A Comparative Study Using the Balloon Indicator Syringe and Conventional Loss of Resistance (LOR) Syringe to Identify the Epidural Space in Adult Patients Undergoing Elective Lower Abdomen and Lower Limb Procedures – A Randomized Controlled Study

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KEYWORDS
Epidural anaesthesia, Loss of resistance syringe, LOR balloon indicator syringe, Dural puncture, Neuraxial blockade.

ABSTRACT

Introduction: Neuraxial blocks, including spinal and epidural anaesthesia, are widely used for lower abdominal and limb surgeries because of reduced blood loss and prolonged analgesia. Epidural anaesthesia offers versatile intraoperative and postoperative pain management to improve accuracy and safety. This study aimed to assess the efficiency of the LOR balloon indicator syringe in successfully identifying the epidural space in terms of number of attempts.

Methods: This prospective comparative study was conducted on 292 patients at SRM Medical College Hospital, Chennai, for 18 months. Patients were randomised into Group C (n=146), who received epidural anaesthesia with a conventional LOR syringe, and Group B (n=146), who used an LOR balloon indicator syringe. All patients underwent preoperative evaluation, standard monitoring, and epidural anaesthesia using aseptic techniques. Epidural space identification was assessed on the basis of the number of attempts, time required, and complications.

Results: Group B required significantly fewer needle redirections and had more patients successfully identifying the epidural space on the first attempt (72.6%) than Group C (43.2%) (p=0.001). Complications were lower in Group B, with fewer cases of dural puncture (0.7% vs. 3.4%; p=0.036) and less bleeding (6.2% vs. 12.3%). The time to identify the epidural space was slightly shorter in Group B than in Group C (91.97±32.45 vs. 97.56±22.45; p=0.453). The heart rate, blood pressure, and oxygen saturation remained stable across both groups.

Conclusion: The LOR balloon syringe significantly reduced the number of attempts and time required to identify the epidural space compared with the conventional LOR syringe. It is easy to use, offers an objective method, and results in fewer complications than other methods.

1. Introduction

A neuraxial blockage is commonly preferred in lower abdominal and lower limb surgery. These techniques have several advantages over general anaesthesia, including reduced blood loss, prolonged postoperative analgesia, reduced opioid consumption, and enhanced recovery.[1]The type and level of neuraxial blockage required depends on the surgery type, duration, level of skin incision, and surgical manipulation. Different types of neuraxial blockages include spinal anaesthesia, epidural anaesthesia, and caudal block.[2] Epidural anaesthesia involves injecting local anaesthetic drugs into the epidural space. Previously, it was more frequently used with general anaesthesia for surgical procedures, but recently it has become the principal anaesthetic for surgeries from the mediastinum to the lower extremities. It also provides intraoperative analgesia during postoperative and peripartum pain management.[3,4]

Over the past several decades, there has been a tremendous expansion in the clinical indications for both epidural anaesthesia and analgesia.[5] It produces reversible motor and sensory block. Used as a stand-alone neuraxial blockade technique, a continuous infusion of local anaesthetic through an epidural catheter placed at an appropriate level can provide good postoperative analgesia.[6] The concentration can be titrated to provide sensory blockade alone post-operatively, aiding early patient ambulation. Epidural analgesia is widely used by pain specialists as epidural steroid therapy.

Despite their usefulness, budding anaesthetists sometimes struggle to identify the epidural space. This may be due to improper position, level, and direction of needle insertion, spinal deformity, obesity, old age, and pregnancy. The epidural space is nearest to the subarachnoid space; thus, mastering it is tough. Accidental dural puncture incidence is high, leading to postdural puncture headaches.[7] Additionally, dural puncture increases the risk of the catheter threading into the subarachnoid space. If unrecognised, the large drug volumes deposited here can produce a detrimental high spinal blockade.[8]

