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SHORT COMMUNICATION

A pilot study to compare epidural identification and catheterization using a saline-filled syringe versus a continuous hydrostatic pressure system

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Abstract We are introducing a new continuous hydrostatic pressure system for identification and catheterization of epidural space in adults. One hundred and eight patients scheduled for elective endoscopic urological procedures were enrolled in this prospective randomized study. They were assigned to perform loss of resistance epidural technique by either the conventional saline-filled syringe (group C) or the new pressure technique (group P). The latter depends on observing passage of free flow of pressurized normal saline (50 mmHg) connected to epidural needle during its advancement, and then the epidural catheter was inserted to "float" easily while saline was flowing. Ten ml of bupivacaine 0.5 % with 50 μg fentanyl were injected. Time to identify epidural space, number of attempts, ease of catheterization, sensory and motor block by Bromage scale after 20 min, quality of anesthesia and any side effects were recorded. Significant reduction was found in group P versus group C concerning time to identify epidural space [20 (6–40) vs. 60.5 (23–75) s with $p = 0.001$], number of attempts [1 (1–2) vs. 1 (1–4) with $p = 0.02$] and motor block [1 (0–3) vs. 2 (0–2) with $p = 0.02$], respectively. No significant difference in epidural catheterization, sensory block, quality of anesthesia and incidence of side effects. We concluded that this new technique is an easy way to identify epidural space using available tools in the operating room.

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Introduction

The loss of resistance technique is a subjective feeling and most frequently used to detect the epidural space; however, it is sometimes difficult to perform and may be time consuming [1, 2]. Thus, several objective methods for identification of the epidural space such as ultrasound [3], nerve stimulation [4], acoustic signals [5], and the application of a micro-drip infusion set in children [6] have been suggested, without gaining widespread popularity in the anesthesia community. Recently, the Episure autodetect syringe (Indigo Orb, Inc., Santa Clara, CA) was introduced for epidural identification, but is still expensive, not available and not facilitating catheter insertion [7]. We suggested an objective new continuous hydrostatic pressure technique in adults and hypothesized that this will make identification and catheterization of the epidural space easier than the conventional method. Thus, this prospective randomized study was designed to compare the conventional versus the new technique as regards the ease of performance by measuring the time to epidural space identification as a primary outcome. The characteristics of the block, the quality of anesthesia, and the incidence of perioperative or catheter-related complications are considered as secondary outcomes.

Laboratory model was performed using an 18 gauge epidural needle which was attached to a pressure transducer (Siemens SP 844 reusable IBP, Memscap, Norway) through a three-way stopcock (N.I.D., Medical Co., Amerya, Alexandria, Egypt) and a low-resistance saline-filled disposable plastic syringe [Perifix, B. Braun,

Germany (epidural set)] to measure the exerted pressure during its passage through closed-cell foam. Various anesthetists were asked to push the needle and the recorded pressure exerted was high (250–300 mmHg). The flowing saline volume was collected in a calibrated plastic container and was found to be 2–3 ml. Then a normal saline plastic bottle was connected to the three-way stopcock via its side way by a regular IV set and a venous extension line. The bottle was placed in a pressure bag (Fig. 1a) and the pressure was raised incrementally by 10 mmHg. After exiting of the epidural needle from the cell foam, the three-way stopcock was closed. The volume at 50 mmHg was 2–3 ml equivalent to that collected when using saline-filled syringe so we standardized this pressure during the procedure.

After obtaining institutional ethical committee approval and informed written consents, 108 patients aged 25–65 years of either sex ASA physical status I–II scheduled for elective endoscopic urological procedures (TURP, transurethral resection of prostate; TURT, transurethral resection of tumor; URS, ureterorenoscopy) were enrolled in the study. Obese patients (body mass index >35 kg/m^2), those in whom epidural anesthesia is contraindicated (back fusion, coagulopathy or local infection) and patients with spinal column disorders (such as scoliosis, herniated discs, or previous spinal surgery) were excluded from the study.

