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Original Article

Combined epidural/spinal anaesthesia with new needle-beside-needle technique for caesarean section: a randomized controlled trial

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Abstract: Objective: The aim of this study was to compare safety and availability between a new needle-beside-needle (NBN) technique and the traditional needle-through-needle (NTN) technique for combined epidural/spinal anesthesia during cesarean section. This was a prospective randomized controlled trial. Methods: Parturients scheduled for elective cesarean section were randomized to receive NBN (n = 58) or NTN technique (n = 57) for combined epidural/spinal anesthesia (CSEA). An observer, blinded to the study, recorded drug dosages, hemodynamic indexes, procedure times, duration from spinal injection to returning patients to supine position, epidural and spinal puncture counts, maximum sensory levels, adverse events, and evaluation of the anesthetist and patients regarding the two techniques. Results: Procedure time (P = 0.049) and duration from spinal injection to returning patients to supine position (P < 0.001) in NBN group were less than the NTN group. Satisfaction of patients regarding the two techniques were comparable, while anesthetist satisfaction was higher in the NBN group (P = 0.006). In addition, the spinal needle was more stable in the NBN group compared with NTN group (P < 0.001). There were no statistically significant adverse events and requirement of anesthetics between the two groups. No differences were found in maximum sensory levels, count of intra-spinal punctures, and failures on first attempt. Conclusion: The higher stability of spinal needle highlighted the superior performance of NBN technique, compared to the traditional NTN technique, during cesarean section. With less procedure time and less interval from spinal injection to returning patients to supine position, this new NBN technique may be welcomed as the current admirable equipment.

Keywords: Combined spinal/epidural anesthesia, needle-beside-needle, needle-through-needle, cesarean section, operation evaluation, adverse effects

Introduction

Combined spinal and epidural (CSE) technique has been widely employed for labor analgesia and lower extremity surgery, as it combines the advantages of spinal and epidural anesthesia [1-3]. Spinal anesthesia can rapidly offer a reliable conduction block. Epidural anesthesia can flexibly prolong anesthetic duration and provide postoperative pain relief via an epidural catheter, while severe complications of the operations above have remained frustrating [4].

The most widely used technique for performing CSE, the single-segment "needle-through-needle" (NTN) technique still has several potential drawbacks [3, 5]. Intrathecal catheter migration, failure to obtain cerebrospinal fluid (CSF), and paresthesia have appeared in some cadaver studies and isolated case reports [6, 7]. Moreover, stability of the spinal needle during injection of drugs into the subarachnoid still needs improvement. To diminish these complications and improve satisfaction of both operators and patients, several new CSE sets have

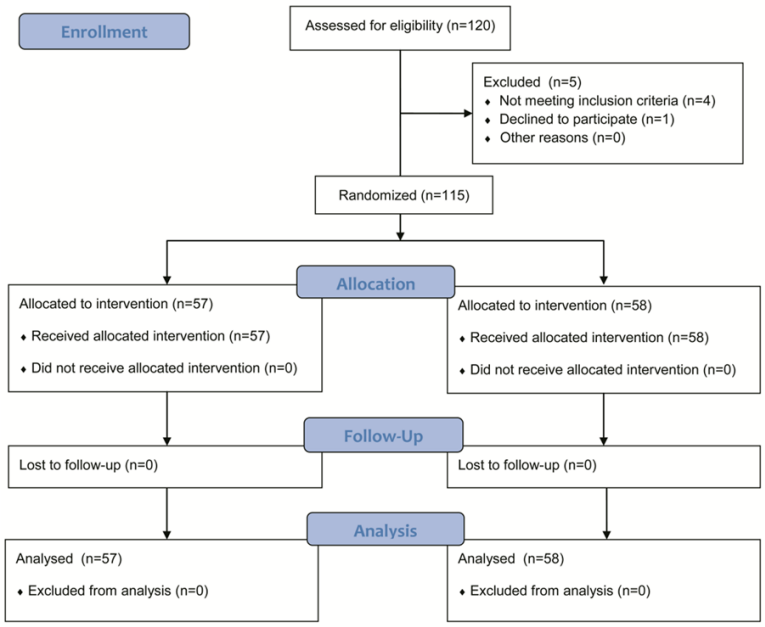

Figure 1. CONSORT flow chart of patient enrollment.

