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Comparison of the effects of nicardipine and remifentanil on surgical visual field and hemodynamic parameters in tympanomastoidectomy cases

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Abstract

In this study; We aimed to compare the surgical visual field and hemodynamic effects of Nicardipine and Remifentanil in microscopic tympanomastoidectomy patients. The study was planned as a prospective, double-blind, and randomized clinical trial. A total of 64 patients aged between 18 and 65 were included in the study and the patients were randomized into 2 groups: Group N (Nicardipine=32) and Group R (Remifentanil=32). The input data were measured at pre-induction (T0), 5 minutes post-incision (T1), 20 minutes post-incision (T2), mastoidectomy during the tour (T3), cholesteatoma clearance (T4), grafting (T5), extubation (T6), 10 minutes post-extubation (T7), at the time of admission to the post-anesthesia care unit (PACU) (T8) and the 15th minute (T9) in PACU along with hemodynamic parameters values. In the evaluation of the visibility of the surgical field, the Boezaart Scale was used. There was no significant difference in demographic data in both groups. Considering the hemodynamic parameters between the groups, HR values were higher in Group N during the whole period (T1-T9) ($p<0.05$). T1, T6, T7, and T8, while DAB and MAP were lower in Group N. No difference was observed between the groups in terms of Boezaart Scoring, nausea-vomiting and pain scoring. Remifentanil and Nicardipine provided similar surgical field visual quality in CH application in tympanomastoidectomy cases. We think that nicardipine may be preferred in cases with sensitivity to the pathological effects of bradycardia because it does not have a bradycardia-producing effect.

Keywords: Surgical visual field, tympanomastoidectomy, nicardipine, remifentanil

Introduction

In a type of microsurgery that is performed in a closed and narrow field, such as middle ear surgery, even a small amount of blood can affect the quality of the view of the surgical field and make the surgical procedure more difficult [1].Therefore, a clean and visible surgical field offers many advantages, such as the prevention of complications and the shortening of the duration of the operation.

Controlled hypotension (CH) is frequently preferred for intraoperative bleeding management in microscopic tympanomastoidectomy surgery [2,3]. However, poorly managed CH procedure may lead to target organ hypoperfusion and cause unwanted complications. Cerebral, renal and cardiovascular systems are the most commonly affected organs [4].

CH is one of the most frequently applied effective methods to reduce surgical complications by decreasing intraoperative bleeding. It has taken its place in the literature as a method that increases surgical success in closed and narrow field surgery (functional endoscopic sinus surgery (FESS), septoplasty, and tympanolasty) [2,3].

A review of the literature shows that many pharmacologic agents (volatile anesthetics, sodium nitroprusside, nitroglycerin, α2 agonists) are used for CH [5] .

Nicardipine is a vasoselective dihydropiperidine derivative. Because of its rapid onset of action, nicardipine is used in cases where blood pressure control is required in a short period of time [6]. Since nicardipine does not have a serious depressant effect on the cardiac conduction system, dromotropic is negligible [7,8].

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Studies on the ideal anesthetic agent for CH are still in progress. However, in our search of the literature, we did not find any study that compared nicardipine and remifentanil in cases of microscopic tympanomastoidectomy.

In this study, we aimed to compare the effects of CH with nicardipine and remifentanil on surgical field visibility quality and hemodynamic parameters in endoscopic tympanomastoidectomy cases.

Material and Methods

Protocol

This study was approved by the Local Ethics Committee (protocol code 2021/181) and has been registered with the US National Institutes of Health (ClinicalTrials.gov) (#NCT06130527). Our study was conducted in accordance with the tenets of the Declaration of Helsinki and the Consolidated Standards for the Reporting of Studies [9].

Inclusion Criteria

This study was planned as a prospective, double-blind, randomized clinical trial in a total of 64 patients planned to undergo microscopic tympanomastoidectomy. The study included cases aged 18-65, ASA (American Society of Anesthesiologists) I-II groups. Patients were randomized to 2 groups, N (Nicardipine=32) and R (Remifentanil=32).

