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흡입마취 또는 전정맥마취 하 갑상선 절제술 후 통증 및 합병증에 대한 전향적 무작위 비교 연구

A prospective randomized comparison of postoperative pain and complications after thyroidectomy under different anesthetic techniques: volatile anesthesia versus total intravenous anesthesia

울 산 대 학 교 대 학 원

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흡입마취 또는 전정맥마취 하 갑상선 절제술 후 통증 및 합병증에 대한 전향적 무작위 비교 연구

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ABSTRACT

Background

Continuous remifentanil infusion during general anesthesia effectively and easily maintains vitals. However, high pain levels and increased demand for postoperative analgesics in the early postoperative period are often encountered. This study investigated pain intensity and the need for rescue analgesics in the immediate postoperative period in patients after total intravenous anesthesia with remifentanil compared with intravenous induction and volatile maintenance anesthesia.

Methods

Seventy-two patients undergoing total thyroidectomy under general anesthesia were examined. Patients were randomly assigned to either total intravenous anesthesia with remifentanil and propofol (TIVA, n=35) or propofol induction and maintenance with desflurane and nitrous oxide (VA, n=37). Pain scores based on a numeric rating scale (NRS) and the need for rescue analgesics were compared between groups at the postoperative anesthetic care unit (PACU).

Results

The immediate postoperative NRS values of the TIVA and VA groups were 5.7±1.7 and 4.7±2.3, respectively (P=0.034). Postoperative morphine equianalgesic doses in the PACU were higher in the TIVA group than in the VA group (16.7±3.8 mg vs. 14.1±5.9 mg, P=0.027). The incidence of immediate postanesthetic complications did not differ significantly between groups.

Conclusions

In conclusion, more rescue analgesics were required in the TIVA group than in the VA group to adequately manage postoperative pain while staying in the PACU after thyroidectomy.

Key words: general anesthesia, postoperative pain, rescue analgesics, thyroidectomy, anesthetic methods, intravenous anesthetics, volatile anesthetics

TABLE OF CONTENTS

ABSTRACT ····· i

LIST OF FIGURES·····

LIST OF TABLES····· v

INTRODUCTION ····· 1

MATERIALS AND METHODS ····· 2

RESULTS ····· 6

DISCUSSION ····· 23

REFERENCES····· 27

ABSTRACT IN KOREAN····· 29

LIST OF FIGURES

Figure 1 ····· 7

Figure 2 ····· 11

Figure 3 ····· 14

Figure 4 ····· 18

Figure 5 ····· 20

LIST OF TABLES

Table 1 ····· 9

Table 2 ····· 12

Table 3 ····· 16

Table 4 ····· 22

INTRODUCTION

Remifentanil is a synthetic opioid that is widely used as an analgesic during anesthesia and is a direct antagonist of the μ-opioid receptor.[1] The onset of remifentanil action is very rapid, and its terminal elimination time is only 10-20 min.[1] Because the context-sensitive half time is only 3-5 min,[1-3] remifentanil can be infused continuously during general anesthesia or sedation. Because its properties are known to be almost unaffected by a patient's hepatic or renal function,[1-5] many practitioners use remifentanil, especially in patients undergoing high-risk surgeries. Despite its properties of rapid onset and recovery, which are appropriate for simple day surgeries, questions have been raised over the years on whether patients undergoing general anesthesia with remifentanil infusion experience a greater degree of pain and whether they require more analgesics in the early postoperative period, as well as their incidence of complications.[6-8]

Previously, we retrospectively conducted propensity score matching analysis with 7,511 thyroidectomy patients and showed that continuous remifentanil infusion during general anesthesia can cause a higher intensity of immediate postoperative pain than general anesthesia without remifentanil infusion.[9] Although this was a large-scale study, it was retrospective, and there were limitations due to several uncontrolled conditions.

Therefore, in this current randomized controlled study, we mainly aimed to investigate whether intraoperative continuous infusion of remifentanil during thyroidectomy leads to a high intensity of immediate postoperative pain and more demand for rescue analgesics. Furthermore, other postanesthetic complications were also evaluated as secondary outcomes.

MATERIALS AND METHODS

Ethical approval and study population

We obtained approval from the Institutional Review Board of Asan Medical Centre, Seoul, Korea (2016-0463) and registered at cris.nih.go.kr (KCT0005047). We got written informed consent from all participants. We included 80 patients from 20–79 years of age of either sex with American Society of Anesthesiologists physical status I-III and who were undergoing elective thyroid surgery by the same surgeon. The exclusion criteria were as follows: allergy or contraindication to opioids or non-steroidal anti-inflammatory agents (NSAIDs); severe renal dysfunction with limited use of NSAIDs; bronchial asthma; psychiatric disease; intake of opioids within 1 month before surgery or any analgesics 6 hours before surgery; reoperation on thyroid; or simultaneous radical neck lymph node dissection or other surgeries.

