

A RANDOMIZED SINGLE BLINDED STUDY COMPARING THE INCIDENCE OF POST DURAL PUNCTURE HEADACHE AFTER SPINAL ANESTHESIA USING 25 GAUGE WHITACRE NEEDLE WITH MEDIAN AND PARAMEDIAN APPROACH IN CESAREAN SECTION PATIENTS

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Abstract

Introduction: Subarachnoid block is the most commonly used anaesthetic technique for caesarean sections. Post-dural puncture headache (PDPH) is an iatrogenic complication of spinal anaesthesia. Reported risk factors for PDPH include sex, age, pregnancy, needle tip shape and size, bevel orientation, approach and others. The aim of this study is to assess the incidence of postdural puncture headache in the median and paramedian approach using 25G Whitacre spinal needle in pregnant females undergoing caesarean section.

Materials and methods: After obtaining institutional ethical committee approval, 100 patients of ASA I and ASA II of pregnant women undergoing caesarean section belonging to age group of 18-35 years randomized by computer generated numbers into two groups (50 each) after fulfilling inclusion criteria. The patients were randomized to receive spinal anaesthesia by either a median (n=50) approach or paramedian approach (n=50). After informed written consent, all patients were premedicated with Inj. Metoclopramide 10mg and all patients received 500ml of Normal saline intravenously over 30 minutes before the procedure. Each patient received 9-12mg of hyperbaric bupivacaine with 25G Whitacre spinal needle either through median approach (group M, n=50) or paramedian approach (group PM, n=50). The patients were followed for 48 hours for PDPH, presence of PDPH was assessed by visual numerical analogue scale.

Results: Out of total 100 caesarean section patients, six patients developed PDPH. 4/50 (8%) had PDPH in median approach and 2/50 (4%) had PDPH in paramedian approach. However the difference in incidence of PDPH in both median and paramedian approaches is not statistically significant (p value=0.4000) and the severity of PDPH in both groups was of mild degree.

Conclusion: Even though we noticed the incidence of PDPH is less with 25G Whitacre spinal needle in paramedian approach compared to median approach, but there was no

significant statistical difference on incidence of PDPH using 25 G Whitacre spinal needle between median and paramedian approach in caesarean section patients.

Key Words: Postdural puncture headache (PDPH), Whitacre needle, caesarean, median and paramedian approach.

INTRODUCTION

Subarachnoid block is one of the most commonly used anaesthetic technique for caesarean sections. It is easy to perform, provides fast onset of sensory and motor block, and offers a high success rate and excellent anaesthesia. The common post operative problems with sub arachnoid block are visceral pain, nausea, vomiting and post-dural puncture headache.

Post dural puncture headache (PDPH) is an iatrogenic complication of spinal anaesthesia, exact mechanism is unclear, however there are two possible explanations for PDPH. First, the decrease in CSF pressure may cause traction on the pain sensitive intracranial structures in the upright position leading to characteristic headache. Secondly, the loss of CSF may produce a compensatory vasodilatation.¹

The onset of PDPH is usually within 24–48 h after dural puncture, but contrary to the above definition, it could be delayed by up to 12 days, the postural nature of the headache is very characteristic and the symptoms are usually self-limited, but sometimes it may be severe enough to immobilize the patient. Headache after lumbar puncture is usually dull or throbbing in nature, and can start in the frontal or occipital region, which can later become generalized. It is possible for the pain to radiate to the neck and shoulder area, and could be associated with neck stiffness. Head movements exacerbate the pain and any maneuvers that increase intracerebral pressure, such as coughing, sneezing, straining or ocular compression, may also worsen the symptoms. Headache usually resolves within a few days, but the longest reported headache after lumbar puncture lasted for 19 months.¹

Some high risk factors for developing PDPH has been found, including female sex, young age, the needle size and design, the needle bevel direction and a previous history of PDPH.²

The first incidence of PDPH was reported as early as 1898 by August Bier and presumed it to be due to CSF loss. The incidence of PDPH varies with design and the gauge of the needle used. Thus, in the last 50 years with the development of fine gauge needles and needle tip modification there is a significant reduction in the incidence of post dural puncture headache.³

PDPH occurs more often in young adults, especially in the 18–30 year age group. Young women with a lower body mass index and those who are pregnant have the highest risk of developing the headache. Similarly a less stretchable duramater due to either atherosclerosis or age-related mechanical changes in the epidural space might explain why the incidence is low in elderly patients.

Subarachnoid space can be approached from the posterior aspect of the vertebral body either through the midline or paramedian approach (PMA). PMA approach has been proven to decrease the incidence of PDPH.¹ The paramedian approach is a useful technique that allows for successful identification of subarachnoid space, especially in difficult cases, obese, pregnant and geriatric patients.⁴ Whitacre needle has been proven to decrease the incidence of post dural puncture headache.⁵

Various cutting and pencil needles and different gauge needles have been studied in attempt to prevent incidence of PDPH. Whitacre is one among pencil point needle studied and proven to decrease the incidence of PDPH.⁵

Hence we decided to see the advantage of Whitacre needle when used in paramedian approach compared to median approach. We planned to evaluate by combining the advantage of Whitacre needle with advantages of paramedian approach to further decrease the incidence of PDPH.

