

Use of the On-Q system for pain management after robot - assisted endoscopic transaxillary thyroidectomy

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Use of the On-Q system for pain management after robot - assisted endoscopic transaxillary thyroidectomy

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Special thanks to my parents who devoted for me.

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And thank you for loving my wife and children.

<TABLE OF CONTENTS>

ABSTRACT	7
I. INTRODUCTION	8
II. MATERIALS AND METHODS	9
III. RESULTS	12
IV. DISCUSSION	15
V. CONCLUSION	17
REFERENCES	18
ABSTRACT(IN KOREAN)	19
PUBLICATION LIST	20

LIST OF FIGURES

Figure 1. Study Plan	9
Figure 2. Surgical position and approach route to thyroid ...	10
Figure 3. Placement of Soaker™ catheter	11
Figure 4. Localization of postoperative pain in control & group I	14

LIST OF TABLES

Table 1. Demographic data	12
Table 2. Postoperative VAS pain scores.....	13
Table 3. Rescue analgesic requirements.....	13
Table 4. Clinical characteristics of the patients & side effects	14

ABSTRACT

Use of the On-Q system for pain management after robot - assisted endoscopic transaxillary thyroidectomy

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Purpose: The robot-assisted transaxillary approach to thyroid surgery is a novel method that has recently been used in hopes of improving patient safety and cosmetic outcomes. We evaluated post-operative pain after robot-assisted endoscopic transaxillary thyroid surgery and pain relief using a continuous wound perfusion system with local anesthetics.

Materials and Methods: In a control group of 25 female patients who underwent robot-assisted endoscopic transaxillary thyroidectomy, post-operative pain scores and characteristics as well as analgesic use were monitored. 50 female patients undergoing robot-assisted endoscopic transaxillary thyroidectomy were given an On-Q system, and were randomly assigned to receive one of two different local anesthetic doses: group I (0.25% Ropivacaine, n=25), group II (0.375% Ropivacaine, n=25). Pain score, pain site, analgesic requirements and side effects in each group were recorded during 48h after surgery.

Results: Post-operative pain scores and analgesic demand were lower in the On-Q groups than in the control group. No difference was found between group I and group II. Until 6-12h after surgery, pain was mainly located in the axilla, while after 6-12h the primary location of pain had a tendency to move to the neck. Pain scores gradually decreased with time in all patients.

Conclusions: Patients who underwent robot-assisted endoscopic transaxillary thyroidectomy with an On-Q system injecting 0.25% ropivacaine had a low pain score, showing the effectiveness of the system. As a potential pain blocker, continuous wound perfusion with the On-Q system attenuates side effects. This could lead to shortened hospital stays after robot-assisted endoscopic transaxillary thyroidectomy.

Key words : Robotics, Thyroidectomy, Local anesthetics, Subcutaneous infusion, Pain relief

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I. INTRODUCTION

Recently, The da Vinci System (Intuitive Surgical, Mountain View, CA) has been used to access the thyroid for surgery with a gasless transaxillary approach¹⁻⁵. The benefits conferred by the endo-wrist of the instruments facilitate superior visualization and thyroid operation through an anterior subcutaneous chest tunnel. Though no studies have addressed long-term results, early surgical outcomes have been satisfactory compared to open thyroid surgery^{1, 6-8}. Postoperative pain following robot-assisted endoscopic transaxillary thyroidectomy remains one of the main obstacles to comfort, safety and early recovery. We believe that effective pain treatment should be given to address the different pain characteristics of endoscopic thyroid operation as compared to open thyroid operation.

The On-Q system is a device that delivers a continuous infusion of local anesthetics directly into a wound for pain management. Owing to multiple side holes along the catheter, it relieves surgical wound pain over a wide area.

In this study, we continuously injected 0.25% or 0.375 % ropivacaine for 2 days after surgery using the On-Q system. This On-Q system trial was conducted to determine if local anesthetic infiltration into a wide surgical wound could relieve postoperative pain, decrease systemic analgesic demands, attenuate side effects and hasten patient progress.

II. MATERIALS AND METHODS

After obtaining approval from the institutional ethics committee and written informed consent from patients, a total of 75 female patients, American Society of Anesthesiologists (ASA) physical status I or II, 21-60 years of age who were scheduled for elective gasless robot-assisted endoscopic transaxillary total thyroidectomy were enrolled in this study. Patients with a thyroid tumor larger than 5 cm by pre-operative thyroid sonogram and with definite evidence of extra-capsular metastasis were excluded from this study (Fig. 1).

