Journal of The Cardiovascular Thoracic Anaesthesia and Intensive Care Society

GKDA Derg 2022;28(1):97-103
DOI: 10.14744/GKDAD.2022.74508

Research Article / Araştırma

Deep Sedation and Patient Safety in Pediatric Patients Undergoing Radiofrequency Catheter Ablation: A Prospective Study

Radyofrekans Kateter Ablasyon Uygulanan Pediyatrik Hastalarda Derin Sedasyon ve Hasta Güvenliği: Bir Prospektif Çalışma

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ABSTRACT

Objectives: There is no globally accepted anesthetic method in pediatric cases undergoing cardiac catheterization. The purpose of anesthetic management of these patients includes adequate analgesia, sedation, and immobility, with minimal depression of cardiac and respiratory functions. In the present study, we analyzed how the propofol-ketamine mixture affects the hemodynamics, sedation level, and recovery period in these patients.

Methods: We retrospectively evaluated the data of the pediatric patients who had radiofrequency catheter ablation in the electrophysiology laboratory from July 2019 to October 2019 at our institution. Intraoperative heart rate (HR), mean arterial blood pressure, peripheral oxygen saturation, the amount of end-tidal carbon dioxide, BIS value, and complications were noted.

Results: There were 113 patients in the study. More than 20% increase in HR at the 5th min of the procedure was seen in 21 patients ($p<0.001$). More than 20% HR increase was observed in 11 patients at the 30th min of the procedure ($p<0.05$). The mean end-tidal CO_2 is 37.8±1.86 (35-40). After the 5th min, the mean BIS value is under 40. The most observed complication is increase in secretion.

Conclusion: The present research shows that in pediatric cases undergoing cardiac catheterization, the combination of ketamine with propofol maintains optimal mean arterial pressure and HR without prolonging the recovery period.

Keywords: BIS index, deep sedation, non-invasive end-tidal carbon dioxide measuring, pediatrics, radiofrequency catheter ablation

ÖZ

Amaç: Radyofrekans kateter ablasyonu yapılan pediatrik olgularda kabul görmüş standart bir anestezi yöntemi yoktur. Bu hastaların anestezi yönetiminin amacı, kalp ve solunum fonksiyonlarında minimal depresyona neden olurken yeterli analjezi, sedasyon ve hareketsizliği sağlayabilmektir. Bu çalışmada, propofol-ketamin kombinasyonunun bu hastalarda hemodinamiyi, sedasyon düzeyini ve derlenme süresini nasıl etkilediği incelendi.

Yöntem: Temmuz 2019-Ekim 2019 tarihleri arasında kurumumuzda elektrofizyoloji laboratuvarında radyofrekans kateter ablasyon yapılan çocuk hastaların verileri prospektif olarak toplandı. Hastaların demografik verileri, intraoperatif kalp hızı, ortalama arteriyel kan basıncı, periferik oksijen satürasyonu, end-tidal CO_2 değeri, bispektral indeks (BIS) değeri ve komplikasyonlar kaydedildi.

Bulgular: Çalışmaya 113 hasta alındı. Yirmi bir hastada işlemin beşinci dakikasında kalp hızında %20'den fazla artış görüldü ($p<0,001$). On bir hastada işlemin 30. dakikasında %20'den fazla kalp hızı artışı gözlendi ($p<0,05$). Ortalama end-tidal CO_2 değeri 37,8±1,86 idi (35-40). Beşinci dakikadan sonra ortalama BIS değeri 40'ın altındaydı. En sık görülen komplikasyon sekresyonlarda artıştı.

Sonuç: Bu araştırma, radyofrekans kateter ablasyonu uygulanan pediatrik olgularda, ketamin-propofol kombinasyonunun, derlenme süresini uzatmadan optimal ortalama arter basıncı ve kalp hızını koruduğunu göstermektedir.

Anahtar sözcükler: BIS indeksi, derin sedasyon, non-invaziv end-tidal karbondioksit ölçümü, pediatri, radyofrekans kateter ablasyon

Please cite this article as: "Ferhatoğlu SY, Ballı Ş, Kudsioğlu T. Deep Sedation and Patient Safety in Pediatric Patients Undergoing Radiofrequency Catheter Ablation: A Prospective Study. GKDA Derg. 2022;28(1):97-103".

