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Comparative Study Between Intravenous Ketamine and Propofol as Induction Agents on Postoperative Recovery Scores in Neonates Undergoing Tracheoesophageal Fistula (TEF) Repair Surgery

Trakeoözofageal Fistül (TÖF) Onarım Cerrahisi Geçiren Yenidoğanlarda İndüksiyon Ajanı Olarak İntravenöz Ketamin ve Propofolün Postoperatif İyileşme Skorları Üzerine Etkilerinin Karşılaştırılması

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ABSTRACT

Objective: Tracheoesophageal fistula (TEF) is a congenital anomaly necessitating early surgical intervention. Enhanced recovery after surgery - ERAS principles are increasingly applied in neonatal surgical care to improve outcomes. The choice of anesthetic induction agent plays a pivotal role in determining recovery quality and duration.

Method: This was a randomized, double-blind, prospective clinical trial involving 60 neonates under 10 days old undergoing TEF repair. Subjects were assigned to receive either propofol (1.5 mg kg^{-1}) or ketamine (1 mg kg^{-1}) as induction agents, with standard maintenance anesthesia and postoperative care. The primary outcome was recovery score at extubation using the Modified Steward Score. Secondary outcomes included duration of mechanical ventilation, postoperative pain using the neonatal pain agitation and sedation scale, and hemodynamic stability.

Results: Recovery scores were significantly higher in the propofol group (mean 4.86 ± 0.89) compared to the ketamine group (mean 3.09 ± 1.01) (p<0.001). The mean duration of mechanical ventilation was shorter in the propofol group (18.00 ± 3.70 h) than in the ketamine group (21.45 ± 2.55 h), (p=0.001). Postoperative pain scores were consistently lower in the ketamine group at all time intervals, with significant differences (p<0.05). Hemodynamic parameters were more stable and elevated in the ketamine group post-induction.

Conclusion: Propofol is associated with faster recovery and reduced ventilation time, whereas ketamine offers superior postoperative analgesia and hemodynamic stability. Anesthetic choice should be individualized based on surgical and patient-specific needs.

Keywords: Tracheoesophageal fistula, infant, newborn, propofol, ketamine, outcome, ERAS

ÖZ

Amaç: Trakeaözofageal fistül (TÖF), erken cerrahi müdahale gerektiren konjenital bir anomalidir. Cerrahi sonrası hızlandırılmış iyileşme protokolleri - ERAS, sonuçları iyileştirmek için yenidoğan cerrahi bakımında giderek daha fazla uygulanmaktadır. Anestezik indüksiyon ajan seçimi, iyileşme kalitesini ve süresini belirlemede önemli bir rol oynar.

Yöntem: Randomize, çift kör ve prospektif olarak dizayn edilen çalışmamıza TÖF onarımı geçiren 10 günden küçük 60 yenidoğan dahil edildi. Katılımcılara indüksiyon ajanı olarak propofol (1,5 mg kg^{-1}) veya ketamin (1 mg kg^{-1}) verildi, standart idame ve postoperatif bakım uygulandı. Çalışmamızın birincil sonucu, Modifiye Steward Skoru kullanılarak ekstübasyondaki iyileşme skoruyken, ikincil sonuçlar arasında mekanik ventilasyon süresi, yenidoğan ağrı ajitasyon ve sedasyon ölçeği kullanılarak postoperatif ağrı ve hemodinamik stabilite yer aldı.

Bulgular: Propofol grubunda derlenme skorları (ortalama 4,86 ± 0,89) ketamin grubuna (ortalama 3,09 ± 1,01) kıyasla anlamlı derecede daha yüksekti (p<0,001). Propofol grubunda ortalama mekanik ventilasyon süresi (18,00 ± 3,70 saat) ketamin grubuna (21,45 ± 2,55 saat) kıyasla daha kısaydı (p=0,001). Ameliyat sonrası ağrı skorları ketamin grubunda tüm zaman aralıklarında tutarlı bir şekilde daha düşüktü (p<0,05). Hemodinamik parametreler ketamin grubunda indüksiyon sonrası daha stabil ve yüksekti.

