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ULTRASOUND GUIDED LUMBAR PUNCTURE IN CHILDREN – A RANDOMIZED CONTROLLED STUDY

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Abstract

Aim: Lumbar puncture (LP) is one of the most common procedures performed in Pediatric department. First-attempt success rates remain low with frequent traumatic LP. The objective of the study was to evaluate whether the use of ultrasound imaging improves the effectiveness of lumbar puncture (LP) procedures in Pediatric medicine and to examine any potential complications compared to the traditional palpation method. **Material & Methods:** A Randomized controlled study was conducted in a tertiary care center. Eligible participants were children younger than 14 years of age, requiring LP as a part of the clinical workup and were randomized to either the standard landmark-based LP (SLP) or ultrasound-assisted LP (UALP) groups. The primary outcome was the first-attempt LP success rate. **Results:** 66 children were enrolled, with 34 in the UALP and 32 in the SLP group. Our primary outcome, the proportion of successful first-attempt LP success was higher in the ultrasound group (64.7%) than for the standard procedure (56.2%). However, this failed to reach statistical significance (p=0.97). The Total Time for Lumbar puncture was 6.38±1.93 min in control group and 3.59±1.04 min in experimental group. The difference was found statistically significant (p value <0.001) as was change of provider in UALP (p value 0.02) **Conclusion:** The study found no statistically significant difference in carrying out successful LP in first attempt. However, Ultrasound-assisted LP reduced traumatic taps and the number of puncture attempts in the pediatric age group but it was also statistically not significant in our study. Time for LP as well as change of provider was significantly less in experimental group. Studies with larger populations and different methodologies like real time ultrasound while doing Lumbar puncture are required on this subject.

Keywords: Ultrasonography, Pediatric, Lumbar puncture, Meningitis.

INTRODUCTION

Lumbar puncture (LP), also known as spinal tap, is a commonly performed procedure that involves obtaining and sampling cerebrospinal fluid from the spinal cord. It is a diagnostic procedure that aids in diagnosing meningitis, subarachnoid hemorrhage, and certain neurological disorders. It is also used in the measurement of intracranial pressure and

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administration of medications or diagnostic agents (1-2).

The palpation method of performing a lumbar puncture involves positioning the patient, identifying the L4/L5 intervertebral space, and advancing a spinal needle into subarachnoid space until cerebrospinal fluid is obtained. Using this technique, new operators were unsuccessful in over 60% of LPs and 37% experienced providers failed to obtain clear fluid on the first attempt (3-5). There are several potential adverse effects from each unsuccessful LP attempt like prolonged pain, extended restraint, and the potential of traumatic LPs. Traumatic LPs are difficult to interpret, resulting in diagnostic uncertainty, extended hospital stays and the possibility of iatrogenic complications. Reduction of unsuccessful and traumatic LPs in infants can improve diagnostic ability and reduce patient harm (6-11). Ultrasonography is being used increasingly in Paediatric emergency care. It emits no radiation, is inexpensive, and requires little training to perform. It is hypothesized that using ultrasound to identify the optimal intervertebral space and puncture point will improve lumbar puncture success rates (3).

Point-of-care ultrasound is increasingly being utilized to assist in performing procedures at the patient's bedside. While many clinicians can successfully perform lumbar punctures (LP) by relying on anatomical landmarks, there is growing evidence supporting the use of ultrasound guidance, especially in obese patients where landmarks may be less palpable (12). The primary advantage of using ultrasound to locate the puncture site is the ability to easily identify traditional anatomical landmarks. It has been found that relying solely on the anatomical assessment of the intervertebral space level for a lumbar puncture can be misleading in over 36% of cases (13). By utilizing ultrasonography for anatomical localization, the rates of failure and complications associated with lumbar puncture can be reduced. Additionally, ultrasound can provide valuable anatomical information, such as the depth of the ligamentum flavum and the width of the interspinous spaces, which can aid in guiding the lumbar puncture procedure (13-14).

