Anesthesiologists (ASA) with full-term and singleton pregnancies who were candidates for elective cesarean section with spinal anesthesia in Al-Zahra Hospital (Tabriz University of Medical Sciences). The women were selected by convenience sampling using sequential order and using randomized software (Rand list online). The sample size was calculated according to the results of the study by Nazemi et al. (34) about the effective factors on the prevalence of spinal

anesthesia failure. Considering the study's power, significance level of 0.8 and 0.05 and confidence level of 95%, failure rate in the Sprotte group = 18% and in the Quincke group =15%, respectively, the minimum required sample was calculated as 43 cases for each group. Finally, due to the availability of sufficient patients and considering 10% of loss to follow up, the sample size was considered as 50 cases in each group (Figure 1).

Inclusion and exclusion criteria

Inclusion criteria were elective cesarean section candidates, spinal anesthesia candidates, age of 18-40 years, ASA class I or II and singleton term pregnancy. Exclusion criteria were contraindications to spinal anesthesia, allergy to local anesthetic drugs, mental illness, history of systemic diseases (cardiovascular, liver, kidney, etc.), spinal canal stenosis or lumbar disc, multiple pregnancies, weight more than 100 kg and height less than 150 cm, uterine myoma, hemorrhage>1000 ml during surgery, emergency cesarean section and active delivery.

Study Design and Procedures

At first, informed written consent was obtained from all patients to enter the study. Patients were randomly divided into two study groups using the online randomization method for needle type (Sprotte [Non-cutting] or Quincke [Cutting]). Spinal anesthesia was performed after obtaining cerebrospinal fluid (CSF) flow and aspiration. In patients of the study group (n=50), anesthesia was done with Sprotte spinal needle No. 25 (PAJUNK SPROTTE ® cannula 25G x103mm) and in patients of the control group (n=50) with Quincke spinal needle No. 25 (B. Braun, Melsungen AG. Germany 25GX90mm).

