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Ropivacaine versus ropivacaine plus dexmedetomidine in serratus anterior plane block patients undergoing post-thoracotomy surgery: a randomized, double-blinded clinical trial

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Abstract

Background This study was designed and implemented to investigate the addition of dexmedetomidine to Serratus Anterior Plane Block (SAP) with ropivacaine in reducing pain in patients undergoing post-thoracotomy surgery.

Methods This study included patients classified as American Society of Anesthesiology (ASA) Physical Status II, with a body mass index (BMI) under 40, who were undergoing thoracotomy at Imam Khomeini Hospital in Ahvaz. The subjects were randomly divided into two groups using a randomized controlled trial design. After surgery, in the recovery room, SAP was performed for patients with ropivacaine (0.4 ml/kg of 0.2% ropivacaine solution) (group R) and ropivacaine plus dexmedetomidine (0.5 µg/kg) (group RD). Pain (with verbal rating scale, VNRS), blood pressure (systolic, diastolic, and mean arterial pressure (MAP)), heart rate (HR), and blood oxygen saturation (O₂ sat) were measured and recorded before the intervention, and 1, 6, 12, 24, and 48 h after the intervention.

Results Finally, 74 patients were included in this study. Both groups exhibited significant pain reduction at one hour, with sustained pain relief observed in the RD group at 6, 12, and 24 h ($P < 0.001$). The RD group also showed having lower values HR and MAP at 6 and 12 h ($P < 0.001$). Patients in the RD group received painkillers faster ($P = 0.005$) and required lower total narcotic usage ($P < 0.0001$). Two RD group patients experienced transient bradycardia, which resolved without treatment.

Conclusion The findings of this study show that SAP block with dexmedetomidine is an effective and safe drug along with ropivacaine as a nerve-blocking agent in thoracotomy candidates.

Keywords Thoracic surgical procedures, Thoracotomy, Pain, Serratus anterior plane block, Ropivacaine, Dexmedetomidine

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Introduction

Thoracotomy surgery is accompanied by severe postoperative pain, which is one of the most severe pains caused by surgery [1]. The resulting pain, in addition to causing patient suffering, has many undesirable physiological and pathological side effects that significantly impact the prognosis and outcome of the disease and surgery [2, 3]. The pain caused by surgery leads patients to move less and try to reduce their pain with shallow breathing and less chest movement. As a result, this decrease in breathing causes hypoxia and pulmonary dysfunction [4]. Pulmonary dysfunction after surgery can delay recovery and even threaten the patient's life. Hypoxia can also reduce wound healing and cognitive function. Immobility causes atelectasis, which makes the patient prone to infection and respiratory failure [5, 6]. Postoperative analgesia is a crucial element of this type of surgery, and many efforts have been made to achieve effective pain management. Various methods of analgesia have been developed, including systemic or regional methods [7, 8]. Thoracic epidural block is the gold standard method for pain control after thoracotomy, but it is associated with complications like dural puncture, hypotension, and urinary retention [9]. Anterior serratus nerve block is a suitable method for creating analgesia in thoracic surgery, providing analgesia at T2-T9 levels [10]. Given the increasing number of chest surgeries, preventing chronic pain syndrome, benefits of serratus nerve block, reducing non-steroidal anti-inflammatory drugs' side effects, reducing local anesthetic consumption, pulmonary complications, recovery time, improving quality of life, reducing economic costs, physical and psychological complications caused by pain, and treatment costs, using a safe, easy, and minimally invasive method are the advantages of using a Serratus Anterior Plane Block (SAP) [11, 12].

Drugs used for this block include ropivacaine and dexmedetomidine. Ropivacaine is a long-acting local anesthetic of the amide group, used for epidural block, peripheral nerve block, and anesthesia [13, 14]. Dexmedetomidine, an α_2 adrenergic agonist, has various uses in anesthesia and intensive care units. It is used as a sedative and analgesic drug, reducing nausea and vomiting after surgery and maintaining stable hemodynamics in laparoscopic surgery [15]. This drug has fewer side effects and is more selective for the α_2 receptor than drugs like clonidine. Additionally, dexmedetomidine has been reported to prolong analgesia in abdominal, lower limb, and cesarean surgeries when added to spinal anesthetic drugs [16]. This study aimed to compare the effect of ropivacaine and the combination of ropivacaine and dexmedetomidine in SAP for reducing pain in patients after thoracotomy surgery.