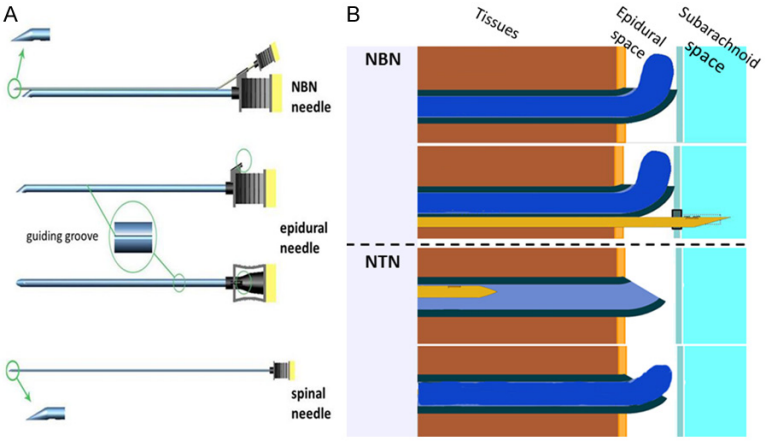

Figure 2. Pattern diagram of NBN technique. A. Detailed diagram of NBN needles; B. Different usages between NBN and NTN techniques. NTN, needle-through-needle; NBN, needle-beside-needle.

been yielded. One new set is the "needle-beside-needle" (NBN) technique. NBN is an orbital CSE needle with greater curvature of the epidural needle tip and with a groove on the epidural needle for spinal needle guidance. This new production is a big improvement compared to the conventional Touhy needle, benefiting manipulators and patients theoretically. Anesthetists can lead the epidural catheter into the lumen and then insert spinal needle through the guiding groove on the epidural needle. Thus, operators don't need to execute spinal anesthesia before epidural catheter insertion.

We were impressed by the new device and carried out the current randomized controlled trial (RCT). The aim of this study was to evaluate the safety and efficacy of this newly introduced modified epidural needle (NBN technique) on parturients receiving labor analgesia compared with the conventional Tuohy epidural needle (NTN technique).

Materials and methods

Ethics statement

This prospective randomized trial was conducted at Liaocheng Dongchangfu District Maternal and Child Health Hospital, Shandong, China. It was approved by the Institutional Review Board of the Hospital and written informed consent was obtained from all subjects.

Trial design and patient population

This study (ChiCTR-IOR-15-006437) was registered at www.chictr.org.cn by Jingchun Guo, on March 7, 2015, before patient enrollment. One of the study investigators (F.X.) produced a computer-generated random sequence. In total, 120 patients were assessed for eligibility and 115 parturients (ASA physical status I-II, age 18-35 years, healthy singleton term fetus), scheduled for elective caesarean section, were eventually recruited (**Figure 1**) and randomized to receive CSE by NTN (n = 57) or NBN (n = 58) techniques. All participants were blinded to the group allocation using numbered opaque envelopes prepared by the investigators (B.F., Y.B.). Patients with multiple pregnancies and significant cardiac, pulmonary, hepatic, or renal comorbidities and

Table 1. Patient characteristics

	NTN group (n = 57)	NBN group (n = 58)	t/X^2	
Age (year)	29.58 ± 4.08	28.60 ± 4.37	1.243	0.217
Height (cm)	160.35 ± 4.42	159.69 ± 5.00	0.750	0.455
Weight (kg)	73.88 ± 7.73	71.66 ± 9.29	1.392	0.167
BMI	28.80 ± 2.83	28.03 ± 2.78	1.472	0.144
ASA I/II (n)	0/57	0/58	-	-
Gestation (weeks)	39.28 ± 1.05	39.19 ± 1.10	0.449	0.655

Note: Values are mean ± sd. There were no significant differences between the groups. NTN, needle-through-needle; NBN, needle-beside-needle; BMI, Body Mass Index; ASA; physical status, gestation.

any contraindications to regional anesthesia were excluded.

Anesthetic methods

A rapid fluid preload with Ringer's lactate was administered at 800 mL/h after reaching the operating room. Oxygen was administered via a nasal cannula at a flow rate of 3 L/min. Electrocardiogram, non-invasive blood pressure, and pulse oximetry were monitored and recorded. All neuraxial blocks were implemented, following strict aseptic techniques, with patients awake and in the right lateral position. Midline approach and loss of resistance-to-air techniques were used in both groups.

