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Comparative effects of intraplexus and extraplexus interscalene block approaches on rebound pain in arthroscopic shoulder surgery

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Abstract

Although interscalene brachial plexus block provides effective analgesia for arthroscopic shoulder surgery, a subset of patients develops a marked increase in pain as the block resolves. Advances in the understanding of the brachial plexus sheath have led to wider use of intraplexus and extraplexus injection techniques; however, their comparative effects on rebound pain remain unclear. In this prospective, randomized, double-blind clinical trial, patients aged 18–65 years with ASA physical status I–II undergoing arthroscopic shoulder surgery under ISB with sedation were enrolled. Patients were randomly assigned to receive ultrasound-guided intraplexus ISB or extraplexus ISB using a total of 20 mL of 0.5% bupivacaine. Rebound pain was operationally defined as the onset of severe pain (numerical rating scale [NRS] ≥ 7) following an initial phase of satisfactory analgesia (NRS ≤ 3) coinciding with resolution of the block. Among the 94 enrolled participants, outcome data from 85 patients were available for analysis. Rebound pain occurred more frequently in patients receiving the intraplexus approach than in those treated with the extraplexus technique (37.2% vs. 16.7%). In addition, rebound pain duration was shorter and Quality of Recovery-15 scores on postoperative day 1 were higher in patients receiving the extraplexus approach. Although sensory and motor block onset was delayed with the extraplexus technique, paresthesia occurred more frequently in the intraplexus group. No meaningful differences were observed between groups with respect to postoperative pain intensity or rescue analgesic use. Overall, the extraplexus ISB technique appears to attenuate rebound pain and support better early postoperative recovery, offering a favorable safety profile.

Keywords: Interscalene brachial plexus block, arthroscopic shoulder surgery, rebound pain, extraplexus injection, intraplexus injection

Introduction

The interscalene brachial plexus block (ISB) is frequently incorporated into arthroscopic shoulder surgery because it improves perioperative comfort and can decrease opioid exposure; it may also contribute to better early postoperative experience, including reduced nausea and improved patient-reported satisfaction [1,2]. Recently, increasing attention has focused on determining the optimal injection site for local anesthetic delivery in ISB [1].

The injection site may influence the quality, onset, and duration of ISB [3]. Franco et al., in a cadaveric study, described a sheath encasing the brachial plexus, which has led to comparative evaluation of intraplexus injections (into the C5–C6 nerve roots located within this sheath) and extraplexus injections (outside the sheath) [1,4]. Clinical studies on this topic have reported conflicting results regarding block onset. Nevertheless, a lower rate of block-related paresthesia has been reported with the extraplexus approach [1,5]. Importantly, none of these studies have investigated rebound pain.

Rebound pain refers to an abrupt escalation of postoperative pain that typically emerges within 12–24 hours after the effects of a peripheral nerve block (PNB) have subsided [6-8]. This phenomenon may diminish the overall benefits of PNB, with an estimated incidence of 40% [6-8]. Although its precise pathophysiology remains unclear, ongoing nociceptive input from surgical stimulation, transduction, and transmission persists despite neural blockade, promoting central sensitization that manifests as hyperalgesia and allodynia. Once the block wears off, this sensitization contributes to an abrupt increase in pain intensity [6]. Reported risk factors include female sex, younger

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age, and orthopedic procedures—particularly those affecting the upper extremity [6,8].

The role of nerve injury in the development of rebound pain after PNB remains uncertain [9]. Needle–nerve contact during block procedures rarely leads to permanent injury, except in cases where an intraneural injection takes place. Such injections can elevate intraneural pressure beyond capillary perfusion levels, leading to ischemia and focal demyelination. Ischemia may also arise from epineural vessel damage, occlusion, or perineural hemorrhage. Additionally, high local anesthetic volumes, prolonged exposure, or high-pressure injections between fascicles can impair neural blood flow, further contributing to ischemia [9,10]. These mechanisms, together with the proinflammatory and reversible neurotoxic effects of local anesthetics, may underlie rebound pain once the block resolves [6,8]. Based on these considerations, we hypothesized that extraplexus injection—by delivering local anesthetic around the nerve sheath rather than directly between the roots during ISB—could reduce the incidence of rebound pain.