Various methods have been developed to overcome this situation, such as the Conventional LOR technique, spring-loaded loss of resistance syringe,[9] Macintosh balloon technique,[10] hanging drop technique, capillary tube, odom manometer indicator syringe technique, and drip infusion technique.[11]Few advanced techniques, such as acoustical signal and ultrasound-guided methods, have been used in difficult cases where the identification of the epidural space is very difficult.[12] These methods are not routinely performed because of their availability and ease of use. Among these methods, the conventional LOR syringe is the most commonly used to identify the epidural space. This method of identification is subjective, and its accuracy in identifying the epidural space varies from beginner to expert anaesthetist. Only a few objective methods are available for identifying the epidural space using the LOR technique. Therefore, we conducted a study to compare the ease and comfort of using LOR balloon indicator syringes with those of conventional LOR syringes in identifying the epidural space.

1.1. Aim

This study aimed to assess the efficiency of the LOR balloon indicator syringe in successfully identifying the epidural space in terms of a number of attempts.

2. Materials and Methods

This prospective comparative study was conducted on 292 patients, who were scheduled for elective lower abdominal and lower limb surgical procedures in the SRM Medical College Hospital and Research Center, Chennai, for 18 months. The study was approved by the Institutional Ethics Committee, and informed consent was obtained from all patients before the initiation of the study.

2.1 Inclusion criteria

Patients aged 18–65 years with a BMI of 18-25 kg/m², classified as ASA I or II, and undergoing elective lower abdominal and lower limb surgical procedures suitable for epidural anaesthesia were included.

2.2 Exclusion criteria

Patients undergoing emergency procedures, those with infection at the injection site, bleeding disorders, coagulopathy, deformed spine, pregnancy, known allergy to local anaesthetic drugs, and those who refused the procedure were excluded.

2.3 Methods

Patients were randomised into two groups generated by computer randomization and concealed using the sealed envelope technique. Group C (n=146) received epidural anaesthesia using a conventional LOR syringe and Group B (n=146) received epidural anaesthesia using an LOR balloon indicator syringe. In all patients, preoperative evaluation was performed the day before surgery in the ward. The standard fasting protocol was followed according to the hospital guidelines. After shifting to the operating theatre, all patients were monitored using electrocardiography, oxygen saturation, and non-invasive blood pressure measurements.

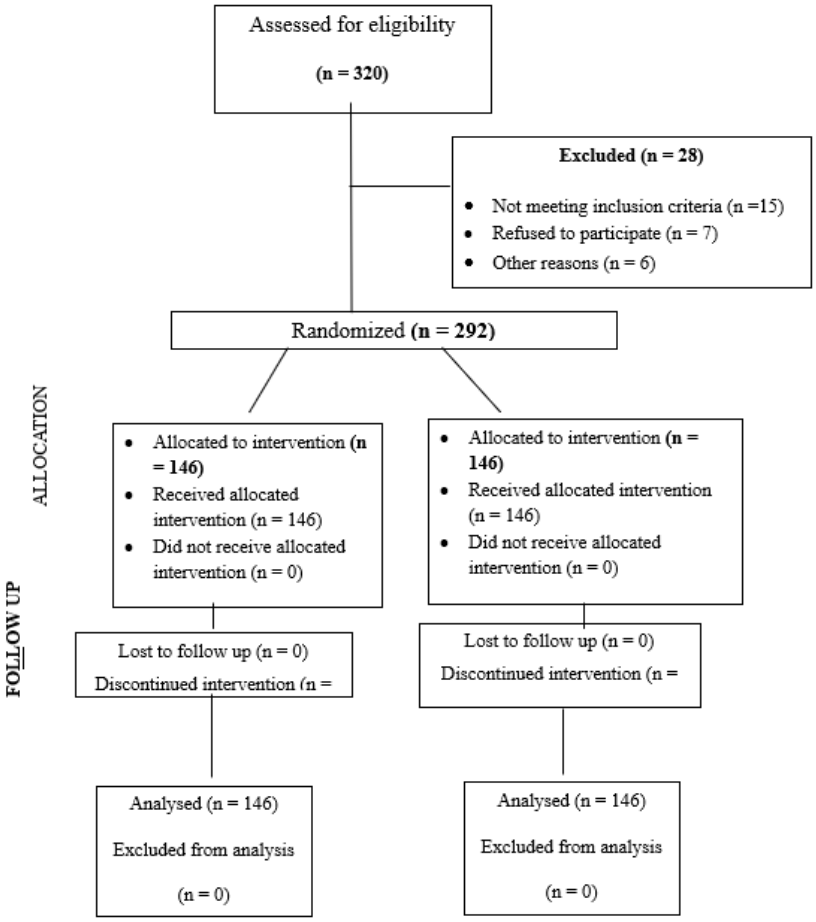
An anesthesiologist who administered more than 50 epidural anaesthesia performed the epidural procedure in all patients. Under aseptic conditions, the parts were painted and draped. After identifying the interspinous space, local anaesthesia was induced using 2 ml of 2% Inj. Lignocaine.