The objective of this study was to evaluate whether the use of ultrasound imaging improves the effectiveness of lumbar puncture (LP) procedures in Paediatric medicine and to examine any potential complications compared to the traditional palpation method. Ultrasound can enhance the success rate of LPs and reduce the occurrence of traumatic procedures by allowing visualization of the termination of the conus, which ranges from the T12 to L4 interspace in infants (14).

MATERIALS AND METHODS

Study Design

Randomized Controlled Study

- Experimental group (UALP): Bedside ultrasonography to identify and mark the terminal end of conus medullaris and the most appropriate intervertebral space.
- Control (SLP): Standard Landmark Palpatory Method

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Primary Outcome

Our primary outcome was successful LP, defined as obtaining a sample of clear CSF on the first attempt.

Inclusion Criteria: Children less than 14 years of age with a clinical indication for a lumbar puncture

Exclusion Criteria

- Known spinal cord abnormality e.g., tethered cord, spina bifida.
- Presence of skin and soft tissue infection at insertion site
- Signs of raised intracranial pressure
- Recent failed LP, traumatic LP attempts within the preceding 48 hours
- Recent diagnosis of intraventricular haemorrhage, within the preceding 7 days
- Clinically unstable patient, as determined by the clinical team

Ethical Clearance

Ethical clearance was obtained from Institutional ethical committee. Informed consent was obtained from the parents of all the children enrolled in the study.

METHODOLOGY

It was a randomized controlled study conducted on infants and children undergoing LP as part of their standard clinical workup. After obtaining consent from the parent or legal guardian, patients were enrolled into either the Ultrasound assisted LP group (UALP) or the Standard Landmark Palpation group (SLP). Simple randomization was done by a software Sealedenevelop.com. Randomization sequence was prepared from a computer-generated sequence.

For patients who were randomized to standard landmark palpatory group, no other intervention was done and lumbar puncture was performed by standard landmark palpatory approach.

The focus of the study was on ultrasound-assisted lumbar puncture (UALP); a Fujifilm Sonosite M-Turbo ultrasound machine was utilized for bedside ultrasonography. The procedure was performed by a Paediatric resident who received specific training in using a Linear 5-13MHz probe for lumbar punctures under the guidance of an interventional radiologist.

The time taken for the LP procedure was defined as the period "beginning when the needle pierces the skin until either the collection of cerebrospinal fluid is completed or the procedure is halted (including instances of changing providers, repeating ultrasound, or discontinuing the procedure entirely)." If the needle was adjusted within the skin without being withdrawn, it was not considered a new attempt.

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For the experimental group, the Ultrasound duration was also measured and defined as the time from the initial placement of the ultrasound probe until the final marking on the skin. A research assistant at the bedside timed both procedures using their personal stopwatch or smartphone timer.

The patient was positioned either in a sitting or lateral decubitus (side-lying) posture, and the healthcare provider used the palpation method to locate the interspace between vertebrae L3-L4 or L4-L5. Using a linear probe, the conus medullaris (lower end of the spinal cord) was identified, and a sterile pen was used to mark a horizontal line on the patient's back at this level. By using a transverse view, the healthcare provider located the midline of the patient's spine and made two vertical markings on either side of the probe (Fig. 1a, b).

The probe was then positioned longitudinally to identify the adjacent spinous processes, and two horizontal markings were made on either side of the probe (Fig. 2 a, b). Finally, the four lines were connected at a point where they intersected, which indicated the predetermined site for attempting the lumbar puncture (LP).

Statistical analysis was performed by the SPSS program for Windows, version 23.0. Continuous variables were presented as mean & SD, categorical variables were presented as absolute numbers and percentages. Data was checked for normality before statistical analysis. Normally distributed continuous variables were compared using the unpaired t test, whereas the Mann-Whitney U test were used for those variables that were not normally distributed. Categorical variables were analysed using either the chi square test or Fisher's exact test. $P<0.05$ was considered statistically significant.