Methods

Study design and setting

In 2021, a randomized, double-blind clinical trial was undertaken at Imam Khomeini Hospital in Ahvaz, Iran, adhering to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [17]. Patients undergoing thoracotomy were randomly assigned to either treatment or control groups. The research received ethical clearance from Ahvaz Jundishapur University's (AJUMS) Ethics Committee (*IR.AJUMS.REC.1402.615*) and was registered with Iran's Clinical Trials Registry (IRCT) (<https://irct.behdasht.gov.ir/>; *IRCT20221222056890N1*, Registration date: 2024-02-15). Participants provided informed consent, ensuring compliance with the Declaration of Helsinki's standards for human research (DoH, Finnish: Helsingin julistus).

Population

Inclusion criteria

This study enrolled individuals aged 18 to 60 who met specific health criteria. Eligible participants had a low to moderate physical health risk based on the American Society of Anesthesiology (ASA) Physical Status II, a healthy weight (BMI under 40), and no history of substance misuse. Furthermore, eligible patients were non-pregnant, non-breastfeeding, and free from coagulation disorders, anticoagulant medications, and severe heart conditions, except for controlled atrial fibrillation and first-degree heart block. Their cardiac function also met a minimum threshold, with a left ventricular ejection fraction exceeding 30%. Furthermore, patients without acute or chronic hepatitis, psychiatric diseases, or neuropathy, and those who did not require complementary renal treatments or have a history of kidney failure, were also eligible to participate.

Exclusion criteria

Allergy to the study drugs and a patient's unwillingness to cooperate, pregnancy, breastfeeding, coagulopathy, anticoagulant drug use, and had a left ventricular ejection fraction less than 30% were the reasons for exclusion from this study.

Interventions

Upon entering the operating room, patients underwent routine vital sign monitoring, including blood pressure, heart rate, oxygen saturation, and electrocardiogram. A standardized general anesthesia protocol was administered, consisting of fentanyl (3 $\mu\text{g}/\text{kg}$), midazolam (0.05–0.03 mg/kg), propofol (1 mg/kg), and atracurium (0.5 mg/kg). Following intubation, patients received isoflurane and remifentanyl (1 $\mu\text{g}/\text{kg}/\text{min}$) to maintain anesthesia during surgery. During the procedure, carbon dioxide levels and respiratory volume were

closely monitored and adjusted to ensure optimal ranges (ETCO₂: 35–45 mmHg, tidal volume: 7–10 ml/kg). Post-surgery, patients were extubated and transferred to either the recovery room or ICU for further care.

Once hemodynamically stable, the serratus anterior plane block was performed under ultrasound guidance (Sonosite S II, USA) by the pain fellowship (Fig. 1). Patients were positioned either on their back or side, and the area was prepared and draped for the procedure. A high-frequency ultrasound transducer was positioned along the mid-axillary line, allowing for clear visualization of the underlying anatomy, including the rib, latissimus dorsi, serratus anterior, and pleura. Next, a fine spinal needle was inserted using either a direct or indirect approach, and after confirming proper placement, the solution was administered in two stages. The initial injection targeted the serratus anterior and latissimus dorsi muscles, while the remaining solution was delivered deeper into the serratus anterior muscle and adjacent to the rib.

After removing the needle, a pressure dressing and cold compress (Ice Pack) were applied. In the R group, 0.4 ml/kg of 0.2% ropivacaine solution were injected, while in

the RD group, 0.4 ml/kg of 0.2% ropivacaine solution plus 0.5 µg/kg dexmedetomidine were injected, according to the described method.

Outcomes

Initial patient characteristics, such as age, gender, height, weight, and body mass index (BMI), were documented. The primary outcome of interest was pain intensity, while secondary outcomes included blood pressure, heart rate, oxygen saturation, narcotic usage at various time intervals (2–48 h post-recovery), ICU walking time, length of stay, and adverse effects.

Pain levels were evaluated using the Verbal Numeric Scale (VNS), where patients rated their discomfort on a 0–10 scale, with 0 indicating no pain and 10 representing extreme pain. Patients with a VNS score above 3 received 1 mg/kg of meperidine and total narcotic consumption was tracked for each patient.

Sample size

Using the sample size formula and data from Menshawi et al. [18], the required sample size was calculated to be 37 individuals per group, for a total of 74.

