International Journal of Clinical Research

Original Research

# 3 mL Versus 5 mL of 0.75% Ropivacaine for Ultrasound-Guided Interscalene Block: A Randomized Clinical Trial

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doi: https://doi.org/10.38179/ijcr.v4i1.163

Received: 2021.11.30
Accepted: 2022.03.29
Published: 2024.04.17

**Financial support:** None
**Conflict of interest:** None
**Patient Consent:** Ethical approval for the study was obtained from the Institution Review Board of the Saint Georges Hospital University Medical Center.

## Abstract

**Background:** Ropivacaine is a local anesthetic used in nerve blocks for post-operative analgesia with dose-dependent side effects. Research indicated that ropivacaine may have better safety profiles than most local anesthetics, but toxicity and other dose-dependent side effects can still occur. Our aim is to show that a lower dose of ropivacaine is as effective when it comes to anesthesia and has a lower rate of complications.

**Methods:** This study aims to compare 3 mL and 5 mL of 0.75% ropivacaine used for ultrasound-guided interscalene nerve block in shoulder arthroscopy in terms of postoperative analgesia and complications. We compared two groups (group 3 and group 5). Each group consisted of 30 patients. One group received 3 mL of 0.75% ropivacaine while the other group received 5 mL of the same product. The pain scale was evaluated in the post-anesthesia care unit (PACU) every 30 minutes up to two hours, then via phone call questionnaire for patients discharged during the first 24 hours. The incidence of complications was also evaluated in both groups.

**Results:** Both groups had the same analgesic effect. No difference in the incidence of postoperative complications was noted however, more hemidiaphragmatic paralysis was observed in group 5 (p=0.023).

**Conclusion:** Both 3 mL and 5 mL of 0.75% ropivacaine had the same post-operative analgesic effect with a lower incidence of hemidiaphragmatic paralysis seen in group 3, Further investigation on respiratory function must be undertaken.

*Keywords: Postoperative analgesia, Ultrasound-guided interscalene block, Arthroscopy, Diaphragmatic paralysis, Local anesthetic*

## Introduction

Interscalene block (ISB) of the brachial plexus is one of the most reliable and used techniques to control both intra and post-operative pain of the shoulder [1,2]. It is usually ultrasound-guided to achieve maximum efficacity while reducing systemic side effects to the minimum [3]. The most common anesthetic agent used in this technique is ropivacaine, and it is used with various dosages to achieve both motor and sensory block for shoulder arthroscopies [3-5].

Research indicated that ropivacaine may have better safety profiles than most local anesthetics such as bupivacaine, but toxicity and other dose-dependent side effects can still occur [6]. Studies have shown that there are distinct side effects reported following the administration of ropivacaine such as cardiovascular side effects including hypotension and bradycardia [6,7]. Headache, dizziness, and hypoesthesia can also occur, as well as nausea and vomiting [6,7].

Hemidiaphragmatic paralysis is a known complication following ISB; this is due to the effect of the anesthetic on the cervical plexus [8]. It is especially noted in increasing doses of the anesthetic. This is proven by a study done by Lee et al, comparing ISB under ultrasound guidance with 5 mL of 0.75% ropivacaine to 10 mL of 0.75% ropivacaine, which shows similar analgesic efficacy but with a lower incidence of hemidiaphragmatic paralysis [7]. Therefore, the objective of this research is to evaluate the analgesic efficacy and side effects of 3 mL of 0.75% ropivacaine compared to 5 mL of 0.75% ropivacaine in ISB for shoulder surgery.

## Materials & Methods

### Patients

This trial is a monocentric, randomized, single-blinded clinical trial and follows the ethical standards of the responsible committee on human experimentation and the Helsinki Declaration of 1975, as revised in 2000. A total of 60 adult patients (age > 18 years) undergoing shoulder arthroscopy for various etiologies were assessed. The study has been approved by the institutional review board of Saint George Hospital University Medical Center. The recruitment started in March 2018 and ended in February 2020. The research included 60 patients above the age of 18 years old. Thirty patients were recruited in each group and the participants were not aware of the allocations. The patients were of both sexes, having no significant health history or current health issues. The information about the participants' medical records was reviewed and investigated.

