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ORIGINAL RESEARCH

Pre-Procedural Ultrasound-Guided Technique Versus Landmark Technique For Localization of Epidural Space in Elective Surgeries: A Randomised Controlled Trial

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Abstract
Aim: To evaluate pre-procedural ultrasound-guided technique versus landmark technique for localization of epidural space in elective surgeries.
Material and methods: The present randomised controlled trial was conducted in the department of anaesthesiology, at tertiary health care centre among patients scheduled for elective surgeries requiring epidural (catheterization) block during February 2021 to February 2022. 124 participants were divided in to two groups by randomization i.e. the study group in which pre procedural Ultrasound guided scan (Group U) was done and the control group (Group C) in which landmark technique was used. Number of attempts taken, procedure time (sec), actual epidural space depth (cm), vitals (Heart rate, Respiratory rate [RR], SpO2, Blood Pressure) and complications like bloody puncture, dural puncture and paraesthesia by yes/no criteria was recorded.
Results: The difference between the two groups in relation to mean hematological parameters was not statistically significant. On an average, group U patients have Ultrasound measured distance (in Cm.) with mean± SD of 3.66± 0.33 and 95% confidence limit (CL)[3.58-3.75] as compared to group C having Actual epidural space depth (in Cm.) with mean± SD of 3.77± 0.39 and 95% CL[3.67-3.87], & the difference in two groups was statistically significant (P value = 0.0011). On an average, group U required less procedure time (in min)[2.75±0.43] as compared to group C[4.69±0.92], & the difference in two groups in terms of procedure time was statistically significant (P=0.0001).
Conclusion: We concluded that USG-guided epidural space localization reduced time taken to insert epidural needle and it also reduced number of attempts for the localization of epidural space.
Keywords: USG, Epidural space, Attempts

Introduction

Epidural administration is an effective and popular treatment for surgical anesthesia, postoperative analgesia, and labor pain relief.[1] The placement of the epidural catheter can be considered one of the most difficult manoeuvres in clinical anaesthesia, this may be due to several factors such as the use of what currently named the “blind approach”, involving the anatomical identification of the optimal intervertebral space and epidural space [2,3]

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Reducing the technical difficulty of neuraxial blockade is desirable because multiple needle insertion attempts may increase the risk of complications, such as postdural puncture headache, paraesthesia, and epidural hematoma.[4,5]
Ultrasound pre-puncture scanning can identify the intervertebral level, and the midline. As a means to improve successful placement, it can also provide information about best angle, direction of approach, and depth to the epidural space.[6-9] Ultrasound procedures have been recently gaining attraction as a modality to guide neuraxial needle insertion. Ultrasound has been used for pre puncture scanning and has been shown to increase the success rate of epidural catheter placement when compared with a conventional loss of resistance (LOR) technique. Ultrasound has also been successfully used as a rescue modality after failure of the conventional LOR technique [10].
Methods should thus be adopted to reduce the technical difficulty, to prevent the procedural complications and patient discomfort. [11] Ultrasound has been used for pre-puncture scanning and has been shown to increase the success rate of epidural catheter placement when compared with a conventional Landmark technique. There are very less studies where Pre-procedural ultrasonography is compared with landmark technique used for facilitating epidural space localization. So we planned a study comparing these two procedures in our population to collect more evidence. The objectives of the study are as follows:

Primary Objectives
To compare the pre procedural ultrasound-guided technique and landmark technique for the localization of epidural space in elective surgeries in terms of
1) Number of attempts taken
2) Procedure time

Secondary Objectives
To compare the pre procedural ultrasound-guided technique and landmark technique for the localization of epidural space in terms of complications such as
1) Dural puncture
2) Bloody puncture and
3) Paresthesia

Material and methods
The present randomised controlled trial was conducted in the department of anaesthesiology, at tertiary health care centre among patients scheduled for elective surgeries requiring epidural (catheterization) block during February 2021 to February 2022. Sample size was determined considering difference in mean number of attempts between two groups as the main outcome measure. Following assumptions are made from the study conducted by **Sahu et al.(2017):**
1) Mean +/-SD in group 1= 1.32+/-0.53
2) Mean +/-SD in group 2=1.11+/-0.39
3) Effect size(mean difference)=0.21
4) alpha error(1 sided)=5%
5) Power (1- β)=80%

On calculation, n was found to be 62. Therefore, total 124 subjects were induced in this study and randomised into two groups.