Exclusion Criteria

Patients with allergy to any agent used in the study and systemic and chronic diseases such as hypertension were excluded from the study.

In addition, patients with ASA >3 and difficult intubation (Mallampati score 3-4, thyromental distance <6) were not included in the study.

Randomization and Blinding

A total of 64 patients who were scheduled for elective microscopic tympanomastoidectomy surgery (Group N: 32, Group R: 32) were randomly distributed to a total of 2 groups. For randomization, it was ensured that the patients were assigned to the study groups completely by chance and selection bias was prevented. MedCalc for Windows, version-16 statistical software (medcalc.com.tr) was used for this purpose. The drugs to be used in the study were prepared by an anesthesia technician who was unaware of the randomization. Anesthesia management and hemodynamic data were performed and recorded by an anesthesiologist who did not know the groups. The operator who performed the surgical procedure was also unaware of the patient groups. In this way, double blinding was achieved.

Preoperative Procedures

For premedication, 0.05 mg/kg iv midazolam was administered 30 min before surgery.As a standard for all patients taken to the operation room, SAP, MAP, DAB, HR, electrocardiography (ECG), $EtCO_2$, and SpO_2 monitoring were performed.

Anesthesia Management

After preoxygenation (100% 5 L/min O2, 3 minutes) was applied to all cases, the same anesthesia protocol was applied to the groups by an experienced anesthetist for anesthesia induction. In anesthesia induction, Propofol 2-2.5 mg/kg, Fentanyl 1.5 mcg/kg and 0.6 mg/kg Rocuronium i.v. was used. To measure neuromuscular agent activity, quadruple stimulation (quadruple TOF sequence) was measured using TOF-Watch SX, and intubation was performed orally when TOF was completely suppressed. The cuffs of the intubation tubes were inflated to not exceed 25 cm H2O. Pressure values were checked with a pressure manometer. After intubation, tidal volume (6-8 ml/kg) and ventilation rate were adjusted so that the $EtCO_2$ value was 35-40 mmHg. Anesthesia was maintained in a 50% O2-air mixture with a fresh gas flow of 3 L/min and a Sevoflurane concentration of 1 MAC. During all procedures, the patients' heads were kept 15˚ above their bodies. BIS Monitor was used to evaluate the depth of anesthesia and BIS was set between 40-60.

After intubation, remifentanil infusion was started at an i.v dose of 0.05 µg/kg/min in group R and nicardipine 1.0 µg/kg/min in group N. Target MAP was set at 50-65 mmHg in group N and group R. HR below 45 beats/min was considered bradycardia and remifentanil dose was reduced. Atropine 0.5 mg i.v. was administered if response was inadequate. In groups in which MAP was above 65 mm/Hg for more than 5 minutes, nicardipine and remifentanil infusions were increased by titration.

At the end of the surgery, patients who opened their eyes with stimulation, had regular spontaneous breathing, a respiratory rate of 12-20/min, and SpO_2 above 95% were extubated and taken to the recovery room. Postoperative nausea in the PACU was scored on a 4-point scale (0=no nausea, 1=moderate nausea, 2=severe nausea, 3=retching, vomiting, or both). If the nausea scale was 2 and above, ondansetron 50 µg/kg iv was administered as an antiemetic. Pain scores were 0-1 none, 2-4 mild, 5-7 moderate, and 8-10 severe. Patients' pain scores were assessed at the 15th minute of their stay in the PACU. In cases with a pain score of ≥5, 15 mg/kg IV acetaminophen was administered as rescue analgesia. Those with a modified Aldrete score ≥9 were transferred to the otolaryngology department [10]. The other researcher who followed the patients in the recovery room was unaware of the group to which the patient belonged.

Outcome Criteria

At the time intervals specified below, SAP, DAB, MAP, HR, and SpO_2 values were recorded. T0: pre-induction, T1: 5 minutes after surgical incision, T2: 20 minutes after surgical incision, T3: during mastoidectomy tour, T4: during Cholestatum clearance, T5: during grafting, T6: during extubation, T7: 10 minutes after extubation, T8: PACU entry, T9: PACU 15th min and Et-CO_2 values were recorded at T1, T2, T3, T4, T5, T6 time intervals.

