Original paper

Conscious sedation with the combination of midazolam and fentanyl is effective and safe for cryoablation of paroxysmal atrial fibrillation

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A b s t r a c t

Introduction: Studies on anesthesia for cryoablation, one of the methods used in the treatment of atrial fibrillation (AF), and its effect on perioperative parameters are limited.

Aim: To compare the effects of conscious sedation with a combination of midazolam-fentanyl and unconscious sedation with propofol-midazolam on the success of the procedure.

Material and methods: 242 patients who underwent AF cryoablation for the first time were included. The ASA score and baseline SaO_2 before the procedure, and the minimum SaO_2, systolic and diastolic blood pressure change and the Richmond Agitation Sedation Scale (RASS) score during the procedure were obtained. Study data were divided into 2 groups – conscious sedation and unconscious sedation – and compared.

Results: Demographic, laboratory and echocardiographic findings did not differ significantly between the two groups ($p > 0.05$). When the hemodynamic parameters of the periprocedural AF ablation process and the effects of anesthesia were examined according to the anesthesia groups of the patients, minimum SaO_2 during the procedure was significantly higher in the group that underwent conscious sedation (93.6 ±2.21% vs. 92.4 ±1.96% and $p < 0.01$). RASS score, blood pressure changes were found to be significantly lower in the conscious sedation group ($p < 0.01$ for each). However, procedural time, fluoroscopy time, ASA score, non-invasive mechanical ventilation (NIMV) requirement, basal SaO_2, procedure success and frequency of AF recurrence were not significantly different between prolonged recovery groups ($p > 0.05$ for each).

Conclusions: In our study, it was found that the conscious sedation preference during AF cryoablation could be applied with similar success and recurrence compared to unconscious sedation with propofol and midazolam.

Key words: atrial fibrillation, cryoablation, conscious sedation and unconscious sedation.

S u m m a r y

In our study, it was found that the conscious sedation preference during atrial fibrillation cryoablation could be applied with similar success and recurrence compared to unconscious sedation with propofol and midazolam.

Introduction

Atrial fibrillation (AF) is the most common (2–3%) arrhythmia in the general population and is associated with stroke, heart failure, impaired quality of life and increased mortality [1]. Among the AF rhythm control strategies, the gold standard treatment is 3-dimensional (3D) radiofrequency (RF) ablation, but cryoballoon catheter ablation has similar efficacy and safety, especially in

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the treatment of paroxysmal AF [1]. AF catheter ablation is an invasive and relatively long and painful procedure. During AF 3D RF or cryoablation, general anesthesia (GA), deep and moderate sedation can be applied according to the center protocol, experience and preference of electrophysiologists and anesthesiologists [2–5]. The purpose of anesthesia during ablation is to: i) reduce pain due to RF or cryoenergy, ii) stabilize body movement, and iii) provide catheter stability and effective energy delivery. Especially in 3D RF ablation, ablation map and catheter efficiency can be reduced with minimal movement, so deeper anesthesia is preferred in these procedures.

Different results were obtained in studies comparing the choice of GA and sedative anesthesia for AF ablation [4, 6–13]. While some studies reported that GA preference was superior to sedation, especially in terms of repetitive procedure requirements [6, 7, 12], some studies reported that the two anesthesia methods were similar [4, 8, 9, 13]. In a meta-analysis, it was reported that the procedural parameters such as fluoroscopy time, procedure time, procedure-related complications and AF recurrence rates were similar in patients who underwent GA or sedation [2]. Conscious sedation with a combination of midazolam and fentanyl and unconscious sedation with a combination of propofol and/or midazolam can be used in AF ablation. According to the 2017 AF ablation guideline, preference for anesthesia during AF ablation is 73% GA, 13% unconscious sedation and 14% conscious sedation. However, these results were mostly obtained from patients who underwent 3D RF ablation [4, 6–10, 12, 13]. There are limited data on the anesthesia method used during the procedure in patients who underwent AF cryoablation [11].

Aim

In our study, we aimed to compare the effects of conscious sedation and unconscious sedation preferences on the success of the procedure and on the hemodynamic and clinical parameters associated with the procedure in patients who were cryoablated for the first time due to paroxysmal AF.