This study primarily examined whether the extraplexus ISB approach influences the incidence of rebound pain in patients undergoing arthroscopic shoulder surgery. Secondary outcomes included block performance measures, block characteristics, postoperative pain and analgesic requirements, block-related complications, rebound pain duration, and recovery quality assessed by the QoR-15 score.

Material and Methods

We conducted a prospective, randomized, double-blind clinical trial at Ankara Bilkent City Hospita between March 20 and September 10, 2025. Ethical approval was granted by the local ethics committee (Approval no. E2-25-10421), and the trial was prospectively registered on ClinicalTrials.gov (NCT06883279) prior to patient enrollment on March 20, 2025. All patients provided both written and oral informed consent. Data were collected on the ward before surgery, during the intraoperative period in the operating theatre, and after surgery in the recovery unit, on the ward, as well as via telephone after discharge.

Patient Selection and Eligibility Criteria

Patients aged between 18 and 65 years with ASA physical status I–II who were scheduled for arthroscopic shoulder surgery in the beach-chair position under interscalene block were eligible for inclusion. Exclusion criteria comprised refusal to participate, block failure, obesity (BMI > 35 kg/m²), diabetes, psychiatric or central nervous system conditions, vestibular disorders, pre-existing neuropathy or motor deficits, gestation, conversion to open shoulder procedures, hypersensitivity to local anesthetic agents, coagulation abnormalities, marked thrombocytopenia, infection at the needle insertion site, inability to achieve 90° of shoulder abduction before surgery, requirements for postoperative nerve surveillance, perioperative administration of steroids, anti-inflammatory drugs, opioids, or antiemetics, severe cardiopulmonary disease, baseline hypoxemia, and limited postoperative cooperation (e.g., delirium or language barriers).

Intervention and Randomization

Patients were randomly assigned to the intraplexus (Group I) or extraplexus (Group E) group using a computer-generated sequence. Allocation order was determined before enrolment and concealed from investigators, surgeons, and perioperative staff. A single anesthesiologist with over 10 years of experience performed all blocks. Group allocation details were kept in consecutively numbered sealed envelopes and were revealed only after informed consent had been obtained. Because the block procedure required knowledge of the technique, the anesthesiologist could not be blinded; however, patients, surgical personnel, post-anesthesia care staff, and outcome assessors were unaware of group assignment.

Preoperative fasting was implemented in accordance with institutional guidelines for all participants. Preoperatively, demographic and baseline data were collected, including age, comorbidities, BMI, ASA physical status, and preoperative Quality of Recovery (QoR-15) scores. During surgery, the anesthesiologist documented block performance duration, the number of needle insertions, sensory and motor block onset times, as well as block-related adverse events (paresthesia, Horner's syndrome, dyspnea, and dysphonia). Hemodynamic variables (heart rate, blood pressure), intraoperative fluid administration, dexmedetomidine use (μg), and the durations of anesthesia and surgery were also documented. Postoperatively, block duration, pain and rebound pain status, postoperative nausea and vomiting, rescue analgesia requirements, and QoR-15 scores on postoperative day 1 were recorded. QoR-15 scores were reassessed via telephone on postoperative day 7.

ISB procedures were performed with patients in the supine position, the head of the bed elevated to 45°, and the head rotated slightly contralateral to the surgical side. Under sterile conditions, a 5–12 MHz linear ultrasound probe (MyLabFive Portable Ultrasound, UK) was used to visualize the C5–C7 nerve roots. The skin was infiltrated with 2 mL of 2% lidocaine using a 27G needle. In Group I (intraplexus), a 21-gauge, 50-mm short-bevel needle (Stimuplex Ultra 360®, Braun, Germany) was advanced between the C5–C6 nerve roots along a posterior-to-anterior path, passing through the middle scalene muscle under an in-plane ultrasound-guided technique [1,2,11]. After confirming needle tip position with 1 mL of hydrodissection, 20 mL of 0.5% bupivacaine was injected [11,12]. In Group E (extraplexus), the needle was advanced above the C5 root toward the anterior plexus, where 10 mL of 0.5% bupivacaine was administered following hydrodissection confirmation. The needle was then redirected to the posterior plexus surface, confirmed again, and an additional 10 mL was injected [1,11,12]. Patients were instructed to report any paresthesia, defined as abnormal sensations such as pins, tingling and needles, severe pain, or an electric shock in the arm [1]. If paresthesia occurred, the procedure was paused, the needle repositioned, and injection withheld until symptoms resolved.

