Research Article



Volume 5 Issue 1

Comparative Study of Ketofol and Propofol-Fentanyl Combination for Sedation and Analgesia during Tubal Sterilisation Procedures at a Tertiary Care Centre in Hyderabad

Nori A*, Chakravarthy K, Alagandala A and Naik RP

Department of Anaesthesiology, M.N.J. Institute of Oncology and Regional Cancer Centre, India

***Corresponding author:** Aparna Nori, Senior Resident, Department of Anaesthesiology, M.N.J. Institute of Oncology and Regional Cancer Centre, Red Hills, Hyderabad, Telangana State-500004, India, Email: aparnanori9@gmail.com

Received Date: September 28, 2024; Published Date: October 15, 2024

Abstract

Background: The study aimed to compare the efficacy and safety of two sedation regimens – Ketofol (a combination of ketamine and propofol) and a propofol-fentanyl combination – during tubal sterilization procedures. The parameters evaluated included hemodynamic stability, sedation and recovery times, pain control, and the incidence of adverse effects.

Methods: A prospective, randomized controlled trial was conducted on 100 ASA physical status I/II female patients aged 18-50 years undergoing elective tubal sterilization. Patients were randomly assigned to either Group 1 (KF) receiving Ketofol (n=50) or Group 2 (PF) receiving propofol-fentanyl (n=50). The sedation protocol aimed for a Ramsay sedation score of 5-6, and hemodynamic parameters were monitored every 5 minutes during the procedure. The Visual Analogue Scale (VAS) was used to assess postoperative pain, and any adverse effects were recorded. Data analysis was performed using appropriate statistical tests, with significance set at p < 0.05.

Results: Demographic characteristics were comparable between the two groups. During the procedure, Group 1 (KF) showed significantly more stable hemodynamic parameters, with higher systolic BP ($122.88 \pm 6.85 \text{ mmHg vs. } 111.30 \pm 14.19 \text{ mmHg, p} < 0.001$) and diastolic BP ($79.12 \pm 6.46 \text{ mmHg vs. } 70.26 \pm 14.31 \text{ mmHg, p} = 0.005$) during incision. MAP and SpO2 were also more stable in Group 1. Sedation duration was longer in the KF group ($17.72 \pm 1.28 \text{ minutes}$) compared to PF ($16.46 \pm 0.81 \text{ minutes}$, p < 0.001), with a longer recovery time ($8.74 \pm 1.12 \text{ minutes vs. } 6.34 \pm 1.38 \text{ minutes}$, p < 0.001). VAS scores were significantly lower in Group 1 at all postoperative time points, indicating better pain control. Fewer patients in Group 1 required rescue analgesia (12% vs. 32%, p = 0.037). Adverse effects were more prevalent in Group 2, with a significantly higher incidence of hypotension (28% in PF vs. 0% in KF, p < 0.001).

Conclusion: The Ketofol combination demonstrated superior hemodynamic stability, prolonged sedation, better pain control, and fewer adverse effects compared to the propofol-fentanyl combination in patients undergoing tubal sterilization. Ketofol appears to be an effective and safe sedative alternative, providing improved perioperative outcomes and enhancing patient comfort.

Keywords: Ketofol; Propofol-Fentanyl; Sedation; Hemodynamic Stability; Tubal Sterilization

Abbreviations

VAS: Visual Analogue Scale; MAC: Monitored Anesthesia Care; PF: Propofol-Fentanyl; KF: Ketofol.

Introduction

Tubal sterilization is one of the most widely used permanent contraceptive methods worldwide, particularly in developing countries where it represents a critical approach to population control and family planning. As a minimally invasive procedure, it requires effective sedation and analgesia to ensure patient comfort, safety, and optimal surgical conditions. Given its role as a short and generally well-tolerated procedure, anesthesia techniques that balance sedation, pain control, and quick recovery are of paramount importance in the selection of agents for these procedures [1]. In recent years, the use of various sedative and analgesic combinations, particularly propofol, fentanyl, and ketamine, has gained attention for their effectiveness and safety profiles. However, the optimal combination that offers balanced sedation with minimal side effects remains a topic of research and clinical interest.