Anesthesia type, total fluid amount, anesthesia duration, surgery duration, extubation duration, recovery duration, length of stay

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in PACU, and target MAP duration were recorded. Remifentanil and nicardipine infusions were terminated at the end of the surgery and extubation times were recorded.

Anesthesia duration was defined as the time from the beginning of anesthesia induction until the patient was extubated. Surgical time was defined as the time from the beginning to the end of the surgical procedure. Extubation time was defined as the time from discontinuation of anesthetic drugs to extubation. Verbal response time was defined as a meaningful response to simple verbal commands (open your eyes, etc.) given after extubation. Length of stay in PACU was defined as the time elapsed from the patient's admission to the recovery room to his/her transfer to the Ear Nose and Throat Service.

The evaluation of the visibility of the surgical field was recorded at B1: Skin incision, B2: Mastoidectomy during the tour, B3: Cholestatum clearing and B4: Grafting stages by using Boezaart Scale [11]. According to this scoring, there are 6 different bleeding scores (range 0-5). The amount of bleeding corresponding to the numerical values in this scoring is given in the table below (Table 1).

Table 1. Boezaart scoring

0	No bleeding
1	**Light bleeding:** Does not require aspiration
2	**Mild bleeding:** Aspiration is rarely needed/bleeding does not threaten the surgical field
3	**Mild bleeding:** Frequent aspiration is needed/bleeding threatening the surgical field and the effect of aspiration disappears after a few seconds
4	**Moderate bleeding:** Frequent aspiration is needed/bleeding threatens the surgical field size and the effect of aspiration disappears immediately after aspiration
5	**Severe bleeding:** Continuous aspiration is needed/bleeding more than the aspiration fast, the surgical field is seriously threatened, and surgery is not possible

Sample Size

In the Student t-Test, in which two independent groups were compared by using the G-Power 3.1.9.7 program (Franz Faul, Universitat Kiel, Germany), the total sample was taken as a=0.05 power (1-β)=0.80 and the effect size (0.71) was calculated as 32 persons for each group.

Statistical Analysis

Data analysis was performed with IBM© SPSS© Statistics (version 25 for Windows, IBM Corporation, Armonk, New York, USA). Saphiro-Wilk test, histogram distribution, skewness-kurtosis parameters were used for normality analysis. Descriptive statistics were expressed as mean±standard deviation for variables with normal distribution, median (min-max) for variables with non-normal distribution, and number of cases and (%) for nominal variables. Chi-square test and Fisher Exact test were used for analysis between categorical variables. Mann-Whitney U test was used for nonparametric and Student t'test for parametric variables in the evaluation of the relationship between continuous variables. Results were considered statistically significant for $p<0.05$.

Results

A total of 64 volunteers aged 18-65 years, ASA 1-2, Mallampati 1 and 2, who were scheduled to undergo microscopic tympanomastoidectomy under elective conditions, were included in the study. No significant difference was detected between Group N and Group R in terms of gender, age, Body Mass Index, ASA, amount of fluid administered, and duration of surgery and anesthesia. The comparison of demographic distribution and duration parameters between groups is shown in Table 2.

Table 2. Comparison of demographic features and duration parameters

	Group N	Group R	p
Sex, (n,%)			0.131
Male	11 (34.4)	17 (53.1)	
Female	21(65.6)	15 (46.9)	
Age, year	29.1±11.9	29.4±11.92	0.917
BMI, kg/m^2	24.2±3.5	24.9±4.9	0.544
ASA, (n, %)			0.794
1	21 (65.6)	20 (62.5)	
2	11 (34.4)	12 (37.5)	
Total Fluid (ml)	1634.4±320.9	1900±735.6	0.023*
Anesthesia Duration (min)	160.3±44.7	175.3±56.2	0.244
Surgery Duration (min)	139.5±43.1	148.9±54.1	0.445
Length of Stay in PACU (min)	35.4±3.9	32.4±7.3	0.048*
Extubation Duration (min)	8.3 ±3.4	8.1±2.1	0.724
Target MAP Duration (min)	12±6.0	16.4±5.4	0.003*
Recovery Duration (min)	13.5±4.7	12.6±2.3	0.343

