

## ORIGINAL RESEARCH

## CARDIAC ANESTHESIA

# Effect of ketamine versus sevoflurane on the right ventricular pressure during balloon dilatation of congenital pulmonary valve stenosis

Amr Gaber Sayed<sup>1</sup>, Walaa Adel Abd el Moez<sup>2</sup>, Aktham Shoukry<sup>3</sup>, Ahmed Elsayed Elshafeey<sup>4</sup>

**Authors affiliation:**

1. Amr Gaber Sayed, Department of Anesthesia, Intensive Care & Pain Management, Faculty of Medicine, Ain Shams University, Cairo, Egypt; E-mail: [dramrgaber7@gmail.com](mailto:dramrgaber7@gmail.com)
2. Walaa Adel Abd el Moez, Department of Anatomy and Embryology, Faculty of Medicine, Ain-Shams University, Cairo, Egypt; E-mail: [walaa\\_adel@med.asu.edu.eg](mailto:walaa_adel@med.asu.edu.eg)
3. Aktham Shoukry, Department of Anesthesia, Intensive Care & Pain Management, Faculty of Medicine, Ain Shams University, Cairo, Egypt; E-mail: [aktham.shoukry1@gmail.com](mailto:aktham.shoukry1@gmail.com)
4. Ahmed Elsayed Elshafeey, Department of Anesthesia, Intensive Care & Pain Management, Faculty of Medicine, Ain Shams University, Cairo, Egypt; E-mail: [dr.ahmedelshaf3ey@gmail.com](mailto:dr.ahmedelshaf3ey@gmail.com).

**Correspondence:** Dr. Amr Gaber Sayed, E-mail: [dramrgaber7@hotmail.com](mailto:dramrgaber7@hotmail.com); Tel: 00201005013194

## ABSTRACT

**Background & Objective:** Congenital pulmonary stenosis (PS) is a prevalent cardiac anomaly that is commonly treated with balloon dilatation. The procedure can be successfully completed under appropriate anesthetic technique, depending upon the choice of the anesthetist and the patients' physical status. We compared the effect of IV ketamine with sevoflurane inhalational anesthesia on right ventricular pressure in infants undergoing balloon dilatation for congenital pulmonary valve stenosis.

**Methodology:** This double-blinded, randomized, clinical trial included 40 infants, aged from 1 to 12 months, with congenital PS undergoing balloon dilatation. They were randomly allocated to one of the two groups. In the ketamine group, 20 patients received 2 mg/kg of ketamine intravenously till being unconscious. In the sevoflurane group, 20 patients received 3% sevoflurane and were maintained using the open circuit technique till losing consciousness. The right ventricular pressure was the primary outcome. Secondary outcomes were the hemodynamics and oxygen saturation.

**Results:** Compared to sevoflurane, ketamine showed a non-significant difference in the right ventricular pressure before and after induction of anesthesia and after balloon dilatation. The mean arterial blood pressure significantly dropped immediately after sevoflurane induction and after the initial 10 min ( $P = 0.031$  and  $0.041$ , respectively). The heart rate significantly decreased immediately after sevoflurane induction ( $P = 0.028$ ). The oxygen saturation remained comparable in both groups at 10 and 20 min after induction, and at postoperative anesthesia care unit.

**Conclusion:** Intravenous ketamine is considered a safe and effective alternative to sevoflurane for infants with congenital pulmonary stenosis undergoing balloon dilatation. It maintains the right ventricular pressure with stable hemodynamic effects, compared to sevoflurane inhalational anesthesia.