Sonuç: Propofol TÖF onarımı geçiren yenidoğanlarda daha hızlı derlenme ve daha kısa ventilasyon süresi ile ilişkiliyken, ketamin daha üstün postoperatif analjezi ve hemodinamik stabilite sağlar. Anestezi seçimi cerrahiye ve hastaya özgü ihtiyaçlara göre kişiselleştirilmelidir.

Anahtar sözcükler: Trakeaözofageal fistül, infant, yenidoğan, propofol, ketamin, sonuç, ERAS

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INTRODUCTION

Tracheoesophageal fistula (TEF) is a rare but life-threatening congenital anomaly. Patients usually present with respiratory distress, inability to tolerate feeds, or inability to pass an orogastric tube. The defect may be isolated or associated with other congenital abnormalities, such as VACTERL syndrome (1). Advances in maternal and fetal ultrasound have improved the accuracy of prenatal diagnosis in many cases. Neonatal surgical correction is essential to prevent aspiration and systemic complications.

Enhanced recovery after surgery (ERAS) protocols are multimodal perioperative care pathways designed to achieve early recovery by maintaining preoperative organ function and reducing the physiological stress response to surgery (2). Key elements of ERAS protocols include preoperative counselling, nutritional optimization, standardized analgesic and anesthetic regimens, and early mobilization (2). With increasing application of ERAS principles in pediatric populations, anesthetic technique and drug selection have gained significant attention for their impact on recovery outcomes.

Early extubation, defined as extubation within 24–48 hours of surgery, has been associated with lower mortality and reduced re-intubation rates compared with delayed extubation beyond 48 hours (3). The benefits of early extubation extend to neonates undergoing complex cardiac surgeries, such as transposition of the great arteries or anomalous pulmonary venous return. In pediatric surgical settings, early extubation has also contributed to improved resource utilization by reducing intensive care unit (ICU) stay and overall hospital length of stay (4).

Although neonatal physiology differs significantly from that of older children and adults, the benefits of enhanced recovery pathways should not be overlooked. While prematurity may theoretically justify delayed extubation, premature infants have been successfully supported with non-invasive ventilation (NIV), and re-intubation after failed extubation should not necessarily be deemed a failure (5). Delaying extubation postoperatively in neonatal intensive care unit (NICU) patients adversely affects respiratory status, increasing NICU and hospital stay, the risk of complications, and overall healthcare costs (6).

Propofol and ketamine are widely used intravenous induction agents in pediatric anesthesia. Propofol is a sedative-hypnotic agent commonly used for induction, maintenance, and sedation due to its rapid onset, short duration of action, and additional antiemetic properties. Ketamine, an N-methyl-D-aspartate (NMDA) receptor antagonist, is primarily used for induction and maintenance of anesthesia. Propofol exerts its hypnotic effects by activating gamma-aminobutyric acid receptors and selectively inhibiting acetylcholine release in the basocortical and septo-hippocampal pathways (7).

Ketamine produces dissociative anesthesia characterized by sedation, amnesia, and analgesia. Additionally, ketamine has stimulatory effects on the cardiovascular and respiratory systems, increasing heart rate, cardiac output, and arterial and central venous pressures (8).

Despite these pharmacological differences, comparative studies in neonates undergoing TEF repair remain scarce. The aim of the present study was to compare intravenous ketamine and propofol as induction agents in TEF repair surgery. The primary outcome of this study was the Modified Steward Score (MSS) at the time of extubation. Secondary outcomes included postoperative pain assessment using the neonatal pain agitation and sedation scale (N-PASS) and duration of mechanical ventilation.

MATERIAL and METHODS

After obtaining ethical clearance from the Institutional Review Board, Institute of Medical Sciences, Banaras Hindu University (approval number ECR/526/Inst/UP/2014/RR20; No. dean/2021/EC/2502, dated 15 February 2021), patients were recruited during the study period from 2021 to 2023. The principles of the Declaration of Helsinki (2013) and the Good Clinical Practice guidelines were followed. The study adhered to the Consolidated Standards of Reporting Trials (CONSORT) statement (Figure 1). Informed written consent was obtained from all participants. This prospective, randomized, double-blinded study was conducted with permission to use the data for educational and research purposes.