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Anesthesia Management

Standard preoperative monitoring (electrocardiography, peripheral oxygen saturation, noninvasive arterial pressure) was applied in the operating room. Intravenous dexmedetomidine was administered as an initial loading dose of 1 μg/kg over a 10-minute period, after which a maintenance infusion of 0.2–0.7 μg/kg/h was continued. Sedation depth was adjusted to maintain a Ramsay Sedation Scale score between 3 and 4, corresponding to responsiveness to verbal commands or a brisk reaction to tactile or auditory stimulation [13]. Postoperatively, patients with an Aldrete score > 8 were transferred to the ward. Postoperative analgesia included intravenous dexketoprofen administered at a dose of 50 mg every 8 hours, together with paracetamol 1 g given at the same dosing interval. For numerical rating scale (NRS) pain scores > 4, 100 mg intravenous tramadol was provided as rescue analgesia.

Measurements and Outcome Parameters

Patient demographics (age, sex, BMI) were recorded. The primary outcome was rebound pain incidence. Rebound pain was defined as a transition from an initial period of well-controlled pain (NRS ≤ 3) consistent with effective interscalene block to a severe pain episode (NRS ≥ 7) occurring around the time of block resolution [8]. Postoperative NRS scores (0–10) were recorded at 4, 6, 8, 12, 16, 18, 24, and 36 hours. Secondary outcomes were the number of needle passes, block time, sensory and motor onset, block duration, intraoperative dexmedetomidine requirement, postoperative pain, PONV, rescue analgesia, complications (paresthesia, Horner syndrome, dyspnea, dysphonia), recovery room stay, rebound pain duration, and QoR-15 scores (Table 1) [1,8,14,15]. Patients who developed postoperative paresthesia were contacted daily until symptoms resolved.

Table 1. Outcome definition

Outcome	Definition
Primary outcome	
Rebound pain	Severe pain episode (NRS ≥ 7) following an initial period of well-controlled pain (NRS ≤ 3) around the time of block resolution
Secondary outcomes	
Number of needle passes	Number of times the needle was reinserted after withdrawal
Block performance time (min)	Time from needle insertion to completion of local anesthetic administration
Sensory block onset (min)	Time from injection until pinprick pain disappears while touch sensation remains in the relevant dermatomes
Motor block onset (min)	Time from injection until motor strength decreases, while arm movement remains possible
Intraoperative dexmedetomidine use (μg)	Total dose required to maintain a Ramsay Sedation Scale (RSS) score of 3–4
Recovery room length of stay (min)	Time from entry into the recovery room until discharge criteria were met
Block duration (min)	Time from block administration to the first report of significant pain increase
Pain scores	Measured using the 0–10 Numerical Rating Scale (NRS): 0 = no pain, 10 = worst imaginable pain
Rebound pain duration (min)	Time from the onset to the resolution of rebound pain
Rescue analgesic	Administration of 100 mg IV tramadol when NRS ≥ 4
QoR-15 score	Measured using the QoR-15 questionnaire (score 0–150). Classification: Excellent (> 135), Good (122–135), Moderate (90–121), Poor (< 90)
Paresthesia	Abnormal sensations such as tingling, pricking, or radiating electric shock in the arm reported during block placement
Horner's syndrome	Ipsilateral miosis and ptosis
Dyspnea	Patient-reported shortness of breath
Dysphonia	Patient-reported change or alteration in voice quality
PONV	Significant nausea, vomiting, and/or need for rescue antiemetic

NRS: Numerical Rating Scale, QoR-15: Quality of Recovery-15, RSS: Ramsay Sedation Scale, PONV: Postoperative Nausea and Vomiting

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Sample Size Calculation and Statistical Analysis

In an unpublished pilot study conducted by our team, rebound pain was observed in 11 of 20 patients (55%) in the intraplexus group and 5 of 20 patients (25%) in the extraplexus group. Sample size estimation was performed with the G*Power software (version 3.1.9.7; Franz Faul, University of Kiel, Germany) based on these preliminary data. With 80% power and a 5% significance level, at least 82 patients (41 per group) were required. Allowing for potential dropouts, 94 patients were enrolled (47 per group).

