

Comparison of loss of resistance technique between Epidrum[®] and conventional method for identifying the epidural space

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Background: Epidrum[®] is a recently developed, air operated, loss of resistance (LOR) device for identifying the epidural space. We investigated the usefulness of Epidrum[®] by comparing it with the conventional LOR technique for identifying the epidural space.

Methods: One hundred eight American Society of Anesthesiologists (ASA) physical status I or II patients between the ages of 17 and 68 years old and who were scheduled for elective surgery under combined spinal-epidural anesthesia were enrolled in this study. The patients were randomized into two groups: one group received epidural anesthesia by the conventional LOR technique (C group) and the second group received epidural anesthesia using Epidrum[®] (ED group). While performing epidural anesthesia, the values of variables were recorded, including the number of failures, more than 2 attempts, the incidence of dural puncture, the time needed to locate the epidural space, the distance from the skin to the epidural space and ease of performance, and the satisfaction scores.

Results: The ED group showed a lower failure rate, fewer cases of more than 2 attempts, a lesser time to identify the epidural space, and better ease and satisfaction scores of procedure than the C group, with statistical significance.

Conclusions: Using Epidrum[®] compared to the conventional LOR technique is an easy, rapid, and reliable method for identifying the epidural space. (Korean J Anesthesiol 2012; 62: 322-326)

Key Words: Epidrum[®], Epidural anesthesia, Loss of resistance.

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Introduction

The epidural technique is one of the neuraxial techniques widely used for providing anesthesia for surgical operation, postoperative pain control, acute or chronic pain management, and obstetric analgesia [1-3].

The loss of resistance (LOR) technique is the most commonly used method for identifying the epidural space. With the LOR technique, a sudden change in resistance is detected by the easier injection of air, saline or both, and this is associated with the passage of the epidural needle tip from the ligamentum flavum into the epidural space [4-6].

However, the ideal technique for the identification of the epidural space is controversial. The conventional LOR technique often depends on inaccurate and subjective measures of the mechanical resistance to an injection of air, saline or both, rather than depending on objective and confirmatory methods [7,8]. Furthermore, factors such as the anesthesiologist's experience and the spinal anatomy of patients often influence success of the epidural technique [9-11].

Epidrum[®] (Exmoor innovations Ltd., Taunton, UK) is a recently developed air operated, LOR device for identification of the epidural space. It is placed between the epidural needle and the syringe and has a thin diaphragm on the top. The diaphragm is rapidly deflated when the epidural needle tip is located in the epidural space and this allows the operator to interpret the position of the needle tip.

There have been no reports concerning identification of the epidural space using the Epidrum[®]. Therefore, we investigated the usefulness of Epidrum[®] as compared with the conventional LOR technique for identifying the epidural space.



Fig. 1. The Epidrum[®] is 2.5 × 2 cm in size and consists of a hard plastic body chamber, an injection port with a one way valve (right side), an outlet port to connect to the epidural needle (left side), and a soft, thin silicon membrane diaphragm on top of the device.

Materials and Methods

After receiving approval from the Institutional Review Board, written informed consent was obtained from all patients. One hundred eight patients who were scheduled for elective gynecologic or orthopedic surgery under combined spinal-epidural anesthesia (CSE) were enrolled in this study. All patients were ASA physical status I or II and were between the ages of 17 and 68 years. They were randomized into two groups: a group to receive epidural anesthesia by the conventional loss of resistance techniques (C group) and a group to receive epidural anesthesia using an Epidrum[®] (ED group). Patients with contraindications for CSE, including coagulopathy, local skin infection, and uncorrected hypovolemia, were excluded from the study.

The Epidrum[®] consists of a hard plastic body chamber, an injection port, an outlet port, and a soft, thin silicon membrane diaphragm (Fig. 1). The device is placed between the epidural needle and syringe (Fig. 2). The injection port connected to the syringe has a one-way valve. When air is injected by the connected syringe, the silicon membrane diaphragm assumes the inflated position if the epidural needle end through the outlet port on either end is plugged (Fig. 2). When the epidural needle tip penetrates the ligamentum flavum into the epidural space, the diaphragm assumes a deflated position due to the decreased intra-chamber pressure through the epidural space (Fig. 3).

On arrival in the operating room, standard monitoring devices including an electrocardiogram, pulse oximetry, and a noninvasive blood pressure cuff were applied to the patients.

