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EASE OF ADMINISTRATION OF CONVENTIONAL LANDMARK GUIDED SPINAL ANAESTHESIA VERSUS PREPROCEDURAL ULTRASOUND GUIDED SPINAL ANAESTHESIA THROUGH MIDLINE APPROACH IN PATIENTS UNDERGOING LOWER ABDOMEN AND LOWER EXTREMITIES SURGERY: A RANDOMISED CONTROLLED STUDY

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Abstract

Background: Standard technique of performing spinal anaesthesia through lumbar puncture for surgeries involving lower abdomen, perineum and lower extremities has lower yield in patients with obesity, pregnancy etc where there is difficulty to identify the landmarks. Pre-procedural ultrasound guided identification of landmarks can overcome these shortcomings. The objective of this study aimed to compare conventional landmark guided spinal anaesthesia and pre procedure ultrasound guided spinal anaesthesia through midline approach in patients who underwent surgery in lower abdomen and lower extremities and determine which technique is better in reducing number of attempts and passes. **Methodology:** Prospective randomized control study was conducted between June 2018 to June 2019 on 106 patients. Patients were randomized to two groups of 53 each by computer generated table to receive one of the following for the subarachnoid block: Group A (n=53) was patients underwent conventional landmark technique anaesthesia & Group B (n=53) was patients underwent ultrasound guided anaesthesia through midline approach and the number of

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attempts and passes were documented for both the groups. All the data were analysed using SPSS v.23.0. Data was presented in the form of percentages, mean and SD. Tests like Chi-square ($\chi 2$)/Freeman-HaltonFisher exact test and unpaired t test was applied. A p-value of <0.05 was considered to be significant. **Results:** In group A, mean number of attempts was 1.36 with standard deviation of 0.48 and mean number of passes was 1.50 with standard deviation of 0.51. In group B, mean number of attempts was 1.34 with standard deviation of 0.48 and mean number of passes was 1.49 with standard deviation of 0.51. This difference was not found to be statistically significant (P value = 0.840 & 0.907 respectively) **Conclusion:** Study revealed that pre-procedural ultrasound guided identification of landmarks and subsequent administration of spinal anaesthesia was not superior to conventional anatomical landmark identification. Hence medical strategy based on above conclusions needs further investigation.

Key words: Conventional spinal anaesthesia, USG guided spinal anaesthesia, Lower abdomen surgery, Lower extremity surgery, Randomized Controlled Study

Introduction

In1898, August Bier performed surgery under spinal anaesthesia. It avoids the complications of general anaesthesia like airway manipulation, poly-pharmacy and allows the patient to remain awake. Spinal anaesthesia is economical, easier to perform and onset of anaesthesia is faster favouring the surgical incision to be made sooner with better post operative analgesia.[3] Lower abdominal and lower limb surgeries may be performed under local, regional (spinal or epidural) or general anaesthesia. Spinal block is still the first choice because of its rapid onset, superior blockade, less failure rates and cost-effective. USG guided approach to neuraxial block involves performing a pre-procedural scan which helps to identify relevant landmarks and thus guide subsequent needle insertion. Over the last decade, a large body of evidence has accumulated to support the benefit of this approach.[1,2]

The practice of neuraxial block has traditionally relied on the palpation of bony anatomical landmarks, namely iliac crests and the spinous processes, together with tactile feedback during needle insertion. However, these landmarks may be difficult to identify accurately. A problem exacerbated by altered patient anatomy, including obesity, age related changes and previous spinal surgery. The risk of traumatic or failed neuraxial blockade may be reduced by the use of ultrasound. Therefore, the present study was conducted to compare pre-procedural ultrasound guided spinal anaesthesia versus landmark guided conventional palpatory technique for lower abdomen and lower limb surgeries.[1,2] Considering these factors, this study was taken up to compare the effectiveness of pre-procedural use of ultrasound in routine practice for identification of the subarachnoid space at levels L3-L4, L4-L5 with respect to the number of attempts and passes required to enter the space.