Data analysis was conducted using SPSS Statistics software (version 27; IBM Corp., Armonk, NY, USA). Continuous variables were summarized using descriptive statistics, while categorical data were expressed as frequencies. Between-group comparisons were performed using parametric or nonparametric methods according to data distribution, with the independent t test applied for normally distributed variables and the Mann–Whitney U test used otherwise. Associations between categorical variables were evaluated with the chi-square test. Statistical significance was defined as a two-sided p value below 0.05.

Results

Of 105 patients assessed, 94 met inclusion criteria and were randomized equally (47 per group). In the intraplexus group, four patients were excluded (two for block failure, one for surgical conversion, one for postoperative delirium). In the extraplexus group, five were excluded (three for block failure, two for surgical conversion). The final analysis included 85 patients (43 in Group I, 42 in Group E; Figure 1).

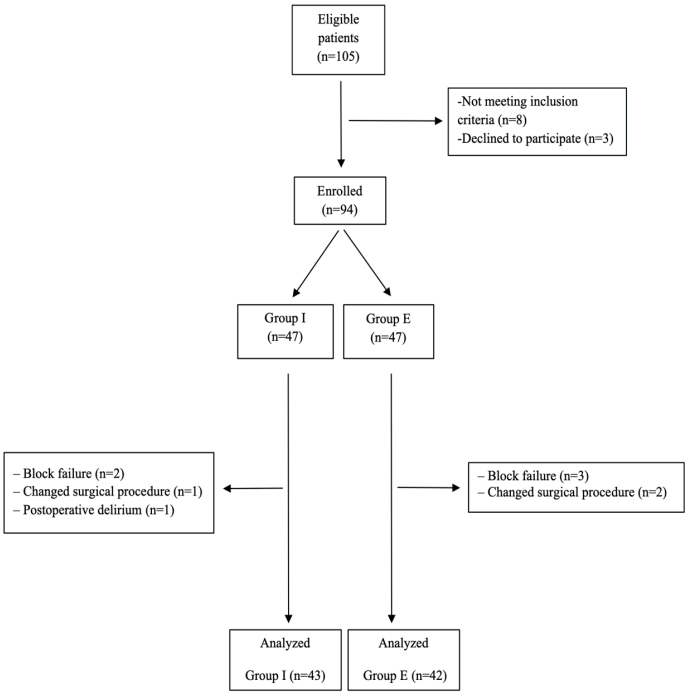

Figure 1. Flow diagram of study participants

Baseline characteristics (age, sex, BMI, ASA score, surgical and anesthesia duration, intraoperative fluid balance, and use of dexmedetomidine, ephedrine, or atropine) were comparable between the two groups (Table 2). Intraoperative hemodynamics (pulse, blood pressure) were similar across groups.

Table 2. Comparison of baseline demographic and clinical characteristics between groups

Variable	Group I (n = 43)	Group E (n = 42)	p-value
Age (years), mean ± SD	38.23 ± 11.43	37.32 ± 11.16	0.711
Sex, n (%)			0.748
Female	23 (53.5)	21 (50.0)	
Male	20 (46.5)	21 (50.0)	
BMI (kg/m²), mean ± SD	27.34 ± 3.56	27.50 ± 3.60	0.837
ASA score, n (%)			0.939
I	14 (32.6)	14 (33.3)	
II	29 (67.4)	28 (66.7)	
Duration of surgery (min), mean ± SD	85.20 ± 17.90	89.59 ± 15.20	0.228
Duration of anesthesia (min), mean ± SD	95.93 ± 16.37	101.23 ± 14.90	0.122
Dexmedetomidine use (µg), mean ± SD	113.76 ± 17.42	115.54 ± 20.54	0.667
Intraoperative fluids (mL), mean ± SD	846.52 ± 149.75	896.42 ± 159.79	0.141
Ephedrine use, n (%)	7 (16.3)	6 (14.3)	0.799
Atropine use, n (%)	4 (9.3)	4 (9.5)	0.972