Sample Size

Our estimated sample size was based on efficacy in terms of success rate of pre procedure ultrasound in lumbar puncture in two groups & was based on a relevant clinical difference of 30% in success rate between two groups. (3) Thus, sample size of 33 patients per group provided an 80% power for detecting a significant difference between two groups at an alpha level of 0.05 one sided.

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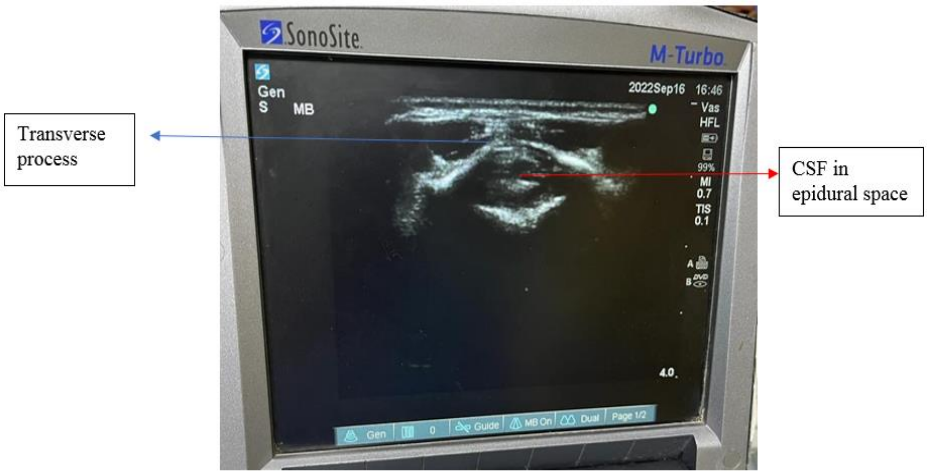
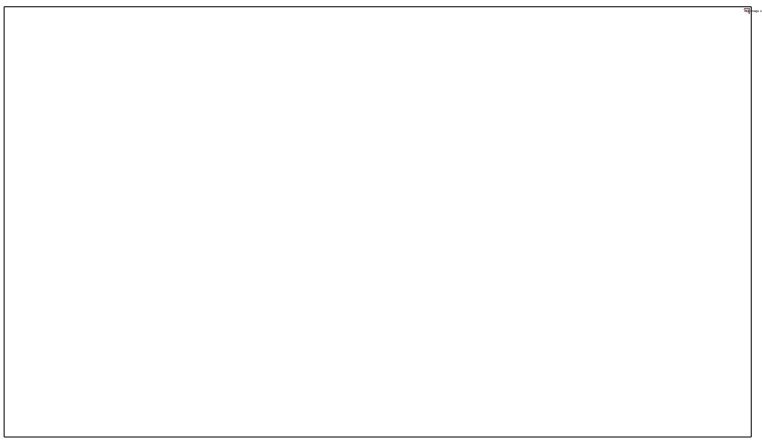
(a)



(b)

Figure 1: (a) (b): Transverse View with Spinous Process Midline and Transverse Processes Lateral



