Challenge Journal of PERIOPERATIVE MEDICINE

Vol.2 No.3 (2024)

acute pain anesthesiology artificial intelligence decision making erector spinae evaluation evidence-based care fluid management monitoring nerve block pain management perichondral approach perioperative medicine plane blocks postoperative pain reanimation recovery program regional anesthesia remedy risk score simulation models surgery surgical optimization ultrasou[illegible]ests

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ACADEMIC PUBLISHING

ISSN 2980-292X

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Research Article

Comparison of ultrasound-guided fascia iliaca compartment block versus the combined obturator nerve and adductor canal block application in postoperative analgesia for patients undergoing arthroscopic knee surgery

Betül Sevgi Sarıkaya [a,*], Bora Bilal [a], Feyza Çalışır [a], Cengizhan Yavuz [a], Gözen Öksüz [a], Ziya Kurşun [a], Hafize Öksüz [a]

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ABSTRACT

Background: Arthroscopic knee surgery is a surgical intervention that is frequently performed by orthopedic clinics and new studies are constantly carried out by anesthetists to ensure effective pain control. This study aimed to compare the efficacy of ultrasound-guided suprainguinal fascia iliaca compartment block (FICB) versus the combined adductor canal and obturator nerve block application in terms of postoperative analgesia in patients undergoing arthroscopic knee surgery under spinal anesthesia.

Materials and Method: Sixty patients, who underwent arthroscopic knee surgery under elective conditions were included in the study. They were randomly divided into two groups, Group 1 (n=30) and Group 2 (n=30), using a lottery method. Patients operated under spinal anesthesia received ultrasound-guided suprainguinal fascia iliaca compartment block (FICB) for Group 1. The combined adductor canal and obturator nerve block for Group 2 at the end of the surgery. Intravenous patient-controlled analgesia (PCA) device containing tramadol was connected to all patients in both groups, and they were evaluated for Visual Analog Scale (VAS) scores at 0, 2, 4, 12, and 24 hours of ward follow-up. The amount of PCA used at 24 hours, additional analgesic use, development of side effects, mobilization capabilities, and satisfaction levels were assessed at the end of 24 hours.

Results: There were no significant differences between the groups in terms of demographic characteristics and the type of surgery performed ($p>0.05$). In Group 1, where fascia iliaca block was applied the block administration time was observed to be significantly shorter compared to Group 2 ($p<0.05$). No significant differences were observed between the two groups in terms of postoperative VAS scores, PCA usage amounts, incidence of side effects, postoperative mobilization abilities, and satisfaction measures ($p>0.05$).

Conclusions: Ultrasound-guided fascia iliaca compartment block alone can be effectively applied for postoperative analgesia in patients undergoing arthroscopic knee surgery, instead of combined adductor canal and obturator nerve block.

ARTICLE INFO

Article history:
Received 21 April 2024
Revised 19 September 2024
Accepted 30 September 2024

Keywords:
Fascia iliaca compartment block
Adductor canal block
Saphenous nerve block
Obturator nerve block
Arthroscopic knee surgery

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ISSN: 2980-292X / DOI: https://doi.org/10.20528/cjpm.2024.03.001

1. Introduction

Knee arthroscopy is a surgical procedure frequently performed by orthopedic clinics [1]. Therefore, there has been increased interest in recent years in neuroaxial interventions, which allow for effective anesthesia while not restricting mobilization and have a narrow side effect profile, to accommodate this rapid turnover in anesthesia management [2].

Femoral nerve block (FNB) has long been used to treat postoperative pain in knee surgery. However, the need for new techniques has arisen due to its limitation on hip mobilization. Adductor canal block is one of these developed blocks, aiming to reduce this adverse effect by blocking the femoral nerve more distally. Barely, its analgesic effect being limited to only the anterior aspect of the knee has narrowed its utility. Combining it with obturator nerve block aims to broaden the area of effect. However, the simultaneous application of both blocks may not always be feasible in terms of technical proficiency and may prolong the procedure compared to a single-block application, restricting its usage [3–5].

In this study aimed to compare the effects of combined adductor canal block and obturator nerve block with the single application of ultrasound-guided suprainguinal fascia iliaca compartment block (FICB) on postoperative pain. According to this study, both block groups can be applied instead of each other, but FICB will be more preferred because ıt can be applied easily.

2. Materials and Method

This study was conducted prospectively and randomized between June 1, 2019, and September 30, 2020, with the approval of the Clinical Research and Ethics Committee of Kahramanmaraş Sütçü İmam University Health Practice and Research Hospital in its session dated May 29, 2019, numbered 2019/10, and decision number 20. A total of 60 patients who underwent arthroscopic knee surgery at the orthopedic clinic, after obtaining informed consent, were included in the study. Patients aged between 18 and 65 years with ASA I-II who underwent surgery under spinal anesthesia were examined.

Patients were informed in detail about the study during the preoperative period, and after obtaining voluntary consent using a consent form, they were randomized by the lottery method into two groups: those who underwent fascia iliaca compartment block were assigned to Group 1, and those who underwent adductor canal and obturator nerve block were assigned to Group 2. Blocks were performed after the completion of surgery for patients under spinal anesthesia and block applications in both groups were performed by the same person.

Group 1: Following the completion of the surgery, patients in Group 1 received a suprainguinal fascia iliaca block using the technique. For this application, the patient was placed in a supine position, and after ensuring the necessary skin asepsis conditions, a linear ultrasound probe was placed on the distal and medial 1/3 of the imaginary line connecting the superior iliac crest and the pubic tubercle, 1 cm above the inguinal ligament, in the transverse plane. In the imaging, femoral artery, femoral vein, iliac and sartorius muscles, and fascia lata and iliaca were visualized in a hyperechoic manner. The needle was directed from lateral to medial in an in-plane technique, penetrating the fascia iliaca after the fascia lata and the junction of the iliac and sartorius muscles. After negative aspiration, a total of 40 ml of 0.25% concentration bupivacaine was injected slowly and intermittently with controlled aspiration. Spread of the local anesthetic laterally and medially was observed.

Group 2: In this group, adductor canal block followed by obturator block was applied. After the surgery, the patient was placed in a supine position, and the leg to be treated was slightly externally rotated for the adductor canal block procedure. After ensuring skin asepsis, a linear ultrasound probe was placed on the inguinal crease of the patient's thigh and approximately at the midpoint of the medial condyle of the knee. Underneath the sartorius muscle, the femoral artery within the adductor canal, the femoral vein beneath the femoral artery, and the saphenous nerve laterally were visualized. Using an in-plane technique, a 100mm 22G block needle was inserted 1–2 cm lateral to the ultrasound probe. The needle was advanced under the sartorius muscle and laterally to the femoral artery and saphenous nerve, and then 10 ml of 0.25% concentration bupivacaine was injected after negative aspiration.

To perform obturator nerve block, after ensuring aseptic conditions of the skin surface in the inguinal region while the patient was in the supine position, the same ultrasound probe was used for the procedure. Underneath the fascia lata in the inguinal region, the femoral artery and vein were visualized. The probe was shifted medially to visualize the 'Y' shaped boundary formed by the pectineus muscle, and the adductor longus and brevis muscles immediately medial to it. For blocking the anterior branch of the obturator nerve, the needle was advanced in-plane towards the hyperechoic linear structure in the fascial gap at the junction of the middle and posterior thirds of the pectineus and adductor brevis muscles. After negative aspiration in this area, 5ml of 0.25% bupivacaine was injected. Similarly, the needle was advanced in-plane towards the posterior branch of the obturator nerve between the adductor brevis and adductor magnus muscles, and after negative aspiration in this area, 5ml of 0.25% bupivacaine was injected. Proper spread of the local anesthetic agent was observed, with the agent spreading in the fascial gap and separating the target muscle groups from each other.

After achieving full cooperation from the patients following the procedure, intravenous patient-controlled analgesia (PCA) was administered, and its usage was thoroughly explained before they were sent to the ward. Pain assessment using the Visual Analog Scale (VAS) was conducted and recorded at postoperative 1, 2, 4, 12, and 24 hours in the ward. Patients with a VAS score of 4 or higher, despite using PCA analgesia, were administered intravenous analgesics. The amount of analgesic used at the end of 24 hours, additional analgesic requests, development of side effects, the type of side effects, were evaluated and recorded. Satisfaction levels were assessed using a four-point Likert scale (very satisfied, satisfied, neutral, and dissatisfied).

Mobility abilities of patients were assessed at the 24-hour ward visit. This assessment included evaluating their ability to sit up, stand, walk, and extend, and it was compared between groups.

Patients who received general anesthesia, those with allergies to local anesthetics and/or drugs used in the study, those who did not use the PCA device for any reason within the first 24 hours postoperatively, those who were not willing to participate in the study, and patients with a history of peripheral neuropathy or neuromuscular disease were not included in the study

3. Sample Size and Statistical Analyses

Sample size was calculated using G Power3 analysis program (Heinrich-Heine University, Dusseldorf, Germany) before the study. A pilot study was conducted on 5 patients from each group. The power analysis was conducted based on the average postoperative analgesic consumption with PCA. The sample size was calculated with a power of 95% and a significance level of 5%. It was determined that approximately 27 patients per group were needed to obtain a statistically significant value. Considering possible data deficiencies and patient dropouts for any reason, 30 patients were included in each group.

For the statistical analysis of the data obtained in the study, SPSS (Statistical Package for Social Sciences) for Windows 22.0 program was used. Chi-square analysis was used for comparing categorical data. Data were presented as mean ± standard deviation, median (Min-Max), number, and percentage. The normal distribution of numerical data was tested using the Kolmogorov-Smirnov test. Independent samples t-test was used for comparing normally distributed paired numerical data, one-way ANOVA test was used for comparing more than two groups, and Mann-Whitney U test was used for comparing non-normally distributed paired numerical data. Kruskal-Wallis test was used for comparing more than two groups of non-normally distributed data. Significance was considered at $p<0.05$ level.

4. Results

A total of 60 patients were included in the study, with 30 patients receiving Fascia Iliaca compartment block (Group 1) and 30 patients receiving Adductor Canal + Obturator nerve block (Group 2). Table 1 presents the characteristics of the participants in terms of gender, age, weight, height, body mass index, and ASA scores within the study groups. According to the data, there was no statistically significant difference observed between the study groups in terms of sociodemographic characteristics (Table 1).

Table 1. Comparison of sociodemographic characteristics of the groups.

		Group 1		Group 2		p
		Number	%	Number	%	
Gender, n(%)	Female	4	13.3	3	10	0.688[a]
	Male	26	86.7	27	90	
ASA	ASA-1	18	60.0	24	80.0	0.091[a]
	ASA-2	12	40.0	6	20.0	
Age (Years), Mean±SD		33.7±13.8		31.1±10.3		0.401[b]
Weight (kg), Mean±SD		81.6±12.0		77.3±12.0		0.173[b]
Height (cm), Mean±SD		173.0±8.8		172.9±6.0		0.945[b]
BMI (kg/m2), Mean±SD		27.4±4.4		25.8±3.7		0.134[b]

[a]Chi-square; [b]t-test was applied in independent groups

In terms of evaluating the type of surgery for both groups (p=0.898), the lateralization of the surgery (p=0.436), and the duration of the surgery (p=0.646), no statistically significant difference was observed.

When groups were compared in terms of procedure durations according to the type of block performed, in Group 1, the minimum duration of the procedure was 5 minutes, the maximum was 10 minutes, and the median was 10 minutes, whereas in Group 2, the minimum duration of the procedure was 7 minutes, the maximum was 15 minutes, and the median was 12 minutes. The application duration of the adductor canal block and obturator nerve block was found to be significantly higher compared to the application duration of the fascia iliaca compartment block alone ($p<0.001$) (Table 2).

Table 2. Comparison of the block application durations between the groups.

	Group 1			Group 2			p[a]
	Median	Min	Max	Median	Min	Max	
Block application duration (min)	10	5	10	12	7	15	<0.001

[a]Mann Whitney U test was applied

When compared in terms of the type of block performed and postoperative pain levels, the mean VAS scores at 1st, 2nd, 4th, 12th, and 24th hours for Group 1 were 1.3±1.5, 1.6±1.8, 2.6±1.8, 4.1±2.3, and 1.9±1.1, respectively, while the mean VAS scores for Group 2 were 1.5±1.6, 1.7±1.5, 2.9±1.5, 4.9±2.4, and 2.6±1.8, respectively. No significant difference was observed in the evaluation of postoperative pain for both groups in terms of VAS scores at different time points (Table 3).

Similar results were obtained in terms of the number of requests to use patient-controlled analgesia device and the number of boluses administered through the patient-controlled analgesia device in both groups (Table 4). When patients are compared in terms of additional analgesic need; It was observed that additional medication was administered to 14 patients in group 1 and 16 patients in group 2, and no statistically significant difference was observed (p=0.606).

No significant difference was observed in terms of chair test, walking distance, and extension duration conducted to evaluate the effectiveness of applied blocks on postoperative mobilization (Table 5).

Table 3. Comparison of VAS scores at different time points between groups.

	Group 1	Group 2	p[a]
	Mean±SD	Mean±SD	
VAS 1st hour	1.3±1.5	1.5±1.6	0.735
VAS 2nd hour	1.6±1.8	1.7±1.5	0.698
VAS 4th hour	2.6±1.8	2.9±1.5	0.532
VAS 12th hour	4.1±2.3	4.9±2.4	0.214
VAS 24th hour	1.9±1.1	2.6±1.8	0.074

[a]Mann Whitney U; [b] t test was applied in independent groups

Table 4. Comparison of PCA request and PCA bolus numbers between groups.

	Group 1			Group 2			p
	Median	Min	Max	Median	Min	Max	
PCA request count	12.5	0	69	15	1	42	0.728[a]
PCA bolus count, Mean±SD		8.6±4.9			9.5±6.8		0.573[b]

[a]Mann Whitney U; [b] t test was applied in independent groups

Table 5. Comparison of groups in terms of chair test, walking distance, and extension duration.

	Group 1			Group 2			p[a]
	Median	Min	Max	Median	Min	Max	
Chair test count	3	0	7	2	0	6	0.928
Walking distance (m)	37.5	0	90	32.5	0	90	0.458
Extension time (s)	11.5	2	60	14	0	55	0.711

[a]Mann Whitney U test was applied. Chair test: The number of sit-to-stand repetitions within 30 seconds; Walking distance: The distance walked within 3 minutes provided in meters

5. Discussion

The success of anesthesia applications in outpatient surgical procedures depends on early ambulation, minimizing pain, and minimal postoperative side effects, especially in lower extremity surgery [6–8]. In this study was evaluated the postoperative analgesic efficacy, effects on postoperative mobilization, effects on length of hospital stay, side effects, and effects on additional analgesic use of fascia iliaca compartment block (FICB) compared to adductor canal block and obturator nerve block, which are commonly performed in knee arthroscopy surgery. In the literature review, no studies were found comparing the combination of suprainguinal fascia iliaca compartment block with adductor canal block and obturator nerve block in patients undergoing knee arthroscopy surgery, as in this study. The most similar research to this study was conducted by Abu Elyazed et al. [9]. However, in this study, the obturator nerve block was added to the adductor canal block to standardize the nerve block. Abu Elyazed et al. [9] found no significant difference in VAS evaluations performed within the first 24 hours in patients undergoing knee arthroscopy surgery who received fascia iliaca compartment block and adductor canal block.

In this study, it was found that both groups were similar in VAS evaluations at postoperative 1, 2, 4, 12, and 24 hours, and there was no statistically significant difference. Likewise, there was no significant difference in the amount of tramadol and additional analgesic used. In a study by Abu Elyazed et al. [9], it was stated that the adductor canal block was better in the assessment of quadriceps strength at 6, 12, and 18 hours, and there was no significant difference at the 24-hour assessment [9]. In this study, both groups were evaluated for mobilization capability at postoperative 24 hours, and no significant statistical difference was found between the two groups.