Sixty neonates aged below 10 days, of both sexes and weighing >1.8 kg, undergoing primary TEF repair were included. Neonates with parental refusal for consent, weight <1.8 kg, hemodynamic instability, established sepsis, hypoxic-ischemic encephalopathy, long-gap TEF (>3 cm), or associated cardiac anomalies were excluded. Neonates were randomly assigned to one of two groups using a computer-generated randomization table (OpenEpi.com, Version 3), with assignments placed in sealed, opaque envelopes. The allocation ratio was 1:1. Blinding was ensured as follows: the anesthesiologist administering the study drug and the observer recording outcomes were both unaware of group allocation. Study drugs were prepared by an independent anesthesiologist not involved in patient management or data collection.

Group P: Induction with propofol 1.5 mg kg^{-1}

Group K: Induction with ketamine 1 mg kg^{-1}

All neonates received intravenous fentanyl 0.5 µg kg^{-1} as premedication immediately before induction to provide analge-

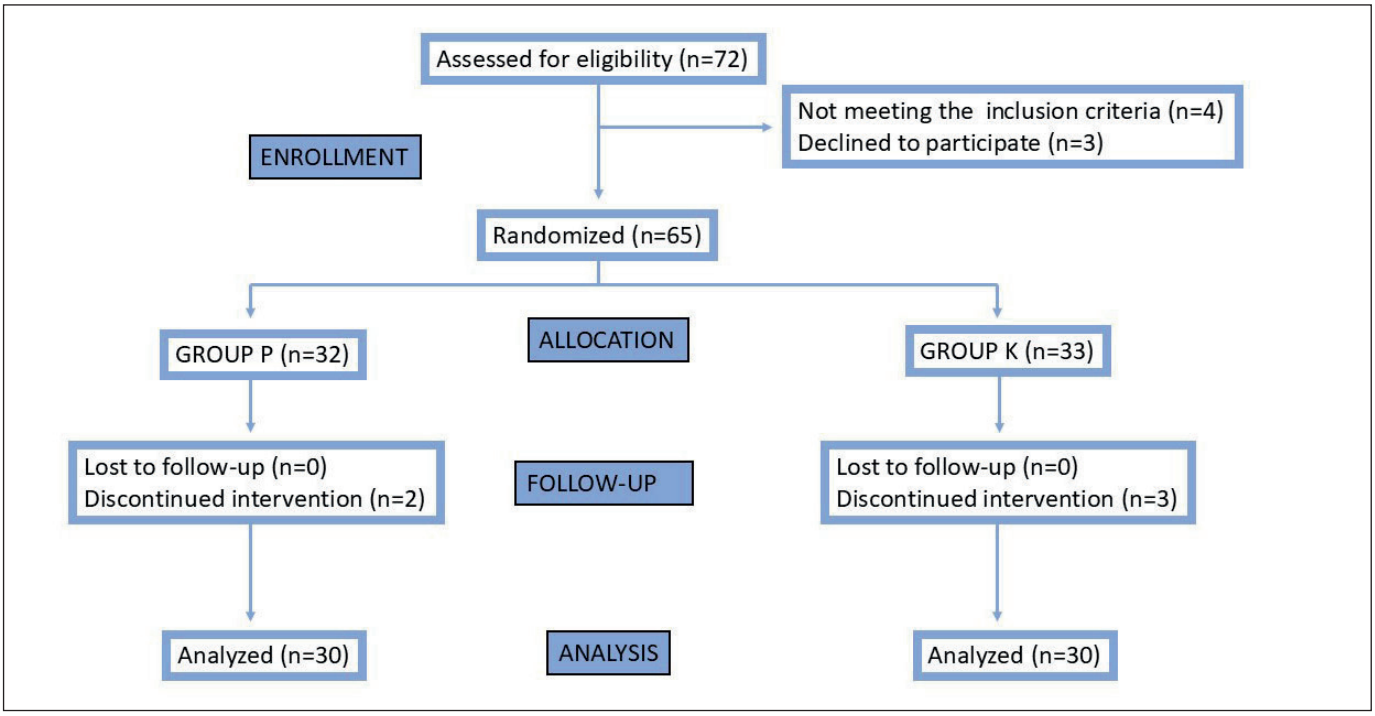

Figure 1. Flowchart of participants through the study. **Group P:** Group Propofol, **Group K:** Group Ketamin.

sia and blunting of the intubation response. Cisatracurium 0.15 mg kg^{-1} was administered after induction to facilitate endotracheal intubation. Endotracheal intubation was performed using conventional laryngoscopy, and an appropriately sized endotracheal tube was positioned below the level of the fistula and above the carina. Correct tube placement was confirmed using a fiberoptic bronchoscope. Anesthesia was maintained with sevoflurane minimum alveolar concentration of 1.8. Postoperative analgesia was provided with iv paracetamol 10 mg kg^{-1} every 8 hours.

