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Application of cipepofol combined with alfentanil in catheter ablation of atrial fibrillation

ZHAO Wenyu, ZHANG Yuan, ZHANG Tongnan, WANG Haifeng

Department of Anesthesiology, Heze Hospital of Shandong Provincial Hospital, Heze Municipal Hospital, Heze, Shandong 274000, China

Corresponding author: ZHAO Wenyu, E-mail: zhaowenyu202411@163.com

Abstract: **Objective** To investigate the efficacy of cipepofol combined with alfentanil in catheter ablation for atrial fibrillation, and to compare the effects of cipepofol and propofol on patients circulatory and respiratory functions as well as adverse reactions. **Methods** Seventy patients who underwent catheter ablation for atrial fibrillation at Heze Municipal Hospital from May 2022 to May 2024 were selected as the study subjects. They were divided into a cipepofol group（*n*= 35）and a propofol group（*n*=35）using a random number table method. The cipepofol group received intravenous induction with 0.2 mg/kg cipepofol and 3 μg/kg alfentanil, while the propofol group received intravenous induction with 1 mg/kg propofol and 3 μ g/kg alfentanil. Surgery-related indicators and the incidence of adverse reactions were compared. Mean arterial pressure（MAP）, heart rate（HR）, saturation of peripheral oxygen（SpO2）, and bispectral index （BIS）values were observed at the following time points: upon entering the operating room（T0）, at the start of surgery （T1）, at the start of radiofrequency ablation（T2）, 30 min after radiofrequency ablation（T3）, and at the end of surgery （T4）. **Results** The additional dose of alfentanil in the cipepofol group was lower than that in the propofol group [（3.11± 0.40）μg *vs*（3.94±0.24）μg, *t*=10.487, *P*<0.01]. There was no statistically significant difference in recovery time, time to full alertness, or time to orientation recovery between the two groups（*P*>0.05）. At T1 and T2, the MAP in the cipepofol group was higher than that in the propofol group（*P*<0.05）, while no statistically significant difference was observed at other time points（*P*>0.05）. There was no statistically significant difference in HR and SpO2 between the two groups（*P*>0.05）. The BIS values in both groups showed a trend of first decreasing and then increasing. At T1, T2, and T3, the BIS values in the cipepofol group were lower than those in the propofol group, with greater fluctuations（*P*< 0.05）. The incidence of injection pain [8.57%（3/35）*vs* 57.14%（20/35）, $\chi 2$=18.714, *P*<0.01] and intraoperative respiratory depression [28.57%（10/35）*vs* 54.29%（19/35）, $\chi 2$=4.769, *P*=0.029] in the cipepofol group was lower than that in the propofol group. **Conclusion** Cipepofol combined with alfentanil provides reliable sedation for catheter ablation of atrial fibrillation, with effects similar to those of propofol. Additionally, it has less impact on circulatory and respiratory functions, along with a lower incidence of injection pain and respiratory depression.

Keywords: Atrial fibrillation; Catheter ablation of atrial fibrillation; Cipepofol; Alfentanil; Propofol; Respiratory depression; Sedation

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Atrial fibrillation, abbreviated as AF, is a severe disorder of atrial electrical activity, whose main hazards include heart failure and thromboembolic events such as acute cerebral infarction [1]. Surveys show that the incidence of AF in adults is approximately 3%, and it can reach as high as 6% in the elderly over 65 years old, which seriously affects patients' quality of life and increases the burden on families and society [2]. In recent years, studies have confirmed the efficacy and safety of catheter ablation for AF, which has become a first-line treatment strategy for the disease [3]. The main anesthesia methods for AF catheter ablation are general anesthesia or local anesthesia combined with sedation. Among them, general anesthesia can provide patients with a better surgical experience, effectively reduce intraoperative model deviation, and promote the recovery of pulmonary vein potential after surgery [4]. However, general anesthesia management is relatively complex and time-consuming for preparation. Moreover, most hospitals in China face the problem of a serious shortage of anesthesiologists [5]. Therefore, performing AF catheter ablation under local anesthesia combined with sedation has become the preferred anesthesia option in most domestic hospitals. Alfentanil is a rapid-acting opioid analgesic with fast onset, definite analgesic effect, moderate sedative effect, and mild inhibitory effect on the respiratory and circulatory systems [6]. Cipepofol is a new type of short-acting γ-aminobutyric acid receptor agonist. Based on propofol, a cyclopropyl group is introduced to form a chiral structure, which can enhance the stereoscopic effect [7]. Cipepofol has a sedative effect similar to propofol, but with higher safety and more stable circulatory and respiratory functions, and it has obvious advantages in improving injection pain [8]. At present, cipepofol has been widely used in digestive endoscopy, bronchoscopy and other examinations, but there are few reports on its application in AF catheter ablation. Based on the above background, this study aims to analyze the application effect of cipepofol combined with alfentanil in AF catheter ablation.