According to a meta-analysis comparing femoral block and fascia iliaca block applied to patients undergoing hip and knee arthroplasty by Wang et al. [10], there

was no significant difference between the two groups in terms of VAS scores at 12 hours and the amount of analgesics used in PCA. Similarly, it was reported that VAS scores at 24 and 48 hours and analgesic use were similar. In a study where the same blocks were performed on adolescent patients undergoing knee surgery, no significant difference was found between the groups in terms of VAS values between hours and the amount of opioids used postoperatively [11].

A meta-analysis comparing adductor canal block with femoral nerve block in patients undergoing total knee arthroplasty found that postoperative VAS scores were between low and moderate, and there was no significant difference in activity and rest between them [12]. In the meta-analysis of Jenstrup et al. [4], it was stated that the level of pain and analgesic consumption with femoral nerve block and adductor canal block were similar. Additionally, it was mentioned that patients receiving adductor canal block had less negative effects on mobilization, thus minimizing complications that could arise due to prolonged immobilization and reducing length of hospital stay [3,13].

There are studies indicating that obturator nerve block alone does not provide sufficient postoperative analgesia. However, it is theoretically known that it is responsible for innervation of the medial part of the knee and that adequate analgesia cannot be achieved if it is not blocked. Therefore, various studies have shown that it is applied in addition to other peripheral nerve blocks such as femoral nerve block and femoral+sciatic nerve block and adductor canal block to increase the effectiveness of postoperative analgesia [13–15].

One of the common complications of peripheral nerve blocks is neurovascular trauma. There is a risk in all three block types we applied. In a study by McNamee et al. [14], no neural trauma or deficit was found in the fascia iliaca group, but deficit developed in one out of 47 patients in the femoral block group. In a study, myotoxicity developed in 3 patients due to adductor canal block application [16]. With the widespread use of ultrasound in regional anesthesia applications and the widespread dissemination of education on this subject, the risk of complication development has significantly decreased. In this study, no complications such as neurotoxicity, myotoxicity, or vascular injection were observed in the applied blocks.

In the literature review, no evaluation was found regarding the ease of application of fascia iliaca compartment block compared to other blocks in this study. However, the application time of fascia iliaca compartment block was found to be significantly shorter than the combined application time of adductor canal block and obturator nerve block.

When evaluated in terms of early discharge, one of the most important parameters of outpatient surgery, both groups' patients were generally discharged within twenty-four hours, and no significant difference was observed. According to a meta-analysis comparing femoral block with fascia iliaca compartment block, it was stated that both groups were similar in terms of length of hospital stay [9]. In conclusion, evaluating dermatomes and early mobilization ability along with VAS assessment in this study could have made our study stronger; however, it could have been misleading as the orthopedic clinic required patients to be immobilized for the first 24 hours and the operations were performed under spinal anesthesia. Thirty patients who received a fascia iliaca block technique and thirty patients who received obturator nerve and adductor canal blocks were included in the study. When the sociodemographic characteristics of the participants were compared, they were found to be similar. This ensured the elimination of some bias sources that could lead to bias in the study results, and it was considered that the type of block applied could directly contribute to the differences or similarities observed in the study results.

6. Conclusions

The fascia iliaca compartment block, which has proven analgesic efficacy like other long-established and effective blocks used in the lower extremity, can easily replace other block applications due to its short application time, ease of administration, and low risk of complications.

Acknowledgements

None declared.

Funding

The authors received no financial support for the research, authorship, and/or publication of this manuscript.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this manuscript.

Author Contributions

All of the authors made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; were involved in drafting the manuscript or revising it critically for important intellectual content; and gave final approval of the version to be published.

Data Availability

The datasets created and/or analyzed during the current study are not publicly available, but are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was approved by the ethics committee of Kahramanmaraş Sütçü İmam University Faculty of Medicine (May 29, 2019; numbered 2019/10; and decision number 20). Written informed consent was obtained from the participants. All methods were performed in accordance with relevant guidelines and regulations.

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Research Article

Effectiveness of dry needle therapy in patients with chronic nonspecific low back pain

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ABSTRACT

Background: Low back pain is a prevalent symptom worldwide, with various underlying causes, making differential diagnosis essential. This study aims to investigate the efficacy of dry needling treatment added to exercise in patients with chronic Nonspecific Low Back Pain (NLBP). The McKenzie exercise program was applied to all participants.

Materials and Method: The study comprised sixty participants, randomly allocated into two groups: the dry needling (DNG) and the exercise group (EG). The participants in DNG received a total of six sessions of dry needling treatment, two days a week, to the gluteus medius and quadratus lumborum and multifidus muscles. All participants were given a McKenzie exercise program two sets per day for three weeks.

Results: A significant difference was noted in the VAS-night values of the patients within the DNG before treatment (p: 0.004), and the EG also exhibited a significant difference in the VAS-activity (p: 0.017) and VAS-resting (p: 0.024) values following the treatment. A statistically significant decrease was observed in favor of DNG in VAS-rest, VAS-night, VAS-activity values (p>0.001) in the comparions of the groups.

Conclusions: Dry needling treatment added to exercise therapy in chronic NLBP patients is effective on activity and rest pain severity in the shortterm results. However, no additive efficacy of dry needling treatment was found on the number of trigger points, disability, and depression.

ARTICLE INFO

Article history:
Received 4 June 2024
Revised 25 September 2024
Accepted 4 October 2024

Keywords:
Dry needle therapy
Chronic nonspecific low back pain
Exercise
Trigger point

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1. Introduction

Low back pain is a symptom that is very common all over the world, can be caused by many reasons and requires differential diagnosis [1]. It is one of the leading non-fatal pains that cause disability worldwide for the last 30 years. In addition, the most common form of low back pain is NLBP with a prevalence of 85%, where the cause of the pain cannot be revealed [2–5]. It is recommended to investigate whether there is a specific anamnesis and physical examination that can explain the cause of pain in patients having non-specific low back pain. NLBP treatment includes physical therapy modalities such as hot pack and transcutaneous electrical nerve stimulation. In addition, drug treatments such as acetaminophen, non-steroidal anti-inflammatory drugs, tramadol, tricyclic antidepressants are applied in medical treatment. Methods such as spinal manipulation, exercise, massage therapy, acupuncture, dry needling and cognitive behavioral therapies are involved in the management of NLBP [6,7].

Trigger points are palpable tight bands or hypersensitive points within the muscle that cause muscle pain, spasm, or referred pain [8]. Studies have shown that the problem in trigger points is not only a localized muscle problem, but also hypersensitivity in the peripheral and

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ISSN: 2980-292X / DOI: https://doi.org/10.20528/cjpm.2024.03.002

central systems, somatic-visceral relationship, deterioration in microcirculation and inflammatory mediator proliferation [9–14]. Trigger points in the multifidus muscles, quadratus lumborum and gluteus medius can cause low back pain [8].

Dry needling, which is applied directly to the myofascial trigger point with acupuncture needles, is a method that has been used quite frequently in the treatment of musculoskeletal pain recently [15]. Dry needling reduces the number and sensitivity of trigger points, resulting in a reduction in local and referred pain. Thus, dry needling improves joint range of motion, decreases muscle activation and peripheral and central hypersensitivity [11].

The aim of this study is to assess the effectiveness of dry needling treatment added to exercise in patients with chronic NLBP.

2. Materials and Method

This study was carried out as a prospective, randomized, accessor blinded between 15/08/2020–15/02/2021 in outpatient clinic. The study included patients who presented to the outpatient clinic with complaints of chronic low back pain characterized as mechanical and were diagnosed with chronic non-specific low back pain (NLBP).

Approval for this study was obtained from the University Clinical Research Ethics Committee (Approval Number: 015-KAEK-43-20-09, Date: 27/07/2020), adhering to the principles outlined in the Helsinki Declaration of 2008. The CONSORT checklist for the study is available in Fig. 1.

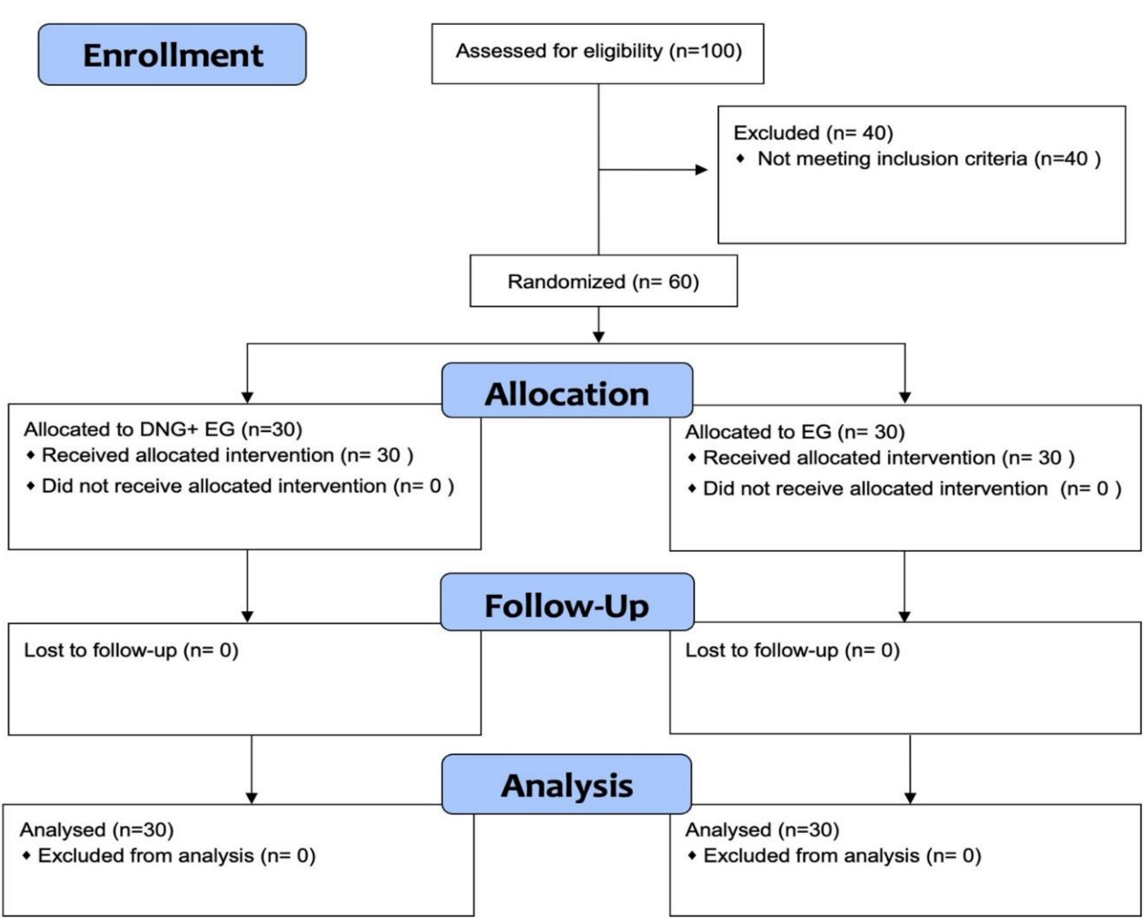

Fig. 1. Consort flow diagram of the study.

The study involved patients aged 20–70 years and diagnosed with NLBP who had not received any treatment in the last three months. Patients with inflammatory low back pain, rheumatological or oncological disease, motor and neurological deficits, spinal fracture or dislocation were excluded. All patients were informed in detail about the study and a voluntary consent form was signed. In all cases with low back pain, physical and neurological examination was performed after a detailed anamnesis. The study incorporated sixty participants, who were randomly allocated into two groups: the dry needling (DNG) and the exercise group (EG). Randomization was done using the closed envelope technique.

2.1. Interventions

After the trigger point was palpated and the skin was cleaned with alcohol, it was applied to the gluteus medius and quadratus lumborum muscles at an angle of 90 degrees to the participants in the dry needling treatment group while the patient was lying on their side.

The multifidus muscle was applied at an angle of 90 degrees with the patient lying face down. In the application, 0.25×0.40 mm and 0.30×0.60 mm thin and stainless steel needles were used (Fig. 2).

The participants underwent a total of six treatment sessions, administered twice a week. Session times were

planned as a minimum of 20 minutes. At the tenth minute of each session, the needle was re-rolled to increase stimulation [8,16].

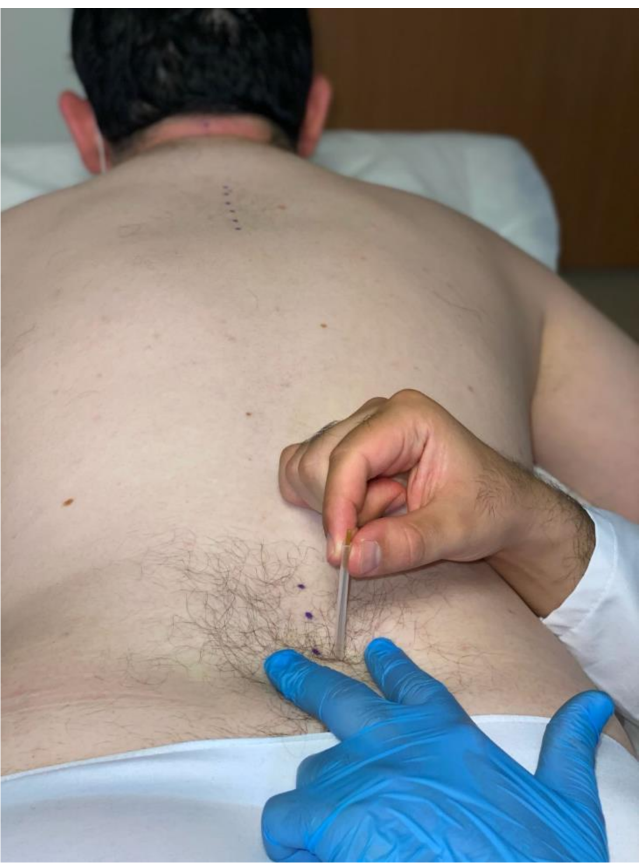

Fig. 2. Dry needling to multifidus muscle.

McKenzie's method was used for the exercise program. This method is defined for patients having low back pain, it is also considered as pain postural syndrome, dysfunction (dysfunction) syndrome and derangement syndrome. The treatment principle in postural syndrome is to correct the posture, in dysfunctional syndrome it is exercise in the direction with dysfunction, and in dysregulation syndrome, exercises depending on the directional preference of the patient are recommended. Thus, it allows the patient to plan individual exercises [17].

The exercise program was applied to all participants. The exercises were given to two sets per day, starting with at least five repetitions of each movement, and ten repetitions after 1 week. The exercises were continued for three weeks.

2.2. Measurements

The primary outcome of this study was to investigate the effectiveness of dry needling in NLBP.

Secondary outcomes included:

- The level of pain relief: Measurement methods.
- Functional improvement: Patient assessment scales.
- Response time to treatment: Initial signs of improvement.
- Complication rates: Side effects and adverse events.

The patients included in the study were evaluated according to age, gender, height, weight, educational status and occupation. In addition, the number of active and latent trigger points on the gluteus medius, quadratus lumborum, and multifidus muscles were determined. [8,18] Patients were evaluated before treatment and at 3 months after treatment [18].

The severity of low back pain was measured through the Visual Analogue Scale (VAS). While evaluating the VAS, patients were prompted to indicate the severity of their pain by marking a point on a 0-10 cm line with: 0, no pain; 10, the most severe pain possible. VAS evaluation was evaluated in three different categories including during physical activity, at night and at rest [19].

The Modified Oswestry Pain Inquiry Form (MOS), which consists of seven questions scored between 0 and 5, was used for functional status assessment. Personal care, lifting, pain severity, walking, sitting, standing, sleeping, pain in travel, social life, and the degree of change in pain were investigated using MOS. According to MOS, 1-10 points are considered as mild functional disability, 11–30 points as moderate functional disability, 31-50 points as severe functional disability [20].

