

Efficacy of ropivacaine by the concentration of 0.25%, 0.5%, and 0.75% on surgical performance, postoperative analgesia, and patient's satisfaction in inguinal hernioplasty: a randomized controlled trial

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Background: The purpose of this study was to evaluate the use of different concentrations of ropivacaine in ultrasound-guided regional anesthesia with regard to postoperative analgesic and patient's satisfaction in elderly patients undergoing inguinal hernioplasty in the People's Republic of China.

Methods: A total of 60 patients (>75 years of age) who scheduled inguinal hernioplasty at the Shenzhen People's Hospital from December 2013 to March 2015 were randomly assigned to three groups: 0.25% ropivacaine (n=20), 0.5% ropivacaine (n=20), and 0.75% ropivacaine (n=20). Ultrasound-guided regional anesthesia was performed before every surgery. Non-invasive blood pressure and heart rate were recorded before the operation, during the first 5 minutes of the surgical procedure, and 5 minutes after the operation of the patients, and compared between the groups. Incidence of adverse reactions, postoperative Visual Analog Scale score, and analgesic effect were also recorded and analyzed.

Results: The surgical procedure and anesthesia was performed successfully in all patients. Patients with high-dose ropivacaine (0.5% and 0.75%) in ultrasound-guided regional anesthesia exhibited lower arterial pressure and lower heart rate during the operation when compared to low-dose group. The interquartile range of Visual Analog Scale scores in both group C (0.75% ropivacaine) and group B (0.5% ropivacaine) were significantly lower ($P<0.05$) than in group A (0.25% ropivacaine). Accordingly, the interquartile range of satisfactory scores in both group C (0.75% ropivacaine) and group B (0.5% ropivacaine) were significantly higher ($P<0.05$) than in group A (0.25% ropivacaine). More cases in high-dose groups reported abnormal skin sensation; however, it did not negatively affect the satisfaction level of patients.

Conclusion: The use of ultrasound-guided regional anesthesia with ropivacaine as an anesthetic in inguinal hernia repair for elderly patients is safe and effective, and ropivacaine is optimally effective at the concentration of 0.5% with least side effects.

Keywords: ropivacaine, ultrasound guided ilioinguinal nerve block, inguinal hernioplasty, analgesic effect

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Introduction

Inguinal hernioplasty is one of the most common procedures performed in general surgery.¹ Inguinal and umbilical hernias are common in the elderly due to the loss of strength of the abdominal wall.² The operation of inguinal hernioplasty has been commonly done under sedation or general anesthesia combined with an ilioinguinal (IN)/iliohypogastric nerve block or surgical field infiltration with a long-acting local anesthetic agent.^{3,4} Day surgery of inguinal hernioplasty operated under regional

anesthesia has been significantly expanded in recent years, and the application of day surgery will be able to ensure less interference in the everyday life of patients and a faster return to the comfort of their own homes.

During the last several years, advancements in ultrasound technology have enabled direct visualization of peripheral nerves, and thereby helped in the increase of the use of ultrasound-guided regional anesthesia.^{5,6} Ultrasound-guided IN and iliohypogastric nerve blocks have been applied in adult patients and showed a significant reduction of the volume of local anesthetic drugs and probable side effects to achieve an appropriate block.^{7,8} However, data on the use of IN block in elderly patients (>75 years of age) and their lowest effective doses undergoing inguinal hernia repair and their analgesic effect are rare. Therefore, we performed a controlled study to systematically evaluate the analgesic and clinical effects of ultrasound-guided blocks of the IN nerves in 60 elderly patients in the People's Republic of China.

Patients and methods

Participants

The study was conducted from December 2013 to March 2015 at the Department of Surgery, Shenzhen People's Hospital, Shenzhen, Guangdong, People's Republic of China. The clinical trial registration number for this study is NHFPC, Shenzhen201402009. In a previous preliminary study (data not shown), the responses of patients regarding anesthesia onset time determined by pinprick test within each subject group were normally distributed with standard deviation of 3 minutes. We planned a study with 20 experimental subjects in each group. We were able to determine that if the true differences in the onset time of mean onset time would be 5 minutes, we were able to determine that if the true differences in the onset time would be 5 minutes, we would be able to reject the null hypothesis with the power of 0.999. The type I error probability associated with this test of this null hypothesis was set to be 0.05. Therefore, a total of 60 patients aged from 75 to 84 years who scheduled for inguinal hernia repair were recruited for the study.