Study design and blindness

This study was a prospective, assessor-blinded, randomized controlled study. Because of significant differences between the two anesthetic techniques, the attending anesthesiologist could not be blinded to group identity. However, the patient and the outcome assessors were blinded to group identity.

Subjects were randomly assigned in a 1:1 ratio to two groups using an online randomization program (www.randomization.com). Randomization was done the day before surgery and each patient was randomly assigned to the TIVA (total intravenous anesthesia) or VA (volatile anesthesia) group. Standard monitoring including non-invasive blood pressure, heart rate, electrocardiogram, and a bispectral index (BIS) monitor (BIS-Vista™ monitors; Aspect Medical Systems, Newton, MA). Blood pressure was measured from the calf to prevent errors in

measurement because the cuff was pressed by the surgeons' bodies during surgery.

Regardless of the assigned group, all patients were induced with general anesthesia with 1.5 ~ 2.5 mg/kg propofol and 0.6 mg/kg rocuronium. Patients assigned to the TIVA group were maintained on anesthesia with an effect-site target-controlled infusion (TCI) of propofol and remifentanil using a commercial TCI pump (Orchestra® Base Primea; Fresenius Vial, Brezins, France). The effect-site concentration of propofol was controlled between 2.0 and 2.5 mcg/mL to maintain a BIS of 40 to 60 and that of remifentanil was titrated to maintain the patient's baseline blood pressure within 20%. In the VA group, general anesthesia was maintained with desflurane and 50% nitrous oxide (N2O) in oxygen and the concentration of desflurane was controlled to maintain the patient's baseline blood pressure within 20%, which was approximately 1 minimum alveolar concentration of desflurane. At the end of surgery, the anesthetic agents were immediately discontinued. After enough oral suctioning, the inhaled oxygen fraction and the fresh gas flow rate were increased to 100% and 8 L, respectively, in order to facilitate emergence. Neuromuscular blocking was reversed with 0.4 mg glycopyrrolate and 15 mg pyridostigmine and confirmed by a train-of-four monitor. Endotracheal tubes were removed when patients regained consciousness with spontaneous respiration. Patients were then transferred to the postanesthetic care unit (PACU) and scored for pain.

Pain management at the PACU was performed in the same manner in both groups. If the pain score was over 5, the anesthesiologists ordered intravenous rescue analgesics. The first rescue analgesic was an NSAID, which was 0.5 mg/kg ketorolac with a maximal dose of 30 mg. After 15 min, the pain score was re-evaluated, and the second rescue analgesic medication administered was fentanyl (1 mcg/kg, maximal dose 50 mcg) if the pain score was still over 5. At 30 min after entering the PACU, the pain score was evaluated again, and when exceeding 5, the previously administered opioid was re-administered in the same amount.

Outcome assessment

The primary outcome was the pain intensity assessed at the PACU at pre-defined timepoints: upon arrival to PACU, 30 min after surgery, and 60 min after surgery. This was assessed by experienced nurses who were blinded and independent of the study based on numeric rating scales (NRS) at the PACU. The NRS scale was an 11-point numerical rating scale (0 = no pain, 10 = unbearable pain). Simultaneously, the amount of rescue analgesics administered to manage postoperative pain was recorded. Morphine equianalgesic doses (MED) were used to quantitatively compare the effects of the sum of various rescue analgesics (fentanyl or ketorolac) administered to each group. The conversion to morphine-equivalent consumption in mg was based on the following scale: 1:100 for fentanyl; 1:0.4 for ketorolac.[10,11]

From induction of general anesthesia to skin incision, the patient's blood pressure, heart rate, and BIS were recorded at 5 pre-defined time points: before induction of general anesthesia (T1), before intubation (T2), 1 min after intubation (T3), before skin incision (T4), and 1 min after skin incision (T5). Incidences of postanesthetic complications such as postoperative nausea and vomiting (PONV), itching or urticaria, shivering, and desaturation due to respiratory depression were also evaluated as secondary outcomes.

Sample size calculation and statistical analysis

To calculate sample size, we used G*Power 3.1.9.4. According to a previous retrospective study, the difference of the NRS score immediately after surgery was 1.58 between two groups with or without remifentanil during thyroidectomy and the standard deviations of these groups were 2.610 and 1.706, respectively.[9] Thus, we originally needed 64 subjects (32 in each group) to achieve a study power of 80% and detect a difference in score of 1.58 using a two-sided Student's t-test at a significance level of 0.05. Finally, a total of 80 subjects (40 in each group) were needed assuming a 20% dropout rate.

All continuous variables are expressed as means ± standard deviations and categorical variables are expressed as frequencies and percentages. To compare perioperative data, an unpaired, two-tailed t-test was used for continuous variables and a chi-squared test was used for categorical variables. Data manipulation and statistical analysis was performed using SPSS Statistics for Windows, Version 21.0 (IBM; Armonk, NY). All reported P-values are two-sided and P-values < 0.05 were considered statistically significant.