The effect of low back pain on patient psychology was evaluated with the Beck depression scale (BDI). In the BDI, each question has 21 questions with the lowest score being 0 and the highest score being 3. According to the results of the evaluation, depressive symptoms are determined as minimal level between 0 and 9 points, mild level between 10 and 16 points, moderate level between 17 and 29 points, and depressive symptoms between 30 and 63 points [21].

3. Sample Size and Statistical Analyses

The power analysis was conducted using the G.Power–3.1.9.7 program. The calculations were based on an independent t-test, with an effect size of 0.8, alpha of 0.05, power of 0.8, two groups, and one measurement. The total sample size was calculated to be 60. SPSS software package were employed for the statistical analyses. Quantitative variable behaviors were conveyed through variance and central tendency (Mean ± SD). Fisher Exact test was applied in cases of low sample size, and the Chi-square test was utilized to discern differences in categorical variables. The Mann-Whitney U-Test methods were employed to demonstrate behavioral differences in group means when normality and equivalence assumptions were met, and the Student T-Test conditions were not met. Statistical significance was established at p=0.05 for all analyses.

4. Results

The mean age of the patients involved in the study was 43.9 ± 13.62 in DNG and 41.23 ± 8.96 in EG. In DNG, 26.7% of the patients were male, 73.3% were female, and in EG, 36.7% were male and 63.3% were male. Regarding gender, age, weight, height, educational status, and occupation, no statistically significant differences were observed between the groups (p>0.05) (Table 1).

A significant difference was observed in DNG (p<0.05) in VAS-night values before treatment, and in VAS-activity (p=0.017), VAS-resting (p=0.024) values in EG after treatment (Tables 2 and 3).

A difference was detected in DNG (p=0.004) in the VAS-night values of the patients before the treatment. In addition, a significant difference in the VAS-activity values (p=0.017), VAS-resting (p=0.024) values in the EG was observed after the treatment (Tables 2 and 3). In order to compare the treatment efficacy between the groups, the differences in the 1st month values prior to and following the treatment were compared. A statistically significant decrease favoring the DNG was observed in VAS-rest, VAS-night, and VAS-activity values between the groups (p>0.001) (Table 4).

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Table 1. Demographic data.

Parameters	DNG (n:30)	EG (n: 30)	p-value
Height (cm)	165.37 ± 6.7	165.27 ± 6.98	0.845
Weight (kg)	71.67 ± 10.99	70.63 ± 10.34	0.709
Pain duration (month)	11.93 ± 12.92	7.1 ± 5.35	0.099
BMI	26.84 ± 4.53	25.87 ± 3.88	0.377
Age	43.9 ± 13.62	41.23 ± 8.96	0.251
Gender Female/Male	22 / 8	19 /11	0.579
Education status Non-university/University	20/10	18 /12	0.789
Jobs			
Retired	2	0	
Housewife	21	16	
Employee	4	9	0.256
Officer	2	4	
Student	1	1	

Table 2. Baseline parameters.

Parameters	DNG (n:30)	EG (n:30)	p-value
BDI	29.0 ± 6.87	31.87 ± 10.12	0.204
	28 (13- 43)	30 (10- 50)	
TP-Gluteus Mediıus-Right	16.07 ± 3.08	16.83 ± 4.63	0.952
	16 (12- 25)	16 (12- 32)	
TP-Gluteus Mediıus-Left	15.0 ± 1.6	15.77 ± 2.97	0.729
	15 (11- 20)	15 (12- 26)	
TP-Multifidus-Right	16.13 ± 2.93	16.6 ± 3.17	0.623
	15 (12- 22)	15.5 (12- 22)	
TP- Multifidus-Left	15.2 ± 1.47	14.83 ± 5.01	0.976
	15 (12- 18)	15.5 (0- 26)	
MOS	20.73 ± 7.22	21.7 ± 7.24	0.631
	22 (8- 28)	22 (8- 36)	
TP-Quadratus Lumborum-Right	17.67 ± 7.18	15.23 ± 3.91	0.13
	16 (0- 35)	15 (10- 26)	
TP-Quadratus Lumborum-Left	15.73 ± 2.13	17.07 ± 4.49	0.332
	16 (11- 20)	16 (12- 32)	
VAS-Activity	8 (5- 10)	8 (6- 10)	0.053
VAS-Night	8 (0- 10)	6 (0- 10)	0.004
VAS_Rest	8 (5- 10)	8 (6- 10)	0.121

BDI: Beck Depression Inventory; MOS:Modified Oswestry Pain Inquiry Form;
VAS: Visual Analogue Scale; TP: Trigger Points

Table 3. Comparison of post-treatment values between groups.

Group	DNG (n:30)	EG (n:30)	p-value
BDI	14.37 ± 4.37	16.6 ± 6.99	0.384
	13.5 (5- 24)	14 (5- 32)	
TP-Gluteus Mediıus-Right	23.1 ± 3.01	21.73 ± 2.65	0.272
	22 (20- 32)	22 (16- 26)	
TP-Gluteus Mediıus-Left	21.2 ± 2.01	20.37 ± 2.57	0.402
	21.5 (18- 26)	21.5 (14- 26)	
TP- Multifidus-Right	23.6 ± 3.82	23.3 ± 4.8	0.868
	26 (16- 30)	26 (14- 30)	
TP- Multifidus-Left	21.4 ± 3.11	19.9 ± 6.73	0.441
	22 (16- 30)	21 (0- 33)	
MOS	8.7 ± 4.71	10.8 ± 5.89	0.17
	10 (2- 18)	10 (0- 22)	
TP-Quadratus Lumborum-Right	24.53 ± 7.09	24.23 ± 6.57	0.445
	25.5 (0- 36)	24 (16- 40)	
TP-Quadratus Lumborum-Left	23.87 ± 4.0	23.6 ± 4.42	1
	24 (18- 32)	24 (16- 32)	
VAS-Activity	3 (2- 5)	4 (3- 5)	0.017
VAS-Night	3 (0- 5)	3 (0- 5)	0.377
VAS-Rest	3 (2- 5)	4 (3- 5)	0.024

BDI: Beck Depression Inventory; MOS: Modified Oswestry Pain Inquiry Form;
VAS: Visual Analogue Scale; TP: Trigger Points

Table 4. Comparing the distribution of the difference values of the parameters between the groups.

Group	DNG (n:30)	EG (n:30)	p-value
Diff- BDI	14.63 ± 5.49	15.27 ± 6.64	0.738
	15 (4 - 30)	15 (5 - 40)	
Diff-TP-Gluteus Mediıus-Right	-7.03 ± 2.25	-4.9 ± 6.04	0.127
	-7 (-10 - -4)	-5 (-10 - 16)	
Diff-TP-Gluteus Mediıus-Left	-6.2 ± 1.75	-4.6 ± 4.51	0.357
	-6 (-11 - -4)	-6 (-7 - 12)	
Diff-TP- Multifidus-Right	-7.47 ± 3.25	-6.7 ± 4.69	0.861
	-8 (-12 - -4)	-8 (-12 - 7)	
Diff-TP- Multifidus-Left	-6.2 ± 2.38	-5.07 ± 4.03	0.497
	-7 (-12- -3)	-6.5 (-1 - 6)	
Diff-MOS	12.03 ± 7.43	10.9 ± 6.92	0.543
	12.5 (-2- 26)	10 (-7 - 28)	
Diff-TP-Quadratus Lumborum-Right	-6.87 ± 5.66	-9.0 ± 3.47	0.237
	-7.5 (-16 - 12)	-8 (-14 --5)	
Diff-TP-Quadratus Lumborum-Left	-8.13 ± 2.67	-6.53 ± 6.31	0.597
	-8 (-14- -4)	-8 (-14 -15)	
Diff-VAS-Activity	5 (-7)	4 (3 - 5)	<0.001
Diff-VAS-Night	5 (0-10)	3 (0-5)	<0.001
Diff-VAS-Rest	5 (-7)	4 (3-5)	<0.001

BDI: Beck Depression Inventory; MOS:Modified Oswestry Pain Inquiry Form;
VAS: Visual Analogue; Diff: Difference

5. Discussion

This study evaluates the effectiveness of combining dry needling treatment with the McKenzie exercise program for individuals with chronic NLBP.A notable difference was observed in the VAS-night scores of patients in the dry needling group (DNG) before treatment. Additionally, the exercise group (EG) showed significant differences in VAS-activity and VAS-resting scores after treatment. Comparisons between the groups revealed a statistically significant reduction in VAS-rest, VAS-night, and VAS-activity scores in favor of DNG

According to many studies in the literature, it has been reported that dry needling treatment has a local effect on the taut band with dilatation, and also provides pain inhibition by activating the descending pathways in the central nervous system and plays a role in peripheral segmental inhibition. However, the mechanism of action of dry needling therapy has not yet been fully elucidated [22]. Martín-Corrales et al. [23] evaluated the long-term results of dry needling treatment with an exercise program for low back pain that they applied for 4 weeks in their study where they evaluated the effectiveness of dry needling treatment. In the study of Martín-Corrales et al., forty-six patients were randomly divided into two equal groups and a total of eight sessions of dry needling and sham dry needling were applied twice a week for four weeks. They evaluated the patients before and after treatment. As a result of their study, a decrease in VAS values was observed in both groups, but they could not find a difference between the two groups. In our study, pain measurements decreased in both dry needling and post-exercise evaluations, but when you evaluated the difference before and after treatment, results in favor of dry needling were obtained. Tüzün et al.'s [24] study was conducted with 34 patients having low back pain. In their research, in addition to dry needling, massage therapy and classical physical therapy program (hot pack, TENS, ultrasound and exercise) were compared to the patients for six sessions for three weeks. They found a significant difference in regarding McGill Pain Questionnaire, VAS, Beck Depression Questionnaire and Tampa Kinesiophobia Scale. Another randomized controlled trial in 50 patients with low back pain compared the effectiveness of dry needling and exercise therapy. While no significant results were found in the Oswestry disability index and paraspinal muscle length evaluations performed before and after the treatment, significant results were obtained in the visual analog scale and algometer measurements. A significant difference detected in pre-treatment and post-treatment analyses of the two groups [25]. In a meta-analysis examining the effectiveness of dry needling therapy in low back pain, it was stated that dry needling therapy was superior to laser, physical therapy, trigger point injection and other combined treatments. However, there are uncertainties regarding its efficacy during and after treatment. It was also reported in this meta-analysis that adverse effects may be underreported due to the risk of bias for the safety of dry needling therapy. It has been reported that large-scale and long-term randomized controlled studies with more rigorous methodological data are needed [26]. In a recent study evaluating the effectiveness of electrical dry needling and physical therapy in patients having chronic low back pain, a significant difference was found in both patient groups [27].

Exercise therapy, which is another treatment method, is a series of special movements applied to improve or rehabilitate the body [28]. A meta-analysis of 249 controlled randomized trials reported moderate evidence that exercise is effective in pain and functionality in patients having low back pain compared with no treatment or placebo treatments [22]. Another meta-analysis examining the effects of conservative treatments on low back pain reported high-level evidence for the effectiveness of exercise therapy and stated that exercise programs implemented after low back pain treatment reduced work loss, disability, risk of recurrence of low back pain, and severity of low back pain [29]. Due to differences in the duration, symptoms, causes and origins of low back pain, different results about exercise efficacy emerge in randomized controlled studies. There are opinions that exercise treatments planned by dividing into subgroups are more effective in patients with low back pain [23]. In our study, the McKenzie method, which is a more specific exercise program, was applied [19,20] According to the results of a study examining the efficacy of McKenzie exercises and manual therapy in patients suffering from chronic low back pain, a significant difference was found in patients who underwent the McKenzi method. In addition, in a meta-analysis of 5578 patients and 89 studies in which exercise types were analyzed in patients suffering from chronic low back pain, low-level evidence was reported that the Mc-Kenzie method was more effective than other types of exercise on pain [29]. The most important limitation of this valuable randomized accessor blinded study comparing dry needling with a specific exercise therapy without dry needling in patients having chronic low back pain is the absence of an untreated control group. Another limitation is the lack of long-term evaluation. However, most studies in the literature evaluated short-term (three-month) results. It is undeniable that studies with a longer duration and large population should be added to evaluate the efficacy of treatment.

6. Conclusions

According to the results of this study, dry needling treatment added to exercise therapy in chronic NLBP patients, is effective on activity and rest pain severity in the short term results. However, no additive efficacy of dry needling treatment was found on the number of trigger points, disability, and depression.

Acknowledgements

None declared.

Funding

The authors received no financial support for the research, authorship, and/or publication of this manuscript.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this manuscript.

Author Contributions

All of the authors made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; were involved in drafting the manuscript or revising it critically for important intellectual content; and gave final approval of the version to be published.

Data Availability

The datasets created and/or analyzed during the current study are not publicly available, but are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was approved by the ethics committee of University Clinical Research Ethics Committee (Approval Number: 015-KAEK-43-20-09; Date: 27/07/2020). Written informed consent was obtained from the participants. All methods were performed in accordance with relevant guidelines and regulations.

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Research Article

The effect of modified paramedian and median approaches of spinal anesthesia on postspinal acute low back pain in patients undergoing urological surgery: a prospective cohort study

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ABSTRACT

Background: Low back pain after spinal anesthesia may be a complicated issue for many patients. We aimed to evaluate the incidence of postspinal low back pain in the modified paramedian approach of spinal anesthesia compared to the classical median approach.

Materials and Method: The study is a prospective non-randomized observational trial. We included 297 patients aged 20 to 80 years who underwent urological surgery under spinal anesthesia. Patients were allocated into two groups: In Group P, patients underwent spinal anesthesia by using a modified paramedian approach and in Group M, the classical median approach was used. Primary outcome was the incidence of postoperative low back pain. Secondary outcomes were number of needle insertion attempts, needle bone contacts and patient satisfaction.

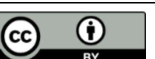
Results: The incidence of low back pain in Group M was 70.3% on the first day, 39.5% on the 7th day and 5.9% at the end of one month after surgery. In Group P, the incidence of low back pain was 30.7% on the first day, 12.4% on the 7th day and 0.7% at the end of one month after surgery. The low back pain scores were significantly lower in group P at all-time points. Patient satisfaction was significantly higher in group P (p=0.038). The number of needle interventions (p=0.001) and bone contact (p=0.000) were significantly lower in group P.

Conclusions: Low back pain was less common with the modified paramedian approach compared to the classical median spinal approach. We found lower number of needle insertion attempts and bone contacts in the modified paramedian technique. Patient satisfaction was also higher in the paramedian technique.

ARTICLE INFO

Article history:
Received 23 June 2024
Revised 18 September 2024
Accepted 12 October 2024

Keywords:
Spinal anesthesia
Median approach
Modified paramedian approach
Postspinal low back pain



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1. Introduction

Spinal anesthesia is a technique frequently used in urological, obstetric, orthopedic, lower abdominal and anorectal surgeries. There are several complications associated with spinal anesthesia. Low back pain is one of the complications of spinal anesthesia which affects the length of stay and recovery time in patients undergoing urologic surgery. The incidence of postspinal low back pain has been reported to vary between 9% and 29% [1–3].

The "modified paramedian technique" for spinal and epidural anesthesia was first described by Chen et al. in 2020. The researchers inserted the spinal needle from 0.5 cm caudal and 0.5 cm lateral to the spinous process in cesarean section patients. It has been reported that the shorter distance between the needle insertion site and the interspinous space reduces the risk of lamina contact [4]. This technique may possibly reduce the incidence of low back pain due to high success rates and low bony contact.

