Original Article

Acoustic puncture assist device versus loss of resistance technique for epidural space identification

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ABSTRACT

Background and Aims: The conventional techniques of epidural space (EDS) identification based on loss of resistance (LOR) have a higher chance of complications, patchy analgesia and epidural failure, which can be minimised by objective confirmation of space before catheter placement. Acoustic puncture assist device (APAD) technique objectively confirms EDS, thus enhancing success, with lesser complications. This study was planned with the objective to evaluate the APAD technique and compare it to LOR technique for EDS identification and its correlation with ultrasound guided EDS depth. **Methods:** In this prospective study, the lumbar vertebral spaces were scanned by the ultrasound for measuring depth of the EDS and later correlated with procedural depth measured by either of the technique (APAD or LOR). The data were subjected to descriptive statistics; the concordance correlation coefficient and Bland–Altman analysis with 95% confidence limits. **Results:** Acoustic dip in pitch and descent in pressure tracing on EDS localisation was observed among the patients of APAD group. Analysis of concordance correlation between the ultrasonography (USG) depth and APAD or LOR depth was significant ($r \geq 0.97$ in both groups). Bland–Altman analysis revealed a mean difference of 0.171cm in group APAD and 0.154 cm in group LOR. The 95% limits of agreement for the difference between the two measurements were – 0.569 and 0.226 cm in APAD and – 0.530 to 0.222 cm in LOR group. **Conclusion:** We found APAD to be a precise tool for objective localisation of the EDS, co-relating well with the pre-procedural USG depth of EDS.

Key words: Acoustic puncture assist device, epidural space localization, sonography of epidural space

INTRODUCTION

Loss of resistance (LOR) is the most frequently used technique to identify the epidural space (EDS), and the confirmation of space is perceptible to the hand in use and relatively subjective, which can lead to incorrect placement of epidural catheters, patchy or inadequate analgesia, and epidural failures,[1] along with chances of dural puncture and neurological complications.[2] Objective confirmation of EDS and correct catheter placement is ideal to prevent the grave neurological complications and consistent analgesia but rarely accomplished in routine practice.[3]

Trustworthiness of sonography to reveal the distance and the trajectory of EDS with a preview of the spinal anatomy is well proven in literature,[4-6] thus increasing the success of the procedure. Acoustic puncture assist device (APAD) is a compact device which works on the principle of LOR technique with the integration of audio signals and visual graphics. Lechner, the founder of APAD used it for more than 5000 interventions till 2011, and concluded that the device was reliable, safe and simple to use for objective confirmation of space.[7]

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Not many studies have been reported in literature where APAD has been used for EDS localisation to substantiate the above-mentioned advantages of the device. Hence, we planned our study to evaluate the APAD technique for identification of the EDS and objective confirmation of catheter placement in comparison to LOR technique and its correlation with ultrasonography (USG) depth.

METHODS

After approval from the Institutional Ethics Committee and informed consent from all the participants, this prospective randomised control trial was planned and registered in CTRI (CTRI/2014/09/004963). Allocation size was calculated by taking success rate of conventional LOR to be 98% in the patients; assuming 80% power, with 95% confidence interval (CI) of two techniques and 30% margin of error, the total sample size was estimated at 88 (44 per group), but we took 50 patients per group for covering possible drop-outs. One hundred and seventy-eight patients were screened and after exclusion, 104 oncosurgical patients requiring epidural block for abdominal and lower limb surgery were enrolled in the study from May 2014 to December 2014. Patients were examined pre-operatively and exclusion criteria were local site infection, previous spine surgery and deformity, coagulation disorders, obesity (body mass index ≥30 kg/m^2), neuromuscular disorder, allergy to local anaesthetics, opioids or latex, previous epidural catheter insertion and patients not willing for participation. Enrolled patients in the study were randomised for group allocation according to the computer generated sealed envelope [Figure 1].

Objective confirmation of the EDS with APAD and correct catheter placement was primary objective and correlation of USG depth with procedural depth was secondary objective of the study.