In the NTN group, traditional Tuohy needles CSE kits (Tuoren Medical Device Co., Ltd. Henan, China) were used to perform CSE in L3-4 interspaces. After confirming the epidural space, a 113-mm 25 G pencil-point spinal needle was inserted through the traditional Tuohy needle (80 mm, 18 G). Spinal needle was inserted slowly and stopped after the dural click. After confirming correct spinal needle placement by aspiration of cerebrospinal fluid, 3 mL 0.5% hyperbaric ropivacaine (2.0 mL 0.75% ropivacaine +1.0 mL 10% glucose solution) was injected. If the anesthesiologist failed to observe or aspirate free flow of CSF through the spinal needle, a second attempt was made after redirecting the epidural needle. After spinal needle removal, epidural catheter was inserted 4 cm into the epidural space and fastened after removing the epidural needle. The epidural catheter was used to prolong anesthetic duration in time with 2% lidocaine hydrochloride.

In the NBN group, CSE was performed using Anesthesia Puncture Set for Single Use, NBN Kits (AS-E/S) (Wuyishan Jiean Medical Device Manufacturing Co., Ltd. Fujian, China), as shown in **Figure 2**. The 18 G orbital epidural needle was inserted into the L3-4 interspace. A catheter was then introduced through the lumen. The specially designed 25 G beaked spinal needle was inserted along the guiding groove on the epidural needle. Spinal needle protruded 14 mm beyond the epidural needle tip when completely inserted into the epidural needle. Spinal anesthesia methods were conducted with the same approach as the NTN group. After fastening of the catheter to the back, patients were turned supine for surgery.

Measurements

A blinded investigator (S.W.) helped to record all measurements during the CSEA performance. Procedure time (from local infiltration to epidural catheter fixation) and time needed from subarachnoid injection to returning patients to supine position were recorded. Procedure-related paresthesia, when advancing the spinal needle or epidural catheter, was inquired and recorded during the procedure. Sensory levels were measured by pinprick after subarachnoid injections. Non-invasive blood pressure and heart rate (HR) were measured and recorded every 2 or 5 minutes during the first 30 minutes of anesthesia. When systolic blood pressure was less than 80 mmHg or 20% below pre-induction levels, ephedrine 5-6 mg was given intravenously. When pain persisted, patients were injected with 2% lidocaine (5 mL) via the epidural catheter. Patient characteristics and adverse events caused by manipulation and drug dosage were also recorded. Degree of nausea/vomiting was assessed as: 0- none; 1- mild; 2- moderate; and 3- severe. A 0-10 visual analogue scale (VAS) was used to evaluate pain perception by patients as well as the entire procedure by the CSEA manipulator (including epidural/spinal puncture, epidural catheter placement, stability of spinal needle, and anesthetist satisfaction) and patients (patient satisfaction). Zero represented satisfaction and 10 represented the worst experience ever.

Primary end points for this study included times from spinal injection to supine position and

Table 2. Characteristics of anesthesia and block performance

	NTN group (n = 57)	NBN group (n = 58)	$t/X^2/Z$	P
0.5% ropivacaine hydrochloride (mL)	2.08 ± 0.16	2.12 ± 0.17	1.299	0.197
2% lidocaine hydrochloride (mL)	1.46 ± 2.73	1.12 ± 2.49	0.698	0.487
Number of patients required lidocaine	13 (22.81)	11 (18.97)	0.257	0.612
Ephedrine (mg)	9.12 ± 10.23	7.26 ± 8.42	1.065	0.289
Use frequency of ephedrine	1 (0-4)	0 (0-3)	-0.646	0.518
Rehydration fluids (mL)	1538.60 ± 238.68	1537.93 ± 183.61	0.017	0.987
Puncture				
Epidural puncture counts	1 (1-4)	1 (1-2)	-1.397	0.162
Failure on first attempt	7 (14.89)	3 (5.17)	1.830	0.176
Spinal puncture counts	1 (1-3)	1 (1-2)	-1.767	0.077
Failure on first attempt	7 (14.89)	2 (3.45)	3.109	0.078
Maximum sensory level	T6 (T4-T8)	T6 (T4-T8)	-	-
Interval from spinal anesthesia to settle supine position (s)	142.30 ± 32.57	103.76 ± 34.52	6.156	< 0.001
Procedure time (s)	364.56 ± 79.07	339.71 ± 52.78	1.986	0.049

Note: Values are mean ± SD, median (range) or number (%). NTN, needle-through-needle; NBN, needle-beside-needle.