All patients signed their informed consent and participated in the study voluntarily. Using a computer-generated table of random numbers, the patients were randomly divided into three groups, ie, group A (0.25% ropivacaine; n=20), group B (0.5% ropivacaine; n=20), and group C (0.75% ropivacaine; n=20). The inclusion criterion was American Society of Anesthesiologists physical status I–II. Exclusion criteria included known allergies, severe respiratory, neurological or cardiovascular disease, narcotic drug dependence,

hepatic or renal dysfunction, and recent history of immunosuppressant drug use.

Anesthesia methods

Ultrasound-guided IN nerve block was used in all 60 patients in this study. The research data were collected and analyzed in a double-blinded fashion by one of the authors, who was not involved in anesthesia processes. None of the patients in this study were informed of the doses of anesthetic drug(s) for their operations. All IN nerve blocks were performed before operations by two anesthesiologists with substantial expertise in regional anesthesia. The 7.5 MHz transducer was used for real-time ultrasound guidance, and the needle tips were inserted from slightly below the plane of view (caudal to the transducer in the short axis), and were then advanced directly over the IN nerve where 20 mL of different concentrations of ropivacaine (according to pre-assigned group) were applied slowly. Tramadol (50 or 100 mg) or fentanyl (0.05 mg) was chosen to assist in regional anesthesia when the surgery process required (patients complain about pain or surgeons complain about the lack of muscle relax).

Physical indices

Mean arterial pressure of left arm and heart rate were recorded in each patient before surgery, 5 minutes into surgery, during the separation of hernia sac, and postoperation. Length of surgery, amount of bleeding, incidence of vomiting, limb movement, respiratory depression, and other adverse reactions were also recorded.

Clinical evaluations

Postoperative pain was assessed using a 10-point Visual Analog Scale (VAS: no pain, 0; mild pain, 1–4; severe pain, 5–8; unbearable pain, 9–10) 12 hours after the surgery.⁹ Patients were also instructed how to rate their satisfactory degree of the anesthesia into five levels to evaluate the stress level from the pain inflicted by the surgery: 1 as “very bad”, 2 as “bad”, 3 as “mediocre”, 4 as “good”, and 5 as “very good”.

Data analysis

The data are shown as the mean \pm standard deviation. Measured data of independent samples in all the groups were conducted through a *t*-test, and the χ^2 test was used for categorical data. Results with $P < 0.05$ were considered to be statistically significant. All data were analyzed using Statistical Package for the Social Sciences version 14.0 software (SPSS Inc, Chicago, IL, USA).

Table 1 Demographic and physical features of participants in groups

Groups	A	B	C
Sex, n (%)			
Male	15 (75)	15 (75)	16 (80)
Female	5 (25)	5 (25)	4 (20)
ASA, n (%)			
I	8 (40)	7 (35)	7 (35)
II	12 (60)	13 (65)	13 (65)
Age (years)	79.90±3.04	80.10±2.83	80.15±2.90

Abbreviation: ASA, American Society of Anesthesiologists.

Ethics approval and informed consent

The study protocol was approved by the Institutional Human Ethics Committee at The Shenzhen People's Hospital and written informed consent was obtained from each patient.

Results

Patient demographic and clinical characteristics

There were no significant differences among the three groups with regard to age, sex, and American Society of Anesthesiologists physical conditions (Table 1).

Generally, patients with higher dose of ropivacaine (0.5% and 0.75%) in ultrasound-guided regional anesthesia exhibited low arterial pressure and low heart rate during the operation process (Table 2, both 5 minutes into the surgery and during the separation of hernia sac) when compared to group A (0.25%). In line with these findings, the patients with high-dose ropivacaine required less use of tramadol or fentanyl (Table 2). These three groups with different doses of ropivacaine (0.25%, 0.5%, and 0.75%) did not show

significant differences in arterial pressure or heart rate before or after the operation. It indicates that low arterial pressure and low heart rate observed during the operation process was due to better pain management rather than the side effect of ropivacaine.

Postoperative VAS and satisfactory scores, incidence of adverse reactions

As shown in Figure 1A, the interquartile range of VAS score in both group C (0.75% ropivacaine) and group B (0.5% ropivacaine) were significantly lower ($P<0.05$) than in group A (0.25% ropivacaine). Accordingly, the interquartile range of satisfactory scores (Figure 1B) in both group C (0.75% ropivacaine) and group B (0.5% ropivacaine) were significantly higher ($P<0.05$) than in group A (0.25% ropivacaine), indicating that the patients were more satisfied with the surgery process when there was less pain after the surgery. No abnormal skin sensation reported in patients from group A (self-report), while one case in group B ($n=20$) and six cases in group C ($n=20$) reported abnormal skin sensation including tickling, burning, or tingling. The skin sensation reports were collected at the same time as the VAS and satisfactory scores were collected (12 hours after the operations). The abnormal skin sensation did not negatively affect the satisfaction level of patients (Figure 1C) while we observed a reverse correlation of satisfaction level to VAS scores (Figure 1D).