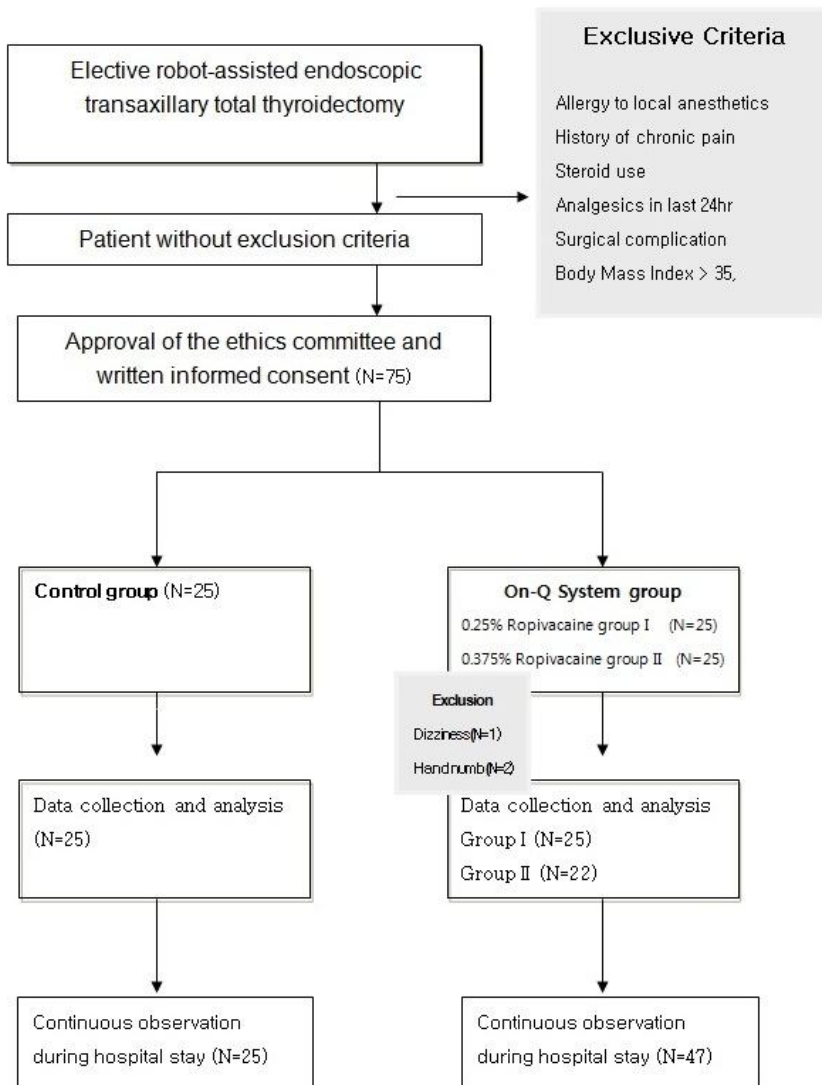


Figure 1. Study plan

To assess pain characteristics, the primary site of discomfort and the severity of pain after robot-assisted endoscopic transaxillary thyroidectomy, we observed 25 patients not given the On-Q pain system as a control group. Then, 50 patients were randomly assigned to two groups receiving analgesic through the On-Q system (On-Q[®] Pain Buster[®] Post-Op Pain Relief System, I-Flow Corp, Lake Forest, CA). Group I received 0.25% ropivacaine, and group II received 0.375% ropivacaine). The On-Q system uses an elastomeric system providing a constant infusion of ropivacaine at 2 mL/hour for 2 days through a thin soaker[™] catheter. The catheter is 1mm in diameter and has multiple side holes extending approximately 12.5 cm from the tip. Standard general anesthesia was performed with propofol, remifentanyl, rocuronium and sevoflurane. After the main surgical procedure, the catheter was passed percutaneously using a peel away introduction sheath and driven into the deep subcutaneous tissue in a line with parallel and running under the axillary skin incision starting 5 cm inferior to the incision. The tip of the catheter was placed and directed to the neck by vascular clamp before skin closure (Fig. 2, 3). Before starting the continuous infusion of local anesthetics, a 5mL bolus infusion was given with 0.25% or 0.375% ropivacaine via the catheter line. The catheter was removed easily 2 days after surgery when the surgical drain was removed.