Intraoperatively, ventilation parameters and hemodynamic variables were recorded every 15 minutes. Heart rate, non-invasive blood pressure, pulse oximetry (SpO_2), end-tidal carbon dioxide, temperature, and capillary refill time were documented. Ventilatory parameters including peak and plateau pressures, tidal volume, positive end-expiratory pressure, and inspiratory-to-expiratory (I:E) ratio were noted to ensure permissive hypercapnia. An additional bolus of fentanyl 0.25 µg kg^{-1} was administered in aliquots if HR increased >20% above baseline after ruling out other causes of tachycardia and when pain was suspected.

Patients were monitored in the NICU and extubated after a minimum mandatory ventilation period of 4 hours. The primary outcome was recovery at the time of extubation, assessed using the MSS. Secondary outcomes included postoperative pain scores using N-PASS at 4^{th}, 8^{th}, 12^{th}, 16^{th}, 20^{th}, and 24^{th} hours, postoperative fentanyl consumption in the first 24 hours, and duration of mechanical ventilation. Rescue fentanyl (0.25 µ kg^{-1}) was administered for N-PASS >3. Patients who were not extubated within 24 hours were excluded from further analysis.

The sample size was calculated using OpenEpi.com, Version 3, based on a pilot study of eight patients, which identified a minimum expected difference of 12.5% between groups. In the pilot study, MSS was 4.5 ± 0.85 in Group P and 4.0 ± 0.90 in Group K. For statistically significant results with $\alpha = 0.05$, $\beta = 0.80$, and 95% confidence interval, 22 patients per group were required (Fleiss, Statistical Methods for Rates and Proportions). Allowing for a 10% dropout rate, minimum 30 patients were enrolled in each group.

Statistical Analysis

All data were compiled and analyzed using Microsoft Excel (Office 365), GraphPad Prism 8.4.2, and the Statistical Package for the Social Sciences (SPSS) Version 27 (IBM Corp., Armonk, NY, USA). Normality of distribution was tested using the Kolmogorov–Smirnov test. Descriptive statistics were presented as proportions for categorical variables (sex) and mean (SD) for normally distributed continuous variables (age, weight, heart rate, blood pressure, duration of mechanical ventilation, N-PASS). These were compared using Student's t-test. Non-normally distributed variables (Modified Steward Score) were expressed as median and interquartile range (IQR) and compared using the Mann–Whitney U test. A two-tailed p value <0.05 was considered statistically significant. The chi-square test was used for categorical variables.

Table I. Baseline Patient Demographics

Parameters	Group P (n=30)	Group K (n=30)	p-value
Gestational age (weeks), mean (SD)	37.1 (1.4)	37.3 (1.5)	0.62
Age (days), mean (SD)	1.77 (0.81)	1.68 (0.71)	0.696
Preterm birth, n (%)	8 (26.7)	7 (23.3)	0.76
Weight (kg), mean (SD)	2.12 (0.26)	2.17 (0.27)	0.712
Sex (Male/Female)	22/8	20/10	0.470
Heart rate (beats minute^{-1}) mean (SD)	148.81 (11.50)	145.78 (11.70)	0.498
SBP (mmHg), mean (SD)	69.90 (10.04)	72.09 (9.75)	0.630
DBP (mm Hg), mean (SD)	39.27 (6.80)	39.72 (5.68)	0.789
MAP (mm Hg), mean (SD)	46.82 (12.87)	46.04 (11.41)	0.785
Duration of surgery (minutes), mean (SD)	92.4 (12.6)	94.1 (13.2)	0.54
Duration of anesthesia (minutes), mean (SD)	128.6 (15.4)	130.2 (16.1)	0.68
Intraoperative fentanyl bolus requirement (µg kg^{-1}), mean (SD)	0.32 (0.14)	0.28 (0.12)	0.21

Data expressed as mean (SD) [95% confidence interval] or frequency. **SD:** Standard deviation, **SBP:** Systolic blood pressure, **DBP:** Diastolic blood pressure, **MAP:** Mean arterial pressure, **kg:** kilogram, **n:** number. The haemodynamic parameters are the baseline values noted prior to induction of anesthesia. **Group P:** Group Propofol, **Group K:** Group Ketamin.