Inclusion Criteria
1) Participants scheduled for elective surgeries requiring epidural anaesthesia.
2) American society of Anaesthesiologist (ASA) status I, II and III.

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3) Age group between 18 and 70 years of either sexes.
4) Patient willing to participate in study.
5) BMI<30(kg/m2).

Exclusion Criteria

1) Patient having Neurological disorder.
2) Patient with Spine deformity.
3) Pregnant and lactating women.

Method

1. The present study was carried out after the approval of the institutional ethics committee.
2. Written informed consent was obtained from each participant.
3. Detailed medical history was obtained, physical examination will be done, required investigations were obtained and ASA physical status was determined.
4. 124 participants were divided in to two groups by randomization.
5. Participants in the study were randomly assigned to one of two groups the study group in which pre procedural Ultrasound guided scan (Group U) was done and the control group (Group C) in which landmark technique was used.
6. Study group (Group U): In this group pre-procedural Ultrasound scan was used for localization of epidural space.
7. Control group (Group C): In this group landmark technique was used for localization of epidural space.
8. Multipara monitor was used to measure pulse rate, non-invasive blood pressure (Systolic blood pressure, Diastolic Blood Pressure, Mean Blood Pressure), SpO2 and respiratory rate.
9. Pre procedural USG scanning for epidural space localization will be performed using (6-13 Mhz) GE HEALTHCARE USG AND COLOUR DOPPLER (MODEL-LOGIC E) curvilinear transducer.
10. Ultrasound visibility score of nine neuraxial structures (Lamina, LF, interlaminar space, epidural space, posterior dura, intrathecal space, cauda equina, pulsations of cauda equina & anterior dura-posterior longitudinal ligament complex) [0- not visible, 1-hardly visible, 2-well visible, 3-very well visible, maximum score possible=27].

Methods of Measurement

1) Number of attempts taken
2) Procedure time (sec)
3) Actual epidural space depth (cm)
4) Vitals (Heart rate, Respiratory rate [RR], SpO2, Blood Pressure)
5) Complications like bloody puncture, dural puncture and paraesthesia by yes / no criteria.

Ultrasonography Measured Distances

1) Vertical measurement-Skin to ligamentum flavum(cm) with USG probe placed vertically
2) Oblique measurement-Skin to ligamentum flavum(cm) with USG probe placed obliquely

Statistical analysis

The data was collected and statistical analysis was performed on it. Depending on the type of data, various tests of significance such as chi square test, t-test, degree of freedom were used for statistical analysis.

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Results

On an average, group U had patients with age group 21-60 (40.47±8.65) as compared to group C with age group 21-60(38.59± 8.52), and the difference in mean number of age groups in two groups was not statistically significant (P=0.2278). Group U had patients with male female ratio of 48:13 as compared to group C with male female ratio of 44:17, and the difference in two groups on the basis of gender was not statistically significant (P=0.400). Group U having patients with ASA grade I/II of 48/13 as compared to group C having patients with ASA grade I/II of 46/15, but the difference in ASA grading of two groups was not statistically significant (P=0.667).

On an average, the difference in two groups in relation to mean hematological parameters [Hb, P=0.2905; TLC, P=0.4494; platelets, P=0.2873; urea, P=0.6762; sr. creatinine, P=0.5116; sodium, P=0.337; potassium, P=0.1709] was not statistically significant (graph 1).

No. of attempts	**Study Group**		**Control Group**	
	No.	**%**	**No.**	**%**
1	51	83.61	41	67.21
2	8	13.11	17	27.87
3	2	3.28	3	4.92
Total	**61**	**100**	**61**	**100**
Pearson $chi^2(2) = 4.5270$ P value = 0.104. NS				
Mean ± SD	**1.20± 0.48**		**1.38± 0.58**	
Mean diff.	**0.18**			
P value	0.0637, NS			
Table 1: Comparison of number of attempts				

On an average, study group required less attempts (0.18) as compared to control group, but the difference in mean number of attempts in two groups was not statistically significant (P=0.0637).

