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ORIGINAL ARTICLE

Paramedian versus midline approach of spinal anesthesia: a systematic review and meta-analysis with trial sequential analysis

Ka Ting Ng[1] · Wei En Lim[2] · Wan Yi Teoh[3] · Ina Ismiarti Shariffuddin[1] · Lian Kah Ti[4] · Mohd Fitry Bin Zainal Abidin[1]

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Abstract

Purpose Midline approach of spinal anesthesia has been widely used for patients undergoing surgical procedures. However, it might not be effective for obstetric patients and elderly with degenerative spine changes. Primary objective was to examine the success rate at the first attempt between the paramedian and midline spinal anesthesia in adults undergoing surgery.

Methods Databases of MEDLINE, EMBASE, and CENTRAL were searched from their starting date until February 2023. Randomized clinical trials (RCTs) comparing the paramedian versus midline approach of spinal anesthesia were included. The primary outcome was the success rate at the first attempt of spinal anesthesia.

Results Our review included 36 RCTs ($n=5379$). Compared to the midline approach, paramedian approach may increase success rate at the first attempt but the evidence is very uncertain (OR: 0.47, 95% CI 0.27–0.82, $\rho=0.007$, level of evidence:very low). Our pooled data indicates that the paramedian approach likely reduced incidence of post-spinal headache (OR: 2.07, 95% CI 1.51–2.84, $\rho<0.00001$, level of evidence:moderate). The evidence suggests that the paramedian approach may result in a reduction in the occurrence of paresthesia (OR: 1.61, 95% CI 1.06–2.45, $\rho=0.03$, level of evidence:low).

Conclusions Our meta-analysis of 36 RCTs showed that paramedian approach may result in little to no difference in success rate at the first attempt owing to its very low level of evidence. However, given the low level of evidence and studies with small sample sizes, these findings need to be interpreted with caveat.

Clinical Trial Registration Number: CRD42023397781.

Keywords Anesthesia · Spinal · Spinal puncture · Post-dural puncture headache · Paresthesia · Back pain

Introduction

The midline approach is the most used method for spinal anesthesia among anesthetists [1]. However, it can be technically challenging for obstetric patients who are unable to fully bend their spine [2], elderly patients with

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✉ Mohd Fitry Bin Zainal Abidin
mohdfitry@yahoo.co.uk

Ka Ting Ng
katingng1@gmail.com

Wei En Lim
weien752@gmail.com

Wan Yi Teoh
twy1063@hotmail.com

Ina Ismiarti Shariffuddin
ismiarti@ummc.edu.my

Lian Kah Ti
anatilk@nus.edu.sg

[1] Department of Anesthesiology, Faculty of Medicine, University of Malaya, Jalan Universiti, 50603 Kuala Lumpur, Malaysia

[2] Department of Anesthesiology, University of Glasgow, Glasgow G12 8QQ, UK

[3] Department of Anesthesiology, University of Liverpool, Liverpool L69 3BX, UK

[4] Department of Anesthesiology, National University of Singapore, Singapore 119077, Singapore

degenerative calcified spine changes [3, 4], and patients suffering from spinal deformities such as kyphoscoliosis and ankylosing spondylitis [5]. In the event of unsuccessful midline spinal anesthesia, the paramedian approach is normally utilized [6] to overcome calcified ligaments or narrower facet joints to reach subarachnoid space for drug delivery [7].

In recent years, several studies have suggested the application of paramedian approach in spinal anesthesia to improve the success rate at the first attempt [3, 8, 9] and minimize postoperative complications, namely incidence of post-dural puncture headache and backache [10]. Post-dural puncture backache is believed to be caused by needle punctures causing trauma to the ligaments, leading to paraspinous muscles undergoing reflex spasm and inflammation [11]. According to the findings of several studies, the association of fewer attempts of dural punctures in the paramedian group would lead to a lower incidence of post-dural headache and blood in the needle [12, 13]. However, several published RCTs reported conflicting findings on the efficacy and safety profiles of paramedian versus midline approach in spinal anesthesia [14, 15]. Thus, a robust meta-analysis is warranted prior to any further recommendation of the paramedian approach for spinal anesthesia.

We hypothesized that the paramedian approach yielded to higher success rate at the first attempt when compared to the midline approach of spinal anesthesia. The primary outcome of this systematic review and meta-analysis was to investigate the effects of midline and paramedian approaches of spinal anesthesia on the success rate at the first attempt. Secondary outcomes included the incidence of backache, incidence of post-dural headache, incidence of paresthesia, number of attempts, and incidence of blood in the needle.

Methods

This systematic review was carried out in the accordance with the Cochrane Handbook of Systematic Reviews of Interventions [16]. The study protocol was published in the database of PROSPERO (CRD42023397781) prior to the commencement of systematic search. The review questions were developed based on the Population (adult surgical patients), Intervention (paramedian approach), Comparison (midline approach), and Outcomes (PICO) framework. The primary outcome of this study was the success rate at the first attempt; the definition of primary outcome is illustrated in the Supplementary Table S1. Secondary outcomes included the incidence of backache (24-h, 72-h, and 7-day after surgery), incidence of post-spinal headache (24-h, 48-h, 72-h, and 7-day after surgery), incidence of paresthesia, number of attempts, and incidence of blood in the needle.