BMI: body mass index, ASA: American Society of Anesthesiologists, PACU: postanesthetic care unit, MAP: mean arterial pressure; *Significant difference between groups ($p<0.05$)

Although the mean length of stay in PACU was 35.4±3.9 minutes in Group N, it was 32.4±7.3 minutes in Group R. This was statistically significantly lower in Group R (p=0.048). Although the mean extubation duration was 8.3±3.4 minutes in Group N, it was 8.1±2.1 minutes in Group R. This was not statistically significant (p=0.724). The target MAP duration was 12±6.0 min in Group N and 16.4±5.4 min in Group R. This difference was statistically significant (p=0.003). Although the mean recovery duration was 13.5±4.7 minutes in Group N, it was 12.6±2.3 minutes in Group R. This difference was not statistically significant (p=0.343) (Table 2).

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There was a significant difference in SAP values at T1, T7 and T8 (p<0.005). There was a significant difference between the groups in DAP values at T1, T6, T7 and T8 (p<0.005). There was a significant difference in MAP values at T1, T6, T7 and T8 (p<0.005) (Figure 1). There was a statistically significant difference in HR values between the groups at T1-T9 time intervals (p<0.005). There was no significant difference in SpO_2 and $EtCO_2$ values (Figure 2).

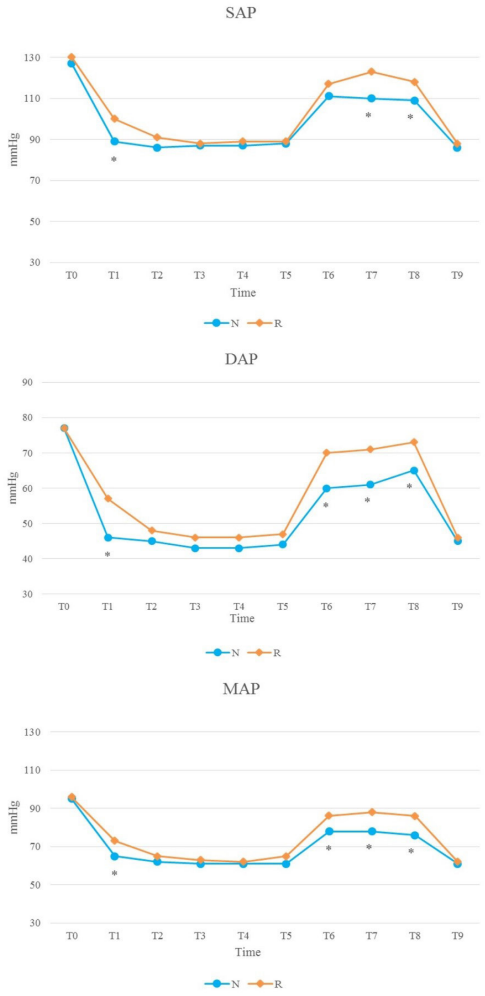

Figure 1. Comparison of SAP, DAP and MAP values between two groups in specified time periods (*Significant difference between groups (p<0.05))

When the groups were compared in terms of Boezaart Scoring, the Boezaart Score in Group N in B1 was 1.5, while this value was 1.0 in Group R and there was no statistically significant difference (p=0.288). In B2, the Boezaart Score in Group N was 2.0, while this value was 1.5 in Group R. This difference was not significant (p=0.450). In B3, although the Boezaart Score was 2.0 in Group N, this value was 2.0 in Group R and there was no statistically significant difference between the groups (p=0.431). In B4, although the Boezaart Score was 1.0 in Group N, this value was 2.0 in Group R. There is no significant difference (p=0.396). When pain scores were compared between the groups, it was found to be 3.0 in Group N and 1.0 in Group R. The difference between the groups was not statistically significant (p=0.091) (Table 3).

