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Original Research Article

To evaluate and correlate the effectiveness of epidural depth equation versus pre-procedural US guided epidural block: A randomized controlled trial

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ABSTRACT

Background: Ultrasound assisted pre-procedural epidural depth estimation has improved the safety and efficacy of epidural block. Currently, the incorporation of pre-procedural ultrasound guided epidural derived equation(EDE) has significantly improved the accuracy of epidural depth estimation especially in the parturients. However, the accuracy of EDE derived epidural depth alone has not been compared to the actual epidural needle depth in non-obstetric patients.

Aim & Objective: This study compared the efficacy of epidural depth equation (EDE) versus pre-procedural US-guided epidural block in patients scheduled for orthopedic surgeries under the combined spinal epidural block (CSE). The primary outcome was the number of attempts for successful epidural insertion, the secondary outcomes were correlations of EDE-calculated epidural depth with actual needle depth and pre-procedural US-guided epidural depth.

Materials and Methods: One hundred patients, 20-60 years, ASA physical status I and II, body mass index (BMI) 18.5–29.9 $kg.m^{-2}$ were randomized into two groups. In group US (n=50), the pre-procedural US-guided skin to epidural depth was measured and the point of insertion of the epidural needle was marked. Whereas, in group E (n=50), the skin epidural depth was measured using the epidural depth equation (EDE). The epidural block was instituted by the loss of resistance technique in both groups. The primary outcome was the number of attempts for successful epidural insertion, the secondary outcomes were correlations of EDE-calculated epidural depth with actual needle depth and pre-procedural US-guided epidural depth.

Results: The needle passes were 1.10±0.08, and 1.18±0.05 in groups US, E respectively (P=0.251). A significantly strong correlation was observed between epidural depth by US and EDE (r2=0.915, P=0.001). Whereas, a weak correlation was observed in the EDE-measured epidural depth and actual needle depth (r^2=0.402, P =0.04).

Conclusion: Although comparable needle attempts were observed in both groups, the weak correlation of epidural depth by EDE with actual needle depth doesn't support its use alone. The strong correlation of epidural depths by EDE and US encourages EDE assisted with pre-procedural US-guided epidural block.

1. Introduction

Recently, there has been substantial attention to the use of point-of-care ultrasonography for instituting neuraxial anesthesia, and it has been proposed as a preoperative assessment tool for ensuring a successful block.[1–3]

An ultrasound examination before neuraxial blocks (pre-puncture US) has been observed to increase the success rate on the first attempt, reduce the number of attempts, and improve technical and clinical outcomes. Various studies have supported the role of US-guided neuraxial blockade for different patient populations.[4–8] However,

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using ultrasound guidance requires the availability of expensive US machines. Moreover, the successful nerve block under US guidance to a great degree depends upon the sufficient experience of anesthesiologists as well.

Recently, a few studies have observed that the prior use of the epidural depth equation (EDE) for calculating the skin-to-epidural depth helps reduce epidural insertion attempts or passes.[9,10] The epidural depth equation(EDE) was calculated using a preprocedural ultrasound scan of the lumbar spine and the equation was computed to determine the distance from the skin to the epidural space using stepwise multivariate linear regression analysis using height and weight as noteworthy variables. The authors were of the opinion that the prior measurement of the estimated epidural depth using EDE helps in reducing the attempt failure rates and accidental lumbar puncture.[9,10] In a prospective study by Vallejo et al. 370 parturients with body mass index ranging between 38 to 39 kg.m-^{2}requesting labor epidural analgesia were randomized to have their epidural block by first year anaesthesia residents with or without prior ultrasound determination of epidural space depth. The authors observed that the ultrasound group had less epidural catheter replacements ($P < 0.02$), and attempts ($P < 0.01$) as compared to the control group. The epidural depth equation (EDE) was calculated using a preprocedural ultrasound scan of the lumbar spine and the equation was computed to determine the distance from the skin to the epidural space using regression analysis using height and weight as noteworthy variables. The authors were of the opinion that the prior measurement of the estimated epidural depth using EDE helps in reducing the attempt failure rates and accidental lumbar puncture.[9] Whereas in another study the authors enrolled 160 morbidly obese parturients with BMI more than 40 kg.m^{-2} for labor epidural analgesia. The EDE was used in conjunction with US assisted epidural block. Before epidural catheter placement, EDE was used to estimate depth to the epidural space. This estimation was used to visualize and measure the epidural space depth under US guided parasagittal oblique and transverse view. The authors observed that prior use of the EDE along with the longitudinal and transverse US views resulted in strong correlation with the actual epidural needle depth.[10] With this background information, we planned a prospective study to evaluate and compare the use of the epidural depth equation EDE versus US-guided epidural needle evaluation depth in patients scheduled for surgeries under the combined spinal epidural block. This study was also intended to validate the efficacy of epidural depth equation in non parturients and patients having BMI less than 30kg.m^{-2}, as in the previously mentioned study[10] the obese parturients were enrolled.