Literature search and study identification

The following databases were utilized: MEDLINE, EMBASE, and CENTRAL (Cochrane Controlled Register of Trials). Searches were conducted systematically for the relevant literature from its respective starting dates until 20th February 2023. Two main trial registries, namely ClinicalTrials.gov and World Health Organization International Clinical Trials Registry Platform were searched for any ongoing or unpublished studies. The search terms and strategy are listed in the Supplementary Table S2. Eligibility criteria were shown as below:

1. Randomized Controlled Trials only
2. Midline approach of spinal anesthesia
3. Paramedian approach of spinal anesthesia
4. Adult patients undergoing all types of surgery, regardless of reported outcomes

No restrictions were applied regarding duration of the study and language of publication. Trials published as conference abstracts, case reports, case series, observational studies, letters to editors, and non RCTs were excluded. Trials that compared midline and paramedian interventions of lumbar puncture in cadaveric or animal studies were also excluded. The bibliographies of all the included RCTs were manually searched for any papers that fulfill the inclusion criteria. Authors of the relevant papers were contacted at least three times for any incomplete data.

Study selection and data extraction

The review was reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement 2020 [17, 18]. Two screeners (WT and WL) were given a briefing by the third author (KN) for the inclusion and exclusion criteria. Titles and abstracts were screened for eligibility criteria by two authors (WT and WL) independently. All studies that underwent screening were classified by 3 main categories, namely "Yes", "No", and "Maybe" by two authors (WT and WL) independently. Studies categorized as "No" were excluded. With regards to studies coded with "Yes", full text articles were downloaded and screened independently by both authors (WT and WL). For articles classified as "maybe", these articles were discussed with the principal author (KN). The final selection of all the included RCTs were discussed and agreed among all the three authors (WT, WL, KN). The clinical characteristics of all included studies were recorded independently by two authors (WT and WL) using an online data extraction form. Any conflicts were resolved by the third author (KN).

Risk of bias assessment

All the included RCTs were evaluated for the risk of bias with the Cochrane Collaboration Risk of Bias Assessment Tool by two authors (WT and WL) independently [19]. Any conflicts were consulted with the third author (KN) until an agreement was achieved among the authors. The summary of findings and the evaluation on the certainty of evidence were carried out independently by two authors (WT and WL) with the GRADEpro/GDT software [20]. Any disagreements or conflicts were discussed with the principal author (KN).

Summary measures and synthesis of results

Review Manager version 5.4 (The Cochrane Collaboration, Copenhagen, Denmark) was utilized to conduct statistical meta-analysis [21]. All ρ values were two-tailed, with statistical significance denoted as less than 0.05. For dichotomous outcomes, the odd ratios (OR) and 95% confidence interval (CI) were reported. For continuous outcomes, mean difference (MD) and 95% confidence interval (CI) were calculated. The *I*-square (I^2) test was used as a tool to evaluate heterogeneity of the pooled outcomes, where the values of < 40%, 40–60%, and > 60% were indicated as low, moderate, and high heterogeneity, respectively. A fixed-effect model was used to sum up the estimates of the primary and secondary outcomes. If high heterogeneity ($I^2 > 60\%$) was observed, a random-effect model was used. When the values were reported as median or interquartile range, these values were converted to mean and standard deviation [22]. Publication bias was assessed using funnel plots graphically for any asymmetry [23]. Subgroup analysis (obstetrics and non-obstetrics population) and sensitivity analysis (low risk of bias trials) of the primary outcome were conducted to explore the high degree of heterogeneity.

Trial sequential analysis

Trial sequential analysis was performed on the primary outcome (success rate at the first attempt) to assess the risk of random error and multiplicity phenomenon due to repeated significant testing in meta-analyses [24]. The required meta-analysis information size and adjusted significance thresholds were calculated based on a two-sided sequential analysis-adjusted random effects model with 5% risk of type 1 error and power of 80%.

Results

The study selection process is demonstrated in the PRISMA diagram (Fig. 1). Our search generated 172 articles for title and abstract screening. Of all, 70 articles were retrieved for full text screening. Applied to the inclusion and exclusion criteria, 44 articles were excluded. Thirty-six RCTs ($n = 5379$) were included as the final included studies. Searching of 2 trial registries identified 6 ongoing studies and 2 completed but unpublished studies (Supplementary Table S3) whilst the list of excluded studies is illustrated in the Supplementary Table S4.