1 Materials and Methods

1.1 General Information

This prospective study selected 70 patients who underwent AF catheter ablation in Heze Municipal Hospital from May 2022 to May 2024 as the research subjects Inclusion criteria:(1) Meeting the indications for AF catheter ablation;(2) Receiving AF catheter ablation for the first time;(3) Aged over 18 years old;(4) American Society of Anesthesiologists (ASA) physical status classification I - II;(5) Ineffective after active conservative medical treatment;(6) Patients signed the informed consent form. Exclusion criteria:(1) Long-term use of analgesics or psychotropic drugs;(2) Hypersensitivity to cipepofol, propofol and other study-related drugs;(3) Complicated with severe lung diseases, abnormal liver and kidney functions, cardiovascular and central nervous system diseases;(4) History of brain injury and increased intracranial pressure;(5) History of alcohol addiction. The 70 patients were divided into the cipepofol group (n=35) and the propofol group (n=35) using a random number table method. There were no statistically significant differences in general data between the two groups (P>0.05), indicating good comparability (see **Table 1**). This study was approved by the Medical Ethics Committee of Heze Municipal Hospital (approval number: 2024-KY006).

Tab.1 Comparison of baseline data between the two groups(n=35)

Item	Cipepofol group	Propofol group	χ^2/t value	P value
Age (years)	58.06±4.76	58.60±4.68	0.481	0.632
Male [case(%)]	23(65.71)	19(54.29)	0.952	0.329
Body mass (kg)	63.41±6.95	64.03±6.82	0.377	0.708
Height (cm)	161.45±9.70	159.33±9.82	0.912	0.365
Smoking history[case(%)]	12(34.29)	14(40.00)	0.245	0.621
Drinking history[case(%)]	6(17.14)	5(14.29)	0.108	0.743
ASA grade[case(%)]			0.230	0.631
I	20(57.14)	18(51.43)		
II	15(42.86)	17(48.57)		
Diabetes [case(%)]	4(11.43)	5(14.29)	0.128	0.721
Hypertension[case(%)]	12(34.29)	13(37.14)	0.062	0.803

1.2 Methods

All patients in both groups fasted for 6 - 8 hours before surgery. After entering the operating room, electrocardiographic monitoring and electrophysiological monitoring were connected. Routine monitoring of mean arterial pressure (MAP), heart rate (HR), saturation of peripheral oxygen (SpO_2) and electroencephalogram was performed, and intravenous access was established. Patients in both groups received nasal catheter oxygen inhalation at a flow rate of 4 L/min before surgery until full recovery of consciousness after surgery.

1.2.1 Anesthesia Induction in the Cipepofol Group

Cipepofol 0.2 mg/kg and alfentanil 3 μg/kg were intravenously injected. Immediately after the initial dose administration, the Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale was used to evaluate the sedation status. Surgery was performed immediately when the score was ≤ 1. If the MOAA/S score was > 1 at 1 min after the completion of the initial dose administration, an additional dose of cipepofol 0.2 mg/kg was required, with the administration time ≥ 30 s. Subsequently, cipepofol was continuously infused at a rate of 1 mg/(kg·h) until the end of the surgery. If the MOAA/S score was still > 1 after the first additional dose of cipepofol, propofol was used for rescue induction.

1.2.2 Anesthesia Induction in the Propofol Group

Propofol 1 mg/kg and alfentanil 3 μg/kg were intravenously injected. The anesthesia status of patients was evaluated according to the MOAA/S scale, and surgery was performed immediately when the score was ≤ 1. If the MOAA/S score was > 1 at 1 min after the completion of the initial dose administration, an additional dose of propofol 1 mg/kg was required, with the administration time ≥ 30 s. Subsequently, propofol was continuously infused at a rate of 4 mg/(kg·h) until the end of the surgery.

1.2.3 Anesthesia Maintenance

During the operation, patients in both groups received continuous intravenous infusion of alfentanil at a rate of 0.5 μg/(kg·min). If patients had body movement, alfentanil 3 μg/kg was intravenously injected. When the dose of alfentanil exceeded the maximum administration dose but the analgesic effect was still unsatisfactory, the anesthesia method was changed to tracheal intubation general anesthesia. If patients had respiratory depression, jaw thrust intervention was given. If there was no obvious relief, mask positive pressure oxygenation was performed, and mechanical ventilation was applied if necessary. If the intraoperative systolic blood pressure decreased to 20% below the baseline value or < 80 mmHg, ephedrine 3 - 6 mg was intravenously injected.

1.3 Evaluation Indicators

The following indicators were recoded. (1) The additional dose of alfentanil, awakening time, full recovery time and orientation recovery time in both groups.(2) The MAP, HR and SpO_2 at the time of entering the operating room (T0), the start of surgery (T1), the start of radiofrequency ablation (T2), 30 min after radiofrequency ablation (T3) and the end of surgery (T4) in both groups.(3) The bispectral index (BIS) values at T0, T1, T2, T3 and T4 in both groups.(4) The occurrence of adverse reactions such as intravenous injection pain, respiratory depression and bradycardia in both groups.