Values are presented as mean ± SD, number (%) or (n); BMI= Body mass index, ASA: American Society of Anesthesiologists, SD: Standard deviation, M/F: Male/Female

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Block characteristics, efficacy, and safety outcomes were similar between the two groups, including needle passes, block application time, recovery room stay, block duration, or the incidence of Horner's syndrome, dyspnea, dysphonia, and PONV ($p > 0.05$). Sensory and motor onset times were significantly longer in Group E ($p < 0.001$), whereas paresthesia occurred more frequently in Group I ($p < 0.05$) (Table 3).

Rebound pain incidence was significantly higher in Group I compared to Group E (37.2% vs. 16.7%; $p < 0.05$) (Table 4, Figure 2). Rebound pain duration was also longer in Group I ($p < 0.05$). By contrast, postoperative pain scores at the assessed time points and the requirement for rescue analgesia within the first 36 hours were comparable between the two groups ($p > 0.05$) (Table 4).

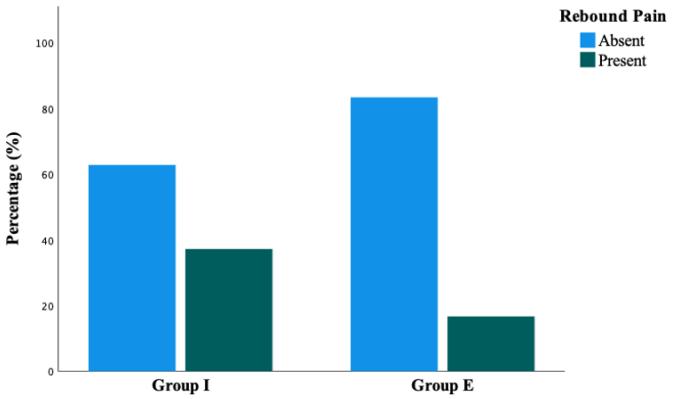

Figure 2. Incidence of rebound pain in Group I and Group E; Bars represent the percentage of patients with and without rebound pain

Table 3. Comparison of block performance characteristics, efficacy, and safety outcomes

Variable	Group I (n = 43)	Group E (n = 42)	p-value
Number of needle passes, median (IQR)	2 (2, 3)	2 (2, 3)	0.242
Block performance time (min), mean ± SD	3.51 ± 0.90	3.45 ± 0.86	0.759
Sensory block onset (min), mean ± SD	3.44 ± 0.95	4.50 ± 1.15	**< 0.001**
Motor block onset (min), mean ± SD	6.62 ± 1.54	7.88 ± 1.64	**< 0.001**
Recovery room length of stay (min), mean ± SD	45.51 ± 9.59	46.35 ± 8.04	0.661
Block duration (h), median (IQR)	12 (8, 16)	12 (12, 16)	0.299
Paresthesia, n (%)	17 (39.5)	7 (16.7)	**0.019**
Horner's syndrome, n (%)	3 (7.0)	2 (4.8)	0.663
Dyspnea, n (%)	1 (2.3)	1 (2.4)	0.987
Dysphonia, n (%)	1 (2.3)	1 (2.4)	0.987
PONV, n (%)	10 (23.3)	9 (21.4)	0.840

Data are presented as mean ± standard deviation (SD), n (%), or median (interquartile range, IQR); PONV: Postoperative nausea and vomiting, SD: Standard deviation, h: Hour

Table 4. Rebound pain outcomes, postoperative pain severity, and rescue analgesic use

