



DEPARTMENT OF ANESTHESIOLOGY

JOURNAL CLUB

**Tuesday June 25th 2013
1800 HOURS**

**LOCATION:
AQUA TERRA BY CLARK RESTAUBISTRO
1 JOHNSON STREET**

**PRESENTING ARTICLES:
Dr. V. SHYAM & Dr. J. YOUNG**

**SPONSORED BY:
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SUGGESTED GUIDELINES FOR CRITICAL APPRAISAL OF PAPERS
ANESTHESIOLOGY JOURNAL CLUB
QUEEN'S UNIVERSITY
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Two presenters will be assigned to choose and present summaries of their papers. Ideally the two papers will represent similar topics but contrasting research methodologies. The focus remains on critical appraisal of the research and manuscript, more than on the actual contents of the article. Each presenter will then lead an open discussion about the article, based around the guidelines below. The object is to open up the appraisal to wide discussion involving all participants, who will be expected to contribute pending suspension of bar privileges.

GENERAL

1. Title of paper: Does it seem like an important problem? Does it reflect the purpose/results?
2. Authors, institution and country of origin

INTRODUCTION

1. What is the problem being addressed?
2. What is the current state of knowledge of the problem studied?
3. What is the hypothesis being tested?
4. How does testing the hypothesis help solve the stated problem?

METHODOLOGY

1. Study design:
 - a) Clinical trial vs. systematic review/meta-analysis
 - b) Prospective vs. retrospective
 - c) Observational vs. Experimental
 - d) Randomized or not
 - e) Blinded or not
2. Population studied:
 - a) Human, animal, other
 - b) Justification
 - c) Control groups: experimental vs. historical
 - d) Is the sample size/power calculated, and how?
 - e) Is the population similar to your own practice?
 - f) Single vs. multi-centre
3. Is the study ethically sound?
 - a) Clinical equipoise
 - b) Does treatment meet standard of care (esp controls)?
 - c) Appropriate consent and institutional ethics approval
4. Exclusions: what groups are excluded and why?
5. Experimental protocol
 - a) Is it designed to test the hypothesis?

- b) Is it detailed enough to be reproducible?
 - c) Is the methodology validated?
 - d) Are the drugs/equipment used detailed?
 - e) How does the randomization take place?
- 6. What are the primary endpoints?
- 7. Is power sufficient to justify secondary endpoints?
- 8. Is the protocol clinically relevant?
- 9. Data collection and analysis
- 10. Statistical analysis: Is it appropriate? Are results

RESULTS

- 1. Are the groups comparable?
- 2. Were any subjects/data eliminated?
- 3. Analyzed by intent to treat?
- 4. Are adequate details of results provided? - data, graphs, tables

DISCUSSION

- 1. What is the main conclusion of the study?
- 2. Do the results support this conclusion?
- 3. Do the results address the stated purpose/hypothesis of the study?
- 4. How do the authors explain the results obtained?
- 5. Are there any alternative interpretations to the data?
- 6. Are the results clinically as well statistically relevant?
- 7. How do the results compare with those of previous studies?
- 8. What do the results add to the existing literature?
- 9. What are the limitations of the methods or analysis used?
- 10. What are the unanswered questions for future work?

APPLICABILITY OF THE PAPER

- 1. Have you learned something important from reading this paper?
- 2. Will the results of this study alter your clinical practice?
- 3. Was the food and wine up to the high standards expected by self-respecting anesthesiologists?

Ultrasound-Guided Interscalene Block Anesthesia for Shoulder Arthroscopy

A Prospective Study of 1319 Patients

Anshu Singh, MD, Charles Kelly, MD, Travis O'Brien, BS, Jeffrey Wilson, MD, and Jon J.P. Warner, MD

Investigation performed at the Orthopaedic Ambulatory Surgery Center at Mass General West, Waltham, Massachusetts

Background: Ultrasound guidance improves the localization of anesthetic placement during regional anesthesia, but a decreased rate of adverse events has not been demonstrated in the current literature. In this large prospective study, we evaluated the safety, efficacy, and patient satisfaction associated with ultrasound-guided interscalene block.

Methods: A cohort of 1319 patients undergoing arthroscopic shoulder surgery at an outpatient surgery center was prospectively evaluated. Interscalene blocks were performed by experienced anesthesiologists and trainees with use of ultrasound guidance. Patients were queried by a physician twenty-four hours postoperatively regarding their satisfaction with the interscalene block and were screened for a comprehensive register of minor and major adverse events. Individuals with adverse events were followed until symptoms resolved.

Results: Interscalene block was ultimately successful in 99.6% of the cases. A total of thirty-eight adverse events (prevalence, 2.88%) were noted. At the time of the latest follow-up, permanent sequelae were present in three patients (0.23%), all of whom had relevant comorbidities. With regard to patient satisfaction, 99.06% of the respondents were “satisfied” or “very satisfied” with the interscalene block, whereas 0.94% of respondents were unsatisfied. In addition, 97.8% of the patients stated that they would elect to have an interscalene block again in the future.

Conclusions: The present study supports the use of ultrasound-guided interscalene block by trained anesthesiologists for well-screened patients undergoing shoulder arthroscopy, given the high rate of patient satisfaction and the low rate of adverse events.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

In North America, arthroscopy is commonly performed as an outpatient procedure, whereas European and Asian practitioners often admit patients overnight. There is no national or international consensus regarding the optimal perioperative management of the patient undergoing arthroscopic shoulder surgery. The choice of general anesthesia, sedation, and/or regional block anesthesia is a key factor in facilitating out-

patient surgery. As the health-care industry worldwide increasingly focuses on cost control, outpatient surgery will be preferred over more expensive inpatient procedures provided that outpatient practices are safe and efficacious and maximize patient satisfaction.

Interscalene block anesthesia has many potential benefits for outpatient shoulder arthroscopy^{1,2}. It provides excellent

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A commentary by Ashley Shilling, MD, is linked to the online version of this article at jbjs.org.

intraoperative anesthesia and muscle relaxation without the need for high-dose intravenous opiates and paralytics. Paralytics require airway protection and reversal, which potentially extends operative time if not tightly managed. High-dose intravenous opiates may cause nausea, vomiting, and/or sedation, which may prolong the time to discharge. The benefits of interscalene block extend to excellent postoperative analgesia that obviates or reduces the need for oral and intravenous pain medication in the hours after surgery. Interscalene block can allow patients to bypass acute (phase-1) postoperative anesthesia care for earlier discharge³. Patients who have undergone sequential general anesthesia followed by interscalene block on the contralateral shoulder strongly prefer interscalene block when queried the day after surgery⁴.

The apprehension of some orthopaedic surgeons to recommend or endorse regional anesthesia is likely due to trepidation about adverse events. Earlier orthopaedic literature demonstrated high rates of neurological, cardiac, and respiratory complications, some of which were permanent⁵⁻¹⁰. Recent studies of interscalene block performed with nerve stimulation have demonstrated lower rates of permanent complications, although a meta-analysis by Brull et al.¹¹ demonstrated that transient neuropathy after interscalene block still occurs about 3% of the time. Interscalene block had the highest rate of transient neuropathy among the peripheral blocks examined in that meta-analysis.

Ultrasound guidance clearly demonstrates the brachial plexus anatomy for block localization¹². In vivo studies have demonstrated that even with direct nerve-to-needle contact on ultrasound, there is a 13.5% false-negative rate with nerve stimulation¹³. This means that, in more than one in seven cases, no stimulation is elicited even when the tip of the needle is in the nerve, potentially increasing the risk of nerve injury via intraneural injection.