1.4 Statistical Methods

Data analysis was performed using SPSS 25.0 software. Count data were expressed as cases (%), and the chi-square test was used for inter-group comparison. Measurement data conforming to the normal distribution were expressed as $\bar{x}\pm s$, and the independent samples t-test was used for inter-group comparison. Repeated measurement data were analyzed by repeated measures analysis of variance, and the LSD-t test was used for pairwise comparison. A P < 0.05 was considered statistically significant.

2 Results

2.1 Comparison of Surgical Indicators between the Two Groups

The additional dose of alfentanil in the cipepofol group was significantly lower than that in the propofol group (P<0.05). There were no statistically significant differences in awakening time, full recovery time and orientation recovery time between the two groups (P>0.05) (see **Table 2**).

Tab.2 Comparison of surgical indicators between the two groups (n=35, $\bar{x}\pm s$)

Group	Additional Dose of Alfentanil (μg)	Awakening Time (min)	Full Recovery Time (min)	Orientation Recovery Time (min)
Cipepofol group	3.11±0.40	7.51±1.54	9.89±3.14	11.00±2.04
Propofol group	3.94±0.24	7.65±1.63	10.60±3.14	10.95±1.96
t value	10.487	0.369	0.946	0.105
P value	<0.001	0.713	0.348	0.917

2.2 Comparison of MAP, HR, SpO_2 and BIS at Different Time Points between the Two Groups

For MAP comparison between the two groups, there were statistically significant differences in inter-group, time and interaction effects (P<0.05). For HR and SpO_2 comparison, there were no statistically significant differences in inter-group, time and interaction effects (P>0.05). At T1 and T2, MAP in the cipepofol group was higher than that in the propofol group (P<0.05). At T0, T3 and T4, there were no statistically significant differences between the two groups (P>0.05). The BIS values of both groups showed a trend of first decreasing and then increasing, with statistically significant differences in inter-group, time and interaction effects (P<0.01). At T1, T2 and T3, the BIS values in the cipepofol group were lower than those in the propofol group (P<0.05), and the fluctuation range was larger than that in the propofol group (see **Table 3**).

2.3 Comparison of Adverse Reactions between the Two Groups

The incidence rates of intravenous injection pain and intraoperative respiratory depression in the cipepofol group were lower than those in the propofol group (P<0.05). There were no statistically significant differences in the incidence rates of hypotension, postoperative nausea and vomiting, intraoperative body movement, bradycardia and hypoxemia between the two groups (P>0.05) (see **Table 4**).

Tab.3 Comparison of MAP, HR, SpO2, and BIS between the two groups at different time points (n=35, $\bar{x}\pm s$)

Time	MAP(mmHg)		HR(beats/min)		SpO_2(%)		BIS	
	Cipepofol group	Propofol group	Cipepofol group	Propofol group	Cipepofol group	Propofol group	Cipepofol group	Propofol group
T0	97.94±5.58	98.03±5.25	82.40±4.81	82.11±4.60	97.90±0.90	98.00±0.94	95.09±2.39	95.83±1.69
T1	92.17±5.25[a]	86.06±5.95	77.40±4.82	76.51±4.75	96.23±1.85	96.20±1.98	43.14±4.29[a]	50.49±4.58
T2	88.06±4.66[a]	83.00±4.52	74.40±4.99	73.94±5.20	95.71±1.81	95.40±1.96	39.17±4.26[a]	44.69±4.60
T3	95.34±6.84	96.51±6.81	80.37±5.59	79.37±5.59	97.03±1.18	97.20±1.26	52.00±7.32[a]	57.09±7.45
T4	98.00±5.58	98.03±5.43	81.34±6.11	80.34±6.51	97.71±1.07	97.86±0.97	66.54±8.31	68.83±7.19
Time Effect	F=72.156,P<0.001		F=2.186,P=0.289		F=2.379,P=0.266		F=46.860,P<0.001	
Group Effect	F=6.264,P<0.001		F=0.069,P=0.991		F=0.330,P=0.807		F=1 023.879,P<0.001	
Interaction Effect	F=10.152,P=0.002		F=1.565,P=0.215		F=0.012,P=0.912		F=3.900,P=0.011	

Note: Compared with the propofol group at the same time point, [a]P<0.05.

Tab.4 Comparison of the incidence of adverse reactionsbetween the two groups [n=35, case (%)]

Adverse Reaction	Cipepofol group	Propofol group	χ^2 value	*P* value
Intravenous injection pain	3 (8.57)	20 (57.14)	18.714	<0.001
Hypotension	12 (34.29)	11 (31.43)	0.065	0.799
Intraoperative respiratory depression	10 (28.57)	19 (54.29)	4.769	0.029
Postoperative nausea and vomiting	1 (2.86)	2 (5.71)	0.348	0.555
Intraoperative body movement	10 (28.57)	13 (37.14)	0.583	0.446
Bradycardia	7 (17.14)	4 (11.43)	0.971	0.324
Hypoxemia	4 (11.43)	10 (28.57)	3.214	0.073

