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ORIGINAL RESEARCH **PAIN MANAGEMENT**

Bilateral superficial cervical plexus block improves pain control after thyroidectomy under general anesthesia: a randomized, double-blind, clinical trial

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ABSTRACT

Background: Thyroidectomy is a surgical procedure that causes mild to moderate pain after surgery, which needs adequate management. Various pain control regimens have been used for this purpose including narcotic analgesics, non-steroidal anti-inflammatory drugs (NSAIDs) and regional techniques. We studied the efficacy of bilateral superficial cervical plexus blocks (SCPB) under ultrasound guidance on post-operative pain after thyroidectomy under general anesthesia.

Methodology: This randomized double-blind clinical controlled trial was conducted on sixty patients, who were randomly allocated to either Group I, to receive bilateral ultrasound guided SCPB with 8 ml of ropivacaine 0.5%, or to Group II (control group) to receive injection of normal saline. Rescue analgesics were used if VAS was ≥ 4. For the primary evaluation of first 24 h after surgery, the criteria included VAS score at rest, at neck movements, at swallowing and vocalization; and analgesic-related variables such as time to first rescue analgesia, *the number of patients requiring analgesics rescue*, the incidence of PONV and the rate of complications. To obtain the long-term outcome, the enrolled patients were monitored to observe the rate of chronic pain after three months of thyroidectomy based on the Douleur Neuropathique 4 questions (DN4) score.

Results: Within 24 h after surgery, the postoperative VAS score in the Group I was lower than in the control group. Moreover, the Group I patients could tolerate the pain longer than those of Group II, and required the first dose of analgesic later. They also required a lower dose of ketorolac and had reduced the incidence of postoperative nausea or vomiting (PONV). In addition, after 3 months, the frequency of chronic pain in the Group I was lower compared to the control group.

Conclusions: The results of our study confirm that bilateral superficial cervical plexus blocks under ultrasound guidance method as a part of multi-modal analgesia have a great potential in managing pain after thyroid surgery. The side effects and complications were observed to be statistically non-significant.

Abbreviations: NSAIDs - non-steroidal anti-inflammatory drugs; PONV - postoperative nausea or vomiting; SCPB - superficial cervical plexus block; VAS - Visual analogue scale;

Key words: Analgesic; Superficial cervical plexus block; Thyroidectomy; Regional anesthesia.

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1. INTRODUCTION

Thyroidectomy is one of the most common surgical interventions to treat many thyroid conditions. The quality of postoperative recovery is highly dependent on adequate pain management including postoperative wound pain as well as chronic pain.[1,2] Many studies have shown that pain after thyroidectomy is mild to moderate within first 24 h after the surgery.[3] Therefore, opioids and non-steroidal anti-inflammatory drugs (NSAIDs) are often administrated to relieve the postoperative pain. However, these drugs can increase the rate of postoperative nausea or vomiting (PONV) and even increase the risk of bleeding after surgery.[4,5] One of the current solutions to reduce pain after thyroid surgery as well as to significantly reduce unwanted effects when using systemic analgesics is ultrasound-guided bilateral superficial cervical plexus block (SCPB). SCPB should be performed under ultrasound guidance due to its superiority over anatomical landmark-based techniques such as the ability to directly observe nerves and anatomical structures. It reduces the volumes of local anesthetics used, and avoids complications from regional anesthesia such as injecting into a blood vessel or a nerve, or damage to the surrounding anatomical structures.[6] Most of the published works tried to apply this technique and evaluate the VAS score in early period of time showing its potential.[7,8] However, the long term evaluation of pain control has been missed.

In this prospective, randomized, controlled trial, we aimed to investigate the effectiveness of the bilateral SCPB under ultrasound guidance with general anesthesia on pain for 24 h and its long-time effect in reducing chronic pain after surgery in thyroidectomy patients.

2. METHODOLOGY

2.1. Design and patients

This randomized clinical trial is reported according to the statement of Consolidated Standards of Reporting Trials (CONSORT). The study was approved by the Ethics Committee of Hanoi Medical University and the patients gave written informed consent as required in the Declaration of Helsinki.

The study was conducted at the Departments of Anesthesiology, Resuscitation & Pain Management as well as Department of Oncology at Hanoi Medical University Hospital from March 2020 to March 2021. Sixty patients, undergoing bilateral thyroidectomy, over 18 y of age, ASA 1−2 were enrolled. Patients who had a mental or neurological disease, a contraindication to ropivacaine or the drugs used in the study, and who refused to cooperate in the research were excluded. Patients with preoperative hemodynamic and respiratory disorders, infection at the needle puncture site, and history of complications of surgery or anesthesia were excluded.

