Pediatric Anesthesia and Critical Care Journal 2021;9(2):116-122
doi:10.14587/paccj.2021.19a

PACCJ

Comparison of the effect of paramedian and median methods on postdural puncture headache among candidates for elective cesarean sections undergoing spinal anesthesia. A double blind clinical trial

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Keypoints

No significant difference between median and paramedian methods in terms of PDPH incidence has been demonstrated, therefore paramedian method can be used in patients who cannot be easily given median position.

Abstract

Introduction

Spinal anesthesia is the most common method used to reduce pain throughout the birthing process. Post-dural puncture headache (PDPH) is the most common complication of neuraxial anesthesia. This study was aimed to compare the effect of median and paramedian methods on the incidence of PDPH in cesarean section.

Materials and Methods

This double-blind clinical trial was performed on 140 patients undergoing cesarean section referred to an educational center in Urmia from March 1, 2020 to March 1, 2021. Data were collected through a demographic profile checklist and the visual analogue scale (VAS) tool.

Results

The mean ± SD of patients' age was 27.81 ± 5.92 years. There was no significant difference between median and paramedian groups in terms of age (P = 0.079). Seven patients from each group had PDPH, and according to VAS tool, the mean headache severity was 4.14 and 4 in the median and paramedian groups, respectively. There was no significant difference between the two groups in terms of incidence and severity of PDPH (P = 0.76 and P = 1, respectively). Patients with PDPH were significantly younger (P<0.001). Thirteen of the fourteen patients with PDPH aged 18 to 25 years, which was significantly higher than other groups (P<0.001).

Conclusion

The results of the present study showed that the type of spinal anesthesia, i.e., median and paramedian, has no effect on the incidence and severity of PDPH. However, young age can be considered as a risk factor for PDPH.

Keywords

Post dural puncture headache, PDPH, Cesarean section, Spinal anesthesia

Introduction

Cesarean section is one of the popular methods for delivery. Iran is the fourth country in terms of cesarean section rate after Brazil, Cyprus, and Colombia [1]. This figure was 46% in 2014, however, world health organization (WHO) estimates that the global standard for cesarean section was 5-15% in 2014 [2]. Studies have shown that

both local anesthesia and general anesthesia are acceptable methods for caring for women undergoing cesarean delivery [3]. but due to the many complications and risks, approximately 5% of cesarean section (C-section) deliveries in the United States and the United Kingdom are currently performed using general anesthesia, making local anesthesia a more common and safer method than general anesthesia for obstetric anesthesia [4].

According to data from the UK National Health Service, the rate of general anesthesia for C-section has dropped from 50% to 5% over the past 25 years [5]. Among regional anesthesia methods, spinal anesthesia is one of the most common methods for C-section, which is mainly performed using two techniques, median and paramedian [6]. Complications of spinal anesthesia can include neurological complications, transient neurological symptoms, and cardiovascular complications [7] . One of the most common complications of spinal anesthesia is PDPH. PDPH with an incidence of 1.3-16% is one of the unpleasant complications of spinal anesthesia that causes many problems for both the patient and the anesthesiologist [8]. The incidence and severity of PDPH are significantly variable. There are several effective factors such as the needle size and shape, the frequency of PDPH, the direction of the needle in the case of PDPH, which is carried out using median and paramedian methods, age and sex [9]. Some studies have shown that the incidence of PDPH is higher in the paramedian method than the median method [10,11], while some other studies have shown no significant difference between these two methods in terms of the incidence of PDPH [12]. In general, there is no consensus on the difference in the incidence of PDPH after using these two methods. Since this complication disrupts the daily activities, and according to the different results obtained in previous studies, this study was aimed to compare the effect of median and paramedian methods on the incidence of PDPH during cesarean section.

Materials and Methods

Study design

This double-blind clinical trial was performed on 140 female patients undergoing elective cesarean section referred to Shahid Motahari Educational Hospital in Urmia in northwestern Iran from March 1, 2020 to March 1, 2021. Inclusion criteria included patient consent to participate in the study. Exclusion criteria also included having a history of migraine, reaching stages 3 and 4 of anesthesia, two cases of PDPH, patients with indication for emergency cesarean section, previous history of PDPH, having contraindications for spinal anesthesia, lack of cooperation, failure of spinal block or adjuvant injection due to incomplete spinal block, having surgical complications such as atony and heavy bleeding or hysterectomy, incompletion of 3-day follow-up period for any reason.