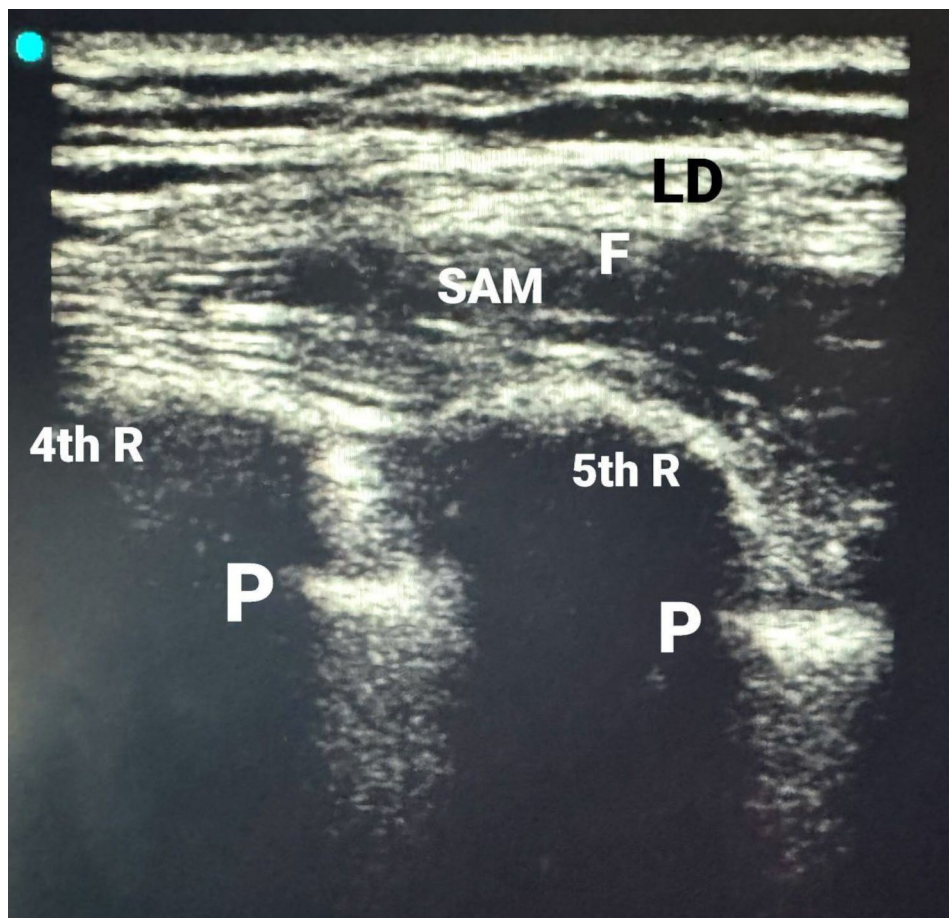


Fig. 1 Ultrasound view of SAP block, F: Fascia, LD: Latissimus dorsi muscle, P: Pleura, R: 4th and 5th rib, and SAM: Serratus anterior muscle

$$\begin{aligned}
 Z1-\alpha/2 &= 1/96 \\
 Z1-\beta &= 0.85 \\
 S1 &= 1/96 \\
 S2 &= 0.94 \\
 D &= 0.9 \\
 N &= z1-\alpha2 + z1-\beta2(S12 + S22)d2 = 37
 \end{aligned}$$

Randomisation

Allocation of patients was done in random order in this way, which is done using the randomization table. The information was entered into the checklist. The checklists were already numbered by the statistical consultant, and this numbering was the basis for the allocation of patients, but the allocation of numbers to groups were revealed until the results are analyzed.

Blinding

In this way, the patient and the specialist doctor were both unaware of the type of medicine. The patient and the person responsible for registering their information were unaware of the patient's diagnostic group. The information was entered into a checklist. The checklists had already been numbered by a statistical consultant, and this numbering was the basis for patient allocation. However, the allocation of numbers to groups was not revealed until the results were analyzed. The person tasked with injecting the medication was aware of the treatment being administered but was not engaged in collecting or analyzing the study data.

Statistical methods

This study employed descriptive statistics (mean, standard deviation, frequency, and percentage) to summarize the data. Inferential statistics, including independent samples t-tests, chi-square tests, logistic regression, and repeated measures analysis of variance, were used to investigate relationships between variables. The Kolmogorov-Smirnov test verified data normality.

Data analysis was performed using SPSS version 27, with a significance threshold of $p < 0.05$. Additionally, effect sizes were calculated using Cohen's d, with guidelines for interpretation: small (0.20–0.49), medium (0.50–0.79), and large (≥ 0.80) [19].

Results

Finally, 74 patients were evaluated in this study. The participants were included 59.46% (44 male) (Fig. 2). Moreover, the mean age of patients was 40.57 ± 12.20 years (Table 1).