All patients included in the study were randomized by computer-generated tables into 2 groups; Group I to receive ultrasound-guided bilateral SCPB with 8 mL of ropivacaine 0.5% on each side, and Group II in which sham blocks were performed with 8 ml of normal saline on each side. All participants, medical care personnel, and data collectors were blind of the group assignment.

2.2. Anesthetic procedure

In the preparation room, intravenous access was secured and Ringerfundin® (B.Braun) 10 mL/kg intravenously (IV) was administered. The patients received oxygen supplementation 2-3 L/min through a nasal cannula and pulse, blood pressure, respiratory rate, and SpO_2 were monitored throughout the procedure.

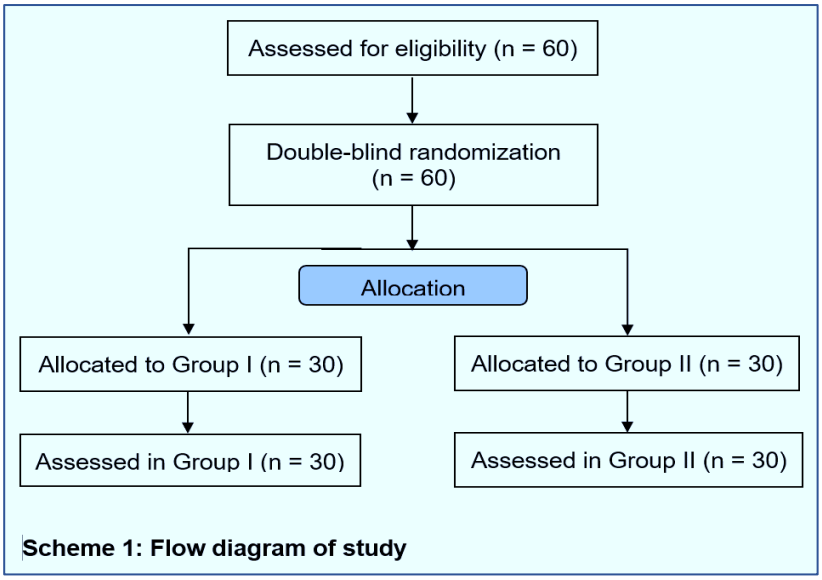
Ultrasound-guided bilateral SCPB was administered before the general anesthesia in a lateral decubitus position. A single experienced anesthesiologist performed all the SCPBs using a real-time ultrasound. The transducer was placed over the lateral side of the neck at the midpoint of the posterior border of the clavicular head of the sternocleidomastoid muscle (SCM). The transducer was positioned such that the tapering end (posterior border on the ultrasound image) of the SCM was in the center of the screen. The 22-G needle was then introduced from the posterior aspect through the skin and platysma; the needle tip was directed to lie in the space between the SCM and the prevertebral fascia, close to the posterior border of the SCM, and the block solution was deposited just behind this landmark. Same process was performed in the opposite side.

Patients received 4 mg of dexamethasone and 8 mg of ondansetron IV before surgery. Anesthesia was induced with fentanyl 2 µg/kg; propofol 2.5 mg/kg, and rocuronium bromide 0.6 mg/kg. Maintenance of anesthesia was done with 2% sevoflurane, fentanyl (repeat), 1 µg/kg before skin incision, and rocuronium bromide 0.2 mg/kg, if the surgery lasted for more than one hour. The end-tidal concentration of sevoflurane was adjusted so that the patient's heart rate and systolic blood pressure were maintained within 20% of baseline values. Thyroid surgery was performed according to the standardized procedure by the same surgeon.

After the block was completed, the patient was monitored for the pulse, blood pressure, respiratory rate, and SpO_2. Muscle relaxants were used, and the endotracheal tube was extubated when all criteria were met. The patient was monitored in the recovery room, and then transferred to the postoperative room for

follow-up until the next day. After that transferred to the oncology ward.

Postoperative pain management was standardized as follows: 1 g of paracetamol was infused at a rate of 100 drops/min at the end of the procedure, followed by 1 g every 8h for the next 24 h. If the VAS score ≥ 4 after 30 min, intravenous ketorolac 30 mg was administered as a rescue analgesic. If the VAS score continued ≥ 4 after 30 min, 2 mg morphine was injected until VAS was < 4; the maximum dose was restricted to 10 mg. The side effects were monitored, detected, and treated in the first 24 h after surgery.