2. Materials and Methods

After approval by the Institutional Ethics Committee (No. HFW-H DRPGMC /Ethics /2019 /240) and written informed consent, a prospective, randomized study was carried out in 100 patients aged 20–60 years, American Society of Anesthesiologists (ASA) physical status I/II having body mass index (BMI) of 18.5–29.9 kg.m^{-2} and scheduled for orthopedic surgeries under combined spinal epidural (CSE) from the period of October 2020 to November 2021 in a tertiary healthcare institute (Figure 1). The trial was registered with the Clinical Trials Registry-India (CTRI 2020/10/028560). Exclusion criteria were patient refusal for neuraxial anesthesia, previous spinal surgery, anticipated difficult spinal/ epidural block, and coagulopathies. Parturients and patients with a BMI greater than 30 kg.m^{-2} were also excluded from the study. All patients were kept nil per oral for 6 h for solid foods and 2 h for clear liquids. The patients were explained the procedure in detail during the preoperative visit, one day before the surgery. A computer-generated block randomization schedule was used to allocate patients keeping the block size two having two probable sequencies of EU and UE respectively. After shifting the patient to the operating theatre, intravenous access was started with an 18 Gauge cannula, and normal saline (0.9%) was started. After the application of standard monitoring (non-invasive blood pressure, pulse oximetry, and five-lead electrocardiogram), the patients were positioned sitting on the operating table. Group allocation and concealment were done by a closed envelope technique. The envelope was opened by the attending anesthesiologist immediately before performing the procedure. In group E: The pre-procedural epidural depth was measured utilizing the epidural depth equation for patients randomized in this group.

Epidural Depth equation (cm) = 5.63- [0.025xHeight (cm)] + [0.040x weight (kgs)]

In the group E, the preprocedural epidural depth was calculated using the EDE using and noted. After that the epidural block was given by the anesthesiologist using conventional loss of resistance to the saline technique and the actual epidural needle depth was noted on the tuohy needle and recorded.

In group US, under all aseptic conditions with the patients in the sitting position, preprocedural US imaging of the spine was performed using 2–5 MHz curved array (SonoSite® MicroMaxx® US system, SonoSite INC, Bothell, WA) probe covered with a sterile sleeve. Initially, the paramedian sagittal oblique (PSO) view was used to identify specific lumbar interspaces with the procedure starting at the sacrum and moving cephalad to identify the successive laminae (L5, L4 and L3). The L3-4 intervertebral interspace was identified and the US probe was rotated to 90 degrees in the transverse midline plane. The spinous process was identified as a small hyperechoic signal, beneath

the skin. The upper or lower intervertebral spaces were identified in an acoustic window followed by visualization of the ligamentum flavum–dura mater complex posterior complex (PC) and posterior longitudinal ligament-vertebral body termed as anterior complex (AC). Thereafter, the image having PC and the AC as midline structures, producing a hyperechoic "=" sign in the middle of the interspace was obtained. The depth of epidural space was measured by a built-in caliper from the skin to the inner surface of the posterior complex. With the transducer in the same position, the midpoints of the upper and lower horizontal border were marked on the skin with a skin marker. Similarly, the midpoints of both lateral borders of the probe were marked. Thereafter, two lines were drawn joining the respective marks. The needle insertion site was the point of intersection of both lines.