Traditionally, tubal sterilization has been performed under general anesthesia or local anesthesia with sedation. However, the advent of monitored anesthesia care (MAC) has facilitated better patient experiences by combining sedative and analgesic medications to achieve conscious sedation while maintaining spontaneous respiration and cardiovascular stability [2]. The primary objective is to achieve an adequate level of sedation while ensuring rapid recovery and minimal side effects, which are crucial in outpatient surgical settings like tubal sterilization [3].

Ketofol, a mixture of ketamine and propofol, has been proposed as an alternative sedation regimen that may offer a balanced profile of sedative, analgesic, and hemodynamic effects [4]. Ketamine, an NMDA receptor antagonist, provides potent analgesia and dissociative sedation without significantly depressing respiratory or cardiovascular function. Unlike propofol and fentanyl, ketamine has the advantage of maintaining airway reflexes and providing bronchodilation, which is particularly useful in patients with reactive airway disease [5]. However, ketamine's side effects, such as emergence phenomena (hallucinations, nightmares), increased secretions, and tachycardia, may limit its use as a single agent. When combined with propofol, the two agents' complementary pharmacological profiles mitigate each other's side effects: propofol reduces ketamine-associated emergence reactions, and ketamine minimizes the risk of hypotension from propofol [6]. Therefore, ketofol has gained popularity as a sedative-analgesic combination for various

short procedures requiring MAC.

Multiple studies have explored the use of ketofol as an alternative to traditional sedative-analgesic combinations like propofol-fentanyl, particularly for short surgical procedures, with demonstration of superior hemodynamic stability, reduced postoperative pain, and quicker recovery times compared to other regimens [7,8]. In addition, ketofol's balanced sedation and analgesia provide a better experience for patients undergoing procedures requiring MAC. However, the literature reveals some heterogeneity in dosing, formulation ratios, and outcomes measured across studies, leading to a need for more standardized comparisons between ketofol and propofol-fentanyl combinations.

This study aimed to compare the efficacy and safety of the above combination with that of propofol-fentanyl for sedation and analgesia during tubal sterilization procedures. The primary objective was to evaluate the hemodynamic stability, sedation levels, recovery profiles, and patient comfort associated with each regimen. The secondary objective was to assess the incidence of side effects, such as hypotension, respiratory depression, PONV, and any adverse reactions, which could influence the selection of the optimal sedation protocol.

Maintaining hemodynamic stability during sedation is critical to ensuring patient safety and comfort, particularly in procedures like tubal sterilization where short durations and low invasiveness require prompt but safe sedation, and the ability of ketamine to preserve blood pressure and heart rate due to its sympathomimetic effects makes it a potentially advantageous component in the ketofol combination, which would result in smoother procedures and quicker recovery times.

Another important consideration in sedation for tubal sterilization is the recovery profile and depth of sedation achieved. An optimal sedation regimen should allow for quick and clear-headed recovery post-procedure, with minimal side effects and discomfort. Propofol is well-known for its rapid recovery profile; however, its effects can be prolonged when used in higher doses or combined with opioids like fentanyl. Ketofol, on the other hand, may offer a similar depth of sedation with reduced risk of oversedation and faster recovery times, as demonstrated in studies where patients returned to baseline alertness quickly without prolonged sedation or hangover effects [9].

Postoperative pain management and patient comfort are also critical factors in determining the optimal sedation protocol for tubal sterilization. While fentanyl provides effective analgesia during the procedure, its relatively short half-life means that pain may re-emerge in the immediate postoperative period unless supplemental analgesia is provided. In contrast, ketamine provides prolonged analgesia due to its NMDA receptor antagonism, which may result in lower pain scores postoperatively and reduced need for rescue analgesics [10].

Side effects of sedative-analgesic combinations play a significant role in their clinical utility and patient acceptance. The use of propofol-fentanyl is often associated with respiratory depression, hypotension, and PONV, which can complicate the perioperative period and delay recovery [11]. Ketofol, by virtue of its balanced sedative and analgesic properties, has been reported to have a favorable side effect profile, with minimal respiratory depression and lower incidences of hypotension [12]. However, ketamine's potential to cause dysphoric reactions or increased salivation requires careful dosing and administration, usually offset by the propofol component.

