

## Original Article

# Comparison of Epidrum, Epi-jet, and Loss of Resistance Syringe Techniques for Identifying the Epidural Space in Obstetric Patients

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### ABSTRACT

**Background:** Identifying the epidural space is essential during epidural anesthesia (EA). Pressure of the epidural space in pregnancy is higher than that in nonpregnant woman. Loss of resistance (LOR) method is the most commonly preferred method for identifying the epidural space. Epidrum and Epi-Jet are recently innovated supporting devices that facilitate identifying process for epidural space. In this study we aimed to compare Epidrum, Epi-Jet, and LOR methods in identifying the epidural space, feasibility of technique. **Methods:** Two hundred and forty pregnant women who were scheduled for caesarian section surgery under lumbar EA or combined spinal epidural anesthesia (CSEA) were randomized into three groups (Group I Epidrum,  $n = 80$ ), Group II (Epi-Jet,  $n = 80$ ), and Group III (LOR,  $n = 80$ ). We recorded the time required to identify the epidural space and deflation of Epidrum balloon and Epi-Jet syringe, number of attempts, additional methods used to identify epidural space, usefulness of methods, accuracy of identification of epidural space, and outcomes of epidural catheterization. **Results:** There were no significant differences between the groups with respect to demographic data, duration of deflation of Epidrum balloon and Epi-Jet syringe and distance between skin and epidural space. The mean time required to enter epidural space in Group I was shorter than that in Group II ( $P = 0.031$ ). Feasibility of Epi-Jet was easier than that of Epidrum ( $P = 0.015$ ). Number of uncertainties of epidural space identification was higher in Group I than that in Group II ( $P = 0.009$ ). Also, the requirement for LOR to confirm epidural space and failure rates was higher in Group I than Group II ( $P < 0.001$ ). **Conclusion:** We suggest that Epi-Jet is superior to Epidrum in pregnant patients in terms of clarity of epidural space identification, usefulness, and success rates of EA or CSEA.

**KEYWORDS:** *Epi-Jet, Epidrum, epidural anesthesia*

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## INTRODUCTION

Epidural anesthesia (EA) and combined spinal epidural anesthesia (CSEA) are commonly preferred techniques in obstetric patients because of effectiveness and acceptable safety profile with minimal adverse effects.<sup>[1]</sup>

Different techniques with various devices including hanging drop, drip infusion, Oxford detector, spring loaded loss of resistance (LOR) syringe (Episure Autodetect Syringe, Indigo Orb, Santa Clara, CA, USA), Machintosh

epidural balloon, Epidrum balloon, and continuous hydrostatic pressure system have been identified so far. Also several techniques such as acoustical signal and ultrasound-guided methods have been developed; however, these methods have not been accepted widely.<sup>[2]</sup>

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LOR technique was first described in 1933 and has become the most popular technique following innovation in special sensitive syringe technology.<sup>[2]</sup> Epi-Jet (Egemen International, İzmir, Turkey) is an automatic LOR syringe with sensitive spring loaded mechanism that generates low positive pressure used for determining epidural space with fluid or air technique. Before innovation of Epi-Jet similar devices such as Episure Autodetect Syringe,<sup>[4]</sup> and spring-loaded<sup>[3]</sup> have been developed. Positive pressure generated by the spring mechanism causes collapsing of syringe and subsequently facilitates objectively identification of epidural space.<sup>[5]</sup>

Epidrum (Exmoor Innovations Ltd., Taunton, UK) is an optimal, constant, low pressure LOR device to facilitate epidural space identification procedures. Interposed between needle and syringe, the device is filled with air to expand its diaphragm with a 1–1.5 ml volume of air. When the needle is advanced, the sudden collapse of the diaphragm via low positive pressure indicates the needle's penetration into the epidural space. Epidrum device enables both hands on needle so that improves control/advancement of needle.<sup>[6,7]</sup>