Material and methods

Patient group

Patients who were admitted to the University of Health Sciences Adana City Training and Research Hospital Cardiology Clinic between October 1, 2017 and March 1, 2021 with the diagnosis of paroxysmal AF and planned to undergo cryoablation for the first time and who underwent a full perioperative anesthesia evaluation before the procedure were included in this retrospective study. The diagnosis of AF was made by 12-lead superficial electrocardiography (ECG) before or at the time of admission. Patients with acute or end-stage liver or kidney disease, acute coronary syndrome, end-stage chronic obstructive pulmonary disease, active malignancy and/or an active infectious process in last 2 weeks, coagulopathy, history of hemorrhagic stroke, severe aortic and mitral valvular disease, stage III or IV heart failure, left atrium (LA) diameter > 55 mm, left ventricular (LV) systolic dysfunction (EF < 45), patients with a survival expectancy of less than 1 year, and patients whose consent was not obtained for the study were not included in the study. After screening, 242 patients (128 males, 114 females and mean age 54.9 ±11.8 years) with paroxysmal AF were included in the study.

Biochemical and echocardiographic evaluation

A detailed history was obtained from each patient and detailed physical examinations were performed. Patients' heart rates in normal sinus rhythm were recorded before the procedure. Concomitant systemic cardiac and non-cardiac diseases were recorded. Blood biochemistry and the hemogram of all patients were evaluated. Biochemical tests were performed before the cryoablation procedure and after 12 h of fasting. Urea, creatinine, uric acid, alanine aminotransferase, aspartate aminotransferase and C-reactive protein levels were measured. In addition, complete blood count and white blood cell counts were obtained. The height and weight measurements of the patients were obtained and the body mass index was calculated according to the formula of body weight (kg)\height^2 (m^2).

All patients were taken to the echocardiography laboratory for M-mode and 2D transthoracic echocardiography measurements before the procedure. Measurements were performed with a Siemens Acuson SC2000 Prime (Siemens Medical Solutions USA, Mountain View, CA) echocardiography device. All measurements were made in accordance with the European Association of Cardiovascular Imaging and the American Society of Echocardiography guidelines [14]. LV EF and volumes were calculated from apical 2-chamber and apical 4-chamber images by the Simpson method. LA diameter was measured from parasternal long axis views at the end of diastole and systole, respectively.

Evaluation of anesthesia, sedoanalgesic drug grouping and perioperative hemodynamic evaluation

All patients underwent a full preoperative anesthesia evaluation before the procedure. During the anesthesia evaluation, the American Society of Anesthesiologists (ASA) score was first evaluated in all cases. Patients who received approval for anesthesia for the paroxysmal AF cryoablation procedure underwent ablation the next morning after at least 12 h of fasting. Baseline systolic blood pressure (SBP), diastolic blood pressure (DBP), baseline SaO_2 without oxygen and heart rate measurements were obtained from all cases on the morning of the procedure after at least 10 min of bed rest.

All cases underwent AF ablation by sedation with the consensus decision of the Anesthesia and Arrhythmia clinics. Sedo-analgesia was performed by the anesthesia team, and its preference was made based on the experience and expertise of the anesthesiologist. According to the sedoanalgesic agents applied, all patients included in the study were divided into 2 groups, as patients who had a combination of midazolam and fentanyl (conscious sedation) and patients who had a combination of propofol and midazolam (unconscious sedation).

Propofol (PROPOFOL-PF 1%, Polifarma, Turkey) used for sedation was started at a slow intravenous dose of 1 mg/kg and the continuation dose was determined as 4 mg/kg/h. Intravenous (IV) midazolam (Zolamid, Vem İlaç, Turkey) treatment was given as 0.003 mg/kg slowly for 1 min long. IV fentanyl (Fentaver, Haver Pharma, Turkey) was initiated at a dose of 0.8 μg/kg intravenously and continued at a dose of 1 μg/kg/h.

All patients were given nasal O_2 at 2–8 l/min throughout the procedure, and SaO_2 was maintained > 95%. During the procedure, SaO_2, electrocardiography and blood pressure monitoring were performed. A complete hemodynamic evaluation was performed at a frequency of 3–5 min. The Richmond Agitation-Sedation Scale (RASS) score was calculated for each patient to determine the level of sedation during the procedure. SBP and DBP monitoring was performed invasively using the Artis zee angiography system (Siemens AG, Forchheim, Germany) with a 6F sheath from the left femoral artery. O_2 saturation measurements were made with a pulse oximeter and Avance CS2 Pro anesthesia device (GE Healthcare, Madison, WI). Sudden increases and decreases in SBP and DBP were noted. SBP and DBP changes were calculated by taking the difference between the measured maximum and minimum values. After the procedure, the patients were followed up in the postoperative recovery unit until their modified Aldrete score was 9 or above, and then they were taken to the coronary intensive care unit. No anesthesia reversal medication was administered to the patients. The patient's unresponsiveness or disorientation, or inability to fully awaken 4 h after the procedure, was defined as prolonged recovery, and patients meeting this definition were noted. The patients were discharged the next morning.