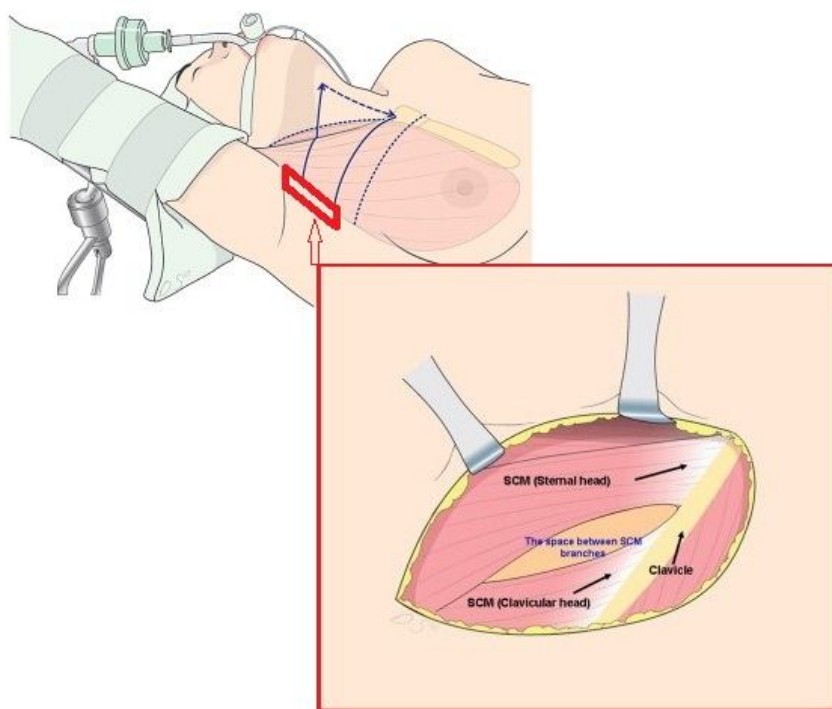


Figure 2. Surgical position and approach route to thyroid⁷

The study conducted on groups I and II was double blind. A visual analog score (VAS, 0 -> 10) for postoperative pain and primary pain location were assessed in the recovery room and at 6h, 12h, 24h and 36-48h in the general ward. Postoperative side effects including sedation, nausea, vomiting, dizziness, hand or arm sensory changes and motor block were recorded and treated. If side effects worsened during use of the On-Q system, the infusion of ropivacaine was stopped. When patients requested additional rescue analgesics, they were prescribed fentanyl (0.1 µg/kg) if they were in the recovery room, 50mg intravenous Tramadol HCl from discharge of the recovery room until 12h post-op, and 200mg oral Ibuprofen tablets if they were between 12 and 48h post-op.

The number of patients in the study was predetermined using a power analysis based on the assumptions that the chance of requiring an analgesic in patients undergoing robot-assisted endoscopic transaxillary thyroidectomy would be more than 35%, that a reduction of pain scores by the On-Q system from 30% to 10% is clinically important, and that $\alpha = 0.05$ with a power ($1 - \beta$) of 0.8. This analysis led us to conclude that 20 patients per group would be sufficient.

All data are mean \pm standard deviation and medians. Statistical analysis was performed using the program SPSS (version 11.5, SPSS INC, USA). The chi-square or Mann-Whitney *U* test and unpaired t-test were applied. A *P* value < 0.05 was considered statistically significant.

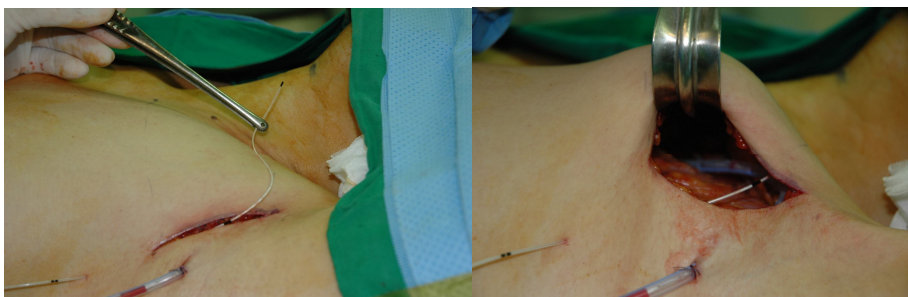


Figure 3. Placement of Soaker™ catheter

III. RESULTS

There were no significant differences with respect to age, body mass index and operation & anesthesia time between the 3 groups (Table 1). Postoperative pain scores in the recovery room and at 6h and 12h in group I and II were lower than in the control group (Table 2). Postoperatively, significantly fewer patients in groups I and II received rescue analgesic medication compared to the control group, but there were no significant differences in rescue analgesic use between groups I and II (Table 3).