After randomisation and group allocation by primary assessor, anaesthesiologist A (who had performed >200 spine scans) blinded to group allocation, performed spine USG for epidural procedure, sitting and using the portable ultrasound machine (Micromaxx™ Ultrasound system; Sonosite Inc. Bothell, WA, USA, with convex transducer probe of 5–2 MHz) for the two adjacent chosen EDS (L1-2, L2-3 or L3-4) to calculate the distance from skin to ligamentum flavum to determine the EDS depth. The saved scans were inspected by the primary investigator to record the USG depth.

Anaesthesiologist B (anaesthesia experience >8 years), blinded to USG epidural depth, identified EDS with either of the techniques (APAD or LOR) using 16 gauge Tuohy epidural needle. Maximal three attempts were allowed, either redirection in same space or choosing two different spaces for EDS localisation; more than three attempts was considered as failure. Acoustic dip and constant pressure trace in the APAD and loss of resistance in LOR technique were the end points for successful localisation of space.

APAD device connected through the transducer to epidural needle sensor records change in pressure, which reflects as amplified acoustic signal and visual graphics. In group LOR, space localization was accomplished using saline filled LOR syringe. A brief description of APAD unit: One end of the disposable kit of the APAD is connected to 50 ml saline filled syringe (delivers fluid at 50 ml/h. through infusion pump), the other end is connected to epidural needle through the transducer [Figure 2]. The diaphragm senses the pressure changes as the needle is advanced through the ligaments, which are displayed on the monitor as visual graph and as amplified audio signals. Before starting the procedure, proper functioning of the kit is assessed by occluding the needle end of the tubing by the thumb. The pressure rise in the tubing causes a rise in the pitch of acoustic signal; higher the pressure, higher is the pitch tone; release of occlusion is followed by the sudden drop in the tone and of pressure and device is cleared for the procedure.

After patient's positioning, the skin was infiltrated with 2% lignocaine, the epidural needle advanced towards the EDS with both hands while focussing on alterations in sound and the tactile sensation of resistance to the needle. The gradual rise in pressure and pitch tone, maximal at ligamentum flavum, is followed by sudden drop in pressure and the pitch tone once the needle pierces the ligamentum flavum and at this point, further needle insertion is stopped and the actual pressure level is checked on the monitor [Figure 3]. A constant pressure level displayed on the APAD monitor screen confirms the EDS. After detaching the pressure tubing, catheter was threaded up-to 4 cm into the EDS, again the pressure tubing was reconnected to the catheter for objective confirmation of correct catheter placement (display of constant pressure tracing). The device records the graph of the pressure change on the monitor and stores the data on the secure digital (SD) card, later used for data collection by the primary investigator.