The available data suggest that ultrasound guidance may be superior to previous methods of administering regional anesthesia in terms of a reduction in the number of needle sticks, more rapid block onset times, higher block success rates, prolongation of both surgical anesthesia and postoperative analgesia, reduction in block procedure times and procedure-related discomfort, lower effective doses of local anesthetic, and less time for trainees to learn the technique¹⁴. However, a lower complication rate has not been proven¹⁵⁻²⁰.

The purpose of the present study was to prospectively analyze the use of ultrasound-guided interscalene block at a hybrid academic-private outpatient surgery center in terms of efficacy, complications, readmissions, and patient satisfaction. Our hypothesis is that interscalene block is efficacious and safe and is associated with a high level of patient satisfaction.

Materials and Methods

A collaborative perioperative protocol was established by the anesthesia, nursing, and orthopaedic departments at the inception of an outpatient surgery center in 2005. Anesthesia and analgesia were optimized by using both ultrasound-guided interscalene block and supplemental laryngeal mask airway anesthesia. Institutional review board approval was obtained, and prospective data collection for all cases began in September 2005.

TABLE I Shoulder Arthroscopy Primary Procedures (N = 1319)

Primary Procedure	Number of Patients
Rotator cuff repair	512
Subacromial decompression	289
Labral repair	135
Stabilization/Latarjet/plication	94
Acromioclavicular joint resection	90
Biceps tenodesis	67
Diagnostic arthroscopy	41
Debridement/other	91

Individuals were included if they were classified as American Society of Anesthesiologists grade 1 or 2 (ASA 1 or 2) and had shoulder arthroscopy between September 2005 and October 2008. Patients gave informed consent for interscalene block and subsequent data collection. Unlike in other studies, patients with diabetes and patients undergoing neurologically high-risk procedures such as manipulation or capsular releases were included in this cohort. The surgical diagnoses of this cohort are presented in Table I.

Patients were excluded if there was any evidence of neurological compromise that might constitute the first insult of a “double crush” syndrome to the brachial plexus. Such insults included thoracic outlet syndrome, multiple sclerosis, cervical disc disease with ipsilateral radiculopathy, or any preexisting neuropathy or brachial plexopathy. Active infection at the block site or coagulopathy (hemophilia, von Willebrand disease, or an international normalized ratio [INR] of >2) that might increase risk of hematoma or bleeding complications were cause for cancellation of interscalene block. Given that temporary ipsilateral phrenic nerve paralysis is commonly associated with interscalene block, patients with evidence of chronic obstructive pulmonary disease (COPD) were denied interscalene block. Finally, patients who refused interscalene block after informed consent, and those who were managed by surgeons who declined use of interscalene block, were excluded.

All blocks were performed preoperatively by either attending anesthesiologists or senior anesthesia residents under direct attending supervision. All attending anesthesiologists had performed more than fifty ultrasound-guided interscalene blocks prior to commencement of the study. Routine electrocardiography [EKG], noninvasive blood-pressure monitoring, and pulse oximetry were applied. The patient was placed in the supine position with the head turned to the contralateral (nonoperative) side. A procedural “time out” was performed. Midazolam (1 to 4 mg) and remifentanyl, titrated in 10 to 20- μ g increments, were administered intravenously. The skin was prepared with 2% chlorhexidine in 70% alcohol. Two different ultrasound machines were utilized (Envisor [Philips, Andover, Massachusetts] or Sonix CEP [Ultrasonix, Burnaby, British Columbia, Canada]). A linear high-frequency probe (L12-3 MHz [Philips] or L14-5 MHz [Ultrasonix]) covered with a sterile dressing (Tegaderm; 3M, St. Paul, Minnesota) was used. A “trace back” method was used to identify the brachial plexus. The ultrasonic scanning began in the supraclavicular fossa, with identification of the subclavian artery and then the adjacent brachial plexus. The brachial plexus was then followed in a cephalad direction to the level of the root-trunk divisions. Once the optimum level was located, the skin posterior to the probe was anesthetized with a skin wheal of 2% lidocaine. With use of a posterior “in-plane” approach, the 23-gauge needle was pushed through the middle scalene and then was advanced under direct ultrasonic guidance through the prevertebral fascia adjacent to the C5-C6 nerve roots or the upper trunk of the brachial plexus. We directly visualized the entire needle parallel with the ultrasound beam. After negative aspiration, 30 to 40 mL of 0.5% mepivacaine with 1:400,000 epinephrine was injected with low resistance. If there was paresthesia, pain, increased pressure, or difficulty with the injection, the needle was repositioned and the block was resumed.

The patient was examined by the anesthesiologist after block placement and was observed in the block area by nursing staff until transport to the operating room. Block failure was defined as an inadequate sensory blockade after thirty minutes of block placement. Desaturation, seizure, ear numbness, or other complications were noted. Patients with block failure were offered the option of a second interscalene block. In nearly every case, interscalene block was used as an adjuvant, and laryngeal mask airway general anesthesia was induced in the usual fashion. If the block was used as the primary anesthetic, the patient was positioned and sedated to the desired level with use of midazolam, fentanyl, and propofol.

Arthroscopy was performed at the discretion of the orthopaedic surgeon. If subpectoral biceps tenodesis was performed, the incision site was infiltrated with 10 mL of 0.5% bupivacaine as the axilla is not consistently covered by the interscalene plexus block.

Postoperatively, the patient was monitored in the postanesthesia recovery room. Discharge was allowed when the patient was awake, able to walk, and hemodynamically stable and after the surgeon had spoken to the patient and/or family. The time between arrival in the recovery room and discharge was recorded.

The patient was contacted by a physician twenty-four hours after discharge. As many as three telephone calls were made if necessary. Set data points were prospectively collected, including the onset of pain and the severity of pain on a 10-point scale. The efficacy of interscalene block was defined as the number of hours of sensory blockade as reported by the patient. The patient was queried with regard to a comprehensive registry of complications, including admission to the emergency department, ear numbness, nausea, difficulty voiding, shortness of breath, neuropraxia, and incomplete block. The patient was asked whether he or she would have the block again if another shoulder arthroscopy was needed. Finally, patient satisfaction with interscalene block was rated as very satisfied, satisfied, or dissatisfied. Patients who responded "dissatisfied" were asked for the cause of their dissatisfaction.

Patient charts were reviewed for postoperative emergency department visits, new neurological findings, and other significant complications. Any individuals with adverse events identified during the phone call, during chart review, or by the surgeon were followed until final resolution of symptoms.

Source of Funding

No external funding sources were utilized for this study.

Results

Demographic and Block Characteristics

The mean age (and standard deviation) of the 1319 patients undergoing arthroscopic shoulder surgery was 47 ± 15 years (range, fifteen to eighty-two years). Forty percent of the patients were ASA 1, and 60% were ASA 2. The mean weight was 82 ± 17 kg (range, 42 to 180 kg). Thirty-nine percent of the procedures were on the left side, and 61% were on the right side.

There were four immediate block failures in the preoperative area, and one patient was admitted to the hospital for severe pain in the recovery room (overall rate of block failure, 0.38%). Two patients were ultimately managed with a repeat block preoperatively with successful sensory blockade, leaving three interscalene blocks (0.23%) that were ultimately unsuccessful in terms of providing analgesia. The ultimate success rate was thus 99.77%.