The clinical characteristics of all included studies are illustrated in Table 1. The definition of paramedian approach for all the included studies was puncture point 1–1.5 cm lateral to the midpoint of spinous process. Among all the included studies, fourteen trials were obstetrics surgery [12, 13, 25–36] and the rest were non-obstetrics surgery [9, 37–39], which included lower limb surgery [40, 41], abdominal surgery [8, 10, 42–44], orthopedic surgery [45–52], urology surgery [3, 14, 15, 53]. The mean body mass index (BMI) ranged 20–31 kg/m^2 in the midline group and 23–39 kg/m^2 in the paramedian group. In addition, the mean age of the midline group and paramedian group ranged 19–90-year-old and 22–89-year-old, respectively. The year of publication for all the included studies ranged from 2005 to 2022 with sample size ranging from 40 to 655 patients. Data analysis of the primary and secondary outcomes are shown in Table 2. A list of summary findings and level of evidence is illustrated in Table 3. In the overall risk of bias assessment, 22 studies were assessed as low risk of bias, except for 14 studies were of unclear [14, 32, 39, 40, 43, 53] and high risk of bias [3, 27, 35, 38, 48, 50, 52, 54] due to lack of blinding of participants or personnel and lack of blinding of outcome assessors (Supplementary Table S5).

Primary outcome: success rate at the first attempt

A combination of 13 trials [3, 8, 9, 25–28, 38, 39, 41, 43, 48, 50, 52] investigated the effect of midline versus paramedian approach on the success rate at the first attempt of spinal anesthesia. Our pooled data demonstrated that the paramedian group was associated with higher success rate of spinal anesthesia at the first attempt as compared to the midline group, which was statistically significant (studies = 13, $n = 1573$, OR: 0.47, 95% CI 0.27–0.82, $\rho = 0.007$, level of evidence:very low, Fig. 2). However, the evidence is very uncertain about the effect of paramedian approach on the success rate of dural puncture at first attempt. The level of evidence is very low owing to risk of bias, inconsistency, and strong suspicion of publication bias. In addition, the degree of heterogeneity was evaluated as high ($I^2 = 76\%$) across all the included trials. Funnel plot showed asymmetry, which indicated publication bias. The trial sequential analysis of a diversity-adjusted required information size for success rate at the first attempt was 4491 patients (Fig. 3). At the current meta-analysis, with 1573 patients, only 35% of the required information size was achieved to detect or reject a relative