Table 1. Demographic data

	Control (n=25)	Group I (n=25)	Group II (n=25)
Age (year), all female	42.7 ± 8.7	43.6 ± 8.0	41.8 ± 9.8
BMI (kg / m ²)	18.8 ± 7.8	19.2 ± 9.2	18.2 ± 6.2
Operation time (min)	150.1 ± 36.0	141.6 ± 47.6	147.6 ± 40.9
Anesthesia time (min)	192.4 ± 23.4	185.9 ± 33.7	198.8 ± 45.6

All values are expressed as mean ± standard deviation. Group I: On-Q system applied with 0.25% ropivacaine. Group II: On-Q system applied with 0.375% ropivacaine. There were no significant differences between 3 groups.

Also, there were no significant differences in side effects such as sedation, nausea and vomiting between the 3 groups. In Group II, 1 patient with dizziness and 2 patients with hand numbness were excluded from further study and their On-Q pump infusions were stopped. Significantly, patients' hospital day in Group I was shorter compared to the control group (Table 4). No wound infections occurred as a result of the catheters.

At 6h post-surgery, the axilla was the primary site of pain in most patients because the skin incision was made along the axillary crease. Over time, the primary site of pain moved to the neck and the pain score decreased. This trend was more evident in the control group than in the On-Q group (Fig. 4).

Table 2 Postoperative VAS pain scores

	Control (n=25)	Group I (n=25)	Group II (n=22)
Recovery room			
Admission	6.1 ± 2.1	4.4 ± 3.5*	4.5 ± 2.5*
Discharge	3.6 ± 1.5	3.4 ± 2.1	3.3 ± 2.3
General Ward			
6 hours	3.3 ± 1.2	2.1 ± 1.8*	2.4 ± 2.4
12 hours	3.6 ± 2.8	2.3 ± 1.1*	2.8 ± 2.2*
24 hours	2.8 ± 1.8	2.3 ± 1.4	2.5 ± 1.9
36-48 hours	2.1 ± 1.4	1.8 ± 0.8	1.4 ± 1.2

10 points VAS pain scores (0: no pain, 10: intractable pain) were used, expressed as mean ± standard deviation. There were no significant differences between 3 groups except * marked. *: P value < 0.05 comparing to control.

Table 3. Rescue analgesic requirements

	Control (n=25)	Group I (n=25)	Group II (n=22)
Recovery room			
Patients requesting rescue fentanyl intravenous (%)	11(44.0%)	3(12.0%)*	4(18.2%)*
6-12 hours			
Patients requesting Tramadol HCl intravenous (%)	10(40.0%)	3(12.0%)*	4(18.2%)
12-48 hours			
Patients requesting oral Ibuprofen tablet(%)	16(64.0%)	4(16.0%)*	5(22.7%)*

There were no significant differences between group I and group II except * marked. *: P value < 0.05 comparing to control.

Table 4. Clinical characteristics of the patients & side effects

	Control (n=25)	Group I (n=25)	Group II (n=25)
Recovery room			
Sedation	10	5*	6*
Nausea / vomiting	9 / 1	4* / 0	5* / 0
Recovery room stay (min)	31.8 ± 23.9	21.2 ± 32.2	18.0 ± 21.7*
General ward			
Sedation	2 / 0	1 / 0	1 / 0
Nausea / vomiting	1 / 0	1 / 0	0 / 0
Dizziness	0	0	1
Hand or arm numbness	0	0	2
Hospital day (day)	3.8 ± 1.2	3.0 ± 0.8*	3.2 ± 1.4

All data represent number of patient or mean ± standard deviation. There were no significant differences between 3 groups except * marked. *: P value < 0.05 comparing to control.