Scheme 1: Flow diagram of study

2.3. Evaluation parameters

VAS scores were monitored at rest, at neck movements, at swallowing, and at vocalization after 24 h postoperative; time to first rescue analgesia, the number of patients requiring analgesics rescue; the incidence of PONV. Occurrence of complications from SCPB such as perforation of blood vessels, nerve damage, hematoma at the injection site, dyspnea, pain headache, hoarseness, and Horner's syndrome were noted.

After 3 months, the patients participating in the study were contacted by phone to survey the chronic pain situation through the Douleur Neuropathique 4 questionnaire (DN4) score.

2.4. Statistical analysis

Data were processed using SPSS software (version 20.0). The results are shown as mean and standard deviation. Comparison of two values in the same group was calculated by t-test and comparison between two different groups was conducted by ANOVA test. Statistical significance was set at the P < 0.05 level.

3. RESULTS

Table 1: Demographic parameters of patients

Parameters	Group I (n = 30)	Group II (n = 30)	P value
Age (y)	46.7 ± 12	47.3 ± 13.4	> 0.05
Gender			
Male	6 (20)	5 (16.7)	> 0.05
Female	24 (80)	25 (83.3)	
Data presented as Mean ± SD or n (%)			

The study was conducted as a double-blind randomized control trial by computer-generated tables (Scheme 1). Due to time constraints and dropouts, the sample size was taken as 30 patients per group.

The comparative demographic data of the patients in both groups is given in Table 1. The comparative data regarding type of surgery, the duration of anesthesia and surgery and the drugs used is given Table 2.

The amount of fentanyl and propofol in Group I was less than in Group II, the difference was statistically significant (p < 0.05). The amount of rocuronium used in

Table 2: Comparative data of anesthesia, surgery and drugs used

Parameters	Group I (n = 30)	Group II (n = 30)	P value
Anesthesia time (min)	74.8 ± 9.3	79.2 ± 10.7	> 0.05
Type of surgery			
• Thyroid cancer	21	23	> 0.05
• Multinodular goiter	8	5	
• Grave's disease	1	5	
Surgery time (min)	63.7 ± 9.2	66.0 ± 10.2	> 0.05
Used medicine			
• Fentanyl (mg)	111.7 ± 25.2	173.3 ± 34.1	< 0.05
• Propofol (mg)	91.2 ± 12.4	106.3 ± 15.2	< 0.05
• Rocuronium bromide (mg)	35.2 ± 3.7	36.5 ± 3.4	> 0.05
Data presented as Mean ± SD or n (%)			

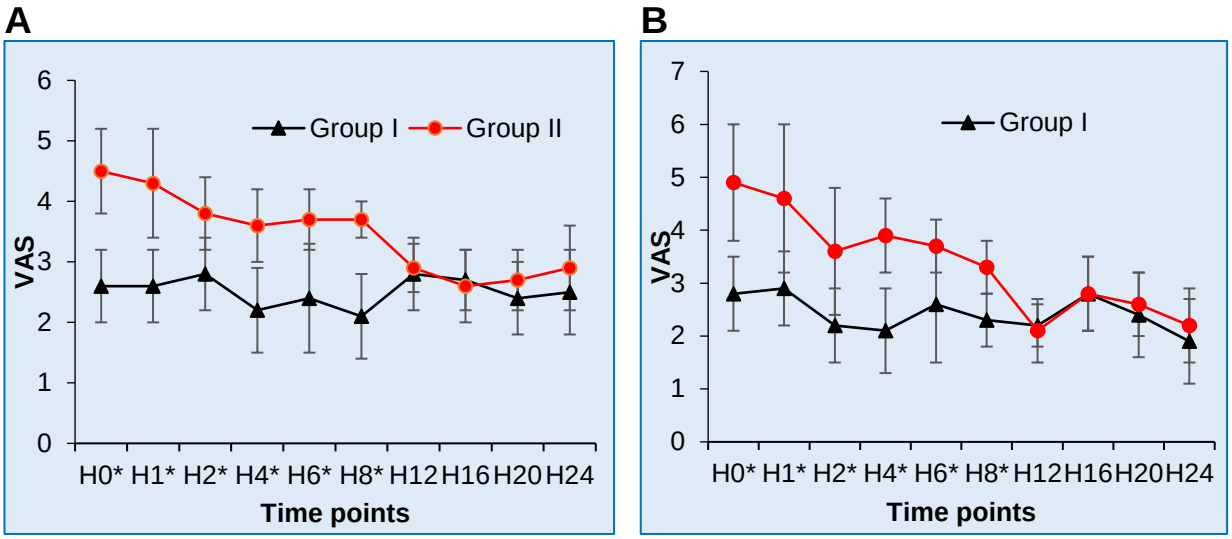


Figure 1: VAS score at rest (A) and at neck movements (B) after surgery. Hx demonstrates for the time point of x h after surgery. x = 0, 1, 2…, 24