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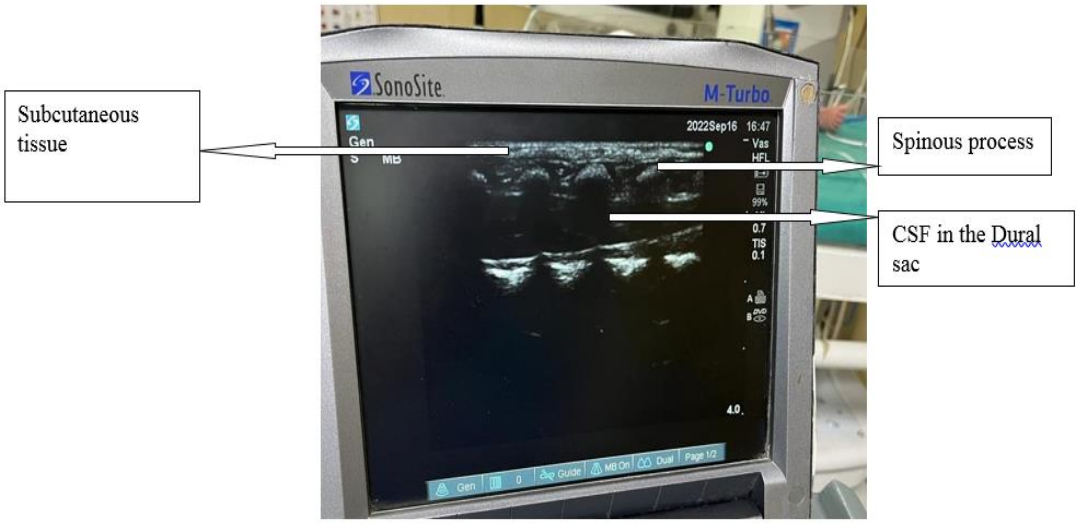

(b)

Figure 2: (a) (b): Longitudinal View to Identify Vertebral Interspace and Conus medullaris

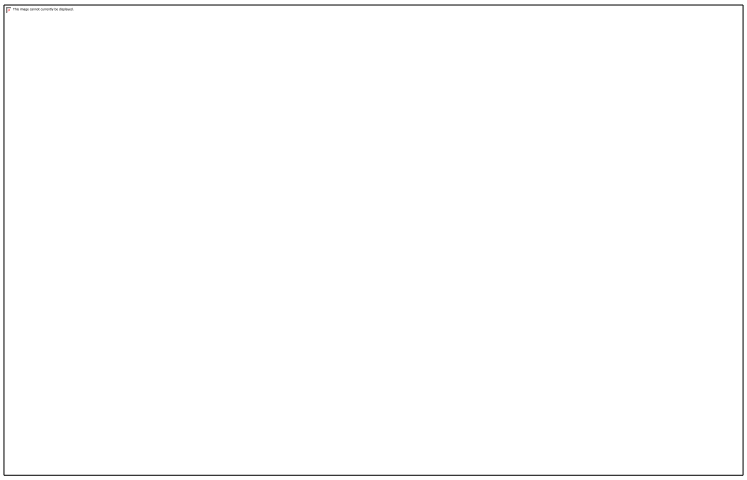

Figure 3: Showing Lumbar Puncture Site with a Cross Marking and CSF Collection

RESULTS

During the study period, a total of 80 children were found eligible to participate. Out of which 66 parents gave consent and then randomized in the UALP group and palpation group. The main reason for not participating was parental anxiety related to the child's work-up. All participants were included in the primary analysis.

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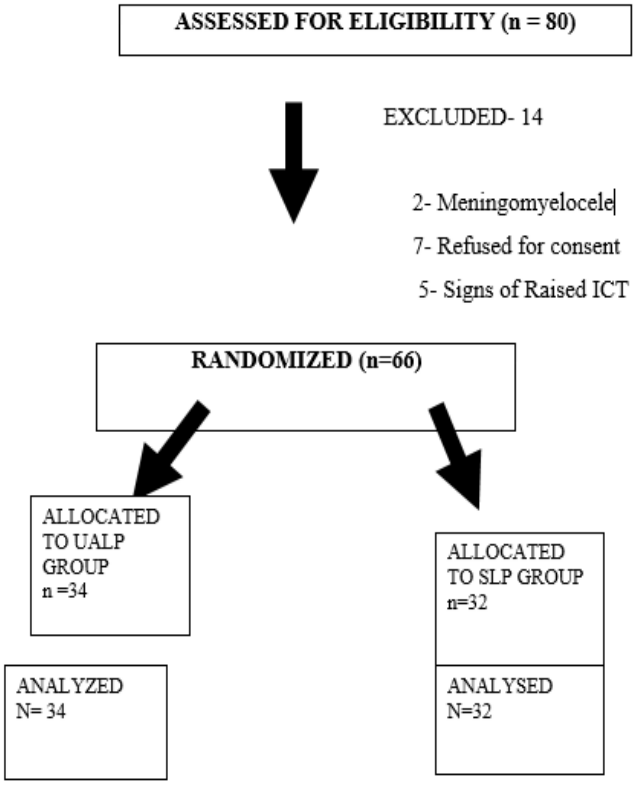