MATERIALS AND METHODS

SOURCE OF DATA: The present study has been carried out on patients aged between 18 to 35 years pregnant women undergoing caesarean section in Karnataka Institute of Medical Sciences, Hubballi from January 2021 to January 2022.

METHODS OF DATA COLLECTION:

This is a randomized single blinded study containing 100 patients of ASA I and ASA II of pregnant women undergoing caesarean section. This study was conducted in age group of 18-35 years satisfying the inclusion criteria and was randomly allocated into two equal groups.

GROUP M (n=50): patients were given spinal anaesthesia using 25G Whitacre spinal needle by median approach.

GROUP PM (n=50): patients were given spinal anaesthesia using 25G Whitacre spinal needle by paramedian approach.

After obtaining institutional ethical committee approval, informed written consent was obtained from patients involved in the study. Intravenous access in peripheral veins was obtained, anaesthesia machine was checked, resuscitative equipments and drugs kept ready.

INCLUSION CRITERIA:

- ASA I-II
- Age 18-35 years
- Scheduled for caesarean section under spinal anaesthesia
- Pregnant patients giving informed, written and valid consent
- At least 36 weeks of gestational age

- Singleton pregnancy

EXCLUSION CRITERIA:

- Pregnant women with history of cardiac, liver or kidney disease
- Any contraindication to spinal anaesthesia
- Patients belonging to ASA III, IV and V
- Anatomical abnormalities of spine
- Patient refusal
- Pregnant women with allergy to amide local anaesthetic
- More than 2 dural punctures
- History of migraine or any chronic headache preoperatively or on the morning of surgery.

METHOD OF STUDY:

This is a prospective randomized, single blinded study of patients satisfying all the inclusion criteria. Informed, written, valid consent was obtained from all the patients participating in the study. A total of 100 patients was included in the study. The patients were randomly assigned into 2 groups. Randomization of study participants was performed by computer generated numbers. The anaesthesiologist was not blinded to patient group allocation, but the patients were blinded.

The two groups were:

Group M: received 9-12 mg of hyperbaric bupivacaine with 25 G Whitacre spinal needle through median approach.

- Group PM: received 9-12 mg of hyperbaric bupivacaine with 25G Whitacre spinal needle through paramedian approach. Number of cases in each group -50.

Patients were kept nil by mouth for solid food for 8 hours and clear fluids for 2 hours before surgery. In the operating room electrocardiography, non invasive blood pressure, oxygen saturation and heart rate monitored. 18G or 20G IV cannula inserted into a patient peripheral vein. Operating room temperature maintained at 23-25 degree Centigrade with a humidity of 55-65%. No other warming device was used. Before administering spinal anaesthesia, standard monitoring established and patient were given 500 ml of Normal saline intravenously over 30 minutes. All patients premedicated with inj. metoclopramide 10 mg. Spinal anaesthesia administered either by median approach (Group M, n=50) or paramedian approach (Group PM, n= 50) at the L3-L4 / L4- L5 inter vertebral space. All patients received 9-12mg of hyperbaric bupivacaine using 25G Whitacre spinal needle. The patient were blinded to the approach used. The patients were followed for 48 hours for PDPH, presence of PDPH was assessed by Visual Numerical Analogue Scale (VAS) using Facial

pain scale revised, Score of “0“ considered as absence of PDPH while score of “1-10“considered as presence of PDPH.

PDPH was diagnosed if,

1. The headache had postural component (aggravated by sitting up and relived by lying down)
2. It had occipital and/or frontal components.
3. It was relieved by abdominal compression or binder
4. External stimuli like loud noise or light irritating the patient.
5. Previously the patient did not have headache. Headache was taken in to account even if it was complained once, or if it lasted only a few hours.

All the patients, who complained of headache, were treated with one or more of the following along with Tab. Paracetamol and/or Tab. Tramadol.

1. Psychological support and positive reassurance of recovery.
2. Confinement to bed and head down position if necessary
3. Application of ice bag to head.
4. General body hydration – administration of large volumes of fluids by orally and/or by IV route (ringer lactate, Normal saline)
5. Sedation and or analgesia. Tab. Diazepam 10mg orally, inj.Diclofenac sodium IM
6. Oxygen inhalation
7. Abdominal compression. Use of tight abdominal binder to raise pressure in peridural venous plexus and thereby increase CSF pressure, where possible.

RESULTS

Table 1: Comparison of two groups (Median and Paramedian) according to age groups.