**Abbreviations:** PS - Pulmonary Stenosis; TS – Tricuspid Stenosis; PACU – Post Anesthesia Care Unit; TTE - Transthoracic Echocardiography

**Key words:** Balloon Dilatation; Infants; Ketamine; Pulmonary Stenosis; Sevoflurane.

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## 1. INTRODUCTION

Critical pulmonary stenosis (PS) is a life-threatening congenital heart disease, which manifests itself during the neonatal period with cyanosis. Surgical valvotomy has been the procedure of choice for critical PS; however, balloon pulmonary valvuloplasty has now become the standard management.<sup>1</sup>

Ketamine is a selective antagonist of the N-methyl-D-aspartate receptor and it results in analgesia, amnesia and sedation. It is often used for procedural sedation or as an adjunct for general anesthesia in infants with congenital heart disease, with minimal impact on hemodynamics as well as the systemic and pulmonary vascular resistances.<sup>2-6</sup>

Sevoflurane is an inhalational anesthetic used for induction and maintenance of general anesthesia. It proved to be safe as induction agent in noncardiac as well as cardiac surgeries. Compared to halothane, sevoflurane has a low blood solubility, produces less arrhythmia, and causes less inhibition of cardiac contractility without changing pulmonary to systemic blood flow ratio in infants with congenital heart disease.<sup>7-10</sup>

The aim of this study was to assess the safety and efficacy of ketamine versus sevoflurane used for induction of anesthesia in infants undergoing balloon dilatation for congenital PS.

## 2. METHODOLOGY

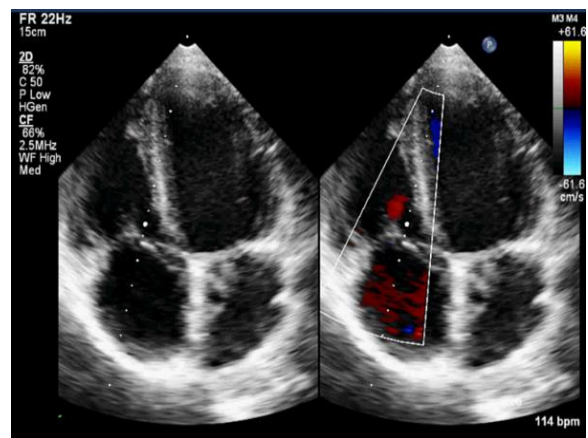
The study proposal was approved by the Ethics Committee of the Faculty of Medicine, Ain Shams University, Egypt. This trial was registered at the clinicaltrials.gov (Trial ID: NCT05582213; Date: October 17, 2022). After the explanation of the aim and procedure of the study, written informed consents were acquired from the participants' parents or guardians. The participants' data were kept confidential.

This double-blinded, parallel-group, randomized trial was conducted at the Pediatrics Catheterization Unit, Cardiology Department, Ain Shams University Hospitals, Egypt between October 2022 and March 2023. The study included 40 infants aged 1 month to 1 y, of both genders, who underwent balloon dilatation for isolated congenital PS. We excluded patients who had multiple cardiac congenital anomalies, previous open-heart surgery, or other non-cardiac congenital anomalies. All complicated cases like cardiac arrest, cardiac tamponade, or malignant arrhythmias were also excluded from the study. Parents refusal to participate also excluded the infant from the study.

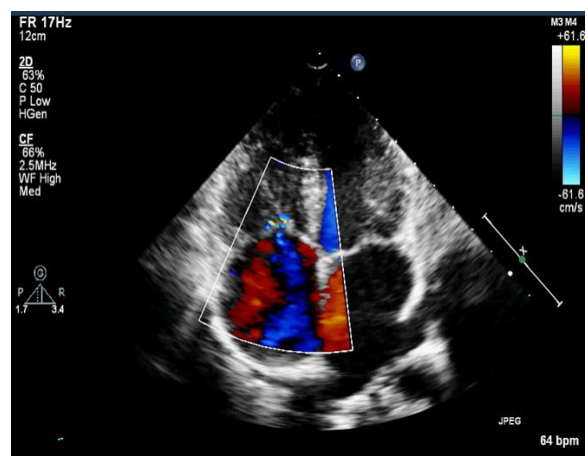
Randomization and allocation concealment were performed using the computer-generated random

number table and sequentially numbered, opaque, sealed envelopes. The patients and the outcome evaluators were blinded to the group allocation.