Figure 4: Study Flow Diagram

The baseline characteristics of the children and procedure were similar for both groups (Table no.1). The age wise distribution of study participants showed that majority of them was in the age group of less than 1 month and 7-14 years with median age of study population being around 3 years and there was predominance of males (53%) in our study. In our study, the main indication for performing LP was meningitis (41.2 %) in UALP group and (34.4 %) in SLP group followed by late onset neonatal sepsis 17.6% in UALP group while 18.8 % in SLP group. 12 patients had acute encephalitis syndrome in which 6 patients were in the UALP group and 6 in SLP group (17.6 % in UALP group and 18.8 % in SLP group.) out of which 2 were found to have positive CSF serology for Japanese encephalitis. (Table no.2)

Our primary outcome, the proportion of successful first-attempt LP success was higher in the ultrasound group (64.7%) than for the standard procedure (56.2%). However, this failed to reach statistical significance (p=0.97). The ultrasound group had a higher success rate of 82.4% (28 out of 34 attempts) compared to the standard procedure group, which had a success rate of 71.9% (23 out of 32 attempts). However, the difference between the two groups was not statistically significant. The overall failed attempt due to traumatic lumbar puncture was 6 (11%) of patients in the ultrasound group vs. 9 (8%) of patients in the standard procedure. Total time of procedure was 6.38±1.93 min in control group and 9.38±1.97 min in experimental group. Total Time for Lumbar puncture was 6.38±1.93 min in control group and 3.59±1.04 min

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in experimental group. The difference was found statistically significant (p value <0.001). In standard palpatory group, the provider was changed in 9 (28.1%) while in the ultrasound assisted group, the provider was changed in 2 (5.9%) patients. The difference was also statistically significant. (Table No.3). The provider was only changed when there was inability to have access to CSF or traumatic LP. Midazolam sedation was not given in 29.4 % of children in ultrasound assisted group and 28.1%in control group.

Most of the lumbar puncture attempts including both experimental and control group were done at the level of L3-L4(58.8% in UALP Group and 56.3 % in SLP Group). The most common side effect after lumbar puncture was headache (20.6 %) in ultrasound assisted group and (9.4 5%) in standard palpatory group.

Table 1: Socio Demographic Profile of Cases and Controls

	EXPERIMENTAL GROUP (N=34)	CONTROL GROUP (N=32)
Median Age in Years	3	3
Sex; Male (%)	18 (52.9 %)	17 (53.1%)
Need of Midazolam Sedation	24 (70.6 %)	23 (71.9 %)
Side Effects of Procedure- Headache	7 (20.6 %)	3 (9.4 %)

Table 2: Indications for Performing Lumbar Puncture

Indication of LP	Experimental group (n=34)		Control group (n=32)	
	No.	%	No.	%
Acute Encephalitis Syndrome (AES)	6	17.6	6	18.8
Early Onset Neonatal Sepsis (EONS) With Seizure	2	5.9	3	9.4
Late Onset Neonatal Sepsis (LONS)	6	17.6	6	18.8
Prolonged Fever	1	2.9	0	0.0
Congenital Syphilis	1	2.9	0	0.0
Meningitis	14	41.2	11	34.4
Neonatal Seizure	0	0.0	1	3.1
Potts Spine/ Tb Meningitis	1	2.9	0	0.0
Seizure under evaluation	2	5.9	4	12.5
Sepsis with Seizure	1	2.9	1	3.1