When the groups were compared in terms of Boezaart Scoring, the Boezaart Score in Group N in B1 was 1.5, while this value was 1.0 in Group R and there was no statistically significant difference (p=0.288). In B2, the Boezaart Score in Group N was 2.0, while this value was 1.5 in Group R. This difference was not significant (p=0.450). In B3, although the Boezaart Score was 2.0 in Group N, this value was 2.0 in Group R and there was no statistically significant difference between the groups (p=0.431). In B4, although the Boezaart Score was 1.0 in Group N, this value was 2.0 in Group R. There is no significant difference (p=0.396).

When the pain scores were compared between the groups, it was found to be 3.0 in Group N and 1.0 in Group R. There was no significant difference (p=0.091) (Table 3).

When the nausea-vomiting scores were compared between the groups, it was found to be 1.0 in Group N and 1.0 in Group R. There was no significant difference (p=1.000). The distribution of Boezaart Scoring, pain and nausea-vomiting scores between the groups is shown in Table 3.

Table 3. Comparison of Boezaart score, pain score and nausea-vomiting score (median)

	Group N	Group R	p
BS – B1	1.5	1.0	0.288
BS – B2	2.0	1.5	0.450
BS – B3	2.0	2.0	0.431
BS – B4	1.0	2.0	0.396
Pain score	3.0	1.0	0.091
Nausea-vomiting score	1.0	1.0	1.000

BS: Boezaart score, B1: skin incisoin, B2: during the mastoidectomy tour, B3: cholesteatoma removal, B4: grafting stage

Discussion

In tympanomastoidectomy cases who underwent microsurgery in the middle ear, the surgical field visibility score (Boezaart Scale) was similar in the groups (Group N and Group R), and there were no statistically significant differences. The time to reach the target MAP was statistically significantly shorter in Group N. Also, MAP values in Group N; SAP values in T1, T6, T7, T8; DAB values were statistically significantly lower in T1, T7, T8, and T1, T6, T7, and T8. HR values were statistically significantly lower in Group R at T1-T9 time intervals. In the evaluation of the 15th-minute pain score in PACU, the scores were similar in the groups and there was no statistically significant difference.

In middle ear microsurgery, the bloodless surgical field positively affects the duration and quality of the surgery. CH is one of the methods used for this purpose for many years.. CH is one of the

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methods used for this purpose for many years. Many studies show that CH provides a quality surgical field [12]. The ideal hypotensive agent to be used in CH must be easy to administer and titrate, its dose-related effect must be predictable, and it must be rapidly eliminated without breaking down into toxic metabolites. Nicardipine and remifentanil are favorite drugs that have long been used as well as volatile anesthetics to create CH. Nicardipine causes activation in the sympathetic nervous system and decreases the parasympathetic nervous system. However, Remifentanil causes decreased sympathetic nervous system and activation in the parasympathetic nervous system. Although remifentanil does not have a sympathetic stimulating effect during CH, it has been reported that nicardipine stimulates the sympathetic nervous system and therefore caution should be exercised in sensitive patients [13].

When applying techniques that reduce blood flow and provide a bloodless surgical field, mechanisms that control microcirculation must be considered. The purpose must be to maintain protective autoregulatory mechanisms and avoid deep hypotension in CH (<50 mmHg), which may trigger morbidity and mortality, causing tissue hypoxia by reducing end-organ perfusion. In a study, the mortality rate because of ischemic organ failure in CH was reported as 0.02-0.06% [14]. Deep HR was avoided and the target MAP was maintained between 50-65 mmHg in the present study. MAP, DAB, and SAP values were statistically significantly lower in Group N In some time intervals evaluated in our study.