Age groups	Group M (Median approach)(%)	Group PM (Paramedian approach) (%)	Total	P-value
<=20yrs	2 (4)	6(12)	8	0.4390
21-25yrs	25(50)	26(52)	51	
26-30yrs	17(34)	14(28)	31	
>=31yrs	6(12)	4(8)	10	
Total	50(100)	50(100)	100	

Mean age	25.70	25.04	25.37	
SD age	3.50	3.75	3.62	

Chi-square value =2.7100

Figure 1: Comparison of two groups (Median and Paramedian) according to age groups

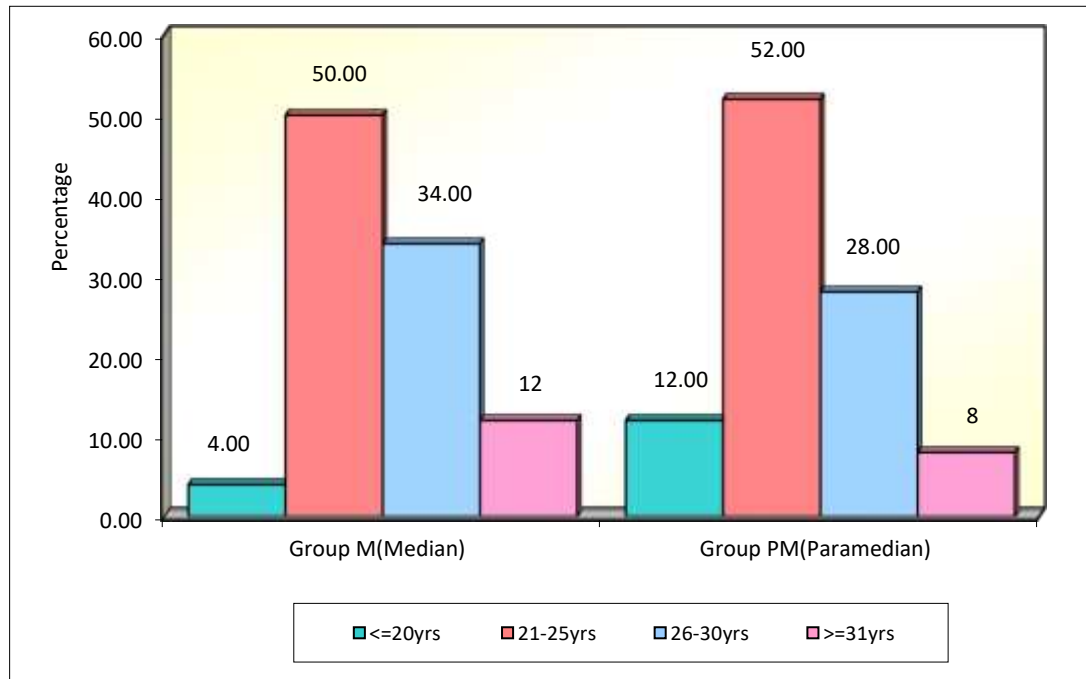


Table 1 depicts the age distribution of study participants based on the median and Paramedian approaches using 25G Whitacre spinal needle in the patients undergoing spinal anaesthesia for caesarean section and it was found that majority of participants were belonging to age group of 21-25 years in both the approaches 50% in median and 52% in paramedian and the difference between the groups was not statistically significant (p value-0.43). The mean age in the median approach was 25.70 ± 3.5 and in paramedian approach was 25.04 ± 3.75 .

Table2: Comparison of two groups (Median and Paramedian) according to BMI

Obesity	Group M (Median approach) (%)	Group PM (Paramedian approach) (%)	Total	P-Value
Normal	23(46)	20(40)	43	0.6990
Overweight	24(48)	28(56)	52	
Obesity-1	3 (6)	2 (4)	5	
Total	50 (100)	50(100)	100	
Mean BMI	25.02	25.00	25.01	
SDBMI	2.69	2.25	2.47	