Patients were randomly allocated to one of the two groups (20 patients each). Patients in the sevoflurane group (Group S) received sevoflurane 3% (Sevotec 5; Blease Medical Equipment Ltd, Chesham, UK) using an open circuit (modified Ayre's T-piece) till losing consciousness. Then, they were maintained on an oxygen mask with the same concentration of sevoflurane. Patients in the ketamine (K) group received ketamine (2 mg/kg) intravenously (IV) till being unconscious. The oxygen mask was connected to a capnogram in all patients. The maintenance of anesthesia was done using an open circuit (modified Ayre's T-piece) with sevoflurane 1 to 2%



**Figure 1: The apical four-chambers view used to assess the right ventricular systolic pressure using continuous wave and color doppler on the tricuspid valve**



**Figure 2: Color Doppler in apical four chambers view for the detection and quantification of the severity of TR and so, assess the right ventricular systolic pressure using modified Bernoli equation**

All patients were subjected to full history taking, clinical examination, and laboratory investigations. A 22-gauge peripheral cannula was inserted using EMLA cream. Midazolam (0.05 mg/kg), dexamethasone (0.02 mg/kg), ondansetron (0.1 mg/kg), and ceftriaxone (50 mg/kg) were administered IV to all patients.

The patients were monitored by electrocardiography, pulse oximetry, and non-invasive blood pressure. Right ventricular systolic pressure was measured using trans-thoracic echocardiography (TTE) before and just after anesthesia induction and after balloon dilatation. The apical four-champers view was used in all patients to assess the degree of tricuspid regurgitation (TR), Color flow imaging was used to detect the presence of tricuspid regurgitation (Figures 1 & 2). This is present physiologically in 80% of healthy subjects. Continuous wave (CW) and color Doppler were the main methods of detection and quantification of the severity of TR. The maximum velocity of tricuspid regurgitant flow represents the pressure difference between the right ventricle (RV) and right atrium (RA). The most important use of the CW Doppler signal was the estimation of the right ventricular systolic pressure. The modified Bernoulli equation ( $P = 4v^2$ ) measures the maximal TR jet velocity, and pressure is estimated.

Blood pressure, heart rate, and oxygen saturation were recorded before and after induction of anesthesia, then every 10 min intraoperatively, and at the post-anesthetic care unit (PACU). Hypotension was defined as systolic blood pressure reduction > 30% compared to the basal readings throughout a 30-second period. If hypotension developed, a bolus dose of a crystalloid (20 mL/kg) was

given. Bradycardia was defined as a decline in heart rate less than 30% compared to the basal readings

throughout a 30-second period. A reduction in baseline peripheral oxygen saturation of 15-20% that lasted longer than 15 sec is referred to as arterial desaturation. Propranolol was administered for infundibular vasospasm after balloon dilatation. Other catheter related complications such as bleeding and cardiac tamponade were recorded and managed.

The primary outcome was the right ventricular systolic pressure. The secondary outcomes included the patients' hemodynamics (mean blood pressure and heart rate) and oxygen saturation.