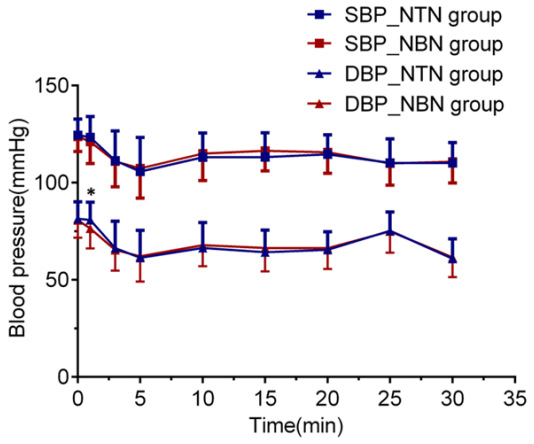

Figure 3. Changes in systolic and diastolic blood pressure (SBP and DBP) after subarachnoid injection in NTN and NBN group. *P < 0.05 compared with NTN group. NTN, needle-through-needle; NBN, needle-beside-needle; SBP, Systolic blood pressure; DBP, diastolic blood pressure.

incidence of paresthesia, a significant adverse event [8]. Secondary end points included procedure time (from local infiltration to epidural catheter fixation), adverse events caused by manipulation and drug dosage, evaluation by the CSEA manipulator (including epidural/spinal puncture, epidural catheter placement, stability of spinal needle, and anesthetist satisfaction), and patients (patient satisfaction).

Statistical analysis

For power analysis, this study intended to estimate the time from spinal injection to supine position and incidence of paresthesia. In the present study, 57 per group would be able to detect a difference in the time from spinal injection to supine position (140 s versus 100 s, standard deviation = 40, superiority margin = 20), with a power of 85% and an α error of 0.05, and paresthesia rate (38% versus 15%) with a power of 80% and an α error of 0.05. Each group included an additional 3 patients with cases of withdrawal. Student's t-test was used to compare continuous variables. Categorical data were assessed using Chi-square test or Fisher's exact test, as necessary. Comparison of VAS scores was performed using Mann-Whitney rank sum test. *P*-values < 0.05 were regarded as statistically significant. SPSS 17.0 (SPSS Inc) was used for calculation of these data.

Results

Patient characteristics

One hundred and fifteen parturients were involved and completed this clinical trial (**Figure 1**). There were no significant differences in baseline characteristics of patients between groups, including age, height, weight, BMI (Body Mass Index), ASA physical status, and gestation (**Table 1**).

Characteristics of anesthesia and block performance

No significant differences between groups were found in the requirements of ropivacaine, epi-

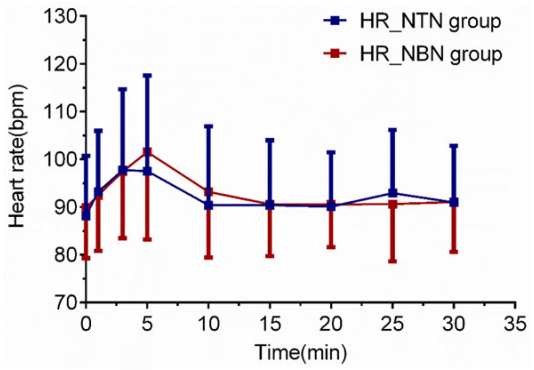

Figure 4. Changes in heart rate (HR) after subarachnoid injection in NTN and NBN group. There were no statistical differences between groups. NTN, needle-through-needle; NBN, needle-beside-needle.

dural lidocaine, ephedrine, and rehydration fluids (**Table 2**). There were still no statistical significances in epidural and spinal puncture counts and failures on first attempt (**Table 2**). Maximum sensory levels in both groups were kept around T6 level. Procedure time (364.6 ± 79.1 vs 339.7 ± 52.8 in NTN and NBN group respectively, P = 0.049) and duration from spinal injection to returning to the supine position (142.3 ± 32.6 vs 103.8 ± 34.5 in NTN and NBN group respectively, P < 0.001) in NBN group were less than NTN group (**Table 2**). Systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rates (HR) were equivalent between the groups before anesthesia and 1 minute, 3 minutes, 5 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, and 30 minutes after spinal anesthesia, except that DBP in NBN group was slightly lower than NTN group 1 minute after spinal anesthesia (**Figures 3** and **4**).