Chi-square=0.7170,

Figure 2: Comparison of two groups (Median and Paramedian) according to BMI

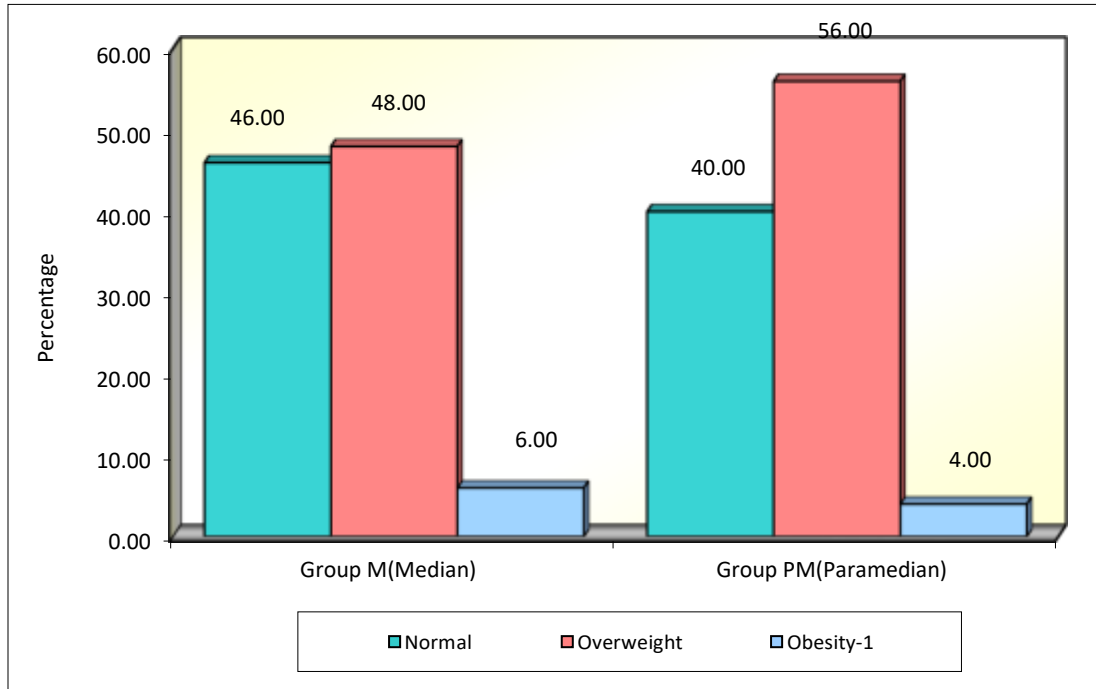
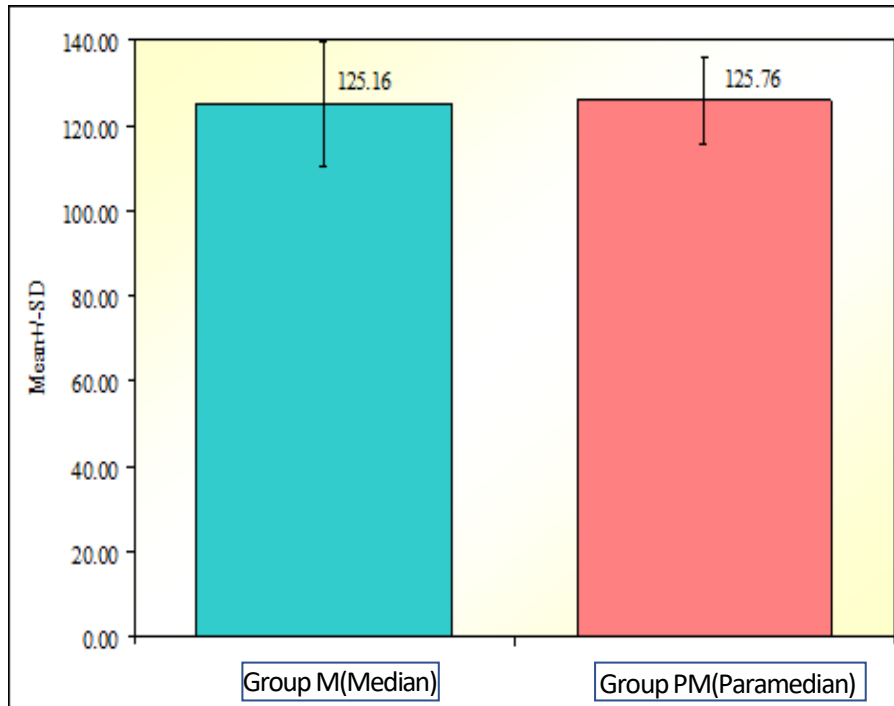


Table 2 depicts the comparison of two groups according to obesity and it was found that in median approach (48%) as well as in paramedian approach (56%) the study participants were overweight followed by Normal BMI in 46% in median approach and 40% in paramedian approach and this difference in between the groups was not statistically significant (p value-0.69). The mean BMI in median approach participants was 25.02 ± 2.69 and in paramedian approach participants was 25 ± 2.25 .

Table 3: Comparison of two groups (Median and Paramedian) with mean SBP (mmhg) by independent t test

Groups	Mean	SD	Min	Max	t-value	p-value
Group M(Median)	125.16	14.57	100.00	150.00	-0.2395	0.8113
Group PM(Paramedian)	125.76	10.08	110.00	150.00		

Figure 3: Comparison of two groups (Median and Paramedian) with mean SBP(mmhg)