Methods and/or devices that drive positive pressure have many advantages include facilitating the procedure, providing acceptable objectivity, and providing visually confirmation of epidural space. Additionally, these techniques are recommended for special conditions such as patients with spinal deformities, morbid obesity, and thoracic EA.<sup>[8]</sup>

Epidural pressure during pregnancy is elevated secondary to increased edema, elevated vena cava inferior pressure, enlarged venous plexus, and elevated intraperitoneal pressure.<sup>[9]</sup> Also positive correlation has been found between increased epidural pressure and contraction of abdominal and uterine muscles.<sup>[10]</sup> These factors may complicate identifying epidural space in gravid patients.

In this study, we compared LOR syringe, Epi-Jet, and Epidrum in terms of time required to reach epidural space, number of attempts, feasibility of methods, clarity, and success of identifying epidural space during EA or CSEA in obstetric patients.

## METHODS

The study was approved by the Clinical Research Ethics Committee of Turgut Ozal University, Faculty of Medicine. Written informed consent was obtained from each patient. We enrolled 240 adult patients [American Society of Anesthesiologists (ASA) physical status I or II] who were scheduled for elective caesarean

section surgery under lumbar epidural or CSEA. Three study groups were organized in a randomized, controlled clinical trial by the envelope technique. Patients refused to participate in the study, those with lumbar spinal disease, local skin infection at injection site, psychiatric disease, known coagulation disorders, or severe obesity [body mass index (BMI; 35 kg/m<sup>2</sup>)] were excluded. All patients received 10 ml/kg of Ringer's lactate solution intravenously just prior to anesthesia. Monitoring in the operating room included lead D II and V5 electrocardiography, pulse oximetry, and noninvasive blood pressure.

Either epidural or CSE anesthesia was performed by anesthesiologists with at least 3 years of experience. The blocks were performed between L3-4 interspaces in the sitting position. EA set with 18-G needle (Perifix, Braun, Germany) was used for epidural only procedure while combined set with 18-G epidural and 27-G spinal needles (Espocan + Docking System + Perifix Soft Tip) was used for CSEA. The puncture site was disinfected using an antiseptic solution and covered with a sterile drape; after subcutaneous local anesthetic infiltration with lidocaine 2% [1 ml (20 mg)], an epidural block was performed using an 18-gauge Tuohy needle (Espocan; B. Braun, Melsungen, Germany) with using midline approach. The needle was moved forward until advanced reach the subcutaneous tissue and then the stylet was then removed depending on the patient's group either Epidrum connector (Exmoor Innovations Ltd), Epi-Jet, or LOR syringe was attached to the hub of Tuohy needle.

### Group I: Epidrum (n = 80)

The diaphragm of the Epidrum was inflated with 1.5 ml of air, and 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 [Figure 1]. The needle was advanced until the diaphragm of the Epidrum deflated [Figure 2]. Observers confirmed the epidural space with LOR syringes when in doubt about needle placement.

### Group II: Epi-Jet (n = 80)

Epi-Jet (Egemen International) is a newly innovated automatically LOR syringe that is used to determine the location of epidural space either with air or saline. There are two locking points on the piston that permit sucking 4–6 ml air or liquid. We filled the syringe with 4 ml saline and locked the piston [Figure 3]. Tuohy needle was advanced until the piston deflated due to lower pressure levels in epidural space. In cases when

in doubt about the localization, it was confirmed with LOR.

### Group III: LOR syringe (n = 80)

The needle was moved forward until the subcutaneous tissue and then the stylet was removed. LOR syringe filled with 5 ml saline was attached to the hub of Tuohy needle. The needle was moved forward until LOR noted clearly. Procedures were repeated in doubtful cases.

A 27-gauge spinal needle was inserted through the epidural needle for application of spinal anesthesia for CSEA. The epidural space was enlarged using 3 ml of saline in all groups. After that, a 20-gauge epidural catheter was inserted through the epidural needle 3–4 cm into the epidural space, firmly fixed in this length.