The patients that were recruited for the research are former and current patients admitted to Saint Georges University Medical Center Hospital and had been approved to be subjects of this experiment. Consent forms from the patients themselves were obtained. They were provided with all the needed information about the operation, and the whole procedure, and were aware of the adverse events that may occur with the precautions that are prepared in case these events happen. Patients were also informed about the study and signed an informed consent for the study as well as for the surgery. They were informed about the computer-based randomization of the study and about the dose of anesthesia that they would receive depending on the randomization. The allocation sequence was concealed from patients, the staff members collecting the data both intra and post-operatively, health workers, and study personnel except for the anesthesiologist performing the block. Patients were excluded if they were 18 or younger, if they had a severe respiratory disease, if they had an ASA score of 2 or more, a coagulopathy, a preexisting neuropathy, a severe renal or hepatic failure, or an allergy to the medications used in the study. The groups were similar concerning age, sex, weight, and duration of surgery (Table 1).

### Technique

The patients were divided into two groups: Group 3 received 3 mL, and Group 5 received 5 mL of 0.75% ropivacaine.

Table 1: Patients' characteristics

| | Group 3 | Group 5 | P-value |
|---|---|---|---|
| Number of patients | 30 | 30 | X |
| Sex (Male/Female) | 19/11 | 20/10 | X |
| Weight (kg) (mean) | 74.3 | 71.8 | 0.15 |
| Age (mean) | 52.33 | 53.45 | 0.2 |
| Duration of surgery (min) (mean) | 129.3 | 128.5 | 0.18 |

Ultrasound-guided ISB was performed using the in-plane technique. The final target position of the needle was immediately posterior to the space between the C5 and C6 roots. When needle placement was confirmed, 3 or 5 mL of 0.75% ropivacaine were injected carefully with intermittent aspiration. All blocks were performed under ultrasound guidance alone and by the same attending anesthesiologist who is experienced in ultrasound-guided regional anesthesia. Both groups were treated equally. The blockade was evaluated 20 minutes after injection to verify its efficacy (the patients were not able to move or sense the area around their shoulders). Afterward, patients were given general anesthesia using the same technique for both groups and without adding anything that could potentiate the effects of the block.

## Postoperative assessment

The patients were followed up in the post-anesthesia care unit (PACU) and on respective wards for assessment of postoperative pain (evaluated through the numerical rating scale (NRS), rating pain on a scale from 1 to 10, with 1 being the lowest possible, and 10 the highest), hemidiaphragmatic paralysis both serving as primary outcomes, postoperative nausea and vomiting, and miscellaneous complications serving as secondary outcomes. The assessment time scale was on a half-hourly basis in the PACU for the first two hours and then via phone call questionnaire for patients discharged during the first 24 hours. Hemidiaphragmatic paralysis was defined as the elevation of the diaphragm > 4 centimeters above its preoperative position when comparing pre and post-operative chest X-rays [9]. The X-rays done the same day after the surgery were examined and interpreted by the same radiologist.

The results for each group were assessed solely; any case that showed a negative reaction was investigated to probe whether the reaction was the result of the injected dose of ropivacaine or a technical slip. This was carried out to be strictly conclusive about the results and to acquire information about expected reactions induced with any dose of ropivacaine which will serve as an added value for both this research and the literature.

## Statistical analysis

Descriptive statistics are generated to illustrate the results in the form of tables giving information about each patient. As the total sample size is 60 (>30), the test used is the independent sample t-test to compare the two groups in terms of sex, weight, age, and duration of surgery.

Since the frequency of side effects is low, a Fisher test was used to compare the two groups in terms of postoperative nausea, vomiting (PONV), ptosis, diaphragmatic hernia, and hematoma.