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Submitted Date: February 06, 2022 **Accepted Date:** February 09, 2022 **Available Online Date:** February 26, 2022

Introduction

Radiofrequency catheter ablation (RFCA) is a safe and practical treatment method for pediatric cases with congenital health diseases.[1] Thus, RFCA is being increasingly performed in this patient group. There are still additional points to deal with in pediatric cases than in adult cases. In particular, sedation anesthesia is required in most pediatric patients.[2]

Arterial gas sampling is the best way to assess carbon dioxide levels, which is the most satisfactory way to evaluate alveolar ventilation. Yet, arterial blood sampling is not easy in the pediatric population. Therefore, end-tidal carbon dioxide ($ETCO_2$) monitoring through capnograph, a continuous and non-invasive method of measuring carbon dioxide, has been accepted as a practical method to monitor carbon dioxide levels. However, many of these devices can estimate $ETCO_2$ only in intubated cases.[2,3] However, newer technology capnography devices can continuously scan $ETCO_2$ levels non-invasively through a nasal sampling line at the patient's bedside,[4,5] which eases to anesthetic management of the pediatric patient population.

Although propofol provides smooth anesthesia induction with prompt recovery, it may cause depression in cardiac and respiratory functions, poses considerable stress in pediatric cardiac cases undergoing RFCA.[6] On the other hand, another drug commonly applied in cardiac catheterization laboratories is ketamine,[7] which may cause vital problems such as hypertension and tachycardia, psychotomimetic effects, and prolonged recovery time.[8] Investigations have demonstrated that a mixture of propofol with ketamine limits propofol cardiac and respiratory side effects and the psychotomimetic side effects of ketamine with sufficient sedation and analgesia.[9,10]

In the present study, we analyzed how the propofol-ketamine combination influences the hemodynamics, sedation level, and recovery period in pediatric cases undergoing RFCA.

Methods

We prospectively collected the data of the pediatric patients (0-16 years) who had RFCA in the electrophysiology laboratory from July 2019 to October 2019 at Dr. Siyami Ersek Cardiothoracic Surgery Training and Research Hospital, Istanbul.

Exclusion Criteria

One case was excluded from the study protocol because of hemodynamic instability, and the RFCA was performed under general anesthesia.

Pre-operative Evaluation

Demographics, type of arrhythmia, chronic diseases, physical examination, complete blood count, kidney and liver function tests, and hemostasis parameters were evaluated.

Perioperative Evaluation

The anesthesia drugs and doses, intraoperative heart rate (HR), mean arterial blood pressure (MAP), peripheral oxygen saturation (SpO_2), Ramsey sedation score (Table 1), time of RFCA, and complications were noted. The amount of $ETCO_2$ measured by capnography (Capnostream™, Covidien®, U.S.A.). In addition, bispectral index monitoring (BIS) (BIS monitor™, Covidien®, U.S.A.) was conducted, and we documented the baseline value (Table 2).

Recovery Period Follow-up

All cases were transferred to the recovery room following the completion of the cardiac catheterization and were followed up with vital signs and the Steward modified score (Table 3). When the score becomes 6, the patient is transferred to the clinic.

Anesthesia Technique

The premedication was utilized by administering midazolam (DORMICUM®, Deva Ilac, Istanbul, Turkey) 0.05 mg/kg intravenously before the procedure. Suppose the parenteral way is not available intranasal midazolam 0.3 mg/kg administered. After monitoring the patients, the induction was delivered with 1 mg/kg intravenous propofol (Propofol-PF %1 200 mg/20 ml®, Polifarma Ilac, Istanbul, Turkey) and 1 mcg/kg fentanyl (Talinat 0.1 mg/2 ml®, Vem Ilac, Istanbul, Tukey).

Table 1. Ramsey sedation score

1. Nervous, agitated, and/or restless
2. Cooperative, oriented, quite patient
3. Only obeying the orders
4. Sleeping, hitting the glabella, and responding to a high voice suddenly
5. Sleeping, hitting the glabella, and responding to high voice slowly
6. No response to any of these stimulations.

Table 2. Bispectral index

Consciousness	Score
No brain activity	0
Burst suppression	1-20
Deep hypnotic state	20-40
General anesthesia	41-66
Responds to loud commands	67-85
Responds to normal voice	86-100

Table 3. Modified Steward scoring system

Evaluated parameters	Score
Consciousness	
Awake	3
Responds to verbal stimuli	2
Responds to tactile stimuli	1
Not responding	0
Airway	
Cough on command or cry	2
Maintains good airway	1
Requires airway assistance	0
Motor	
Moves limbs purposefully	2
Non-purposeful movement	1
Not moving	0

Then, propofol 50-60 mcg/kg/min and ketamine 20-30 mcg/kg/min infused during the procedure. Sedation level was evaluated with Ramsey's sedation score. When the sedation score reached 6, the operation was initiated.