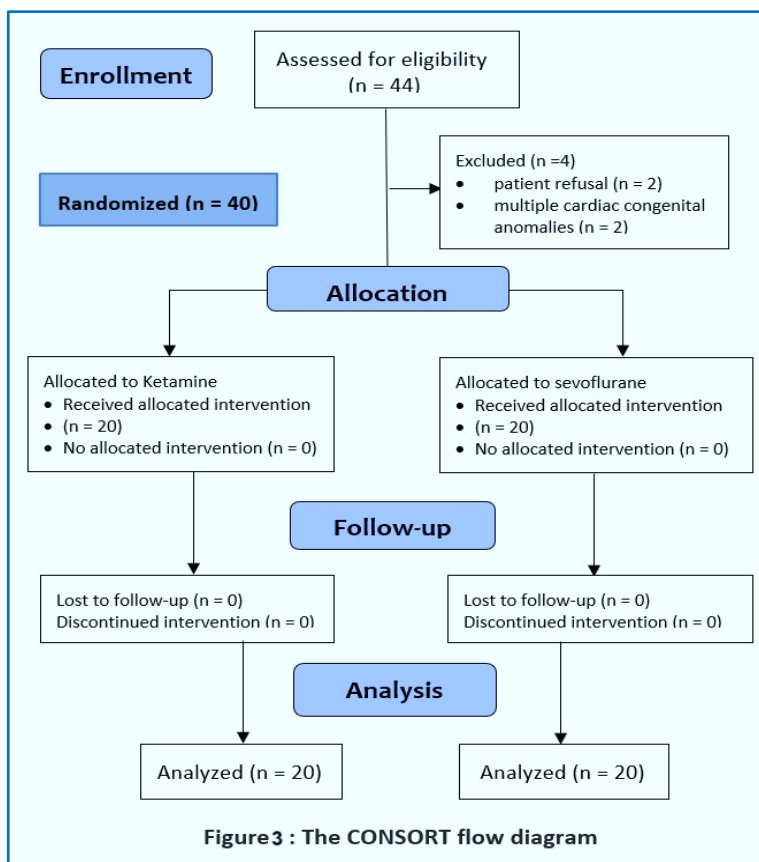


Figure 3 : The CONSORT flow diagram

Parameter	Group S (n = 20)	Group K (n = 20)	P-value
Age (months) Median (IQR)	5 (2.5 – 8.5)	7 (2.5 – 9)	0.596
Gender, n (%)	Male	8 (40.0%)	0.749
	Female	12 (60.0%)	
Weight (kg)	5.50 ± 1.78	5.98 ± 1.80	0.407

SD: standard deviation; n: numbers; IQR: interquartile range;  
Group S: sevoflurane group; group K: etamine group.

### Statistical analysis

The sample size was calculated using NCSS PASS 11.0 after setting the used statistical test to a one-sided, two-sample t-test, with a unilateral  $\alpha$  of 0.05, and 82% power. According to Sungur Ulke et al.,<sup>12</sup> the margin of non-inferiority was -70.000 and the true difference between the means was assumed to be 8.000.

**Table 2. Right ventricular systolic pressure at different times**

Right ventricular pressure (mmHg)	Group S (n = 20)	Group K (n = 20)	P-value
<b>Baseline</b>	76.40 ± 9.78	74.65 ± 10.24	0.584
<b>After induction</b>	66.55 ± 8.65	69.35 ± 8.71	0.314
<b>After balloon dilatation</b>	38.60 ± 5.45	38.85 ± 5.66	0.888

Data given as mean ± SD; Group S: sevoflurane group; Group K: ketamine group.

**Table 3: Comparative non-invasive blood pressure at different times**

NIBP recording time	Group S (n = 20)	Group K (n = 20)	P-value
<b>Before induction</b>	51.10 ± 5.97	52.85 ± 6.28	0.372
<b>After induction</b>	49.60 ± 5.53	53.70 ± 6.05	0.031*
<b>at 10 min</b>	48.40 ± 5.09	52.10 ± 5.96	0.041*
<b>at 20 min</b>	47.60 ± 4.94	50.55 ± 5.54	0.083
<b>at PACU</b>	50.60 ± 5.91	52.55 ± 6.15	0.313

Data given as mean ± SD; Group S: sevoflurane group; Group K: ketamine group;

\*: significant at  $P \leq 0.05$ .

**Table 4: Heart rate at different time periods**

Heart rate recording time	Group S (n = 20)	Group K (n = 20)	P-value
<b>Before induction</b>	136.20 ± 17.02	133.35 ± 17.72	0.607
<b>After induction</b>	110.90 ± 7.05	118.20 ± 12.39	0.028*
<b>at 10 min</b>	101.70 ± 4.52	105.00 ± 6.33	0.065
<b>at 20 min</b>	99.10 ± 4.61	99.60 ± 4.08	0.719
<b>at PACU</b>	111.70 ± 5.30	110.55 ± 5.98	0.524

Data given as mean ± SD; Group S: sevoflurane group; Group K: ketamine group;

\*: significant at  $P \leq 0.05$ .