Patients were premedicated with 0.05 mg/kg midazolam given i.v. then routine monitoring included five leads ECG, non invasive blood pressure, SpO_2 (Infinity Kappa, Dräger, Lübeck, Germany) was attached to the patients. Five operators with the same level of experience by their log book (senior registrar) participated to randomly perform both techniques (about 20 procedures each). The patient was placed in the lateral position and loss of resistance epidural technique by normal saline was performed at L_{2-3} level using an 18 gauge Tuohy epidural needle and a 20 gauge catheter. Once the epidural needle was in the stable position (i.e., in the supraspinous ligament), patients were assigned by computer generated random numbers into one of two groups by connecting the needle with a saline-filled syringe in the conventional group (group C) or with the new continuous hydrostatic pressure system (group P) as described in the laboratory model. Time was calculated from this connection until identification of epidural space. The attempt was defined as the needle repositioning without exiting from the skin. In group P, the plastic normal saline bottle in the pressure bag adjusted at 50 mmHg was placed in the field of vision of the anesthetist in charge while opening the three-way stopcock and the intravenous set. The needle was then slowly pushed forwards (Fig. 1b) and when the epidural space was reached, a free flow was observed in the set chamber. The stopcock was then closed and rotated to open the epidural needle on the air to ensure absence of CSF or blood leak (Fig. 1c). Then, the stopcock was redirected to make its back opening, the fluid and the needle in continuity. While normal saline was flowing, the catheter was inserted from the back of stopcock and advanced in the epidural space to "float" easily (Fig. 1d). In both groups, 3 ml of test dose (2 % lidocaine with adrenaline 1:200000) were injected through the catheter. Then 10 ml of bupivacaine 0.5 % with 50 μg fentanyl were injected incrementally. After 20 min, a blinded observer made bilateral assessment of sensory block levels by pinprick and the degree of motor block by the Bromage scale. Unilateral, patchy or low sensory level block were regarded as "incomplete block". An additional 5 ml of anesthetic solution was administered and if they persist, general anesthesia was administered. Thus, failure to reach satisfactory sensory level or inability to thread the catheter was considered as "failed epidural" and these patients were excluded from the study. On the other hand, "successful block" was defined as preoperative bilateral loss of pinprick to T10. An "excellent surgical condition" was a successful block without patient complaining of discomfort during surgery. Any perioperative side effect as nausea, vomiting, bradycardia, or hypotension was recorded.

No previous similar research is available to calculate the sample size. Thus, we intended to perform a pilot study of about 50 patients per group which is greater than the number needed (30) to satisfy the central limit theorem so any distribution will be changed into normal. Results are expressed as mean ± standard deviation (SD), median

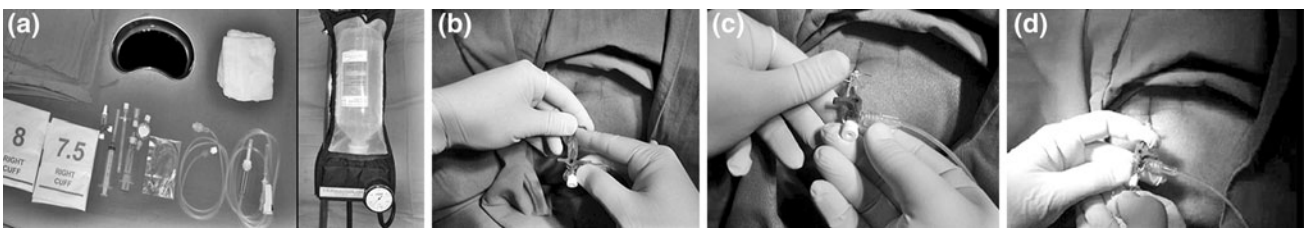

Fig. 1 **a** Tools required for the new technique. **b** Tuohy needle is connected to three way stopcock and advanced till epidural space is reached. **c** Cap is removed and the needle is opened on air to exclude CSF and blood leak. **d** The stopcock is redirected so that its back opening, fluid and the needle were in continuity and the epidural catheter is inserted

(range) or number (%). Comparison between the two groups was performed using the Student t test or Wilcoxon rank sum test whenever it was appropriate. Comparison between categorical data was performed using the Chi-square test. The data are considered significant if p values were ≤ 0.05. Statistical analysis was performed with the aid of the SPSS computer program, version 12 windows (IBM, USA).

One hundred and eight patients were enrolled in the study, 54 patients per group. Failure rate was 7.4 % in group C (4 patients: 2 cases with patchy block, one case with unilateral block and one case with impossible catheterization) and 3.7 % in group P (2 patients had patchy block) with p value 0.4. Thus, in total, six patients were excluded from the study. This means that the success rate was 92.6 and 96.3 % in groups C and P consequently with p value 0.4. Among the remaining 102 patients randomized for the study (50 patients in group C and 52 patients in group P), there were no significant differences between both groups in demographic data, or type and duration of surgery (Table 1). In group P, the time to identify epidural space, number of attempts and the motor block at 20 min were significantly lower compared with group C but no significant difference in epidural catheterization, sensory block, quality of anesthesia and incidence of side effects (Table 1).