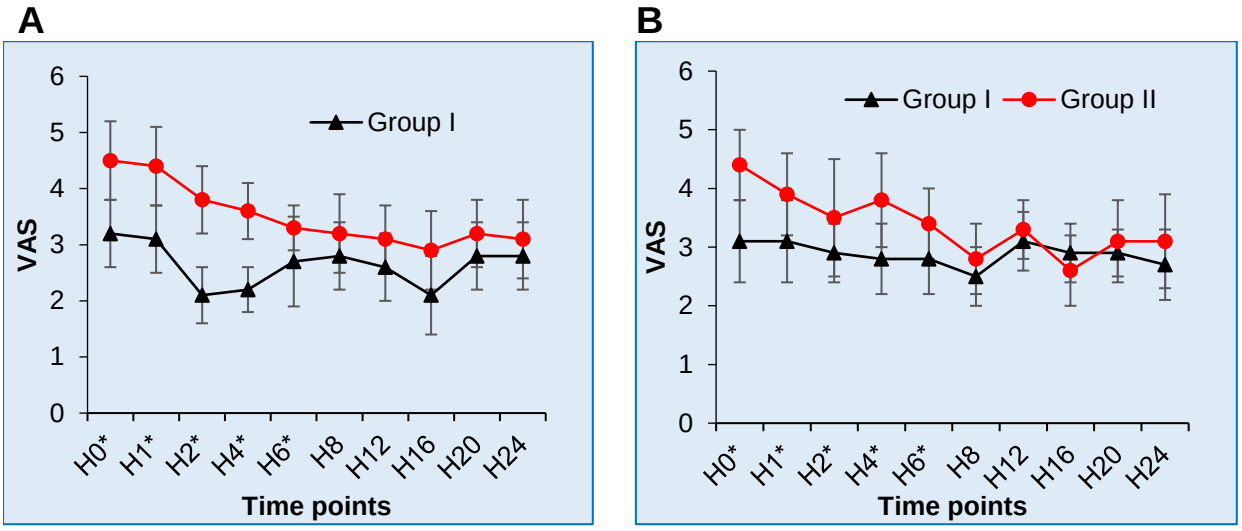


Figure 2: VAS score at swallowing (A) and at vocalization (B) after surgery. Hx demonstrates for the time point of x h after surgery. x = 0, 1, 2…, 24

Group I was less than in Group II, but the difference was not statistically significant (P > 0.05) (Table 2).

VAS score at rest was evaluated (Figure 1A). There was a statistically significant difference at some time points of the study. The highest VAS score was recorded right after 10 min of intubation, when the patient was fully cooperative. As shown in Figure 2, the VAS scores at swallowing and vocalization tend to decrease in the first 24 h after surgery. At time H0, the VAS score at swallowing of Group I was 3.2 ± 0.6, while Group II had a VAS score of 4.5 ± 0.7 (Figure 2A). There is a statistically significant difference at all time points within first 6h after surgery between the two groups with p < 0.05. Similarly, at vocalization, the VAS score between the 2 groups also had a statistically significant difference at the time points H0, H1, H2, H4, H6 (p < 0.05). The time required for the first analgesic dose was more in Group I, than in Group II (P < 0.01). The number of patients requiring ketorolac rescue in Group I was much lower than Group II, (P < 0.01). No patient required morphine. The rates of PONV of the study were 6.67%, 26.67% in Groups I and II respectively (P < 0.01). No SCPB-related complications such as a vascular puncture. Only one patient (3.3%) experienced

Table 3: Outcomes during the period of study

Variables	Group I (n = 30)	Group II (n = 30)	P value
Starting time for painkiller (h)	7.52 ± 1.59	3.23 ± 1.19	< 0.01
Number of patients requiring ketorolac rescue analgesic	7 (23.3)	21 (70)	< 0.01
Frequency of PONV	2 (6.67)	8 (26.67)	< 0.01
Complications from SCPB	1 (3.33)	0 (0)	> 0.05

Data presented as Mean ± SD and n (%)

hoarseness after 10 min of regional anesthesia in Group II. Then, the voice returned to normal after surgery without any treatment (Table 3).