Procedure Time (min.)	**Study Group**		**Control Group**	
	No.	**%**	**No.**	**%**
2	15	24.59	0	0.00
3	46	75.41	4	6.56
4	0	0.00	26	42.62
5	0	0.00	16	26.23
6	0	0.00	15	24.59
Total	**61**	**100**	**61**	**100**
Pearson $chi^2(4) = 107.2800$ **P value = 0.001 Significant**				
Mean ± SD	2.75 ± 0.43		4.69 ± 0.92	
P value = 0.0001, Significant				
Table 2: Comparison of procedure time				

On an average, group U required less procedure time (in min)[2.75±0.43] as compared to group C[4.69±0.92], & the difference in two groups in terms of procedure time was statistically significant (P=**0.0001**).

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Depth (Cm.)	Study Group		Control Group	
	No.	%	No.	%
3	6	9.84	3	4.92
3.5	21	34.43	16	26.23
4	29	47.54	37	60.66
4.5	5	8.20	5	8.20
Total	**61**	**100**	**61**	**100**
Pearson $chi^2(3) = 2.6454$ P value = 0.450, NS				
Mean ± SD	**3.77± 0.39**		**3.86± 0.34**	
Mean diff.	**0.09**			
P value	0.1799, NS			
Table 3(a): Comparison of actual epidural space depth				

Variable	Mean	SD	95% CI
Ultrasound measured distance (in Cm.)	3.66	0.33	3.58-3.75
Actual epidural space depth (in Cm.)	3.77	0.39	3.67-3.87
P value = 0.0011, Significant			
Table 3(b): Comparison of actual epidural space depth			

On an average, **Actual epidural space depth** in study group was less (0.09) as compared to control group, but the difference in mean **Actual epidural space depth** in two groups was not statistically significant (P=0.1799).

Bloody TAP	Study Group		Control Group	
	No.	%	No.	%
No	61	100.00	61	100.00
Total	**61**	**100**	**61**	**100**
Table 4(a): Comparison of complications				

Paraesthesia	Study Group		Control Group	
	No.	%	No.	%
Yes	2	3.28	4	6.56
No	59	96.72	57	93.44
Total	**61**	**100**	**61**	**100**
Pearson $chi^2(1) = 0.7011$ P value = 0.402				
Table 4(b): Comparison of complications				

On an average, the difference in two groups was not statistically significant in terms of paraesthesia (P=0.402).

Dural Puncture	Study Group		Control Group	
	No.	%	No.	%
No	61	100.00	61	100.00
Total	**61**	**100**	**61**	**100**
Table 4(c): Comparison of complications				

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Discussion

Traditional insertion methods use a landmark technique for selection of the lumbar vertebral interspace and identification of the midline.[12] Although the feasibility of neuraxial ultrasound imaging was first reported several decades ago it was not until the early 2000s that the role of neuraxial ultrasound as we understand it today became established following pioneering work by Grau et al[3] and significant advances in ultrasound technology resulting in greater resolution.[13]

The scope of ultrasound imaging guidance for regional anesthesia is growing rapidly & the data suggest that ultrasound can improve block success rate and decrease complications. Several factors can cause procedural difficulty during spinal or epidural technique including obesity, spinal deformity, and previous spinal surgery. USG can be useful to identify midline, to predict the depth of epidural space and to direct the insertion needle (4).

Ultrasound is a noninvasive, safe, easily accessible and portable machine. It can unblind the spinal structures and give crucial information on the structure of the spine in different planes. Although, detailed training, efficiency and technical difficulty limit its use for neuraxial blockade. Ultrasound has been shown to be more accurate in the identification of intervertebral level than clinical assessment.[11,13] The estimation of epidural depth measured by preprocedural ultrasound scan, also increases safety outcomes by decreasing procedural complication like accidental dural puncture [11]

For neuraxial USG we need of large curvilinear transducers to achieve adequate depth and field of view. The size of these transducers make them cumbersome to use in real-time procedures and is difficult to maintain in one position on the back of a sitting patient. Real-time techniques are possible in a paramedian approach only. [7,5,12].