The risks associated with the experiment are not severe if preventive measures are taken; recognition and prompt treatment of potential complications should result in a favorable outcome. However, the outcome of this research would determine whether to recommend anesthesiologists to use 3 mL of ropivacaine instead of 5 mL since it results in the same anesthetic result with a decreased amount of side effects.

## Results

The same amount of fentanyl was required in both groups (100 micrograms) intraoperatively. No fentanyl was given during the operation except during the induction period.

Both groups had 0 pain scores in the PACU during the first two hours (Table 2). There was no difference between the two groups with respect to the number of patients requiring rescue analgesia for pain (5 in both groups) at 12 hours and (6 in both groups) at 24 hours. Rescue analgesia consisted of anti-inflammatory drugs and paracetamol.

Table 2 Pain Scores in PACU

| | Group 3 | Group 5 |
|---|---|---|
| 30 min | 0 | 0 |
| 60 min | 0 | 0 |
| 90 min | 0 | 0 |
| 120 min | 0 | 0 |

Concerning post-operative side effects, the incidence of PONV, ptosis, and hematoma did not differ significantly between groups (Table 3). However, the incidence of hemidiaphragmatic paralysis on post-operative chest x-rays was significantly greater in group 5 (7 patients) when compared to group 3 (1 patient) (P = 0.023).

Table 3: Postoperative Complications

Abbreviations: PONV: postoperative nausea, vomiting

| | Group 3 Nb (%) | Group 5 Nb (%) | P-value |
|---|---|---|---|
| PONV | 3 (10) | 4 (13.3) | 0.28 |
| Ptosis | 0 (0) | 0 (0) | |
| Hemi-diaphragmatic paralysis | 1 (3.3) | 7 (23.3) | 0.023 |
| Hematoma | 1 (3.3) | 2 (6.7) | 0.38 |

## Discussion

Although shoulder arthroscopy is not considered very painful, adequate post-operative analgesia must be administered in order to prevent pain with ISB being the most implemented technique for post-operative analgesia. In this study, a single injection technique was used without a catheter. This was sufficient after pain control and post-operatively for up to twenty-four hours. Rescue drugs used (anti-inflammatory drugs and paracetamol) were satisfactory as well.

Ultrasound helps facilitate imaging of the nerve plexus and neighboring anatomical structures. It also permits an accurate deposition of the local anesthetics due to a dynamic visualization of the needle [10]. In peripheral nerve block, the use of ultrasound permits a small anesthetic volume to achieve a successful blockade therefore reducing complications that are usually related to the dosage [5,10-12].

A 100% incidence of ipsilateral hemidiaphragmatic paralysis after ISB was shown by previous investigations [8,13]. Whereas in this study, after reading the postoperative X-rays, we showed that the incidence of hemidiaphragmatic paralysis was significantly lower in Group 3 in comparison to Group 5 but without any clinical difference. The results of this study show that interscalene block ISB under ultrasound guidance with 3 mL of 0.75% ropivacaine is as effective as 5 mL of the same drug in shoulder arthroscopy surgeries precisely in terms of postoperative analgesia seeing that pain scores did not differ between both groups. Other than the incidence of hemidiaphragmatic paralysis, no statistical difference is noticed in both groups.

Thus, by using a small volume of local anesthetic for interscalene block, the incidence of hemidiaphragmatic paralysis was reduced which is important in itself regardless of the absence of clinical repercussions after diaphragmatic paralysis. This is significant, especially for the fact that our patients were healthy subjects and the paralysis was unilateral.

This study was limited by the small sample and the absence of post-operative respiratory function assessment. More research is needed to confirm the findings of this study and to evaluate pulmonary functions post-operatively.

## Conclusion

When combined with general anesthesia, targeted and ultrasound-guided ISB with 0.75% ropivacaine produced the same post-operative analgesia with 3 mL compared to 5 mL. However, with lesser volume (3 mL), less diaphragmatic paralysis is observed on

the chest x-ray when compared to pre- and post-operatively. This finding is very important in patients with respiratory diseases undergoing surgery with ISB. Further investigations on post-operative respiratory functions must be undertaken.

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