Table II. Comparison of Modified Steward Score and Duration of Mechanical Ventilation Among Both Groups

Parameters	Group P (n=30)	Group K (n=30)	p-value
Modified Steward Score median (IQR)	6 (5, 3)	4 (3, 2)	**0.001**
Duration of mechanical ventilation (hours) mean (SD)	18.24 (3.70)	21.45 (2.59)	**0.001**

Data expressed as mean (SD) [95% confidence interval]. Data expressed as median (IQR) (Min: Max). **IQR:** Interquartile range, **n:** Numbers. p<0.05 is statistically significant using Mann-Whitney's U-test and paired t-test. **SD:** standard deviation, **n:** numbers, **Group P:** Group Propofol, **Group K:** Group Ketamin.

Table III. Comparison of N-PASS Between 2 Groups at Various Time Intervals

	Group P (n=30)	Group K (n=30)	p-value
N-PASS 4th hour	1.29 (0.38)	0.39 (0.78)	0.011
N-PASS 8th hour	2.01 (0.26)	0.65 (0.71)	0.001
N-PASS 12th hour	2.05 (0.36)	0.82 (0.88)	0.002
N-PASS 16th hour	2.82 (0.79)	0.91 (0.91)	0.001
N-PASS 20th hour	2.86 (0.88)	1.27 (1.2)	0.001
N-PASS 24th hour	3.55 (1.22)	1.59 (1.1)	0.001

Data expressed as mean (SD) [95% confidence interval]. **SD:** Standard deviation, **N-PASS:** Neonatal pain agitation and sedation scale. p<0.05 is statistically significant using Mann-Whitney's U-test. **Group P:** Group Propofol, **Group K:** Group Ketamin, **SD:** Standard deviation.

RESULTS

A total of 72 patients were assessed for eligibility; 12 were excluded, and 60 patients were finally analyzed in the study. The CONSORT flow diagram for this trial is shown in Figure 1. There was no significant difference between the two groups with respect to baseline characteristics such as age, weight, sex distribution, and SpO_2 levels (Table I).

The primary outcome- MSS, was significantly higher in Group P compared with Group K (4.86 ± 0.89 vs. 3.09 ± 1.01; p< 0.001) (Table II). The duration of mechanical ventilation was also significantly shorter in Group P than in Group K (18.00 ± 3.70 h vs. 21.45 ± 2.55 h; p=0.001) (Table II).

The N-PASS scores were significantly lower in Group K than in Group P across all time intervals from 4 to 24 hours (Table III). Heart rate was significantly higher in Group P compared with Group K at all recorded intervals (Figure 2). Mean arterial pressure was significantly higher in Group K than in Group P up to the 12th postoperative hour (Figure 3).

Postoperative fentanyl requirement was significantly higher in Group P compared with Group K (1.18 ± 0.32 vs. 0.54 ± 0.27 µg kg^{-1}; p<0.001). Group P also required more rescue doses overall, with 60% of neonates receiving ≥2 rescue doses compared with 20% in Group K (p=0.001).

DISCUSSION

This randomized controlled study highlights important differences between propofol and ketamine when used for induction in neonatal TEF surgery. Propofol led to significantly faster recovery and a shorter duration of mechanical ventilation, making it a preferred agent in ERAS protocols that emphasize rapid return to baseline physiology.