Table 3: Primary and Secondary Outcome of the Study

OUTCOMES	EXPERIMENTAL GROUP N=34	CONTROL GROUP N=32	P VALUE
Primary Outcome First-Attempt Success (%)	22 (64.7%)	18 (56.2%)	0.97
Overall, Success (%)	28 (82.4 %)	23 (71.9 %)	0.31
Failed LP (First-Attempt) (%)	2 (5.9%	2 (6.2%)	
Overall Failed Attempt (%)	6 (17.5 %)	9 (28.1%)	0.31
Total Time of Procedure (min)	9.38±1.97	6.38±1.93	<0.001
Time For Lumbar Puncture (Min)	3.59±1.04	6.38±1.93	<0.001
Change In Provider (%)	2 (5.9 %)	9 (28.1%)	0.02

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DISCUSSION

This randomized controlled study was conducted in a tertiary care centre for a duration of 18 months among 66 subjects (0-14 years). This study aimed to assess if ultrasound imaging increases the success of LP procedures in Paediatric practice.

The preferred method for diagnosing bacterial meningitis is through a positive cerebrospinal fluid (CSF) culture, typically obtained using a lumbar puncture. The clinical suspicion of meningitis is greater in the presence of convulsions, fever, bulging fontanelles, and impaired consciousness, but in infancy the initial signs are often subtle, especially in young infants. This procedure can be carried out using either the conventional palpation technique or the more precise ultrasound-guided approach. However, when lumbar punctures are traumatic or unsuccessful, they may result in unclear diagnoses, leading to unnecessary antibiotic treatment, hospital stays, and patient discomfort (5).

Point of care ultrasound has achieved mainstream status in emergency medicine for both diagnostic and therapeutic interventions, with a variety of ultrasound-assisted procedures being a common practice. Several authors have shown that ultrasonography is feasible for viewing the lumbar spine and identifying specific landmarks (15-20). Moon et al and Chen et al showed that an ultrasound examination using a linear array probe was an acceptable modality for viewing spinal structures (15, 19).

The age wise distribution of study participants showed that majority of them was in the age group of less than 1 month and 7-14 years with median age of study population being around 3 years and there was predominance of males in our study. The most common indication for lumbar puncture was suspected meningitis (37.8 %) in children while late onset neonatal sepsis (LONS) was the most common reason for lumbar puncture in neonates below 1 month. Meningitis is a significant complication of late onset neonatal infection, which has significant treatment implications. This includes the need to consider longer therapy duration or the use of antimicrobial agents with higher cerebrospinal fluid (CSF) penetration (21). Our primary outcome, the proportion of successful first-attempt LP success was higher in the ultrasound group (64.7%) than for the standard procedure (56.2%). However, this difference did not have statistical significance (p=0.97).

Our research did not show any improvement in the success rate of first-attempt lumbar punctures (LP) when using ultrasound in pediatric patients. Our study was similar to the works of Zummer et. al. (22) and Kessler et. al. (3) where the ultrasound group had a higher proportion of successful first-attempt LPs (68%) compared to the traditional method group (60%), but this difference did not reach a statistical significance. In the study by Kessler et. al., the proportion of successful first-attempt LPs was 47.5% in the ultrasound group and 45% in the traditional group. Our study revealed that there was a tendency towards fewer traumatic lumbar punctures (LPs) in the ultrasound group (17.6%) compared to the standard palpatory group (28.2%). However, this difference did not reach statistical significance (p=0.31). Our findings aligned with those of Kessler et. al., who observed similar rates of traumatic taps in the ultrasound group (19.4%) and the standard palpatory group (29.7%). Despite observing a decrease in

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traumatic taps with ultrasound, there was no statistically significant difference. A meta-analysis conducted by Gottlieb et. al. demonstrated that the use of ultrasound imaging in children reduced the risk of failed LP procedures compared to the palpation method, although this reduction did not reach statistical significance (23).