With the patient in the lateral position, local anesthetic was infiltrated into the subcutaneous tissue or muscle at the L3/4 or



Fig. 2. The injection port connected to the syringe has a one way valve. When air is injected by the connected syringe, the silicon membrane diaphragm assumes the inflated position if the epidural needle end through the outlet port on either end is plugged.

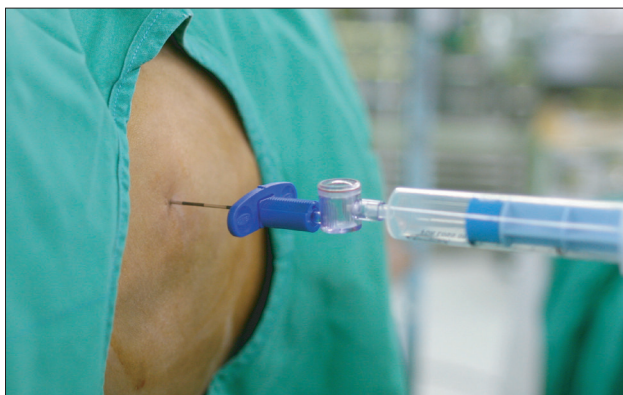


Fig. 3. When the epidural needle tip penetrates the ligamentum flavum into the epidural space, the diaphragm assumes the deflated position because of decreased intra-chamber pressure through the epidural space.

L4/5 interspinous space. In the ED group, the diaphragm of an Epidrum® was tested by occluding the exit port and injecting air. In both groups, an 18-gauge Tuohy needle was inserted using midline approach until the operator felt the needle was imbedded into the interspinous ligament in both groups. In the C group, a syringe filled with air was attached to the hub of the Tuohy needle and the needle was advanced until LOR was noted. In the ED group, an Epidrum® was attached between the hub of the Tuohy needle and the syringe filled with air. Thereafter, Epidrum® was inflated with 1.5 ml air, and the Tuohy needle was advanced with both hands until the inflated silicone membrane became deflated. After deflation of the diaphragm, the Epidrum® and syringe were disconnected and a 27-gauge spinal needle was inserted through the epidural needle to inject bupivacaine into the intrathecal space. After the spinal needle was removed, an epidural catheter was inserted into the epidural space. All CSE was performed by one second year resident who had performed more than 300 cases. One anesthesiologist also performed observation and recording.

Multiple attempts over 4 times were considered as failure. We recorded the number of failures, more than 2 attempts, the occurrence of dural puncture, the time to locate the epidural space (from the interspinous ligament to the epidural space and from the skin to the epidural space), and the distance from the skin to the epidural space. The ease of identifying the epidural space was scored using a five point score (1 = very easy, 2 = easy, 3 = moderate, 4 = difficult, 5 = extremely difficult) by both the operator and an observer. The satisfaction scores of the procedure were recorded from 1 to 5 points by the operator.

Statistical analysis

Statistical analysis was performed with SPSS 17.0 (SPSS Inc.,

Table 1. Patient Demographic Data

	ED group (n = 54)	C group (n = 54)
Gender (M/F)	15/39	16/38
Age (yr)	45 ± 11.3	45.4 ± 10.4
Height (cm)	162.1 ± 8.8	162.5 ± 8
Weight (kg)	62.3 ± 10.2	63.5 ± 10.5

Values are presented as the mean ± SD or the number of patients.

Chicago, IL, USA). The data is expressed as mean ± SD, medians (range) or numbers of patients. In our pilot study, the time to identify the epidural space (from the interspinous ligament to the epidural space) using the conventional method was 30 ± 10 sec. The sample sizes were calculated assuming that the time to identify the epidural space in the ED group would be reduced by 20% compared to that of the control group, with an alpha error of 0.05 and a power of 80%. A total of 45 patients per group was needed to demonstrate statistical significance. Therefore, we enrolled 54 patients in each group to allow for possible protocol violations during the study period. To compare variables between the two groups, the Kolmogorov-Smirnov test was used to identify the variables with a normal distribution. The variables with a normal distribution were compared by independent t-tests and those without a normal distribution were compared by the Mann-Whitney U-test. The number of patients was compared between the groups using the chi-square test. A P value less than 0.05 was considered statistically significant.

Results

Patient demographic data is shown in Table 1. The patient characteristics were not significantly different between the two groups.

There was one case of unintentional dural puncture and 5 cases of multiple attempts over 4 times in the C group. The distance from the skin to the epidural space was not significantly different in both groups.