We designed a laboratory model (cell foam) to calculate the minimal pressure needed to yield the same volume obtained by the conventional method for detecting loss of resistance and then applied in the clinical situation for epidural identification. This new technique reduced the time required for identifying the epidural space and the number of attempts when compared with the conventional method. These results are similar to the Episure AutoDetect syringe (Indigo Orb, Inc., Santa Clara, CA) [8] and the Epidrum (Exmoor innovations Ltd., Taunton, UK), a device with a diaphragm connected to the epidural needle, filled with air and collapsed when reaching the epidural space [9].

A similar trial was performed in pediatrics using a micro-drip infusion set and achieved an almost similar success rate (97.7 %) [6], which differs from our technique in that we apply pressure on the drip to overcome the resistance faced during introducing the epidural needle in adults.

Ghelber et al. [10] performed a prospective pilot study evaluating continuous pressure measurement during low speed injection with a computerized injection pump to objectively identify the epidural space, and provided 100 % success rate. The difference in success rate compared to our study may be due to the small sample size they used (20 patients).

Injection under pressure did not increase the incidence of accidental dural puncture as the pressure used was found to be one fifth the pressure applied by the anesthetist's hand. Discrepancy between motor and sensory block in both groups may be dilutional due to flow of more saline during identification of epidural space and introduction of

Table 1 Demographic data, operative type and time, characteristics of the epidural technique, catheter-related complications and quality of anesthesia

	Group C ($n = 50$)	Group P ($n = 52$)	P value
Age (years)	48.6 ± 8.7	49.7 ± 8.3	0.562
Gender (female/male)	14/36 (28/72)	14/38 (26.9/73.1)	0.903
Weight (kg)	75.8 ± 7.7	76.3 ± 7.6	0.757
Height (cm)	162.7 ± 5.9	163.6 ± 5.0	0.406
BMI (kg/m^2)	28.6 ± 2.3	28.5 ± 2.7	0.830
ASA (I/II)	33/17 (66/34)	34/18 (65.4/34.6)	0.948
Type of operation (TURP/TURT/URS)	6/12/32 (12/24/64)	8/14/30 (15.4/26.9/57.7)	0.793
Operative time (min)	96.9 ± 20.4	95.5 ± 17.3	0.706
Number of attempts	1 (1–4)	1 (1–2)	0.023*
Time to identify epidural space (s)	60.5 (23–75)	20 (6–40)	0.001**
Motor block by Bromage at 20 min	2 (0–2)	1 (0–3)	0.018*
Peak sensory block at 20 min	T6 (T5–10)	T6 (T5–10)	–
Inadvertent dural puncture	3 (6)	1 (1.9)	0.289
Parasthesia during catheterization	1 (2)	1 (1.9)	0.978
Intrathecal catheterization	0 (0)	0 (0)	–
Intravenous catheterization	2 (4)	1 (1.9)	0.535
Difficult catheterization	2 (4)	1 (1.9)	0.535
Excellent surgical conditions	38 (76)	40 (76.9)	0.913
Discomfort but intervention not necessary	5 (10)	5 (9.6)	0.948
Required reinjection through catheter	7 (14)	7 (13.5)	0.937

Group C conventional group, *group P* pressure group. Data are expressed as mean ± SD, median (range) or number (%)

* $p < 0.05$, ** $p < 0.01$

the catheter in the new technique. Lower number of attempts by the hydrostatic pressure may be referred to its easiness of epidural identification.

The advantage of this technique is to facilitate teaching the epidural technique to clinicians. Both the trainee and the trainer will get an objective, visual signal when the needle tip enters the epidural space. This technique might also be valuable under difficult circumstances such as the performance of epidural anesthesia in the thoracic spine, with spinal abnormalities, with morbid obesity or in pediatric patients where false loss of resistance subjective sensation can be detected leading to failed epidural anesthesia.

Large studies continue to show relatively high epidural failure rates [2, 11]; however, approximately 50 % of the reported failure rates were attributable to either intravascular epidural catheterization placement or unilateral block, and it is questionable whether any objective method of epidural space identification would have prevented these misplacements. No statistical differences can be detected in our study between both groups as regards the failure rate and epidural catheterization. Demonstration of these outcomes may be a difficult task because of their low incidence and the large number of patients required to have adequate power in the study. Our technique clinically provided an equivalent epidural anesthetic effect to that of the conventional technique. A limitation to this study is that we could not blind the equipment.

However, we conclude that identifying the epidural space with the aid of this continuous hydrostatic pressure technique is reliable, simple, and easy way using available tools in the operating room. This new technique offers several advantages in terms of shorter time required for successful detection of epidural space, and lower number of attempts. Larger studies are required to determine if this new technique leads to fewer complications or if it reduces the epidural failure rate especially in difficult cases.

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