As well as a quality surgical field, CH can also cause undesirable effects on patients. Although it is argued that keeping MAP between 50-65 mmHg is safe, with the prolongation of the operation time, prolongation of the postoperative awakening period, tachyphylaxis, cyanide toxicity, myocardial depression, tachycardia, cerebral hypoxia, deterioration of cognitive functions, renal, cardiac and hepatic undesirable side effects might also occur [15]. None of the major complications that were defined during the application were observed in the groups in the present study.

In their study, Atighechi et al. have shown in their study that bleeding in endoscopic sinus surgery cases causes visual disturbance in the surgical area and this situation prolongs the surgical time [16]. In a meta-analysis, CH was compared with normotension and reported that surgical field quality was better in CH [17]. In the present study, according to the Boezaart Scale, the highest value was detected in the B3 time interval (Group N/Group R (2.0/2.0)). No statistically significant difference was detected in these values. This score is described as "Mild bleeding; aspiration is rarely needed/bleeding does not threaten the surgical field". It is seen that the applied CH provides a suitable field of view for surgical application in groups. Because of their vasodilation and HR effects, some pharmacological agents may increase bleeding and distort the appearance of the surgical area. It was reported in some studies that HR rather than MAP is a determinant in surgical vision quality [18,19].

The factors determining the quality of the visual field have not been fully explained, especially in closed-field surgical applications. When the results of our study were evaluated with all these data, we think that not only hemodynamic data such as HR and MAP but also surgical conditions and other mechanisms that must be investigated are effective in visual field quality. In a study that compared the effects of Propofol/Remifentanil and Desflurane/Remifentanil in patients who underwent middle ear surgery, on the surgical visual field, it was reported that the Propofol/Remifentanil group had a better surgical visual field. There was no statistical difference between the two groups in terms of In the study of Won et al., in which the effects of Nicardipine and Remifentanil on CH during thyroidectomy were compared in 40 patients, HR was found to be significantly higher in the Nicardipine group when compared to the Remifentanil group (p=0.040) [20]. No significant differences were detected between the groups in terms of intraoperative MAP, extubation time and recovery time, and the incidence of nausea/vomiting [21]. Similarly, in the present study, HR was found to be higher in the nicardipine group when compared to remifentanil at all time intervals except before induction. No significant difference was found in terms of image quality at the surgical site for both groups.

In a previous study [22], it was shown that remifentanil, which is one of the most commonly used agents in CH, suppressed the sinus and atrioventricular nodes. This situation explains the pathophysiology of severe bradycardia associated with remifentanil. We think that nicardipine may be a good alternative to protect from the bradycardic effects of remifentanil in children with cardiac pathology who will undergo CH because it offers a good field of view and does not have a bradycardic effect on HR. When compared to the results of the study of Aslı A. et al. with the title "Effectiveness of Esmolol, Remifentanil and Nitroglycerine in CH for Functional Endoscopic Sinus Surgery", surgical site bleeding scores were lower in Esmolol than in Nitroglycerin. When Esmolol and Remifentanil were compared, bleeding scores were lower in Remifentanil. Also, Remifentanil was found to be more advantageous in achieving HR in a shorter time, stable blood pressure, and long-term targeted MAP [23]. In another study in which arthroscopic muster surgery was performed, the target time to reach MAP was found to be (14.9 min) in the Remifentanil group and the Nicardipine Group (34.1 min). In our study, the time to reach the target MAP was found to be shorter in the Nicardipine group (Group N/Group R: 12 min/16.4 min) and this difference was statistically significant. In the study of Kim JY et al. [24]. the difference in the time to reach MAP between the groups was not considered significant, although it was not more than our study. We think that this occurred because of the high impact power and the low sample size. Also, according to the study of Kim et al., the dose range of Nicardipine was found to be 1.0-7.0 µg/kg/min in our study. We think that the administration of higher doses of Nicardipine shortens the time to reach the target MAP.