VNS

One-hour post-intervention, both groups exhibited substantial pain reductions, as measured by the VNS, with no significant difference between groups (R group: -7.459

units, RD group: -7.649 units; $P = 0.164$). However, at 6, 12, and 24-hours post-intervention, pain reduction was significantly more pronounced in the RD group, with a large effect size ($P < 0.001$), indicating sustained pain relief (Table 2; Fig. 3A).

HR

HR showed no significant intergroup difference one-hour post-intervention ($P = 0.053$). However, at 6 and 12 h, the RD showed lower significantly HR, with substantial effect sizes ($P < 0.001$) (Tables 2 and Fig. 3B). This difference dissipated by 24 and 48 h, with no statistically significant distinction in HR between groups ($P > 0.05$) (Fig. 3B).

Mean arterial blood pressure

No significant difference in MAP was observed between the two groups one-hour post-intervention ($P = 0.149$). However, at 6 and 12 h, the RD group showed lower significantly MAP, with substantial effect sizes ($P < 0.001$) (Tables 2 and Fig. 3C). This intergroup difference dissipated by 24 and 48 h, with no statistically significant variation in MAP between groups ($P > 0.05$) (Fig. 3C).

Blood oxygen saturation

The RD group displayed consistently lower blood oxygen saturation levels throughout the study, but these differences did not reach statistical significance ($P > 0.05$). Meanwhile, the R group showed incremental increases in oxygen saturation at each measurement interval, including 0–1 h (+0.11%), 1–6 h (+0.21%), 6–12 h (+0.35%), 12–24 h (+0.27%), and 24–48 h (+0.33%). Nonetheless, these changes failed to achieve statistical significance ($P > 0.05$) (Fig. 3D).

Hospitalization

Analysis of hospitalization variables revealed that patients in the RD group received painkillers significantly faster (13.32 ± 3.863 h) than those in the R group (16.06 ± 4.41 h), with a large effect size ($P = 0.005$) (Table 3). Conversely, ICU stay duration and time to standing were comparable between groups ($P = 0.97$ and $P = 0.82$, respectively). Nonetheless, the R group demonstrated significantly higher total narcotic usage (180 ± 55.58 mg) compared to the RD group (130.1 ± 57.96 mg), with a substantial effect size ($P < 0.0001$) (Table 3).

Side effects

Bradycardia, defined as a heart rate below 60 beats per minute, was observed in two RD group patients six hours after the procedure. These episodes were self-limiting and did not necessitate treatment. In contrast, the R group did not experience any bradycardic events.