Cryoablation method

All patients were taken to the EPS laboratory for basic diagnostic electrophysiological study in order to rule out AF due to a possible supraventricular tachycardia before the procedure. The AF ablation decision was made for eligible patients. The procedures were initiated by informing the patients beforehand in the presence of the anesthesia team. Two venous interventions were performed on the right femoral and left femoral regions of the patients. A 6 F decapolar catheter (Dynamic Deca, Bard Electrophysiology, Lowell, MA) was placed through the left femoral vein. One arterial intervention was made from the left femoral region of the patients. A 6 F pigtail catheter (Alvimedica) was placed in the aorta from the left femoral artery as a guide. Also, invasive arterial pressure monitoring from the left femoral artery, ECG monitoring and saturation monitoring were performed throughout the procedure. Transseptal puncture was achieved with the modified Brockenbrough technique (BRK-1, St. Jude Medical, Minnetonka, MN). An 8 F guiding transseptal sheath (Biosense Webster, CA) was placed in the left atrium. After the transseptal puncture, a 10,000 IU heparin bolus was administered. During the procedure, heparin boluses were administered to ensure that the activated clotting time was between 300 and 350 s. Later, the sheath was replaced with a 12F steerable catheter (FlexCath, Medtronic CryoCath, Minneapolis, USA). Pulmonary vein (PV) recordings were made with an Achieve recording catheter (Medtronic). Pulmonary vein isolation (PVI) was achieved with a single cryoablation balloon (Arctic Front, Medtronic CryoCath LP, Kirkland, Canada) in all patients. Occlusion was evaluated by injection of 50% diluted contrast into the pulmonary veins. Two freezing cycles of 240 s or single freezing cycle of 300 s were applied to each PV. At the end of the procedure, the PV current was re-evaluated with the Achieve catheter. Successful PVI was defined as the elimination or dissociation of all PV potentials recorded with the Achieve catheter. Direct palpation of the right hemidiaphragmatic movement was performed during phrenic nerve stimulation to prevent any phrenic nerve damage during the isolation of the right upper pulmonary vein.

Follow-up

All patients came for follow-ups at 1, 3, 6, 9, 12 months after discharge. 12-lead ECG was obtained in all follow-ups. The first 3-month period was accepted as a blanking period and arrhythmias during this period were not considered as recurrence. For the detection of AF recurrence, 72-hour Holter monitoring was performed in all cases at the 6th month. In 12-lead ECG and single-lead ECG, a single instance of > 30 s AF recording was considered a recurrence.

Statistical analysis

Variables were divided into two groups: categorical and continuous variables. The Kolmogorov-Smirnov test was used to evaluate whether continuous variables conformed to a normal distribution. Continuous variables were expressed as mean ± standard deviation (mean ± SD). Categorical variables were expressed as numbers and percentages. All analyses were performed using the IBM SPSS Statistics 22.0 statistical software package. Whether the distribution of continuous variables is normal or not was evaluated with the Kolmogorov-Smirnov test. Continuous variables in group data were expressed as mean ± standard deviation. Categorical variables were expressed as numbers and percentages. Continuous variables that showed normal distribution were compared using Student's *t* test, whereas the Mann-Whitney *U* test was used to compare differences between two independent groups when the dependent variable is either ordinal or continuous but not normally distributed. The chi-square (χ^2) test was used to compare categorical variables. The statistical significance level was set at $p < 0.05$.

Results

The study patients were divided into midazolam and fentanyl (conscious sedation) and propofol and midazolam (unconscious sedation) groups according to the anesthesia protocol. The study data were compared between these 2 groups.