Instrument

Data collection was carried out using a two-part questionnaire. The first part focuses on demographic and background characteristics including age (year), Type of anesthesia (Median / Paramedian), PDPH (Yes / No), arterial oxygen saturation, bradycardia, nausea and vomiting, ephedrine use, atropine use, hypotension, level of anesthesia and PDPH severity (VAS). VAS criterion was used to assess pain intensity. In this scale, visual scoring was explained to patients (0=no pain, 10= the worst pain ever experienced). No pain, mild, moderate, and severe pain are indicated by numbers 0, 1-3, 4-6, and 7-10. The validity and reliability of this instrument have been confirmed in previous studies by Williamson and Hoggart [13].

Intervention

Sampling was carried out using convenience method. Sample size was estimated at least 70 people in each group based on the following formula, taking into account the frequency of nausea and vomiting (median= 29.3% and paramedian method= 10.78%) based on the previous study by Pourbahri et al. (11), considering 95% confidence interval and a test power= 80%. Therefore, a total of 140 people were included in the present study.

($Z_{1-\beta}$=1.96 = $Z_{1-\alpha/2}$= 0.84)

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 [P_1(1-P_1) + P_2(1-P_2)]}{(P_1 - P_2)^2}$$

After coordination with the officials of hospital and operating room, all possible patients were found. Then the patients were evaluated for the inclusion criteria. First, 140 people were selected using convenience sampling method, and patients were divided into two groups of median and paramedian based on a table of simple random numbers (median group=odd numbers and paramedian group= even numbers). Sampling was then continued until finding 70 eligible patients in each group. The median method (mid-line) is technically simpler and the needle passes through a less sensitive tissue structure, thus requiring less local anesthesia solution to ensure patient comfort. Paramedian method (lateral) is more suitable in challenging cases where the space between the vertebrae is narrow or it is difficult to bend the patient's back. With regard to the midline method, the needle is inserted from the upper edge of the spinous process of the lower vertebra of the selected space. However, the insertion site in the paramedian is one centimeter away from the midline. After providing two intravenous routes using 18-gauge catheter, patients received 500 cc of Ringer's serum before anesthesia. The basic monitoring included electrocardiography, blood pressure, arterial blood oxygen saturation percentage and heart rate. Hemodynamic parameters and early vital signs of all patients were measured and recorded. Then the patients were placed in a sitting position. To induce spinal anesthesia, 0.5% marcaine (10 mg) was injected into the lumbar intervertebral space 4 and 5 by the anesthesiologist using a 25-guage quincke needle in both median or paramedian groups. Patients were postioned in 15° left-lateral tilt position to prevent abdominal vena cava compression syndrome. At the same time, the head was lowered by about 5-10° to achieve the required spinal height.

The sensory block height was determined and recorded by pinprick test at 5 minutes after anesthesia injection. Patients with sensory block height between T6 andT8 were returned from Trendelenburg position to simple supine and surgery was allowed to begin. Patients' vital signs and anesthesia level were recorded before spinal anesthesia after 1, 3, 5 and 10 minutes after spinal block. Systolic blood pressure (SBP)<90 mm Hg or <75% of baseline was defined as hypotension.

Ephedrine (5 mg) was injected in the case of hypotension and atropine (0.6 mg) for bradycardia (HR< 60 bpm). Intraoperative fluid intake was the same in all patients (10 ml ringer/kg). The postoperative conditions of all patients were evaluated for 7 days and once a day. Level of anesthesia, prevalence of nausea and vomiting, ephedrine and atropine use, and vital signs as well as time of discharge from the recovery room, ward, time of detachment from from bed, and time of hospital discharge, follow-up, and responses were recorded in the checklist. Moreover, in the case PDPH, treatments including hydration, painkillers and caffeine were recommended, and in case of severe PDPH lasting more than a week, the patient was recommended to go to the anesthesia clinic for epidural blood patch. The PDPH severity was assessed by the patient by pointing to a number on VAS scale. In the present study, the patient, surgeon, and project executor evaluating the results of the study were unaware of the median or paramedian approaches to anesthesia. (Figure 1)

Ethical Considerations

The present study has been approved by the Ethics Committee of Urmia University of Medical Sciences under the Ethics Code (IR.UMSU.REC.1398.443). The protocol of the present study has been registered in the Iranian Registry of Clinical Trials (IRCT) (IRCT registration number: IRCT20170516033992N5). Written and oral consent was received from all participants. Participants are assured that their information will remain confidential. The CONSORT checklist was used to report the study.

