

# Comparison of the Use of Epidrum® with Air or Saline for Identifying the Epidural Space

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## Abstract

### Background

Identification of the epidural space has a critical role in epidural anesthesia. Epidrum® has been a recently developed air operated device used for identifying the epidural space. This study compares the usage of Epidrum® with saline or air to identify epidural space in performing epidural or combined spinal-epidural(CSE) anesthesia; by paying attention to the ease and duration of the application process, certainty of epidural space distinction, and possible complications.

### Methods

Sixty ASA I or II patients between the ages of 18 and 60 years old scheduled for elective gynecologic, orthopedic or hip surgery under CSE anesthesia were enrolled in this study. The patients were randomly assigned to two groups: either, Epidrum® was used with air (Group A) (n=30) or with saline (Group S) (n=30).

### Results

No significant differences were noted between the two groups in terms of the time taken to determine the epidural space or the number of attempts required to find it. Deflation time in Group A was statistically shorter than Group S (p=0.024). It was reported that Epidrum® usage with air was easier to apply (73% vs. 30%), and discrimination of the epidural space was more significant (63% vs. 13%) compared to saline (p=0.001 in both groups). No complications were recorded in both groups.

### Conclusion

Despite more significant discrimination of the epidural space, shorter deflation time and ease of application of Epidrum® use with air versus saline, saline could be also used successfully in consideration of possible complications with air.

Keywords: Epidrum®; Saline; Air; Epidural anesthesia

## Introduction

Epidural analgesia or anesthesia is the preferred method for obstetric analgesia, postoperative pain control, pain management and related surgical operations. This method not only has positive effects on cardiovascular, respiratory, gastrointestinal and metabolic systems and immune functions, but also leads to shorter hospital stays by allowing for early mobilization [1,2].

Identification of the epidural space has a critical role in epidural anesthesia. Success in identifying the epidural space differs according to the ability and experience of the operator and the anatomic features of the patient. In spite of the popularity of loss of resistance (LOR) techniques, hanging drop techniques and ultrasounds are still used for guiding the placement of the epidural catheter. However, consensus on the ideal technique or method still remains controversial. Since the LOR techniques are one of the most common methods for identifying the epidural space [3,4], using them with assistant apparatus like spring-loaded syringes, classic sensitive needles and Epidrum® may significantly increase the success rate of epidural anesthesia [1,5,6].

Epidrum® has been a recently developed device created to facilitate identifying the epidural space. It has a soft, thin silicon membrane on top that can be filled to a 1-1.5 ml volume and a one-way valve that allows passage of air or water in a single direction at the syringe connection site. The Epidrum® connector is placed between the epidural needle and the syringe, and the device is charged with air to expand its diaphragm. When the needle is advanced, sudden collapse of the diaphragm provides a positive visual signal that the needle has penetrated to the epidural space. An advantage of Epidrum® is that it enables the anesthesiologist to control the Tuohy needle with both hands [5,7].

Air, saline or both together are used in conventional LOR techniques. After using LOR with air, difficulty in placement of the epidural catheter and side effects like headaches, incomplete blocks, back and neck pain, pneumoencephalus, venous air embolisms, subcutaneous emphysema and nerve root compression were reported [8-11]. Difficulty by discrimination unintentional dural puncture, inadequate block and delay in block beginning is undesirable conditions during LOR to saline [4,12]. The usefulness of using Epidrum® with air to identify the epidural space was demonstrated before. No previous reports were found concerning identification of the epidural space using Epidrum® with saline [1,5].

This study compared the usage of Epidrum® with saline or air when determining the epidural space in patients underwent epidural or CSE anesthesia, with focus on ease and the duration of the application process, certainty of epidural space distinction and possible complications.

## Methods

The study took the form of an open, single center trial, approved by the Clinical Research Ethics Committee of Turgut Ozal University Medical Faculty. Written informed consent was obtained from each patient prior to data collection. Sixty ASA I or II patients between the ages of 18 and 60 years

old scheduled for elective gynecologic, orthopedic or hip surgery under CSE anesthesia were enrolled in this study.

Patients with known coagulation disorders, contraindications for CSE, uncorrected hypovolemia were excluded from the study. The patients who have lumbar spinal disease, extremes of height and weight (BMI <20 kg/m<sup>2</sup> or >35 kg/m<sup>2</sup>, height <145 cm or >180 cm) were ruled out unreliable effects of possible anatomical differences on our study.

All patients received 10 ml/kg of Ringer's lactate solution intravenously just prior to block performance. Monitoring in the operating room included lead D II electrocardiography, pulse oximetry and noninvasive oscillometric blood pressure cycled at 3 minute intervals (Datex Engstrom AS/3 Anesthesia Monitor, Helsinki, Finland).