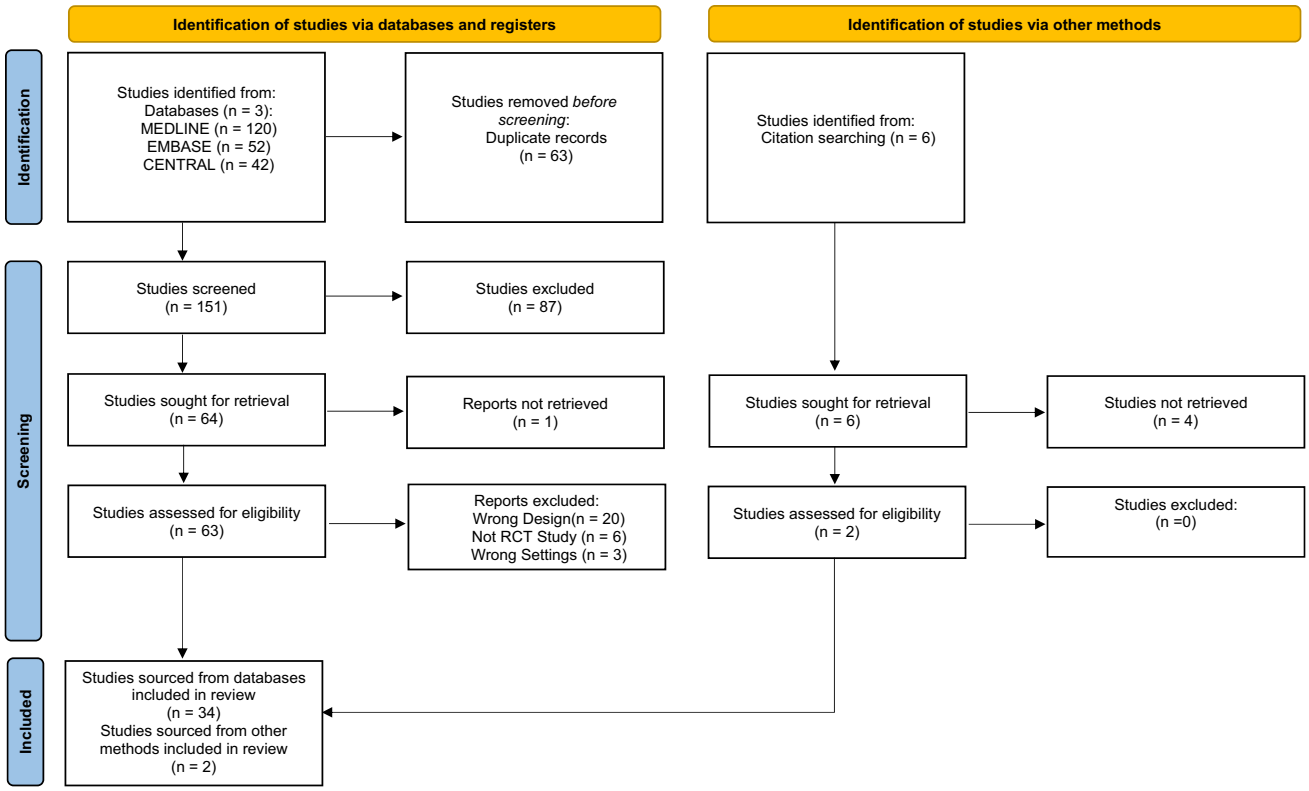

Fig. 1 Prisma diagram of systematic review. A total of 36 studies were included

risk reduction of 10.8%, based on a 5% risk of Type 1 error (two-sided), a power of 80%, incidence in the control arm of 71.6% and incidence of intervention arm of 79.3% with a model variance-based heterogeneity correction (Fig. 3).

In subgroup analysis of obstetrics and non-obstetrics studies, it demonstrated that the paramedian group yielded to higher success rate at the first attempt in the population of obstetrics patients (studies = 4, $n = 510$, OR: 0.54, 95% CI 0.33–0.89, $\rho = 0.02$, $I^2 = 0\%$) but not the non-obstetrics population (studies = 9, $n = 1063$, OR: 0.47, 95% CI 0.22–1.00, $\rho = 0.05$, $I^2 = 83\%$). Sensitivity analysis of low risk of bias studies revealed higher success rate at the first attempt for the paramedian group (studies = 7, $n = 820$, OR: 0.41, 95% CI 0.28–0.61, $\rho < 0.00001$, $I^2 = 0\%$).

Secondary outcomes: incidence of post-spinal headache, incidence of paresthesia, incidence of backache, number of attempts, incidence of blood in the needle

A total of 6 RCTs [10, 14, 15, 26, 35, 37] with a total of 1087 patients evaluated the effects of midline versus paramedian approach on the incidence of post-spinal backache. There are no significant differences between the paramedian group and the midline group on the incidence of backache. (OR: 1.37, 95% CI 0.77–2.45, $\rho = 0.29$, $I^2 = 52\%$, level of evidence:low). Paramedian approach in spinal anesthesia may result in little to no difference in the occurrence of post-spinal backache.

Our pooled data showed that patients who were randomized to the midline approach had a significantly higher incidence of paresthesia than the paramedian group after the spinal anesthesia (studies = 12, $n = 1556$, OR: 1.61, 95% CI 1.06–2.45, $\rho = 0.03$, $I^2 = 16\%$, level of evidence:low) [8, 9, 13, 15, 28, 31, 38, 39, 41, 43, 48, 52]. Evidence suggests paramedian approach may reduce the incidence of paresthesia.

In terms of the incidence of headache, a combination of 17 RCTs with 4704 patients [9, 10, 12, 13, 25, 26, 28–30, 32, 36, 39–43, 45] showed that the paramedian group was associated with significantly lower incidence of headache than the midline group (OR: 2.07, 95% CI 1.51–2.84, $\rho < 0.00001$, $I^2 = 11\%$, level of evidence:moderate). In terms of certainty of evidence, paramedian approach likely results in a large reduction in the incidence of headache.

Ten RCTs [3, 27, 28, 38, 48–53] with 1129 patients recorded the number of attempts in performing spinal anesthesia. Our pooled analysis denoted that no significant differences between the midline and paramedian groups. (MD:0.02, 95% CI −0.22 to 0.27, $\rho = 0.84$, level of evidence:very low). Statistical heterogeneity ($I^2 = 90\%$) was high across all the included studies. The level of evidence is very low because of risk of bias, inconsistency, and publication bias. Paramedian approach in spinal anesthesia may

Table 1 Characteristics and intra-operative data of patients receiving paramedian approach or midline approach of spinal anesthesia