Demographic data, distance from the skin to the epidural space, duration of the procedure, number of attempts, deflation time of the Epidrum diaphragm or Epi-Jet syringe, requirement of additional methods to confirm epidural space identification, occurrence of paresthesia, patchy block or accidental dural puncture, feasibility of method (easy, moderate, difficult) and certainty level of epidural space identification (certain, moderately certain, uncertain), percentage of using LOR to confirmation, success rate of the procedures were noted.

### Statistical analysis

Statistical analysis was performed using SPSS 21 (SPSS Inc., Chicago, IL, USA) for Windows. Data were evaluated for normal distribution using histograms and the Kolmogorov–Simirnov test. ANOVA test was used to analyze normal distribution of numeric variables. Significant differences among groups were compared using Tukey test. Non-normally distributed variables were compared using Kruskal–Wallis test. Significant differences between two groups were analyzed using Mann–Whitney *U* test. Differences between intergroup frequencies were analyzed using  $\chi^2$  test. Descriptive analysis was presented with mean  $\pm$  standard deviation, median (minimum-maximum), or number of patients (%). Data with a *P* value of  $<0.05$  were considered as statistically significant.

## RESULTS

Two hundred and forty patients were enrolled into the study, but two patients in Group I and five patients in Group II were excluded due to high BMI ( $>35$  kg/m<sup>2</sup>). There were no statistically significant differences between groups regarding demographic data (age, height, weight), type of surgery (caesarian/ painless

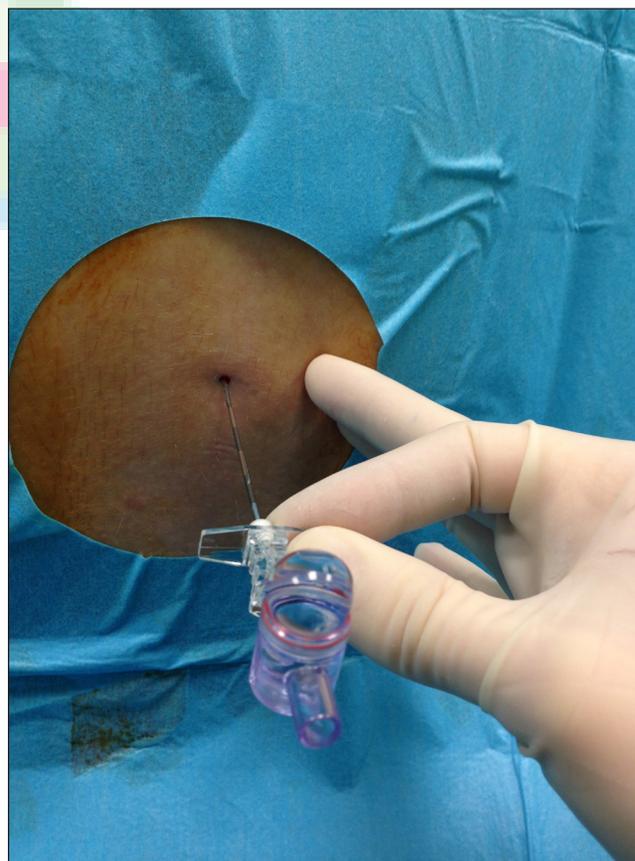
labor), type of procedure (EA/CSEA), and level of intervention ( $P > 0.05$ ) [Table 1].