RESULTS

During the entire trial, a total of 124 patients were planned to undergo thyroidectomy, but 14 were excluded because they did not meet the inclusion criteria, and 30 refused to participate in the trial. Finally, 80 patients were enrolled (Figure 1). One patient in the TIVA group was reopened due to bleeding in the wake of anesthesia, and seven patients (four from the TIVA group, three from the VA group) were excluded from the analysis because rescue analgesic administration in the recovery room was not the same as planned. Finally, data from 72 patients was used for analysis.

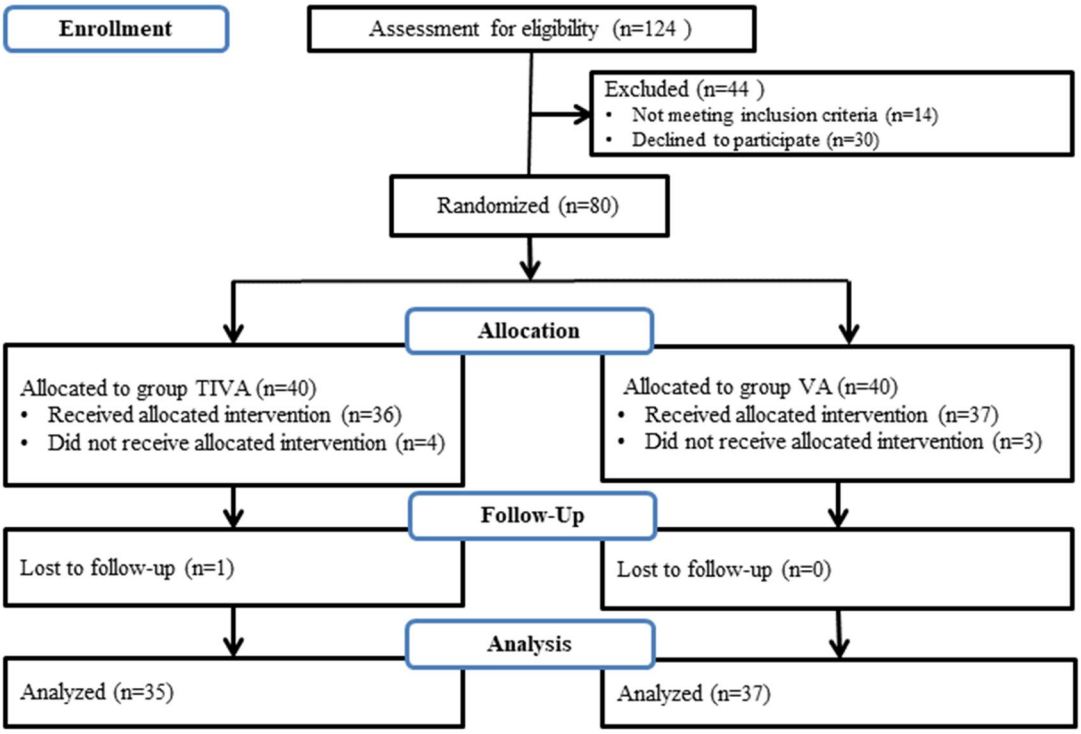

Figure 1. **CONSORT diagram of participant flow.** Abbreviations: TIVA, Total intravenous anesthesia; VA, volatile anesthesia

Table 1 shows that the demographic data and basal characteristics were not different between groups. The TIVA and VA anesthetic durations were 91.0 ± 24.7 min and 89.5 ± 20.2 min, respectively (P=0.776). The mean administered dose of remifentanil was 1977.7 ± 722.5 mcg in the TIVA group, which was approximately 0.268 ± 0.118 mcg/min/kg during surgery.

Table 1. Demographics of study population and basal characteristics.

	TIVA group (n=35)	VA group (n=37)	*P*-value
Age (year)	49.3 ± 13.5	48.4 ± 11.5	0.752
Male	7 (20.0)	9 (24.3)	0.659
Weight (kg)	65.3 ± 12.7	63.1 ± 11.3	0.431
Height (cm)	159.8 ± 7.0	161.0 ± 8.0	0.505
Body mass index (kg/m^2)	25.5 ± 4.1	24.2 ± 2.8	0.123
Comorbidities			
Diabetes mellitus	3 (8.6)	2 (5.4)	0.670
Hypertension	13 (37.1)	10 (27.0)	0.358
Smoking*	5 / 4 (14.3 / 11.4)	1 / 2 (2.7 / 5.4)	0.114
Alcohol	11 (31.4)	12 (32.4)	0.927
Vital signs at ward in the morning of surgery			
Systolic blood pressure	120.6 ± 14.9	117.2 ± 14.8	0.336
Diastolic blood pressure	76.7 ± 8.5	72.3 ± 14.8	0.132
Heart rate	75.2 ± 11.6	75.8 ± 12.5	0.831
Anesthetic duration (min)	91.0 ± 24.7	89.5 ± 20.2	0.776