In the present study it was found that the ultrasound group had a shorter duration of the LP portion of the procedure compared to the standard palpatory group. However, when considering the entire procedure, including all steps, the ultrasound group took longer than the standard technique (9.38±1.97 min vs 6.38±1.93 min). Our findings were similar with the study by Gottlieb et.al. (23). in which the Overall, mean (SD) time to perform a successful LP was 6.87 (6.77) minutes in the ultrasound-assisted group and 7.97 (10.11) minutes in the land-mark-based group. Our study and Gottlieb et. al. favoured the ultrasound assisted LP and results found to be statistically significant. In both the experimental group and the control group, the majority of the patients (70.6%) received midazolam sedation. Naik et. al. (24) concluded in his study that the use of sedation decreased the likelihood of unsuccessful LP attempts in which Midazolam was the most preferred medication followed by fentanyl, propofol, morphine, ketamine, and nitrous oxide.

Analgesia use varied inversely with patient age using various modalities; lidocaine, anesthetic creams, and oral sucrose. A mixture of lidocaine 2.5% and prilocaine 2.5% (EMLA) takes 60 minutes or longer to be effective, but it has been shown beneficial for non-emergent LPs. Shenkman et. al. (25) discovered that EMLA reduced the number of traumatic LPs in an emergency department population of less than 2 months of age when compared to a historical cohort (OR: 0.31; 95% CI 0.13-0.73). In the present study, provider was changed in 9 patients in the control group either due to traumatic LP or inability to have access of CSF while in the experimental group, provider was changed only in 2 patients (5.9 %) and the difference was statistically significant (p=0.02). A linear probe, which has been used in previous studies of ultrasound examination of the lumbar spine was used in the study (26). The linear probe is a high frequency probe with a short focal length, making it ideal for observing structures closer to the skin surface.

The most frequent intervertebral space chosen for lumbar puncture in the ultrasound group was L3-L4, accounting for 58.8% of cases. The procedure was performed with the patient lying on their side (lateral decubitus position). Baxter et al. in his study found that 82% preferred the lateral decubitus position, but 39% were willing to adjust the position based on the holder's preference (27, 28). Oncel et. al. used bedside sonography to measure interspinous distance, and they found that having the patient sit with maximal hip flexion provided the widest interspinous space for the majority of infants (p=0.001). On the other hand, the lateral recumbent position without flexing the hips resulted in the narrowest interspinous space for lumbar puncture (p=0.001 for all positions) (29). In the present study, older children experienced post-lumbar puncture headache (PLPH) (20.6 %) in ultrasound assisted group and (9.4 5%) in standard palpatory group. PLPH is thought to be caused by intracranial hypotension caused by CSF leakage after LP. Yan Wei Ling's review showed that there is no significant relationship between PLPH and either age or sex. The frequency of prior LPs and a lesser

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volume of collected CSF did not significantly correlate with PLPH either (30). To summarize, our study demonstrated no statistically significant difference in performing successful LP on the first attempt. However, Ultrasound-assisted LP (UALP) reduced traumatic taps and the number of puncture attempts in the pediatric age group, though results were statistically insignificant. When pre-procedure ultrasound was used, the time for lumbar puncture was shortened, and the results were statistically significant. Similarly change of provider results favoured UALP & were statistically significant. This issue requires more research with larger populations and alternative approaches such as real-time ultrasonography and lumbar puncture.

CONCLUSION

The present study found no statistically significant difference in carrying out successful LP in first attempt. Though ultrasound-assisted LP reduced traumatic taps and the number of puncture attempts in the pediatric age group but results did not achieve statistical significance. The time for lumbar puncture as well changes of provider reduced when pre-procedure ultrasound was performed and the results were statistically significant. Studies with larger populations and different methodologies like real time ultrasound and Lumbar puncture are required on this subject

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