Grau et al. [3] performed US scans of the lumbar spine and employed three different ultrasonography (US) planes, namely the transverse, median and paramedian longitudinal planes. Their study showed that, because of providing better visibility of the anatomical features and the needle target, the paramedian plane is the optimal plane for US images of the lumbar anatomy. Also, in a recent study, Srinivasan et al. [9] compared the conventional palpation based midline injections versus US-guided paramedian needle insertion. In their study, one hundred patients were consented and were randomized into group C (conventional) and group P (preprocedural ultrasound-guided) with 50 patients in each group. Their results showed that the average number of needle insertion attempts in group P was significantly lower than those of group C. However, landmark identification in paramedian US took a significant amount of time which slowed down the procedure.[9]. Also, for estimating the depth to the epidural space, and the optimal skin puncture site for epidural needle placement tranverse plane was suggested by Balki. M et al [14]. He also stated that incorporating the use of lumbar spine US scaning in day-to-day clinical practice may improve the ease of performing epidurals as well as add to patient safety and comfort.

Hemodynamic parameters like heart rate, respiratory rate, spo2, systolic and diastolic blood pressure were comparable in both the groups.

In 51 patients in group U and 41 patients in group C successful epidural space localization was made in first attempt. However, 8 patients group U and 17 in group c required second attempt. Very less patients, 2 in group U and 3 in group C required third attempt for epidural space localization. In this study, group U required less attempts (0.18) as compared to group C , but the difference in mean number of attempts in two groups was not statistically significant (P=0.0637). Multiple needle attempts were defined as needle insertion attempts exceeding more than two [11].

On an average, group U patients have ultrasound measured distance in range of 3.15- 4.5 (3.66 ± 3.15). In our study, actual epidural space depth in group U was less (0.09) as

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compared to group C, but the difference in mean actual epidural space depth in two groups was not statistically significant (P=0.1799). On an average, group U patients have Ultrasound measured distance (in Cm.) with mean± SD of 3.66± 0.33 and 95% confidence limit (CL)[3.58-3.75] as compared to group C having actual epidural space depth (in Cm.) with mean± SD of 3.77± 0.39 and 95% CL[3.67-3.87], & the difference in two groups was statistically significant **(P value = 0.0011**). In the study proposed by **Sahu D.K. et al .2017[4],** the Pearsons correlation coefficient between the USG-measured distance between skin to LF and the actual epidural depth by needle mark in the USG-guided group was significant. Thus a preview of USG scan can be used to accurately predict the depth of insertion of epidural needle.

Group U required less procedure time (in min)[2.75±0.43] as compared to group C[4.69±0.92], & the difference in two groups in terms of procedure time was statistically significant (P=**0.0001**). Similar findings of mean time taken for localization of epidural space by epidural needle in the USG-guided group was less than landmark-guided group was observed by **Sahu D.K. et al .2017[4] and Grau T. et al [3]**

Only 2 patients in group U as compared to 4 patients in group C complained of paresthesia. The difference in two groups was not statistically significant in terms of paraesthesia (P=0.402) and significant in terms of paraesthesia. It is observed in study proposed by **Jain K. et al. 2019[11]** that the estimation of epidural depth measured by pre-procedural ultrasound scan, also increases safety outcomes by decreasing pre procedural complication like accidental dural puncture.

Pre-procedure ultra-sound gives the anaesthesiologist time to mark the approximate location of the transducer and to become familiar with the procedure, thus saving time in the operating room. Improved precision with Utrasonography may results into higher success rate and can reduce needle- related complications during epidural acesss. Real-time two-dimentional ultrasound can be used for epidural catheter insertion as suggested by Belavy et al [15].

Limitation of the study includes non‑blinding of the subjects and observer as it was infeasible. Other parameters like trajectory of the probe used for guiding trajectory of the needle while insertion, time taken for the duration of the procedure and efficacy of different USG view and CSEA approaches were also not studied. Another limitation of our study was that the angle of insertion of epidural needle was neither determined nor measured. The variable angle of insertion used this study could contribute to the difference between ultrasound-measured depth and the actual epidural space depth measured by the needle. Another limitation of ultasonography guided epidural space localization is that the success may depends on the quality of US images.

There are limited data on comparison between conventional and USG guided localization of epidural space and further research in this area is required.

Conclusions

We concluded that USG-guided epidural space localization reduced time taken to insert epidural needle and it also reduced number of attempts for the localization of epidural space. With the use of USG, the depth of epidural space can be measured more accurately.

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