Adverse events by needle type

There were no statistically significant differences in adverse events either during or after the procedure between the groups (**Table 3**), although most of the side-effects (unintentional dural puncture with epidural needle, paresthesia, hypotension, nausea/vomiting, postoperative lower limbs paresthesia, lumbar pain, and headache) were less in NBN group. Incidence of paraesthesia (spinal needle: 17.5%, epidural catheter: 31.6% in NTN group) in this study was higher than in previous studies (5-11%), because we inquired its presence before patient complaints [9, 10]. No patients encountered intrathecal catheter in either group. Intravascular catheter happened in one and two patients, respectively, in NTN and NBN groups, with seven in NTN group and 11 in NBN group experiencing extradural hemorrhage (not significant).

Evaluation of the anesthetist and patients

Stability of spinal needle in the NBN group received higher evaluation compared to the NTN group (P < 0.001). Evaluation of epidural or spinal puncture and epidural catheter placement by the anesthetist were comparable in the two groups. There were no significant differences between the two groups regarding patient satisfaction, while anesthetist satisfaction was higher using the NBN technique (P = 0.006), see **Table 4**.

Discussion

Application of the CSE technique for labor analgesia is prevalent, using the single-segment needle-through-needle technique. However, arguments about needle handling and risk of catheter migration are of great concern [11]. More and more special new CSE sets have been produced to minimize these potential problems [3, 12].

Recently, a new orbital NBN kit, showing great progress compared to the conventional Tuohy NTN kit, has been invented and used in clinical practice. **Figure 5** shows the difference of operation procedures between NBN needle and commonly used NTN needle. This present study was designed to compare these two techniques. As expected, there were no differences regarding the consumption of ropivacaine, epidural lidocaine, ephedrine, and rehydration fluid between groups. These are not the targets of this improved technique. However, this study still recorded these indexes for overall comparison and assessment. Procedure time in NBN group was less than NTN group, indicating the convenience and usability of this new technique. Notably, the time from spinal injection to adjusting the patient to dorsal position could be greatly shortened compared with the traditional NTN technique. This new NBN kit allows insertion of the epidural catheter prior to spinal injection (**Figures 2B** and **5**). This is the most impressive improvement, thus, making the anesthetist leisured to settle catheter prob-

Table 3. Adverse events by needle type

	NTN group (n = 57)	NBN group (n = 58)	X^2	P
Adverse events during the procedure				
Intrathecal catheter	0 (0)	0 (0)		
Intravascular catheter	1 (1.75)	2 (3.45)	-	0.496*
Unintentional dural puncture with epidural needle	1 (1.75)	0 (0)		0.496*
Extradural hemorrhage	7 (12.28)	11 (18.97)	0.973	0.324
Paresthesia				
EN	10 (17.54)	5 (8.62)	2.018	0.155
EC	18 (31.58)	18 (31.03)	0.004	0.950
Overall (EN or EC)	25 (43.86)	20 (34.48)	1.061	0.303
Hypotension	37 (64.91)	30 (51.72)	2.056	0.152
Postoperative adverse events				
Lower limbs paresthesia	1 (1.75)	0 (0)		0.496*
Lumbar pain (VAS scale)	1 (0-4/0-2)	0.5 (0-5/0-1)	-1.345	0.176
Headache (VAS scale)	1 (0-5/0-2)	1 (0-3/0-1)	-0.515	0.607
Nausea/vomiting (grade)	1 (1-3/1-2)	1 (0-3/1-1.25)	-1.665	0.096

Note: NTN, needle-through-needle; NBN, needle-beside-needle; EN, epidural needle; EC, epidural catheter. Values are number (%) or median (range/quartile). There were no significant differences between the groups. *Fisher's exact test.

Table 4. Evaluation of the anesthetist and patients on the two types of needles

VAS score	NTN group (n = 57)	NBN group (n = 58)	Z	P
Epidural puncture	0 (0-5/0-1)	0 (0-4/0-1)	-0.879	0.380
Spinal puncture	0 (0-5/0-1)	0 (0-4/0-1)	-0.538	0.560
Epidural catheter placement	1 (0-5/0-2)	0 (0-5/0-2)	-1.165	0.244
Stability of spinal needle	1 (0-5/0-2)	0 (0-1/0-0)	-7.627	< 0.001
Anesthetist satisfaction	1 (0-5/1-2)	1 (0-7/0-1.25)	-2.769	0.006
Patient satisfaction	2 (0-6/0-3)	1 (0-5/0-3)	-1.102	0.263

Note: Values are medians (range/quartile). NTN, needle-through-needle; NBN, needle-beside-needle.

lems. This improvement has been praised by anesthetists, especially the young and inexperienced. Moreover, the abridged duration from spinal injection to returning patients to supine position in NBN group is another obvious advantage allowing anesthetists to adjust anesthesia levels, observe vital signs of patients, and deal with dangerous hemodynamic changes.