The mean amount of time from the end of the procedure to discharge to home was ninety-two minutes. The average duration of pain relief was 14.3 ± 4.1 hours with 1:400,000 epinephrine.

Perioperative Complications

A total of thirty-eight major and minor perioperative complications occurred, for a rate of 2.88%. This rate includes all cancellations, emergency department visits, and hospital ad-

TABLE II Miscellaneous Adverse Events*

Presentation	Ultimate Outcome
Flank pain after block (1 case)	Observed in recovery room; negative workup
Unable to secure airway (2 cases)	Procedures canceled; awake intubations in hospital operating room
Nausea and vomiting (2 cases)	Emergency department visits only
Allergy to pain medication (1 case)	Emergency department visit only
*Six cases (prevalence, 0.46%).	

missions that may have been even peripherally attributable to interscalene block complications.

The majority of complications were transient neurological events. Fourteen patients experienced ear numbness; this complication was likely due to the placement of the patients in the beach-chair position as eight of these cases involved the contralateral ear. Eight individuals reported digital numbness. One patient reported distal ulnar mononeuropathy. All of the aforementioned conditions resolved over a period of days to four months. There were three cases of postoperative brachial plexitis. One individual was managed with immunoglobulin G (IgG) and had complete resolution of symptoms. The other two patients, as reported in the section on "Permanent Sequelae" below, did not have resolution of symptoms but had substantial underlying comorbidities.

Four procedures were canceled as a result of events before or during the initiation of anesthesia. One patient had chest pain, and another experienced flank pain during block placement. Both patients with pain had a negative cardiac workup. Two patients had oropharyngeal anatomy that precluded laryngeal mask airway placement. These patients were rescheduled for awake intubations in the hospital setting, which proceeded without complication.

Hospital/Emergency Department Admissions

Medical complications, while unrelated to interscalene block, are included to better understand the complications associated with shoulder arthroscopy and to demonstrate the rigor with which adverse events were vetted. Three patients presented to the emergency department. All three were discharged after a few hours of observation. Two of these three patients had emesis that required resuscitation with intravenous crystalloids. The third patient had an allergic reaction to the oral opiate medication that had been given for postoperative pain control. These adverse events are summarized in Table II.

Finally, six patients required overnight admission to the hospital for workup of conditions encountered during the perioperative period. Three of these patients had cardiac issues that were likely not related to the interscalene block. One of

TABLE III Hospital Admissions*

Etiology	Ultimate Outcome
Aspiration	Young male with 85% oxygen saturation in recovery room, bilateral lung consolidation on chest radiograph, 23-hour admission, no long-term sequelae
Postoperative chest pain	23-hour admission, negative cardiac workup
Myocardial infarction	Sternal chest pain with inferior STEMI† on Postoperative Day 1; clot at right coronary artery demonstrated with cardiac catheterization; female patient, receiving estrogen, with May-Thurner syndrome (possible higher clotting risk)
Postoperative pain	23-hour admission
Factitious seizure	23-hour admission, negative neurological workup
Intraoperative bradycardia (procedure halted)	Intraop. heart rate of 48 beats per minute and blood pressure of 71/37 mm Hg, necessitating 23-hour admission; negative cardiac workup

*Six cases (prevalence, 0.46%). †STEMI = ST segment elevation myocardial infarction.

these three patients had a myocardial infarction. The second patient had postoperative chest pain and a negative workup. The third patient experienced intraoperative bradycardia that necessitated the halting of the procedure and admission; telemetry and laboratory workup were negative. Hospital admissions are summarized in Table III.

Noncardiac complications varied in this large study group. One patient had substantial pain in the recovery room and was admitted for twenty-three hours for pain control. A young male patient aspirated during the procedure, resulting in mild hypoxemia and bilateral lung consolidation. The patient was discharged after twenty-three hours of observation. Finally, a sixth patient required admission to the hospital because of an apparent seizure in the recovery room. Full neurological workup was negative. A neurologist later made the diagnosis of factitious seizure.

Permanent Sequelae

Although the majority of adverse events proved to be transient, three patients (0.23%) had persistent sequelae at the time of the

latest follow-up. Each of these individuals had comorbidities that explained part or all of the pathology. The first patient presented with perioperative myocardial infarction. Concomitant emboli in the left and anterior descending arteries necessitated cardiac catheterization despite the placement of sequential compression devices during surgery. The second individual initially was believed to have persistent brachial plexitis but subsequently was diagnosed with transverse myelitis with substantial involvement of all four extremities. The third patient, also with persistent brachial plexopathy, was subsequently diagnosed with multiple sclerosis, which was later identified as a potential risk factor for brachial plexopathy after interscalene block²¹. Multiple sclerosis is a relative contraindication for interscalene block. Neurological complications are summarized in Table IV.

Patient Satisfaction

Of the 1319 patients who were managed with the aforementioned protocol, seventeen could not be contacted the next day despite a series of three calls initiated by the anesthesiologist. Thirty-one

TABLE IV Neurological Complications*

Presentation	Ultimate Outcome
Ear numbness (14 cases)	All cases resolved by 4 months
Digital numbness (8 cases)	100% resolved between 2 days and 4 months
Distal ulnar neuropathy (1 case)	100% resolved; likely secondary to sling
Brachial plexitis (3 cases)	1 patient managed with immunoglobulin G (IgG), with 100% symptom resolution; 2 patients with permanent demyelinating disease on electromyogram (one with multiple sclerosis, the other with transverse myelitis)

*Twenty-six cases (prevalence, 1.97%).

TABLE V Patient Satisfaction (N = 1271)*

Very satisfied	1161 (91.35%)
Satisfied	98 (7.71%)
Unsatisfied	12 (0.94%)

*The values are given as the number of patients. Overall, 99.06% of the patients were satisfied and 0.94% were unsatisfied.

patients had partially incomplete data sheets. Thus, complete next-day follow-up was available for 1271 patients (96.4%).

One thousand one hundred and sixty-one patients (91.35%) were “very satisfied” with the interscalene block, ninety-eight (7.71%) were “satisfied,” and twelve (0.94%) were “unsatisfied.” Of the twelve unsatisfied patients, four reported pain earlier than expected, three felt uncomfortable with the sensation of numbness/paresthesia, two reported pain at the subpectoral biceps tenodesis site, and three gave no reason for their dissatisfaction. The percentage of “satisfied” and “very-satisfied” respondents was 99.06%. These data are summarized in Table V.

Finally, 97.8% of individuals reported that they would elect to have another ultrasound-guided interscalene block if they required shoulder arthroscopy in the future.

Discussion

To our knowledge, this is the largest prospective study of interscalene block anesthesia for shoulder arthroscopy and it is one of the few to employ modern ultrasound guidance or to evaluate patient satisfaction²². This study is unique in several respects. We included only shoulder arthroscopy cases. No adjunctive local anesthesia (suprascapular or axillary nerve block) was performed. Set data points were collected prospectively with great sensitivity for both major and minor adverse events. Patient satisfaction has been largely ignored in the literature but was included in the present study. The greatest strength of the present study is the large study cohort. The large cohort was essential in order to screen for the rare major complications that dissuade orthopaedic surgeons from recommending interscalene block.