References	Category/type of surgery	Study of design	Type of anesthesia drug	Volume of drug	Total sample size	Paramedian distance
Haider et al. [42]	Abdominal	RCT	0.75% Hyperbaric Bupivacaine	–	50	–
Rabinowitz et al. [46]	Orthopedics	RCT	1% Lidocaine Without Epinephrine	–	40	1 cm lateral to the midline of the L4–5 Interspace
Mosaffa et al. [45]	Orthopedics	RCT	0.5% Isobaric Marcaine	4 mL	150	1 cm lateral and 1 cm caudal to the spinous process
Sohail et al. [8]	Abdominal or Orthopedics	RCT	0.75% Hyperbaric Bupivacaine	2.0 mL	100	2 cm lateral to inferior aspect of superior spinous process of the desired level
Sheybani et al. [34]	Obstetrics	RCT	0.5% Marcaine	15 mg	140	1 cm lateral and below the caudal edge of spinous process
Bapat et al. [39]	All surgery	RCT	0.5% Heavy Bupivacaine	2.5–3.5 mL	100	–
Behery et al. [13]	Obstetrics	RCT	0.5% Heavy Bupivacaine	2.2 mL	120	–
Montasser [12]	Obstetrics	RCT	0.5% Hyperbaric Bupivacaine	2.4–3 mL	180	–
Srinivasan et al. [48]	Orthopedics	RCT	1% Lidocaine	2.5 mL	100	–
Ali et al. [41]	Lower limb	RCT	0.5% Heavy Bupivacaine	2.5-3.5 mL	60	–
Batra et al. [35]	Obstetrics	RCT	2% Xylocaine	5 mL	100	1.5 cm lateral to the caudal part of the spinous process of L4
Firdous et al. [36]	Obstetrics	RCT	0.75% Bupivacaine	1.6 mL	120	–
Nisar et al. [32]	Obstetrics	RCT	0.75% Bupivacaine	1.5 mL	100	–
Singh et al. [43]	Abdominal	RCT	0.5% Heavy Bupivacaine	2.5-3.5 mL	100	1 cm lateral to the midline
Singh et al. [10]	Abdominal	RCT	–	–	100	–
Bansal et al. [25]	Obstetrics	RCT	0.5% Hyperbaric Bupivacaine	1.8 mL	200	–
Batova et al. [33]	Obstetrics	RCT	0.5% Hyperbaric Bupivacaine	0.06–0.07 mg cm-1 of patient height	655	–
Khajavi et al. [14]	General and Urology	RCT	0.5% Hyperbaric Bupivacaine	Depends on duration of surgery	220	–
Shehzad et al. [49]	Orthopedics	RCT	0.75% Hyperbaric Bupivacaine	2.0 mL	170	–
Srinivasan et al. [48]	Orthopedics	RCT	0.5% Hyperbaric Bupivacaine	3.5 mL	120	–
Gurulingaswamyl et al. [26]	Obstetrics	RCT	0.5% Heavy Bupivacaine	10 mg	100	1 cm lateral and caudal to the spinous process of L3
Rizk et al. [38]	All surgery	RCT	0.5% Bupivacaine	12–15 mg	180	–
Uluer et al. [29]	Obstetrics	RCT	Hyperbaric Bupivacaine	10–15 mg	200	–
Dadkhah et al. [15]	Urology	RCT	0.5% Bupivacaine	2.5 cc	157	1 cm inferior and 1 cm lateral to the spinous process

Table 1 (continued)

References	Category/type of surgery	Study of design	Type of anesthesia drug	Volume of drug	Total sample size	Paramedian distance
Kartal et al. [53]	Urological or Orthopedic surgery	RCT	–	–	86	1 cm lateral and 1 cm caudal from the planned vertebral space point
Kumar et al. [27]	Obstetrics	RCT	0.5% Bupivacaine	15 mg (3 mL)	110	–
Lee et al. [37]	All surgery	RCT	0.5% Lidocaine	3 mL	223	–
Nasir et al. [40]	Lower limb or Lower abdominal surgery	RCT	0.5% Heavy Bupivacaine	2.5 mL	214	2 cm lateral to the inferior aspect of the superior spinous process
Aswathy and Radhika [9]	All surgery	RCT	0.5% Bupivacaine	2.5-3.5 mL	160	1 cm lateral to the inferior spinous process
Bano et al. [51]	Orthopedics or Abdominal	RCT	0.5% Heavy Bupivacaine	3 mL	120	1 cm lateral to midpoint
Karami et al. [30]	Obstetrics	RCT	0.5% Marcaine	10 mg	136	–
Kumari et al. [28]	Obstetrics	RCT	–	–	100	–
Mahrous et al. [13]	Obstetrics	RCT	0.5% Hyperbaric Bupivacaine	2 mL	296	–
Arslan et al. [47]	Orthopedics	RCT	Heavy Bupivacaine	10–15 mg	110	1 cm lateral and 1 cm caudal distance of the interspinous space at L3-L4 Level
Park et al. [50]	Orthopedic	RCT	0.5% Hyperbaric Bupivacaine	–	112	–
Zeng et al. [3]	Urology	RCT	0.75% Ropivacaine	2 mL (0.2 mL/s)	150	1.5 cm lateral to midline

have little to no effect on the number of attempts, but the evidence is very uncertain.

A combination of 10 RCTs [8, 9, 28, 35, 38, 39, 43, 47, 48, 52] ($n=1117$) showed no significant difference between the midline and paramedian groups on the incidence of blood in the needle (OR: 0.66, 95% CI 0.42–1.04, $\rho=0.07$, $I^2=0\%$, level of evidence:moderate). With regards to quality of evidence, paramedian approach likely results in little to no difference in the incidence of blood in the needle.