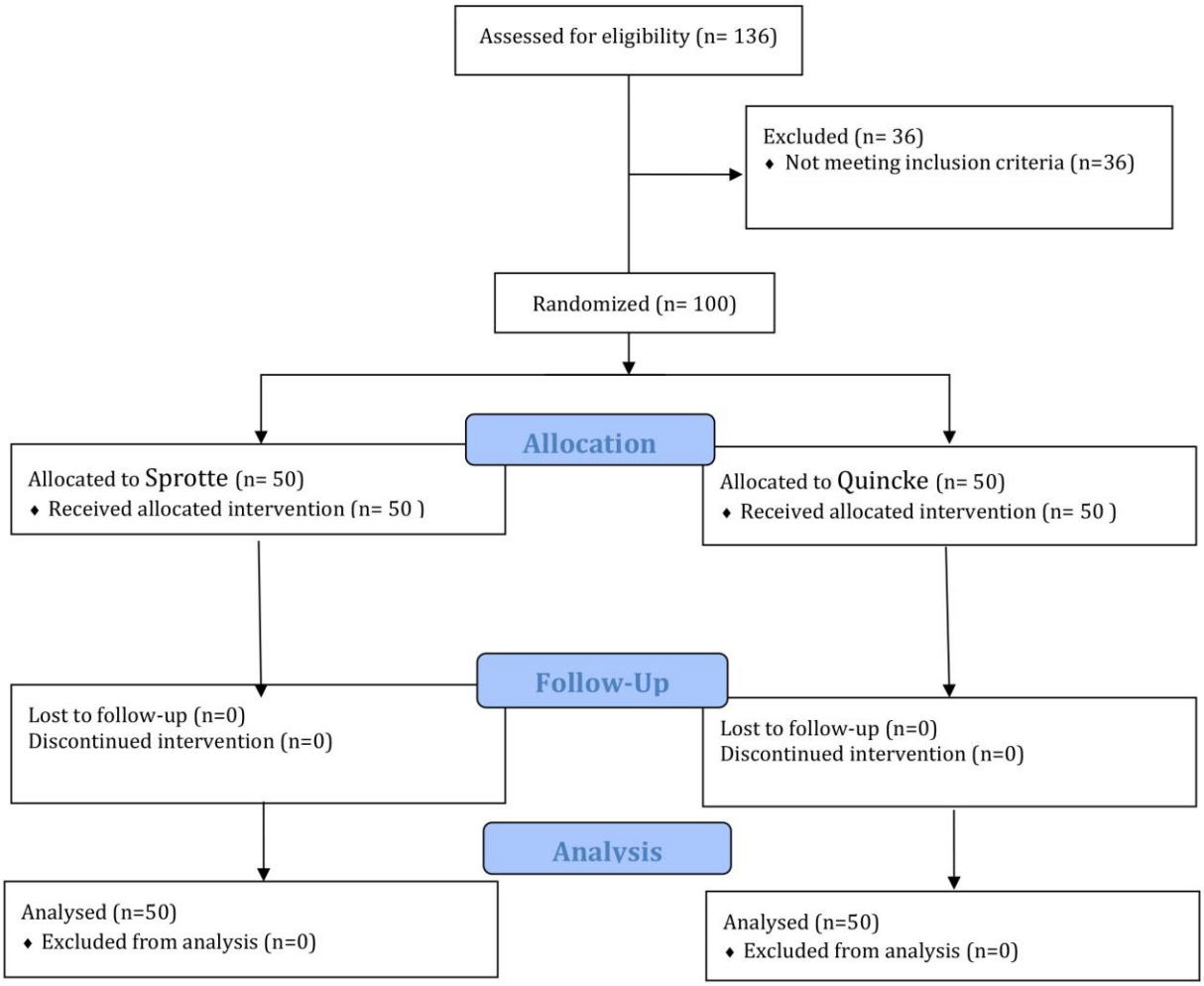

Figure 1. The study's flowchart

All Single-shot spinal anesthetics and study outcome record were performed by an anesthetist and senior assistant (study outcome record). After stabilization of standard monitoring including automatic sphygmomanometer, electrocardiogram and pulse oximetry, venous route was established, and 8 ml/kg of Ringer's solution was infused within 15 minutes. All blocks were performed in a sitting position in the L2-3, L3-4 or L4-5 intervertebral space with a midline approach. After prep & drep, 2 ml of 1% lidocaine was injected into the skin, subcutaneously and supraspinous ligament for local anesthesia. Then a combination of 10 mg hyperbaric bupivacaine (0.5%) (Marcaine 0.5% spinal heavy, AstraZeneca, CENEXT, France) and 20 µg fentanyl with a total volume of 2.2 ml were injected in the subarachnoid space and the spinal needle was removed after re-aspiration at the end of injection.
Demographic information of patients (age, weight, height and BMI), gestational age, reason of cesarean section and history of spinal anesthesia were recorded by senior assistant. Anesthesia information were recorded which includes the level of cold sensation loss, spinal anesthesia failure as total failure (defined as the need to re-block or convert spinal anesthesia to general anesthesia) or and partial failure (defined as fentanyl was prescribed when the patient had mild pain or a pain score less than 3 based on the VRS numerical score (0-10)). In the case of moderate to severe pain or a VRS greater than 3 during surgery, repeated spinal anesthesia or general anesthesia were done respectively. Duration of surgery (interval between incision to close the incision) and duration of anesthesia (interval between the end of the intrathecal drug injection until the sensory block returned under the T12 dermatome) were recorded.
Complications of spinal anesthesia (hypotension, bradycardia, shivering, nausea, vomiting, anxiety, and impaired respiration) were treated with ephedrine or phenylephrine, atropine, midazolam, metoclopramide, and respiratory support, respectively. In the case of surgical complications such as adhesions, up to two months after surgery, the complications mentioned in the clinical examination were performed by the relevant physician. One of the important complications of surgery is Transient Neurologic Symptoms (TNS) such as dizziness, loss of consciousness, seizures, etc. To accurately evaluate this complication, it is possible to examine and take a detailed history of the patient and perform several initial tests. In more severe cases, methods such as computed tomography (CT) of the brain and magnetic resonance imaging (MRI) and electroencephalography should be used. The tool used for this study was initially designed using the results of similar studies (6, 19, 33, 35). Then, in order to know whether this tool is suitable for this study or not, we provided the questions to the professors in the field of anesthesia and asked them to express their opinions to complete the mentioned tool; their comments were added to the questions of the tool. Finally (in the final session), the tool was used after approval by all anesthesiologists (Content Validity). Also, Intraclass Correlation Coefficient (ICC) was used to evaluate the reliability of the tool.
An anesthesiologist or senior assistant was in charge of the anesthesia and senior anesthesia assistant (aware of the study) and another anesthesiologist and other anesthesia assistant (unaware of the study) were responsible to record the patients' information.