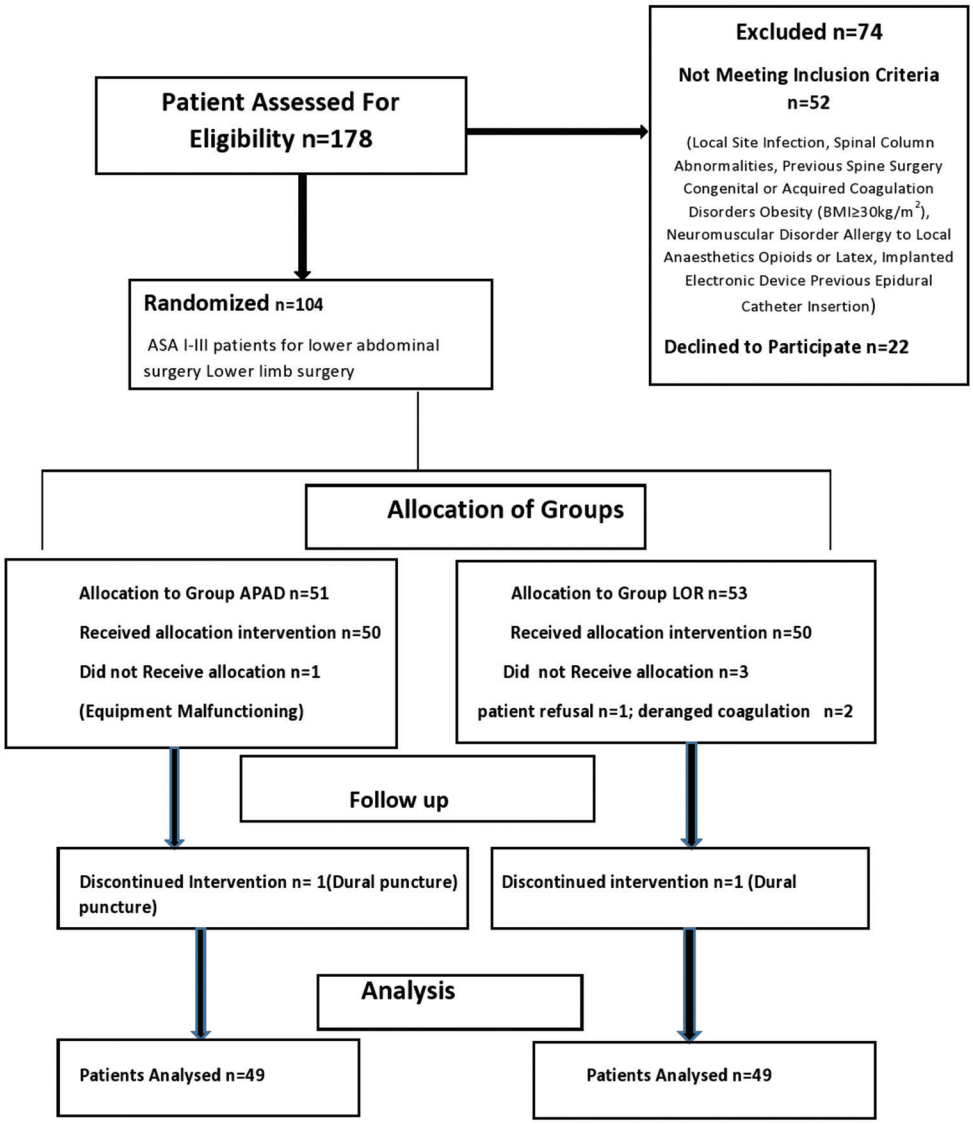

Figure 1: CONSORT flow diagram of the study

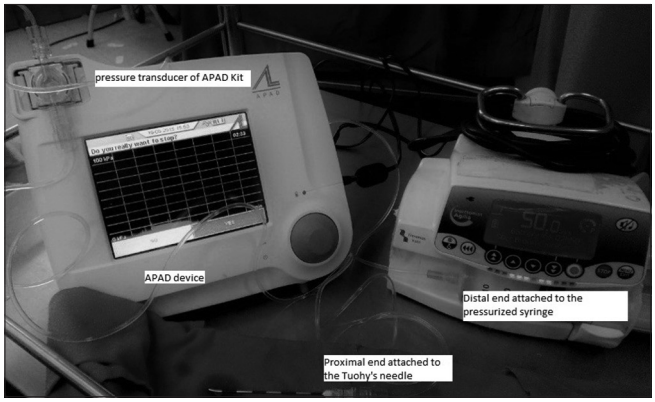

Figure 2: Acoustic puncture assist device (Medky equipment's Schansestraat, The Netherlands) with the assembly

Depth of the EDS from skin, number of attempts, repositioning of needle, change of space, time taken for space localisation (time in seconds taken from skin puncture with epidural needle until the successful space localisation within three attempts), ease of catheter insertion, give way feel, paraesthesia after test dose complications (dural puncture, blood in catheter and root irritation) were recorded. After the EDS localisation, patients were asked for the discomfort during the procedure as rated by visual analogue scale (VAS) score 0–10 in number (<3 mild discomfort, 4–6 moderate and 7–10 severe discomfort), explained earlier in the PAC.

In both the groups, two test doses of 2% lignocaine with adrenaline in boluses of 3 ml each at the interval of 5 min was administered. Five minute after the test dose, paraesthesia related to two higher dermatomal levels was considered as successful catheter placement.