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ISSN: 2980-292X / DOI: https://doi.org/10.20528/cjpm.2024.03.003

The aim of this prospective observational study was to evaluate the effect of modified paramedian spinal technique on low back pain after spinal anesthesia in patients undergoing urologic surgery. We compared the 'modified paramedian approach' with the classical 'median' approach. The primary aim was to compare acute low back pain rates. The secondary aims were to assess the number of needle passes, the frequency of bone contact and to determine patient satisfaction in the modified paramedian technique.

2. Materials and Method

Ethics committee approval dated 23/06/2022 and numbered 92 was obtained from Sakarya University Faculty of Medicine, Non-Drug Clinical Research Ethics Committee for this prospective observational study. Informed consent forms were obtained from all patients. Patients who underwent urologic surgery under spinal anesthesia between 15/07/2022 and 15/04/2023 were included. Inclusion criteria were patients aged between 20-80 and having American Society of Anesthesiologists (ASA) classification of I, II or III. Exclusion criteria were: patients with a history of low back pain, patients with a history of previous vertebral surgery, patients whose surgery time exceeded 2.5 hours.

The spinal blocks were performed by a resident or specialist physician with 3 years or more experience. Median and modified paramedian approaches are the main methods used for spinal anesthesia in our clinic. The preferred technique and the intervertebral level for needle insertion when administering spinal anesthesia was determined by the clinician who performed the spinal block. Standard monitoring is applied to all patients before the spinal procedure. All procedure was performed in the sitting or lateral position after the block site was prepared with povidone iodine. A 25 Gauge Quincke spinal needle (25 G, Egemen Spinal İğne®, İzmir, Turkey) was used for all patients. A guide for spinal needle or skin infiltration of local anesthetics before needle insertion was not implemented. The appropriate intervertebral space (L3-4, L4-5 or L5-S1) was determined by the operator who performed the spinal block. The needle is inserted 0.5 cm lateral and 0.5 caudal to the spinous process for the modified paramedian approach. Acute low back pain was questioned by surgical ward visit and by telephone contact. The patients were followed up in the surgical ward on the first day of surgery and questioned for acute low back pain. Later, the patients were called by telephone on Day 7 of the surgery and 30 days after the surgery.

Demographic data were recorded as gender, age, height, weight, body mass index. Spinal approach (modified paramedian/median), intervertebral level preferred by the performer of spinal blocks (L3-4, L4-5, L5-S1), patient position during performance of spinal block (sitting, lateral), and patient position during the surgery (lithotomy, supine, prone), duration of surgery, number of interventions and bone contacts, postoperative hospitalization time were recorded.

Postoperative low back pain of the patients was questioned by using the NRS (numeric rating scale between 0 and 10; 0 is no pain and 10 is worst pain) which was recorded as mild (1-3/10), moderate (4-6/10), severe (7-10/10). When NRS was 4 and above, rescue analgesics (oral paracetamol, nonsteroidal anti-inflammatory drugs) were given. At the end of 30 days, patient satisfaction of the spinal technique was questioned as yes or no.

3. Sample Size and Statistical Analyses

In a previous study, 2% incidence of low back pain was found in the paramedian method and 10% in the median method [5]. When the sample size was calculated based on this study and considering the alpha 0.05, beta 0.2 and the power 0.8, the total number of patients was calculated as 274. Considering possible data losses, a total of 353 patients were included in the study in the projected study period. Descriptive statistics of the data included mean, standard deviation, median (min-max), frequency. Distribution of variables was analyzed by Kolmogorov Smirnov test. Independent sample t test, Mann-Whitney u test were used to analyze quantitative independent data. The analysis of qualitative independent data was done by using chi-square test. If chi-square test conditions were not met, Fisher's exact test was used. SPSS 28.0 program was used in the analysis. $p<0.05$ was considered statistically significant.

4. Results

Records of 353 patients were analyzed. Of these patients, 34 were excluded because they did not meet the inclusion criteria. 9 patients were excluded because they did not respond to the phone calls and 13 patients left the study voluntarily. The number of patients who underwent spinal anesthesia by using median approach was 152 in Group M and the number of patients who underwent modified paramedian approach was 145 in Group P. The flowchart of the study was shown in Fig. 1.

The demographic data (age, gender, height, weight, and ASA classification) were comparable between the groups (Table 1). BMI was 27.7±4.4 with a median value of 27.7 in the Group P and 26.6±5.0 in Group M with a median value of 25.9. BMI was significantly higher in the paramedian approach group (p=0.018) (Table 1).

There was no significant difference between the groups in the distribution of surgery type, anesthesia and surgical position. L3-L4 intervertebral space for spinal block was preferred in 92 patients in Group M (60.5%) and in 70 patients (48.3%) in Group P. L4-L5 intervertebral space was preferred in 55 patients in Group M (36.2%) and in 75 patients (51.7%) in Group P and L5-S1 intervertebral space was used in 5 patients in Group M (3.3%) and in no patients in Group P. The L3-L4 intervertebral space was preferred significantly higher in Group M and the L4-L5 intervertebral space was preferred significantly higher in Group P (p=0.004) (Table 2).

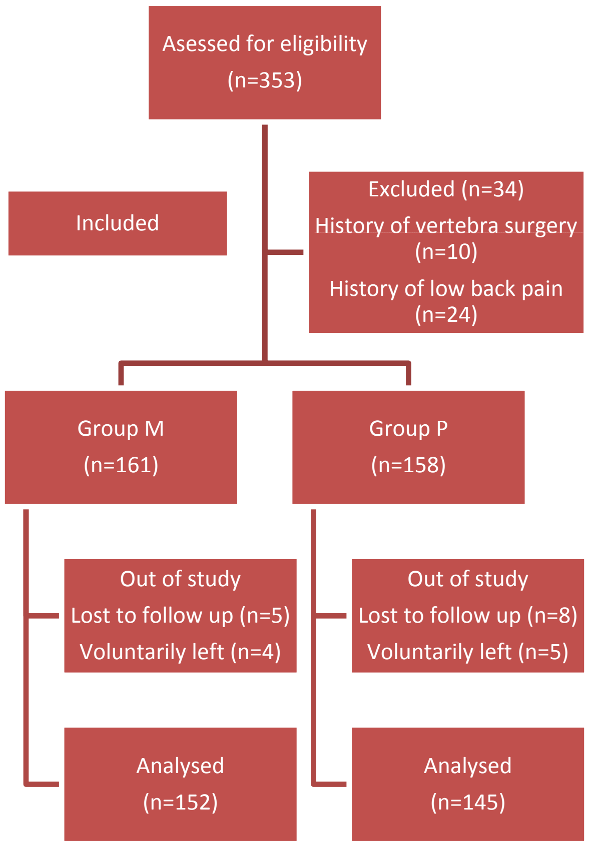

Fig. 1. Flow chart of the study.

Table 1. Comparison of demographic data.
Data is given as numbers (n), percentage, mean ± standard deviation (SD) and median values.

		Group M				Group P				p	
		Mean	±	SD	Median	Mean	±	SD	Median		
Age		58.17	±	14.43	62.00	59.79	±	14.33	65.00	0.231	m
Gender	Female	30		19.7%		23		15.9%		0.383	X^2
	Male	122		80.3%		122		84.1%			
Height (cm)		170.2	±	8.9	170.0	169.6	±	7.1	170.0	0.525	m
Weight (kg)		76.9	±	14.3	78.0	79.6	±	12.4	78.0	0.219	m
BMI (kg/m²)		26.6	±	5.0	25.9	27.7*	±	4.4	27.7	0.018	m
ASA	I	18		11.8%		15		10.3%		0.784	X^2
	II	93		61.2%		86		59.3%			
	III	41		27.0%		44		30.3%			

BMI: Body mass index; ^{m} Mann-Whitney u test; $^{X^2}$ Chi-square test (Fisher's exact test)

There was no significant difference regarding the duration of surgery and length of hospital stay between the groups. The number of needle insertion attempts and the frequency of bone contacts were significantly lower in Group P (p=0.000 and p=0.001 respectively) (Table 3).

The incidence of low back pain in Group M was 70.3% on the first day, 39.5% on the 7th day and 5.9% at the end of one month after surgery. In Group P, the incidence of low back pain was 30.7% on the first day, 12.4% on the 7th day and 0.7% at the end of one month after surgery.

The comparison of low back pain scores on day one, day 7 and at the end of one month after surgery are given in Table 4. The low back pain scores were found significantly lower in the paramedian approach group. Patient satisfaction was 98.6% in Group P and 94.1% in Group M. Patient satisfaction was significantly higher in Group P (Table 4).

Table 2. Comparison of type of surgery, anesthesia methods and approaches. Data is given as numbers (n), percentage.

		Group M		Group P		p	
		n	%	n	%		
Case							
TUR-P		29	19.1%	37	25.5%	0.858	X^2
TUR-T		28	18.4%	26	17.9%		
URS		44	28.9%	33	22.8%		
Cystoscopy		13	8.6%	17	11.7%		
Hydrocelectomy		5	3.3%	5	3.4%		
Internal Urethrotomy		8	5.3%	5	3.4%		
RIRS		10	6.6%	8	5.5%		
DJ Stent		6	3.9%	5	3.4%		
Other		9	5.9%	9	6.2%		
Injection level	L3-L4	92	60.5%*	70	48.3%	0.004	X^2
	L4-L5	55	36.2%	75	51.7%*		
	L5-S1	5	3.3%	0	0.0%		
Anesthesia Position							
Sitting		146	96.1%	142	97.9%	0.510	X^2
Lateral		5	3.3%	3	2.1%		
Surgical Position							
Lithotomy		145	95.4%	138	95.2%	0.928	X^2
Supine		7	4.6%	7	4.8%		

TUR-P: Transurethral resection of prostate; TUR-T: Transurethral resection of bladder tumor; URS: Ureteroscopy; RIRS: Retrograde intrarenal surgery; X^2 Chi-square test (Fisher's exact test); * p<0.05

Table 3. Comparison of surgical time, needle insertion attempt, bone contact and length of hospitalization. Data is given as numbers (n), percentage, mean ± standard deviation (SD) and minimum-maximum values.

	Group M						Group P						p	
	Mean	±	SD	Min	-	Max	Mean	±	SD	Min	-	Max		
Surgery duration (min)	49.7	±	19.0	15.0	-	125.0	47.5	±	20.0	15.0	-	135.0	0.314	m
Needle insertion attempt	1.3	±	0.5	1.0	-	3.0	1.1	±	0.4	1.0	-	3.0	0.001*	m
Number of bone contact	0.9	±	0.9	0.0	-	3.0	0.4	±	0.6	0.0	-	3.0	0.000*	m
Hospitalization (day)	1.9	±	1.5	1.0	-	13.0	2.0	±	1.8	1.0	-	19.0	0.262	m

^{m} Mann-Whitney u test; *p<0.05

5. Discussion

The present study demonstrated that modified paramedian approach of spinal anesthesia resulted in less low back pain compared to the classical median approach in patients undergoing urological surgery. In our study, patient satisfaction was higher in the modified paramedian approach compared to the median spinal approach. In the modified paramedian technique, the needle is inserted 0.5 cm lateral and 0.5 cm caudal to the spinous process. This technique was first described by Chen et al. [4]. By using this technique, number of bone contacts by needle was also lower than the median technique.

In the literature, there are studies with different methodologies investigating the effect of median and paramedian spinal techniques on low back pain [5–8]. In the study of Behary and Mohammed [9], the incidence of low back pain in patients undergoing cesarean section was reported 1.7% in the paramedian technique and 7.1% in the median technique. In this study, paramedian technique was defined as 1 cm lateral and 1 cm caudal to the midline. In the study by Singh et al. [5] which investigated 100 patients undergoing lower abdominal surgery, the incidence of low back pain in the paramedian approach was reported as 2% and in the median approach as 10%. The paramedian technique used in the study was described as inserting the needle 1 cm lateral and 1 cm caudal to the spinous process.

In contrast to these studies, there are studies reporting that the paramedian approach has no effect on postspinal low back pain. In a retrospective study by

Bayındır et al. [10] evaluating the early and late complications of spinal anesthesia among 80 patients, one patient in the paramedian group and 4 patients in the median group complained about "pain at the injection site". No significant difference was found between the groups regarding the incidence of low back pain.

Table 4. Comparison of pain scores on day one, day 7 and at the end of one month after surgery. Comparison of patient satisfaction. Data is given as numbers and percentage.

		Group M		Group P		p	
		n	%	n	%		
Day one	No pain	45	29.6%	86	59.3%	0.000	X^2
	Mild	25	16.4%	27	18.6%		
	Moderate	47	30.9%	22	15.2%		
	Severe	35	23.0%	10	6.9%		
Day 7	No pain	92	60.5%	127	87.6%	0.000	X^2
	Mild	35	23.0%	15	10.3%		
	Moderate	23	15.1%	3	2.1%		
	Severe	2	1.3%	0	0.0%		
Day 30	No pain	143	94.1%	144	99.3%	0.012	X^2
	Mild	5	3.3%	1	0.7%		
	Moderate	4	2.6%	0	0.0%		
	Severe	0	0.0%	0	0.0%		
Patient satisfaction	Yes	143	94.1%	143	98.6%	0.038	X^2
	No	9	5.9%	2	1.4%		

X^2 Chi-square test (Fisher's exact test); * $p<0.05$

Lee et al. [11] investigated the effect of paramedian and median approach on early postspinal low back pain and found that the incidence of low back pain was 36% (18/50) in the median spinal technique and 16% (8/50) in the paramedian spinal technique. Patients were questioned about postspinal low back pain on day one, day 7 and at the end of 1st, 2nd and 3rd months. Postspinal low back pain was significantly lower in the paramedian spinal technique only on day 7. The three months follow-up was comparable between the groups. The paramedian technique was described as needle insertion from 1 cm lateral and 1 cm caudal to the spinous process.

Dadkbah et al. [12] reported the incidence of postspinal low back pain in the first 24 hours as 21% with the median approach and 25% with the paramedian approach. The paramedian approach was performed with a 25 G Quincke spinal needle 1 cm lateral and 1 cm caudal to the midline and the patients were followed up for one week postoperatively. In this study, there was no significant difference between the two approaches in terms of postspinal low back pain. The researchers reported that more than two attempts may be associated with low back pain. Mishra et al. [13] performed compared paramedian with median spinal approach in 60 obese female patients and reported that low back pain after one week was lower in patients underwent paramedian approach. No significant differences were found in the three months follow-up.

The advantages of the modified paramedian spinal technique in our study seems that number of needle passes and bone contact were lower compared to the classic median technique. This may lead to a lower incidence of low back pain as we found in our study. In our study, we evaluated a different and modified paramedian technique which is different from the aforementioned studies howbeit, our results are consistent with these studies. The disadvantages of the modified paramedian technique are being a less performed technique resulting in the lack of experience.

The limitations of the study are that it was single centered and the patients were not randomized. Lithotomy was not among the exclusion criteria, and postoperative analgesia follow-up was not performed. Another limitation is the BMI was significantly higher in the paramedian approach group. As expected, a higher BMI may lead to possible difficulties such as higher number of spinal attempts or bone contacts. However contrarily, needle insertion attempts and frequency of bone contact were lower in the paramedian approach group. It seems that the difference in BMI in favor of the median approach group did not affect the results clinically. The preference of the intervertebral level was L3-L4 interspace in the median approach group as there was more patients with lower BMI in this group. On the other hand, the preference of the intervertebral level was L4-L5 interspace in the median approach group as there was more patients with higher BMI in this group. Another limitation is sitting and lateral position during spinal anesthesia may affect the number of needle passes and pain and the distinguishment of these positions and evaluation of both positions separately was not done in our study. Bone contact is something that can be recognized by the practitioner therefore, it cannot be blinded. Post dura-puncture headache is one of the main complica-

tions of spinal anesthesia however we could not assess this in our study due to different incidences of dura-puncture headache and low back pain which required different number of sample sizes.