Bishop et al.²³ retrospectively reviewed 568 blocks that had been performed with nerve stimulator guidance. Both open and arthroscopic shoulder procedures were included in that study. The authors reported a 97% success rate, a 2.3% minor complication rate, and no major complications. Only neurologic complications were reported; events such as readmissions, emergency department visits, and medical events were not included in the 2.3% complication rate. Patient satisfaction was not reported. In our cohort of 1319 cases, we found a 99.6% rate of successful blockade on the first attempt, representing a reduction in the failure rate from 3% (as reported by Bishop et al.) to 0.4%. Ultrasound guidance resulted in approximately one failure in 300 patients, as compared with one failure in forty patients managed with nerve stimulation.

A similar study in the anesthesia literature was a well-designed prospective study by Borgeat et al.⁵, who followed

520 patients who were managed with interscalene block for shoulder surgery performed with nerve stimulation. Those authors reported more early symptoms than we found in the current study, but they reported a nearly identical rate of catastrophic permanent sequelae. Patient satisfaction was not evaluated.

In another recent prospective study, Liu et al.²⁴ compared ultrasound-guided interscalene block (n = 515) with supraclavicular block (n = 654) for shoulder arthroscopy procedures. They reported no permanent neurological injuries, a 0.9% rate of transient neurological symptoms with interscalene block, no need for conversion to general anesthesia, and high patient satisfaction.

Understandably, some orthopaedic surgeons remain guarded when recommending interscalene block to their patients, given earlier case reports documenting catastrophic events such as signs of toxicity, seizure, pneumothorax, arrhythmia, peripheral neurological complications, and death. These severe adverse outcomes, highlighted in a retrospective review by Lenters et al.²⁵, led some surgeons to abandon the use of interscalene blocks for fear of adding a potential source of morbidity to shoulder arthroscopy^{26,27}. Those early studies, however, were retrospective in nature. More importantly, they only included blocks performed with paresthesia or nerve stimulator techniques.

Nerve stimulation and paresthesia-guided interscalene blocks require more time, require more needle sticks, have a shorter effective duration, require more training, and are less efficacious than interscalene blocks performed with ultrasound guidance^{14,28-31}. One recent study demonstrated that with direct needle-to-nerve contact on ultrasound, nerve stimulation elicited a positive response in only 75% of cases³², whereas the paresthesia technique was even less accurate³³⁻³⁶. Superior localization of the needle in relation to the brachial plexus should result in increased quality and success of interscalene block, as demonstrated in the studies by Kapral et al.²⁹ and Soeding et al.³⁷. Given these data, it is reasonable to assume that blind techniques would lead to more direct trauma to nerves or would result in a hazardous bolus of local anesthetic being injected intraneurally, causing transient or permanent nerve injury. Decreased neurologic complications with ultrasound guidance, however, have not been scientifically proven^{5,20,38,39}.

In a study of 218 patients, Weber and Jain reported a high (13%) rate of interscalene block failure, a 3.7% rate of major complications, and higher cost as compared with general anesthesia²⁶. They concluded that the benefits and risks of the procedure were equivocal. The current study differs from that study in several important respects. First, Weber and Jain used the imprecise awake blunt needle nerve stimulation technique, leading to an unacceptably high rate of block failure, complications, and a high rate of utilization of narcotic medications postoperatively. The use of postoperative narcotics significantly added to the overall expense of the procedure in that study. Narcotic use is minimal after well-placed interscalene block, and the narcotic use in the study by Weber and Jain points to the imprecision of block placement. Second, we performed

interscalene block in the preoperative area, decreasing the use of expensive operating room time and increasing efficiency. Our turnover time averaged less than fourteen minutes. Multiple authors⁴⁰ have subsequently challenged the findings of the study by Weber and Jain.

Neurological complications of regional anesthesia have been the subject of multiple recent studies. Fredrickson and Kilfoyle prospectively examined such complications following 1000 peripheral blocks that were placed under ultrasound guidance, including 659 indwelling interscalene catheters⁴¹. These resulted in neurological symptoms in 8.2% of patients at ten days and in 3.7% at one month. The increased prevalence of nerve injury in that study was possibly due to the longer exposure to anesthetic and out-of-plane technique.

The levels of training and experience of the anesthesiologist are directly proportional to success and safety of regional anesthesia. The data collected in the present study are all from a single outpatient surgery center where both academic and community orthopaedists practice. The nursing and anesthesia groups are run in a private practice model and are experienced with outpatient procedures and ultrasound-guided interscalene block, respectively. Resident anesthesiologists rotate through the center and are closely supervised during block placement by an experienced attending anesthesiologist. We believe that these factors, and thus our results, are reproducible in most practice settings.

While most of the reported complications in the present study were not related to the interscalene block but rather were related to patient comorbidities or to perioperative, anesthetic, or orthopaedic causes, they were included for the sake of transparency and because we were unable to directly assign a cause-and-effect relationship.

One limitation of the present study is that we did not review narcotic administration in the recovery room. There were two reasons for this. First, it has been well documented that narcotic use is very low after interscalene block^{1,42,43}. Second, unlike complication rates and patient satisfaction, which were the primary outcomes evaluated in this study, narcotic utilization is not a barrier to surgeon adoption of interscalene anesthesia.

Another limitation of the present study is the lack of a nerve stimulator-guided control group. Given the growing body of evidence regarding improved block placement effi-

ciency, effect duration, patient tolerance, and reduced failure rates with ultrasound guidance, we believed that it would have been regressive to utilize a nerve stimulator when ultrasound is readily available at our institution. Given this factor, we cannot draw direct conclusions between the safety of ultrasound-guided and nerve stimulator-guided interscalene block.

A third limitation of the present study is the extensive use of patient-reported metrics. Patients were screened over the telephone by a physician who assessed a broad set of issues, but only individuals who reported any adverse events were followed by the surgeon and anesthesiologist until resolution. After the initial assessment, there was no regular reporting of a broad set of data but rather a more focused approach to the problem. This approach could be seen as a disadvantage that may have allowed late complications to be missed or as an advantage that allowed us to obtain data on what actually matters to patients in such a large cohort.

Our study strongly supports the use of interscalene block for operative anesthesia and postoperative analgesia in patients undergoing shoulder arthroscopy. The rate of successful sensory blockade was 99.77%, including the few individuals who had a repeat block. Patients were "very satisfied" or "satisfied" 99% of the time. The major and minor complication rate was an acceptable 2.88%, with the majority of complications being unrelated to the interscalene block. Permanent sequelae were present in only three patients (0.23%), each of whom proved to have comorbidities that help to explain the complications. ■

Anshu Singh, MD
5893 Copley Drive, San Diego, CA 92111.
E-mail address: anshu_singh@hotmail.com

Charles Kelly, MD
Travis O'Brien, BS
Jeffrey Wilson, MD
Jon J.P. Warner, MD
Department of Anesthesia (C.K. and J.W.)
and The Harvard Shoulder Service (T.O'B. and J.J.P.W.),
Massachusetts General Hospital,
55 Fruit Street, YAW 3G, Boston, MA 02114.
E-mail address for J.J.P. Warner: jpwarner@partners.org

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Effects of Adductor-Canal-Blockade on pain and ambulation after total knee arthroplasty: a randomized study

M. T. JENSTRUP¹, P. JÆGER², J. LUND¹, J. S. FOMSGAARD³, S. BACHE³, O. MATHIESEN², T. K. LARSEN³ and J. B. DAHL²

¹Department of Anaesthesia, Hamlet Hospital, Frederiksberg, Denmark, ²Department of Anaesthesia, Centre of Head and Orthopaedics, Copenhagen University Hospital, Rigshospitalet, Denmark and ³Department of Anaesthesia, Copenhagen University Hospital, Glostrup, Denmark

Background: Total knee arthroplasty (TKA) is associated with intense post-operative pain. Besides providing optimal analgesia, reduction in side effects and enhanced mobilization are important in this elderly population. The adductor-canal-blockade is theoretically an almost pure sensory blockade. We hypothesized that the adductor-canal-blockade may reduce morphine consumption (primary endpoint), improve pain relief, enhance early ambulation ability, and reduce side effects (secondary endpoints) after TKA compared with placebo.