3 Discussion

AF catheter ablation is a minimally invasive procedure for patients. However, repeated energy release by the catheter during ablation can induce a burning sensation in the myocardium, which is likely to cause anxiety and body movement in patients. These reactions may lead to disorders of the electroanatomic mapping system and displacement of the radiofrequency catheter, thereby increasing surgical risks [9]. Therefore, appropriate sedative anesthetics should be selected during AF catheter ablation to ensure surgical efficacy and reduce the incidence of complications. Alfentanil is a novel opioid analgesic, which has been recommended as an optional agent in sedation and anesthesia protocols by domestic and international expert consensus for bronchoscopy. It exerts favorable efficacy when combined with intravenous anesthetics [10]. Compared with other anesthetics, propofol has the advantages of rapid onset and short half-life. It can take effect within 30 seconds after the first injection, reach peak concentration at 2 minutes, with an initial distribution half-life of 2–4 minutes and an elimination half-life of 30–60 minutes. Stable plasma concentration can be maintained through continuous infusion [11-12]. Nevertheless, studies have confirmed that propofol can induce respiratory and circulatory depression, which is more pronounced especially in elderly patients [13].

Structurally similar to propofol, cipepofol is the first domestically synthesized intravenous anesthetic in China.

Compared with propofol, it has higher lipid solubility and potency, which is approximately 5 times that of propofol [14]. In recent years, numerous studies have explored the pharmacodynamic and pharmacokinetic characteristics of cipepofol, confirming its favorable efficacy and safety [15]. The present study found that at T1, the MAP in the cipepofol group was significantly higher than that in the propofol group, while no statistically significant differences were observed in MAP, HR, and SpO_2 between the two groups at other time points. These results indicate that cipepofol has a similar effect to propofol in maintaining hemodynamic stability. In addition, this study showed that the BIS values of both groups exhibited a trend of first decreasing and then increasing during surgery, and the fluctuation amplitude of BIS in the cipepofol group was significantly higher than that in the propofol group. The underlying reason may be that although no significant differences in MAP, HR, and SpO_2 were observed between cipepofol and propofol during anesthesia induction, the higher potency of cipepofol combined with alfentanil may significantly enhance the inhibitory effect on cerebral blood flow, or this phenomenon may be related to the dose-effect relationship, which requires further precise dose observation trials for verification.

This study also demonstrated that cipepofol could significantly reduce the dosage of alfentanil during AF catheter ablation compared with propofol. The reason for this may be that BIS monitoring during AF catheter ablation can effectively control the depth of anesthesia in patients, prevent excessive or insufficient anesthesia, reduce the risk of complications, and ensure medication safety. Both cipepofol and propofol are novel short-acting γ-aminobutyric acid receptor agonists with similar chemical structures and pharmacokinetic characteristics, resulting in no significant differences in awakening time, full recovery time, and orientation recovery time between the two groups. This finding is basically consistent with the research results of Zeng *et al* [16].

Moreover, the present study revealed that the incidence rates of intravenous injection pain, intraoperative respiratory depression, and hypoxemia in the cipepofol group were lower than those in the propofol group, suggesting that cipepofol has a lower risk of intravenous injection pain, intraoperative respiratory depression, and hypoxemia compared with propofol. Cipepofol has high lipid solubility, and the concentration of free molecules in its emulsion is significantly lower than that of propofol, which can effectively reduce the stimulation of vascular endothelial cells by the drug, thereby decreasing the incidence of injection pain. In comparison with propofol, cipepofol has significantly higher affinity for γ-aminobutyric acid receptors and sedative potency; thus, at the same depth of anesthesia, its plasma drug concentration is significantly lower, leading to less impact on the circulatory and respiratory systems of patients, and lower incidence rates of respiratory depression and hypoxemia [17]. A phase Ⅱ clinical trial in China showed that cipepofol has a rapid and stable onset of action and quick awakening. During the induction period of anesthesia, patients maintain stable hemodynamics, and the impacts on the circulatory and respiratory systems as well as the incidence of injection pain are all lower than those of propofol [18].

In conclusion, cipepofol combined with alfentanil exerts a definite sedative effect in AF catheter ablation, which is similar to that of propofol. Meanwhile, this combination regimen has less impact on circulation and respiration, and a lower incidence of intravenous injection pain and hypoxemia.