Statistical analysis was performed by the SPSS programme for windows, version 17.0 (SPSS, Chicago, Illinois, USA). Continuous variables are presented as mean ± SD, median (interquartile range [IQR]) and categorical variables are presented as absolute numbers and percentage. Normally distributed continuous variables were compared using the unpaired *t* test, whereas the Mann–Whitney U-test was used for those variables that were not normally distributed. Categorical variables were analysed using either the Chi-square test or Fisher's exact test. A Bland–Altman plot was performed to assess for any potential bias by comparing the USG and procedure depth in individual techniques. The strength of relationship was performed using Pearson correlation. The value of $P < 0.05$ was taken as significant.

RESULTS

Of 104 patients enrolled in the study, data of 100 patients were analysed with the data of 4 not considered arising out of technical mistakes. The mean age, sex, weight, height and type of surgeries of the patients were comparable in both groups [Table 1]. The primary objective of EDS localisation based on the acoustic dip in pitch and constant pressure trace [Figure 3] was observed among all patients except one in group APAD, whereas the LOR was elucidated in all patients of LOR group. The first attempt success rate for space localisation was higher in Group APAD as compared to LOR (84% vs. 80%) but was comparable ($P = 0.461$) [Table 2].

Mean time for EDS localisation was significantly lesser in group APAD than in group LOR (26.54 ± 24.07 s vs. 54.18 ± 28.97 s), $P < 0.001$ and median (IQR) time was 19 s (15–25 s) in APAD group and 48 s (36.75–58) in LOR group [Table 2].

In both groups, paraesthesia (after test dose of the drug through catheter) was elicited in almost all patients. In APAD group, all but 1 patient (dural puncture) confirmed paraesthesia; in LOR Group, 2 patients (cerebrospinal fluid was aspirated in one patient while no specific reason could be found in another, later analgesia was found) did not reveal paraesthesia.

Feel of piercing ligamentum flavum was more in LOR group ($P < 0.001$) as compared to APAD group [Table 2]. Patients in group APAD were statistically more comfortable during the procedure ($P < 0.001$); post procedure mean VAS score for discomfort was 1.92 ± 1.12 vs. 3.26 ± 1.32 for LOR group [Table 2].

Table 1: Demographic parameters and types of surgeries between both the groups

Parameters	Mean±SD		*P* value
	APAD	LOR	
Age (years)	51.60±12.14	48.52±13.70	0.237
Sex (male/female)	24/27	29/24	0.266
Weight (kg)	63.00±11.26	63.16±10.76	0.942
Height (cm)	160.96±8.53	162.76±7.80	0.274
Lower abdominal surgeries	47	45	0.137
Lower limb surgeries	3	5	

APAD – Acoustic puncture assist device; LOR – Loss of resistance; SD – Standard deviation

Table 2: Procedure related information in the groups

Procedural information	APAD	LOR	*P* value
Time to locate space (seconds)			
Median (IQR)	19 (15-25)	48 (36.75-58.0)	<0.001
Attempts			
Mean±SD	1.26±0.66	1.24±0.52	0.867
Repositioning			
Mean±SD	1.50±0.53	1.40±0.70	0.743
Space change			
Mean±SD	1.33±0.58	0±0	
Feel of ligamentum flavum (number/frequency)	18/36%	39/78%	<0.001
VAS score			
Mean±SD	1.92±1.12	3.26±1.32	<0.001

LOR – Loss of resistance; APAD – Acoustic puncture assist device

The USG depth and procedural depth showed a close correlation in both the groups. There was statistically insignificant difference found in between the groups for USG depth (4.15 ± 0.76 cm in APAD vs. 4.26 ± 0.80 cm in LOR) ($P = 0.799$) and procedural depth (4.11 ± 0.73 cm in APAD vs. 4.30 ± 0.82 cm in LOR) ($P = 0.796$). The mean USG and procedural epidural depth were found to be 4.15 ± 0.76 cm and 4.30 ± 0.82 cm in APAD group while it was 4.11 ± 0.73 cm and 4.26 ± 0.80 cm in LOR group. Procedure depth in group APAD correlated closely with USG depth (correlation coefficient $r = 0.970$, $P < 0.0001$). Similar results were observed in group LOR, which also exhibited close correlation (correlation coefficient $r = 0.972$, $P < 0.0001$) [Figure 4].