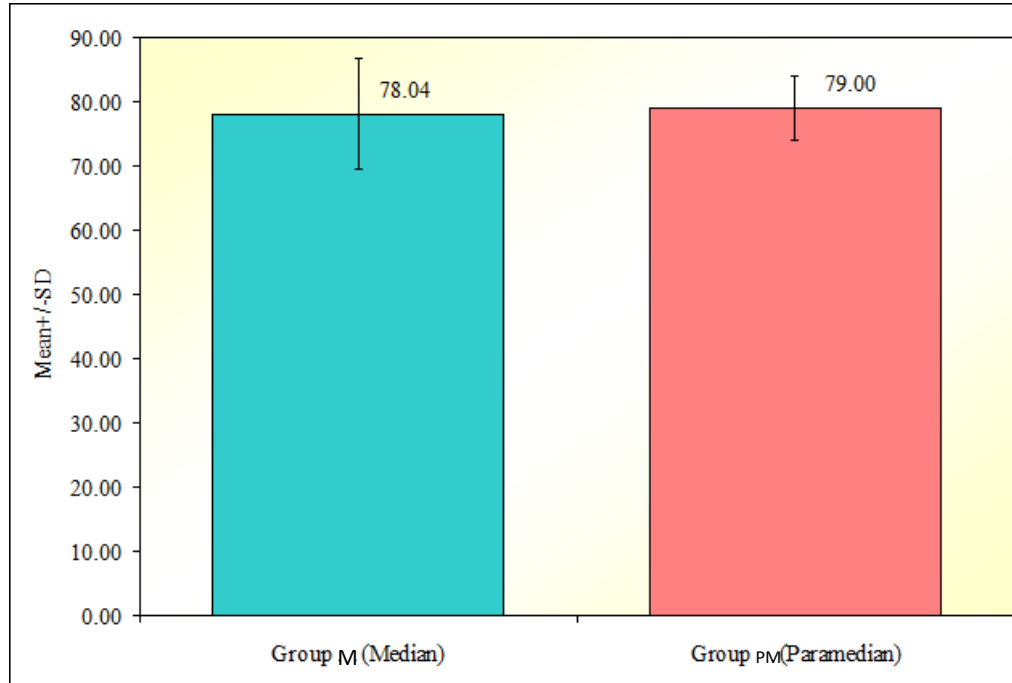


In the above table 3, the mean systolic blood pressure is compared between the groups and we found that, the mean SBP in median approach patients was 125.16 ± 14.57 mm hg and in paramedian approach was 125.76 ± 10.08 mm hg and there was no significant association between the SBP and the groups with p value 0.8.

Table 4 : Comparison of two groups (Median and Paramedian) with mean DBP (mmhg) by independent t test

Groups	Mean	SD	Min	Max	t-value	p-value
Group M(Median)	78.04	8.60	60.00	100.00	-0.6820	0.4968
Group PM(Paramedian)	79.00	5.00	70.00	90.00		

Figure 4: Comparison of two groups (Median and Paramedian) with mean DBP (mmhg)



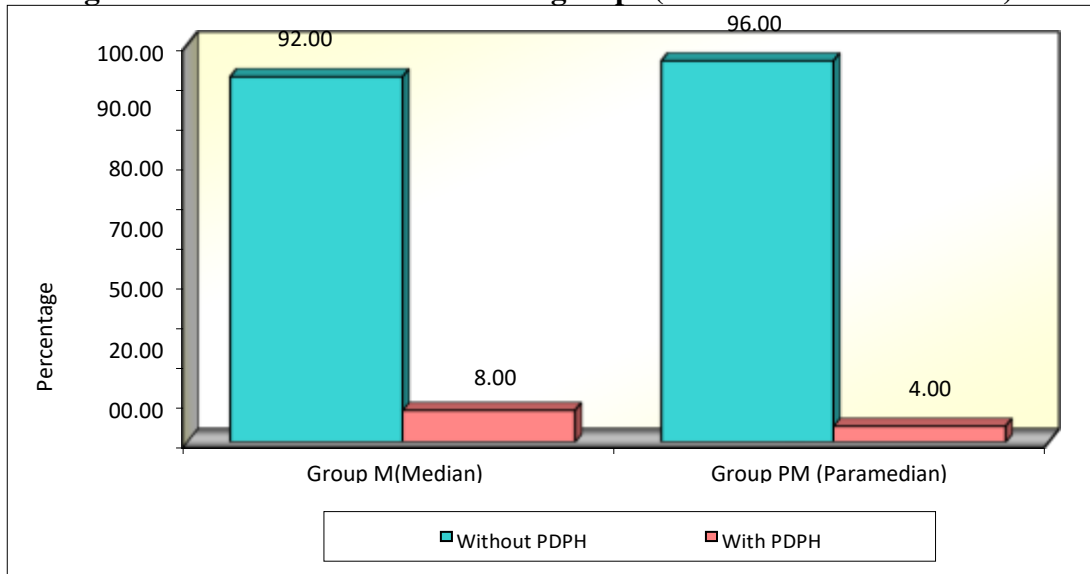
In the above table 4, the study participants mean diastolic blood pressure (DBP) was compared between the groups and was found that, the mean DBP among median approach was 78.04 ± 8.6 mm hg and paramedian approach was 79 ± 5 mmhg and the association between the DBP and the groups is not significant with p value 0.49.

Table 5: Incidence of Post Dural Puncture Headache (PDPH) in two groups (Median and Paramedian)

PDPH	Group M (Median) (%)	Group PM (Paramedian) (%)	Total	P value
Without PDPH	46(92)	48(96)	94	0.400
With PDPH	4 (8)	2 (4)	6	
Total	50(100)	50(100)	100	

Chi-square=0.7090

Figure 5: Incidence of PDPH in two groups (Median and Paramedian)



In the above table 5, the incidence of Post dural punctural headache (PDPH) in two groups was assessed and we found that, the incidence of PDPH in median approach group was 8% and in paramedian approach group was 4% and the association between the incidence of PDPH with both groups was statistically not significant with p value 0.4000.