Either epidural or CSE anesthesia was performed by anesthesiologists with at least 3 years of experience. The blocks were performed between L3-4 or L4-5 interspaces in the sitting position. The puncture site was disinfected using an antiseptic solution and covered with a sterile drape; after subcutaneous local anesthetic injection, an epidural block was performed using an 18 gauge Tuohy needle (Espocan; B. Braun, Melsungen, Germany) with a midline approach. The needle was moved forward until the subcutaneous tissue and then the stylet was then removed. The Epidrum® connector (Exmoor Innovations Ltd., Taunton, UK) was attached to the hub of Tuohy needle. The diaphragm of the Epidrum® was inflated with 1.5 ml of air in Group A (air) and 1.5 ml of saline in Group S (saline). The Tuohy needle was advanced with both hands in a controlled manner, and rapid deflation of the Epidrum® diaphragm was used to determine the location of the epidural space. Observers and operators confirmed the epidural space with LOR syringes by insufficient deflation of the Epidrum® diaphragm, resulting in a category of moderately uncertain or uncertain epidural space distinction.

The needle was advanced until the diaphragm of the Epidrum® deflated. The time taken to locate the epidural space was recorded by an observer using a timer that was started as soon as the Tuohy needle was attached to the skin and stopped when the epidural space was identified by visual inspection of deflection of Epidrum® diaphragm. After deflation, the Epidrum® was disconnected and a 27-gauge spinal needle was inserted through the epidural needle for application of spinal anesthesia. The epidural space was enlarged using a 3 ml serum physiologic in both groups. After this, a 20-gauge epidural catheter was inserted through the epidural needle 3-4 cm into the epidural space, firmly fixed in this length.

Various demographic data were recorded, including: distance from the skin to the epidural space; duration of the procedure; number of attempts; deflation time of the Epidrum® diaphragm; requirement of additional methods to confirm epidural space identification; occurrence of paresthesia; patchy block or accidental dural puncture; and certainty level of epidural space identification (certain: rapid and clear deflation of Epidrum® diaphragm; moderately certain: slow or partial deflation of Epidrum® diaphragm; uncertain: no deflation). When in doubt (patients with moderately certain or uncertain epidural space distinction), the epidural space was confirmed using LOR syringes and subsequently recorded.

Patients were observed during postoperative 48 hours in terms of side effects like headaches, incomplete blocks, back and neck pain, pneumoencephalus, subcutaneous emphysema and nerve root compression.

### Statistical Analysis

Statistical analysis was performed using SPSS 20 for Windows. Data were evaluated for normal distribution using histograms and the Shapiro-Wilk test. Descriptive analysis was presented with mean  $\pm$  standard deviation, median (minimum-maximum) or number of patients (%). The variables within a normal distribution were compared using Student's t-tests, and those without a normal distribution were compared using the Mann-Whitney U test. The number of patients was compared between the groups using a chi-square test. Data with a p value of less than 0.05 were considered as statistically significant.

### Results

Sixty five patients were enrolled in this study, but three BMI >35 patients in Group A and two in Group S were excluded. Demographic data of patients showed no statistically significant differences between the groups (p >0.05) (Table 1).

Distance between skin and epidural space in both groups was found to be similar in this study (mean 5.1) (p = 1). No differences were found between Group A and S in terms of time to reach the epidural space (p=0.859). Deflation time in Group S was statistically longer than in Group A (p = 0.024) (Table 2). Discrimination of the epidural space was more significant in Group A compared to Group S (63% vs. 13%) (p <0.001) (Table 2). Epidural space determination was confirmed with LOR due to uncertain epidural space distinction for one patient in Group A and three patients in Group S.

Table 1. Demographic Data

Variables	Group A (n=30)	Group S (n=30)
Age (years)	34 $\pm$ 11	35 $\pm$ 14
Height (cm)	162 $\pm$ 5	163 $\pm$ 5
Weight (kg)	76 $\pm$ 10	80 $\pm$ 12
BMI (kg/m <sup>2</sup> )	28.6 $\pm$ 4.9	29.6 $\pm$ 3.7

Values are presented as the mean  $\pm$  SD.

Table 2. Study Values during Identification of Epidural Space

	Group A (n=30)	Group S (n=30)	P
Distance from the skin to the epidural space (cm)	5.1 $\pm$ 1.3	5.1 $\pm$ 0.7	1.0
The time required to identify the epidural space (sn)	29 (12-122)	35 (11-155)	0.859
Deflation time of the Epidrum diaphragm (sn)	2 (1-6)	3 (1-5)	0.024
Certain of epidural space distinction			
Certain	19 (%63)	4(%13)	
Moderately certain	9(%30)	23(%77)	0.001
Uncertain	2 (%7)	3(%10)	
Number of attempts			
1	21 (%70)	23 (%77)	0.85
2	6 (%20)	5 (%17)	
3	3 (%10)	2 (%7)	
Applicability of the procedure			
Easy	22(%73)	9(%30)	
Moderate	6(%20)	20(%67)	0.001
Difficult	2(%7)	1(%3)	

Values are presented as the mean  $\pm$  SD, the number of patients (%), or the median (min-max)

No difference was recorded between the groups in terms of the number of attempts required to find the epidural space (p = 0.826) (Table 2). Reports showed that Epidrum® usage with air was easier to apply compared to saline (p = 0.001). 73% of patients in Group A and 30% of patients in Group S

considered application to be easy; 20% in Group A and 67% in Group S categorized it as moderately easy; and 7% in Group A and 3% in Group S as difficult (p < 0.001) (Table 2).