Discussion

Currently, inguinal hernia repair under local anesthesia is generally a well-codified and widely performed surgery in the People's Republic of China. It has been recommended

Table 2 Clinical features and circulatory monitoring of participants in groups

Groups	A	B	C	P-value
Onset time	24.50±3.00 ^a	19.25±2.20	14.75±1.45	10 ⁻³
Requirement of tramadol (mg)	50.00±36.27 ^b (n=15, 50–100 mg each)	2.50±11.18 (n=1, 50 mg each)	0	10 ⁻³
Requirement of fentanyl (mg)	0.005±0.15 ^b (n=2, 0.05 mg each)	0	0	0.13
Arterial pressure				
Before operation	81.90±4.38 ^b	82.25±3.42	81.30±3.13	0.713
5 minutes after operation started	84.50±4.73 ^b	81.20±3.33	79.35±3.13	
During hernia sac separation	85.15±4.93 ^b	80.35±2.98	79.80±3.53	
Postoperation	81.75±4.15 ^b	82.10±3.21	81.15±2.96	0.685
Heart rate				
Before operation	68.55±4.85 ^b	68.40±4.92	68.55±4.78	0.994
5 minutes after operation started	76.00±6.10 ^b	68.55±4.48	68.75±3.99	10 ⁻³
During hernia sac separation	73.75±5.54 ^b	68.85±4.30	68.20±4.25	0.001
Postoperation	69.10±4.01 ^b	68.45±4.70	68.45±4.36	0.863

Notes: ^a $P<0.05$ when compared with low-dose group B; ^b $P>0.05$ when compared with group B. Data are presented as mean ± standard deviation