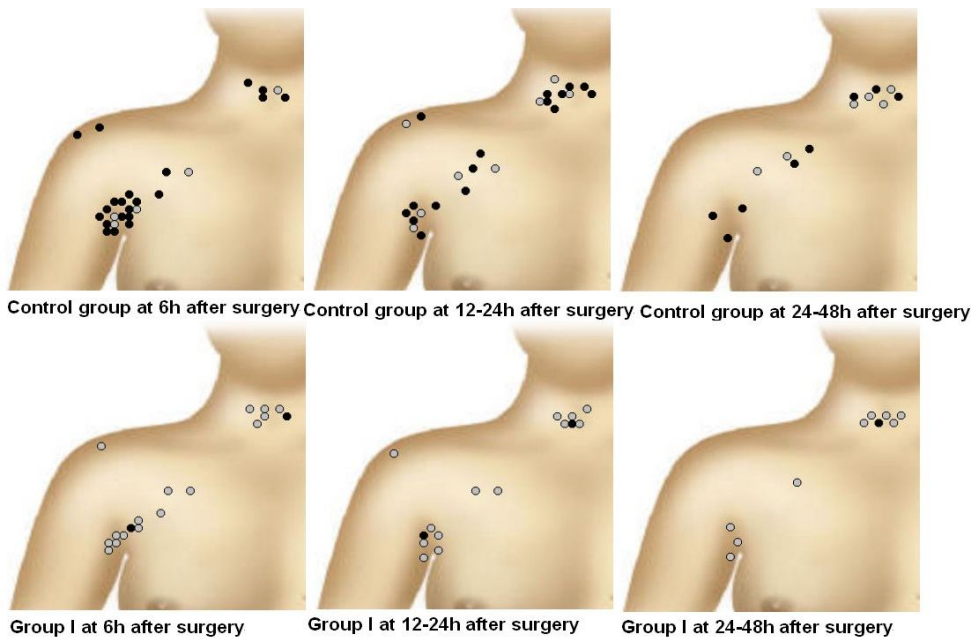


Figure 4. Localization of postoperative pain in control & group I

Circles are expressed as most discomfort area per patient. Black closed circle: visual analogue score > 4, Gray closed circle: visual analogue pain score ≤ 4

IV. DISCUSSION

In this study we observed specific advantages of robot-assisted endoscopic transaxillary thyroidectomy and assessed the feasibility of application of the On-Q system for this novel method of thyroid surgery. As demonstrated in previous reports comparing it to open thyroid surgery¹⁻⁸, robot-assisted endoscopic transaxillary thyroidectomy was associated with faster recovery, better patient safety and increased patient satisfaction with cosmetic results⁵.

The da Vinci robot-assisted endoscopic system allows for the safe use of a gasless transaxillary approach for thyroid operation. To access the thyroid, a 5-7 cm vertical skin incision along the axillary crease is made for access to the triangular tunnel. The borders of the tunnel are the clavicle, the anterior surface of the pectoralis major muscle, and the avascular interspace between the two branches of the sternocleidomastoid. It is essential for the operation that there is free movement of the robotic instruments (Fig. 2). To maintain the 3-dimensional structure of the access tunnel without gas, a surgical retractor is used during the majority of the operation. This retractor is the reason for postoperative anterior chest pain, and postoperative shoulder pain with hyper-raised arm position.

These results in the postoperative anterior chest pain we observed, as the lesion-side arm is fixed in a raised position to prevent postoperative shoulder pain.

Contrary to our expectations, this study shows that the area of pain is diffuse, wide and moves with time. Until 6h after surgery, the primary site of pain is the axilla, but over time it moved to the shoulder, anterior chest and finally the neck. The axillary pain was severe, sharp, aggravated by arm movement and easily relieved by pain medication. The neck pain was not as severe, dull, worsened by coughing and hardly blunted by any medication.

Although soakerTM catheters are long with multiple side holes, the On-Q system was more effective in blocking axillary pain than neck pain. This observation could be explained by the fact that the catheter is not enough for full coverage of the pain area because the average distance from skin incision to neck was more than 15 cm. Ropivacaine leakage was also possible via the surgical drain directly connected to the neck. However, we are certain that the catheter's placement was proper in this study, because the axillary pain was more severe than the neck pain in all patients.