To rule out the possible bias, Bland–Altman plot was designed for assessing the average and difference of the procedural depth and the USG depth. A bias of 0.171 cm and 0.154 cm (mean difference of procedure depth US depth) was observed between the group APAD and LOR [Figure 5]. Precision was

defined as 95% CI for the difference between USG and procedure depth measurements. The 95% limits of agreement for the difference between the two measurements were −0.5696 and 0.226 cm in APAD group and −0.530 to 0.222 cm in LOR group.

Dural puncture was observed in one patient in each group, blood in catheter was observed in 5 (10%) patients in APAD group and 8 (16%) patients in LOR group, nerve root irritation was observed in 4 patients in APAD group and 10 patients in LOR group.

DISCUSSION

Objective confirmation of EDS and correct catheter placement was effectively accomplished in APAD group utilising acoustic dip in pitch tone along with visual graph sketching showing constant pressure trace. Our study showed successful EDS localisation by APAD device (49/50 patients), in concordance to Lechner *et al*. (100% success).[8] Objective confirmation of EDS in APAD is due to the integration of basic principle of LOR technique with audio visual aids. The pressure changes were sensed and recorded through the transducer, which were displayed graphically and perceived as augmented audible signals (using synthesisers). Depending on the pressure changes as needle progresses in-between tissue, pitch tone variations helps in better needle handling (the needle is holed and advanced swiftly with both hands, guided by changes in acoustic signals) and thus the success of the procedure.

Figure 3: Graphical representation of pressure trace displayed on the monitor screen of the device. Left horizontal arrow showing dip of pressure trace on voluntary release of occlusion (pre-procedural instrument checking) and right horizontal arrow showed sudden fall in pressure trace on localisation of the space sooner the needle pierces ligamentum flavum, while vertical arrow shows gradual rise of pressure as the needle crossing the ligaments

In LOR group, EDS was elicited subjectively by the LOR with saline; saline being incompressible, the transition from complete resistance to LOR is immediate and convincing.[9] Subjective confirmation of space using tactile sensation by LOR is the most preferred technique used by anaesthesiologists as compared to objective confirmation of space (APAD), probably because of learning, familiarity and confidence related to LOR technique.[10]

The first attempt success rate for EDS localisation was marginally higher in Group APAD, though not statistically significant, and concurs with observations of previous studies.[8,11,12]

Need for redirection of needle between both groups was comparable in either of the technique. In APAD group redirection of needle in our patients were comparable to that of Lechner *et al*.,[8] whereas in LOR group, it was lesser (20%) as compared to other studies (33% -Balki[4] and 26%- Arzola[6]). This discrepancy in results of

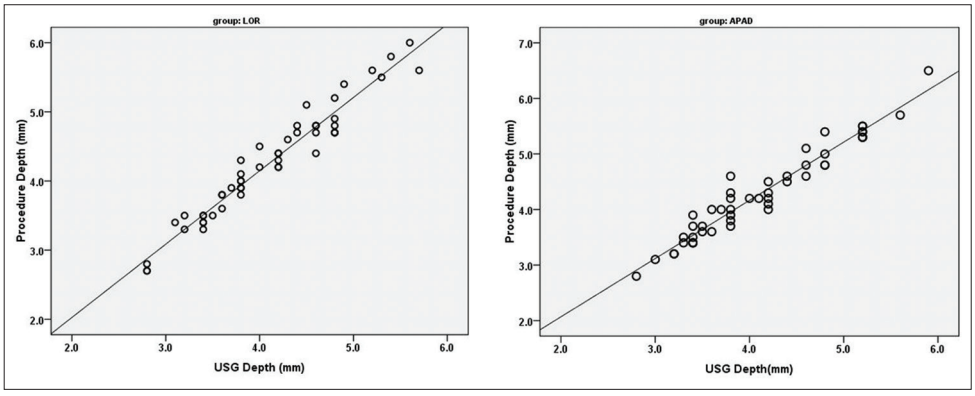

Figure 4: Linear correlation aggregation analysis graph showing the correlation of pre-procedural epidural space depth (calculated by ultrasound scanning of the spine) and the depth measured after the procedure between the acoustic puncture assist device and loss of resistance group. In right graph, acoustic puncture assist device group ($r = 0.9720$, $P < 0.001$) showing close correlation between ultrasonography epidural depth and procedural depth, similar results were found in left graph of loss of resistance group ($r = 0.970$, $P < 0.001$)