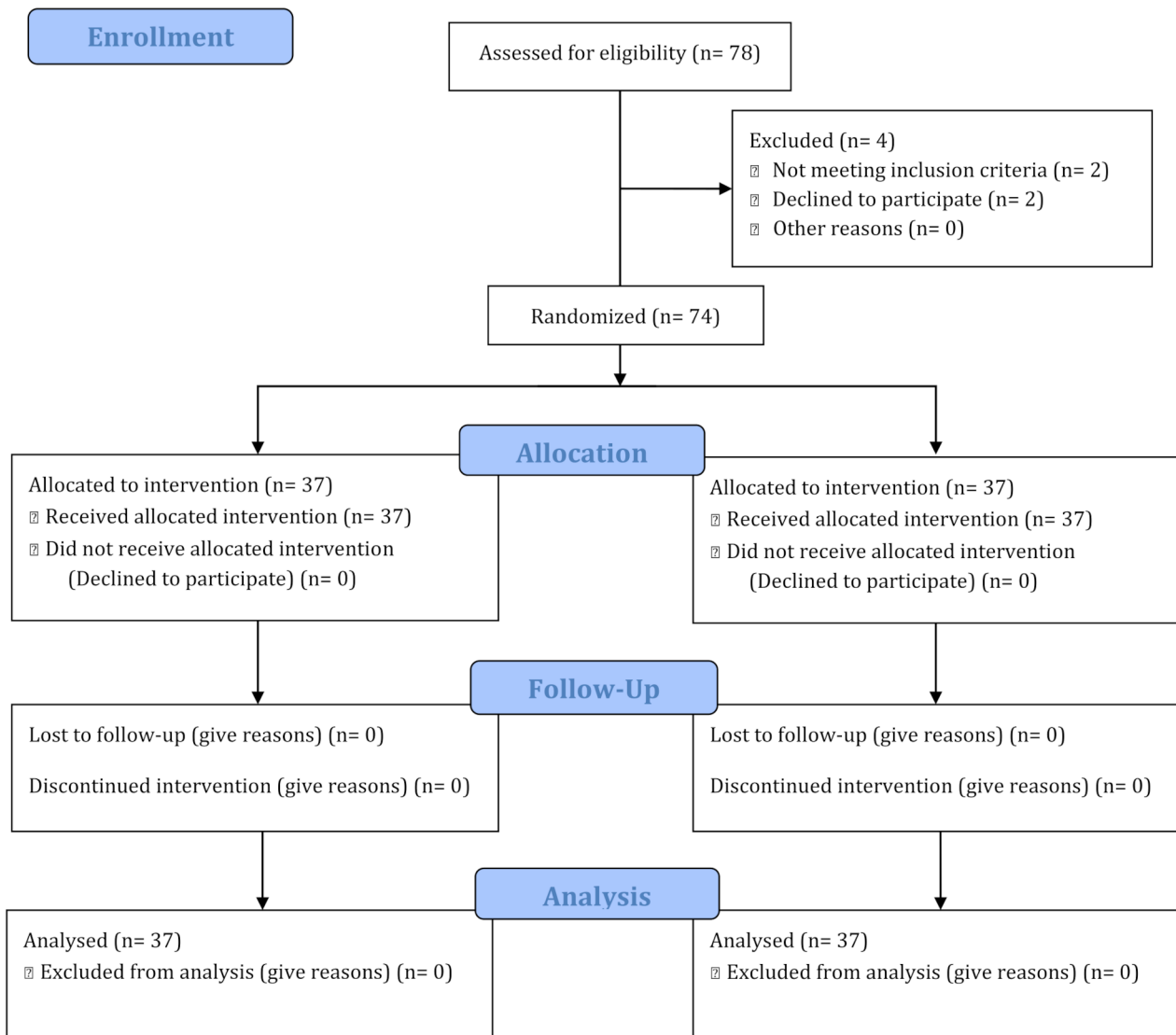


Fig. 2 CONSORT flow diagram

Table 1 Demographic information of the studied patients

Variables	Ropivacaine (N=37)	Ropivacaine+ Dexmedetomidine (N=37)	P-value
Age (years), Mean ± SD	39.78 ± 12.09	41.35 ± 12.42	0.584
Gender (Female), N (%)	13 (35.13)	17 (45.94)	0.344
Height (cm), Mean ± SD	172.6 ± 8.43	173.1 ± 9.32	0.815
Weight (kg), Mean ± SD	82.11 ± 13.83	85.24 ± 13.58	0.329
BMI (kg/m ²), Mean ± SD	27.41 ± 3.22	28.39 ± 3.61	0.221
Duration of surgery (h), Mean ± SD	2.52 ± 0.962	2.79 ± 1.11	0.272

Discussion

Dexmedetomidine is an alpha-2 agonist that has been extensively studied for its effects, such as reducing stress before surgery, reducing inflammation, improving

digestive function, and analgesia in patients after various surgeries, and reducing the number of narcotics consumed [20–23]. The findings suggest that both VNS groups experienced significant pain reduction one hour after intervention, with sustained reductions at 6, 12, and 24 h. Notably, the RD group demonstrated lower pain scores with large effect sizes at 6, 12, and 24 h, indicating enhanced analgesic effects when combining VNS with dexmedetomidine. This is consistent with previous studies showing synergistic effects between VNS and dexmedetomidine in reducing pain. HR and MAP were significantly lower in the RD group at 6 and 12 h, suggesting improved cardiovascular stability. However, these differences did not persist beyond 24 h. Furthermore, the RD group had a significantly longer time to receive painkillers and consumed fewer narcotics overall, indicating

Table 2 Variables effect sizes

Variables		Effect Sizes (Cohen's d)	95% Confidence Interval	
			Lower	Upper
VNS	Pre-Block	-0.3	-0.76	0.16
	Immediately After	-0.33	-0.78	0.13
	After 6 h	1.32	0.81	1.82
	After 12 h	1.68	1.15	2.21
	After 24 h	0.86	0.38	1.33
	After 48 h	0.07	-0.38	0.53
MAP	Pre-Block	-0.34	-0.8	0.12
	Immediately After	0.26	-0.2	0.72
	After 6 h	0.94	0.46	1.42
	After 12 h	0.84	0.36	1.31
	After 24 h	-0.21	-0.67	0.25
	After 48 h	-0.25	-0.71	0.21
HR	Pre-Block	-0.16	-0.62	0.3
	Immediately After	0.46	-0.01	0.92
	After 6 h	1.08	0.586	1.56
	After 12 h	0.98	0.494	1.46
	After 24 h	-0.04	-0.5	0.41
	After 48 h	-0.34	-0.8	0.12
Blood oxygen saturation	Pre-Block	0.21	-0.25	0.66
	Immediately After	0.19	-0.27	0.64
	After 6 h	0.06	-0.4	0.51
	After 12 h	0.26	-0.2	0.71
	After 24 h	-0.02	-0.48	0.44
	After 48 h	0.21	-0.25	0.66