No differences were found between three groups in terms of distance from the skin to the epidural space and

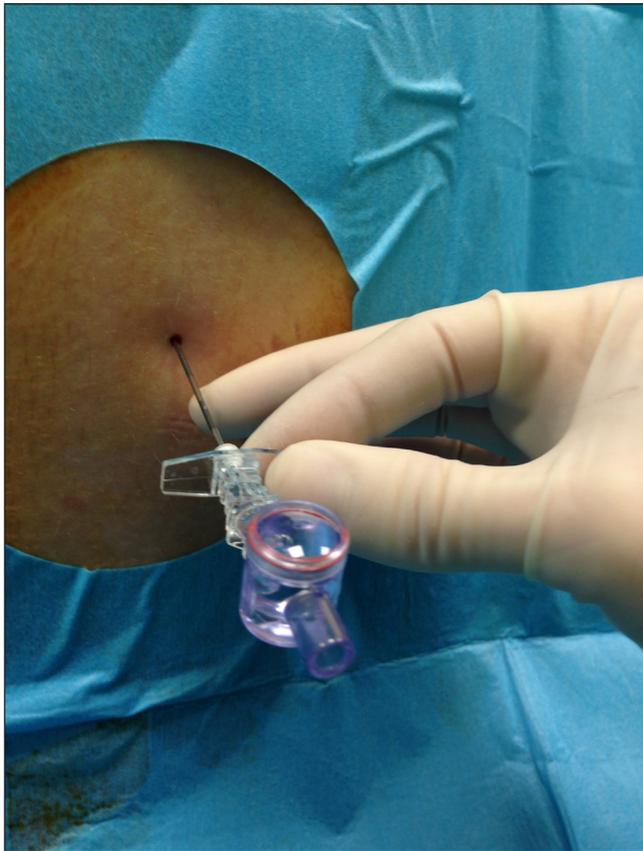
**Table 1: Demographic and operative properties of patients**

Variables	Group I (n = 78)	Group II (n = 75)	Group III (n = 80)	P
Age (year)	31.1 $\pm$ 4.7	31.3 $\pm$ 5.0	31.3 $\pm$ 5.0	0.812
Weight (cm)	160.6 $\pm$ 19.2	163.1 $\pm$ 6.0	163.9 $\pm$ 6.0	0.22
Height (kg)	74.9 $\pm$ 10.9	77.9 $\pm$ 9.7	75.5 $\pm$ 8.8	0.147
Type of operation				
I = Caesarian	[72] (92.3%)	[71] (94.7%)	[74] (92.5%)	0.815
II = Labor analgesia	[6] (7.7%)	[4] (5.4%)	[6] (7.5%)	
Type of anesthesia				
I = EA	[4] (5.1%)	[4] (5.3%)	[0] (0%)	0.114
II = CSEA	[74] (98.7%)	[71] (94.7%)	[80] (100%)	

Values are presented as the mean  $\pm$  SD, or the number of patients (%). \* $P < 0.05$  was considered statistically significant



**Figure 1:** Epidrum balloon placed behind the epidural needle and inflated with 1.5 ml of air



**Figure 2:** When the epidural needle enters into the epidural space, the Epidrum balloon deflated position

number of attempts ( $P > 0.05$ ). Time required for deflation of both Epidrum balloon and Epi-Jet syringe was similar ( $P > 0.05$ ) [Table 2]. Mean time to reach epidural space was significantly shorter in Group I than that in Group II ( $P = 0.031$ ) [Table 2].

Performing Epidrum method was found more difficult than both of other two methods ( $P = 0.015$  and  $P = 0.082$ , respectively) [Table 2]. Certainty level of epidural space identification using Epidrum was significantly lower than those in other study groups ( $P = 0.025$  and  $P = 0.007$ , respectively) [Table 2].

The number of doubtful attempts and subsequently the number of confirmations performed using LOR syringe was significantly higher in Epidrum group than that in Epi-Jet group ( $P < 0.001$ ). Number of failed attempts and repeated procedure with using LOR syringe was significantly higher in Group I than that in Group II ( $P < 0.001$ ).

None of the patients in Group I and Group II suffered any paresthesia whereas in Group III paresthesia was noted in two patients. One patient in Group I, two patients in Group II experienced patchy block whereas none of the patients in Group III experienced patchy block. Accidental dural puncture and intrathecal catheter insertion did not occur.