Table 6: Severity of PDPH in two groups (Median and Paramedian)

Groups	N	With PDPH	Mild
Group M(Median)	50	4	4
Group PM(Paramedian)	50	2	2
Total	50	6	6

Figure 6: Severity of PDPH in two groups (Median and Paramedian)

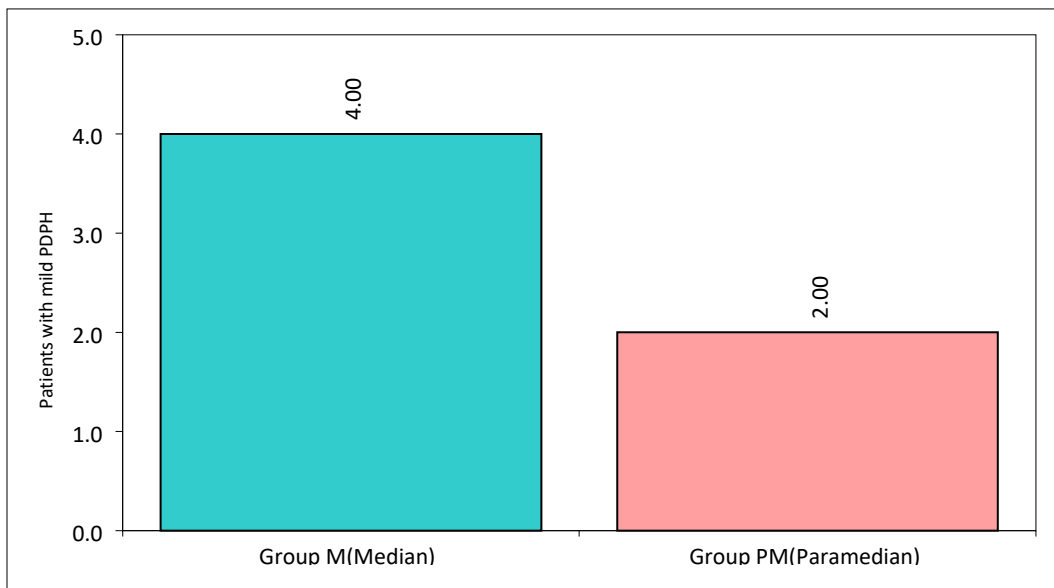


Table 6 depicts about the severity of PDPH and we found that in both the groups i.e., median approach and paramedian approach the severity was mild among all 6 participants with PDPH.

Table 7: Duration of PDPH in two groups (Median and Paramedian)

Groups	With PDPH	Time of onset of PDPH in hrs		Time of maximum PDPH in hrs		Pain scores PDPH	
		Mean	SD	Mean	SD	Mean	SD
Group M(Median)	4	19.75	4.65	30.50	5.00	2.50	0.58
Group PM (Paramedian)	2	13.50	4.95	29.50	3.54	2.00	0.00
Total	6	17.67	5.32	30.17	4.22	2.33	0.52
Mann-Whitney U,Z-value		1.1573		-0.2315		0.6944	
p-value		0.2472		0.8170		0.4875	

Figure7: Duration of PDPH in two groups (Median and Paramedian)

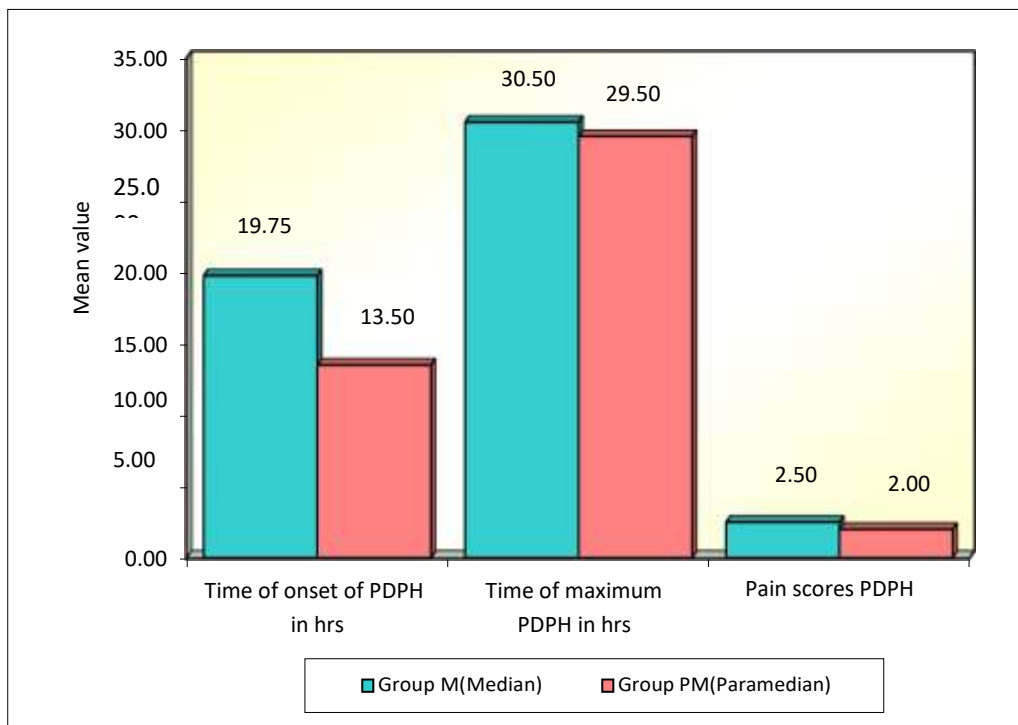


Table 7 depicts about the duration of PDPH in two groups and found that, in median approach the mean time of onset of PDPH was 19.75 ± 4.65 hours after spinal anaesthesia and time of maximum PDPH was 30.50 ± 5 hours after spinal anaesthesia. In paramedian approach, the mean time of onset of PDPH was 13.5 ± 4.9 hours after spinal anaesthesia and time of maximum PDPH 29.50 ± 3.54 hours after spinal anaesthesia. There was no significant association between the duration of PDPH and two groups.