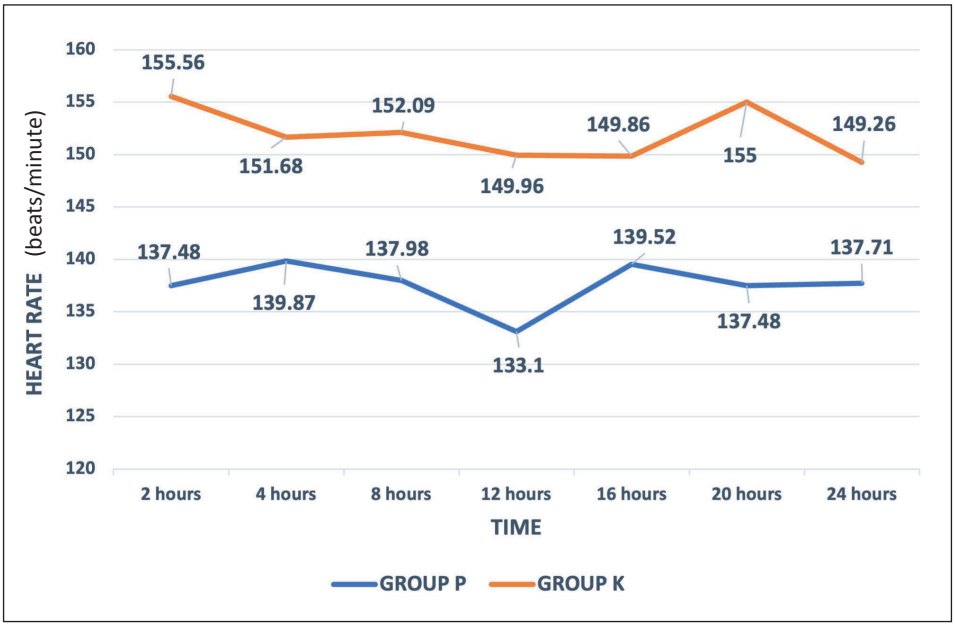

Figure 2. Comparison of heart rate among both groups. **Group P:** Group Propofol, **Group K:** Group Ketamin.

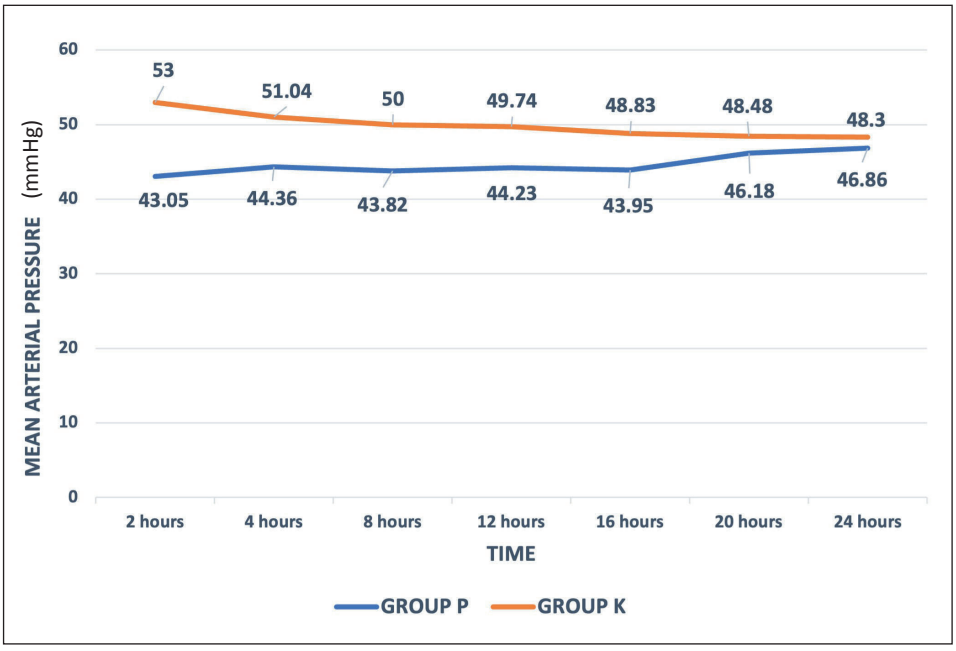

Figure 3. Comparison of mean arterial pressure among both groups.
Group P: Group Propofol,
Group K: Group Ketamin.