Methods: Patients aged 50–85 years scheduled for TKA were included in this parallel double-blind, placebo-controlled randomized trial. The patients were allocated to receive a continuous adductor-canal-blockade with intermittent boluses via a catheter with either ropivacaine 0.75% ($n = 34$) or placebo ($n = 37$) (<http://www.clinicaltrials.gov> Identifier: NCT01104883).

Results: Seventy-five patients were randomized in a 1 : 1 ratio and 71 patients were analyzed. Morphine consumption from 0 to 24 h was significantly reduced in the ropivacaine group

compared with the placebo group (40 ± 21 vs. 56 ± 26 mg, $P = 0.006$). Pain was significantly reduced in the ropivacaine group during 45 degrees flexion of the knee ($P = 0.01$), but not at rest ($P = 0.06$). Patients in the ropivacaine group performed the ambulation test, the Timed-Up-and-Go (TUG) test, at 24 h significantly faster than patients in the placebo group (36 ± 17 vs. 50 ± 29 s, $P = 0.03$).

Conclusion: The adductor-canal-blockade significantly reduced morphine consumption and pain during 45 degrees flexion of the knee compared with placebo. In addition, the adductor-canal-blockade significantly enhanced ambulation ability assessed by the TUG test.

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TOTAL knee arthroplasty (TKA) is associated with intense, early post-operative pain. This surgical population consists primarily of elderly patients, often with significant co-morbidity. The post-operative analgesic regimen should aim to reduce morbidity and enhance functional recovery as well as provide efficient analgesia with minimal side effects.¹

Femoral and lumbar nerve blocks are effective for post-operative pain relief after TKA.^{2–5} However, femoral nerve block (FNB) reduces the strength of the quadriceps muscle by more than 80%.⁶ This adverse effect is particularly undesirable because early mobilization after surgery is important in order to enhance functional recovery and to reduce immobility-related complications. In addition, recent reports have shown that peripheral nerve

blocks involving the femoral nerve may be associated with the risk of falling.^{7–13} Consequently, regional anesthesia techniques with preserved muscle function are warranted.

A number of different nerves and nerve branches traverse the adductor canal (Hunter's canal), including the saphenous nerve, the nerve to the vastus medialis, the posterior branch of the obturator nerve, and in some cases, the medial cutaneous nerve and the anterior branch of the obturator nerve.¹⁴ Except for the nerve to the vastus medialis, these branches have a sole sensory function, and most of them play a major role in the sensory innervation of the knee region. We have recently hypothesized that administration of high-volume local anesthetic into the adductor canal [(‘adductor-canal-blockade’ (ACB))] could be a useful option for post-

operative analgesia after TKA.¹⁴ This hypothesis has not, however, been investigated in controlled clinical trials.

The objective of this prospective, randomized, double-blind, placebo-controlled study was therefore to investigate the efficacy of ACB on opioid consumption, pain relief and ambulation ability after TKA. We hypothesized that ACB would reduce morphine consumption (primary endpoint), and improve pain relief, enhance ambulation ability and reduce side effects (secondary endpoints) after TKA compared with placebo.

Materials and methods

After approval was obtained from the local Regional Ethics Committee (H-1-2009-143), the Danish Medicines Agency (2009-017794-37), and the Danish Data Protection Agency, this prospective, randomized, double-blind, placebo-controlled, parallel group study was conducted at Hamlet Hospital, Frederiksberg and at Glostrup University Hospital, the Capital Region of Denmark. Written informed consent was obtained from all subjects. The study was conducted in accordance with the Helsinki Declarations and the guidelines for Good Clinical Practice (GCP), and was monitored by the Copenhagen University Hospital GCP unit. Data are presented in accordance with the CONSORT statement. The trial was registered at <http://www.clinicaltrials.gov> (NCT01104883).

From August 2010 to March 2011 all patients undergoing TKA at the two centers were screened for inclusion. Eligible participants were patients scheduled for primary TKA under spinal anesthesia, aged 50–85 years, with an American Society of Anesthesiologists physical status classification of I–III, and a body mass index of 18–35. Exclusion criteria were inability to cooperate, inability to speak or understand Danish, allergy to any drug used in the study, a daily intake of strong opioids (morphine, oxycodone, methadone, fentanyl, ketobemidone), alcohol or drug abuse or inability to perform the mobilization test [Timed-Up-and-Go (TUG) test¹⁵] pre-operatively.

Interventions

Pre-medication consisted of acetaminophen 1 g orally 1 h before surgery. Spinal anesthesia was induced with 2 ml 0.5% hyperbaric bupivacaine at the L3/4 interspace (alternatively at the L2/3 or L4/5 interspaces). Sedation with propofol and intra-operative fluid therapy were administered at the

discretion of the anesthetist, and a femoral tourniquet was used at the discretion of the surgeon.

The ACB was performed immediately post-operatively. At the midthigh level, approximately halfway between the superior anterior iliac spine and the patella, a high-frequency linear ultrasound (US) transducer (GE Logiq e, GE, Waukesha, WI, USA) was placed in a transverse cross-sectional view. Underneath the sartorius muscle the femoral artery was identified, with the vein just inferior and the saphenous nerve just lateral to the artery. From the lateral side of the transducer a 10-cm, 18-gauge Tuohy needle (Braun Medical, Melsungen, Germany) was inserted in plane, through the sartorius muscle. With the tip of the Tuohy needle placed just lateral to the artery and the saphenous nerve, 20 ml of study medication was injected to expand the adductor canal. A 21-gauge catheter was then inserted 5–8 cm through the canula. To obtain the correct position of the catheter tip, the catheter was slowly retracted during injection of a further 10 ml of study medication under US guidance, until an expansion between the fascia and the vessels could be visualized. All blocks were performed by one of three anesthesiologists (M. T. J., J. L., J. S. F.), all with considerable experience in US-guided nerve blocks.

Patients were randomly assigned to receive either ACB with ropivacaine 0.75% or isotonic saline. The study groups were given 30 ml of ropivacaine or saline immediately post-operatively according to randomization. Additional boluses of 15 ml of ropivacaine 0.75% or saline were administered at 6, 12 and 18 h post-operatively. At 24 h post-operatively, after assessment of pain, morphine consumption, ambulation ability, and side effects, both the ropivacaine and the saline groups received a bolus of 15 ml of ropivacaine 0.75%.

Intravenous patient-controlled analgesia (PCA) was provided with morphine, bolus 2.5 mg, lock-out time 10 min and no background infusion. If analgesia was inadequate patients received an additional bolus of 2.5 mg morphine i.v. until adequate analgesia was obtained. Additional analgesics consisted of oral acetaminophen 1 g and oral ibuprofen 400 mg administered at 6-h intervals, initiated at 6 h post-operatively.

