Int J Clin Exp Med 2017;10(8):12293-12300
www.ijcem.com /ISSN:1940-5901/IJCEM0048097

Original Article

Spinal anaesthesia for emergency caesarean section better using 25-gauge pencil point needle or 22-gauge cutting needle: a single centre prospective study

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Received January 4, 2017; Accepted January 27, 2017; Epub August 15, 2017; Published August 30, 2017

Abstract: Objective: Less diameter needles may cause less side effect in lumbar anesthesia. However, some Chinese anesthesiologists consider that bigger needles are suitable for emergency surgery, because it can shorten the puncture period. Present study aimed to compare 25-gauge (G) pencil point needle with 22G cutting needle for emergency caesarean section. Methods: In this prospective study, 200 females with full-term labor were enrolled and randomly assigned to receive spinal anesthesia with either 25G pencil point needle (25P) or 22G cutting needle (22C). Subsequently, we compared the duration of spinal puncture, quality effect of analgesia and the incidence of adverse events. Results: The duration of puncture procedure was investigated in the three patients' landmark palpation conditions: easy, moderate and difficult, respectively. The difference was no statistical significance in easy (P = 0.400) and moderate (P = 0.450), while positive (P = 0.028) when patients' landmark was difficult for palpation. However, the absolute value of difference of the two medians was only 5.6 second due to the whole procedure is short. A 22G cutting needle was found easier at insertion. The incidence of post dural puncture headache (PDPH), effect of spinal anesthesia, neonatal Apgar scores were similar in the two groups. Conclusions: The duration of spinal procedure using 22G needle maybe save some time when patients' landmark was difficult to palpate, but maybe only a few seconds; thus, the patients' benefits are limited. Considering the higher PDPH incidence with the bigger needle, 25G pencil needle might be a better choice in the Spinal anesthesia for emergency caesarean section.

Keywords: Spinal anesthesia, emergency cesarean section, needle, duration, post dural puncture headache (PDPH)

Introduction

Caesarean section is a surgery operation when vaginal delivery might do harm to the mother or fetus, or other reasons [1, 2]. Caesarean section performed sometimes as an elective surgery or sometime an emergency operation [3]. The common indications for emergency caesarean sections including fetal distress, antepartum hemorrhage, severe pre-eclampsia and fetal macrosomia, although vaginal delivery is often planned beforehand [4]. For aesthesia method for emergency caesarean sections, the regional anesthesia (spinal anesthesia) is a compatible anesthetic technique and almost always chosen because of its ease in performing, fast onset, good quality of block and safety for the parturient and the baby, although both general anesthesia and regional anesthesia are acceptable for use [3]. Other advantages of regional anesthesia include allows the mother awake and can interact with her baby immediately [5] and absence of risks of general anesthesia, such as pulmonary aspiration of gastric contents, especially for the patients with late pregnancy [6].

Traditionally, it is widely recommended that a large diameter spinal needle is required to achieve adequate cerebrospinal fluid (CSF) flow [7, 8]; but on the other hand, a large diameter spinal needle is relevant to high incidence of complications such as post dural puncture headache (PDPH) [9-11]. The incidence of PDPH

is 40% with a 20G needle, 25% with a 25G needle, 2-10% with a 26G needle, and less than 2% with a 29G needle [12]. The severe PDPH maybe offset the benefits of spinal anesthesia. Besides the needle size, the incidence of PDPH occurrence also have relationship with the needle tip design and the bevel orientation to dural fibers [13, 14]. Most current studies note that a reduced incidence of PDPH with a pencil point needle when compared to the cutting bevel [14-17]. Thus, it is widely accepted nowadays that the smaller diameter, pencil-point needles and with parallel bevel orientation for cutting needles can reduce the incidence of PDPH.