Ethical Approval

All procedures performed in studies involving human participants were following the Helsinki Declaration and its later amendments or comparable ethical standards. Furthermore, the hospital administration committee approved the study protocol.

Informed Consent

Informed consent was obtained from legal guardians of all participants included in the study.

Statistical Analysis

Demographics and categorical data were defined as absolute or frequencies. Continuous variant data were presented as mean values and standard deviation. Fisher's exact test was applied to analyze the qualitative data. We studied the data by the Number Cruncher Statistical System-2007® (USA) computer software. $p<0.05$ was considered statistically significant.

Results

There were 113 patients in the study. Fifty-eight of them were boys and 55 were girls. The mean age of the study population was 13.5±3.33 (range 4.5-22). There were six patients between 3 and 6 years old, and other patients were between 6 and 16 years old. There were no patients under 3 years old. The patient characteristics are shown in Table 4.

Table 4. Patient characteristics and arrhythmia type

Clinical features	Male (n=58)	Female (n=55)
Age (years), Mean±SD (min-max), n (%)	13.5±3.3 (3-16)	13.5±3.3 (4.5-16)
0-1 years	0 (0)	0 (0)
1-3 years	0 (0)	0 (0)
3-16 years	58 (51.3)	55 (48.7)
Weight (kg), Mean±SD (min-max)	56.1±20.9 (17-100)	53.1±17.5 (19-98)
Chronic diseases, n (%)		
Asthma	4 (6,9)	2 (3.6)
Atopic dermatitis	2 (3.4)	1 (1.8)
Thalassemia minor	1 (1.7)	0 (0)
Hashimoto thyroiditis	0 (0)	1 (1.8)
AVSD	0 (0)	1 (1.8)
Arrhythmia type, n (%)		
Wolf-Parkinson-White	26 (50)	6 (10.1)
Atrial fibrillation	1 (1.7)	0 (0)
AV nodal reentrant tachycardia	10 (17.2)	25 (45.4)
Electrophysiology study	7 (12)	8 (14.5)
Fascicular VT	1 (1.7)	0 (0)
Focal atrial tachycardia	1 (1.7)	2 (3.6)
Concealed accessory pathway	0 (0)	1 (1.8)
Supraventricular tachycardia	9 (15.5)	5 (9.1)
Ventricular extrasystole	3 (5.2)	6 (10.1)
Ventricular tachycardia	1 (1.7)	1 (1.8)

*AVSD: Atrioventricular septal defect; AV: Atrioventricular; VT: Ventricular tachycardia.

Table 5. Hemodynamic parameters

Evaluated parameters	0th min† (n=113)	5th min† (n=113)	30th min† (n=113)	60th min† (n=113)	120th min† (n=105)	180th min† (n=45)	240th min† (n=7)	300th min (n=1)	p
HR‡ mean±SD (min-max)	79.2±6.8 (68-98)	80.1±8.5 (66-110)	77.9±6.7 (66-96)	77.5±6.5 (67-94)	76.9±6 (65-94)	78.3±5.6 (67-88)	70.7±4.3 (67-78)	69*	>0.05
$ETCO_2$‡ mean±SD (min-max)	34.9±2.8 (31-47)	33.2±2.1 (30-45)	34.7±2.2 (30-42)	35.4±2.7 (29-43)	36.2±1.1 (31-44)	36±1.9 (32-43)	34.8±2.6 (30-46)	32*	>0.05
MAP‡ mean±SD (min-max)	93.6±5.4 (86-98)	87.6±7.1 (80-97)	85.2±2.9 (81-88)	79.1±0.9 (84-96)	82.5±7.9 (85-94)	86.3±2.7	78.2±5.7 (79-80)	81*	>0.05
BIS‡ mean±SD (min-max)	42±3.2 (35-46)	42±3.2 (32-47)	38±4.7 (36-44)	32±2.8 (30-37)	34±1.7 (31-36)	32±3.6 (30-37)	30±2.1 (29-38)	34*	>0.05

‡HR: Heart rate; †: Time after the procedure begins; *: Since one case reached the 300th min, there is no SD calculation or min-max value; $ETCO_2$: End-tidal carbon dioxide; MAP: Mean arterial pressure; BIS: Bispectral index monitoring.