Outcomes
Primary outcomes were the frequency of total failure and partial failure of spinal anesthesia. Complete failure is defined as the need to repeat spinal anesthesia or to convert spinal anesthesia to general anesthesia, and partial failure is defined as the need for intraoperative complementary analgesia (fentanyl) (8).

Statistical Analysis
Data were presented using descriptive statistical methods (mean ± standard deviation (SD) and frequency, percentage). X2 test was used to compare the qualitative variables between the two groups and independent t-test was used to compare the quantitative variables with normal distribution between the two groups. The normality of data distribution was assessed using Kolmogorov-Smirnov test, which showed that data had a normal distribution. Data were analyzed using SPSS.16 software. $P< 0.05$ was considered statistically significant.

Results
A total of 136 patients referred to Al-Zahra Hospital for elective cesarean section during the study period. Then, 100 patients included in this study according to the inclusion/exclusion criteria. The

Table 1. Demographic characteristics of patients in the Sprotte and Quincke groups

Variable	Sprotte group (n=50)	Quincke group	p-value
Age (years)	30.84±5.76	31.12±5.86	0.810*
Weight (Kg)	78.36±11.34	82.48±11.24	0.071*
Height (cm)	160.24±5.96	161.82±5.81	0.183*
BMI (kg/m^2)	30.51±4.21	31.60±4.87	0.234*
Gestational Age (weeks)	38.10±0.70	38.04±0.72	0.677*
Surgery Duration (min)	51.28±4.89	52.10±5.60	0.438 *
Anesthesia Duration (min)	67.54±4.49	66.54±5.23	0.308*
Gravid (%)			
1	18 (36%)	18 (36%)	
2	22 (44%)	22 (44%)	0.528**
3	10 (20%)	8 (16%)	
4	0	2 (4%)	
Reason of C/S (%)			
History of C/S	33 (66%)	32 (64%)	
Breach	5 (10%)	5 (10%)	0.927**
Infertility	3 (6%)	2 (4%)	
Elective	7 (14%)	7 (14%)	
CPD	2 (4%)	4 (8%)	
History of Previous C/S (%)			
0	17 (34%)	18 (36%)	
1	25 (50%)	22 (44%)	0.734**
2	8 (16%)	9 (18%)	
3	0	1 (2%)	
History of Spinal Anesthesia (%)	30 (60%)	30 (60%)	0.581***

*T-test **Fisher's exact test ***Chi-Square test

patients were randomly assigned into two groups and received the relevant intervention. All patients were present until the end of the study and no sample loss was observed (Figure 1).

Patients' demographic data were presented in Table 1. There was no statistically significant difference between the two groups in terms of age, weight, height, BMI, gestational age, number of pregnancies, cause of cesarean section, number of previous cesarean sections, history of spinal anesthesia, duration of surgery and duration of anesthesia (p> 0.050).