potential benefits in reducing opioid dependence. However, hospitalization length and time to stand up did not differ significantly between groups. The analysis of blood oxygen saturation levels revealed an interesting trend, with the RD group consistently showing lower saturation levels across all measurement times. Although these differences did not reach statistical significance ($P > 0.05$), this observation warrants further exploration.

There is little clinical evidence on the effectiveness of dexmedetomidine in SAP for patients after thoracotomy. Rashidi et al. [24] showed the pain reduction was more intense and effective in the group receiving ketamine. However, changes in MAP, HR, and RR were similar in both groups, with no statistically significant difference observed. Additionally, no side effects were reported in this study. Another study [25], also showed that dexmedetomidine is a useful adjuvant to levobupivacaine for persistent serratus anterior plane block after thoracotomy, providing good analgesic effects up to 12 h postoperatively. The addition of dexmedetomidine enhanced analgesia, covering the first 24 h of the postoperative period, significantly reducing morphine consumption and maintaining stable hemodynamics. Dexmedetomidine also had an excellent sedative effect during the 24 h following the operation, without causing respiratory depression. A clinical study [18] examining the effect of

dexmedetomidine with bupivacaine showed that the analgesic effects of dexmedetomidine with bupivacaine in SAP block for patients undergoing video-assisted thoracoscopic surgeries (VATS) under general anesthesia were significantly reduced at 8 and 12 h postintervention. The present study's outcomes are in concordance with prior research [25–30], which has established that dexmedetomidine supplementation extends postoperative analgesia duration and reduces opioid usage. Notably, these benefits are achieved without an increased incidence of adverse effects. Our results reinforce this clinical evidence, confirming dexmedetomidine's analgesic efficacy in patients undergoing thoracotomy during the critical 24-hour postoperative window.

This study showed that, the addition of dexmedetomidine lowered significantly MAP and HR at 6 and 12 h. Similarly, dexmedetomidine does not appear to have a direct effect on the heart [31]. A biphasic response has been described after the use of dexmedetomidine [32]. The bolus administration of 1 µg/kg of dexmedetomidine initially leads to a transient increase in blood pressure and a reflex decrease in HR, especially in young and healthy patients [33].

The current study's MAP assessments revealed temporal variations, marked by early decreases (1 and 6 h) and a subsequent increase (24 h). Significant between-group differences emerged at 6 and 12 h. Importantly, both groups remained hemodynamically stable, with no instances of shock or necessity for vasopressor support. These findings corroborate previous research, including Kang et al.'s investigation, reinforcing confidence in the intervention's safety and effectiveness [34]. The present study's outcomes align with the dose-response analysis conducted by Shen et al. [35], who observed significant decreases in MAP and HR in medium and high dose dexmedetomidine groups versus control and low-dose groups at 2 and 3 h ($P < 0.05$). Furthermore, the high-dose group demonstrated additional reductions in MAP and HR compared to the medium-dose group at 1, 2, and 3 h ($P < 0.05$), highlighting the dose-dependent efficacy of dexmedetomidine.

It is remarkable that in the RD group, two patients had bradycardia (HR less than 60), while in the R group, no patient showed such a complication. In both patients, this happened six hours after the intervention, and the HR returned to normal without any special treatment. The present study's findings align with Esmaoglu et al.'s [36] research, which demonstrated that the addition of dexmedetomidine to levobupivacaine in axillary brachial plexus blocks resulted in decreased hemodynamic parameters. Specifically, the dexmedetomidine group showed significant reductions in systolic and diastolic blood pressure and heart rate compared to the levobupivacaine-only group. Although that study only measured