Table 6. Changes in hemodynamic parameters during the procedure

Evaluated parameters	5th min† (n=113)	30th min† (n=113)	60th min† (n=113)	120th min† (n=105)	180th min† (n=45)	240th min† (n=7)	300th min (n=1)	p
HR‡ increase> 20%‡‡, n (%)	21	0	4	7	0	0	0	<0.001**
HR‡ decrease> 20%‡‡, n (%)	1	11	2	1	0	0	0	<0.05*
MAP‡ increase> 20%‡‡, n (%)	1	0	2	1	0	0	0	-
MAP‡ decrease> 20%‡‡, n (%)	7	18	28	36	8	2	1	>0.05

‡HR: Heart rate; ‡‡: The data compared with initial heart rate and mean arterial pressure, †: Time after the procedure begins: *: p<0.05; **: p<0.001; MAP: Mean arterial pressure.

The most common type of arrhythmia in patients was AVNRT and WPW.

There is no significant change seen in HR, $ETCO_2$, MAP, and BIS parameters during RFCA procedure (Table 5). More than 20% increase in HR at the 5th min of the procedure was seen in 21 patients (p<0.001). More than 20% HR increase was observed in 11 patients at the 30th min of the procedure (p<0.05) (Table 6).

The mean $ETCO_2$ is 37.8±1.86 (35-40), and the number of patients who had procedure time longer than 4 h is eight. We did not observe severe complications in any of the patients; the most observed complications are increase in secretion (n=10), allergy (n=2), agitation (n=2), and nausea and vomiting (n=2) are most observed complications.

Discussion

The present research demonstrates that in pediatric cases undergoing RFCA, the mixture of ketamine with propofol maintains optimal MAP and HR without prolonging the recovery period.

Several studies showed that sedation anesthesia is generally applied in pediatric cases with congenital heart diseases in cardiac catheterization laboratories. In the present analysis, we specifically applied sedation anesthesia, which has essential advantages of spontaneous breathing, fast recovery, and advancement of venous return. Although general anesthesia with mechanical ventilation controlled breathing allows the control of $PaCO_2$, regulates pulmonary vascular resistance, does not have the risk of airway obstruction, and also the depth of anesthesia is easily regulated and deep enough to blunt the reflexes to painful stimuli and ensure immobility, it is not the preferred method in pediatric cases with congenital heart diseases.[11-13] Positive pressure ventilation decreases the venous return, alters the flow across valves and shunts, reduces the metabolic rate, diminishes oxygen consumption, and further alters hemodynamics. Therefore, most anesthesiologists favor sedation anesthesia for this patient group.[14] However, as an opposing view, many investigations also documented the efficacy and safeness of continuous deep sedation in pediatric cases with congenital heart diseases.[15-19] However, the significant difficulty is desaturation caused by unstable respiration and airway obstruction due to a retracted tongue root. Some investigations suggested assisted ventilation or an anesthesiologist's close attendance during the procedures to avoid these significant problems. However, these services need money, time, and the support of an anesthesiologist, and not all institutions can afford these preparations.

Ketamine is a known anesthetic agent that has been utilized in pediatric RFCA cases. Its advantages are suitable sedation and analgesia by preserving the airway reflexes and respiratory system. Nevertheless, prolonged recovery time and emergent delirium are possible weaknesses of ketamine usage in the pediatric population.[13] Propofol is a practical choice for pediatric RFCA. Propofol infusion with fentanyl analgesia is associated with a shorter recovery period than ketamine/midazolam combination in pediatric cardiac catheterization.[20] Similar to our protocol, Kogan et al.[21] administrated ketamine/propofol mixture for anesthetic induction and maintained sedation and anesthesia by propofol and ketamine infusion. In addition, Tosun et al.[22] assessed the results of dexmedetomidine/ketamine and propofol/ketamine mixtures on hemodynamics, sedation level, and the recovery period in the pediatric population experiencing cardiac catheterization. They showed that the dexmedetomidine/ketamine mixture is not better than the propofol/ketamine combination in pediatric patients undergoing elective cardiac catheterization. Similar to the outcomes of Tosun et al., we showed that propofol/ketamine combination usage in pediatric cases that underwent RFCA had no severe adverse effect on HR and MAP. We believe that this combination is almost ideal for deep sedation with adequate analgesia while preserving hemodynamics and respiratory functions in pediatric patients undergoing RFCA.