In Group C, an 18G Tuohy Needle was gently introduced into the respective interspinous space. A conventional LOR syringe, pre-filled with 3 ml saline, was attached to the Tuohy needle and slowly advanced to the ligamentum flavum. With further advancement of the needle, once the tip of the epidural needle was inserted into the epidural space, saline in the syringe was sucked into the space, indicating the correct epidural space.

In Group B, the 18G Tuohy Needle was attached to the LOR balloon indicator syringe and pre-filled with 3 ml saline. Once the needle tip entered the epidural space, the balloon attached to the syringe deflated suddenly,

indicating the correct epidural space. In both groups, frequency of attempts required to locate the epidural space, duration needed for successful identification, number of catheter insertion attempts, and procedural complications, including dural puncture and haemorrhage were recorded. No attempts were defined as the number of skin pricks with the epidural needle performed by the attending anaesthesiologist to correctly identify the epidural space in the same or different interspinous spaces.

The time taken to locate the epidural space was defined as the interval between the initial needle insertion through the skin and successful epidural space penetration. In Group C, confirmation relied on the loss-of-resistance technique observed by the attending anesthesiologist. In Group B, identification was determined by the abrupt deflation of the balloon in the loss-of-resistance (LOR) syringe, monitored by the attending anesthesiologist. Redirection was defined as the number of times the needle was taken up to skin level and redirected in different directions within the same interspinous space. More than three redirections were considered as 2nd attempt. More than three attempts were considered failed.



3. Consort Flowchart

3.1 Statistical analysis

Continuous data was summarized by presenting mean, standard deviation, frequency, and percent. Comparison between groups of the continuous variable used independent sample t-test. In the categorical variable, it utilized Pearson's Chi-squared test. Statistical significance was based on a P-value of < 0.05 using two-sided testing, and the findings were stated in terms of a 95% CI. Data was analysed using IBM-SPSS version 21.0. (IBM-SPSS Corp., Armonk, NY, USA).

4. Results

The majority of patients in both groups were aged 31-65 years, with similar gender distribution between males

(Group B: 57.5%, Group C: 56.8%) and females (Group B: 42.5%, Group C: 43.2%), showing no significant differences (p>0.05). ASA physical status was comparable, with ASA I being slightly more common in both groups (Group B: 54.1%, Group C: 51.4%; p=0.725). There were no significant differences in age, height, or weight between Groups B and C (p=0.262, p=0.873, and p=0.976)(Table 1).