* Smoking: ex-smoker / current smoker

Represented with mean ± SD for continuous variables, and with number (%) for categorical variables. Abbreviations: TIVA, Total intravenous anesthesia; VA, volatile anesthesia

1) Primary outcome

The comparison of the pain intensity over time evaluated at in the PACU was presented is shown in Figure 2. The NRS assessed upon arrival at the PACU before administration of rescue analgesics was higher in the TIVA group than in the VA group (5.7 ± 1.7 versus vs. 4.7 ± 2.3, P=0.034, Table 2). Pain intensities assessed at 30min and 60min after surgery in both groups did not show statistically significant differences. The NRSs at 30min and 60min after surgery in the group TIVA were 5.9 ± 1.7 and 3.5 ± 1.4 and those in the group VA were 6.0 ± 1.5 and 3.2 ± 1.2. (P=0.824 and P=0.294, respectively, Table 2).

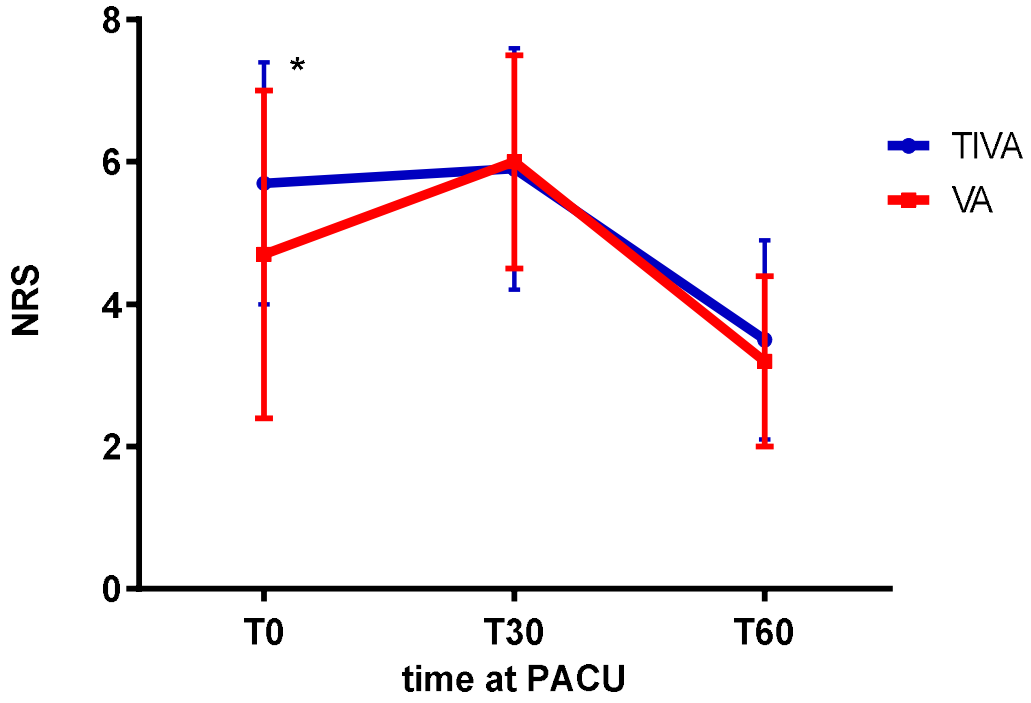

Figure 2. **Pain intensity at postanesthetic care unit (PACU) according to time from arrival** (*: p<0.05). Abbreviations: TIVA, Total intravenous anesthesia; VA, volatile anesthesia; NRS, numerical rating scale; T0: upon arrival to PACU; T30, 30 min after surgery; T60, 60 min after surgery.

Table 2. Pain intensity (NRS) assessed at the PACU at pre-defined timepoints

	TIVA group (n=35)	VA group (n=37)	*P*-value
Time points			
0 min	5.7 ± 1.7	4.7 ± 2.3	0.034
30 min	5.9 ± 1.7	6.0 ± 1.5	0.824
60 min	3.5 ± 1.4	3.2 ± 1.2.	0.294

Data are expressed as mean ± SD. Abbreviations: NRS, numerical rating scale; PACU, post anesthetic care unit; TIVA, Total intravenous anesthesia; VA, volatile anesthesia

The differences in NRS between arrival at the PACU before administration of rescue analgesics and 30min after surgery were not statistically significant in both groups. (0.257 ± 2.441 vs. 1.378 ± 2.628, P=0.065, Figure 3). Also, the differences in NRS between arrival at the PACU before administration of rescue analgesics and 60min after surgery were not statistically significant in both groups. (2.2 ± 2.011 vs. 1.486 ± 2.490, P=0.187, Figure 3).