After 3 months, out of 60 patients participating in the study, we contacted 55 patients to assess their chronic pain status according to DN4 score. The proportion of

patients with the DN4 score ≥ 4 in Group I was 3 (10.7) patients. In Group II, there were 9 (33.3%) patients. The difference was statistically significant (P < 0.01) (Table 4).

Table 4: Evaluation of chronic pain by the DN4 score after surgery 3 months

DN4	Group I (n = 28)	Group II (n = 27)	p value
DN4 ≥ 4	3 (10.7)	9 (33.3)	< 0.01
DN4 < 4	25 (89.3)	18 (66.7)	

5. DISCUSSION

In this study, we used the VAS scale, which is the most commonly used clinical scale to assess the pain. The study assessed VAS in 4 different states: at rest, at neck movement, at swallowing, and at vocalization. VAS scores were compared between the two groups of patients within 24 h after surgery. The pain level of patients after extubation (H0) as well as in the first 24 h after surgery was mild to moderate pain that is mostly common.[9,10]

Regarding the evaluation at rest, the highest VAS score was recorded right after 10 min of extubation, when the patient was fully cooperative and awake. The average VAS score was 4.5 ± 0.7 in Group II, and 2.6 ± 0.6 in Group I. The difference was statistically significant (P < 0.01), similar at the time points H1, H2, H4, H6, and H8 (Figure 1A). A similar trend was also noted in VAS scores during the other three phases of observation (swallowing, neck movements, and vocalization) (Figure 1B, and 2).

We used additional postoperative rescue analgesia when evaluating the VAS score ≥ 4 in different research states (Table 2). In our study, starting time for painkiller and the number of patients requiring rescue were quite different from other studies.[11,12]

This implies that the patients receiving SPCB with ropivacaine 0.5% have superior quality of analgesia than those receiving only the parenteral and oral analgesic. Furthermore, pre-operative ultrasound-guided bilateral SCPB reduced the number of patients requiring rescue analgesia, and the incidence of PONV. We only recorded a single case of hoarseness after regional anesthesia for about 10 min, without other symptoms like breathlessness or drop in oxygen saturation (Table 2). This may be explained by the spread and deposition of the local anesthetic that blocked the recurrent laryngeal nerve of the side. There was no particular change in vital signs after surgery, the patient's voice assessment returned to normal after 2 h of surgery. No other adverse effects or other complications were noted. Bilateral SCPB under ultrasound guidance complication has a very low rate of complications due to distinct landmarks.[6,13]

We studied the rate of chronic postoperative pain at 3 months in thyroidectomy patients by surveying patients by phone. There were 55/60 patients who agreed to participate and answered questions on the DN4 score (Table 4). The DN4 questionnaire “interview” can identify 79.5% of the subjects susceptible to reporting neuropathic pain, with a specificity and sensitivity approaching 80%.[14] Therefore, this methodology might be a convenient and reliable tool for the evaluation of neuropathic pain. Chronic postoperative pain is related to tissue scarring processes, neural damage, and cognitive processes. In this study, there were 12/55 patients with DN4 ≥ 4, including 3/28 (10.7%) patients in Group I, and 9/27 (33.3%) in Group II. Thus, the proportion of patients with chronic postoperative pain in Group II, was about 3 folds higher than in Group I patients that received the bilateral SCPB.

6. LIMITATIONS

The study revealed a potential result but several aspects might limit the bold conclusion including the small number of enrolled patients, and heterogeneous types of surgery. Despite of that, the study collected the outcome long time after the surgery which is the valuable

information indicating the potential of bilateral SCPB under ultrasound guidance in the pain management after thyroidectomy.

7. CONCLUSION

We conclude that ultrasound guided bilateral superficial cervical plexus block in patients undergoing thyroidectomy under general anesthesia reduces pain up to 24 h postoperatively when compared with the control group. It also results in less requirement of analgesic and reduced incidence of PONV. Furthermore, the frequency of development of chronic pain after 3 months was significantly reduced in the superficial cervical plexus block group compared with the control group.

8. Data availability

The numerical data generated during this research is available with the authors.

9. Acknowledgement

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10. Conflict of interest

The authors report no conflicts of interests.

11. Authors' contribution

1. MQP: Concept, Investigation, Methodology, Project administration, Supervision, Writing original draft, Review & editing

2. AXN: Investigation, Methodology, Data analysis

3. TTPT: Data analysis, Writing – original draft, Writing – review & editing

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