**Table 2: Study values during identification of epidural space**

Variables	Group I (n = 78)	Group II (n = 75)	Group III (n = 80)	P
Distance from the skin to the epidural space (cm)	4.9 ± 0.9	5.0 ± 0.8	4.9 ± 0.9	0.98
Number of attempts to identify the epidural space	1.2 ± 0.9	1.2 ± 0.5	1.1 ± 0.3	0.198
Deflation time of the Epidrum diaphragm or Epijet (sn)	3.7 ± 1.5	3.9 ± 1.2		0.417
The time required to identify the epidural space (sn)	22.7±12.6 <sup>#</sup>	28.2 ± 17.2	25.3 ± 9.6	0.041*
Applicability of the procedure				
I = Easy	[47] (60.3%) <sup>#&amp;</sup>	[61] (81.3%)	[59] (73.8%)	0.025*
II = Moderate	[18] (23.1%)	[7] (9.3%)	[16] (20%)	
III = Difficult	[13] (16.7%)	[7] (9.3%)	[5] (6.3%)	
Certain of epidural space				
Distinction				
I = Certain	[41] (52.6%) <sup>#&amp;</sup>	[55] (73.3%)	[57] (71.3%)	0.009*
II = Moderately	[19] (24.4%)	[12] (16.0%)	[18] (22.5%)	
III = Uncertain	[18] (23.1%)	[8] (10.7%)	[5] (6.3%)	
Epidural space confirmed with LOR	45 (57.7%)	17 (22.7%)		<0.001*
The failure rate of the procedure with Epidrum balloon/Epi-Jet	[19] (24.4%)	[8] (10.7%)		<0.001*

Values are presented as the mean ± SD, the number of patients (%) or median (min–max). \* $P < 0.05$ : Comparisons between groups was considered statistically significant. #  $P < 0.05$ : When compared with Group II for Tukey test. &  $P < 0.05$ : When compared with Group III



**Figure 3:** Epi-Jet syringe view. When installed in spring can be obtained positive pressure

## DISCUSSION

Successful epidural or CSEA strongly depends on successful identification of epidural space. LOR is the most commonly used technique however failure rates may increase when performed by inexperienced staff.<sup>[4]</sup> Beyond the experience level of anesthetist several factors related with patients such as posture, anatomy, height and weight of patient, level of planned EA (thoracic or lumbar) and spinal malformations may influence success rates during EA.<sup>[11]</sup> We aimed to minimize patient-related confounding factors, so we standardized position, age, height, and weight of patients in this study.

Both of Epidrum and Epi-Jet have advantage over classic LOR technique in terms of providing both of two hands on needle so that improving control of needle; however, we found higher success rates in determination

of epidural space with easier application with Epi-Jet compared with Epidrum.

Distance between skin and epidural space and number of attempts in order to find epidural space were similar with our previous study in which we investigated Epidrum method.<sup>[5]</sup> Time to reach epidural space using Epidrum in this study was shorter than reported in previous studies (22.7 vs. 29 s).<sup>[5,6]</sup> In contrast, longer deflation time of Epidrum balloon was found in this study (3.7 vs. 2 s).<sup>[5]</sup> Also percentage of anesthesiologists scored the certainty level of epidural space identification as certain and difficulty degree of method as easy were lower in this study when compared with our previous study (52.6 vs. 63% and 60.3 vs. 73%).

Shorter procedural time, easier and more clearly identification of epidural space with Epidrum balloon was reported when compared with LOR syringe technique<sup>[7]</sup>. Moreover, lower failure rates and number of attempts related with Epidrum usage by inexperienced operators have been reported.<sup>[4]</sup> In contrast, different findings have been reported in terms of LOR sensitivity at first epidural insertion and confirming epidural space with Epidrum device.<sup>[6,7]</sup> We suggest that experience level of anesthesiologist with Epidrum device and patient-related factors, including age, height, weight, posture, and position may cause these conflicting results reported in different investigations. In contrast to previous studies, we found lower degree of ease of application and certainty of determination the epidural space with Epidrum when it is compared with classical LOR syringe technique. We think that special patient population enrolled into our study-pregnant patient population with decreased epidural negative pressure levels-may cause findings stated above.