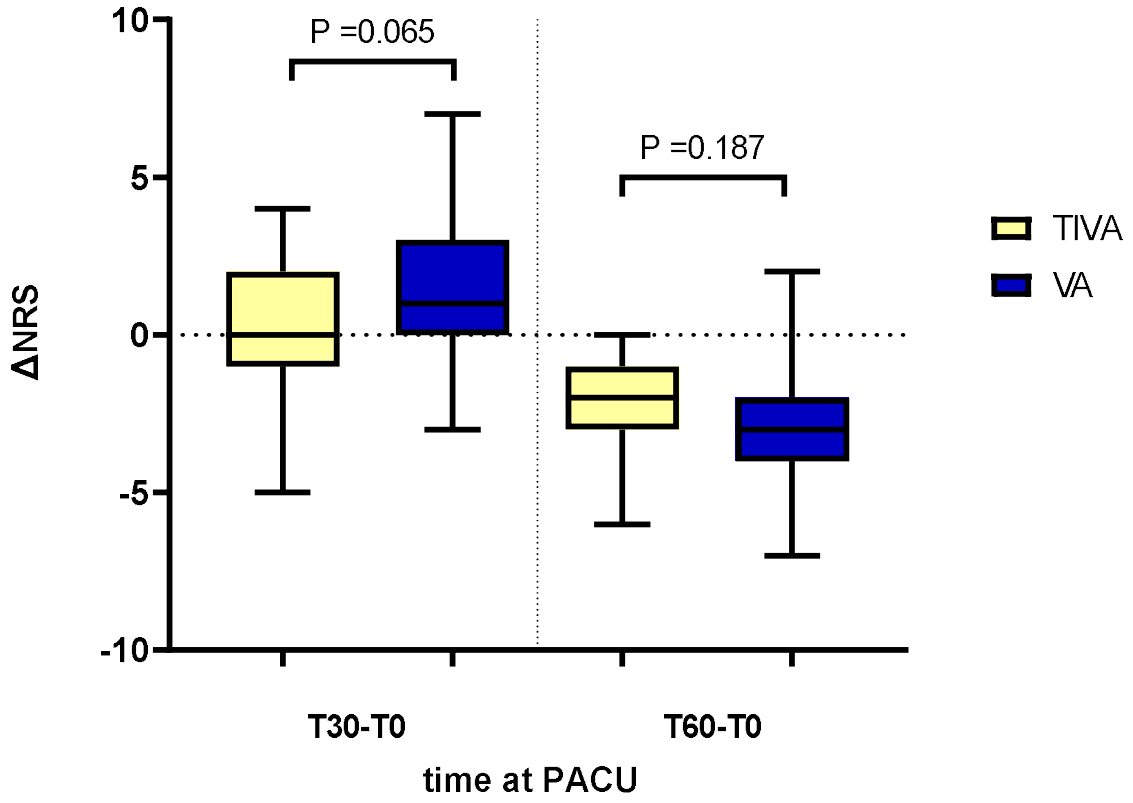

Figure 3. The differences in pain intensity between time interval at PACU. Abbreviations: TIVA, Total intravenous anesthesia; VA, volatile anesthesia; NRS, numerical rating scale; T0: upon arrival to PACU; T30, 30 min after surgery; T60, 60 min after surgery; PACU, post anesthetic care unit

As shown in Table 3, all patients in the TIVA group received rescue analgesics at the PACU. However, 89.2% of patients in the VA group needed rescue analgesics. Doses for rescue analgesics at the PACU are shown in Table 3. Intravenous NSAIDs were administered more in the TIVA group (30.0 ± 0.0 mg vs. 26.8 ± 9.4 mg, P=0.044), but the administered dose of fentanyl between groups was not significantly different (P=0.111).

Table 3. Demands for rescue analgesics administered intravenously during stay at postanesthetic care unit.

	TIVA group (n=35)	VA group (n=37)	*P*-value
Needs for rescue analgesics			
NSAID	35 (100)	33 (89.2)	0.115
Fentanyl	24 (68.6)	21 (56.7)	0.155
Once	14 (40.0)	17 (45.9)	
Twice	10 (28.6)	4 (10.8)	
Doses for rescue analgesics			
NSAID (mg)	30.0 ± 0.0	26.8 ± 9.4	0.044
Fentanyl (mcg)	47.4 ± 38.3	33.8 ± 33.4	0.111
MED (mg)	16.7 ± 3.8	14.1 ± 5.9	0.027

Data are expressed as mean ± SD for continuous variables, and with number (%) for categorical variables. Abbreviations: TIVA, Total intravenous anesthesia; VA, volatile anesthesia; NSAID, non-steroidal anti-inflammatory drug; MED, morphine equianalgesic dose

The sum of rescue analgesics administered to the TIVA group after conversion to MED was significantly higher than that of the VA group (16.7 ± 3.8 mg vs. 14.1 ± 5.9 mg, P=0.027, Figure 4).