The highest frequency of spinal anesthesia level in patients was L3-4 (57%) and CSF withdrawal was observed in all patients (100%). In 92% (n=92) of patients, surgery was performed with the first spinal puncture try. In 3% of patients, spinal anesthesia repeated and in 3% of patients, surgery was completed with analgesic administration. Also, complete failure was observed in 2 patients of the Sprotte group and surgery was performed by general anesthesia. The characteristics of spinal anesthesia in patients of the two study groups were shown in Table 2.

Table 2. Characteristics of spinal anesthesia in the Sprotte and Quincke groups

Variable		Sprotte group (n=50)	Quincke group (n=50)	Total	p-value
Spinal anesthesia level (%)	L2-3	10 (20%)	11 (22%)	21 (21%)	0.545*
	L3-4	31 (62%)	26 (52%)	57 (57%)	
	L4-5	9 (18%)	13 (26%)	22 (22%)	
Spinal anesthesia ease (%)	Easy	36 (72%)	37 (74%)	73 (73%)	0.949*
	More than 3 times try	8 (16%)	8 (16%)	16 (16%)	
	Difficult	6 (12%)	5 (10%)	11 (11%)	
Anesthesia level (%)	T4	10 (20%)	14 (28%)	24 (24%)	0.251*
	T5	26 (52%)	23 (46%)	49 (49%)	
	T6	13 (26%)	8 (16%)	21 (21%)	
	T7	1 (2%)	2 (4%)	3 (3%)	
	>T7	0	3 (6%)	3 (3%)	

Table 2. Continued					
Spinal anesthesia outcome (%)	Success	47 (94%)	45 (90%)	92 (92%)	
	Partial failure	1 (2%)	2 (4%)	3 (3%)	0.749*
	Complete failure	2 (4%)	3 (6%)	5 (5%)	
Anesthesia Management (%)	Successful try	47 (94%)	45 (90%)	92 (92%)	0.102**
	Use of fentanyl	1 (2%)	2 (4%)	3 (3%)	0.500**
	Re-block	0	3 (6%)	3 (3%)	0.121**
	General anesthesia	2 (4%)	0	2 (2%)	0.247**
CSF withdraw (%)		50 (100%)	50 (100%)	100 (100%)	0.999**
Incomplete sensory block (%)		47 (94%)	45 (90%)	92 (92%)	0.002**
Complete motor block (%)		48 (96%)	45 (90%)	93 (93%)	0.001**

*Fisher's exact test **Chi-Square test

Table 3. Frequency of complications after spinal anesthesia and surgery in the Sprotte and Quincke groups

Variable	Sprotte group (n=50)	Quincke group (n=50)	Total	p-value*
Hypotension (%)	11 (22%)	15 (30%)	26 (26%)	0.247
Bradycardia (%)	1 (2%)	2 (4%)	3 (3%)	0.500
Nausea and vomiting (%)	6 (12%)	8 (16%)	14 (14%)	0.387
Anxiety (%)	3 (6%)	2 (4%)	5 (5%)	0.500
Respiratory weakness (%)	0	0	0	-
Shivering (%)	15 (30%)	14 (28%)	29 (29%)	0.826
TNS (%)	2 (4%)	6 (12%)	8 (8%)	0.134
Paresthesia (%)	0	3 (6%)	3 (3%)	0.121
Motor weakness (%)	0	0	0	-
PDPH (%)	0	7 (14%)	7 (7%)	0.006

*Chi-Square test
TNS: Transient neurologic symptoms

The most common complications after spinal anesthesia were hypotension and shivering. PDPH was significantly lower in the patients of Sprotte group (p=0.006). The frequency of complications after spinal anesthesia and surgery were shown in Table 3.