Table 8: Rescue drug used in two groups (Median and Paramedian) for PDPH

PDPH	With PDPH	Inj. Paracetamol	Inj.paracetamol+ inj.tramadol
Group M(Median)	4	2	2
Group PM(Paramedian)	2	0	2
Total	6	2	4

Figure 8: Rescue drug used in two groups (Median and Paramedian)

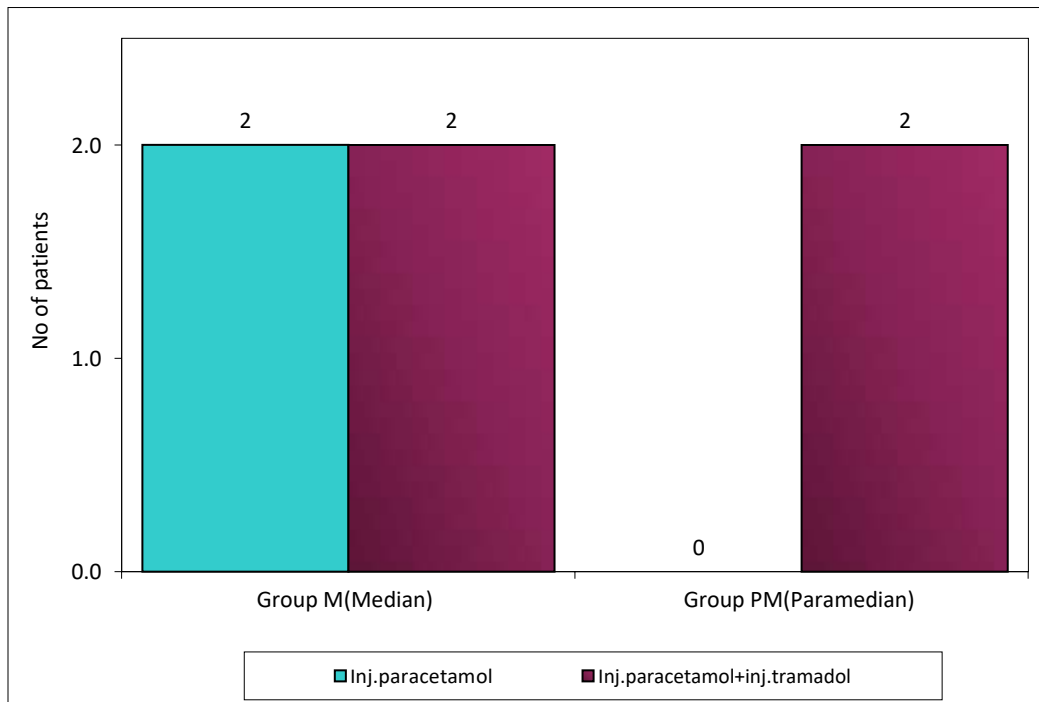


Table 8 depicts the rescue drug used to treat PDPH in both the groups and we found that, out of 4 patients who developed PDPH in median approach, 2 were on inj.Paracetamol and 2 were on

inj.paracetamol + inj.tramadol; and in 2 patients who developed PDPH after paramedian approach were on inj paracetamol+inj.tramadol.

DISCUSSION

Spinal anaesthesia is common anaesthetic technique in many below umbilical surgeries and it's been used widely all over the world especially for caesarean section. Spinal anaesthesia is associated with few of complications. Among them PDPH is persistent problem since the introduction of spinal anaesthesia but with low incidence. Since there is no specific treatment for PDPH, various attempts have been made to prevent it. Among them is decrease in the size of the spinal needle, has achieved significant success in preventing the PDPH but not with hundred percent success. So many other measures have been tried to further decrease the incidence of PDPH. Few among them are by changing the shape of the tip of needle (dura cutting and dura separating needle) and by using median and paramedian approach. In our study we tried to evaluate the effect of the combination of two measures to decrease the incidence of PDPH. We tried to evaluate the effect of the change in the tip of needle (dura separating) along with the change in approach of the needle (paramedian).

The postural nature of the headache is very characteristic and the symptoms are usually self-limited, but sometimes it may be severe enough to immobilize the patient. Headache after lumbar puncture is usually dull or throbbing in nature, and can start in the frontal or occipital region, which can later become generalized. It is possible for the pain to radiate to the neck and shoulder area, and could be associated with neck stiffness. Head movements exacerbate the pain and any manoeuvres that increase intra cerebral pressure, such as coughing, sneezing, straining or ocular compression, may also worsen the symptoms. PDPH is more common in younger age groups, in female patients and in pregnant female and also in patients with the previous history of headache (migraine, tension or cluster headache). Accurate identification of the subarachnoid space is paramount as multiple attempts at needle placement may cause post dural puncture headache, and trauma to neural structures.