Study design

A randomized control study was conducted in BGS Global Hospital, Bangalore, Karnataka between June 2018 to June 2019 for duration of 1 year on patients with American Society of Anaesthesiologists (ASA) status I and II, Age 18 years to 65 years who were scheduled to undergo lower abdominal surgeries and lower extremity surgeries having BMI > 30 were included in the study. Those patients with contraindications to spinal anaesthesia,

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International Normalised Ratio (INR) >1.3, platelet count <75,000/ml, who are on anticoagulant drugs, known cases of neurologic disease (multiple sclerosis, symptomatic lumbar herniated disc, spinal stenosis), fluid restriction (cardiac or renal insufficiency), allergy or intolerance to local anaesthetics or para-aminobenzoic acid, atypical plasma cholinesterase, severe cardiac disease (severe AS, severe MS, HOCM, CHF etc), sepsis, lung disease like diaphragm weakness, pleural effusion were excluded from the study.

The sample size was calculated using the formula $n = 2 \times f(\alpha, \beta/2) \times \pi \times (100 - \pi) / d2$, where π is the true percent 'success' in both the control and experimental treatment groups. Minimum sample size required for the study was 106. If there was truly no difference between the standard and experimental treatment, then 106 patients were required to be 80% sure that the limits of a two-sided 90% confidence interval will exclude a difference between the standard and experimental group of more than 25%. After obtaining the written consent, hundred and six patients were randomly allocated in one of the following two groups consisting of 53 patients each by using computer generated random number method.

Group A: conventional landmark guided spinal anesthesia (n=53),

Group B: pre-procedural ultrasound guided spinal anesthesia (n=53)

Data was analyzed using SPSS software v.23.0.and Microsoft word and excel. All characteristics were summarised descriptively. Mean, standard deviation (SD) were used to describe continuous variables. Proportion and percentage were used to describe categorical data. Bivariate analysis like Chi-square test to determine the significance of differences between groups for categorical data. The difference of the means of analysis variables between two independent groups was tested by unpaired t test. (p-value was < 0.05)

Methodology

Pre-anaesthetic check-up was done one day prior to the proposed day of surgery and all the patients participating in the study were kept nil per orally for at least 6 hours. An informed written consent was taken from the patients at the time of pre-anaesthetic check-up. A total of 106 eligible patients was included in the randomized control study after ethical clearance from the college ethical committee. Each patient was visited pre-operatively and the procedure was explained. All the routine investigations required for pre operative evaluation and the proposed surgery was done. All the patients were pre-medicated with Tab. alprazolam 0.5 mg and Tab. ranitidine 150mg overnight and the morning of surgery. Patients were kept nil per oral for a period of at least 6 hours.

Patients were randomized to two groups of 53 each by computer generated table to receive one of the following for the subarachnoid block:

1. Group A (n=53) is patients undergoing conventional landmark technique anaesthesia
2. Group B (n=53) is patients undergoing ultrasound guided anaesthesia

After arrival in the operating room, a 20G peripheral intravenous catheter was inserted into the patient’s forearm, and approximately 10 mL/kg of crystalloid was infused. Standard monitoring was used throughout the procedure, including non-invasive arterial blood pressure, electrocardiogram (three leads), and pulse oximetry. 53 patients assigned to group A who underwent conventional landmark guided spinal anaesthesia through midline approach and the number of attempts and passes were noted.

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Spinal anaesthesia was performed under sterile conditions in sitting position using conventional landmark technique by palpation L2-L3 or L3-L4 intervertebral disc space identified, after local infiltration of the skin with 2% lidocaine. Using 25G Quinke needle, spinal tap is performed and free flow of Cerebrospinal fluid (CSF) and level of block is tested for temperature and touch sensation using ice cube and cotton swab respectively. Intra-operatively heart rate, blood pressure, O2 Saturation is periodically monitored.

Similarly, 53 patients assigned to group B underwent pre-procedure ultrasound guided spinal anaesthesia through midline approach and the number of attempts and passes were documented. Portable ultrasound machine: FUJIFILM sonosite,M-TURBO, Triple Trasducer Connect 13-6MHz, Made in Malaysia was used. The time of insertion of spinal needle into skin and egress of CSF was also noted down.