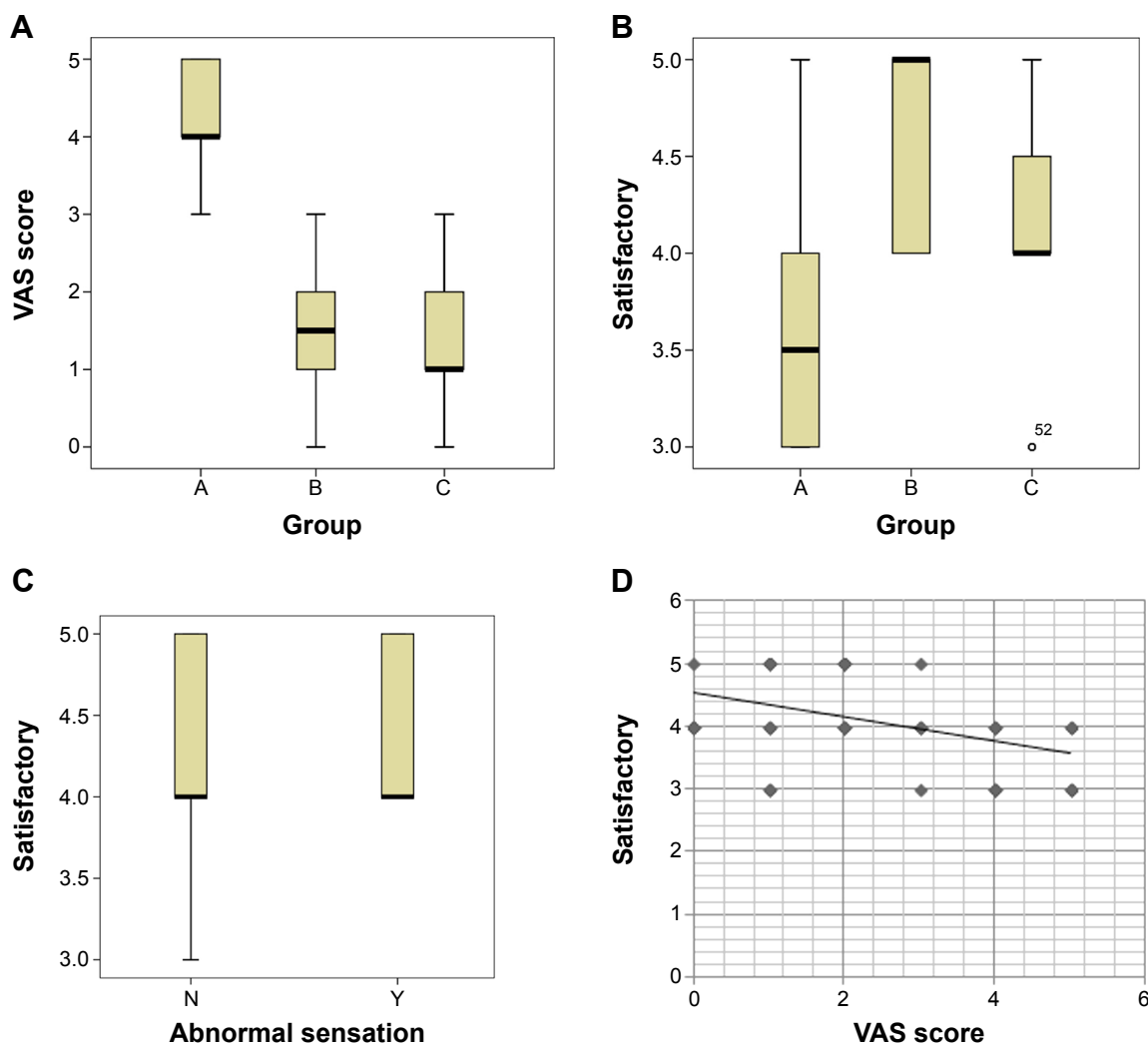


Figure 1 Satisfactory and VAS score in study subjects.

Notes: (A) VAS scores of participants 12 hours after the operations in study subjects. (B) Satisfactory scores of participants 12 hours after the operations in study subjects. (C) Satisfactory scores of participants with or without abnormal skin sensation. N denotes patients with no abnormal skin sensation, Y denotes patients with abnormal skin sensation. (D) Reversed correlation of satisfactory score and VAS score. The scores from 60 patients were plotted where satisfactory score were analyzed as dependent variable and VAS score were considered as independent variable, $P=0.001$. Each diamond shaped plot stands for patient(s) that gave such score. Satisfactory levels are measured as 5=most satisfied and 0=not satisfied.

Abbreviation: VAS, Visual Analog Scale.

for elderly patients not to undergo inguinal hernia repair due to their higher susceptibility to the side effects of anesthesia, which prevented them from a good quality of life. In this study, hernia repair is performed according to the Lichtenstein technique¹⁰ with mesh fixation by fibrin glue under ultrasound-guided IN nerve block with ropivacaine. We found that this technique is safe and higher doses of ropivacaine (0.5% and 0.75%) reduced pain and increased patient satisfaction. The highest dose (0.75%) did not provide significant advantage regarding heart rate reduction, arterial pressure, or perceived pain by patients.

In the present study, we found significant differences in interquartile range of postoperative VAS scores and patients'

satisfactory scores among the groups where different doses of ropivacaine were applied. Consistent with these findings, we observed lower arterial pressure and lower heart rate observed during the operation process in 0.5% and 0.75% ropivacaine groups when compared to 0.25% ropivacaine group, indicating 0.5% and 0.75% ropivacaine concentrations provided patients with better pain management experience with and after the surgeries.

Ropivacaine is usually used in combination with tramadol or fentanyl.^{11,12} We found that for Chinese elderly patients undergoing inguinal hernia repair operations, 0.75% ropivacaine in the volume of 20 mL was enough to avoid using of tramadol or fentanyl in ultrasound-guided

regional anesthesia. Although abnormal skin sensations were more frequent in patients (six out of 20) administered with 0.75% ropivacaine regionally, it did not adversely affect their satisfaction over the anesthesia and surgical process (Figure 1C).

Given the fact that we did not observe significant advantage of 0.75% ropivacaine regarding heart rate reduction, arterial pressure, or perceived pain by patients, and there were more self-reported abnormal skin sensations including tickling, burning, or tingling, we would recommend 0.5% ropivacaine in 20 mL volume as a proper dose for ultrasound-guided regional anesthesia for inguinal hernia repair operations in the Chinese elderly patients.

Conclusion

Our study further confirmed that the use of ultrasound-guided regional anesthesia with ropivacaine as an anesthetic in inguinal hernia repair for elderly patients is safe and effective in pain reduction, except for few adverse reactions. Ropivacaine is optimally effective regarding heart rate reduction, arterial pressure, or perceived pain by patients at the concentration of 0.5% with least side effects.

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Disclosure

The authors report no conflicts of interest in this work.

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