The nature of post-operative pain is expected to be different with the robotic axillary approach than with conventional thyroid surgery. The On-Q system with a long soakerTM catheter was used to deliver local anesthetics^{9,10} diffusely over a large wound area. In this study, 0.375% ropivacaine in group II was expected to supply better pain relief than the 0.25% ropivacaine used in group I. However, we observed no significant difference between the 2 groups. Moreover, some side effects of high dose local anesthetics were found in group II including 1 patient with dizziness and 2 patients with numbness of the hand.

This indicates that 0.25% ropivacaine is a safe and effective concentration of anesthetic for use in this context. Although an infusion of 0.375% ropivacaine at 2 ml per hour is a safe dosage according to the drug manufacturer's recommendations (ropivacaine maximum 24 hour dose: 770 mg)¹¹⁻¹³, 3 patients experienced side effects. We hypothesize that this apparently increased absorption of drug was due to the vessel-rich anatomy of the axilla and possible bleeding of micro vessels from surgical trauma.

Expectedly, the requirement for rescue analgesics in the control group was higher than in Group I. As to unexpected results in Group II, we suspected that ropivacaine was leaked to surgical drain. Opioid sparing may provide clinical benefits in patients including reduced incidence of confusion, respiratory depression, delayed voiding, nausea and vomiting. Our results indicate that the On-Q system can not only provide analgesia superior to moderate doses of systemic pain medication and allow lower narcotic usage, but also hasten recovery in the recovery room without sedation, nausea or vomiting. The longer recovery times of patients in the control group were due to pain itself and narcotic side effects.

In Group I, our results suggest that lowered pain levels and reduction in side effects seen with the On-Q system may lead to shorter hospital stays. As previously reported, robot-assisted endoscopic transaxillary thyroidectomy patients have shorter hospital stays compared to patients undergoing open thyroid surgery.

V. CONCLUSION

We concluded that use of the On-Q system with 0.25% ropivacaine in robot-assisted endoscopic transaxillary thyroidectomy is safe, effective, spares analgesics and ultimately leads to shorter hospital stays.

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ABSTRACT(IN KOREAN)

경액와 로봇 갑상선 절제술 후 통증 조절을 위한 국소마취제
지속 주입 시스템의 사용

<지도교수 민 경 태>

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박 우 영

목적: 경액와 로봇 갑상선 절제술은 환자의 안전과 미용을 개선할 것으로 기대되는 방법이다. 우리는 경액와 로봇 갑상선 절제술 후 국소마취제를 외과적 창상부위에 지속 주입한 후 통증 감소를 평가하였다.

재료 및 방법: 경액와 로봇 갑상선 절제술을 받은 25명의 여성 환자를 대조군으로 하여 수술 후 통증 점수와 진통제의 사용을 조사하였다. 경액와 로봇 갑상선 절제술을 받은 50명의 여성에게 On-Q 시스템을 사용하였고 무작위로 할당하여 실험군 1군(0.25% Ropivacaine, n=25)과 2군(0.375% Ropivacaine, n=25)에 배정하였다. 통증 점수, 통증 부위, 진통제의 요구 빈도, 부작용을 수술 후 48시간 까지 기록하였다.

결과: 수술 후 통증 점수와 진통제 요구 빈도는 대조군에 비해 On-Q 시스템을 사용한 실험군에서 낮았으며 실험군 1군과 2군 사이에는 차이가 없었다. 수술 후 6-12시간까지는 통증이 주로 액와부에서 나타났고 6-12시간 이후에는 목 부위로 이동하는 경향이 나타났다. 통증 점수는 모든 환자에서 시간이 지남에 따라 점차 감소하였다.

고찰 및 결론: 경액와 로봇 갑상선 절제술을 받은 환자에서 On-Q 시스템을 이용하여 0.25% ropivacaine을 주입하였을 때 낮은 통증 점수를 나타내었고 이는 On-Q 시스템이 효과가 있음을 보여 주었다. On-Q system을 이용해 지속적으로 외과적 창상부위에 국소마취제를 주입하는 것은 강력한 통증 차단 효과를 가질 뿐만 아니라 부작용을 적게 하였다. 이로 인해 경액와 로봇 갑상선 절제술 이후 재원기간을 짧게 하였다.

핵심되는 말 : 로봇, 갑상선 절제술, 국소마취제, 피하주입, 통증 완화

PUBLICATION LIST

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