Results

Among 53 study participants in the each study group A and group B, where the study group A consists of 26 (49.1%) male and 27 (50.9%) female. The study group B consists of 24 (45.3%) male and 29 (54.7%) females. The mean age in Group A was 40.06 years with ± 12.29 standard deviation and mean age in Group B was 44.51 years with ± 12.79 standard deviation with a p value of 0.070 and was comparable among the two groups. The Mean BMI in group A was 35.21 and mean BMI in group B was 34.79 with p value of 0.543.

Table 1: Comparison of parameters between landmark guided spinal anaesthesia and USG guided spinal anaesthesia in mean & SD.

	LANDMARK GUIDED SPINAL		**USG GUIDED SPINAL**			
	Mean	**SD**	**Mean**	**SD**	**t value**	**p value**
Comparison of factors between two study groups						
Age (Yrs)	40.06	12.29	44.51	12.79	-1.83	0.070
BMI	35.21	3.34	34.79	3.30	2.20	0.543
Mean no. of attempts & passes between study groups						
No of attempts	1.36	0.48	1.34	0.48	0.20	0.840
No of passes	1.50	0.51	1.49	0.51	0.12	0.907
Mean time for procedure between study groups						
Time (seconds)	29.53	13.77	28.87	14.18	0.24	0.808
Comparison of Peri-procedural patient discomfort VAS score						
VAS score	3.34	1.52	3.64	1.36	1.08	0.283

In group A 50.9% fell in ASA grade I and 49.1% fell in ASA grade II. In group B 41.5% were in ASA grade I and 58.5% were in ASA grade II. In group A 52.8% underwent lower abdominal surgeries and 47.2% underwent lower limb surgeries. In group B 41.5% underwent lower abdominal surgeries and 58.5% underwent lower limb surgeries.

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In group A 35.8% received spinal anaesthesia in L2-3 space and 64.2% in L3-4 space. In group B 30.2% received spinal anaesthesia in L2-3 space and 69.8% in L3-4 space. In group A the incidence of bloody tap was 7.5% and in group B it was 5.7%. The difference in between both the groups with regards to the incidence of bloody tap during the procedure was not statistically significant (p value 0.696).

Table 2: Comparison of parameters between landmark guided spinal anaesthesia and USG guided spinal anaesthesia in proportions

	LANDMARK GUIDED SPINAL		**USG GUIDED SPINAL**		
	N	**%**	**N**	**%**	**P-value**
American Society of Anaesthesiologists (grade) between two study groups					
I	27	50.9%	22	41.5%	0.330
II	26	49.1%	31	58.5%	
Total	53	100.0%	53	100.0%	
Surgery between study groups					
Lower abdomen	28	52.8%	22	41.5%	0.50
Lower limb	25	47.2%	31	58.5%	
Total	53	100.0%	53	100.0%	
Intervertebral disc space between two study groups					
L2 -L3	19	35.8%	16	30.2%	0.536
L3- L4	34	64.2%	37	69.8%	
Complications between two study groups					
Bloody tap	4	7.5%	3	5.7%	0.696
Nil	49	92.5%	50	94.3%	
No. of attempts of procedure between two study groups					
1	30	56.6%	35	66.0%	0.949
2	23	43.4%	18	34.0%	
No. of passes of procedure between two study groups					
1	17	32.1%	18	34.0%	0.906
2	17	32.1%	17	32.1%	
Total	34	64.2%	35	66.0%	

In group A the subarachnoid space was reached in the first attempt in 56.6% of the patients and it was reached in second attempt in 43.4%. in group B the subarachnoid space was reached in the first attempt in 66.0% of the patients and it was reached in second attempt in 34.0% of the patients. In group A the subarachnoid space was reached in one pass in 32.1% and in two passes in 32.1%. In group B the subarachnoid space was reached in one pass in 34% and in two passes in 32.1%.

In group A the mean number of attempts was 1.36 with a standard deviation of ±0.48 and the mean number of passes was 1.50 with a standard deviation of ±0.51. In group B the mean number of attempts was 1.34 with a standard deviation of ±0.48 and the mean number of

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passes was 1.49 with a standard deviation of ±0.51. In group A the mean time for procedure was 29.53 seconds with a standard deviation of 13.77 seconds. In group B the mean time for procedure was 28.87 seconds with a standard deviation of 14.18 seconds.