The MSS at extubation was significantly higher in the propofol group compared with the ketamine group, indicating faster recovery from anesthesia. Propofol provides smooth induction and rapid recovery with minimal postoperative side effects. Its high lipid solubility allows rapid penetration of the blood–brain barrier, resulting in a rapid onset of action. Due to rapid redistribution and elimination, with a required decrease of less than 50% in serum concentration for awakening, recovery from propofol remains fast even after prolonged infusion (9). Previous studies have similarly demonstrated faster recovery with propofol. In pediatric cardiac catheterization, recovery assessed using the Steward scoring system was significantly quicker with propofol (10). Another study reported that the time required for the MSS to reach 6 was longer in the ketamine group than in the propofol group among male pediatric patients undergoing circumcision (11). The longer duration of mechanical ventilation observed in the ketamine group in our study is also explained by the prolonged sedative action of ketamine and its active metabolite, norketamine. These findings support the use of propofol when early extubation is a priority.

Pain was assessed using the N-PASS scale. The N-PASS scores were significantly lower in Group K than in Group P across all postoperative intervals. Ketamine acts on multiple receptor systems, including NMDA, opioid, and monoaminergic receptors. NMDA receptor antagonism plays a critical role in reducing hyperalgesia and preventing antinociceptive tolerance, which may explain the prolonged analgesic effect of ketamine (12). Previous studies have shown that ketamine in combination with acetaminophen results in lower postoperative pain scores than acetaminophen alone, and that low-dose ketamine reduces postoperative pain without significant adverse effects (13). In children with chronic pain due to complex regional pain syndromes, ketamine infusion has been shown to significantly reduce pain scores (14). The prolonged analgesic effect of ketamine is attributed to sustained low concentrations of ketamine and norketamine in blood and tissues. The findings of the present study are consistent with these observations and support ketamine's role as an effective postoperative analgesic and pain modulator.

Heart rate was significantly higher with ketamine than with propofol throughout the postoperative period. Similarly, mean arterial pressure was significantly higher in Group K up to the 12th postoperative hour. Ketamine increases arterial blood pressure, heart rate, and cardiac output through systemic catecholamine release, vagal inhibition, and inhibition of norepinephrine reuptake at sympathetic ganglia (13). In contrast, the decrease in arterial pressure after propofol induction is due to reduced cardiac output and systemic vascular resistance. Propofol may also reset or inhibit the baroreflex, preventing a compensatory increase in heart rate during hypotension (10).

The pharmacokinetic properties of propofol—namely high lipid solubility and rapid redistribution—support our findings of shorter emergence time and lower incidence of emergence delirium. Conversely, ketamine provided superior postoperative analgesia, reflected in consistently lower N-PASS scores during the 24-hour monitoring period. By blocking NMDA receptors and reducing central sensitization, ketamine prolongs analgesic effects and decreases postoperative opioid requirements. Hemodynamically, ketamine demonstrated more stable parameters, with significantly higher heart rate and mean arterial pressure values compared with propofol—an advantage in neonates prone to hypotension. However, this hemodynamic stability comes at the cost of delayed recovery and increased duration of mechanical ventilation.

The ideal anesthetic for neonatal TEF repair remains context-dependent. Ketamine may be more suitable for patients at risk of cardiovascular instability or those requiring enhanced postoperative analgesia. In contrast, for cases where early extubation and shorter ICU stay are desired, propofol appears more favorable.

CONCLUSION

In neonates undergoing TEF repair, propofol facilitates faster postoperative recovery and earlier extubation, whereas ketamine provides prolonged analgesia and superior hemodynamic stability. The choice of anesthetic should be tailored to the patient's clinical condition and ERAS objectives, balancing rapid recovery with the need for adequate pain control and cardiovascular safety. The limited sample size may have restricted the detection of rare adverse events. Furthermore, only type C TEF was included, limiting the generalizability of the findings to other TEF subtypes. Larger, multicenter studies are needed to further evaluate the effects of intravenous anesthetic agents in this population.

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AI tool used was ChatGPT. AI based tools were used only for language refinement and grammar checking, without influencing the scientific content, data interpretation, or conclusions. Also, we made human revisions after receiving this assistance, while still accepting full responsibilitiy.

AUTHOR CONTRIBUTIONS

Conception or design of the work: AR
Data collection: JP
Data analysis and interpretation: R
Drafting the article: NA
Critical revision of the article: KS
The author (JP, AR, Reena, NA, KS) reviewed the results and approved the final version of the manuscript.

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