Table 1: Comparison of demographic details between groups

		Group B	Group C	P value
Age in years	18-30	19 (13%)	16 (11%)	0.563
	31-50	63 (43.2%)	57 (39%)	
	51-65	64 (43.8%)	73 (50%)	
	Mean	45.95±12.04	47.55±12.43	0.262
Gender	Male	84 (57.5%)	83 (56.8%)	0.906
	Female	62 (42.5%)	63 (43.2%)	
ASA	I	79 (54.1%)	75 (51.4%)	0.725
	II	67 (45.9%)	71 (48.6%)	
Height in cm (mean)		165.37±7.77	165.51±7.57	0.873
Weight in kg (mean)		62.85±5.24	62.87±6.18	0.976

Significantly fewer redirections of the needle were observed in Group B, with 37% requiring no redirection compared to only 8.9% in Group C, while more patients in Group C required three redirections (42.5% vs. 18.5%; p=0.001). Group B also had significantly more patients requiring only one attempt to identify the epidural space (72.6%) than Group C (43.2%; p=0.001). The number of attempts to thread the epidural catheter was similar in both groups, with most patients requiring only one attempt (Group B, 89.7%; Group C, 92.5%; p=0.538). Complications were significantly lower in Group B, with fewer cases of dural puncture (0.7% vs. 3.4%; p=0.036) and less bleeding (6.2% vs. 12.3%).

Table 2: Comparison of procedure and its complications between groups

		Group B	Group C	P value
Total number of redirections of needle (0,1,2,3)	0	54 (37%)	13 (8.9%)	0.001
	1	36 (24.7%)	17 (11.6%)	
	2	29 (19.9%)	54 (37%)	
	3	27 (18.5%)	62 (42.5%)	
Total number of attempts	1	106 (72.6%)	63 (43.2%)	0.001
	2	33 (22.6%)	63 (43.2%)	
	3	7 (4.8%)	20 (13.7%)	
Total number of attempts to thread the epidural catheter into the epidural space. (1,2,3)	1	131 (89.7%)	135 (92.5%)	0.538
	2	15 (10.3%)	11 (7.5%)	
Complications	Dural puncture	1 (0.7%)	5 (3.4%)	0.036
	Bleeding	9 (6.2%)	18 (12.3%)	
Time taken to identify the epidural space in seconds (mean)		91.97±32.45	97.56±22.45	0.453
Depth at which the epidural space is identified (1, 2, 3, 4, 5 cm) (mean)		3.69±0.53	3.65±0.56	0.486
Depth at which the epidural catheter tip is placed from the skin in cm (mean)		8.7±0.56	8.66±0.56	0.491

The time taken to identify the epidural space was slightly lower in Group B (91.97±32.45) than in Group C (97.56±22.45), with no significant difference(p=0.453). The depth at which the epidural space was identified was also comparable between the groups, with Group B at 3.69±0.53 cm and Group C at 3.65±0.56 cm (p=0.486). The depth at which the epidural catheter tip was placed from the skin was similar between Group B (8.7±0.56 cm) and Group C (8.66±0.56 cm), with no significant difference (p=0.491) (Table 2).