Conflict of interest None

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·论 著·

环泊酚复合阿芬太尼在心房颤动导管消融术中的应用

赵文宇， 张媛， 张同楠， 王海峰
山东省立医院菏泽医院 菏泽市立医院麻醉科， 山东 菏泽 274000

摘要：目的 探讨环泊酚复合阿芬太尼在心房颤动(房颤)导管消融术中的应用效果，对比环泊酚和丙泊酚对患者循环呼吸及不良反应的影响。**方法** 选择2022年5月至2024年5月在山东省立医院菏泽医院接受房颤导管消融术治疗的70例患者作为研究对象，按随机数字表法将其分为环泊酚组(n=35)和丙泊酚组(n=35)。环泊酚组麻醉诱导采用环泊酚0.2 mg/kg及阿芬太尼3 μg/kg静脉注射，丙泊酚组麻醉诱导采用丙泊酚1 mg/kg和阿芬太尼3 μg/kg静脉注射。对比手术相关指标及不良反应发生率，观察两组入手术室(T_0)、手术开始(T_1)、射频消融开始(T_2)、射频消融30 min后(T_3)、手术结束(T_4)时的平均动脉压(MAP)、心率(HR)、外周血氧饱和度(SpO_2)、脑电双频谱指数(BIS)值。**结果** 环泊酚组阿芬太尼追加剂量低于丙泊酚组[(3.11±0.40)μg vs (3.94±0.24)μg，t=10.487，P<0.01]。两组苏醒时间、完全清醒时间、定向力恢复时间对比差异无统计学意义(P>0.05)。T_1、T_2时，环泊酚组MAP高于丙泊酚组(P<0.05)，其他时间点两组MAP对比差异无统计学意义(P>0.05)。两组HR、SpO_2对比差异无统计学意义(P>0.05)。两组BIS值均呈先降低后升高的趋势，在T_1、T_2、T_3时，环泊酚组BIS值均低于丙泊酚组(P<0.05)，波动幅度大于丙泊酚组。环泊酚组静脉注射痛[8.57%(3/35) vs 57.14%(20/35)，χ^2=18.714，P<0.01]和术中呼吸抑制[28.57%(10/35) vs 54.29%(19/35)，χ^2=4.769，P=0.029]发生率低于丙泊酚组。**结论** 环泊酚复合阿芬太尼应用于房颤导管消融术镇静效果确切，与丙泊酚效果相似，且对循环呼吸影响较小，有更低的静脉注射痛及呼吸抑制发生率。

关键词： 心房颤动；射频导管消融术；环泊酚；阿芬太尼；丙泊酚；呼吸抑制；镇静
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ZHAO Wenyu, ZHANG Yuan, ZHANG Tongnan, WANG Haifeng
Department of Anesthesiology, Heze Hospital of Shandong Provincial Hospital, Heze Municipal Hospital, Heze, Shandong 274000, China
Corresponding author: WANG Haifeng, E-mail: whf2566@163.com

Abstract: Objective To investigate the efficacy of cipepofol combined with alfentanil in catheter ablation for atrial fibrillation, and to compare the effects of cipepofol and propofol on patients' circulatory and respiratory functions as well as adverse reactions. **Methods** Seventy patients who underwent catheter ablation for atrial fibrillation at Heze Municipal Hospital from May 2022 to May 2024 were selected as the study subjects. They were divided into a cipepofol group (n=35) and a propofol group (n=35) using a random number table method. The cipepofol group received intravenous induction with 0.2 mg/kg cipepofol and 3 μg/kg alfentanil, while the propofol group received intravenous induction with 1 mg/kg propofol and 3 μg/kg alfentanil. Surgery-related indicators and the incidence of adverse reactions were compared. Mean arterial pressure (MAP), heart rate (HR), saturation of peripheral oxygen (SpO_2), and bispectral index (BIS) values were observed at the following time points: upon entering the operating room (T_0), at the start of surgery

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通信作者： 王海峰，E-mail: whf2566@163.com
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(T_1), at the start of radiofrequency ablation (T_2), 30 min after radiofrequency ablation (T_3), and at the end of surgery (T_4). **Results** The additional dose of alfentanil in the cipepofol group was lower than that in the propofol group [(3.11±0.40) μg *vs* (3.94±0.24) μg, t=10.487, P<0.01]. There was no statistically significant difference in recovery time, time to full alertness, or time to orientation recovery between the two groups (P>0.05). At T_1 and T_2, the MAP in the cipepofol group was higher than that in the propofol group (P<0.05), while no statistically significant difference was observed at other time points (P>0.05). There was no statistically significant difference in HR and SpO_2 between the two groups (P>0.05). The BIS values in both groups showed a trend of first decreasing and then increasing. At T_1, T_2, and T_3, the BIS values in the cipepofol group were lower than those in the propofol group, with greater fluctuations (P<0.05). The incidence of injection pain [8.57%(3/35) *vs* 57.14%(20/35), χ^2=18.714, P<0.01] and intraoperative respiratory depression [28.57%(10/35) *vs* 54.29%(19/35), χ^2=4.769, P=0.029] in the cipepofol group was lower than that in the propofol group. **Conclusion** Cipepofol combined with alfentanil provides reliable sedation for catheter ablation of atrial fibrillation, with effects similar to those of propofol. Additionally, it has less impact on circulatory and respiratory functions, along with a lower incidence of injection pain and respiratory depression.