However, the emergency cesarean section anesthesia poses a multitude of challenges to the anesthesiologist. The most important thing is the urgency condition requiring rapid caesarean delivery and the decision-to-delivery interval might be less than 30 min [18, 19]. Therefore, this makes anesthesiologist finish the anesthesia procedures as quick as possible and the high emergent situation may force the anesthesiologist to choose "the most confident way" to solve the problem. For the empirical reason, a 22G cutting needle is more commonly used in spinal puncture of emergency cesarean section in most Chinese hospital, including ours, although most centers are using 25G needle even with difficult backs. However, in my opinion, this rationale for using 22G cutting needles do not reflect current practice and absent of special clinical research data support, so the advantage and necessity of using a larger needle for emergency cesarean section anesthesia remains unclear. Given the evidence that is already available in the literature about the increased morbidity (especially PDPH) with the 22 g cutting needle over the 25 g pencil point, the present trial aimed to compare 25G pencil point spinal needle with 22G cutting spinal needle for emergency cesarean section, and to assess which needle is faster, more effective and harmless to use.

Materials and methods

Study design

This prospective, randomized, single center clinical study was prospectively registered (ChiCTR-IOR-14005689) and approved by the Institutional Review Board of Shanghai General Hospital. Two hundred patients with American Society of Anesthesiologists (ASA) physical status I or II women and singleton pregnancy at 36-40 weeks of gestation who underwent emergency cesarean section under spinal anesthesia were randomized equally assigned to the two study arms. The patients who fulfilled the inclusion criteria were treated at our hospital during January 2015 to October 2015. All patients had given consent to this procedure and the written informed consent to participate in the study were obtained.

Patients

To ensure conformity of the study, we only included patients with American Society of Anesthesiologists (ASA) physical status I or II women with singleton pregnancy at 36-40 weeks of gestation who underwent emergency cesarean section under spinal anesthesia. The exclusion criteria included the fetal distress, the patients with coagulopathy, infection, diabetes pre-eclampsia/eclampsia, cardiac disease, neuromuscular disease, and the patients younger than 18 years old or older than 40 years old. According to the inclusion and exclusion criteria screening, the eligible women were consecutively enrolled in the study.

Blinded and randomized grouping

The patients and the data management staff were blinded to the group assignment, but the anesthesia provider was not. Two spinal needle (Tuoren International Trade Co.Ltd. Xinxiang, China) groups: group 25P, 113-mm-long 25G pencil point spinal needle, Whitacre needle style; and group 22C, 90-mm-long 22G cutting spinal needle, Quincke needle style were set. Total 200 patients were numbered according to their sequence of receiving anesthesia and randomly assigned to 22C group or 25P group using random number table and sealed envelope method beforehand prepared by a person who was not a participant in the study.

Intervention

Neither premedication nor crystalloid preload was administered. Upon arrival in the operation room, standard monitoring was applied (Datex S/5, Helsinki, Finland) and Lactated Ringer's solution was given through an 18-gauge cannula inserted in a forearm vein. Fluid was administered as the maintenance requirement and for replacing the ongoing losses.

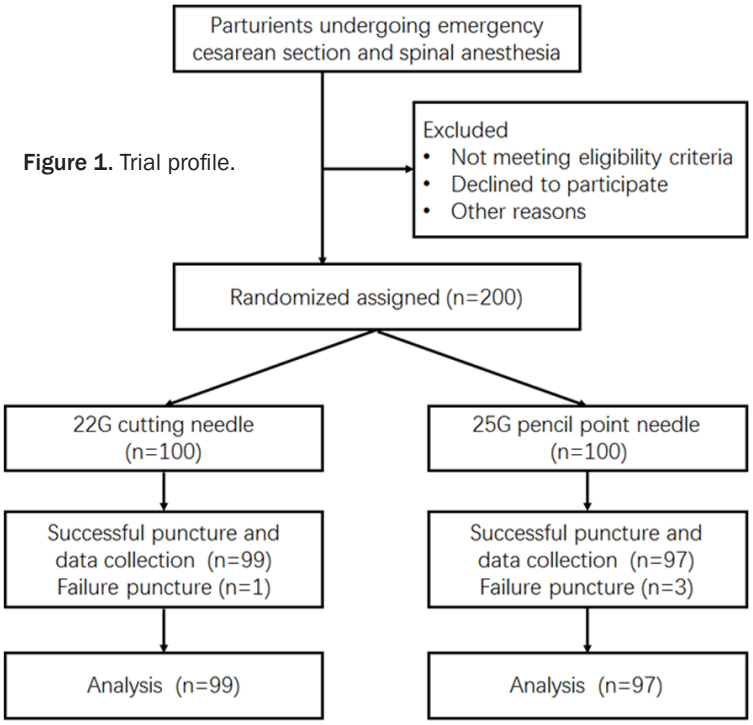

Figure 1. Trial profile.