**Table 5: Pulse oxygen saturation at different times**

Arterial oxygen saturation (%)	Group S (n = 20)	Group K (n = 20)	P-value
<b>Before induction</b>	95.95 ± 3.02	95.90 ± 2.97	0.958
<b>After induction</b>	98.40 ± 1.31	98.15 ± 1.31	0.550
<b>at 10 min</b>	98.80 ± 0.95	98.80 ± 1.11	1.000
<b>at 20 min</b>	98.55 ± 1.10	98.65 ± 0.93	0.758
<b>at PACU</b>	97.00 ± 1.56	97.50 ± 1.40	0.291

Data given as mean ± SD; Group S: sevoflurane group; Group K: ketamine group;  $P \leq 0.05$  considered as significant

The data were drawn from populations with standard deviations of 100.000 and 84.700. The calculated sample size was 20 participants per group, and it was inflated by

10% to account for the attrition problem in prospective studies.

The Statistical Package for Social Sciences (SPSS) version 26 for Windows (IBM© Corp., Armonk, N.Y., USA) was used for performing the analysis. All data were normally distributed and were summarized as mean

± standard deviation (SD) and were compared using the independent samples t-test. Categorical data were summarized as count and percentage, and the associations between the studied groups were tested using the Pearson's Chi-square test or Fisher's exact test as appropriate. A P-value of 0.05 was used to indicate significance of the statistical tests.

### 3. RESULTS

Forty-four patients were recruited, two patients refused to participate and two patients had multiple cardiac congenital anomalies, so were excluded. Forty patients were randomly allocated to two groups, e.g., 20 patients each.

There was no statistically significant difference between the two groups regarding age, gender, and weight (Table 1).

Patients who received ketamine had comparable right ventricular systolic pressure with those in the sevoflurane group before and after anesthetic induction and after balloon dilatation ( $P = 0.584$ , 0.314, and 0.888, respectively) as shown in Table 2.

The mean arterial pressure values immediately at induction of anesthesia and at 10 min after induction were

significantly lower in the sevoflurane group. We found no major differences in the mean arterial pressure between the two groups before induction, at 20 min after induction, and at the PACU (Table 3).

The heart rates immediately after induction were significantly lower in the sevoflurane group. We found no significant difference between both groups in the heart rate before induction, at 10 and 20 min after induction of anesthesia, and at the PACU (Table 4).

The SpO<sub>2</sub> readings were comparable in both groups before and after the induction of anesthesia and at the PACU (Table 5). As regard pulmonary infundibular vasospasm only 4 cases were recorded, two in each group without any statistical significance.

## 4. DISCUSSION

Balloon dilatation is a common procedure for treatment of congenital PS, either fixed or dynamic, that can be discovered during catheterization. Anesthesiologists have long been searching for drugs that can quickly induce and relieve hypnosis without having negative effects on the circulatory and respiratory systems.<sup>4</sup> This study aimed to assess the safety and efficacy of intravenous ketamine versus sevoflurane inhalation used for induction of anesthesia in infants undergoing balloon dilatation for congenital PS. We found no significant difference in the right ventricular systolic pressure between the two groups. Compared to ketamine, sevoflurane significantly reduced the blood pressure and heart rate immediately after induction. The SpO<sub>2</sub> remained comparable in both groups.

In accordance with our findings, Loomba et al. reported that ketamine given at standard clinical doses (3-5 mg/kg) did not appreciably affect the systemic and pulmonary vascular resistance or the cardiac index.<sup>2</sup> Hickey et al.<sup>5</sup> demonstrated that ketamine had no impact on estimated pulmonary artery pressure in individuals with normal or elevated baseline pulmonary vascular resistance in postoperative cardiac surgery. Also, Williams et al.<sup>5</sup> demonstrated that a combination of ketamine and sevoflurane did not worsen pulmonary hypertension and could be a helpful anesthetic approach for cardiac catheterization in children.