The epidural block was performed maintaining the patient in the same position after antisepsis, placement of sterile surgical fields, and local anesthesia of the skin and deeper planes was achieved with 5 mL of 1% lidocaine. An 18G tuohy needle with markings at 1 cm interval was inserted in the midline through the point and angulation was determined previously. Epidural space localization was done with the conventional loss of resistance (LOR) to the saline method by another anesthesiologist, unaware of the epidural depth measured by the US and epidural depth equation, and needle depth on the Tuohy needle was recorded. The subarachnoid block was given in the same interspace with a 26 G quincke spinal needle.

A subsequent needle attempt was defined as needle insertion proceeded by complete withdrawal of the epidural needle from the patient's skin including a change of spinous interspace. A needle redirection was defined as any change in needle insertion trajectory not involving complete withdrawal of the needle from the patient's skin. The total number of insertion attempts and needle redirections were considered as needle passes. The primary outcome was the number of attempts for successful epidural insertion, the secondary outcomes were correlations of EDE-calculated epidural depth with actual needle depth [ND], and pre-procedural US-guided epidural depth.

The data were entered into the Microsoft® Excel workbook 2019 and exported into software SPSS v21.0 (IBM, USA). The normality of numerical variables was tested using the Shapiro Wilk test. The quantitative variables were expressed as mean ± SD, and compared using Student t-test. Mann-Whitney test was used to compare non-parametric variables and expressed as medians and interquartile ranges (25^{th} - 75^{th} percentile). Categorical variables were expressed as frequency and percentage, and compared using Chi-Square test. Correlations were analyzed using the Pearson correlation coefficient. The P-value was considered to be significant when less than 0.05.

The sample size was calculated based on a pilot study recruiting ten patients with five in each group. The number of needle attempts considered to be the primary outcome were mean±SD (1.14 ±0.08 and 1.18±0.05) in groups US and E respectively. At 0.05 significance and 80% power, the required sample size was 44 per group using OpenEpi, Version 3 calculator. We recruited 50 patients in each group.

3. Results

One hundred and five patients were assessed for eligibility and five patients were excluded from the study (Diagram 1). The one hundred patients in the two groups were comparable in age, BMI, ASA physical status, and gender. The mean age of patients in groups US and E was 53.58±5.54 years and 51.62±5.95 years respectively (P=0.503). The mean BMI of patients in group US and group E was 24.4±3.39 $kg.m^{-2}$ and 23.38±3.48 $kg.m^{-2}$ respectively (P=0.881). With regards to ASA physical status, in groups E and US, there were 30 and 27 patients belonging to ASA-II physical status, whereas 20 and 23 patients belonged to ASA physical status I in groups US and E respectively (P =0.841) (Table 1).

The mean needle attempts were [mean (SD),95%Confidence interval 1.10(0.04),1.089-1.111 and 1.18(0.05), 1.166-1.194] in groups US and E, respectively (P=0.251). The mean number of passes were also comparable in group US 1.15(0.06),1.1333-1.167 and group E 1.19(0.05) 1.176-1.204, (P=0.781). The actual mean ND was [mean(SD)CI 4.29(0.37),4.187-4.393] cm and comparable with the mean ND of [4.19(0.39),4.082-4.298] cm as measured by USG in group US (P=0.146). However, the actual mean ND in group E 4.17(0.34), 4.076-4.264] cm was not comparable to the mean ND measured by EDE [4.73(0.24) (4.663-4.797), P=0.001 [(Table 2), (Figure 1). In this study, a significantly strong correlation was observed between epidural depth measured by the pre-procedural US in the transverse median plane and by the epidural depth equation [(r=0.915), 95%CI =0.789-1.042, P =0.001] (Figure 2). A weak correlation was observed between the pre-procedural needle depth measured by the EDE and the actual needle depth in group E [(r=0.402),CI=0.828-1.057, P=0.04] (Figure 3). A strong correlation [(r=0.925), CI=0.854-0.996,P=0.001] was observed between the pre-procedural depth measured by the US and the actual needle depth in group US. (Figure 4)

4. Discussion

Ultrasound guidance for regional anesthesia has gained popularity as it is easily performed and provides an opportunity to confirm the landmarks and deposit the local anesthetic at the correct place besides associated improved safety and decreased rate of complications.[11–15] A pre-puncture ultrasound scan was found beneficial for