Keywords: Atrial fibrillation; Radiofrequency catheter ablation; Cipepofol; Alfentanil; Propofol; Respiratory depression; Sedation

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心房颤动简称房颤，主要危害为心力衰竭及急性脑梗死等血栓栓塞事件，属于严重的心房电活动紊乱[1]。调查显示，成年人房颤发生率约为3%，>65岁的老年人发生率高达6%，严重影响患者生命质量，增加家庭和社会的负担[2]。近年来，研究报道证实了房颤导管消融术治疗的有效性及安全性，已成为房颤的一线治疗策略[3]。射频导管消融术主要麻醉方式为全身麻醉或局部麻醉镇静，其中全身麻醉可为患者提供更好的手术体验，并可有效降低术中模型偏移，促进术后肺静脉电位恢复[4]。然而全身麻醉管理比较复杂，准备耗时较长，且国内大多数医院存在麻醉医师严重短缺等问题[5]。故在局部麻醉镇静状态下实施房颤导管消融术成为国内大多数医院的首选麻醉方案。阿芬太尼是一种速效阿片类镇痛药物，起效迅速，镇痛效果确切，同时还具有呼吸循环系统抑制轻微的优势[6]。环泊酚属于新型短效γ-氨基丁酸受体激动剂，该药物是在丙泊酚基础上加入环丙基，形成手性结构，可以增加立体效应[7]。环泊酚镇静效果与丙泊酚相似，但具有更高的安全性，且循环呼吸功能也更稳定，在改善注射痛方面具有明显优势[8]。目前环泊酚已广泛应用于消化内镜、支气管镜检查等，然而关于其在房颤导管消融术中的使用少有报道。基于上述背景，本研究旨在分析环泊酚复合阿芬太尼在房颤导管消融术中的应用效果。

1 资料与方法

1.1 一般资料 本研究前瞻性选择2022年5月至2024年5月在菏泽市立医院接受房颤导管消融术治疗的70例患者作为研究对象。纳入标准：(1) 符合房颤导管消融术指征；(2) 首次接受房颤导管消融术治疗；(3) 年龄>18周岁；(4) 美国麻醉医师协会(American Society of Anesthesiologists, ASA)分级为Ⅰ~Ⅱ级；(5) 采用积极内科保守治疗后无效；(6) 患者签订知情同意书。排除标准：(1) 长期服用镇痛药物或精神类药物；(2) 对环泊酚、丙泊酚等研究相关药物过敏；(3) 合并严重肺部疾病、肝肾功能异常、心血管、中枢神经系统疾病；(4) 有脑损伤或颅内压升高；(5) 有酒精成瘾史。将70例患者按随机数字表法分组，分为环泊酚组(n=35)和丙泊酚组(n=35)。两组一般资料比较差异无统计学意义(P>0.05)，具有可比性。见表1。本研究获得菏泽市立医院医学伦理委员会批准(批号：2024-KY006)。

1.2 方法 两组患者术前均禁食6~8 h。入室后连接心电监护和电生理监测，常规监测平均动脉压(mean arterial pressure, MAP)、心率(heart rate, HR)、外周血氧饱和度(saturation of peripheral oxygen, SpO_2)、脑电图，开放静脉通路。两组患者均于术前予以鼻导管给氧，氧流量为4 L/min，直至术后患者意识完全恢复。

1.2.1 环泊酚组麻醉诱导 环泊酚0.2 mg/kg及阿芬太尼3 μg/kg静脉注射，于患者初始剂量给药即刻，以改良警觉镇静评分(Modified Observer's Assessment of Alertness/Sedation, MOAA/S)对患者进行评估，当评分≤1分时即刻开展手术操作。在患者初始剂量给药完毕后1 min，若MOAA/S评分>1分，需要追加环泊酚，剂量为0.2 mg/kg，给药时间需≥30 s。随后以环泊酚1 mg/(kg·h)持续泵注至手术结束。若第一次追加

环泊酚后，患者MOAA/S评分仍>1分，则需要换成丙泊酚补救诱导。

1.2.2 丙泊酚组麻醉诱导 丙泊酚1 mg/kg和阿芬太尼3 μg/kg静脉注射，根据MOAA/S评分对患者进行麻醉状态评估，当评分≤1分时即刻开展手术操作。在患者初始剂量给药完毕后1 min，若MOAA/S评分>1分，需要追加丙泊酚，剂量为1 mg/kg，给药时间需≥30 s。随后以丙泊酚4 mg/(kg·h)持续泵注至手术结束。

1.2.3 维持麻醉 术中两组患者均予以0.5 μg/(kg·min)阿芬太尼持续静脉注射，若患者出现体动，则予以3 μg/kg阿芬太尼静脉注射，当阿芬太尼超过给药最大剂量时，患者镇痛效果仍不理想，可更换麻醉方式为气管插管全身麻醉。若患者出现呼吸抑制，予以托下颌干预，未有明显缓解时可行面罩加压给氧，必要时行机械通气。若患者术中收缩压降低至基础值20%或<80 mmHg，予以3~6 mg麻黄碱静脉注射。

1.3 评价指标 (1) 记录两组阿芬太尼追加剂量、苏醒时间、完全清醒时间、定向力恢复时间。(2) 记录两组入手术室(T_0)、手术开始(T_1)、射频消融开始(T_2)、射频消融30 min后(T_3)、手术结束(T_4)时MAP、HR、SpO_2并进行对比。(3) 记录两组T_0、T_1、T_2、T_3、T_4时脑电双频谱指数(bispectral index，BIS)值并进行对比。(4) 记录两组不良反应发生情况，如静脉注射痛、呼吸抑制、心动过缓等。