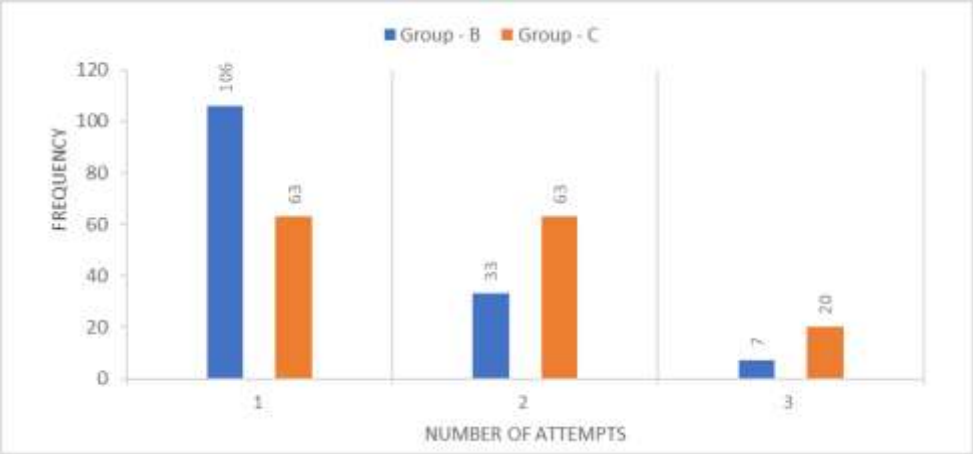


Figure 1: Total number of attempts to identify the epidural space between groups

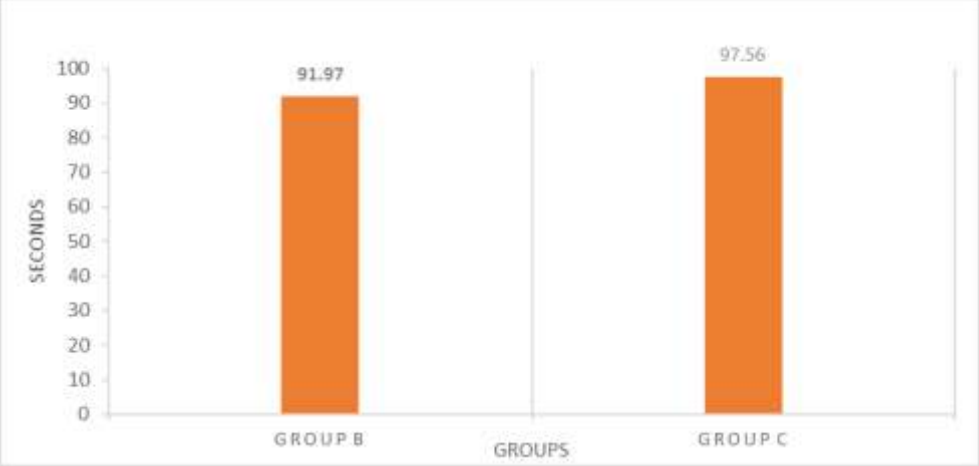


Figure 2: Time taken to identify the epidural space between groups

Figure 3: Changes in heart rate between groups

There was no significant change in the heart rate, systolic blood pressure, diastolic blood pressure, and oxygen saturation between the two groups at various intervals from 1 min to 2 h (p>0.05) (Figures 3 to 6).