Furthermore, ketamine maintained systemic vascular resistance and systemic arterial pressure in pulmonary hypertensive children undergoing cardiac catheterization.<sup>11</sup> This might aid in maintaining coronary blood flow to the right ventricle of these patients. In contrast, systemic arterial pressure was lowered by volatile anesthetics.<sup>12,13</sup> Since the interventricular septum was intact and right ventricular pressures were high, the unfavorable septal shift that take place might be curbed by maintaining systemic vascular resistance and left ventricular systolic pressure.<sup>9</sup>

During the initial 10 min of anesthesia induction, we found a brief drop in the mean arterial blood pressure in the sevoflurane group. Meanwhile, ketamine maintained

the mean blood pressure. According to Sungur Ulke et al.,<sup>7</sup> sevoflurane induction significantly hindered the patients' hemodynamics, which quickly reverted to normal after the inhalational anesthetic concentration was reduced and the sympathetic system was stimulated by endotracheal intubation. The reaction to endotracheal intubation was not overstated, as the systolic and mean arterial pressures just changed from their original levels, and the diastolic pressures remained below the baseline. Additionally, high sevoflurane concentration would put patients in danger of respiratory and hemodynamic compromise including severe bradycardia. Bordes and Cross advised against exceeding 6% inspired sevoflurane concentration in children.<sup>11</sup>

Loomba et al.<sup>2</sup> found that ketamine had little effect on hemodynamics in children with congenital heart disease. Conway et al. reported no appreciable changes in blood pressure or heart rate after administering 2 mg/kg of ketamine.<sup>12</sup> Earlier studies explained that blood pressure and heart rates could be preserved because of the sympathomimetic effects of ketamine. The heart rate showed a transient drop after ketamine administration that allowed the right ventricle to receive coronary flow for a longer amount of time during the cardiac cycle.<sup>13</sup>

On the contrary, Hayman et al. found that ketamine caused tachycardia, hypertension, and increased pulmonary vascular resistance, among other harmful hemodynamic effects.<sup>14</sup> Eldeen and Messeha reported that sevoflurane was a better anesthetic than ketamine and midazolam for children with PS undergoing cardiac catheterization because it caused less myocardial damage and ensured better hemodynamic stability.<sup>15</sup> Also, Rivenes et al. demonstrated that the use of sevoflurane at various concentrations-imposed stability of the hemodynamic and cardiac index parameters during cardiac catheterization.<sup>16</sup> In children with ventricular septal defect, Han et al. reported an initial increase followed by a quick heart rate and arterial pressure decline with ketamine injection intramuscularly, reflecting significant, adverse variations in hemodynamics.<sup>17</sup> The discrepancies in these findings could be attributed to the differences between these studies regarding the age, weight, and ketamine dose, or the presence of other cardiac anomalies.

We found a non-significant difference between the two groups in blood oxygenation. Since 1971, ketamine has been used in juvenile cardiac catheterization because of its safety and provision of excellent sedation. Ketamine has bronchodilator qualities and does not impair reflexes in the airways. Moreover, low-dose ketamine has an antinociceptive effect and produces analgesia in cases of resistance.<sup>18</sup>

## 5. LIMITATIONS

This was a single-center study, with a small sample size, and lacked invasive blood pressure measurement and arterial blood oxygen saturation, which are more accurate in assessing hemodynamics. Multicenter studies with a larger sample size and invasive monitoring are required.

## 6. CONCLUSION

For patients with congenital pulmonary stenosis undergoing balloon dilatation, ketamine seems to be a good alternative to sevoflurane. It is safe and effective and maintains right ventricular systolic pressure, hemodynamic stability, and oxygen saturation.

### 7. Data availability

The numerical data generated during this research is available with the authors.

### 8. Acknowledgement

We gratefully thank the staff of Department of Anesthesia, Intensive Care & Pain Management as well as Department of Anatomy and Embryology, Faculty of Medicine, Ain Shams University, Cairo.

### 9. Conflict of interest

The study utilized the hospital resources only, and no external or industry funding was involved.

### 10. Authors' contribution

AGS: Designed the study, revised the literature and performed a discussion.

AEE: Analysis of data and collection of results.

WAA, AS: Analysis of data, designing methodology, and literature search.

All authors read and approved the final version of the manuscript.

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