Discussion

To the best of our knowledge, this is the first systematic review and meta-analysis that examined the efficacy and safety profile of the midline versus paramedian approach in performing spinal anesthesia. Our pooled result demonstrated that the paramedian approach was associated with higher success rate at the first attempt and lesser incidence of post-spinal headache and incidence of paresthesia as compared to the midline approach. The level of evidence ranged from very low to moderate due to indirectness, imprecision, inconsistency, and publication bias.

It is believed that paramedian approach is carried out at the location nearer to the facet joints and spinal nerves, which contributes to higher success rate at achieving subarachnoid block in narrow interspaces [8]. In the subgroup analysis of obstetrics population only, our findings found that the paramedian group was associated with higher success rate at the first attempt in puncturing ligamentum flavum. Our finding was supported by a few studies conducted by Bansal, Kumar, and other colleagues [25, 27, 28] who recruited a total of 1673 pregnant patients and concluded the paramedian group was associated with higher success rate at the first attempt. However, the evidence is very uncertain about the effect of paramedian approach on this primary outcome and the sample size of obstetrics patients in our pooled data was relatively small. Our trial sequential analysis was not conclusive with less than 50% of required information size was achieved in this meta-analysis. Thus, this finding is premature, and it cannot be generalized to all the obstetrics patients who required spinal anesthesia.

According to the International Headache Society [55], the definition of post-dural puncture headache is headache

Table 2 Data analysis of primary and secondary outcomes

No.	Outcomes	Trials/data sets	Total sample size (*n*)	I^2 (%)	MD/OR (95% CI)[a]	ρ value
1	Success rate at first attempt (main analysis)	13	1573	76	0.47 (0.27, 0.82)	0.007
1.1	Success rate of first attempt—subgroup analysis by type of surgery					
	Non-obstetrics	9	1063	83	0.47 (0.22, 1.00)	0.05
	Obstetrics	4	510	0	0.54 (0.33, 0.89)	0.02
1.2	Success rate of first attempt—sensitivity analysis					
	Low risk of bias	7	820	0	0.41 (0.28, 0.61)	< 0.00001
2	Incidence of backache (main analysis)	9	1087	52	1.37 (0.77, 2.45)	0.29
2.1	Incidence of backache—subgroup analysis by time-points (main analysis)					
	24-h	3	289	0	1.00 (0.55, 1.80)	1.00
	72-h	2	359	0	0.76 (0.44, 1.31)	0.33
	7-day	4	439	0	5.13 (2.03, 12.99)	0.0006
3	Incidence of paresthesia	12	1556	16	1.61 (1.06, 2.45)	0.03
4	Incidence of post-spinal/post-dural headache (main analysis)	21	4704	11	2.07 (1.51, 2.84)	< 0.00001
4.1	Incidence of post-spinal/post-dural headache—subgroup analysis by time points					
	24-h	5	1464	18	2.18 (1.17, 4.06)	0.01
	48-h	7	1374	0	3.68 (1.45, 9.38)	0.006
	72-h	5	1230	17	2.27 (0.99, 5.19)	0.05
	7-day	4	636	52	1.66 (1.05, 2.63)	0.03
5	Number of attempts	9	1129	90	0.02 (−0.22, 0.27)	0.84
6	Incidence of blood in needle	10	1117	0	0.66 (0.42, 1.04)	0.07

Values are mean difference (MD)/odds ratio (OR) and 95% confidence interval

[a]MD, mean difference; OR, odds ratio; CI, confidence interval

that develops less than 7 days after a spinal puncture procedure, which happens or worsens in less than 15 min after the patient in an upright position. To date, the pathophysiology of post-spinal puncture headache is not entirely established. However, the most plausible explanation is the loss of cerebrospinal fluid through a tear in the dura mater, resulted in low cerebrospinal fluid pressure and post-spinal headache [55]. Our findings showed that the paramedian approach was significantly associated with lower incidence of post-spinal headache and evidence suggest that this approach in spinal anesthesia probably results in a reduction in the occurrence of post-spinal headache. It is believed that the paramedian approach involves needle perforation of the dura and arachnoid layer via paraspinous muscle without piercing the supraspinous ligament and interspinous ligament at different angles. According to the Oxford Handbook of Anesthesia [56], in comparison with the midline approach that inserts the needle with a 15-degree cephalad angulation, paramedian approach will require the spinal needle to be inserted 1–2 cm lateral to upper border of the spinous process, then withdraw carefully before reinserting at 30 degrees cephalad, reaching the interlaminar space to achieve subarachnoid block. It is believed that the paramedian approach that has a larger angle of penetration could theoretically create a flap valve [40] that could seal the perforation in dura mater, thus preventing the leakage of cerebrospinal fluid, and lowering the incidence of post-dural puncture headache.