1.4 统计学方法 采用SPSS 25.0软件分析数据。计数资料以例(%)表示，组间比较以χ^2检验。符合正态分布的计量资料以$\bar{x}\pm s$表示，组间比较采用独立样本t检验；重复测量资料采用重复测量方差分析及两两比较的LSD-t检验。P<0.05为差异有统计学意义。

2 结 果

2.1 两组手术指标对比 环泊酚组阿芬太尼追加剂量较丙泊酚组显著减少(P<0.05)，苏醒时间、完全清醒时间、定向力恢复时间与丙泊酚组对比，差异无统计学意义(P>0.05)。见表2。

2.2 两组不同时点MAP、HR、SpO_2以及BIS对比 两组MAP对比，组间、时间及交互效应有统计学意义(P<0.05)；两组HR、SpO_2对比，组间、时间及交互效应均无统计学意义(P<0.05)。在T_1、T_2时，环泊酚组MAP较丙泊酚组升高(P<0.05)；在T_0、T_3、T_4时，两组差异无统计学意义(P>0.05)。两组BIS值均呈先降低后升高的趋势，组间、时间、交互效应有统计学意义(P<0.01)。在T_1、T_2、T_3时，环泊酚组BIS值低于丙泊酚组(P<0.05)，波动幅度大于丙泊酚组。见表3。

2.3 两组不良反应对比 环泊酚组静脉注射痛、术中呼吸抑制发生率低于丙泊酚组(P<0.05)。低血压、术后恶心呕吐、术中体动、心动过缓及低氧血症发生率两组差异无统计学意义(P>0.05)。见表4。

表1 两组基线资料比较 (n=35)

Tab.1 Comparison of baseline data between two groups (n=35)

项目	环泊酚组	丙泊酚组	t/χ^2值	P值
年龄(岁，$\bar{x}\pm s$)	58.06±4.76	58.60±4.68	0.481	0.632
性别为男[例(%)]	23(65.71)	19(54.29)	0.952	0.329
体质量(kg，$\bar{x}\pm s$)	63.41±6.95	64.03±6.82	0.377	0.708
身高(cm，$\bar{x}\pm s$)	161.45±9.70	159.33±9.82	0.912	0.365
吸烟史[例(%)]	12(34.29)	14(40.00)	0.245	0.621
饮酒史[例(%)]	6(17.14)	5(14.29)	0.108	0.743
ASA分级[例(%)]				
Ⅰ级	20(57.14)	18(51.43)	0.230	0.631
Ⅱ级	15(42.86)	17(48.57)		
糖尿病[例(%)]	4(11.43)	5(14.29)	0.128	0.721
高血压[例(%)]	12(34.29)	13(37.14)	0.062	0.803

表2 两组手术指标对比 (n=35，$\bar{x}\pm s$)

Tab.2 Comparison of surgical indicators between two groups (n=35，$\bar{x}\pm s$)

组别	阿芬太尼追加剂量(μg)	苏醒时间(min)	完全清醒时间(min)	定向力恢复时间(min)
环泊酚组	3.11±0.40	7.51±1.54	9.89±3.14	11.00±2.04
丙泊酚组	3.94±0.24	7.65±1.63	10.60±3.14	10.95±1.96
t值	10.487	0.369	0.946	0.105
P值	<0.001	0.713	0.348	0.917

表3 不同时点两组MAP、HR、SpO_2以及BIS对比 (n=35，$\bar{x}\pm s$)

Tab.3 Comparison of MAP, HR, SpO_2, and BIS between two groups at different time points (n=35，$\bar{x}\pm s$)

时点	MAP(mmHg)		HR(次/min)		SpO_2(%)		BIS	
	环泊酚组	丙泊酚组	环泊酚组	丙泊酚组	环泊酚组	丙泊酚组	环泊酚组	丙泊酚组
T_0	97.94±5.58	98.03±5.25	82.40±4.81	82.11±4.60	97.90±0.90	98.00±0.94	95.09±2.39	95.83±1.69
T_1	92.17±5.25[a]	86.06±5.95	77.40±4.82	76.51±4.75	96.23±1.85	96.20±1.98	43.14±4.29[a]	50.49±4.58
T_2	88.06±4.66[a]	83.00±4.52	74.40±4.99	73.94±5.20	95.71±1.81	95.40±1.96	39.17±4.26[a]	44.69±4.60
T_3	95.34±6.84	96.51±6.81	80.37±5.59	79.37±5.59	97.03±1.18	97.20±1.26	52.00±7.32[a]	57.09±7.45
T_4	98.00±5.58	98.03±5.43	81.34±6.11	80.34±6.51	97.71±1.07	97.86±0.97	66.54±8.31	68.83±7.19
组间效应	F=72.156，P<0.001		F=2.186，P=0.289		F=2.379，P=0.266		F=46.860，P<0.001	
时间效应	F=6.264，P<0.001		F=0.069，P=0.991		F=0.330，P=0.807		F=1 023.879，P<0.001	
交互效应	F=10.152，P=0.002		F=1.565，P=0.215		F=0.012，P=0.912		F=3.900，P=0.011	