No paresthesia, patchy block, dural puncture, intrathecal or intravenous catheterization, block failure or postoperative complications were recorded in both group.

## Discussion

This study compared whether Epidrum® connectors, used to determine the epidural space in patients requiring epidural or CSE application, are more applicable and accurate when used with air or saline. Results showed that the usage of Epidrum® with air was more easily identifiable, and the duration of Epidrum® deflation was shorter than when used with saline.

Epidural space pressure is an important factor in identifying the location of the epidural space. Epidural space pressure changes according to various factors; patient's position, weight, height and anatomy, area and level of application (thoracic or lumbar) and spinal malformation [13]. In a study, epidural pressure changes between -5 and + 5 mmHg at the thoracic region were recorded and compared for patients in seated and lateral decubitus positions [14]. For this reason, this study aimed at minimizing the changes dependent on position by applying epidural anesthesia in the seated position at L3-4 space.

Three studies were found in existing Epidrum® related literature. In these studies, the Epidrum® connector was compared with traditional LOR techniques or hanging drop methods, while the current study compared two different methods of using an Epidrum® connector: air and saline. As indicated above, no studies were found on the usage of epidurals with saline in the existing literature. The study conducted by Hirabayashi et al. [7] on 40 patients compared usage of LOR syringes with saline and Epidrum® usage with air. It has been concluded that epidural anesthesia using an Epidrum® was easier and faster, with clearer distinction. Epidrum® application was also determined to be beneficial in terms of epidural space identification for practitioners who have less experience with epidural anesthesia.

In another study by Sawada et al involving 80 patients, the use of LOR techniques in epidural anesthesia and Epidrum® with air was compared. Epidrum® usage with air was found to have a shorter time period from the epidural needle's penetration into skin to its reaching the epidural space in comparison to that of the LOR group (28 and 90 seconds, respectively). It was reported that the epidural needle could be advanced and directed with control in the Epidrum® with air group because practitioners were able to use both hands. However, they found no difference between the two groups when evaluating the certainty of epidural space distinction or feelings of pressure loss after passing the ligamentum flavum with the epidural needle [5]. In the current study, Epidrum® was used in both groups, and the time from skin to the epidural space was similar to the Sawada et al study (29 seconds in Group A; 35 seconds in Group S). Similarly, it was observed that the Epidrum® connector and epidural needle could be advanced using both hands in a controlled manner.

In a study that included 108 patients in lateral decubitus position undergoing CSE anesthesia, Kim et al. [1] compared the use of LOR syringes to that of Epidrum® connectors with air. Epidrum® usage was found to be superior

due to ease of usage, less time required, fewer attempts and a lower failure rate. In the current study, the number of attempts required to find the epidural space and the distance between the skin and epidural space were similar to the Sawada et al. study, but the time required to reach epidural space was significantly longer (18.6 seconds in Sawada vs. 29-35 seconds in the current study). One explanation could be the difference in time required to overcome the distance between the interspinous ligament and epidural space in Sawada et al.'s [5] study vs. the skin and epidural space in the current study.

The LOR is the most widely used technique compared to other methods for finding the epidural space, such as spring-loaded and hanging drop techniques. The LOR syringe can be used with saline or air, and many studies have been conducted to compare one's superiority over the other. No differences between air and saline were discovered in studies done with 3 ml or less of air or saline using LOR syringes in terms of epidural catheter placement, block onset time and side effects [2,4,5].

Several existing studies have demonstrated that instances of accidental dural puncture, headaches, incomplete blocks, difficulty in epidural catheter placement, pneumocephalus, venous air embolisms, subcutaneous emphysema, back and neck pain and nerve root compression rate were significantly higher when 3-5 ml of air was used compared to saline [8-12]. In the studies using saline, any difficulty in accidental dural puncture discrimination or incomplete epidural blocks likely depended on dilution; late onset of epidural block was found at a higher rate [3,14]. In the current study, these complications were not seen in any of the groups. These outcomes may be the result of the low volume used to find the epidural space and the limited number of cases.

This study has several limitations. First, it could not be designed as a double blind study because of the impossibility of using Epidrum® with air or saline without operator knowledge. Secondly, though clear distinction of epidural space and deflation time of the Epidrum® connector were confirmed by an observer next to the operator, the applicability of the process was evaluated subjectively. This is one of the limitations for the study, because evaluation of ease of application could not be assessed in another way.

Due to concerns with the complications listed in existing literature, the current study determined whether an Epidrum® connector originally produced for use with air could be used successfully with saline to avoid possible side effects and complications. In conclusion, when comparing Epidrum® connector use with air vs. saline, air use demonstrated to be more evident in epidural space distinction, shorter Epidrum® balloon deflation time and easier reported usage. However, saline may also be used successfully, as no differences were detected between the two groups in terms of number of attempts, process duration and complications, while air usage might carry the risk of potential complications.

## Declaration of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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