There is increasing interest in using $ETCO_2$ monitoring outside the operating room.[23] Anesthetic guidelines debate the benefit of end-tidal capnography. The American Society of Anesthesiologists and the European Board of Anesthesiology guidelines obligate continuous follow-up of $ETCO_2$ during sedation.[24] The Great Britain and Ireland College of Anesthetists suggests capnography should be immediately available for any patient undergoing sedation.[25] Clinical data regarding $ETCO_2$ monitoring during moderate to deep sedation are little. The review of Conway et al.[26] showed a decrease in hypoxic episodes but no difference in other results, including assisted ventilation. A prospective randomized study indicated no difference in capnography versus standard pulse oximetry monitoring regarding hypoxia.[27] In the lack of further proof, the use of $ETCO_2$ monitoring will generally be dictated by guidelines. Transcutaneous CO_2 monitoring more precisely shows arterial CO_2 than $ETCO_2$; however, it does not directly display apnea occurrences. Since our pediatric catheter laboratory, we monitored the patients using a capnography pediatric catheter laboratory.

The BIS is one of the several technologies utilized to observe depth of anesthesia. BIS monitors are used in supplementing Guedel's classification system for defining the depth of anesthesia. Titrating anesthetic drugs to a specific BIS during general anesthesia allow the anesthesiologist to modify the dose of anesthetic agent to the patient's needs, possibly resulting in a faster emergence from anesthesia.[28] BIS monitoring can objectively inform the anesthesiologist about the patient's sedation status.[29] Our study evaluated the sedation depth using the BIS. The mean BIS was 34.6±4.64 in the present research. Our sedation depth was sufficient for the RFCA, and the cardiologist was comfortable during the procedure.

Although diagnostic procedures in the pediatric population usually do not carry high risk, the necessity of sedation and immobilization makes these procedures riskier.[30] Complication rates in pediatric anesthesia range between 6% and 20.1% in the literature, and the most observed complications are hypotension and hypoxemia caused by insufficient sedation and SpO_2.[31,32] In the presented research, the complication rate was 14.1%; however, all the observed complications were minor.

Limitations of the Study

The main limitation of the present research is being a single-center analysis with small sample size.

Conclusion

Since the propofol-ketamine combination does not carry a higher risk of hypoxemia and provides hemodynamic stability, it seems a safe and practicable choice to maintain deep sedation and analgesia in pediatric cases undergoing RFCA procedures. More randomized controlled investigations are required to verify our outcomes.

Disclosures

Ethics Committee Approval: The study was approved by The Dr. Siyami Ersek Cardiothoracic Surgery Training and Research Hospital Ethics Committee (Date: 05/06/2020, No: 28001928-604-01.01).

Informed Consent: Written informed consent was obtained from all patients.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Financial Disclosure: The authors declared that this study has received no financial support.

Authorship Contributions: Concept – S.Y.F.; Design – S.Y.F.; Supervision – Ş.B.; Fundings – S.Y.F.; Materials – S.Y.F., Ş.B.; Data collection &/or processing – S.Y.F.; Analysis and/or interpretation – S.Y.F.; Literature search – S.Y.F.; Writing – S.Y.F.; Critical review – T.K.

Etik Kurul Onayı: Çalışma Dr. Siyami Ersek Göğüs Kalp ve Damar Cerrahisi Eğitim ve Araştırma Hastanesi Etik Kurulu tarafından onaylandı (Tarih: 05/06/2020, Numara: 28001928-604-01.01).

Hasta Onamı: Hastalardan yazılı onam alınmıştır.

Hakem değerlendirmesi: Dışarıdan hakemli.

Çıkar Çatışması: Çıkar çatışması bulunmamaktadır.

Finansal Destek: Yazarlar bu çalışmanın herhangi bir finansal destek almadığını beyan etmişlerdir.

Yazarlık Katkıları: Fikir – S.Y.F.; Tasarım – S.Y.F.; Denetmeler – Ş.B.; Kaynaklar – S.Y.F.; Malzemeler – S.Y.F., Ş.B.; Veri Toplanması ve/veya İşlemesi – S.Y.F.; Analiz ve/veya Yorum – S.Y.F.; Literatür Taraması – S.Y.F.; Yazıyı Yazan – S.Y.F.; Eleştirel İnceleme – T.K.

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