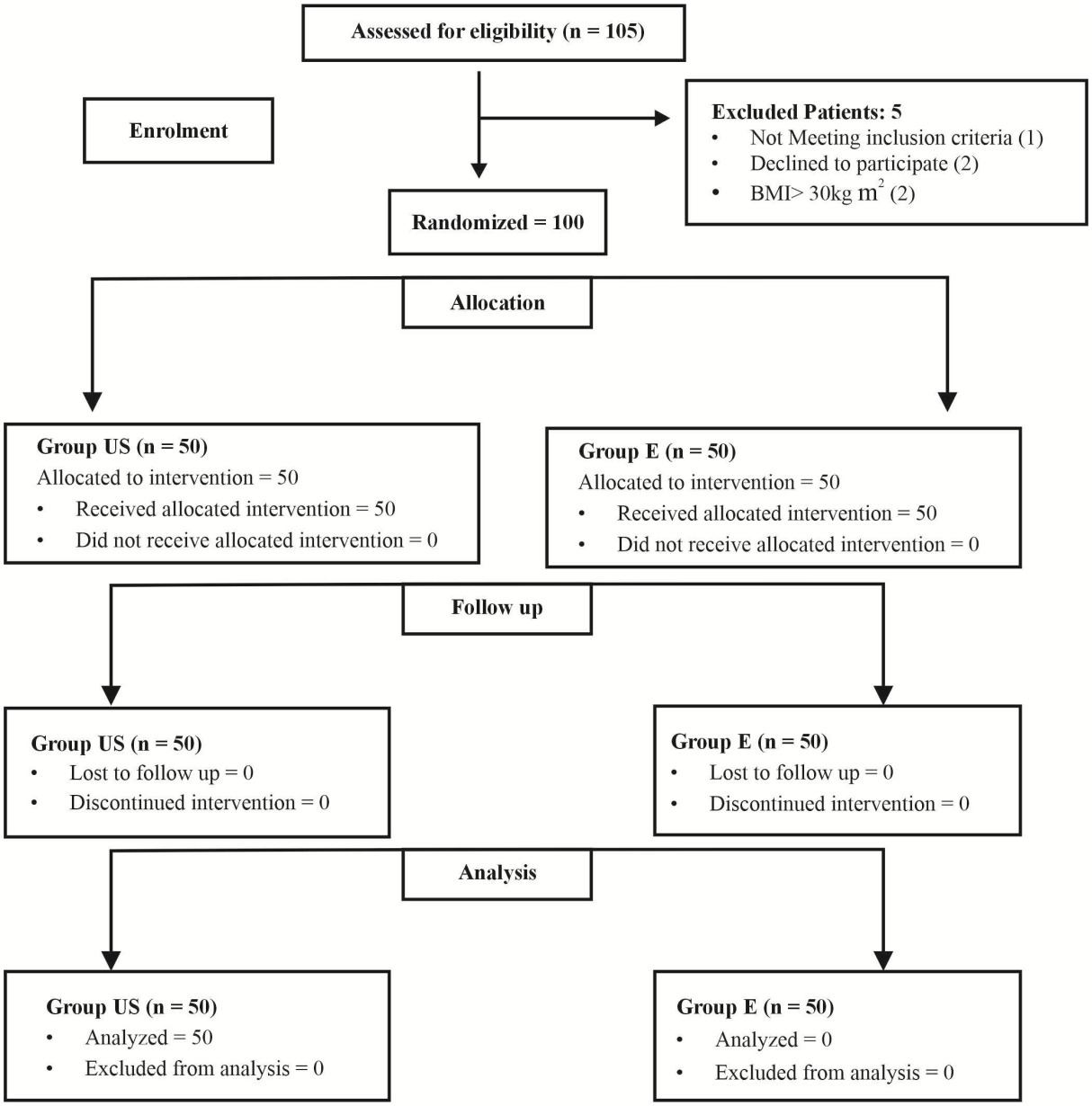

Diagram 1: Consolidated standards of reporting trials (CONSORT) chart of patients

determining the depth of the epidural space from the skin and for identifying the optimal needle insertion site. A good correlation between the skin to the epidural space depth and needle insertion depth was reported in many previous studies.[16] Recently, there has been substantial interest in the usage of ultrasound for refining the technical aspect of neuraxial anesthesia, and pre-procedural US has been encouraged to be used as a pre-operative assessment tool for neuraxial blockade.The pre-procedural US has been perceived to increase the success rate of the first attempt, reduce the attempts, and improve patient satisfaction.[17,18]