6. Conclusions

In our study, the number of needle insertion attempts and frequency of bone contacts were found lower in the modified paramedian spinal approach. However, further research and prospective randomized controlled studies are needed to come to the conclusion that modified paramedian approach reduces the number of needle attempts and bone contacts. Considering the low back-pain scores, the modified paramedian technique can be a strong alternative to the classic median spinal technique.

Acknowledgements

None declared.

Funding

The authors received no financial support for the research, authorship, and/or publication of this manuscript.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this manuscript.

Author Contributions

All of the authors made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; were involved in drafting the manuscript or revising it critically for important intellectual content; and gave final approval of the version to be published.

Data Availability

The datasets created and/or analyzed during the current study are not publicly available, but are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was approved by the ethics committee of Sakarya University Faculty of Medicine Clinical Research Ethics Committee (Ethics application no: E-16214662-050.01.04-149651-92). Written informed consent was obtained from the participants. All methods were performed in accordance with relevant guidelines and regulations.

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Research Article

Assessing the efficacy of sugammadex based on ideal body weight for reversal of moderate neuromuscular blockade in obstetric patients across different BMI categories: A prospective study

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ABSTRACT

Background: This investigation aimed to evaluate the effectiveness of administering 2 mg/kg intravenous (IV) sugammadex, dosed according to the ideal body weight (IBW) of obstetric patients across three different BMI groups, for the reversal of neuromuscular blockade caused by rocuronium.

Materials and Method: A total of ninety female patients, who were categorized as American Society of Anesthesiologists (ASA) II and were 18 years or older, participated in this study. These patients were all scheduled to undergo elective cesarean sections under general anesthesia, providing a well-defined cohort for our investigation. Participants were separated into three groups according to their BMI: Group 1 (n=30) consisted of patients with a BMI less than 30 kg/m^2, Group 2 (n=30) included those with a BMI ranging from 30 to 39.9 kg/m^2, and Group 3 (n=30) comprised patients with a BMI over 40 kg/m^2. At the end of the surgery, each patient received intravenous sugammadex at 2 mg/kg based on ideal body weight, with additional doses as needed, while recording the total amount administered and the times for extubation, motor responses, and first breastfeeding.

Results: The total sugammadex dose was found to be notably higher in Group 3 (p=0.002). The time required to reach a Train of Four (TOF) ratio greater than 90% was similar across the groups (p=0.120). However, the recorded durations between sugammadex administration and extubation, accurate motor response, and the time to first breastfeeding significantly differed between the groups.

Conclusions: We found that IV sugammadex 2 mg/kg, administered according to the IBW of patients, was effective for reversing moderate neuromuscular blockade in patients of weight categories. However, administering a sugammadex dose of IBW+25% appears to be safer for class III obese patients.

ARTICLE INFO

Article history:
Received 20 May 2024
Revised 22 September 2024
Accepted 16 October 2024

Keywords:
Anesthesia
Obesity
Obstetric
Severe obesity
Sugammadex

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1. Introduction

Obesity is a globally expanding health problem, with a higher prevalence in women. A recent study reported that 34.9% of the adult population in the United States has a body mass index (BMI) over 30 kg kg/m^2 [1]. Additionally, 2–5% of the adult population in Western societies has a BMI over 40 kg/m^2 [2]. Obesity is known to have significant effects during pregnancy. Overweight and obese women are at a higher risk of developing hypertension, diabetes mellitus, and cardiovascular problems during pregnancy [3]. Several studies have shown that the incidence of cesarean section (CS) has increased by more than 30% in obese patients [4,5]. Moreover,

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ISSN: 2980-292X / DOI: https://doi.org/10.20528/cjpm.2024.03.004

obesity affects the pharmacokinetics of several drugs due to reductions in body fluids and muscle mass. It is known that rocuronium bromide and vecuronium bromide have an increased duration of action in obese patients compared to those with a normal BMI. Therefore, in clinical practice, neuromuscular blocking agents (NMBs) are recommended to be administered based on the ideal body weight (IBW) of patients [6]. Furthermore, obesity is a significant risk factor for respiratory complications in the recovery room. Consequently, the rapid, reliable, and complete reversal of NMB agents in obese patients is of vital importance [7].

Sugammadex is a well-known drug for effectively reversing neuromuscular blockade induced by both rocuronium and vecuronium bromide [8]. Although several studies have evaluated the optimal dose for patients with normal body weight and morbid obesity, the ideal dose for patients with a BMI between 30 kg/m^2 and 40 kg/m^2 (Obesity Class I and II) remains a controversial issue [9]. Furthermore, previous studies on dose adjustments of sugammadex for morbidly obese (Obesity Class III) patients have reported conflicting results [10–13].

In this study, we aimed to evaluate the efficacy of intravenous (IV) sugammadex at a dosage of 2 mg/kg, calculated according to the ideal body weight (IBW) of obstetric patients in three distinct BMI categories, in reversing moderate neuromuscular blockade induced by rocuronium. The primary objective was to identify the average sugammadex dose required in each BMI group for successful extubation, as determined by Train of Four (TOF) monitoring. Secondary objectives included assessing the time from the initial sugammadex dose to successful extubation, the time to motor response to verbal commands, and the interval between the end of surgery and the first breastfeeding session, evaluated across different BMI groups.

2. Materials and Method

Following approval from the University Clinical Research Ethics Committee (Reference No: LUT–10/60, 06.03.2017), this study was registered with the Australian New Zealand Clinical Trials Registry, carrying the registration number ACTRN12618001633279. It was structured as a prospective, observational, controlled trial. Informed consent was secured from each participant prior to their inclusion in the study. Female patients over the age of 18, classified as American Society of Anesthesiologists (ASA) status II, who were scheduled for elective cesarean sections (CS) under general anesthesia, were recruited for the study between November 5, 2018, and December 20, 2018. Patients were excluded if they had pulmonary conditions such as asthma or chronic obstructive pulmonary disease, had known drug allergies to the medications used in the study, or were taking medications that could impact neuromuscular blockade, including magnesium sulfate, anticonvulsants, macrolides, or aminoglycosides. Individuals who declined participation were also excluded from the study.

The study participants were categorized into three groups based on their BMI: those with a BMI of less than 30 kg/m^2 (normal weight and pre-obesity) formed Group 1 (n=30), patients with a BMI between 30 and 39.9 kg/m^2 (Class I and II obesity) were assigned to Group 2 (n=30), and individuals with a BMI exceeding 40 kg/m^2 (Class III obesity) constituted Group 3 (n=30). In the operating room, all patients were subjected to standard monitoring, including electrocardiography (ECG), non-invasive blood pressure, pulse oximetry, end-tidal CO2, bispectral index (BIS), and Train of Four (TOF) monitoring. A 20-gauge intravenous line was inserted, and an infusion of isotonic saline (15 mL/kg/hour) was initiated. Following three minutes of preoxygenation with 100% O2, general anesthesia was induced with intravenous propofol (1.5–2 mg/kg) and rocuronium bromide (0.9 mg/kg). Anesthetic doses were calculated based on the ideal body weight (IBW) of each patient. Endotracheal intubation was performed when the BIS value fell below 60 and TOF reached less than 10%. Anesthesia maintenance involved 0.8–2.5% end-tidal sevoflurane in a mixture of 40% O2 and 60% N2O, with a target BIS range of 40 to 60. After delivery, fentanyl (1 mcg/kg) and ondansetron (4 mg) were administered intravenously, with dosages based on IBW. For postoperative analgesia, tramadol (2 mg/kg) was given intravenously at the end of surgery. Sugammadex 2 mg/kg was administered intravenously based on IBW when the TOF reached 25% to reverse the moderate neuromuscular blockade. TOF readings were taken every 20 seconds post-sugammadex administration, and if the TOF ratio (T4/T1) remained below 90% after two minutes, an additional dose of sugammadex (2 mg/kg) was given. Once the TOF ratio exceeded 90%, patients were extubated and transferred to the post-anesthesia care unit (PACU), where they were monitored for postoperative residual curarization (PORC) for one hour before being moved to the surgical ward. In the surgical ward, patients were observed for complications such as PORC, allergic reactions, bronchospasm, and postoperative nausea and vomiting (PONV) for 24 hours. For all patients, the total dose of sugammadex administered, the time between sugammadex administration and extubation, motor responses, and the time to first breastfeeding were recorded. Motor response was assessed by asking the patient to stick out her tongue or raise her head in response to verbal commands.

3. Sample Size and Statistical Analyses

The sample size was based on prior studies [13–15] evaluating a 2 mg/kg sugammadex dose according to ideal body weight (IBW) in Class III obese and normal-weight patients. To achieve an α error of 0.05 and a β error of 0.1, at least 27 participants per group were needed. Considering a 10% drop-out rate, each group included a minimum of 30 patients.

Statistical analysis was conducted using SPSS software version 22.0. Initially, descriptive statistics such as mean, median, minimum, maximum, standard deviation,

and ratio were calculated to summarize the data. To compare parametric variables that exhibited a normal distribution among the three groups, a one-way ANOVA was employed, followed by the Bonferroni test for post hoc pairwise comparisons. In cases where parametric variables did not conform to a normal distribution, the Kruskal-Wallis test was utilized to assess differences among the three groups, and the Mann-Whitney U test was applied for pairwise comparisons. For nonparametric variables, the analyses were conducted using Pearson's chi-square test and the Fisher-Freeman-Halton test. Additionally, the relationship between BMI and various intraoperative time periods, as well as the need for supplemental doses of sugammadex, was evaluated using Pearson's correlation test. A p-value of less than 0.05 was deemed statistically significant, indicating a meaningful difference in the results.

4. Results

A total of 96 patients were screened for inclusion in the study, and 90 patients were recruited, all of whom completed the study. Age, height, and IBW were similar across the groups; however, there were significant differences among the groups in terms of weight, BMI, and operation time. The demographic data of the patients are summarized in Table 1.

Table 1. Demographic data of the groups.

	Group I (n:30) (BMI < 30)	Group II (n:30) (30 < BMI < 40)	Group III (n:30) (BMI ≥ 40)	p
Age (years)	28.9±5.2	30.4±4.7	29.2±4.3	0.379
Weight (kg)	66.9±7.3	84.4±6.9	109.5±11.6	0.000**
Height (cm)	150±0.6	160±0.6	158±0.6	0.606
BMI (kg/m^2)	26.0±2.2	32.9±1.9	43.4±2.6	0.000
IBW (kg/m^2)	53.40±4.09	53.67±4.41	52.5±4.44	0.597
Systemic disease (yes/no)	4/26	5/25	1/29	0.294
Smoking (yes/no)	3/27	7/2	3/27	0.279

BMI: Body mass index; IBW: Ideal body weight

Mean rocronium bromide doses applied were similar in all groups (p=0.653), however, total sugammadex dose was found notably high in class III obese group (group 3) compared to other groups (p=0,.05). Eight patients (26.7%) in Group 3, 1 patient (3.3%) in Group 2 needed additional sugammadex dose while none of the patients needed additional sugammedex dose in group 1 (p=0.002) (Table 2).

Table 2. Mean rocuronium bromide and sugammadex doses administered amoung groups.

		Group I (n:30) (BMI < 30)	Group II (n:30) (30 < BMI < 40)	Group III (n:30) (BMI ≥ 40)	p
Rocuronium (mg)		47.46±53.91	47.76±4.19	46.83±3.85	0.653
Sugammadex (mg)		106.46±8.37	110.66±25.92	133.20±50.03	0.005**
Add Sug (n)(%)	No	30 (100)	22 (73.3)	30 (100)	0.002*
	Yes	0 (0)	8 (26.7)	0 (0)	

Add Sug: Additional sugammadex dose

The time needed to reach a TOF value over 90% was 62.2 ± 16.5 seconds in Group 1, 57.7 ± 2 seconds in Group 2, and 79.1 ± 64 seconds in Group 3. The difference among the groups was not statistically significant (p=0.120). The recorded durations between the administration of sugammadex and extubation were 76.1 ± 26 seconds in Group 1, 72.7 ± 28 seconds in Group 2, and 107.1 ± 63 seconds in Group 3. This difference was statistically significant (p=0.012). Additionally, the durations for accurate motor response and the time to first breastfeeding significantly differed between the groups and are summarized in Table 3.

Table 3. The distribution of perioperative durations across the groups.

	Group I (n=30)	Group II (n:30)	Group III (n:30)	p
TOF 0.9	62.2±16.5	57.7±20.9	79.1±63.7	0.120
Sug-extubation (sec)	76.1±25.9	72.7±28.1	107.1±63.0	0.012*
Sug-tongue stick (sec)	177.8±38.6	178.6±47.1	212.0±63.2	0.015*
Sug-breast feeding (h)	3.2±0.8	3.6±1.1	5.7±1.3	0.000**

TOF 0.9: Time needed for Train of Four 0.9; Sug-extubation: Time needed from application of Sugammadex to extubation; Sug-tongue stick: Time needed from application of Sugammadex to sticking out the tongue; Sug-breast feeding: Time needed from application of Sugammadex to first breast feeding

According to Pearson correlation analysis, BMI was positively correlated with the need for an additional sugammadex dose, time to reach a TOF value over 90% (TOF 0.9), extubation time, motor response time, and time to first breastfeeding. These correlations were statistically significant and are summarized in Table 4.

Table 4. Pearson correlation between Body Mass Index and other parameters.

Pearson correlation	r	p
BMI-add sug dose	+0.438	0.000**
BMI-TOF 0.9	+0.243	0.021*
BMI-extubation	+0.338	0.001*
BMI-tongue stick	+0.243	0.021*
BMI-breast feeding	+0.614	0.000**

BMI: Body mass index; add sug dose: Additional sugammadex dose; TOF 0.9: Time needed for Train of Four 0.9; Tongue stick: Time needed from application of sugammadex to sticking out the tongue

The postoperative complications were similar between the groups: PORC; none of the patients experienced PORC in group 1 and 2, but 2 patients (6.7%) in group 3 required an oxygen support in PACU (p=0.326). PONV; two patients (6.7%) in group 1, 4 patients (13.3%) in group 3 had PONV, but none of the patients in group 2 had PONV (p=0.159). Bronchospasm: One patient (3.3%) in group 2 and 4 patients (13.3%) in group 3 had bronchospasm. No patients experienced bonchospasm in group 1 (p=0.122).

5. Discussion

In the current study, we investigated the effectiveness of a standard sugammadex dose administered according to IBW in patients with different BMIs after cesarean section (CS). We found that Class III obese patients required significantly more additional sugammadex doses compared to normal BMI, pre-obese, Class I, and Class II obese patients. Additionally, the extubation time, motor response time, and time to first breastfeeding after sugammadex administration were significantly longer in severely obese patients than in the other groups. Although the time needed to reach a TOF value over 0.9 tended to be longer in severely obese patients, the differences between the groups were not statistically significant.

In pregnancy, the insidence of obesity increases over time and has become the most frequently observed morbidity in obstetric practice [5]. Maternal obesity plays a significant role in the occurrence of chronic hypertension, preeclampsia, and pregestational and gestational diabetes. Previous studies have reported that the rate of CS increases by 30% in obese women [4,5]. Unfortunately, the risk of postoperative respiratory complications is known to be higher in obese patients [16]; even when the TOF value reaches 0.9, obese patients remain at a higher risk of developing repiratory disfunctions such as partial airway obstruction [17]. In a multi-center observational study [18], the incidence of postoperative residual curarization (PORC) was found to be as high as 63.5%, even in the general population in Canada, and PORC has been shown to lead to respiratory insufficiency and hypoxia [19]. Given these risks, applying the most appropriate sugammadex dose based on BMI in obese patients is crucial. However, calculating the optimal dose is challenging in obese patients, as obesity reduces total body fluids and muscle mass, which affects the pharmacokinetics of drugs [20]. It is well established that administering the recommended dose of sugammadex can be insufficient for reversing neuromuscular blockade in Class III obese patients who received rocuronium bromide based on their actual body weight [21,22]. However, even when these drugs are administered according to IBW, their duration of action can be prolonged in Class III obese patients [6]. Specifically in Class III obesity, changes in the pharmacokinetic properties of drugs like sugammadex may necessitate the use of different dosing regimens [23]. Our findings align with this literature: the mean sugammadex dose administered per patient was 2.53 mg/kg, which is approximately 125% of the induction dose in the Class III obese group.