Variable	Group I (n = 43)	Group E (n = 42)	p-value
Rebound pain, n (%)	16 (37.2)	7 (16.7)	**0.033**
Rebound pain duration (min), mean ± SD	156.87 ± 53.50	108.57 ± 32.87	**0.039**
Postoperative pain severity (NRS)			
4 h, median (IQR)	0 (0, 1)	0 (0, 1)	0.926
6 h	1 (0, 1)	0 (0, 1)	0.609
8 h	0 (0, 1)	0 (0, 1)	0.525
12 h	2 (0, 3)	2 (0, 2)	0.724
16 h	2 (1, 3)	2 (1, 3)	0.829
18 h	2 (1, 2)	2 (1, 3)	0.323
24 h	2 (1, 3)	2 (1, 3)	0.941
36 h	1 (1, 1)	1 (1, 2)	0.711
Rescue analgesic use, n (%) (0–36 h)	16 (37.2)	9 (21.4)	0.110

Data are presented as mean ± standard deviation (SD), n (%), or median (interquartile range, IQR); Pain severity was assessed on the Numerical Rating Scale (NRS; 0 = no pain, 10 = worst imaginable pain); NRS: Numerical rating scale, h: Hour

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Preoperative QoR-15 scores were similar across groups, with no statistically significant difference detected ($p > 0.05$). On postoperative day 1, Group E demonstrated significantly higher QoR-15 scores compared with Group I ($p < 0.05$). By postoperative day 7, no differences were observed between groups ($p > 0.05$) (Table 5).

Table 5. QoR-15 scores at preoperative and postoperative assessments

Variable	Group I (n = 43)	Group E (n = 42)	p-value
Preoperative day 1, n (%)			0.527
Excellent	37 (86.0)	34 (81.0)	
Good	6 (14.0)	8 (19.0)	
Moderate	–	–	
Poor	–	–	
Postoperative day 1, n (%)			**0.017**
Excellent	14 (32.6)	28 (66.7)	
Good	12 (27.9)	7 (16.7)	
Moderate	6 (14.0)	2 (4.8)	
Poor	11 (25.6)	5 (11.9)	
Postoperative day 7, n (%)			0.631
Excellent	32 (74.4)	31 (73.8)	
Good	9 (20.9)	7 (16.7)	
Moderate	2 (4.7)	4 (9.5)	
Poor	–	–	

Data are presented as n (%); QoR-15: Quality of Recovery-15

Discussion

This study demonstrated that, in arthroscopic shoulder surgery, the extraplexus interscalene block approach resulted in a lower incidence and shorter duration of rebound pain than the intraplexus approach. The extraplexus technique also reduced paresthesia incidence, although it was accompanied by delayed sensory and motor onset. Moreover, patients in the extraplexus group reported higher QoR-15 scores on postoperative day 1.

Rebound pain is a major source of patient dissatisfaction and has been linked to increased analgesic requirements and delayed recovery [6,7]. While its underlying mechanisms remain unclear, previous studies have identified young age, female sex, upper extremity orthopedic surgery and surgical duration as potential risk factors [6,7,16,17]. In our study, however, demographic and intraoperative variables were comparable between groups, indicating that these factors did not influence the observed differences.

In a systematic synthesis encompassing 50 studies, Admassie et al. estimated the rate of rebound pain after peripheral nerve block resolution to be approximately 40% [8]. In our study, the incidence in the intraplexus group (37.2%) was consistent with this reported average, whereas the extraplexus group demonstrated a markedly lower rate (16.7%). This supports our hypothesis that the extraplexus approach reduces rebound pain. Sort et al. described rebound pain as rapidly emerging but short-lived once block effects resolve [16]. Similarly, in our study, rebound pain duration was shorter in the extraplexus group compared with the intraplexus group, further supporting our hypothesis.