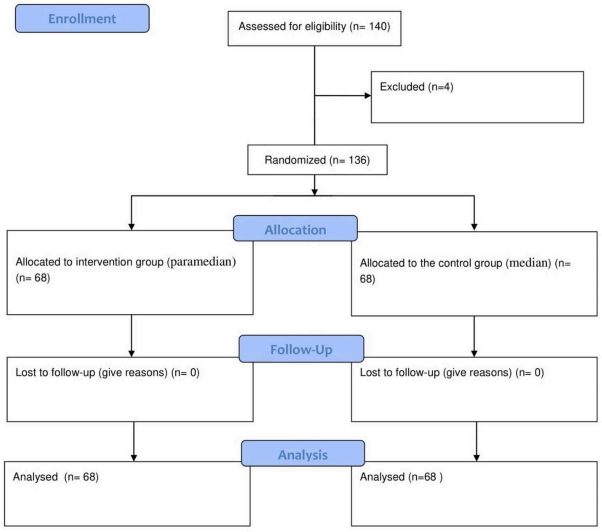

Figure 1. CONSORT 2010 Flow Diagram

Data Analysis

Data analysis was carried out using SPSS Ver. 22. Descriptive statistical tests ((mean, standard deviation, frequency and percentage) were used for quantitative variables and analytical tests (chi-square) were used to describe the demographic characteristics of the participants. Kolmogrove-Smirnov test was used to evaluate the distribution of data. To compare the pain level in the intervention and control groups, independent t-test and chi-square were used. P-value<0.05 was considered as statistically significant level in all tests.

Results

A total of 136 patients were enrolled in the present study. The mean ± SD of patients' age was 27.81 ±5.92 years. There was no statistically significant difference between the two groups of intervention and control in terms of demographic characteristics, including age. The prevalence of hypotension, bradycardia and nausea and vomiting were 24.3%, 23.6% and 24.3%, respectively. The need for atropine and ephedrine in 22.1 and 22.9 of cases, respectively.

There was no statistically significant relationship between the two groups in terms of prevalence of bradycardia and hypotension and nausea and vomiting, need for drug injection and level of anesthesia. Moreover, anesthesia in most patients (75.6%) was performed at T5 level. Results also showed that 14 patients had PDPH after surgery. The severity of PDPH in median and paramedian groups was 4.14 ± 0.9 and 4.81. 0.9, respectively. The results also showed no significant relationship between median and paramedian groups in terms of the prevalence and severity of PDPH (p = 0.9). (Table 1).

Chi-square test was also used to investigate the complications due to the level of anesthesia. Hypotension, bradycardia and vomiting nausea were significantly higher in the anesthesia level above T5 (P <0.001). However, the incidence of PDPH at the T5 anesthesia was more than the anesthesia level above T5, but this difference was not statistically significant (P = 0.28). (Table 2)

Group / Variable	Intervention (n=68) Median	Placebo Paramedian (n=68)	Total (n=136)	P-value
Age (years)	28.69±5.89	**26.94±5.85**	27.81±5.92	0.079
Hypotension	18 (25.7)	16(22.9)	34(24.3)	0.84
Bradycardia	17 (24.3)	16(22.9)	33(23.6)	0.9
Nausea and vomiting	18(25.7)	16(22.9)	34(24.3)	0.84
Need to drugs Atropine Ephedrine	15(21.4) 16(22.9)	16(22.9) 16(22.9)	31(22.1) 32(22.9)	0.9
Level of spinal anesthesia Higher than T5 T5	18(25.7) 52(74.3)	16(22.9) 54(77.1)	34(24.3) 106(75.7)	0.84
Prevalence of PDHD	7(10)	7(10)	14(10)	0.019
Severity of PDHD (M±SD)	4.14±0.9	4.81±0.9	4.07±0.82	0.012

Table 1: Demographic characteristics, prevalence and severity of PDHD among patients

Anesthesia level / Complications	**T5**		**Above T5**		**Total**		**P-Value**
	Number	**Percent**	**Number**	**Percent**	**Number**	**Percent**	
Hypotension	0	0	34	100	34	24.3	0.001
Bradycardia	0	0	33	97.1	33	23.6	0.001
Nausea and vomiting	0	0	34	100	34	24.3	0.001
PDPH	12	11.3	2	5.9	14	10	0.28