In the study, the number of needle redirections with a single skin puncture was considered as the needle passes, whereas the number of needle insertions via different skin pricks was considered needle attempts. In our study, amongst 86% of patients, needle attempts were made only once, while for the remaining 14%, needle attempts were made twice. In the study by Awasthi et al. 87% of patients' needle attempts were made only once, while the remaining 17%, needle attempts were made twice.[19] In another study, real-time ultrasound-guided paramedian epidural access was used via the in-plane technique and the authors achieved 93.3% success on the first attempt.[20] Mean number of attempts were comparable in group US 1.14±0.04 and group E 1.16±0.05 (P=0.781). However, in the study comprising morbidly obese parturients for labor analgesia, the epidural

Table 1: Demographic profile of the patients in the two groups

Parameters	Group US (n=50)	Group E (n=50)	P-value
Age (years) *	53.58±5.54	51.62±5.95	0.503
BMI (kg.m^{-2}) *	24.4±3.39	23.38±3.48	0.881
ASA physical status†			
Grade I	20	23	0.841
Grade II	30	27	
Gender†			
Male	38	35	0.651
Female	12	15	

Data expressed as* mean±SD and †number as appropriate. BMI: Body Mass Index
ASA: American Society of Anaesthesiologist physical status.

Table 2: Summarizing the key outcomes in the two groups

Parameters	Group US (n=50)	Group E (n=50)
Number of attempts [mean±SD]	1.14±0.04	1.18±0.05
Needle passes [mean±SD]	1.15±0.06	1.19±0.05
Pre-procedural measured Epidural depth(cm) [mean±SD]	4.19±0.39	4.73±0.24
Actual Needle depth	4.29±0.37	4.17±0.34

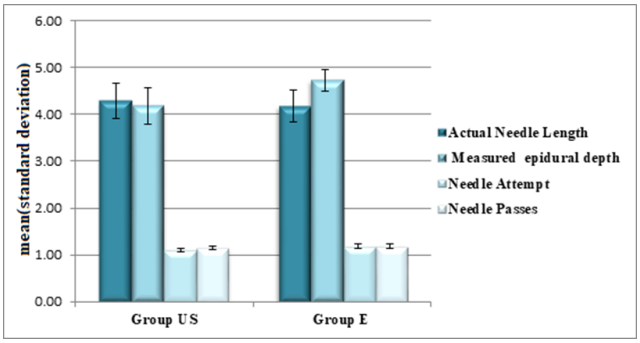

Figure 1: Actual and pre-procedural epidural depths, needle attempts and needle passes in two groups

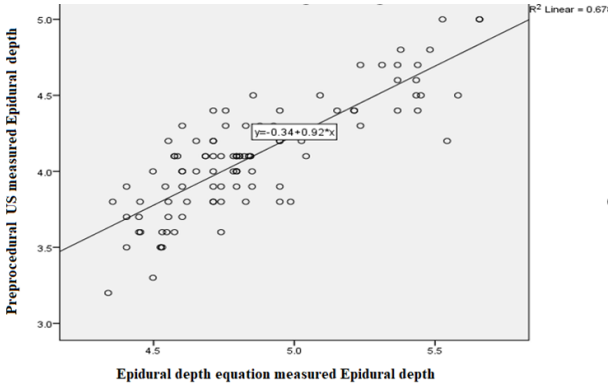

Figure 2: Correlation between pre-procedural US-guided and epidural depth equation measured epidural depth

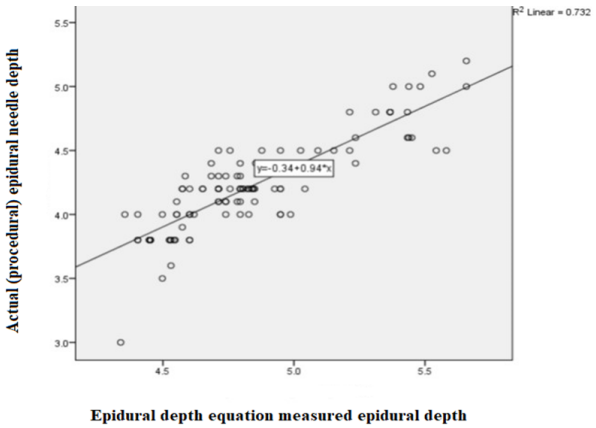

Figure 3: Correlation between actual needle depth and epidural depth equation measured epidural depth