注：与同时点丙泊酚组比较，[a]P<0.05。

表4　两组不良反应发生率对比　[n=35, 例(%)]

Tab.4　Comparison of the incidence of adverse reactions between two groups　[n=35, case(%)]

不良反应	环泊酚组	丙泊酚组	χ^2值	P值
静脉注射痛	3(8.57)	20(57.14)	18.714	<0.001
低血压	12(34.29)	11(31.43)	0.065	0.799
术中呼吸抑制	10(28.57)	19(54.29)	4.769	0.029
术后恶心呕吐	1(2.86)	2(5.71)	0.348	0.555
术中体动	10(28.57)	13(37.14)	0.583	0.446
心动过缓	7(17.14)	4(11.43)	0.971	0.324
低氧血症	4(11.43)	10(28.57)	3.214	0.073

3　讨　论

房颤导管消融术对患者造成的创伤较小，然而在手术消融过程中导管反复多次释放能量，可引发患者心肌灼烧感，容易导致焦虑及肢体移动，引发电解剖测绘系统紊乱及射频导管移位，增加手术风险[9]。故在房颤导管消融术过程中应选择合适的麻醉镇静药物，以确保手术治疗效果，从而减少并发症发生。阿芬太尼属于新型阿片类药物，已成为国内外支气管镜检查镇痛镇静专家共识推荐的镇静麻醉方案的可选择用药，与静脉麻醉药物联合应用效果良好[10]。丙泊酚与其他麻醉药物对比，具有起效迅速及半衰期短的优势，首次注射后30 s即可发挥作用，可在2 min时达峰值浓度，首相分布半衰期为2~4 min，消除半衰期为30~60 min，可通过持续输注维持血浆浓度半衰期稳定[11-12]。然而研究证实，丙泊酚可引发患者呼吸循环抑制，尤其对老年患者更为明显[13]。

环泊酚与丙泊酚结构相似，是中国首个自主合成的静脉麻醉药物，其与丙泊酚相比，具有更高的脂溶性，且效价更高，约为丙泊酚的5倍[14]。近年来，已有大量研究对环泊酚的药效动力学及药代动力学特征进行了探究，证实了其良好的效率及安全性[15]。本研究发现，在T_1时，环泊酚组MAP较丙泊酚组显著升高，而其余各时间点环泊酚组MAP、HR、SpO_2与丙泊酚组对比差异无统计学意义。说明环泊酚在维持血流动力学稳定方面效果与丙泊酚相似。此外本研究发现两组术中BIS值均呈先降低后升高的趋势，环泊酚波动幅度较丙泊酚组显著升高。分析其原因，虽然环泊酚与丙泊酚麻醉诱导期间，患者MAP、HR、SpO_2均未呈现出明显的差异，然而是否因为环泊酚效价更高，与阿芬太尼联合应用明显增强了脑血流的抑制作用，或是存在量效关系相关，还有待进一步开展精准药物剂量观察试验。本研究发现，与丙泊酚相比，环泊酚可明显减少房颤导管消融术中阿芬太尼使用量。分析其原因，在房颤导管消融术过程中，BIS监测可有效控制患者麻醉深度，防止麻醉过深或过浅现象发生，降低并发症发生风险，确保用药安全。而环泊酚与丙泊酚都属于新型短效γ-氨基丁酸受体激动剂，具有相似的化学结构及药代动力学特征，故患者苏醒时间、完全清醒时间、定向力恢复时间无明显差异。这与Zeng等[16]研究结果基本相似。

本研究发现，环泊酚组静脉注射痛、术中呼吸抑制、低氧血症抑制发生率较丙泊酚组降低。说明环泊酚与丙泊酚相比，具有更低的静脉注射痛、术中呼吸抑制、低氧血症抑制发生风险。环泊酚脂溶性较高，乳液中游离分子浓度较丙泊酚显著降低，可有效减少药物对血管内皮细胞刺激，注射痛发生率随之降低。与丙泊酚相比，环泊酚与γ-氨基丁酸受体亲和力及镇静效价均显著增强，故在相同麻醉深度下其血浆药物含量明显减少，对患者循环及呼吸系统的影响更小，呼吸抑制及低氧血症发生率更低[17]。中国一项Ⅱ期临床试验表明，环泊酚起效迅速平稳，且苏醒较快，在麻醉诱导期患者血流动力学比较稳定，且对循环及呼吸系统的影响及注射痛发生率均低于丙泊酚[18]。

综上所述，环泊酚复合阿芬太尼应用于房颤导管消融术镇静效果确切，与丙泊酚效果相似，且对循环呼吸影响较小，有更低的静脉注射痛及低氧血症发生率。

利益冲突　无

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（上接第1830页）

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