Table 2. Comparison of complications in terms of anesthesia level

Discussion

PDPH is the most common complication of neuraxial anesthesia and can occur at any time after dural puncture. The aim of the present study was to compare the effect of median and paramedian methods on the incidence of PDPH in cesarean section. In the present study, the mean age of participants was 27.81 years. The mean age of patients in the study conducted at Shahid Beheshti University by Sadeghi et al., the mean age of patients was 29.6 years, which is more but close to the present study, and there was also no significant difference between the median and paramedian groups in terms of mean age [14]. In Pourbahri et al.'s study, the mean age of the studied population was 29 years, which is more than our study [15]. In this study, consistent with the present study, there was no significant difference between the median and paramedian groups in terms of mean age. In the present study, the anesthesia was performed at the T5 level in 106 patients (75.7%) and there was no significant difference between the two groups in terms of the level of anesthesia. Contrary to the results of the present study, Pourbahri et al. found that the frequency of anesthesia level induced at T4 was significantly higher than the median group. Conversely, the level of anesthesia (T6) in the median group, was significantly lower than the paramedin group. The level of sensory block varies depending on various factors such as drug dose, patient's cerebrospinal fluid volume, old age, pregnancy, patient's position, patient's sex, needle type, technique, procedure, and level of spinal anesthesia [15]. In the present study, different levels of anesthesia can be affected by each of these factors. The present study showed no statistically significant difference between median and paramedian groups in terms of hypotension, bradycardia and nausea and vomiting. Consistent with the present study, Sadeghi et al. found no statistically significant difference between the two groups in terms of mean ± SD of pulse and systolic and diastolic blood pressure before and after spinal anesthesia [14]. Consistent with the present study, Pourbahri et al. also found no statistically significant difference between the median and paramedian groups in terms of incidence hypotension and bradycardia, but the incidence of nausea and vomiting was significantly higher in the median group [15]. Hypotension can occur for a variety of reasons, including anesthesia level above 5th thoracic vertebra, age over 40, basal blood pressure< 120 mm Hg, spinal anesthesia combined with general anesthesia, and the addition of phenylephrine to the anesthetic. Statistical analysis in the present study showed that the incidence of nausea and vomiting, bradycardia and hypotension in people under anesthesia above T5, was clearly higher than people who had anesthesia at T5 level. In the present study, among 140 patients, the prevalence of hypotension, bradycardia, and nausea and vomiting was 24.3% (n=34), 23.6% (n=33), and 24.3%patients (n=34), respectively. The present study reported PDPH among 7 patients (10%) in the median group and 7 patients (10%) in the paramedian group, which was not statistically significant between the two groups. Sadeghi et al., also reported PDPH 6 patients in each median and paramedian group, and there was no statistically significant difference between the two groups in this regard [14]. Pourbahri et al. reported that overall incidence of PDPH was 13.3%, which is slightly higher than the present study, but in this study, consistent with the current study, there was no significant difference between the two groups in terms of PDPH incidence [15]. Karimi et al., reported in their study that the incidence of poat-spinal anesthesia PDPH was 10%, which is the same as in the present study [16]. In this study, the incidence of PDPH in the median and paramedian groups was 7.75% and 8.75%, respectively, but there was no statistically significant difference between the two groups. The above study was performed on patients who were candidates for orthopedic surgery, and the results showed that the incidence of PDPH among women was significantly higher than men. This lack of difference between the median and paramedian groups in terms of incidence of PDPH can be attributed to the same puncturing of longitudinal dural fibers. That is despite the different insertion angles, due to being cylindrical, the

needle insertion is probably the same [14]. Inconsistent with the present study, Janik et al. reported that PDPH incidence in the paramedian group was significantly higher than the median group [17]. This study was performed on patients who had undergone prostate surgery, and this difference may be due to differences in sex and the mean age of the subjects. Haider et al. carried out a study on 50 patients who underwent surgery for various reasons [18].

They showed a significant difference between the median and paramedian to groups in terms of PDPH incidence, so that the PDPH incidence in the paramedian method is clearly reduced, which is inconsistent with the present study.

The main cause of PDPH is still unknown, but several factors, including the patient's age and sex, are involved. The most important cause of PDPH is CSF leakage following dural puncture.

The median method is performed by passing the needle through the supraspinal, intraspinal, and flavum ligaments, but in the paramedian method, the needle does not pass through the supraspinal and intraspinal ligaments and enters the intervertebral space directly through the paraspinal muscles [19]. Paramedian is a more convenient method considering the comfortable patient position, especially in elderly patients. It is difficult to position people with sclerotherapy and degenerative changes in the spine and intervertebral space in the median method.

The most important limitations of the present study included: This was a single-center study that was performed on only a limited number of patients.

Conclusion

The results of the present study showed no significant difference between median and paramedian methods in terms of PDPH incidence, therefore, paramedian method can be used in patients who cannot be easily given median position. Due to the small sample size of the present study, in order to achieve more accurate results, further studies with a larger sample size are recommended.

Authors' contribution

All authors contributed equally. All authors read and approved the final version of the manuscript.

Conflict of interest

None

Sources of funding for research and publication

None

Acknowledgment

We would like to thanks from clinical research development unit of Imam Khomeini Hospital, urmia university of medical science, Urmia, Iran

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