Discussion

The results of the present study showed that no statistically significant difference was observed between the two groups in terms of age, weight, height and BMI of patients, indicating the above variables have no effect on the results. The two study groups were the same in terms of reason for cesarean section, history of cesarean section and spinal anesthesia, duration of surgery and anesthesia. Moreover, the characteristics of spinal anesthesia were evaluated and compared with two types of spinal needles (Non-cutting; Sprotte) and (Cutting; Quincke). Patients of both groups did not statistically differ in terms of the level of intervertebral space for blocking, the frequency of free CSF outflow, ease of technique and the highest level of anesthesia. Failure of spinal anesthesia is an important event for both anesthesiologist and the patient due to the clinical and legal issues, especially after the start of surgery (1,5). The range of failure of spinal anesthesia is between 0.5% and 6% (9). One of the causes of spinal anesthesia failure is the level of anesthesiologist experience. The other cause is that after injection of the drug following free flow of spinal fluid, some or all of the anesthetic solution is deposited outside of the intrathecal space due to incomplete placement of the spinal needle in the sub-arachnoid space before or during drug injection. It has been suggested that the free flow of fluid must be ensured before, during and after injection of intrathecal drugs (8). Hart and et al. showed that needle type is an important risk factor for failure of spinal anesthesia (36). In the present study, the overall rate of complete failure was 5%, which was 2 (4%) in the patients of the Sprotte group and 3 (6%) in the patients of Quincke group. Also, inadequate sensory and motor block in patients of the Sprotte group was less than the Quincke group. The cause of general failure in our center could be due to the insufficient experience of anesthesiologist. It seems that the reason for the greater success of spinal anesthesia with a Sprotte needle was the lack of needle displacement after the free flow of spinal fluid that is due to the presence of a needle to guide the spinal needle. Alabi et

al. (2017) in their study on 197 patients undergoing cesarean section, reported an incidence of 11.7% spinal anesthesia failure (complete and partial) (12). In other study on 3,568 patients undergoing cesarean section, Rukewe et al. showed an overall rate of spinal anesthesia failure of 9.1% with a higher frequency in Quincke needles. They emphasized the inadequate level of anesthesiologist experience as the cause of anesthesia failure (9). In the study of Rukewe et al., only the Quincke needle was used for anesthesia; the anesthesia technique was also performed by different people. The study researchers suggested that in future studies, it is better that the anesthesia technique be performed by one anesthesiologist alone to achieve a failure rate for spinal anesthesia. In the present study, all techniques were performed by one anesthesiologist; also, two different types of needles were compared. In the study of Riley et al., failure rate was 10% and was reported to be the same for both spinal Quincke needles (10). In the study of Crone et al., the incidence of spinal anesthesia failure was reported to be 5.1%, although the rate of failure with the Sprotte needle was higher than that of Quincke needle. The reason is the insufficient experience of anesthesiologist with the Sprotte needle (24). Buettner et al. showed that the puncture profile was better when using a Sprotte needle. They reported a higher incidence of failure with a Quincke needle as bending the needle tip from the midline (28).

In the present study, 2 patients (4%) in the two spinal anesthesia study groups underwent general anesthesia, and some patients with unsuccessful spinal anesthesia underwent surgery with re-spinal block or systemic analgesic (fentanyl). In the study performed on 2031 women undergoing cesarean section, Shrestha et al. examined the incidence and causes of failure of spinal anesthesia using Quincke needle. In their study, 6% of patients needed systemic methods and drugs. Causes of failure were due to technical errors and pharmacological factors (dose, use of epinephrine) or patient's position (37). In the study of Shrestha et al., unlike the present study, only one needle (Quincke) was used for spinal anesthesia. Also, the needle used in the study of Shrestha et al. was thicker than the needle used in the present study, which can increase the success rate of spinal anesthesia, which is different from the present study. Shrestha et al. recommended that other different needles with different thicknesses be used to evaluate the success of the spinal anesthesia technique; the present study confirmed their recommendations.

In terms of complications of spinal anesthesia during surgery, hypotension was the most common complication that there was not statistically difference between the two groups in the present study. Intraoperative complications were found when the block height is higher (8, 23). In the current study, none of the patients in the two groups had a block level higher than T4.