Table 1. Patient characteristics and obstetric data

	Group 22C (n = 99)	Group 25P (n = 97)
Age (year)	29.4 ± 3.5	29.1 ± 3.3
ASA Status (I/II)	59/41	53/44
BMI (kg/m^2)	29.3 ± 2.8	28.3 ± 3.0
Gestational age (week)	38.0 ± 1.1	38.3 ± 1.0

Values are mean ± SD. BMI = body mass index. No statistical significant differences were observed between the two groups in all parameters using independent samples *t* Test.

To minimize bias, we assigned two experienced attending anesthesiologists to perform the spinal puncture and then an independent investigator to record data. The spinal procedure in the right lateral position was attempted by an experienced attending anesthesiologist for up to 5 minutes. If unsuccessful, the anesthesiologist would take all appropriate action to optimize patient care, and the case would be excluded from the study. The spinal puncture was performed at estimated L3-4 interspace with either spinal needle (the needle was inserted using paramedian approach with its bevel parallel to the dura's longitudinal fibers) attached to a 3 mL syringe. Successful identification of subarachnoid puncture was identified by a free flow of cerebrospinal fluid (CSF). 12.5 mg of bupivacaine made up to 2.5 mL with CSF was injected over 10 s before the mother was placed in a supine position. Then all the parturients received prophylactic 6 mg of ephedrine for the prevention of hypotension associated with spinal anesthesia. Surgery was allowed to proceed once the sensory block reached T_{10}.

Outcomes

The duration of spinal puncture procedure, which begin with the needle tip contact the patient's skin and end with see the cerebral spinal fluid flow, was planned as the primary outcome. At the same time, there were two secondary end points characteristics of spinal anesthesia (included the first attempt to successful puncture, easy CSF aspiration, blood vessel trauma, paresthesia, onset of analgesia at T10, highest sensory block level between T8 to T4) and effects on neonatal Apgar score at 1 min and 5 min.

The adverse events included perioperative pain, nausea, vomiting, shivering, dyspnea, hypotension, postoperative backache, transient neurological symptoms and PDPH. The level of sensory anesthesia, defined as the loss of sharp sensation, was evaluated using the pinprick test every 1 minute until delivery and thereafter every 10 minutes till the completion of surgery. Hypotension was defined as a decrease in systolic pressure to less than 80% of the baseline value and treatment was with 6 mg boluses of i.v. ephedrine. Heart rate, noninvasive blood pressure, peripheral oxygen saturation was observed continuously and recorded every 1 minute until delivery and thereafter every 5 minutes till completion of the surgery.

Statistical analysis

There was no similar previous study had reported the produce duration between the two puncture needle. In our preliminary studies of 20