The AF cryoablation procedure was successfully performed in all AF patients included in the study. Only 2 patients (1 patient in each group) had temporary phrenic nerve paralysis during the procedure. General anesthesia was administered to 6 patients (1 patient with conscious sedation and 5 patients with unconscious sedation) due to the need for non-invasive mechanical ventilation (NIMV). Among the complications related to sedation and the procedure, prolonged hypotension, prolonged hypoxia, prolonged recovery, pericardial effusion/tamponade, allergic complications and vascular complications were not observed in any of the patients. No anesthesia reversal treatment was administered to any of our patients. The study data were divided into two groups – conscious sedation and non-conscious sedation – and clinical, demographic, laboratory, echocardiography and periprocedural findings were compared. When the clinical, demographic, laboratory and echocardiographic data of the patients were compared according to the anesthesia groups, none of the parameters was found to be statistically significantly different (Table I). When the hemodynamic parameters of the periprocedural AF ablation process and the effects of anesthesia were examined according to the anesthesia groups of the patients, it was found that the minimum SaO_2 during AF ablation, SBP and DBP change and RASS score were significantly different between the groups (Table II). However, procedural time, fluoroscopy time, ASA score, NIMV requirement, basal SaO_2, and anesthesia were not significantly different between prolonged recovery groups (Table II). The minimum O_2 saturation during the procedure was significantly higher in the conscious sedation group. RASS score, SBP and DBP change were found to be significantly lower in the conscious sedation group (Table II). Procedure success and frequency of AF recurrence were not significantly different between the two groups (Table II).

Discussion

The main finding of our study is that conscious sedation is as effective as unconscious sedation in patients undergoing cryoablation for paroxysmal AF. AF ablation procedure time, success, and recurrence development

Table I. Clinical, demographic, laboratory and echocardiographic findings according to anesthesia group

Variable	Conscious sedation group (*n* = 124)	Unconscious sedation group (*n* = 118)	*P*-value
Age [years]	54.4 ±11.8	55.6 ±11.7	0.33
Sex (male/female)	66/58	62/56	0.51
Hypertension, *n* (%)	30 (24%)	35 (30%)	0.21
Diabetes mellitus, *n* (%)	11 (9%)	15 (13%)	0.11
Current smoker, *n* (%)	19 (15%)	17 (14%)	0.84
Hyperlipidemia, *n* (%)	15 (12%)	11 (9%)	0.23
Systolic blood pressure [mm Hg]	124 ±17	122 ±18	0.45
Diastolic blood pressure [mm Hg]	73 ±11	72 ±12	0.43
Pulse [bpm]	77 ±11	76 ±11	0.40
Body mass index [kg/m^2]	27.9 ±4.3	28.6 ±4.4	0.248
Hemoglobin [g/dl]	14.1 ±1.8	13.4 ±1.7	0.38
White blood cells [× 10^3/µl]	8.2 ±1.5	7.6 ±1.3	0.83
Aspartate aminotransferase [µ/l]	25.6 ±10.7	25.7 ±9.5	0.94
Alanine aminotransferase [µ/l]	22.5 ±9.9	22.2 ±10.2	0.82
Blood urea nitrogen [mg/dl]	31.1 ±10.4	30.9 ±10.9	0.98
Creatinine [mg/dl]	0.82 ±0.19	0.77 ±0.18	0.23
Uric aside	4.98 ±1.16	4.89 ±1.07	0.55
High-sensitivity C reactive protein [mg/dl]	0.54 ±0.42	0.63 ±0.31	0.17
Left atrial end-diastolic dimension [mm]	35.7 ±3.5	35.6 ±4.5	0.99
Left ventricular ejection fraction (%)	61.4 ±4.8	61.4 ±5.8	0.91

Table II. Periprocedural data during AF ablation according to anesthesia group

Variable	Conscious sedation group (*n* = 124)	Unconscious sedation group (*n* = 118)	*P*-value
Procedural time [min]	63.2 ±5.9	64.3 ±4.7	0.13
Fluoroscopy time [min]	30.6 ±2.9	31.2 ±2.4	0.07
ASA score [mm]	1.99 ±0.54	2.05 ±0.55	0.41
Basal O_2 saturation (%)	98.7 ±0.90	98.4 ±0.93	0.12
Minimum O_2 saturation (%)	93.6 ±2.21	92.4 ±1.96	< 0.001
Non-invasive mechanical ventilation, *n* (%)	1 (0.8%)	5 (4.2%)	0.10
Systolic blood pressure change [mm Hg]	13.6 ±3.3	18.1 ±4.79	< 0.001
Diastolic blood pressure change [mm Hg]	9.32 ±5.99	11.5 ±3.56	0.001
Richmond Agitation Sedation Scale	–0.77 ±1.76	0.19 ±1.52	< 0.001
Atrial fibrillation recurrence, *n* (%)	24 (19.4%)	23 (19.5%)	0.54
Prolonged recovery, *n* (%)	2 (1.6%)	5 (4.2%)	0.20

did not differ significantly between conscious sedation and unconscious sedation groups. However, the decreases in SBP, DBP and SaO_2 levels due to anesthetic agents during the procedure were smaller in conscious sedation than unconscious sedation, as we expected.