One potential disadvantage of NTN technique is that the epidural catheter may traverse the dural hole punctured by the spinal needle [6, 13]. However, this is less likely to happen when the NBN technique is administrated. In theory, there is no hole left in the endorachis when placing the catheter, since the epidural catheter is led into the lumen before spinal needle insertion. However, a statistical significant conclusion was not drawn in this study because of low incidence. This theoretic strength still needs future demonstration.

With greater curvature of the epidural needle tip, compared with traditional Tuohy needle (**Figure 2B**), catheter insertion should be smoothly performed and adverse events, like intrathecal catheter and unintentional dural puncture with epidural needle, may be decreased. However, this study could not demonstrate such strengths. Low incidence of these adverse effects in Liaocheng Dongchangfu District Maternal and Child Health Hospital made them difficult to detect. Paresthesia has been associated with conventional epidurals and threading of epidural catheters, with previously reported rates varying from 18% to 44% [11]. Paresthesia during CSEA augments patient discomfort and risk of abrupt movement. Moreover, paresthesia may be associated with neurological damage. Direct trauma to nerve roots or the spinal cord during needle insertion may lead to paresthesia [14]. One patient in the NTN group suffered lower limb paresthesia after surgery, while no such events took place in NBN group during post-operation follow up.

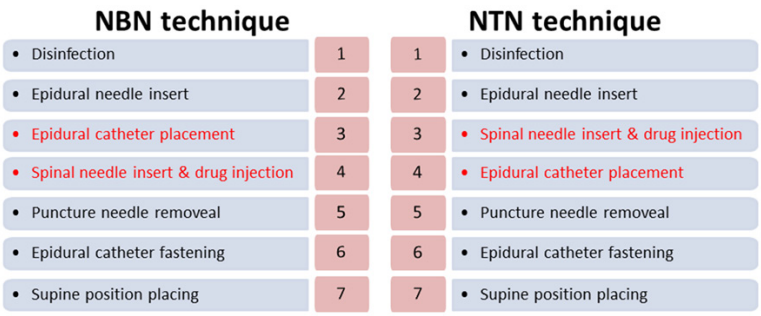

Figure 5. Comparison of operation procedures between NBN and NTN techniques. NTN, needle-through-needle; NBN, needle-beside-needle.

Paresthesia in the NTN group was probably due to angulation of the spinal needle when it traversed through the epidural needle orifice, as compared with the straight angle when inserted through the groove on the orbital epidural needle (**Figure 2B**). Incidence of paresthesia was underestimated in NBN group and overestimated in NTN group at the time of study design, leading to inadequate sample size. This present study did not draw a significant conclusion. It is not unreasonable, however, to expect clinically significant differences because nerve damage is rare but serious during CSEA [9, 15-17]. Given the potential severity and pricy health care costs associated with complications, less incidence of these events might offset the extra expenditure per case.

An adequate length of the spinal needle is also important in CSEA [18]. Spinal needles in the NBN group protruded 14 mm beyond the epidural needle tip when completely inserted into the epidural needle to reliably puncture the dura. Significantly, the new NBN approach has made an obvious advance in maintaining the stability of spinal needle during spinal injection, with higher anesthetist satisfaction.

To the best of our knowledge, this study was the first to compare the new NBN needle with the traditional NTN needle. A lot of effort went into the strict implementation of this randomized study. The greatest advantage of this research was the rigorous randomization and blind method, with independent blinded investigators making assessments. This study could not achieve double blind of both patients and the manipulator, however. Moreover, this study recorded as many parameters as possible to comprehensively assess the new needle. The greatest drawback was attributed to limited generalizability. Individual anesthesiologists differ with respect to preferences for particular devices, thus, multi-center studies are still needed to draw a more convincing conclusion.

In conclusion, with less procedure time and time needed from spinal injection to returning patients to supine position, this new NBN needle is more convenient to operate and improves performance. The unique advantage of higher stability of spinal needle, compared with Tuohy needle, highlights the NBN techniques during spinal injection. However, the rarity of severe complications combined with limited sample size makes it difficult to confirm the resistance of the NBN kit to complications. Generally, it can be regarded as a favorable alternative for CSEA without allowing more complications.

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Disclosure of conflict of interest

None.

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