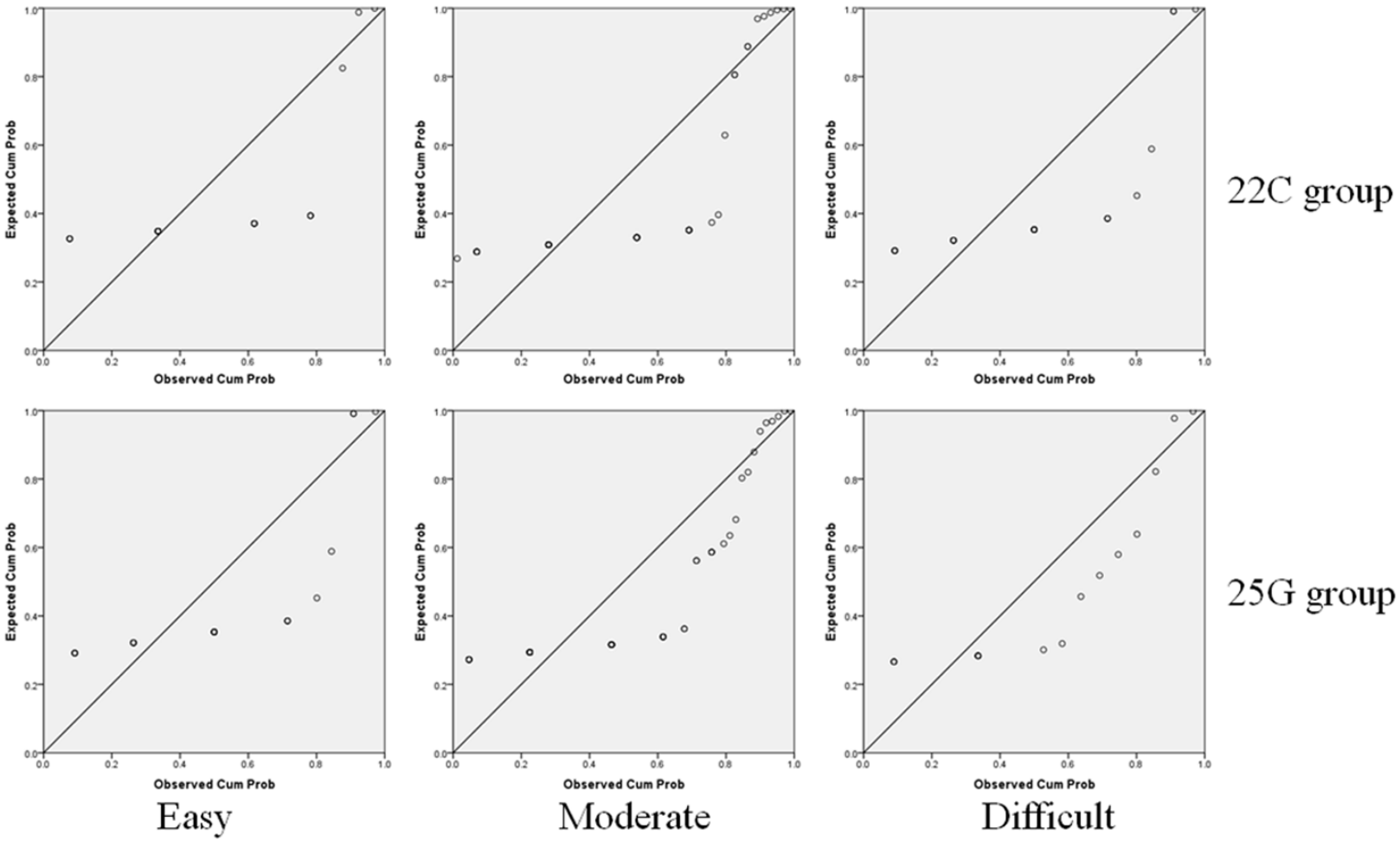

Figure 2. The normal P-P plot of the data of duration of spinal puncture procedure. The patients grouped with conditions of landmarks palpation (easy, moderate or difficult) and which kind of puncture needle used (22C or 25G).

Table 2. The duration of spinal procedure on different conditions of patients' landmark palpation

Landmark palpation		Group 22C (n = 99)	Group 25P (n = 97)	*P* value
Easy	Number	26	23	
	The duration of procedure(s)	6.5 ± 4.2	10.4 ± 11.6	0.400
Moderate	Number	52	56	
	The duration of spinal procedure(s)	13.4 ± 17.0	13.6 ± 15.8	0.450
Difficult	Number	21	18	
	The duration of spinal procedure(s)	11.5 ± 16.6	17.1 ± 19.4	0.028

samples in each group (these data was not included in this study), primary endpoint of the mean duration of 22G protocol was approximate 12 ± 4 seconds and 15 ± 5 seconds in the 25G group. The sample size of this study was calculated using online calculators (http://power and sample size.com/Calculators/) with 80% power (1-β) assuming a two-sided test at type I error rate, alpha = 0.05. The result of the calculating was 78 in each group and allow for up to 25% attrition finally 100 participants in each group were recruited.