The mechanisms responsible for rebound pain following PNB are not yet fully elucidated. Proposed contributors include needle-related nerve injury, the proinflammatory properties of local anesthetics, and their reversible neurotoxic effects [6-10]. Abdallah et al., in a meta-analysis of 1,090 patients, highlighted the role of abrupt nociceptive input transmission after block resolution in triggering rebound pain [18]. Furthermore, intraplexus injections during interscalene blocks carry an increased risk of subepineural or intraneural injection, potentially leading to neurologic injury [1,19,20]. Orebaugh et al. demonstrated in a cadaver study that unintentional subepineurial injection occurred in up to 50% of ultrasound-guided interscalene blocks [20]. In our study, reducing potential contact between the needle and nerve and administering local anesthetic beyond the brachial plexus sheath using the extraplexus approach may lower the risks of nerve root injury, proinflammatory effects, and neurotoxicity, which could underlie the lower incidence and shorter duration of rebound pain observed in this group.

Although results regarding onset and duration of ISB vary across studies, the extraplexus approach has consistently been associated with a lower incidence of paresthesia [1,18,21]. Harbell et al. reported that while the intraplexus approach achieved faster

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sensory and motor onset and required fewer needle passes, it produced a significantly higher rate of paresthesia (35.9% vs. 14.5%) [1]. No significant differences were observed in block performance time, duration, success rate, recovery stay, postoperative pain scores, opioid use, or other complications [1]. Similarly, Maga et al. found that intraplexus injection resulted in a higher proportion of rapid block onset (70% vs. 37% at 10 minutes) but at the cost of a markedly greater paresthesia incidence (96.7% vs. 6.7%) [21].

Variability in ISB onset, duration, and paresthesia rates reported in the literature has been attributed to differences in patient characteristics, operator experience, technique, and the type, volume, or local anesthetic concentration [1,18,21]. In line with previous reports, we found that sensory and motor block onset times were reduced in the intraplexus group. Unlike the findings of Harbell et al., however, the number of needle passes was comparable between groups, likely reflecting the experience of the practitioner [1]. Consistent with prior studies, paresthesia incidence was higher in the intraplexus group (39.5% vs. 16.7%). Although no between-group differences were observed in other efficacy or safety outcomes, the extraplexus group required less rescue analgesia (21.4% vs. 37.2%), a trend that may be explained by the lower incidence of rebound pain, though statistical significance was not reached—possibly due to limited sample size.

Woo et al. reported that, because most surgeries are performed during the day, block resolution typically occurs at night, when rebound pain may impair sleep quality and hinder recovery [22]. In our study, postoperative recovery quality was evaluated with the QoR-15, with higher scores observed in the extraplexus group on postoperative day 1. These findings suggest that the reduced incidence and shorter duration of rebound pain with the extraplexus approach may contribute to improved sleep quality and psychological well-being during the early phase of recovery.

This study has several limitations. First, postoperative pain was assessed only at rest due to shoulder immobilization, and pain with movement could not be evaluated. Second, hemidiaphragmatic paralysis as an indicator of phrenic nerve involvement was not assessed objectively; dyspnea was recorded only by patient self-report, which is less sensitive than ultrasound or spirometry. Third, the study was conducted by a single experienced practitioner at one institution, potentially restricting the external applicability of the findings and obscuring potential differences in the number of needle passes. Fourth, as the sample size was powered for the primary endpoint (rebound pain incidence), the study may have been underpowered for secondary outcomes such as rescue analgesia use and rare complications. Finally, dexmedetomidine was used for sedation and may have influenced pain perception and QoR-15 scores; thus, residual confounding cannot be excluded, despite standardized protocols across groups.

Conclusion

Overall, the findings indicate that the extraplexus ISB approach in arthroscopic shoulder surgery significantly reduces rebound pain incidence, shortens rebound pain duration, and lowers paresthesia rates, while improving early postoperative QoR-15 scores. Although associated with delayed sensory and motor onset, its benefits in safety and recovery quality underscore the practical relevance of the extraplexus technique. Future research should explore its applicability in other surgical settings and block approaches.

Ethical Approval
This study was approved by the Ethics Committee of Ankara City Hospital on March 19, 2025 (Decision No: E2-25-10421) and conducted in accordance with the Declaration of Helsinki.

Patient Consent
Written informed consent was obtained from all participants prior to enrollment.

Conflict of Interest
The authors confirm the absence of any conflicts associated with this work.

Funding
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Trial Registration
This study was registered at ClinicalTrials.gov (NCT06883279) on 19/03/2025.

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