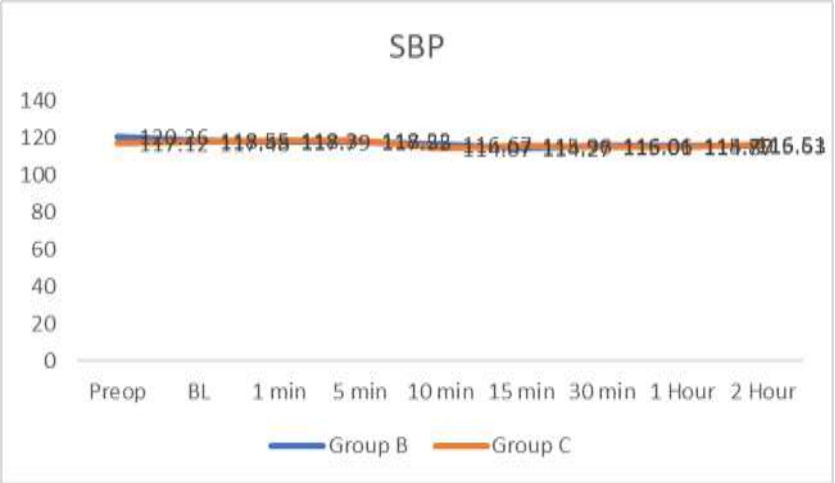


Figure 4: Changes in the systolic BP between groups

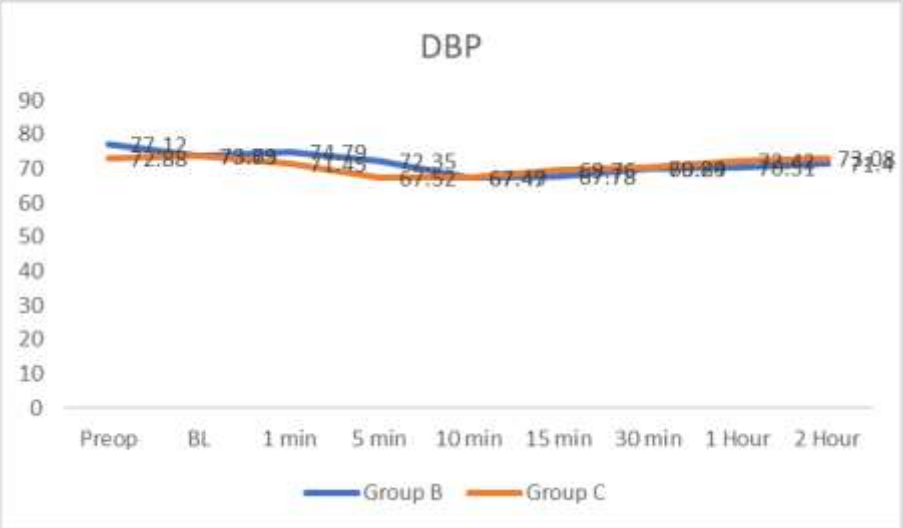


Figure 5: Changes in the diastolic BP between groups

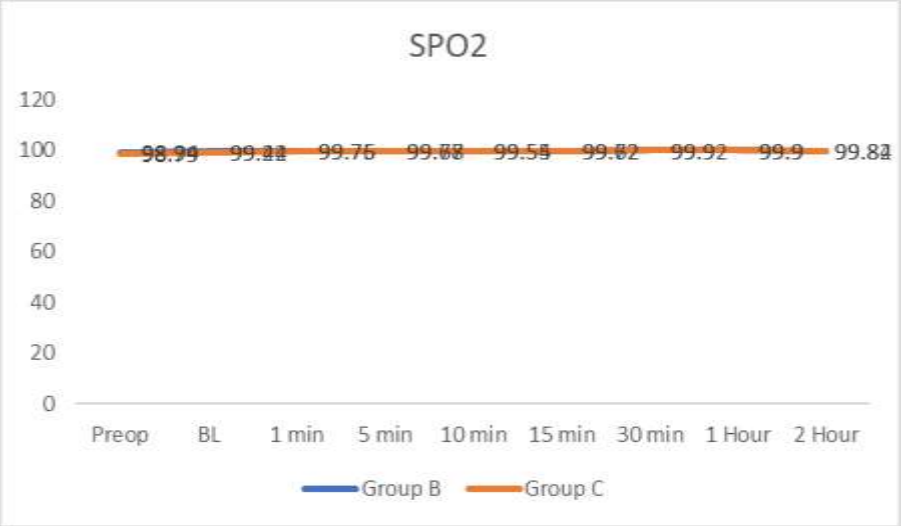


Figure 6: Changes in the oxygen saturation between groups

5. Discussion

The epidural space is formed by loosely bound tissue before the dura, giving little resistance to hydrostatic pressure changes compared to surrounding tissues that are highly resistant to such changes,[13] effectively detecting of the epidural space is challenging. There is a reported 1.5% failure rate due to factors such as a narrowed space with excess fat, undue ossification, and repeated dural puncture.[14] The commonly used technique to identifying the epidural space is loss of resistance. The failure rate of the LOR technique increases due to factors such as patient posture, height, and weight, anaesthetist inexperience, level of planned epidural anaesthesia, and spinal deformities.[15,16]

In our study, the epidural space was identified on the first attempt by 72.6% of the patients in Group B and 43.2% in Group C, which was significant. In the conventional method, 56.9% of the patients required a second or third attempt compared with the balloon technique (27.4%). Nadkarni et al. also showed that 90% of patients identified the epidural space with the epidural balloon group on the first attempt, and 10% required second or third attempts.[13]

Another study done by Fyneface et al. on 50 parturients found that 23 out of 25 women (88%) in the epidural balloon group had successful epidural space localization in the first attempt, compared to 14 out of 25 women (56%) in the LOR-to-air group.[17] However, Singhal et al. reported that the first attempt at epidural space identification with a balloon LOR syringe (88%) was less than that with an LOR saline syringe (96%).The second and third attempts were higher in the Balloon LOR syringe group (12%) than in the LOR saline syringe group (4%), contradicting our results. This may be due to the lack of knowledge regarding the use of epidural balloon syringes. Their study had an inadequate sample size (25 patients in each group), potentially giving an inappropriate result compared with our study.[18]