The measurement data were presented as means ± SD and first the data normality test was done through two methods, P-P plot method and Kolmogorov-Smirnov (K-S) test (data is more than or equal to 50)/Shapiro-Wilk (S-W) test (data is less than 50). Comparison of between-group continuous variables was performed using independent samples t-test if the variables did not violate the assumption of homogeneity of variance; while the Mann-Whitney U test was used to compare differences between the two independent groups when the continuous variable was not normally distribution. The binary variables were displayed as rate and tested using Fisher's exact test. All analyses were carried out using the statistical package SPSS version 19.0 (SPSS Inc., Chicago, IL, USA).

Results

Total 200 parturients were determined to be eligible and agreed to participate and the patients were randomly assigned. Of these, 4 participants were excluded from the study because they finally received general anesthesia duo to failure puncture. Thus, the number of successful subarachnoid puncture was achieved in group 22C was 99 and 97 in group 25P (**Figure 1**). Because the number of this part of the information is too small, so there was no statistical analysis.

Demographic data and baseline characteristics showed well balanced between the two groups (**Table 1**).

The duration of spinal puncture procedure is the primary outcome. In this study, we investigated the index in three different conditions of patients' landmarks palpation: easy, moderate or difficult (**Figure 2** and **Table 2**), because the percentages of pregnant women with obesity in China are huge nowadays and the quality of patients' anatomical landmarks is the first influence factor for successful location of the subarachnoid or the epidural space that might prolong the operating period of the puncture [20]. The measurement data expressed as the mean ± standard deviation (SD). First, normality test was done through two methods, P-P plot method and Kolmogorov-Smirnov (K-S) test (data is more than or equal to 50)/Shapiro-Wilk (S-W) test (data is less than 50). Normal P-P plot (**Figure 2**) showed that the data of the six groups were significantly deviate from the diagonal; while the results of K-S/S-W test showed that the *P* value of the six groups are all < 0.001. Theses revealed that the data were non-normal distributions.

Because the data were not consistent with the normal distribution, it is necessary to use non-parametric test to conduct further statistical analysis. Mann-Whitney U test for two independent samples was used to investigated the difference of the duration of puncture procedure between the different needle groups in the three patients' landmark palpation conditions: easy, moderate and difficult, respectively. The difference between 22C group and 25G group in duration of puncture procedure was statistically significant when the patients' landmark palpation was difficult (P = 0.028, **Table 2**). However, the median duration of 22C group was 11.5 second compared with the 17.1 second of the 25G group; the absolute value of difference of the two medians was only 5.6 second due to the whole procedure is very short

Table 3. Characteristics of spinal anesthesia and effects on neonatal Apgar scores

	Group 22C (n = 99)	Group 25P (n = 97)	*P* value
First attempt to successful puncture	85.9%	71.1%	0.01
Easy CSF aspiration	97.0%	92.8%	ns
Blood vessel trauma	3.0%	0	ns
Paresthesia	2.0%	3.1%	ns
Onset of analgesia at T_{10} (min)	2.9 ± 1.7	3.0 ± 2.0	ns
Highest sensory block level between T_8 to T_4	84.8%	87.6%	ns
Apgar scores at 1 min	9.1±1.2	9.2±1.1	ns
Apgar scores at 5 min	9.8±0.5	9.8±0.4	ns

Values are expressed as mean ± SD or a percentage. ns = not significant; CSF = cerebrospinal fluid.

Table 4. Incidence of adverse events

	Group 22C (n = 99)	Group 25P (n = 97)	*P* value
Intraoperative pain	2.0%	4.1%	*ns*
Perioperative nausea	24.2%	28.9%	ns
Perioperative vomiting	6.1%	9.3%	ns
Perioperative shivering	30.3%	26.8%	ns
Perioperative dyspnea	5.1%	7.2%	ns
Perioperative hypotension	28.3%	32.0%	ns
Postoperative Backache	18.2%	20.6%	ns
Transient neurological symptoms	6.1%	4.1%	ns
Postdural puncture headache	10.1%	8.2%	ns

Values are expressed as a percentage. ns = not significant.

(the maximum of duration was 81 second and the minimum of duration was 4 second in the 25G group; the maximum of duration was 68 second and the minimum of duration was 4 second in the 22C group). With other two conditions (easy palpation or moderate palpation), it seems to suggest similar procedure duration using either puncture needle (P = 0.400 in easy group and P = 0.450 in moderate group, **Table 2**).