In the current literature, there are many strudies investigating the ideal sugammadex dose for class III obese patients. In a meta-analysis by Liao et al [24], administering sugammadex based on IBW was found to cause a delay in the reversal of neuromuscular blockade induced by rocuronium/vecuronium bromide. Similarly, Horrow et al. [25] conducted a multicenter study to compare the effects of sugammadex doses based on actual body weight (ABW) versus IBW in Class III obese patients and reported that doses based on ABW provided faster recovery. On the other hand, Li et al. [26] ompared sugammadex doses calculated using IBW versus corrected body weight (CBW) and found that dosing based on CBW was effective for the reversal of deep neuromuscular blockade (NMB) after continuous infusion of rocuronium in Class III obese patients. Although several studies have evaluated different sugammadex dosing strategies in Class III obese patients, and the results have been conflicting, there is limited data evaluating the efficacy of sugammadex specifically in Class I and II obese patients with a BMI between 30 and 40 kg/m^2. Therefore, we aimed to assess the realiablity and efficiency of a 2 mg/kg sugammadex dose calculated using IBW in normal-weight, pre-obese, Class I & II obese, and Class III obese patients. We found the mean extubation times to be 76.2 seconds, 72.7 seconds, and 107.1 seconds, respectively. Additionally, 8 patients in the Class III obese group required additional sugammadex doses, resulting in a final dose that was 25% higher than the initial dose in this group. These findings are consistent with previous studies in the literature. Van Lancker et al. [12] evaluated the effects of different suggammadex doses in obese patients undergoing laparoscopic bariatric surgery. They administered sugammadex 2 mg/kg based on IBW in Group 1, IBW+20% in group 2 and IBW+40% in Group 3, and based on ABW in group 4. They reported that none of the patients experienced PORC; however, the time to extubation significantly decresaed as sugammadex doses increased.

In the present study, it was observed that the duration from the administration of sugammadex to the onset of motor response was significantly prolonged in the Class III obese group when compared to patients with normal BMI, as well as those classified as Class I and II obese. This prolonged interval is likely attributed to the extended time required for these patients to achieve a Train of Four (TOF) value of 0.9, which in turn results in a delay in the extubation process for individuals with severe obesity.

Furthermore, it is important to consider the implications of anesthesia maintenance on recovery times. The use of sevoflurane, a commonly administered anesthetic agent, may have contributed to a more extended recovery period, hindering the ability of severely obese patients to execute voluntary movements postoperatively. This assertion is supported by findings from Zeidan et al., who reported that the end-tidal concentration of sevoflurane necessary to attain a Bispectral Index (BIS) score below 50 (the effective dose for 95% of the population, ED95) was 1.8% in severely obese patients after receiving propofol induction. In contrast, the average concentration required in the normal population was found to be 1.6% [27].

These findings suggest that Class III obese patients may have been subjected to higher doses of sevoflurane during their anesthetic management. Consequently, this increased exposure could have played a significant role in prolonging their recovery times, ultimately affecting their ability to regain normal function and responsiveness following surgery. Therefore, understanding the specific anesthetic requirements and recovery challenges faced by severely obese patients is crucial for optimizing their perioperative care and improving outcomes.In our investigation, we observed that the time to the first breastfeeding was significantly prolonged in Group 3. This finding aligns with existing literature. Prior studies [28,29] have reported that obese patients experienced delays in initiating breastfeeding and exhibited poorer lactation performance. Furthermore, Buonfiglio et al. [30] noted in their experimental research that obese rats displayed elevated leptin levels, which may contribute to both peripheral and central prolactin resistance. Supporting the literature, our analysis revealed a positive correlation between the time to first breastfeeding and increased BMI, as confirmed by Pearson correlation analysis.

Our study has some limitations. First, we combined patients with normal body weight (BMI between 18.5 and 24.9 kg/m^2) and pre-obese patients (BMI between 24.9 and 29.9 kg/m^2) patients in the same group (Group 1). Similarly, we grouped patients with Class I and Class II obesity together (Group 2). Although we could have divided the patients into five distinct groups, we believed this approach would not have been efficient. Secondly, after the initial dose of 2 mg/kg sugammadex, if the TOF value remained below 90% (T4/T1) at the end of the 2-minute interval, we administered an additional dose of 2 mg/kg sugammadex. We could have used a smaller dose (such as 0.5 or 1 mg/kg) to detect a more significant difference, but we chose to apply the standard dose recommended by the manufacturer.

6. Conclusions

In conclusion, we found that IV sugammadex 2 mg/kg, administered according to the IBW of patients, was effective for reversing moderate muscle blockade in normal body weight, pre-obese, and Class I, II, and III obese patients. However, applying a sugammadex dose of IBW+25% appears to provide a safer reversal in Class III obese patients based on the results of our study.

Acknowledgements

None declared.

Funding

The authors received no financial support for the research, authorship, and/or publication of this manuscript.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this manuscript.

Author Contributions

All of the authors made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; were involved in drafting the manuscript or revising it critically for important intellectual content; and gave final approval of the version to be published.

Data Availability

The datasets created and/or analyzed during the current study are not publicly available, but are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was approved by the ethics committee of Muğla Sıtkı Koçman University Clinical Research Ethics Committee (Reference No: LUT–10/60, 06.03.2017). Written informed consent was obtained from the participants. All methods were performed in accordance with relevant guidelines and regulations.

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Research Article

How does intravenous ondansetron affect motor and sensory block in spinal anesthesia administered with intrathecal levobupivacaine? A prospective randomized controlled study

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ABSTRACT

Background: Spinal anesthesia is commonly performed in surgical procedures, and ondansetron, frequently used as an antiemetic, is often administered to manage post-operative nausea and vomiting. Given their frequent co-administration, we sought to investigate the potential effects of intravenous ondansetron on the block characteristics of spinal anesthesia performed with levobupivacaine.

Materials and Method: In this prospective, randomized controlled study, forty patients were divided into two groups: Group L (spinal anesthesia with levobupivacaine) and Group OL (spinal anesthesia with levobupivacaine plus intravenous ondansetron).

Results: Our findings showed that while motor block duration was similar between the groups ($p>0.05$), sensory block duration was significantly shorter in the ondansetron group ($p<0.05$). There were no significant differences in patient demographics or hemodynamic parameters between the groups ($p>0.05$).

Conclusions: The shortened sensory block with ondansetron administration may be clinically undesirable as it could limit the intended duration of anesthesia. We recommend administering ondansetron at the end of surgery to avoid this effect. Further studies are required to confirm these findings and clarify the mechanisms involved.

ARTICLE INFO

Article history:
Received 30 June 2024
Revised 24 September 2024
Accepted 21 October 2024

Keywords:
Spinal anesthesia
Levobupivacaine
Ondansetron
Motor block
Sensory block

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1. Introduction

Neuraxial anesthesia stands as the foremost technique among regional anesthesia methods employed as primary anesthetic approaches and should be regarded as one of the fundamental skills of an anesthesiologist [1,2]. Spinal anesthesia (SA), the most frequently employed neuraxial technique, aims to provide effective anesthesia while ensuring that the selected local anesthetic and positioning align with the nature and duration of the surgical procedure. To achieve this, various agents with differing durations of action are available, and the objectives of anesthesia can be predicted through appropriate patient positioning [3].

The primary objective of researchers in the field of SA has been to achieve effective and long-lasting postoperative analgesia by extending the duration of sensory block while minimizing the extension of motor block duration spinal anesthesia [4]. This dual objective is crucial for enhancing patient comfort and facilitating early mobilization after surgical procedures. In recent years, numerous studies have focused on this aspect of spinal anesthesia. To achieve this goal, a wide range of techniques and methodologies have been investigated, with the ma-

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ISSN: 2980-292X / DOI: https://doi.org/10.20528/cjpm.2024.03.005

jority of these approaches concentrating on the addition of intrathecal adjuvants and systemically administered agents to the medications [5–7]. These adjuvants are intended to enhance the analgesic properties of the local anesthetics used in spinal anesthesia, thereby providing a more favorable balance between sensory and motor block durations.

Ondansetron is a 5-Hydroxytryptamine type 3 (5-HT3) serotonin antagonist and is commonly used as an antiemetic in perioperative medicine. However, hypotheses have been proposed that intravenous ondansetron administration in patients undergoing surgery with spinal anesthesia may provide more stable hemodynamics in addition to its antiemetic effect [8]. On the other hand, the effects of intravenous ondansetron on the block characteristics in spinal anesthesia procedures performed with bupivacaine, one of the most commonly used local anesthetics, have been investigated; however, conflicting findings have been observed [9,10]. No study has yet been reported that specifically examines the effects of intravenous ondansetron on sensory and motor block characteristics, as well as hemodynamic variables, in spinal anesthesia performed with levobupivacaine, highlighting a gap in the current literature regarding this combination.

This study examines the effects of intravenous ondansetron on sensory and motor block characteristics and hemodynamic variables in patients receiving spinal anesthesia with levobupivacaine. By addressing conflicting findings in the literature, this research aims to clarify the potential benefits of ondansetron administration in this context. The primary outcome of this study was defined as the duration of the sensory and motor block achieved with spinal anesthesia. By evaluating this critical parameter, we aim to provide a detailed understanding of the efficacy of intravenous ondansetron in modulating block characteristics. Additionally, secondary outcomes were identified to include the time to onset of the block and hemodynamic changes during the procedure. These secondary measures are crucial for assessing not only the effectiveness of ondansetron in enhancing anesthetic quality but also its potential impact on patient stability and safety throughout the perioperative period.

2. Materials and Methods

This prospective, randomized controlled study was conducted at Dr. Lütfi Kırdar Kartal Education and Research Hospital between February and September 2010, following ethics committee approval. Written informed consent was obtained from all patients, and the study adhered to the principles outlined in the Declaration of Helsinki and the CONSORT statement for reporting randomized trials. A total of 40 patients, aged 25 to 77 years, classified as ASA (American Society of Anesthesiologists) I-III and scheduled for elective hip and lower extremity surgeries, were included. Patients with ASA IV or higher, peripheral neuropathy, neuromuscular disorders, substance abuse, chronic pain treatment, those receiving α2 agonists or Ca^2+ channel blockers, obese patients (BMI>30), hypersensitivity to local anesthetics, scoliosis, previous lumbar surgery, coagulopathy, and infection were excluded.

Patients were randomized into two groups using sealed envelopes. Group L (n=20) received 4 ml of 0.9% isotonic NaCl intravenously 15 minutes before intrathecal injection. Group OL (n=20) received 8 mg/4 ml of ondansetron intravenously 15 minutes before intrathecal injection. Spinal anesthesia was administered with 2 ml of 10 mg levobupivacaine.

Standard monitoring (ECG, heart rate, blood pressure, peripheral oxygen saturation) was performed. Sensory block was assessed using the "pin-prick" test at 2-minute intervals until loss of sensation at the T10 dermatome. Motor block was evaluated using the Bromage scale every 2 minutes, with the onset of motor block defined as Bromage score 2–3. The presence and level of sensory and motor block were checked every 15 minutes to determine the time to recover from the blocks.

Bromage Scale:
0: No paralysis, full flexion of hip and knee.
1: Only knee and foot movement, unable to lift leg.
2: No knee movement, only foot movement.
3: Complete paralysis, no movement of ankle or toes.

3. Statistical Analyses

Statistical analysis was performed using NCSS 2007 software. Descriptive statistics (mean, standard deviation) were employed alongside Friedman's test for repeated measures, Kruskal-Wallis test for intergroup comparisons, Dunn's multiple comparison test for subgroup analysis, and Mann-Whitney U test for paired comparisons. Chi-square and Fisher's exact tests were used for categorical variables. Statistical significance was set at $p<0.05$ with a 95% confidence interval.

4. Results

A total of 44 patients were evaluated for the study. However, 2 patients declined spinal anesthesia, and 2 others were excluded due to their expected surgical duration exceeding 2.5 hours. Ultimately, 40 patients were included in the analysis, with 20 patients in each group. Group L consisted of patients who received spinal anesthesia with levobupivacaine, while Group OL included those who received spinal anesthesia with levobupivacaine plus systemic ondansetron (Fig. 1). There were no significant differences between the groups regarding descriptive parameters such as age, gender, height, weight, and ASA classification ($p>0.05$) (Table 1).

No significant statistical differences were observed between the groups in terms of non-invasive blood pressure (systolic, diastolic, and mean), heart rate, and oxygen saturation, both before spinal anesthesia and at multiple time points following intrathecal injection (1, 3, 5, 10, 15, 20, 30, 40, 60 minutes) as well as during the initial post-operative recovery room measurements ($p>0.05$ for all parameters at all-time intervals).

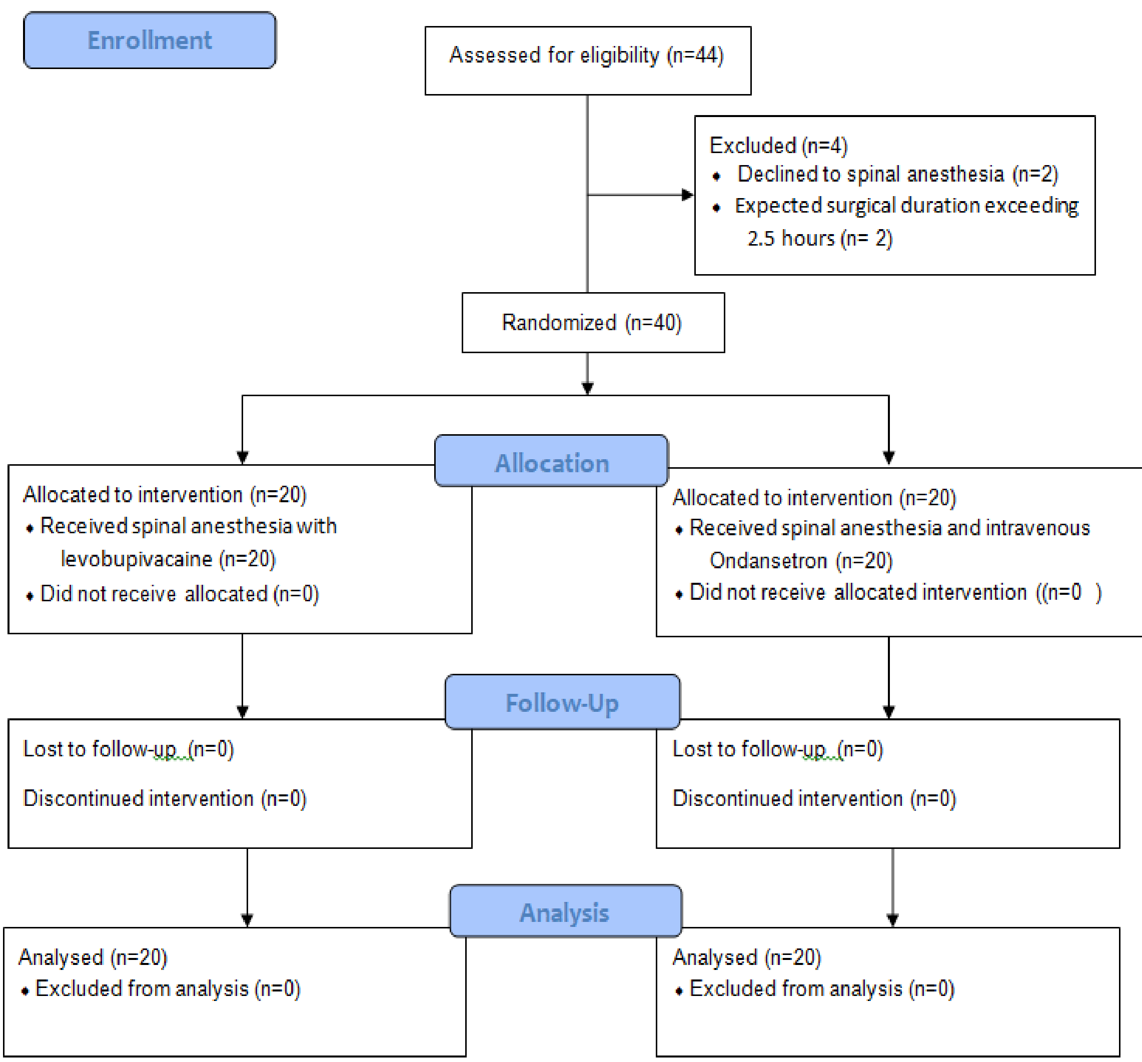

Fig. 1. Flow diagram of the study.