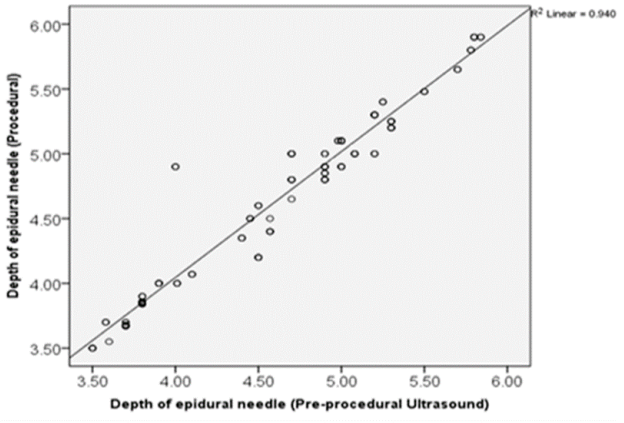

Figure 4: Correlation between actual needle depth and pre-procedural US-guided measured epidural depth

depth was measured by the epidural depth equation (EDE), and a US-guided epidural was placed. The authors observed that the number of epidural attempts were median (IQR): 1(1–2) and without redirection amounting to 86 (54%).[10] The discrepancy could be attributed to two factors in our study, the first being recruitment of non- parturients and patients having body mass index less than 30kg.m^{-2} and secondly in our study the epidural catheter was placed by conventional loss of resistance technique compared to US guided epidural block in the study by Sandeep et al.[10]

In the present study, a significantly strong correlation was observed between epidural depth measured by the pre-procedural US in the transverse median plane and measured by the epidural depth equation (r^2= 0.915, P=0.001). The strong correlation could be attributed to the fact that the EDE has also been computed using pre-procedural US measured epidural depth and deriving the equation utilizing regression analysis. None of the studies

has correlated EDE and US-measured epidural depth. A weak correlation was observed in the pre-procedural needle depth by the epidural depth equation and actual needle depth (r^2=0.442 and P=0.04). Whereas in the study by Singh et al. in morbidly obese parturients, Pearson's correlation coefficients comparing actual (ND) versus US estimated depth to the epidural space and calculated by EDE combined was 0.899 (95% CI: 0.865 to 0.925) in the transverse plane.[10] The contradictory result could be attributed to the fact that in our study after calculating pre-procedural epidural depth with EDE, the patients were given blind conventional epidural block as compared to the study by Singh et al. where pre-procedural US assisted block was given after calculation of probable epidural depth. Secondly the non-obstetric patients having BMI less than 30kgm^{-2} were enrolled in our study.

In this study the EDE and US were applied in the two groups of patients separately, however comparable with relation to age, body mass index and this could be a reason for differing correlation results and can be considered as limitation in the present study. The other limitations of the study are the exclusion of patients with anticipated challenging epidurals, geriatric population and patients with body mass index of more than 30 kg.m^{-2}. Moreover, the US guided epidural depth equation was calculated in the parturients,[9,10] thereby not applicable to the general populations and might have influence the results of the present study.

5. Conclusion

In conclusion, while needle attempts were comparable between groups, the weak correlation between EDE-measured and actual needle depth suggests limitations in EDE's accuracy. However, the strong correlation between EDE and US measurements supports the potential use of EDE in conjunction with pre-procedural US-guided epidural block. This study highlights the importance of calculating the epidural depth using the EDE along with the preprocedural US assisted epidural block to minimize the chances of accidental lumbar puncture. There the study recommends, that in the situations, where the conventional epidural block with loss of resistance to saline technique has to be instituted, the prior calculation of the epidural depth using EDE might of help in reducing the chances of accidental dural puncture and attempt failure. Moreover, forthcoming research studies should emphasis on developing the modified EDE using ultrasound guided epidural measurements especially for non-obstetric patients and having BMI less than 30 kg.m.$^{-2}$

6. Source of Funding

None.

7. Conflict of interest

None.

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