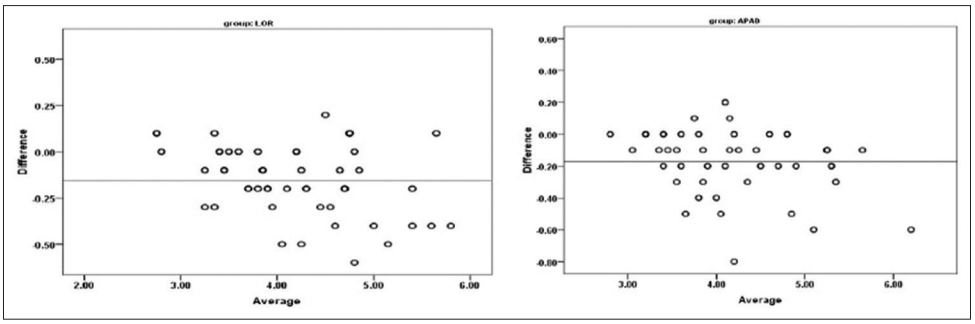

Figure 5: The Bland–Altman analysis plot showing the difference between the procedural depth and the ultrasound estimated depth along Y-axis which is plotted against the average depth on X-axis. The solid lines represent the mean difference of 0.154 cm in loss of resistance group (left) and 0.171cm in acoustic puncture assist device group (right), 95% confidence interval varies from – 0.5301 to 0.2221 cm in loss of resistance group and – 0.5694 to 0.2266 cm in acoustic puncture assist device group

standard LOR technique might be due to the fewer lordotic patients in our study, as compared to full term obese and lordotic pregnant patients in their study.

The continuous and fast progression of needle in APAD, as compared to intermittent advancement of needle in LOR group could be the possible explanation for lesser time to localize space in APAD as equated to LOR group.[7] Fast and uninterrupted movement of needle in APAD technique is due to the fact that the needle advancement is guided by the change in pitch tone. The integration of senses always augment the performance, and the sense of hearing is always better suited to detect small changes, especially with the electronically processed and heightened acoustical signal.[13]

Due to the continuous and fast movement of needle in the APAD, feeling of give way was felt significantly less in APAD group. Slow advancement of needle in the LOR technique is due to intermittent and interjected movement, with the aim of acquiring the tactile sensation of give way for space localisation, which was accomplished in all cases.

The lesser tissue handling and reduced positioning time with continuous and steady movement of needle, also explain significantly lower patient's discomfort during procedure as per VAS score, in APAD group as compared to LOR group.

Correlation of USG depth with procedural depth in our study were in concordance with other studies.[4,6] These results authenticate precise correlation of procedure depth to USG depth in both groups. Not only the correlation, the possible bias (<2 mm) of USG depth and the procedure depth measurement were almost in close approximation in-between the groups. The close correlation of USG depth with procedural depth in both groups was also similar to those observed in other studies[4,6] and such close association enhances the safety and swiftness of the procedure.

We encountered a single dural puncture in group APAD due to equipment malfunction (as no dip in pitch was audible while localising the space); transducer membrane error could be the possible explanation. Minor complications (venous puncture, nerve root irritation) were similar to that described in literature for either of the group without any statically significant difference.[14,15]

Limitations of this study were the objective confirmation of space and catheter placement adopted in the APAD group as compared to subjective confirmation in LOR group. Although equipment has the advantage of audio visual display but assembling the APAD apparatus is time consuming and cumbersome; besides additional cost of device and disposable components is another restraint of the technique. Moreover, anaesthesiologist has to get accustomed to use of APAD technique.

CONCLUSION

Precise correlation of procedural EDS depth with the USG depth and sensing pressure changes with integrated audio visual aids in APAD provides prompt and swift handling of epidural needle during the procedure and also offers an objective endpoint for identification of the space and correct catheter placement. Digital documentation of procedure is unique feature of the device that may aid in medico legal situations.

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Conflicts of interest
There are no conflicts of interest.

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