Table 1. Demographics of patients and comparisons.

	Group L	Group OL	p value
Age (years)	53.95 ± 15.32	49 ± 17.44	0.346
Weight (kg)	74.4 ± 14.34	74.85 ± 9.57	0.908
Height (cm)	171 ± 9.35	173.8 ± 9.51	0.354
Gender (F/M)	7/13	9/11	0.519
ASA (I/II/III)	7/8/5	10/8/2	0.404

ASA refers to the American Society of Anesthesiologists classification. Gender is represented as Female (F) and Male (M). Data are presented as mean ± standard deviation (SD) or as the number of patients.

While the onset times for motor and sensory blocks were similar between the two groups, the regression and termination times for motor blocks were also comparable ($p<0.05$). However, the regression and termination times for sensory blocks were shorter in the ondansetron group ($p<0.001$, $p<0.001$, respectively). No statistically significant differences were observed in the distributions of nausea, agitation, hypotension, hypertension, arrhythmia, bradycardia, and oxygen desaturation between groups ($p>0.05$).

5. Discussion

In this study, we evaluated the effects of administering systemic ondansetron together with spinal anesthesia using levobupivacaine on various clinical parameters and block characteristics in a cohort of 40 patients. Our results indicated no significant differences between Group L (levobupivacaine alone) and Group OL (levobupivacaine plus ondansetron) regarding demographic characteristics, non-invasive hemodynamic parameters,

or oxygen saturation levels at multiple time points. Additionally, the incidence of nausea, agitation, hypotension, hypertension, arrhythmia, bradycardia, and oxygen desaturation was comparable between the groups. Interestingly, while the onset times for both motor and sensory blocks were similar, the regression and termination times for sensory blocks were significantly shorter in the ondansetron group. These findings suggest that ondansetron may influence sensory block characteristics without affecting overall hemodynamic stability or other side effects commonly associated with spinal anesthesia.

Table 2. Comparative analysis of onset, regression, and termination times for motor and sensory blocks across groups.

Time frames	Group L (Mean ± SD)	Group OL (Mean ± SD)	p value
To reach maximum sensory block (min)	10.05 ± 4.33	8.25 ± 2.9	0.131
For 2-segment regression of sensory block (min)	114.85 ± 17.64	73.45 ± 15.99	<0.001
For complete resolution of sensory block (min)	141.8 ± 20	94.45 ± 16.35	<0.001
To onset of motor block (min)	11.2 ± 3.65	10.65 ± 3.23	0.617
For motor block regression (min)	135.2 ± 21.53	132.6 ± 15.73	0.665
For complete resolution of motor block (min)	152.25 ± 21.58	149.65 ± 16.04	0.668

Studies investigating the effects of intravenous ondansetron on the block characteristics of intrathecal bupivacaine occupy an important place in the literature, often presenting conflicting results [9,10]. While some research suggests that the concomitant use of ondansetron may positively influence block characteristics when administered with intrathecal bupivacaine, other studies report limited or no observed effect. This discrepancy highlights the need for further investigation into the pharmacological effects of ondansetron and its interactions with bupivacaine. Therefore, these conflicting findings should be carefully evaluated in the context of clinical practice and anesthesia management.

Ondansetron may affect the duration of spinal anesthesia through various mechanisms, including its antiemetic effect, modulation of serotonin-related pain pathways, and potential direct neurological influence on spinal cord neurons [10,11]. Additionally, its pharmacokinetic properties might alter the absorption and distribution of bupivacaine, and by reducing anxiety, it can help maintain physiological stability, enhancing the anesthetic's effectiveness [12]. These factors together provide a possible explanation for ondansetron's impact on spinal anesthesia characteristics.

In our study, we observed that although ondansetron did not have a significant impact on the duration of the motor block during spinal anesthesia, it notably shortened the duration of the sensory block. This finding is clinically concerning, as a shortened sensory block is generally considered undesirable in the context of spinal anesthesia. The primary objective of spinal anesthesia is to provide sufficient and sustained sensory anesthesia to ensure that patients remain pain-free and comfortable throughout the entire duration of the surgical procedure. A reduction in sensory block duration could potentially result in the premature return of sensation, leading to inadequate anesthesia and patient discomfort if the surgery is still ongoing [13,14]. This outcome runs counter to the fundamental purpose of spinal anesthesia, which is to maintain an effective and reliable sensory block for the necessary duration of the surgery.

Moreover, shortening the sensory block could introduce complications such as the need for additional anesthetic interventions during surgery or even the conversion to general anesthesia if the spinal block wears off too quickly [15]. This would not only increase the complexity of anesthesia management but could also lead to higher risks for the patient and a less predictable course of anesthesia.

Considering these potential clinical implications, we propose that ondansetron be administered at the end of the surgical procedure rather than before or during spinal anesthesia. This would allow the antiemetic benefits of ondansetron to be utilized without interfering with the desired duration of sensory anesthesia. Until more studies are published that confirm or refute the findings of our study, it may be prudent to exercise caution when using ondansetron in conjunction with spinal anesthesia, particularly in cases where maintaining a prolonged sensory block is critical for surgical success. Our recommendation is based on the current understanding of the interaction between ondansetron and spinal anesthesia, but further research is essential to clarify the long-term clinical significance of this interaction.

One of the primary limitations of our study is the absence of a formal sample size calculation. Our study included a total of 40 patients, with 20 patients in each group; however, without a predetermined sample size calculation, the statistical power of our findings may be limited. This lack of power could potentially affect the generalizability of the results, and future studies with larger, calculated sample sizes are necessary to validate our conclusions. Additionally, our study did not assess patient-reported outcomes such as the Quality of Recovery (QoR) score or similar measures, which would have provided valuable insights into the patients' overall postoperative recovery experience, including factors such as comfort, well-being, and satisfaction. Including such assessments would have enriched our evaluation of the clinical impact of ondansetron on spinal anesthesia. Incorporating these parameters into future research could provide a more comprehensive understanding of

the anesthetic and postoperative effects, which was a missed opportunity in our current study.

6. Conclusions

In conclusion, our study demonstrated that intravenous ondansetron significantly shortened the sensory block duration without affecting the motor block in patients undergoing spinal anesthesia with levobupivacaine. This finding suggests a potential interference with the intended duration of sensory anesthesia, which may be clinically undesirable. Administering ondansetron at the end of surgery could help avoid this effect, though further research is needed to support this approach.

Acknowledgements

None declared.

Funding

The authors received no financial support for the research, authorship, and/or publication of this manuscript.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this manuscript.

Author Contributions

All of the authors made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; were involved in drafting the manuscript or revising it critically for important intellectual content; and gave final approval of the version to be published.

Data Availability

The datasets created and/or analyzed during the current study are not publicly available, but are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was approved by the ethics committee of Dr. Lütfi Kırdar Kartal Education and Research Hospital. Written informed consent was obtained from the participants. All methods were performed in accordance with relevant guidelines and regulations.

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Research Article

Comparison of the effects of femoral and axillary artery cannulation on ischemic cerebral injury in acute type A aortic dissection surgery: A retrospective study

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ABSTRACT

Background: Acute Type A Aortic Dissection (ATAAD) is a life-threatening condition requiring emergency surgical intervention. This retrospective study evaluates the impact of femoral and axillary arterial cannulation techniques on ischemic neurological damage and mortality.

Materials and Method: A total of 60 patients who underwent emergency surgery for ATAAD between 2016 and 2021 were analyzed. Patients were divided into two groups based on the arterial cannulation technique: Group A (axillary cannulation) and Group F (femoral cannulation). Preoperative, intraoperative, and postoperative variables were compared between the groups. The primary outcome was incidence of ischemic cerebral injury and secondary outcomes included 30-day all-cause mortality, intensive care unit and hospital length of stay and postoperative complications.

Results: There were no statistically significant differences between the two groups in terms of ischemic cerebral injury (p=0.13). There was no significant difference in 30-day mortality between the groups (p= 0.27). Logistic regression analysis revealed that the cannulation type was a risk factor for ischemic cerebral injury development (OR [95% CI]; 119.034 [1.612–8791.314], p=0.029).

Conclusions: Our findings indicate that the type of cannulation may be a risk factor for the development of ischemic cerebral injury. Further studies are needed to determine the optimal arterial cannulation technique for improving outcomes in ATAAD surgery.

ARTICLE INFO

Article history:
Received 30 June 2024
Revised 28 September 2024
Accepted 21 October 2024

Keywords:
Type A aortic dissection
Arterial cannulation
Ischemic cerebral injury
Retrospective study

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1. Introduction

Acute aortic syndromes (AAS) are among the most life-threatening cardiovascular pathologies. The most severe clinical condition of AAS is Acute Type A Aortic Dissection (ATAAD), which has an incidence of approximately 0.003-0.007% per year [1]. Most patients are hypertensive males aged 50-70 years with a history of smoking. ATAAD, if not treated with emergency surgery, has a very high mortality rate [2]. If untreated within the first 2 days, the hourly mortality rate is 1-2%, and by the end of the second week, only 5% of untreated patients remain alive. The most common causes of mortality include organ malperfusion, aortic rupture, and pericardial tamponade [3]. According to current guidelines, the gold standard treatment for ATAAD is surgical intervention. However, diagnosing aortic dissection is challenging due to its varied clinical presentations and requires differentiation from other conditions such as pulmonary embolism, myocardial infarction, cerebrovascular

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ISSN: 2980-292X / DOI: https://doi.org/10.20528/cjpm.2024.03.006

events, and acute abdomen [4]. Despite advancements in surgical techniques and cerebral protection methods, the 30-day surgical mortality rate for ATAAD remains approximately 20% [5]. The primary goal of surgical treatment is to redirect blood flow to the true lumen, preventing the malperfusion of organs (coronary, cerebral, visceral, and extremity) caused by blood flow into the false lumen [6]. Ischemic cerebral injury (ICI) is one of the most feared complications following surgical treatment of ATAAD and significantly impacts postoperative morbidity and mortality rates. The main causes of ICI include inadequate cerebral protection, thromboembolic events, global ischemia, and the application of hypothermic circulatory arrest (HCA).

In this study, we aim to compare two commonly used arterial cannulation techniques—axillary and femoral—in terms of their impact on 30-day mortality and early postoperative complications, particularly ischemic cerebral injury, in patients undergoing emergency surgical treatment for ATAAD.

2. Materials and Method

The study was conducted in aortic surgery referral center at Samsun Ondokuz Mayis University Hospital. Ethical approval was obtained from the Institutional Review Board of Ondokuz Mayıs University (Ethics Committee Approval No: 2021/428). Due to the retrospective nature of the study, informed consent was not obtained. Hospital records of 60 patients who underwent emergency surgical treatment for ATAAD between 2016 and 2021 were retrospectively reviewed. Patients presenting with symptoms for less than 14 days were classified as ATAAD. The diagnosis was confirmed using intravenous contrast-enhanced 3D computed tomographic angiography and transthoracic echocardiography, and further verified intraoperatively. Both the Stanford and De Bakey classifications were used to describe aortic dissections. Only patients with Acute Type A (Stanford) or Type 1 (De Bakey) aortic dissection were included. Patients under 18 years of age, those without anesthesia records or clinical data, and those who underwent elective ATAAD surgery were excluded. Basic demographic and morphometric characteristics, as well as surgical, intraoperative, and postoperative information, were obtained from electronic medical records. Patients were divided into two groups based on the choice of arterial cannulation: Group A (axillary cannulation) and Group F (femoral cannulation). The selection of arterial cannulation was based on the hemodynamic status of the patient. Axillary cannulation was preferred in hemodynamically stable patients, while femoral cannulation was used in unstable patients or those requiring urgent cardiopulmonary bypass.

The primary outcome was incidance of ischemic cerebral injury (defined as focal brain injury with a permanent functional deficit confirmed on computed tomography scan). Secondary outcomes included 30-day all-cause mortality, length of stay in the intensive care unit and hospital, and postoperative complications.

2.1. Data collection

Preoperative variables included age, gender, weight, comorbidities, prior cardiac surgeries, EuroSCORE, creatinine, glomerular filtration rate, ejection fraction, and pulmonary arterial pressure. Intraoperative variables comprised cardiopulmonary bypass (CPB) time, cross-clamp (CC) time, total circulatory arrest (TCA) time, concurrent procedures (coronary bypass, aortic valve replacement), venous cannulation site, and cerebral protection strategies (antegrade cerebral perfusion, retrograde cerebral perfusion, deep hypothermia). Postoperative variables included mortality, new-onset cerebral events, inotrope requirement (noradrenaline, dobutamine, adrenaline), renal failure status (need for hemodialysis), low cardiac output status, duration of intubation, ICU stay, hospital stay, erythrocyte transfusion requirements, apheresis platelet requirements, cryoprecipitate requirements, random platelet needs, Fresh frozen plasma needs, and reoperation for bleeding.

2.2. Surgical technique

Aortic dissection was diagnosed by contrast-enhanced computed tomography. In ATAAD surgery, CPB plays a vital role in preventing malperfusion and ensuring continuous perfusion without interruption. For this urgent procedure, the choice of cannulation type was determined by the surgical team based on the patient's hemodynamic condition during the preoperative period. After median sternotomy and systemic heparinization, CPB was initiated through cannulation of either the non-dissected femoral artery or the right axillary artery, using direct or Seldinger techniques. In this study, patients were categorized based on the cannulation type into the femoral artery (Group F) or axillary artery (Group A) groups. In our institution, axillary artery cannulation is performed through an "end-to-side" graft attached to the axillary artery. This technique, which is slightly time-consuming, is performed at the start of the procedure and is preferred for hemodynamically stable patients. For hemodynamically unstable patients, direct femoral cannulation is chosen, allowing for rapid initiation of surgery. Venous return was achieved via right atrium or femoral vein cannulation. Moderate systemic hypothermia (nasopharyngeal temperature of 22–26 °C) and myocardial protection with intermittent antegrade and/or retrograde ısothermic blood cardioplegia were employed. Surgery was conducted using the open distal anastomosis technique, with cerebral protection provided by selective antegrade cerebral perfusion. The anatomy of aortic dissection was classified according to the Stanford classification. Patients with Stanford Type A dissections were included in the study. Due to the high variability in hemodynamic parameters—particularly end-organ damage—that can occur from diagnosis to the operating room, patients were retrospectively evaluated using the Penn classification to ensure homogeneity and reduce heterogeneity due to preoperative hemodynamic variations. Patients classified as Penn Class Aa and Ab were retrospectively included. This approach allowed

for a clearer assessment of the impact of perfusion techniques and cerebral protection strategies on outcomes.