In our study, the mean time for epidural space identification by the epidural balloon technique (Group B) was 91.97±32.45 secs, and that for the Conventional LOR technique (Group C) 97.56±22.45 secs. Thus, the balloon technique requires less time than conventional methods. Singhal et al.'s study showed the epidural balloon technique (38.40±12.57 secs) was faster than the LOR air syringe (40.52±9.03 secs).[18]

Nadkarni et al. compared the epidural space identification with the saline-filled syringe technique and epidural balloon technique. They found that the time taken by the epidural balloon technique (20.74±18.55 secs) was less compared to the saline-filled LOR syringe technique (43.54±16.81 secs).[13] This could be due to the intermittent checking of the LOR by manually pushing the plunger in the conventional LOR Syringe (group C), whereas in the epidural balloon syringe, once attached to the Touhy needle, the plunger was pushed to inflate the balloon, and an inbuilt mechanism prevented backward movement. This allowed the anaesthetist to use both hands for needle insertion, without interruption.

In these two studies, the time taken to identify the epidural space was approximately 40 s, whereas in our study, it was approximately 90 s. Our procedure was performed by an anaesthesia resident who had already performed 50 epidural procedures, which could explain the increased time for epidural space identification in both groups. Generally, the depth of the epidural space from the skin varies from 4-6 cm in approximately 80% of the population.

In our study, the mean depth at which the epidural space was identified using balloon LOR and conventional LOR technique was 3.69±0.53 cm and 3.65±0.56 cm respectively, which was non-significant. Tactuk et al. found the mean distance to the epidural space to be 5.3±1 cm, which is slightly higher than our results. In his study, he included 100 obstetric patients, and there were no limits on the patient's BMI.[19] However, in our study, we excluded all patients with BMI > 25.

In our study, the balloon epidural syringe group had nine cases (6.2%) with bleeding complications compared to 18 cases (12.3%) in the conventional method group. In the conventional LOR method, multiple needle redirections have a higher incidence of venous puncture, leading to a bloody tap. However, in the Balloon syringe technique, the anaesthetist can hold the syringe with both hands while introducing the needle into the epidural space, thereby providing more control. Similar results are seen in the study by Nadkarni et al., which showed no bleeding complications in the Balloon syringe group, whereas 8% of cases in the LOR saline syringe group had bleeding complications.[13] Singhal et al. also showed no bleeding complication in either the balloon group or the LOR syringe group.[18]

In our study, dural puncture was more frequent in Group C (3.4%) than in Group B (0.7%). Singha et al. also showed similar results: 1.2% of the cases had a dural puncture in the balloon syringe group and 4.9% of the cases in the LOR syringe group.[20]Fyneface et al. concluded that dural puncture complications were less in the balloon group compared to the conventional LOR group.[17] But our results were in contrast to the study done by Singhal et al., who observed one case in the balloon group had a dural puncture, but no case in the LOR conventional syringe had a dural puncture because their sample size was small when compared to our study.[18]

6. Limitations

In our study, we excluded obese patients with BMI > 25, high-risk patients with ASA physical status III and IV, and emergency cases, focusing solely on elective procedures. Patients with known spinal deformities were excluded from this study. Preprocedural ultrasound was not used to measure the depth or interspinous space, which could potentially reduce the number of redirections and time taken to identify the epidural space.

7. Conclusion

We conclude that the epidural balloon syringe significantly reduced the number of attempts to identify the epidural space compared with Conventional LOR syringes. In addition, the time taken to identify the epidural space was reduced using an LOR balloon indicator syringe. The LOR balloon indicator syringe is easy to use and provides an objective method for identifying the epidural space, with fewer complications.

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