Ondansetron 4 mg i.v. was administered in the case of moderate to severe nausea or vomiting, with supplemental doses of 1 mg, if needed.

Outcomes

The primary endpoint was cumulative morphine consumption during 0–24 h post-operatively.

Secondary endpoints were pain at rest and during 45 degrees flexion of the knee, ambulation ability assessed with the TUG test, post-operative nausea and vomiting (PONV), ondansetron consumption and sedation.

Assessment of outcomes

All patients were tutored by one of the investigators pre-operatively in the visual analog scale (VAS), as well as trained in the TUG test and in the use of the PCA system.

Patients were assessed at 2, 4, 8, 24, and 26 h post-operatively. Recordings made at these time points included cumulative morphine consumption (0–24 h post-operatively), pain at rest, pain during 45 degrees flexion of the knee, nausea, vomiting, ondansetron consumption (0–24 h) and sedation. Ambulation ability (TUG test) was assessed twice, at 24 and 26 h post-operatively.

Pain was evaluated on a VAS with 0 mm = no pain, and 100 mm = worst imaginable pain. Ambulation ability was assessed with the TUG test, a validated test,¹⁵ which measures the number of seconds spent to get up from an ordinary armchair, walk a distance of 3 m, turn, walk back to the chair and sit down. All patients used a highwalker with arm support as assisting walking aid for the test. Nausea and sedation were assessed on a four-point scale (0 = no nausea/sedation, 1 = light, 2 = moderate, 3 = severe). Vomiting was assessed as number of vomiting episodes with a volume greater than 10 ml.

At 26 h post-operatively, patients were assessed for sensibility (sensation of cold) in the saphenous area at the middle and medial part of the lower leg.

Sample size

Based on previous studies^{16–18} we estimated a mean morphine consumption of 50 mg (SD 25) during the first 24 h post-operatively after TKA. A reduction of 20 mg in morphine consumption was considered clinically relevant. With $\alpha = 0.05$ and a power of 90%, 34 patients would be required in each group. To compensate for drop-outs we planned for an inclusion of 70 patients.

Randomization and blinding

The study medication was prepared by the pharmacy in identical glass containers and pre-packed in boxes, one for each patient. These were consecutively numbered according to a computer generated block randomization list, performed by the pharmacy in a 1:1 ratio, each block containing 10

numbers, except for the last block, which only contained five numbers. Upon inclusion into the study the participants were assigned consecutive numbers and received the study medication in the corresponding boxes.

All investigators, staff, and patients were blinded to the treatment groups. The randomization key was first broken once enrollment of all patients was completed and data computed.

Statistical analysis

Statistical analyses (based on intention to treat) were performed using SPSS 18 (SPSS, Chicago, IL, USA). Data are presented as mean and SD, or with medians and range as appropriate. The Kolmogorov–Smirnov test was used to test for normality. For VAS pain scores during flexion of the knee and at rest the area under the curve (AUC) 2–24 h post-operatively was calculated. The 24-h total morphine consumption, AUC-pain scores, the TUG test at 24 h and the change in the TUG test scores and the VAS-pain scores (at rest and during flexion of the knee) from 24 to 26 h were compared using the independent samples *t*-test. Side-effects (nausea, number of vomits and sedation) were compared with the Mann–Whitney *U*-test for unpaired data. For comparison of nausea and sedation, the arithmetic mean scores were calculated by attributing numerical values to the scores from each patient. Categorical data (ondansetron) were analyzed using the chi-squared test. The nature of the hypothesis testing was two-tailed, and $P < 0.05$ was considered statistically significant. The investigators did all statistical analysis.

Results

A total of 168 patients were approached for participation in the study from August 2010 to March 2011. Seventy-five patients were recruited and randomly assigned to their treatment group, of these four patients were excluded after randomization (Fig. 1). Finally, data from 71 patients were analyzed. The groups were similar with respect to demographics and perioperative data (Table 1).

As illustrated in Fig. 2, total morphine consumption from 0 to 24 h post-operatively was significantly reduced in the ropivacaine group compared with the placebo group [40 ± 21 vs. 56 ± 26 mg, respectively (-27 – -5 mg, 95% CI), $P = 0.006$].

Pain scores during 45 degrees flexion of the knee (AUC 2–24 h post-operatively) were lower in the ropivacaine group compared with the placebo

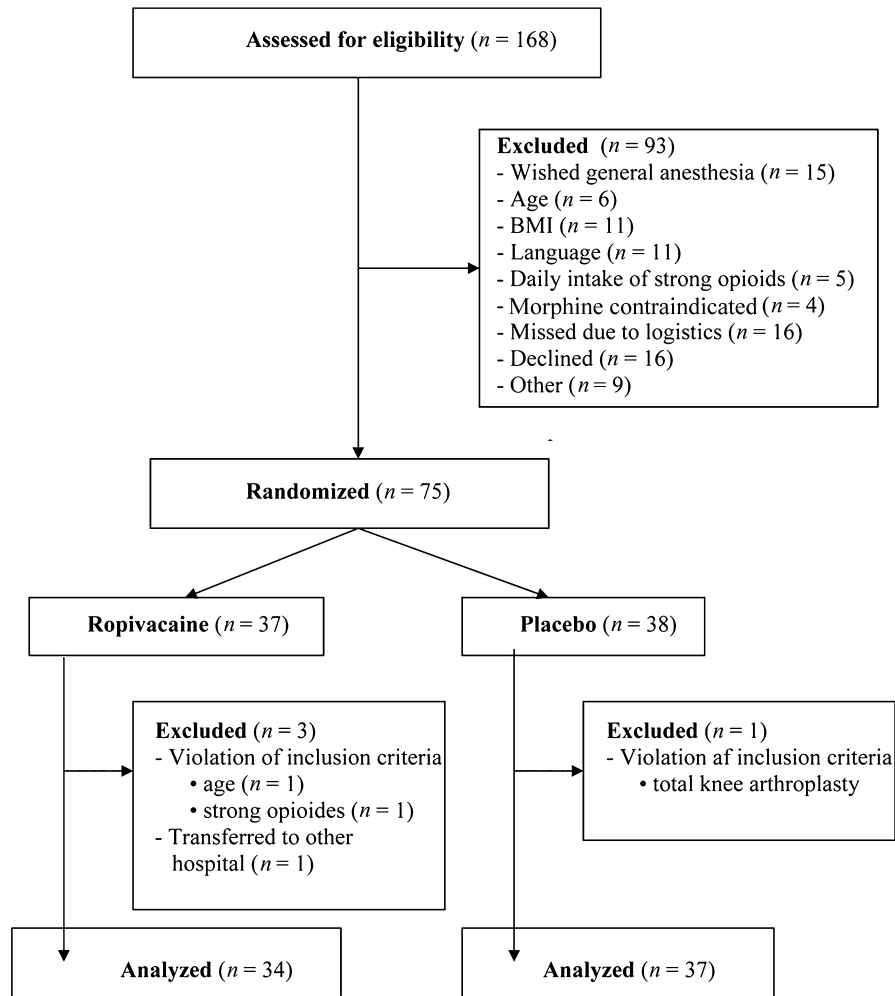


Fig. 1. Flow diagram of patient distribution. BMI, body mass index.

Table 1

Patient characteristics and perioperative data.