For axillary cannulation, a transverse incision was first made in the right infraclavicular region. After dissecting through the pectoralis major and pectoralis minor muscles, the axillary artery was exposed and palpated adjacent to the axillary vein, with caution taken to avoid nerve damage to the brachial plexus located in the same anatomical area. A nylon tape was used to encircle the axillary artery. Vascular clamps were placed proximal and distal to the planned cannulation site, and a vertical arteriotomy was performed. An end-to-side anastomosis with an 8 mm x 5 cm Dacron graft was created. An 18-21F cannula was inserted into the side graft and secured with silk sutures. Backflow was observed from the arterial cannula, confirming effective function, and the cannula was sutured to the skin before the vascular clamps on the axillary artery were released. Following median sternotomy, right atrial venous cannulation was performed. Femoral cannulation was conducted using the Seldinger or direct technique. In terms of cerebral protection, the axillary cannulation group received antegrade cerebral perfusion, while the femoral cannulation group received deep hypothermia.

2.3. Anesthesia management

Upon arrival in the operating room, standard ASA (American Society of Anesthesiologists) monitoring was used, which included five-channel electrocardiography, pulse oximetry, direct arterial and central venous pressure monitoring, cerebral oxygen monitoring (near infrared spectroscopy/NIRS), urinary catheter, and rectal temperature monitoring. Preoperative, intraoperative, and postoperative management followed the institutional standardized cardiac anesthesia protocol. Induction was achieved with intravenous (iv) midazolam (0.05-to-0.1 mg/kg), fentanyl (2-to-5 mcg/kg iv), thiopenthal sodium (4-to-5 mg/kg iv), and rocuronium (1 mg/kg iv). During maintenance, O2/air (FiO2 0.40), 1%-to-2% sevoflurane, and iv fentanyl infusion (2-5 mcg/kg/h) were used. A TEE probe (McGrath MAC; Aircraft Medical, Edinburgh, UK) was inserted gently. Patients were ventilated using a volume-controlled mode, with an inspired oxygen fraction of approximately 0.6 and a positive end-expiratory pressure of 5 cmH2O. End-tidal CO2 values were maintained between 33 and 38 mmHg. At the end of surgery, all patients received 0.05 mg/kg morphine IV and were transferred to the ICU while intubated.

3. Statistical Analyses

Data were analyzed using IBM SPSS Version 23. The Shapiro-Wilk test was used to assess the normality of data distribution. Categorical variables were compared between groups using the Chi-square and Fisher's Exact tests. For comparisons of continuous variables, the Independent Samples t-test was used for normally distributed data, and the Mann-Whitney U test was applied for non-normally distributed data. Results were presented as mean ± standard deviation and median (minimum-maximum) for continuous variables, and frequency (percentage) for categorical variables. A significance level of $p<0.05$ was considered statistically significant.

4. Results

During the study period, data from patients who underwent emergency surgical treatment for ATAAD were evaluated. The study was completed with 60 patients who met the study protocol criteria. It was observed that arterial cannulation was performed using the axillary cannulation method in 49 patients (81.6%) and the femoral cannulation method in 11 patients (18.4%). The demographic and clinical characteristics of the patients, ATAAD type, and systemic diseases according to the cannulation method are summarized in Table 1. A higher incidence of diabetes mellitus was found in patients with femoral cannulation (63.6% vs. 30.6%, p=0.04), while a higher incidence of aortic insufficiency was observed in the group with axillary cannulation (100% vs. 81.8%, (p=0.02). The surgery duration, CPB time and CC time were similar between the groups. As expected, TCA for cerebral protection was applied more frequently in Group A compared to Group F (n [%], 49 [100] vs. 6 [54.5], p<0.01, respectively]. There were no statistically significant differences between the two groups in terms of ischemic cerebral injury (p=0.13) (Table 2). Also, postoperative renal replacement therapy, mechanical ventilation requirement, ICU stay, hospital stay, or mortality. The perioperative variables according to arterial cannulation are summarized in Table 2.

Logistic regression analysis revealed that the cannulation type was a risk factor for ischemic cerebral injury development (OR [95% CI]; 119.034 [1.612–8791.314], p=0.029). Factors affecting ischemic cerebral injury development are summarized in Table 3. Coronary artery disease (OR [95% CI]; 0.050 [0.004–0.555], p=0.015], ejection fraction (OR [95% CI]; 0.856 [0.742–0.988], p=0.034], and Euroscore (OR [95% CI]; 0.643 [0.416–0.994], p=0.047] were found to be associated with mortality. Factors affecting mortality development are summarized in Table 4.

5. Discussion

This single-center retrospective study evaluated the outcomes of patients who underwent emergency surgical treatment for ATAAD. The primary objective was to investigate the effect of two different peripheral arterial cannulation techniques (axillary vs. femoral) on 30-day hospital mortality and early postoperative complications, with a particular focus on ischemic cerebral injury. Our findings indicated that the type of cannulation was a risk factor for the development of ischemic cerebral injury. Additionally, coronary artery disease, ejection fraction, and Euroscore were identified as factors associated with increased mortality.

Table 1. Patient characteristics according to groups.

	Group A (n=49)	Group F (n=11)	p
Age (year) mean ± SD	60.3 ± 12.9	63.0 ± 10.6	0.54
Sex (woman) n (%)	16 (32.7)	3 (27.3)	0.72
BMI (kg/m²) mean ± SD	28.3 ± 4.9	28.9 ± 5.0	0.90
Systemic Disease n (%)			
Diabetes Mellitus	15 (30.6)	7 (63.6)	0.04*
Hypertension	49 (100)	11 (100)	-
COPD	8 (16.3)	3 (27.3)	0.39
CAD	38 (77.6)	7 (63.6)	0.33
CRF	10 (20.4)	3 (27.3)	0.61
Penn Classification			0.93
Penn Aa	35 (71.4)	8 (72.7)	
Penn Ab	14 (28.6)	3 (27.3)	
Valve Disease n (%)			
Aortic Insufficiency	49 (100)	9 (81.8)	0.02*
Mitral Insufficiency	28 (57.1)	7 (63.6)	0.69
Mitral Insufficiency	23 (46.9)	6 (54.5)	0.64
EF (%) mean ± SD	55.2 ± 7.7	54.0 ± 9.1	0.96
PAP (mmHg) mean ± SD	27.3 ± 8.6	29.7 ± 7.1	0.32
Euroscore mean ± SD	7.2 ± 2.9	8.4 ± 3.4	0.21

* Statistically significant difference; EF: Ejection Fraction; CAD: Coronary Artery Disease; CRF: Chronic Renal Failure; COPD: Chronic Obstructive Pulmonary Disease; PAP: Pulmonary Artery Pressure; BMI: Body Mass Index

Table 2. Perioperative variables according to groups.

	Group A (n=49)	Group F (n=11)	p
Surgical time (min) mean ± SD	350.1 ± 61.5	361.8 ± 83.4	0.54
CPB duration (min) mean ± SD	205.3 ± 65.2	253 ± 93	0.09
CC duration (min) mean ± SD	118.8 ± 47.5	164 ± 84.2	0.09
Inotropes n (%)			
Intraoperative Transfusion (IU) median (IQR)			
ES	7 (5)	8 (3)	0.52
FFP	6 (4)	7 (2)	0.04*
Apheresis Platelet	2 (1)	0 (2)	<0.01*
Random Platelet	0 (6)	6 (0)	0.03*
Cryoprecipitate	0 (0)	0 (0)	0.63
TCA n (%)	49 (100)	6 (54.5)	<0.01*
Cerebral protection n (%)			<0.01*
ASP	48 (98)	-	
BASP	1 (2)	-	
RSP	-	1 (9.1)	
Low CO n (%)	16 (32.7)	6 (54.5)	0.17
Resternotomy n (%)	3 (6.1)	1 (9.1)	0.72
RRT n (%)	7 (14.3)	2 (18.2)	0.74
Ischemic Cerebral Injury n (%)	5 (10.2)	3 (27.3)	0.13
Mechanical Ventilation (days) median (IQR)	1 (2)	2 (11)	0.32
ICU (days) median (IQR)	3 (3)	3 (10)	0.77
Hospital duration (days) median (IQR)	10 (11)	10 (13)	0.81
Mortality n (%)	18 (36.7)	6 (54.5)	0.27

* Statistically significant difference; CPB: Cardio Pulmoner Bypass; CC: Cross clamp; ES: Erythrocyte Suspension; FFP: Fresh Frozen Plasma; TCA: Total Circulatory Arrest; IABP: Intraaortic Balloon Pump; RRT: Renal Replacement Therapy; ICU: Intensive Care Unit

Table 3. Effect of variables on the development of ischemic cerebral injury.

	Beta	SE	OR (95% CI)	p
Type of Cannulation	4.779	2.195	119.034 (1.612 8791.314)	0.029*
Diabetes Mellitus	1.338	1.722	3.811 (0.130 111.319)	0.437
Coronary Artery Disease	1.042	1.264	0.353 (0.030 4.204)	0.410
COPD	2.200	1.685	9.025 (0.332 245.552)	0.192
CRF	0.757	1.513	0.469 (0.024 9.096)	0.617
Ejection Fraction	0.008	0.055	1.008 (0.905 1.121)	0.890
Pulmonary Artery Pressure	0.128	0.093	1.137 (0.948 1.363)	0.168
Euroscore	0.479	0.289	1.614 (0.917 2.842)	0.097
Duration of Surgery	0.016	0.024	0.984 (0.939 1.032)	0.513
CPB Duration	0.026	0.026	1.027 (0.976 1.080)	0.307
CC Duration	0.002	0.020	0.998 (0.959 1.039)	0.933
Surgical Revision	23.523	15187.888	1643… (0.000 -)	0.999

* Statistically significant difference; OPD: Chronic Obstructive Pulmonary Disease; CRF: Chronic Renal Failure; CPB: Cardio Pulmonary Bypass; CC: Cross Clamp

Table 4. Effect of variables on mortality.

	Beta	SE	OR (95% CI)	p
Type of Cannulation	1.069	1.261	0.343 (0.029 4.060)	0.396
Diabetes Mellitus	0.247	1.106	0.781 (0.089 6.828)	0.823
Coronary Artery Disease	3.004	1.232	0.050 (0.004 0.555)	0.015*
COPD	0.332	1.073	1.393 (0.170 11.407)	0.757
CRF	1.198	0.937	3.315 (0.528 20.817)	0.201
Ejection Fraction	0.155	0.073	0.856 (0.742 0.988)	0.034*
Pulmonary Artery Pressure	0.024	0.045	0.976 (0.893 1.066)	0.593
Euroscore	0.441	0.222	0.643 (0.416 0.994)	0.047*
Duration of Surgery	0.007	0.019	1.007 (0.970 1.045)	0.721
CPB Duration	0.023	0.019	0.978 (0.942 1.014)	0.223
CC Duration	0.005	0.013	0.995 (0.970 1.021)	0.709
Surgical Revision	1.951	1.584	7.034 (0.316 156.741)	0.218
Type of Cannulation	1.278	1.127	0.278 (0.031 2.537)	0.257

* Statistically significant difference; COPD: Chronic Obstructive Pulmonary Disease; CRF: Chronic Renal Failure; CPB: Cardio Pulmonary Bypass; CC: Cross Clamp

Despite advancements in emergency department, radiology, anesthesiology, and cardiovascular surgery practices, and improvements in medical technology, the surgical mortality of ATAAD remains high. The primary reasons for this are delays in diagnosis, increased risk of organ malperfusion, and the absence of an ideal cerebral/systemic perfusion strategy during the HCA period. Among the 60 patients included in our study, the 30-day hospital mortality rate was 36.7% vs 54.5% in the groups. This rate was higher than expected, possibly due to delays in surgical intervention. Most of the patients in our cohort were referred from hospitals in nearby provinces, leading to increased risks of complications such as aortic rupture and pericardial tamponade.

There is still no ideal peripheral arterial cannulation technique that can provide optimal cerebral/systemic perfusion during emergency surgical treatment of ATAAD. Although many retrospective studies suggest the superiority of axillary cannulation for cerebral protection compared to femoral cannulation, no significant difference in 30-day hospital mortality and major postoperative complications has been demonstrated. Xia et al. [7], in their review, emphasized that the choice of arterial cannulation in patients with ATAAD should be individualized. In the same study, they noted that the ideal arterial cannulation technique should provide rapid and adequate perfusion flow, prevent organ malperfusion, avoid triggering the expansion of aortic dissection or rupture, and be capable of sufficient antegrade cerebral perfusion for cerebral protection. The authors specifically highlighted that double arterial cannulation (DAC)—combining axillary/innominate and femoral artery cannulation—is more reliable for maintaining both cerebral and systemic circulation and is effective in preventing intraoperative malperfusion. However, they pointed out that the main drawback of DAC is the increased number of incisions and prolonged operative time.

Etz et al. [8], in a study reporting the outcomes of a series of 400 patients who underwent surgery for ATAAD, found a hospital mortality rate of 20.3%. There was no significant difference in hospital mortality or

postoperative stroke rates between the axillary and femoral cannulation groups. The study highlighted that the 10-year survival rate was significantly higher in the axillary cannulation group (antegrade perfusion) compared to the femoral cannulation group (retrograde perfusion) (71% vs. 51%). The authors indicated that retrograde perfusion of the true lumen was an independent risk factor for late mortality. Gokalp et al. [9] demonstrated that both femoral and axillary arterial cannulation methods can be safely used in patients with Acute Type A Aortic Dissection, as long as cerebral protection strategies are prioritized. The choice of cannulation method should be guided by the patient's specific medical condition, with consideration for factors such as vascular anatomy, comorbidities, and the urgency of the procedure. Additionally, the surgeon's experience and preference may influence the selection of the technique. This highlights the importance of individualized treatment approaches in complex cases, ensuring that patient safety and optimal outcomes are achieved. Ren et al. [10], in a meta-analysis of nine studies comparing axillary and femoral cannulation for ATAAD, which included a total of 715 patients, found that axillary cannulation was associated with better early mortality and postoperative stroke outcomes compared to femoral cannulation. However, the authors recommended that arterial cannulation strategy should be tailored to individual patient characteristics. They emphasized the need for high-quality, randomized, prospective, and multicenter studies before axillary cannulation can be routinely recommended as the standard technique for ATAAD surgery.

This study has several limitations that must be considered. First, as a single-center retrospective study, the findings may not be generalizable to other institutions with different surgical techniques, patient populations, or perioperative care protocols. The sample size, while reasonable, limits the statistical power of the analysis, particularly when examining rare postoperative complications such as ischemic cerebral injury or mortality. Additionally, the study did not account for potential confounding factors such as preoperative medical optimization, the time from symptom onset to surgery, and variations in the clinical condition of patients at presentation, all of which may influence outcomes. Furthermore, the lack of randomization and the reliance on retrospective data collection increase the potential for selection bias, and specific details of the surgical techniques used may vary slightly among surgeons, despite similar overarching approaches.

6. Conclusions

In conclusion, this study suggests that both axillary and femoral arterial cannulation methods can be used safely in the emergency surgical treatment of ATAAD, with no significant difference in 30-day hospital mortality or major postoperative complications between the two techniques. However, our findings indicate that the type of cannulation may be a risk factor for the development of ischemic cerebral injury, highlighting the need for careful selection of the cannulation method. Furthermore, factors such as coronary artery disease, ejection fraction, and Euroscore were associated with increased mortality, emphasizing the importance of individualized treatment approaches. Future studies should focus on larger, randomized, multicenter trials to further refine the optimal arterial cannulation strategy for improving both early and long-term outcomes in ATAAD surgery.

Acknowledgements

None declared.

Funding

The authors received no financial support for the research, authorship, and/or publication of this manuscript.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this manuscript.

Author Contributions

All of the authors made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; were involved in drafting the manuscript or revising it critically for important intellectual content; and gave final approval of the version to be published.

Data Availability

The datasets created and/or analyzed during the current study are not publicly available, but are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was approved by the institutional review board of Ondokuz Mayıs University (Ethics Committee Approval No: 2021/428). Written informed consent was obtained from the participants. All methods were performed in accordance with relevant guidelines and regulations.

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