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Shin S et al [11]. compared heart rate variability with Nicardipine, Remifentanil, and Dexmedetomidine in 62 patients during CH in orthognathic surgery. They recorded the heart rate values that were measured after induction anesthesia (T1) and the heart rate measured 30 minutes after HR was achieved (T2) (Nicardipine: T1; 80.7±10.7, T2; 114.0±9.5, Remifentanil: T1; 80.1±13.0, T2; 67.5±7.6, Dexmedetomidine; T1; 79.1±13.0, T2; 69.2±5.6, $p<0.05$). In this study, heart rate was significantly increased at T2 when compared to T1, and heart rate was also significantly faster at T2 than with Remifentanil and Dexmedetomidine. Remifentanil and Dexmedetomidine heart rates were found to be significantly slower at T2 than at T1 [13]. In the present study, similarly, HR values were significantly higher in the Nicardipine group during the entire application (T1-T9), which was consistent with the literature data.

In a CH study comparing nicardipine and nitroprusside, nicardipine caused more balanced hypotension than nitroprusside and both drugs can be used in CH [25]. Bernard et al. reported in a study that there was no change in arterial oxygenation in the nicardipine group due to the decrease in MAP with CH administration, unlike sodium nitroprusside, and that this situation may cause minimal effects of nicardipine on hypoxic pulmonary vasoconstriction [26]. In our study, there was no significant difference in SpO_2 and $EtCO_2$ values in both groups. No hypoxic situation was encountered.

Nicardipine has a more cardioprotective effect than other calcium channel blockers by causing strong vasodilation in the coronary vessels. It provides a rapid decrease in blood pressure, increases myocardial contractility and cardiac output. It does not cause a profound hypotensive episode and clinically significant tachycardia. Nicardipine dilates cerebral vessels but does not significantly increase intracranial intracranial pressure [27]. In the current study, time to target MAP was statistically and significantly shorter in group N than in group R. Won et al. compared the effects of nicardipine and remifentanil in thyroidectomy patients undergoing CH. Heart rate was significantly higher in the nicardipine group compared to the remifentanil group ($p=0.040$). Extubation time, recovery time, and incidence of nausea/vomiting during surgery were not significantly different between groups [21]. In our study, no statistically significant difference was detected in terms of anesthesia time, surgical time, extubation and recovery, consistent with literature data.

In summary, the first aim of the study was to improve the quality of vision in the surgical field in microscopic tympanomastoidectomy cases. Consistent with literature data, no significant difference was detected between the two groups in terms of bleeding scores. In our study (T1-T9), heart rate values were significantly higher in Nicardipine than in Remifentanil throughout the entire period, and this finding was found to be consistent with the literature data. In our study, no major complication associated with the application was observed. In the present study, the severity of nausea-vomiting and pain scoring in the recovery unit was similar in the groups, consistent with the literature data. To minimize such undesirable effects and to provide a quality surgical field, more studies are needed to find ideal agents to be used in creating CH.

There were some limitations in our study. It is already known that CH can affect the cognitive functions of patients, especially in cases with prolonged surgical time. In our study, the cognitive functions of the cases were not evaluated. We think that the effect of CH on cognitive functions, especially in elderly patients, must be investigated with randomized controlled studies. Also, we believe that supporting the application with laboratory findings will increase the safety of the study results, even if HR (MAP 50-65 mmHg) is applied within the range considered safe in our study.

Conclusion

In the present study, it was observed that both agents produced a similarly good surgical field image quality in patients who underwent microscopic tympanomastoidectomy. We think that Nicardipine may be preferred in cases with cardiac comorbidity and sensitivity to the pathological effects of bradycardia since it does not have a bradycardia-producing effect. More studies are needed to find ideal agents to be used in creating CH to minimize the undesirable effects of CH and to provide a quality surgical field.

Conflict of Interests
The authors declare that there is no conflict of interest in the study.

Financial Disclosure
The authors declare that they have received no financial support for the study.

Ethical Approval
Institute Registration: The study was approved by the Local Ethic Committee of Inonu University (protocol code: 2021/181). Trial Registration: This trial is registered at the US National Institutes of Health (ClinicalTrials.gov) # NCT06130527

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