	Ropivacaine group	Placebo group
Number of patients	34	37
Sex (male/female)	18/16	19/18
Age (years)	67 (7)	67 (9)
Height (cm)	172 (8)	173 (11)
Weight (kg)	88 (15)	87 (19)
Pre-operative VAS pain at rest (mm)	12 (17)	14 (21)
Pre-operative VAS pain at 45 degrees flexion of the knee (mm)	25 (26)	29 (27)
Operated side (right/left)	15/19	20/17
Hospital site (Hamlet/Glostrup)	18/16	19/18
Duration of surgery (min)	65 (28)	60 (19)
Bleeding (ml)	92 (148)	99 (167)
Isotonic sodium chloride (ml)	815 (454)	854 (470)
Voluven (ml)	0 (0)	27 (164)
Thigh tourniquet (yes/no)	33/1	32/5

Values are reported as number of subjects or mean (SD).
VAS, visual analog scale.

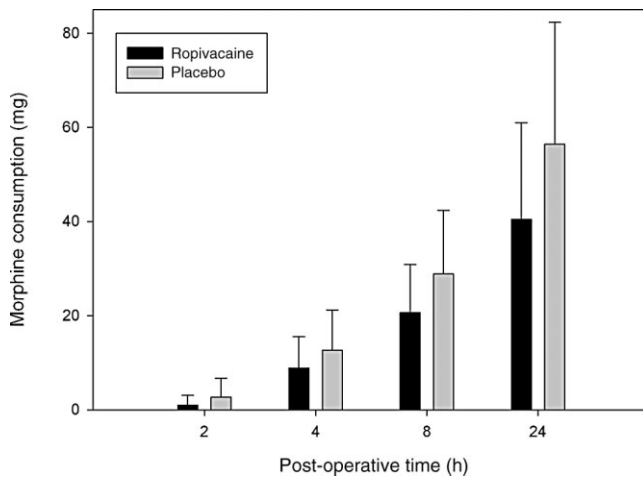


Fig. 2. Effects of the adductor-canal-blockade on cumulative morphine consumption. Data are expressed as mean \pm SD. Cumulate morphine consumption from 0 to 24 h post-operatively was significantly reduced in the ropivacaine group compared with the placebo group ($P = 0.006$).

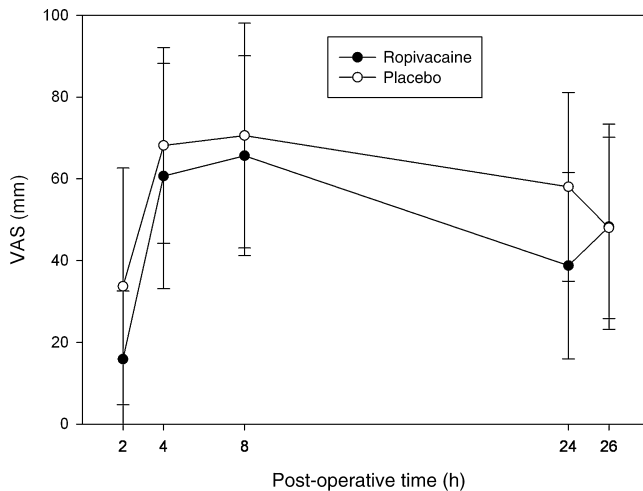


Fig. 3. Effects of the adductor-canal-blockade on pain during 45 degrees flexion of the knee. Visual analog scores (VAS; 0–100 mm, mean \pm SD) calculated as area under the curve (AUC) for the interval 2–24 h post-operatively. Pain scores during 45 degrees flexion of the knee were significantly reduced in the ropivacaine group compared with the placebo group ($P = 0.01$). At 24 h both groups received ropivacaine via the Adductor-Canal-Blockade catheter. From 24 to 26 h post-operatively, pain scores decreased significantly in the saline group compared with the ropivacaine group ($P < 0.001$).

group ($P = 0.01$) (Fig. 3). Pain scores at rest were reduced in the ropivacaine group, but this difference did not reach statistical significance ($P = 0.058$) (Fig. 4). From 24 to 26 h post-operatively, pain scores decreased in the saline group (after administration

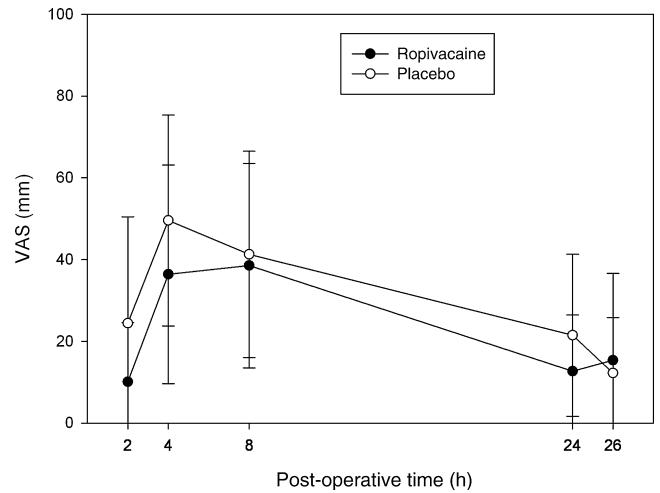


Fig. 4. Effects of the adductor-canal-blockade on pain at rest. Visual analog scores (VAS; 0–100 mm, mean \pm SD) calculated as area under the curve (AUC) for the interval 2–24 h post-operatively. Pain scores at rest were reduced in the ropivacaine group, but this difference did not reach statistical significance ($P = 0.058$). At 24 h both groups received ropivacaine via the adductor-canal-blockade catheter. From 24 to 26 h post-operatively, pain scores decreased significantly in the saline group compared with the ropivacaine group ($P = 0.01$).

of ropivacaine) compared with the ropivacaine group, both during flexion of the knee ($P < 0.001$) and at rest ($P = 0.01$).

Patients in the ropivacaine group performed the TUG test at 24 h post-operatively faster than patients in the placebo group (36 ± 17 vs. 50 ± 29 s, respectively, mean (SD), $P = 0.03$). This difference disappeared at 26 h post-operatively, 2 h after administration of ropivacaine in both study groups (33 ± 20 vs. 41 ± 27 s, respectively, $P = 0.21$) (Fig. 5).

There were no differences between groups with regard to nausea ($P = 0.12$), vomiting ($P = 0.47$) or sedation ($P = 0.15$). The number of patients requiring ondansetron were reduced in the ropivacaine group (8/34) vs. the placebo group (19/37), ($P = 0.01$).

At 26 h post-operatively, 63/71 patients were tested for sensibility in the saphenous area: 59 patients had loss of cold sensation (functional block), and four patients had normal sensation (failed block, all in the placebo group).