22G cutting spinal needle was found easier at insertion: first attempt to successful puncture was 85.9% in group 22C vs. 71.1% in group 25P (*P* = 0.01); while as for other characteristics of spinal anesthesia, there was no significant difference found between the two groups (**Table 3**). Apgar scores at 1 and 5 minutes were also showed no significantly lower or higher No matter which kind of puncture needle used (**Table 3**).

There was no statistically significant difference between the groups in the incidence of adverse events (**Table 4**). Among these, the occurrence of hypotension was 28.3% in group 22C vs. 32.0% in group 25P; the incidence of PDPH was 10.1% in group 22C vs. 8.2% in group 25P and in all patients PDPH was mild to moderate and self-limiting for a few days.

Discussion

Goal of an ideal anesthesia is easy, effective and harmless. The main results of this study revealed that, for receiving emergency cesarean section patients whose surface landmark was not particularly clear, using 22G cutting needle seemingly could shorten about 1/3 operation time [(17.1-11.5)/17.1]; However, the shorten time absolute value be a few seconds only. Except the three-puncture failure, the slowest puncture procedure with 22G needle just cost 81 seconds. Because of the overall operation time is very short, so patients' benefit from larger and harder needle application is very limited. For other landmark palpation ease level groups, the overall operation time has no significant difference between using needle 22G and 25G. Since it has many research works have reported that less diameter puncture needle causes less damage, therefore, it is suggested that a 25-gauge needle should be chosen as far as possible when an anesthesiologist meets an emergency anesthesia, especially for Chinese anesthesiologists. The two groups have a similar ratio of successful subarachnoid puncture (99.0% *vs.* 97.0%), while with a higher ratio of first attempt to successful puncture in 22G group (**Table 2**). Although first puncture success rates of 22G needle is a little higher than 22G needle, this only make the anesthesiologist operate easily, and cannot make patients benefit significantly. Thus, this

should not be regarded as the evidence that 22G cutting needle is more suitable for the emergent patients. Indeed, 25G needle is a little soft so that is a little difficult to operate, while anthologists could increase the level of experience by more practice.

PDPH is the worst complication among all the adverse events in lumbar anesthesia. In this study, PDPH was also observed as the primary side effect parameter. Many factors reported to influence the incidence of PDPH were: female, young age, pregnancy, low body mass index, multiple dural puncture, inexpert operators and past medical history of chronic headache [21, 22]. On the other hand, the size of the needle seemed to have positive correlation with PDPH [9-12]. However, several clinical studies argued that the diameter of pencil point needles ranging from 22G to 26G led to a similar incidence of PDPH [23-26]. In our study, the incidence of PDPH was not statistical significant between group 22C (10.1%) and group 25P (8.2%) (**Table 4**). These headaches were mild to moderate and disappeared within 14 days. In addition, the incidence of PDPH in our study was quite lower than some reports, the possible reasons may related to two factors: firstly, good puncture techniques including the high rate of first attempt to successful, introduction of the needle with its bevel parallel to the dura's longitudinal fibers and paramedian approach; secondly, since sample size was calculated being based on the rate of first attempt to successful puncture, a total of 196 cases may be inadequately powered for the incidence of PDPH and clinical relevance may require a larger series for its determination.

In conclusion, geographical variations in practice are fascinating, and we can often learn from these. It is interesting that in some areas it is common clinical practice to use 22G cutting needle for emergency anesthesia for cesarean sections. This study is important to highlight the fact that there is not a clinically significant advantage in terms of speed of performing procedure by using a 22G cutting needle, even in those with more difficult anatomy. In this study, the duration of spinal procedure results suggests that 22G needle maybe save some time of the puncture operation when the patients' landmark was hard to palpate. However, the shorten time only be a few seconds due to the whole procedure is quite short; thus, the patients' benefits are limited. 22G needle is more convenience to operate compared with 25G needle, but this might be improved by practice more. In consideration of the lower incidence of side effect, such as PDPH, using 25G pencil needle compared with larger needle reported by several clinical research and the limitation in time saving when using 22G needle, 25G pencil needle is recommend in the Spinal anesthesia for emergency caesarean section, especially for Chinese anesthesiologists.

Disclosure of conflict of interest

None.

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