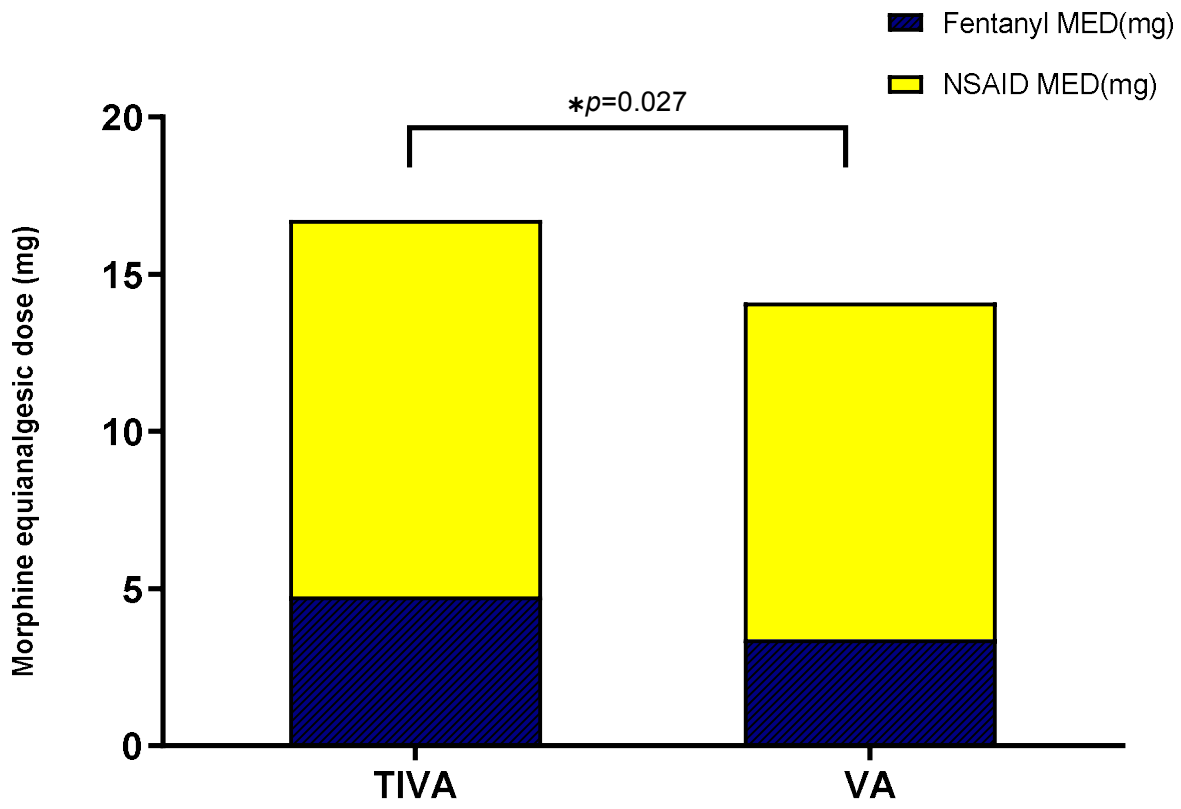

Figure 4. Morphine equianalgesic dose (mg). Abbreviations: TIVA, Total intravenous anesthesia; VA, volatile anesthesia; NSAID, non-steroidal anti-inflammatory drug; MED, morphine equianalgesic dose

2) Secondary outcome

During induction and before and after skin incision, the BIS of both groups was maintained between 30 and 60, but that of the TIVA group was sustained at a higher level than that of the VA group (Figure 5c). The TIVA group showed fewer changes in mean blood pressure and heart rate than the VA group (Figures 5a and 5b).