The postoperative complications related to anesthesia were also evaluated in the current study. The frequency of PDPH was 14% in the Quincke group, while none of the patients in the Sprotte group had PDPH. Non-cutting needles are the gold standard for spinal block surgery, not only because of the lack of dormer fibers cutting, but also due to the smaller number of punctures and less needle tip damage after contact with bone; both of which lead to lower PDPH incidence compared with sharp-bevel needles (23). Young maternal age is a major risk factor for PDPH. After the fetus is removed, the epidural pressure decreases and facilitates increased spinal fluid leakage through the dormer hole. In this way, the meninges are stretched and due to its pain-sensitive nature, it causes headaches. On the other hand, after losing a certain volume of CSF in the body, physiologically, according to the Monro-Kellie hypothesis, compensatory vasodilation and increases the volume of blood inside the skull occurs, which also leads to headache (38). In the study on 320 cesarean section patients, Pal and et al. reported that Whitacre non-cutting needles cause a lower incidence of PDPH compared to conventional inclined needles. Moreover, the failure rate of Sprotte needle was lower than Quincke needle (39). In the study by Vallejo et al. on 102 patients undergoing elective cesarean section, the prevalence of postoperative headache was higher in patients undergoing spinal anesthesia using Quincke needles compared with pencil-point needles (which included needles used in the present study). In the study of Vallejo et al., it was also noted that the use of Pencil-point needles, in addition to the low prevalence of post-puncture headache, has lower cost, easier performance and lower failure; which was also in concordance with the current study (40).

Another important postoperative complication of spinal anesthesia is TNS. In the present study, the frequency of TNS in the Sprotte group was lower than theQuincke group, although this difference was not statistically significant. In the study of Etezadi et al., the frequency of TNS with Sprotte needle was less than Quincke needle. The cause has been explained by dormer's higher trauma with the

Quincke needle than the Sprout needle. In the Etezadi's study, the overall rate of TNS was higher than that reported in the present study (16% vs. 12.2%) (41).
One of the strength of the present study is that all techniques were performed by one anesthesiologist; also, two different types of needles were compared. One of the limitations of the current study was using fixed dose of bupivacaine in volume of 2 ml (10 mg bupivacaine- The minimum recommended dose for spinal anesthesia in all surgeries is 2 ml (6)) for spinal anesthesia that may not be suitable dose for all patients, and may cause partial or incomplete failure due to low dose of bupivacaine in some patients. For this reason, we tried to match the patients in terms of height and short height patients were not included in the study. Since in spinal anesthesia technique, height acts as an important factor in drug distribution, short height causes abnormal distribution of drug in the spinal cord. Other limitations of this study were low sample size and single center patient's recruitment. Also, in this study sedation score and pain during surgery have not evaluated. Although in previous studies higher sample sizes were used to evaluate the success rate of spinal anesthesia with different needles in the present study which was performed with aim to compare Sprotte and Quincke spinal needles on the frequency of spinal anesthesia success in patients undergoing cesarean delivery. Other limitation of this study was the sample size formula showed that a minimum sample size of 50 for each group was sufficient. Also another limitation of this study is that in recent years, there has been a program to prevent elective cesarean section in public and educational hospitals in Iran, and this has limited access to the high number of samples in this study. Other limitation of this study was no possibility to access a large number of sample size in one year and to perform the anesthesia technique by an anesthesiologist. Also, the number of women candidates for elective cesarean section in a hospital (conducting the present study as a single center) is limited during one year.

Implications for practice

According to the findings of this study, headache after dural puncture using a Sprotte spinal needle was lower than using Quincke needle in patients undergoing spinal anesthesia for cesarean delivery. Also, there was no difference between the two types of needles in terms of spinal success. Due to the different definition of spinal success, as mentioned in the working method of this article, these blocks cannot be generalized to the spinal success and failure.

Acknowledgments

The present study was approved by the ethics committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1398.390) and was registered in the Iranian clinical trial system (IRCT20110712007013N25). Both types of spinal needles are the standard tools for spinal anesthesia. The researchers would like to appreciate the financial support of Tabriz University of Medical Sciences as well as the study's participants.

Conflicts of interest

The authors declared no conflict of interest.

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