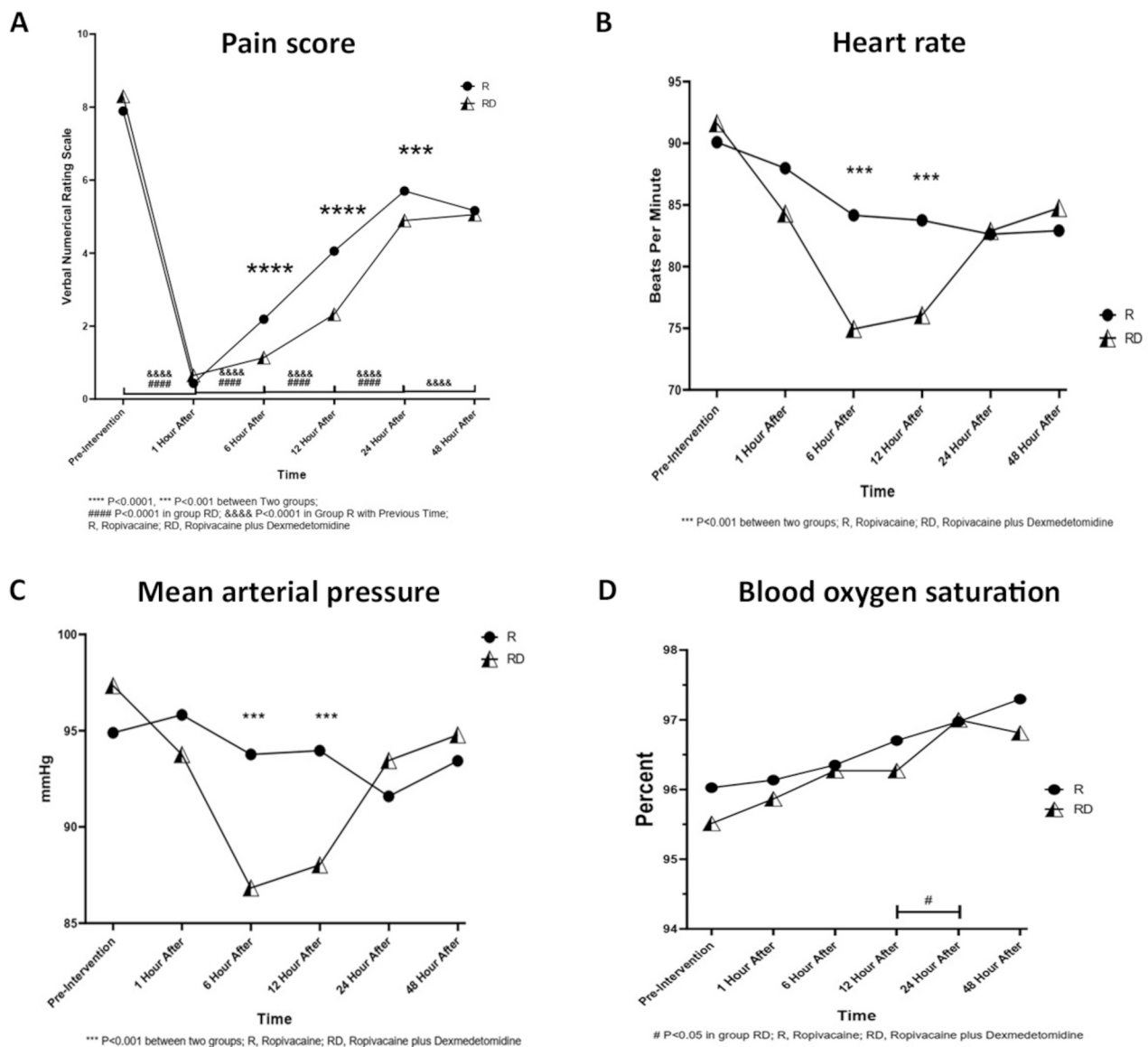


Fig. 3 (A) Comparison of pain scores between the two study groups at the time of measurement, (B) Comparison of heart rates between the two study groups, (C) Comparison of mean arterial pressure (MAP) (mmHg) of patients during measurement times, and (D) Comparison of blood oxygen saturation among study patients