Anesthesia preference during AF ablation is determined by anesthesiology accessibility, anesthetist preference, center protocol and patient characteristics [15]. The choice of anesthesia during AF ablation is still controversial. Approximately 300 cryoablation procedures have been performed annually in our clinic for 10 years, and all procedures are carried out jointly with the anesthesia clinic.

There are 3 sedation strategies during AF ablation in the literature. These are: i) conscious sedation with fentanyl and midazolam, ii) unconscious sedation with propofol and midazolam, and iii) GA. A recent study compared sedation and GA preference in 351 patients who underwent persistent AF ablation [4]. In this study by Wang *et al.* [4], similar results were obtained between conscious sedation with fentanyl and midazolam and GA in terms of procedure time, success of the procedure and cost-effectiveness. A recent study compared the procedural efficacy, safety and duration of moderate sedation with fentanyl and midazolam compared to GA in patients who underwent AF cryoablation [11]. As a result of these studies, while the success and complication of the procedure were similar, it was reported that the total laboratory time was longer in patients who underwent GA. However, this study did not evaluate the hemodynamic and respiratory parameters during the procedure [11].

There are limited studies comparing conscious sedation to unconscious sedation for AF ablation [10, 16]. In one of these studies, it was reported that both methods can be used with similar procedure time and success [10]. In the same study, it was found that the development of hypoxemia was more common with propofol [10]. Similar to the study conducted by Tang *et al.* [10], in our study, it was found that hypoxia occurred more commonly during the procedure in patients who underwent unconscious sedation, similar to the previous study.

During AF ablation, SaO_2, electrocardiogram, intraarterial blood pressure and arterial blood gas are monitored by the anesthesiologist throughout the procedure. At the same time, the patient is managed by an electrophysiologist when complications and adverse events associated with sedation develop. The most important side effects of propofol, especially in high doses, are hypoxia and hypotension [10, 17–19]. Conscious sedation with the combination of midazolam and fentanyl, which is typically used as an analgesic, is preferred in less complex arrhythmias. This method may not be very useful in RF AF ablation. However, cryoablation is a relatively painless, less complex and short procedure compared to RF ablation. The number of studies on conscious sedation in AF cryoablation is limited [11]. Our study has some differences from previous studies in which anesthesia was evaluated in patients who underwent AF ablation. Only paroxysmal AF patients who underwent cryoablation were included in our study and the anesthesia preference was considered as conscious sedation and unconscious sedation. With conscious sedation, similar results in efficacy were obtained.

Limitations. Our study was a single-center, retrospective study which included 242 patients. More meaningful results could be obtained in a multi-center, prospective study with more patients. In our study, the parameters were only compared between conscious sedation and unconscious sedation groups; patients who had GA were not included in the study. If a GA group had been included, more meaningful results could have been obtained. Our study was carried out with patients with paroxysmal AF who underwent cryoablation; there were no patients who had persistent AF and underwent 3D RF. In our clinic, AF ablation with 3D RF is performed in HF patients with reduced EF (LVEF < 45%), and therefore patients with LVEF < 45% were not included in the study. Different results could be obtained especially in these patient groups. In our study, although fluoroscopy and procedure time were shorter in the conscious sedation group, there was no statistically significant difference between the two groups. If more patients had been studied, the procedure and fluoroscopy time could have been significantly shorter in the conscious sedation group. Finally, it would have been better for our study to evaluate the N-terminal pro-B-type natriuretic peptide level, which is especially associated with disease recurrence and cardiac hemodynamics in patients with AF ablation [20].

Conclusions

In our study, it was found that conscious sedation with the combination of midazolam and fentanyl during AF cryoballoon ablation was applied with similar success and recurrence rates as when using unconscious sedation with propofol and midazolam. In conclusion, conscious sedation is a safe and effective anesthesia method that may be preferred in cases where cryoablation is planned for paroxysmal AF.

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Ethical approval

The study was conducted according to the recommendations of the Human Subjects Biomedical Research Helsinki Declaration, and the protocol was approved by the institutional ethics committee. Written consent forms were explained, and all patients were included after written informed consent was obtained.

Conflict of interest

The authors declare no conflict of interest.

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