The ED group showed a lower failure rate, fewer cases of more than 2 attempts, a shorter time needed to identify the epidural space, greater ease of the procedure, and better satisfaction scores of the procedure than in the C group, with statistical significance (Table 2).

Discussion

In our study, Epidrum® offered rapid identification of the epidural space and increased success rates as compared with the conventional LOR technique. The ease and satisfaction scores of the operator performing epidural anesthesia were also

Table 2. Study Values during Identification of the Epidural Space

	ED group (n = 54)	C group (n = 54)	P value
Failure (n)	0	5	0.022
More than 2 attempts (n)	2	13	0.002
Time (s)			
Interspinous ligament-epidural space	18.6 ± 8.7	31.5 ± 16.8	< 0.001
Epidural depth (cm)			
L3-4 interspace	5.0 ± 0.6	4.7 ± 0.6	0.425
L4-5 interspace	4.4 ± 0.5	4.4 ± 0.7	0.767
Dural puncture (n)	0	1	0.155
Ease score of identification (1-5)			
Operator	2 (2-4)	3 (2-5)	< 0.001
Observer	2 (1-4)	3 (2-5)	< 0.001
Satisfaction score of operator (1-5)	2 (2-4)	3 (2-5)	< 0.001

Values are presented as the mean ± SD, the number of patients, or the median (range).

better.

One of the concerns with epidural anesthesia is incomplete or failed anesthetic block. The incidence of unsatisfactory block is inconsistent among reports, and it is reported up to 25% in parturients [12,13]. The etiology and mechanisms of failed epidural anesthesia are complex and multifactorial. Contributing factors in unsatisfactory epidural block can include technical skills and experience. The inflated diaphragm of Epidrum[®] acts as the meniscus of a manometer and allows the operator to interpret the position of the needle tip. This visual sign provides easy interpretation and monitoring by a supervisor during procedure. For an inexperienced operator, Epidrum[®] provides an easier approach to epidural anesthesia than the conventional method.

This study, which compared Epidrum[®] to the conventional method for identifying the epidural space, showed the superiority of Epidrum[®]. In group C, 13 of 54 cases required more than 2 attempts to locate the epidural space and 5 of these 13 cases had more than 4 attempts. The multiple attempts in group C were caused by false positive signals related to the subjective detection of the change in resistance by the operator. The cause of the fewer attempts in the ED group compared to the C group is thought to result from visual signals (the silicon membrane diaphragm) replacing the subjective detection of resistance change by the operator's thumb. In the ED group, only 2 cases had more than 2 attempts, and at that time, the diaphragm of the Epidrum[®] was slowly deflated. Therefore we suggested that the epidural needle tip was not initially placed at the interspinous ligament, and an air leak of the diaphragm occurred into the patient's tissue, including muscles or tendons, but not in the epidural space.

In the ED group, the operators and observers' ease and satisfaction scores were significantly higher than those in group C. The better ease scores for the operators might have been

influenced by placing 2 hands on the needle and the visual endpoint signals. An experienced observer can monitor the visual signals together when placing the epidural needle and detecting the epidural space.

Although there was no statistically significant difference in the depth of the epidural space, the time from the interspinous ligament to the epidural space was shorter in the ED group.

One of the advantages of Epidrum[®] is lowering the incidence of pneumocephalus by preventing repeated air injection. Also, continuous pressure in the device and swift visual signal change provide prompt interpretation to an operator and a supervisor; however, false positive signals can occur. This problem could be resolved when the operator correctly places the epidural needle tip into the interspinous ligament, and it is important to know the qualitative differences between slow deflation of the diaphragm caused by air leak into low density tissue and the rapid deflation caused by entry of the needle tip into the epidural space.

Another instrument called the Episure[®] Autodetect[®] syringe (Indigo, Orb, Inc., Irvine, CA, USA) used for identifying the epidural space has been reported [14-16]. It is also a LOR syringe with an internal coaxial compression spring that supplies a constant pressure while the operator is advancing the epidural needle. Some studies have reported that it provides more accurate identification concerning the epidural space than the conventional method. It would be valuable to conduct a study comparing Epidrum[®] and the Episure[®] Autodetect[®] syringe for identifying the epidural space.

This study has some limitations. First, ease and satisfaction scores are subjective. However, they were collected by one observer and there was a statistically significant difference between the two groups. Second, our study was not "blinded" for the operators and observers.

In conclusion, using Epidrum[®] compared to the conventional

LOR technique is an easier, rapid, and more reliable method for identifying the epidural space.

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