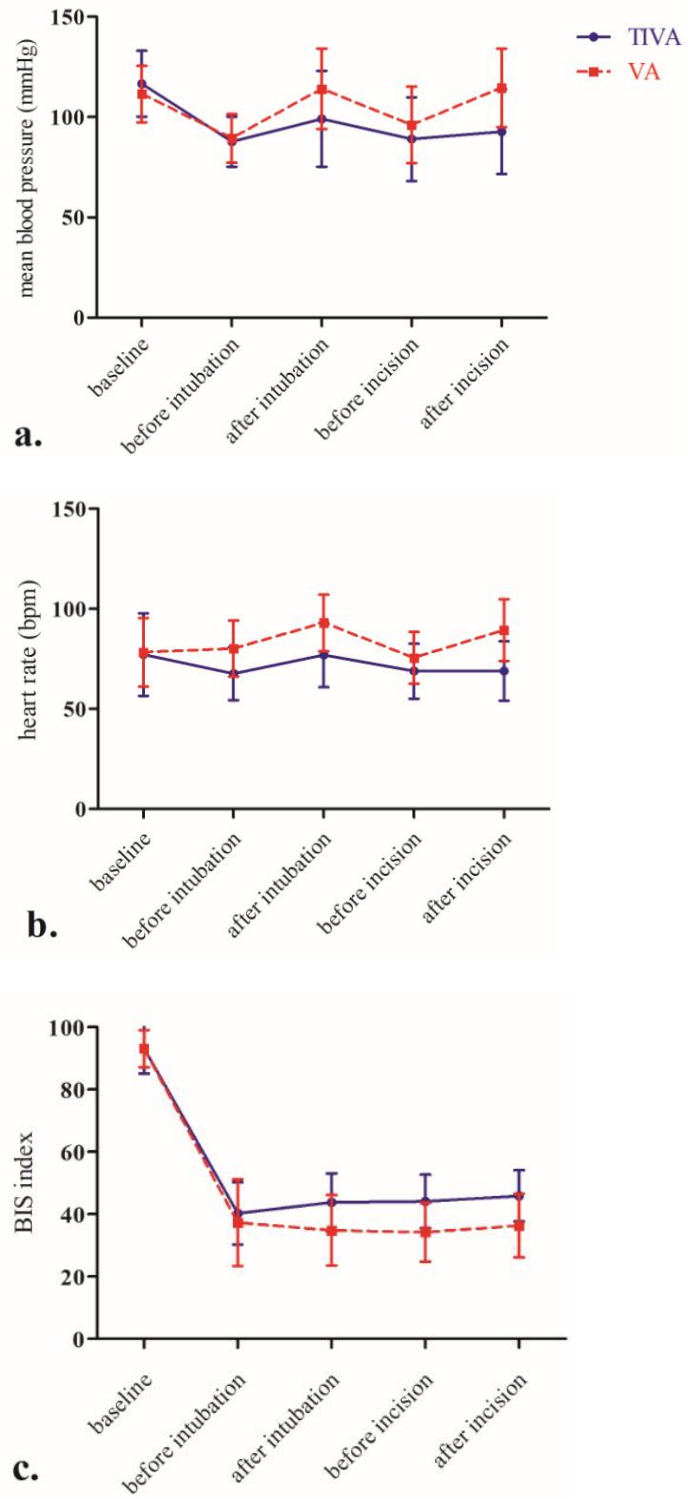

Figure 5. The changes in mean blood pressure, heart rate, and bispectral (BIS) index during surgery. Abbreviations: TIVA, Total intravenous anesthesia; VA, volatile anesthesia; BIS, bispectral index

PONV was the most common postoperative complication in both groups. The incidences of PONV in the TIVA and VA groups were 42.9% and 43.2%, respectively, which was not significantly different. Additionally, other complications including itching or urticaria and shivering were not significantly different between groups (Table 4).

Table 4. Occurrence of postoperative complications

	TIVA group (n=32)	VA group (n=35)	*P*-value
PONV	15 (42.9)	16 (43.2)	0.974
Itching or urticaria	0 (0.0)	1 (2.7)	1.000
Shivering	2 (5.7)	1 (2.7)	0.609
Desaturation	0 (0.0)	0 (0.0)	-

Data are expressed as number (%) for categorical variables. Abbreviations: TIVA, Total intravenous anesthesia; VA, volatile anesthesia; PONV, postoperative nausea and vomiting

DISCUSSION

The main finding in this prospective, assessor-blind, randomized controlled study was that the demand for rescue analgesics during PACU even after thyroidectomy in the TIVA group (with continuous infusion of remifentanil) was higher than that in the VA group for appropriately managing postoperative pain. In addition, there was no difference in the incidence of complications immediately after surgery.

Rapid recovery and emergence from general anesthesia are important in cases of ambulatory surgery or enhanced recovery after surgery. Both TIVA with propofol and remifentanil and VA with desflurane or sevoflurane are popular and reasonable for relatively simple surgeries, which are usually performed as ambulatory surgeries. In particular, volatile agents have become more popular in general anesthesia since sevoflurane and desflurane were introduced because they allow for faster recovery.[12] Propofol, one of the intravenous anesthetics, is also frequently used in ambulatory surgery with the continuous infusion of remifentanil, which has become more popular after the introduction of the TCI pump.[13] In the current study, patients in the TIVA group complained of immediate postoperative pain, which was inferred through the NRS firstly assessed at the PACU. This is thought to be due to opioid-induced hyperalgesia (OIH) and this result is consistent with our retrospective propensity score matching study.[9] As shown in Figure 2, the pain intensities at PACU (excluding the first one) are similar in both groups. According to our study protocol, enough rescue analgesics were administered during PACU stays after the first evaluation of pain intensity. Therefore, the second and third NRSs, obtained at 30 and 60 min after arriving at the PACU, would have been heavily influenced by rescue analgesics. Rather than indicating the intensity of postoperative pain, they are more appropriate as an index to judge whether proper pain management has been achieved.