Table 3 Comparing the amount of variables after the study

Variables	Ropivacaine (N=37)	Ropivacaine + Dexmedetomidine (N=37)	P-value	Effect Sizes (Cohen's d) (95% CI)
Time to receive Pain Relief Medications (h), Mean ± SD	13.22 ± 3.86	16.06 ± 4.41	0.005	0.89 (0.41, 1.4)
Hospitalization in ICU (d), Mean ± SD	3.28 ± 2.69	3.26 ± 3.57	0.97	0.008 (-0.45, 0.46)
Time to set up (d), Mean ± SD	4.21 ± 3.12	4.37 ± 3.31	0.82	-0.05 (-0.51, 0.4)
Narcotics consumed (mg), Mean ± SD	180 ± 55.58	130.1 ± 57.96	<0.001	0.89 (0.41, 1.37)

and showed this difference in the first two hours after the intervention, this study showed this difference between the two groups up to twelve hours later. In contrast to our findings, Wang et al.'s study [30] on the effects of dexmedetomidine added to ropivacaine in erector spinae plane block (ESPB) for thoracotomy patients revealed no significant changes in MAP and HR with the addition of 0.5 µg/kg dexmedetomidine. This discrepancy highlights potential variations in dexmedetomidine's hemodynamic effects depending on the specific block technique, dosage, or patient population. In this study, two cases of bradycardia were observed (both cases above 50 beats, resolved without treatment), while Wang [30] did not report bradycardia, while Esmaglu [36] reported seven cases of bradycardia treated with atropine. Extensive research has consistently demonstrated the efficacy of dexmedetomidine, compared to normal saline, in significantly reducing mean arterial pressure (MAP), heart rate (HR), and analgesic consumption across various patient populations and surgical procedures. Mao et al.'s study on dexmedetomidine's efficacy in esophageal cancer patients undergoing lateral thoracotomy surgery revealed neutral results, with no statistically significant impacts on various postoperative parameters, including pain management, inflammation, recovery, hospitalization duration, costs, and long-term quality of life [37]. However, in this study, dexmedetomidine had beneficial effects in reducing narcotic consumption during surgery and improving sleep quality after surgery.

The lack of statistically significant differences in blood oxygen saturation between the two groups may be attributed to the relatively small sample size or the variability in individual responses. Nevertheless, the consistent trend of lower oxygen saturation in the RD group suggests potential implications for patient monitoring and management. In contrast, the R group exhibited incremental increases in blood oxygen saturation over time, with improvements of 0.11% in the first hour, 0.21% in the next 6 h, 0.35% between 6 and 12 h, 0.27% in the next 12 h, and 0.33% in the final 24 h. Notably, the observed changes did not achieve statistical significance ($P > 0.05$). However, our findings align with those reported by Agamohammdi et al. [38], who investigated 64 patients with multiple rib fractures. Their study compared the efficacy of bupivacaine alone versus a combination of dexmedetomidine and bupivacaine, yielding similar outcomes. This finding confirms the findings of 10 studies examined in the systematic review of Habibi et al. [39], which stated that the total dose of narcotics consumed in the group receiving dexmedetomidine was significantly lower than in the groups not receiving dexmedetomidine [40].

Several limitations affected the scope of this study. Notably, the absence of a standalone dexmedetomidine injection group and intravenous control arm hindered

our ability to distinguish between the systemic and local effects of dexmedetomidine. Another point is that some patients may have been asleep during the collection of some of the data in this study, which could interfere with the measurements. Although the random nature of the study likely prevents this phenomenon from having a significant effect on the study's results.

Conclusion

The results of this study suggest that dexmedetomidine, when combined with ropivacaine, is an efficacious and safe option for SAP blockade, providing effective pain relief with accepted side effect profile. As in other studies, the risk of low blood pressure and HR was also observed in this study. Additionally, bradycardia was temporarily observed in the dexmedetomidine group, which did not pose any particular risk to the patients. It seems that if dexmedetomidine is used, it is better for patients to undergo cardiac monitoring for at least six hours to prevent adverse effects. It is suggested that different doses of dexmedetomidine be compared in this type of block and this type of operation in future studies to obtain the optimal dose for this procedure.

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Author contributions

M.R. and K.M. main concept, methodology, and wrote the main manuscript text and formal analysis, R.B., A.M., and M.S. caring data. All authors reviewed the manuscript.

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Data availability

Kamran Mahmoodi (Email: biologycell11@gmail.com) guarantees that the data of this research will be provided at the request of other researchers.

Declarations

Ethics approval and consent to participate

The study obtained ethical approval from the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (AJUMS), Iran (IR.AJUMS.REC.1402.615), and was retrospectively registered with the Iranian Registry of Clinical Trials (IRCT) (<https://irct.behdasht.gov.ir/>; IRCT20221222056890N1, Registration date: 2024-02-15). Informed consent was obtained from the participants, and the study was conducted in accordance with the Declaration of Helsinki (DoH, Finnish: Helsingin julistus), which is mandatory for studies involving human subjects.

Consent for publication

Not Applicable.

Competing interests

The authors declare no competing interests.

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