So we limited the number of attempts of dural puncture to less than 2. The main aim of our study was to assess the incidence of PDPH and to compare the incidence of PDPH in median and paramedian approach using 25G Whitacre spinal needle in pregnant female undergoing caesarean section.

Age- wise distribution

In our study, majority 51% of pregnant female were belonging to age group of 21-25 years with mean age of 25.37 ± 3.62 years and the difference in age groups in both the approaches was not statistically significant. Similarly in a study conducted by Kanagarajan M et al⁶, they involved 100 pregnant female and the mean age of patients in median group was 26 ± 4.3 years and in paramedian group was 26 ± 3.9 years and the difference was insignificant. Similar responses were found in the study conducted by Bansal T et al⁷, Gurulingaswamy S et al, and Karami T et al.

BMI

In our study we found that majority of pregnant female were overweight with mean BMI of 25.01 ± 2.47 kg/m² and the difference in BMI with median and paramedian approach with p value of 0.6990 was not significant. In an anomalous study conducted by Behery M et al¹, the mean BMI in median group was 27.8 ± 1.7 kg/m² and in paramedian group was 28.3 ± 1.4 kg/m² and difference was insignificant. Whereas in a study conducted by Uluer MS et al², the mean BMI for both the groups showed obesity type 1 and the difference was insignificant. Similar to our study, various studies such as Gurulingaswamy S et al⁴, have shown the BMI as overweight.

Incidence of Post Dural Puncture Headache (PDPH)

In our study, the incidence of PDPH in median group was 8% and in paramedian group was 4%, with overall incidence of PDPH being 6% and this difference was not statistically significant. Hence we found that though the incidence of PDPH is more in median approach compared to paramedian approach, we could not prove the statistical significance.

In a similar study conducted by Mosaffa F et al⁸, they compared the PDPH in median and paramedian approach among 150 orthopaedic patients and found that the incidence of PDPH in median approach was 9.3% and in paramedian approach was 10.7% and no significant differences were seen between the two groups.

In an analogous study conducted by Kanagarajan M et al⁶, they included total 100 parturients of ASA-II who underwent caesarean delivery under spinal anaesthesia were divided in to two groups, Group M received spinal anaesthesia through median approach while Group PM received spinal anaesthesia through paramedian approach.

The incidence of PDPH was 20% in group M and 10% in group PM, which was not statistically significant ($P = 0.161$).

Similarly a double blinded clinical trial conducted in Iran by Karami T et al⁹, reported PDPH was 10% in both median approach group as well as in paramedian approach group, which was not statistically significant between the two groups. This was slightly higher than the present study.

Contrary to our study, in a study conducted by Behery M et al¹, the incidence of PDPH in median approach was 19.6% and in paramedian approach was 5.2% and this difference was statistically found significant with p value 0.018.

In another study conducted by Gurulingaswamy S et al⁴, they also found that the incidence of PDPH was more with median approach group (18%) when compared to paramedian approach group (4%) with p value of 0.025 which is statistically significant.

Contrary to our study, study done by Janik R & Dick W¹⁰, showed that, the incidence of PDPH was higher in the paramedian approach, when compared to the median approach using 25G Whitacre spinal needle.

TREATMENT USED FOR PDPH

In our study we found that out of 4 patients who developed PDPH after spinal anaesthesia through median approach 2 patients received only inj. Paracetamol and 2 were on inj.paracetamol + inj.tramadol; and the 2 patients who developed PDPH after spinal anaesthesia through paramedian approach were on inj paracetamol +inj.tramadol. All these patients were given adequate hydration, psychological support and confined to bed.

Similarly, study conducted by Uluer MS et al², paracetamol was used to treat in 18% of median approach group and 17% of paramedian approach group. They also used paracetamol + caffeine in 11% and 8% of median and paramedian group respectively.

In a study conducted by Kanagarajan M et al⁶, the medications required to treat PDPH (Tramadol/paracetamol) 18% and 8% in median and paramedian group respectively with p value 0.13. The treatment usage was slightly higher than our study.

In an analogous study conducted by Gurulingaswamy S et al⁴, the rescue analgesic was used in 10% of median and 2 % of paramedian approach group and this was not statistically significant with p value 0.09.

LIMITATIONS

- We have not included ASA III, IV and V patients, hence the results cannot be applied to them.
- Patients >35 years of age are not included.
- Only caesarean section patients are involved in the study.
- Only 25G Whitacre spinal needle used in this study.
- We did follow up for incidence of PDPH only for 48hours.

FUTURE SCOPE OF THE STUDY

Since we used 25G Whitacre spinal needle and nowadays 27G Whitacre spinal needles are available in market. We can continue with similar studies to know the incidence of PDPH with these newer needles and change in approach.

CONCLUSION

Incidence of PDPH is less with 25G whitacre spinal needle when used in paramedian approach (4%) compared to median approach (8%) but it's not statistically significant. Hence paramedian

approach with 25G whitacre spinal needle doesn't further decrease the incidence of PDPH compared to the median approach.

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