According to the protocol, NSAIDs were first administered as a rescue analgesic agent at

the PACU, and opioids were administered additionally. In order to analyze the demands of the two groups in maintaining adequate pain control, the sums of MED of rescue analgesics, including both NSAIDs and opioids, was compared. The result clearly shows that the TIVA group needed more rescue analgesics than the VA group. This could be explained by OIH or acute opioid tolerance (AOT). The exact mechanisms of these two phenomena are unclear yet, and some cellular- and molecular-level explanations have been suggested.[14] According to a systematic review by Kim et al.,[7] the incidence of OIH and AOT is dose-dependent and administering more than 2.7 ng/mL using a TCI pump and 0.1 mcg/kg/min with continuous infusion of remifentanil could lead to OIH and AOT.[2,6,15-19] We used a TCI pump in this study, and the total intraoperative administered dose of remifentanil estimated was enough to lead to OIH and AOT, based on previous studies. Although the amount of rescue analgesics in the TIVA group was larger than in the VA group, the difference in the amount of rescue analgesics is clinically acceptable, and the postoperative pain in both groups was adequately controlled due to the administration of differentiated rescue analgesics.

Remifentanil has the advantage of controlling vital signs with an ultra-short action time. Despite its relatively high cost and the need to set up a special machine for TCI, many clinicians prefer anesthesia by remifentanil infusion in order to maintain hemodynamic stability during surgery.[20,21] We titrated the concentration of the volatile agent to systolic blood pressure within 20% of the baseline, but the control ability of remifentanil in the TIVA group was superior to volatile agents in the VA group. After inducing general anesthesia, the BIS in the VA group remained lower than the TIVA group, inferring that deeper anesthesia was achieved. Nevertheless, vital signs of subjects in the VA group responded significantly to noxious stimulations such as intubation and skin incision, which suggests that the autonomic nervous system was not adequately suppressed by volatile agents alone.

In this randomized controlled study, we did not observe differences in the incidence of

postoperative complications including PONV, shivering, itching, or respiratory complications between the groups. This is inconsistent with a meta-analysis by Schraag et al.[22] that showed that the risk for PONV was lower with propofol and remifentanil than with inhalational agents. This might be because our study was performed in cases of minor surgery with relatively less pain and shorter operation times, so the amounts of anesthetic and opioids used were small. Therefore, for complications following general anesthesia, including PONV, accurate results need to be obtained through studies conducted with more controlled variables and more subjects.

There are several limitations in this study. First, we cannot explain the hyperalgesia after surgery which was induced only by intraoperative continuous infusion of remifentanil. In this study, propofol in the TIVA group and desflurane in the VA group were used as anesthetic agents. The perception of postoperative pain intensity could be affected by the different anesthetic agents in each group. To confirm that remifentanil induced OIH, the study should have been conducted with the same anesthetic agents in both groups. However, in this study, we aimed to compare the two anesthetic methods using completely intravenous anesthetics and completely volatile agents. To our knowledge, there was no study comparing these two anesthetic methods. Second, we did not focus on chronic pain transition. The intensity and duration of acute postoperative pain is known to be a predictor of chronic post-surgical pain.[23] If patients are followed in the long-term, we could find the incidence of transition from acute to chronic pain.

In conclusion, general anesthesia with TIVA with continuous infusion of remifentanil could lead to a higher intensity of immediate postoperative pain, but it can be controlled by administering appropriate rescue analgesics. Moreover, there was no difference in the incidence of postoperative complications between the two methods. Therefore, in the case of

minor surgery, anesthesiologists may choose between TIVA and VA depending on the level of technical expertise and availability of resources at each institution.

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국문요약

배경

전신 마취 중 지속적인 레미펜타닐 주입은 효과적이고 쉽게 활력징후를 유지하게 한다. 하지만 수술 이후 초기에는 높은 통증 정도와 진통제 요구량 증가가 종종 발생한다. 본 연구에서는 레미펜타닐을 이용한 전정맥마취와 정맥유도를 통한 흡입마취 사이에 수술 직후 통증 강도와 구조 진통제의 필요성에 대해 비교한다.

연구방법

전신 마취 하에 갑상선 절제술을 받은 72명의 환자를 대상으로 하였다. 레미펜타닐과 프로포폴을 이용한 전정맥 마취(35명) 혹은 프로포폴 유도 및 데스플루란과 아산화질소를 이용한 유지(37명)에 무작위 배정하였다. 술 후 마취회복실에서 숫자 등급 척도에 기반한 통증 점수와 구조 진통제의 필요성을 각 그룹 간에 비교하였다.

연구결과

전정맥 마취 군과 흡입 마취 군의 통증 점수 값은 각각 5.7 ± 1.7 및 4.7 ± 2.3이었다 (P = 0.034). 마취 회복실에서 술 후 모르핀 동등 환산 용량은 흡입 마취 군보다 전정맥 마취 군에서 더 높았다 (16.7±3.8 mg vs. 14.1±5.9 mg, P=0.027). 즉각적인 마취 후 합병증의 발생률은 군 간의 유의한 차이가 없었다.

결론

결론적으로, 갑상선 절제술 후 마취 회복실에 머무르는 동안 술 후 통증을 적절히 관리하기 위해서는 흡입 마취 군보다 전정맥 마취 군에서 더 많은 구조 진통제가 필요하다.

중심단어: 전신 마취, 술 후 통증, 구조 진통제, 갑상선 절제술, 마취 방법, 정맥마취, 흡입마취