Deighan *et al.*<sup>[12]</sup> have also compared Epidrum and LOR techniques in terms of accidental dural puncture rate, failure rate of epidural catheter insertion, analgesia, postdural puncture headache, and epidural blood patch in obstetric patients. They concluded unchanged complication and success rates despite Epidrum usage in EA. We found similar results in conjunction with previous study in terms of failure rate and repeated epidural procedure rates whereas none of the patients in Epidrum group experienced complications such as accidental dural puncture, failure of analgesia, postdural puncture headache, and epidural blood patch.

Slightly higher positive pressure level generated by Epi-Jet than generated by Epidrum, may provide advantage. Also several studies reported safe and successful EA with Epi-Jet in thoracic, lumbar EA in pregnant patients and children.<sup>[3,4,13-15]</sup> Similar to Epidrum balloon, Epi-Jet allows handling, controlling the Tuohy needle with two hands and objectively making

discrimination of epidural space via deflation of syringe piston. Time to reach epidural space with Epi-Jet was similar with previous studies conducted by Gülen *et al.*<sup>[3]</sup> and Joseph *et al.*<sup>[13]</sup> whereas shorter time intervals were found by others.<sup>[4,8]</sup> We suggest that this discrepancy might arise in relation with different patient populations investigated in different studies. Time required to reach epidural space was found shorter in Group I than in Group II. But, we suggest that this difference is clinically insignificant because Epi-Jet is a heavier device than Epidrum and so one can pay more attention and has to move needle more slowly when using Epi-Jet.

Deflation time of Epidrum balloon and Epi-Jet were found similar and deflation time of Epidrum was found longer than that found in nonpregnant patient population investigated in our previous study<sup>[5]</sup> (3.9 vs. 2 s). Confirmation with LOR syringe, success rate and feasibility of methods, discrimination of epidural space are firstly investigated parameters in a study comparing Epidrum balloon and Epi-Jet. We found that Epi-Jet is superior to Epidrum with respect to identifying epidural space, less requirement of confirmation with LOR, lower failure rate. and ease of application.

There are several limitations for this study. First, the study was not planned as double-blinded investigation because of the impossibility of using these devices without operator knowledge. Second, although it is accepted as an objective method, assessment of technical feasibility is a subjective process depending on anesthesiologists. Finally, the data may be affected by observations, personal choices, routines, and experience level of anesthesiologist. However, anesthesiologists performed equal number of cases with each devices in all three study groups in this way we tried to reduce the confounders and bias.

In conclusion, both Epidrum and Epi-Jet have advantage that devices enable the anesthesiologist to control the Tuohy needle with both hands during EA. However, success rates and facilitating feature of Epidrum that reported in previous studies conducted in nonpregnant populations were noneffective during EA/CSEA in pregnant patients. Changes in epidural pressure levels in pregnancy complicate the application of Epidrum, and as a result it increased uncertainty in identification of epidural space. Furthermore, the need for confirmation with LOR and failure rates are higher with Epidrum than Epi-Jet so we suggest that Epijet may serve better EA or CSEA success rates in obstetric patients. On the other hand, Epi-Jet and LOR syringe methods are superior to Epidrum in terms of true epidural space identification rates. Also performing EA or CSEA using Epi-Jet was significantly easier and has provided higher success rates than Epidrum technique. There is need for future studies to make clear

conclusions and strong recommendations related with all these devices in different surgical specialties.

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### Conflicts of interest

There are no conflicts of interest.

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