All US-guided ACBs were performed as described in the Materials and Methods section and without any complication registered. Three patients were withdrawn during the study: one received an erroneously injection of part of the study medication intravenously at 24 h (data from 0 to 24 h included); one developed a crural compartment syndrome and

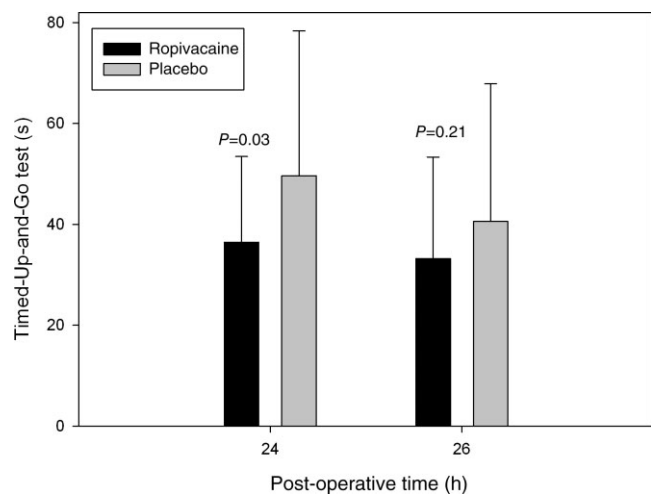


Fig. 5. Effects of the adductor-canal-blockade on ambulation ability, assessed with the Timed-Up-and-Go (TUG) test. Data are expressed as mean \pm SD. Patients in the ropivacaine group performed the TUG test at 24 h post-operatively significantly faster than patients in the placebo group ($P = 0.03$). This difference disappeared at 26 h post-operatively, 2 h after administration of ropivacaine via the adductor-canal-blockade catheter in both study groups ($P = 0.21$).

was transferred to another hospital for fasciectomy (no data available for analyses); one withdrew his consent at 5 h post-operatively (data from 0 to 4 h included). In addition one patient had missing values for pain assessments at 26 h, and six patients had missing values for the test for sensibility. All other patients had complete data set for all assessments at all time points.

Discussion

This is the first randomized, placebo-controlled study investigating the effect of high-volume, repeated administration of local anesthetic into the adductor canal, via a catheter with a midhigh, sub-sartorial approach, in patients undergoing TKA. Results showed that an ACB with ropivacaine significantly reduced 24 h morphine consumption. Further, pain during 45 degrees flexion of the knee was reduced throughout the study ($P = 0.01$), and ropivacaine administered to the control group at the end of the study significantly reduced pain at rest and during flexion. Moreover, ambulation ability (TUG test) in patients with the active treatment was improved compared with placebo ($P = 0.03$). Although common, opioid-related side effects such as PONV and sedation only demonstrated a trend towards reduction, but patients with an active ACB required ondansetron less frequently than patients

in the control group ($P = 0.01$). A possible explanation for this discrepancy might be that while nausea was only assessed at specific time points, the outcome of ondansetron consumption covers the entire time period from 0 to 24 h.

At first glance the observed effects on opioid requirements and pain demonstrated in the current study may seem clinically modest. However, all patients in our study received a basic analgesic regimen with acetaminophen, ibuprofen, and PCA morphine. This will obviously blunt the opioid-sparing and pain relieving effect of the ACB *per se*. Nevertheless, we observed significant differences in several outcomes between the study groups. Further, our results are comparable with those from a recent review of continuous FNB in similar patients.² Thus, compiled data from that analysis showed that continuous FNB reduced morphine consumption during the first 24 h post-operatively by 15 mg,² compared with 16 mg in the present study. In addition, continuous FNB reduced pain during activity at 24 h by 1.5 cm on a VAS scale,² whereas the ACB reduced pain during 45 degrees flexion of the knee at 24 h by 1.9 cm. Neither the FNB² nor the ACB had any significant effect on pain at rest. Importantly, none of the blocks are expected to result in complete analgesia, and consequently these techniques should be evaluated in combination with other analgesics or analgesic methods.

Notably, the ropivacaine group performed the TUG test at 24 h post-operatively significantly faster than the placebo group. While all patients in the ropivacaine group could be mobilized at 24 h post-operatively, two patients in the placebo group could not, because of pain and discomfort. These two patients were mobilized at 26 h, 2 h after injection of ropivacaine via the catheter. In the ropivacaine group one patient could not perform the TUG test at 26 h post-operatively. This patient reported no pain in the knee, but severe pain in the muscles of the thigh, provoked during the first TUG test.

The ACB is an almost pure sensory block, with the vastus medialis muscle as the only muscle with potentially affected motor function. Our results show that the blockade may enhance early ambulation compared with placebo. This is a potentially important advantage compared with the FNB as it has been demonstrated that even a very low dose/low volume continuous FNB reduces the strength of the quadriceps muscle by more than 80% in human volunteers.⁶

Recently, focus has been on the risk of falling associated with peripheral nerve blocks for the lower

limbs.⁷⁻¹³ Ilfeld et al. reported seven falls in 171 patients receiving a peripheral nerve block involving the femoral nerve.⁷ All of these falls occurred in the active treatment group showing a probable causal relationship between peripheral nerve blocks involving the femoral nerve and fall episodes. The quadriceps muscle is essential in mobilization. The ACB leaves three out of the four components of the quadriceps muscle unblocked, which potentially reduces the risk of falling caused by quadriceps weakness. Obviously, further studies are needed to validate the effect of ACB on muscle strength.

In the treatment group we used 0.75% ropivacaine in relatively large volumes to ensure evenly distribution throughout the adductor canal. With these large volumes we cannot rule out a systemic effect of the local anesthetic. However, it should be noted that after injection of ropivacaine 0.75%, 15 ml at 24 h post-operatively, pain scores during flexion and at rest in the placebo group were reduced compared with pre-injection values. This decrease was more pronounced than in the ropivacaine group. This finding validates the significant results observed between groups during the first 24 h post-operatively, and is unlikely to be caused by a systemic effect of ropivacaine. The ACB is a novel technique and studies are needed to investigate the optimal concentration and volume of local anesthetic to be utilized in this block.

Insertion of a catheter in the adductor canal is a relatively simple technique, and as all patients received ropivacaine at 24 h post-operatively, we were able to test the block at 26 h for cold sensation in the saphenous area. The success rate of the block was 94% (59/63, eight patients not tested), which is comparable with the success rate seen in other studies investigating US-guided blockade of the saphenous nerve in the adductor canal.^{19,20} We consider this to be acceptable, especially because three different anesthesiologists at two different hospitals performed the blocks, thereby enhancing the probability that the set-up can be adapted to other hospitals.

Controversy exists regarding whether continuous peripheral nerve blocks with a catheter technique offer superior analgesia compared with a single-shot technique.^{1,2,21} Several studies have shown a reduction in pain or morphine consumption during a continuous infusion compared with a control group^{3,22-27} but only few studies directly compare a continuous infusion with a single-shot technique.^{16,28,29} However, to ensure the appropriate spread throughout the adductor canal we believe that intermittent boluses are preferable to continu-

ous infusions. Studies have shown that intermittent boluses provide superior analgesia compared with continuous infusions via an epidural catheter.³⁰ Although the mechanism is unknown, this phenomenon might also be present with peripheral nerve blockades. Whether the ACB should be performed as a catheter technique (repeated boluses or continuous infusion) or by a single-shot technique should be subject to further investigation.

In conclusion, the ACB significantly reduced morphine consumption and pain during 45 degrees flexion of the knee compared with placebo after TKA. Furthermore it significantly enhanced ambulation ability at 24 h assessed with the TUG test. This almost pure sensory block may be a useful analgesic adjuvant for acute post-operative pain management after TKA. The degree of motor blockade, as well as the optimal volume and concentration of local anesthetic, should be subject to further investigation.

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Address:
Pia Jæger
Department of Anaesthesia 4231
Centre of Head and Orthopaedics
Rigshospitalet, Blegdamsvej 9
DK-2100 Copenhagen Ø
Denmark
e-mail: pia.jaeger@rh.regionh.dk