Although the exact mechanism of paresthesia is unknown, it is believed that paresthesia is produced by the contact of the tip of the needle with the spinal nerve root found in the subarachnoid space [57, 58]. Various factors could influence the incidence of paresthesia such as the direction of the bevel, the spinal needle design, and the technique of puncture [59]. Incidence of blood in the needle is a measure of the extent of damage to any radicular vessels and adjacent soft tissues around the targeted region during the dural puncture procedure [60]. Several studies highlighted that the midline approach was superior in reducing the incidence of blood in the needle as the chance of crossing or damaging a blood vessel is lower as compared to the paramedian method [8, 44]. However, our review did not show any significant difference in the incidence of blood in the needle between the paramedian and midline approach during spinal anesthesia and evidence indicates paramedian approach likely results in little to no difference in the number of episodes of blood in the needle. Regarding the number

Table 3 Level of evidence

Certainty assessment							№ of patients		Effect		Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Paramedian	Midline	Relative (95% CI)	Absolute (95% CI)	
Success rate at first attempt											
13	Randomised trials	Serious[a]	Serious[b]	Not serious	Not serious	Publication bias strongly suspected[c]	620/782 (79.3%)	566/791 (71.6%)	OR 0.47 (0.27–0.82)	174 fewer per 1000 (from 311 to 42 fewer)	⊕◯◯◯ very low
Incidence of paresthesia											
12	Randomised trials	Serious[a]	Not serious	Not serious	Not serious	Publication bias strongly suspected[c]	39/735 (5.3%)	63/821 (7.7%)	OR 1.61 (1.06–2.45)	41 more per 1000 (from 4 to 92 more)	⊕⊕◯◯ low
Number of attempt											
11	Randomised trials	Serious[a]	Very serious[b]	Not serious	Not serious	Publication bias strongly suspected[c]	565	564	–	MD 0.02 higher (0.22 lower to 0.27 higher)	⊕◯◯◯ very low
Incidence of blood in needle											
13	Randomised trials	Serious[a]	Not serious	Not serious	Not serious	None	46/529 (8.7%)	41/588 (7.0%)	OR 0.66 (0.42–1.04)	23 fewer per 1000 (from 39 fewer to 3 more)	⊕⊕⊕◯ moderate
Incidence of post-dural/post-spinal headache											
17	Randomised trials	Serious[a]	Not serious	Not serious	Not serious	None	68/2353 (2.9%)	128/2351 (5.4%)	OR 2.07 (1.51–2.84)	52 more per 1000 (from 26 to 86 more)	⊕⊕⊕◯ moderate
Incidence of backache											
6	Randomised trials	Serious[a]	Serious[d]	Not serious	Not serious	None	66/524 (12.6%)	86/563 (15.3%)	OR 1.37 (0.77–2.45)	45 more per 1000 (from 31 fewer to 154 more)	⊕⊕◯◯ low

The level of evidence ranged from very low to moderate for all measured primary and secondary outcomes

Author(s): Ka Ting Ng (KN)[1], Wei En Lim (WL)[2], Wan Yi Teoh (WT)[3], Ina Ismiarti Shariffuddin (SI)[1], Lian Kah Ti (LT)[4], Mohd Fitry Bin Zainal Abidin (AM)[1]