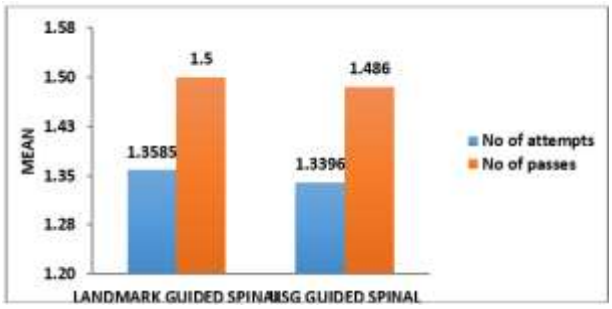

Figure 1: Mean no. of attempts & passes between two study group

In group A the mean Visual Analogue Scale (VAS) score was 3.34 with a standard deviation of 1.52. In group B the mean VAS score was 3.64 with a standard deviation of 1.36. The observed difference in between both the groups in any of the above parameters described was not found to be statistically significant.

Discussion

The mean age in Group A was 40.06 years and in Group B was 44.51 years. The mean BMI in group A is 36.21 with standard deviation of 3.34 and of group B is 34.79 with a standard deviation of 3.30. In group A 35.8% received spinal anaesthesia in L2-L3 space and 64.2% in L3-L4 space, in group B 30.2% and 69.8% respectively. In group A the incidence of bloody tap was 7.5% and in group B it was 5.7%.In group A the subarachnoid space was reached in the first attempt in 56.6% of the patients and it was reached in second attempt in 43.4%. In group B, 66.0% and 34.0% respectively. In group A the subarachnoid space was reached in one pass in 32.1% and in two passes in 32.1%. In group B, it was 34% and 32.1% respectively. The difference in between both the groups was not found to be statistically significant (p-value >0.05).

In group A, mean number of attempts was 1.36 with a standard deviation of 0.48 and the mean number of passes was 1.50 with a standard deviation of 0.51. In group B, it was 1.34 with a standard deviation of 0.48 and 1.49 with a standard deviation of 0.51 respectively. Similar study done by Srinivasan K *et al.* found that routine use of para-median spinal anaesthesia at L5-S1 inter space, guided by pre-procedure ultrasound, in patients undergoing lower limb joint arthroplasties did not reduce the number of passes or attempts needed to achieve successful dural puncture (p value 0.02).[3] However study done Kalliadaikurichi Srinivasan K *et al.* on orthopaedic patients undergoing joint replacement surgery and studies done by Creaney M *et al.*, and Dhanger S *et al.*in parturients found that use of ultra sonography to locate the needle insertion point reduced the number of needle passes for successful lumbar puncture as it reduces the number of attempts with fewer side effects as compared to conventional landmark technique (p value <0.001)[4-6]

In group A the mean time for procedure was 29.53 seconds with a standard deviation of 13.77 seconds. In group B the mean time for procedure was 28.87 seconds with a standard deviation of 14.18 seconds. Similar study done by Ansari T *et al.* studied ultrasound-guided

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spinal anaesthesia in obstetrics to assess if there is an advantage over the landmark technique in patients with easily palpable spines, found out that when performed by anesthetists experienced in both ultrasound and landmark techniques, the use of ultrasound does not appear to increase the success rate of spinal anaesthesia, or reduce the procedure time or number of attempts in obstetric patients with easily palpable spines.[33] Similar finding was found in study done by Creaney M *et al.*[5.6]

In group A the mean VAS score was 3.64 with a standard deviation of 1.36. In group B the mean VAS score was 3.34 with a standard deviation of 1.52. The difference in between both the groups with regards to VAS scores was not found to be statistically significant (p-value of 0.283).

Limitations

Even though it is a randomized clinical trial it is not a double blinded study hence bias cannot be eliminated. In our study the investigator was not blinded for the study results. This information might have impacted the observations made.

Conclusion

The pre-procedural ultrasound guided identification of landmarks and subsequent administration of spinal anaesthesia was not superior to conventional anatomical landmark identification and spinal anaesthesia in terms of number of passes, number of attempts, time for the procedure, VAS scores and the incidence of bloody tap. Hence we conclude that both the methods are comparable and equally efficacious. However this study is rife with limitations, hence a medical strategy based on the above conclusions warrants further investigation.

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