Question: Paramedian compared to midline in spinal anesthesia

Setting: Adult patients undergoing surgery

CI, confidence interval; MD, mean difference; OR, odds ratio

Explanations

[a]More than half of the studies possess high or unclear risk of bias

[b]High degree of heterogeneity

[c]Funnel plot asymmetry

[d]Moderate degree of heterogeneity

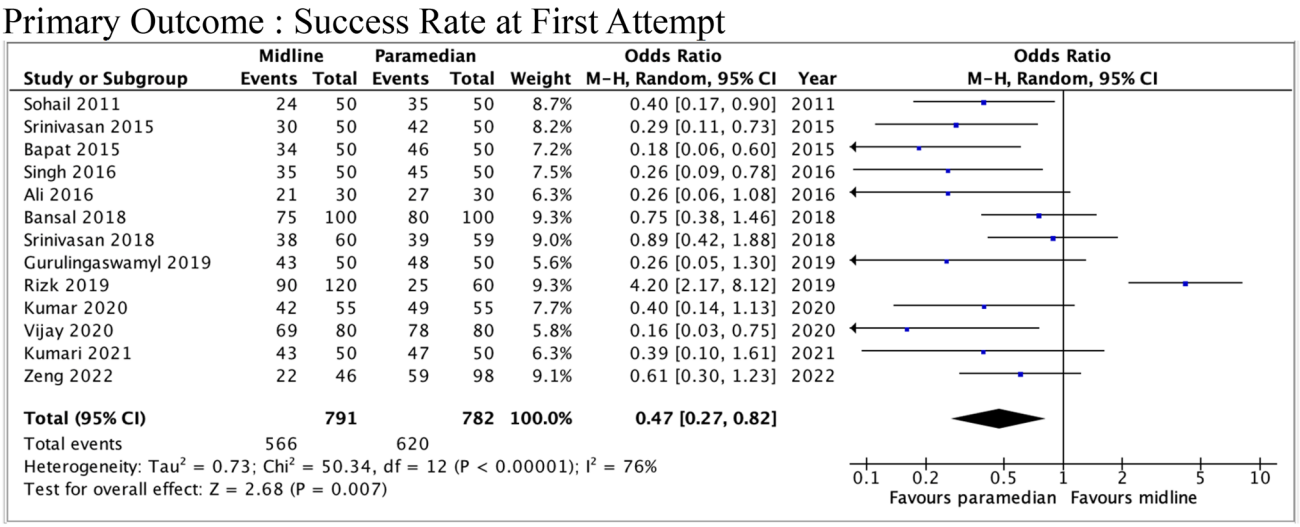

Fig. 2 Success rate of first attempt in patients receiving midline or paramedian approach of spinal anesthesia. Paramedian approach of spinal anesthesia significantly increased the success rate in comparison to the control group

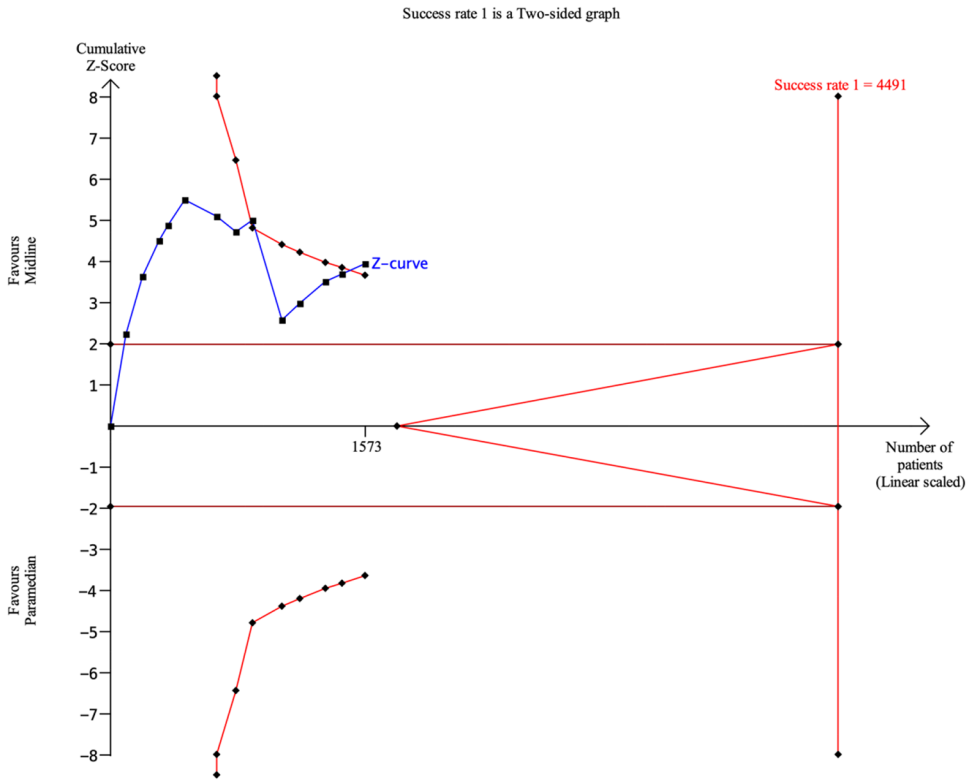

Fig. 3 Trial sequential analysis of success rate at the first attempt

of attempts, no significant difference was noted in both the paramedian and midline groups. The familiarity of paramedian approach and level of training (anesthetic trainees, registrars, or consultants) [61, 62] may introduce bias to the reported findings. According to Chen et. al, the paramedian approach may require a deeper insertion of the needle with a larger puncture angle compared to the midline approach, which makes it more challenging for anesthetics with fewer years of experience [61]. In addition, an extensive survey by Wantman and colleagues concluded that more than 90% of anesthetists applied midline approach to conduct spinal anesthesia for all types of surgeries [1]. Thus, despite the advantages of paramedian approach, anesthesiologists may be less trained to perform this technique.

There are some limitations in our systematic review. First, the majority of the included RCTs were high risk

of bias. Second, some outcomes were reported at high level of heterogeneity across studies. Third, the majority of included studies was not adequately powered for the success rate at the first attempt. Other confounding factors namely, different type/size of spinal needle and different year of anesthetic's experience of operators were unadjusted in this review [54]. However, the majority of included studies were published in the last decade and the impact of advancement in spinal needle may be less pronounced in the result of this meta-analysis.

In this systematic review and meta-analysis, paramedian approach likely resulted in no difference in the success rate at the first attempt due to very low certainty of evidence. However, low level of evidence and high degree of heterogeneity with inconclusive trial sequential analysis warrant future adequately powered RCT to examine the efficacy and safety of paramedian approach and midline approach in spinal anesthesia.

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Data availability All data on the primary outcome and secondary outcomes are included within this paper and its Supplementary Information files.

Declarations

Conflict of interest No potential conflict of interest relevant to this article was reported.

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