Given the increasing interest in optimizing sedation protocols for short procedures like tubal sterilization, it is essential to establish evidence-based guidelines that consider efficacy, safety, and patient comfort. While propofol-fentanyl remains a commonly used regimen, the ketofol combination may offer a more balanced approach with improved hemodynamic stability, faster recovery, better postoperative pain control, and fewer side effects. However, direct comparisons of these combinations in the context of tubal sterilization are limited. This study seeks to address this gap by evaluating and comparing the sedation quality, safety, and patient outcomes between ketofol and propofol-fentanyl combinations.

Methodology

Study Design

The study was designed as a prospective, randomized, controlled trial. It aimed to compare the efficacy and safety of two sedative regimens – Ketofol (a combination of ketamine and propofol) and a propofol-fentanyl combination – for sedation and analgesia during tubal sterilization procedures. Patients were randomly allocated into two study groups, and the outcomes were measured preoperatively, intraoperatively, and postoperatively to evaluate both sedation quality and patient comfort.

Study Setting

The study was conducted at tertiary care centers in Hyderabad, providing a controlled environment suitable for performing tubal sterilization procedures. The hospitals involved were equipped with standard anesthesia facilities, emergency crash carts, and monitoring equipment necessary for both patient safety and accurate data collection.

Study Duration

The research was carried out over a fixed period, allowing adequate time for recruitment, randomization, and follow-up of all participants. The duration encompassed the time needed for preoperative evaluation, anesthesia administration, intraoperative monitoring, and postoperative recovery assessment.

Participants - Inclusion and Exclusion Criteria

The participants of this study were women aged 18 to 50 years, classified as ASA physical status I/II, scheduled to undergo elective tubal sterilization. The inclusion criteria mandated that participants were healthy, with no significant comorbidities, as assessed during their preoperative evaluation. Exclusion criteria included patients classified as ASA III/IV, those with significant comorbidities, hypersensitivity to the study drugs (ketamine, propofol, fentanyl), or those unable to provide informed consent.

Study Sampling

A randomized sampling method was employed to ensure unbiased allocation of participants to either of the study groups. The patients were randomly assigned into two groups using a computer-generated sequence to ensure a fair distribution of participants across both the Ketofol group and the propofol-fentanyl combination group.

Study Sample Size

A total of 100 patients were enrolled in the study. The sample size was determined based on prior data and statistical considerations to achieve adequate power for detecting differences between the two groups. Fifty patients were allocated to Group A (Ketofol), and fifty patients were assigned to Group B (Propofol-Fentanyl).

Study Groups

The study comprised two groups:

- Group A (Ketofol group): Received a combination of ketamine and propofol in a mixture of 1 ml of 50 mg/ml ketamine with 10 ml of 10 mg/ml propofol.
- Group B (Propofol-Fentanyl group): Received propofol at a dose of 1.5–2 mg/kg combined with fentanyl at 2 μg/kg.

Study Parameters

The study parameters included intraoperative hemodynamics (heart rate, blood pressure, respiratory rate, and oxygen saturation), sedation levels using the Ramsay Sedation Scale, recovery time, post-procedure Aldrete score for recovery assessment, and postoperative pain using a Visual Analogue Scale (VAS) for pain over a period of 30 minutes to 2 hours postoperatively.

Study Procedure

Prior to the procedure, a pre-anesthetic evaluation was performed on all patients, which included a detailed history and clinical examination. Hemodynamic parameters such as weight, heart rate, blood pressure, and respiratory rate were documented. Investigations included blood grouping, complete blood picture, bleeding time, clotting time, renal function tests, serum electrolytes, random blood sugar, ECG, and chest X-ray. An IV cannula (18G or 20G) was inserted, and premedication was administered, consisting of IV glycopyrrolate 0.2 mg, ondansetron 4 mg, and midazolam at a dose of 0.05 mg/kg. Preoxygenation was provided for 3-4 minutes before administering the sedation regimen according to the assigned group. The sedation level aimed was a Ramsay sedation score of 5-6, which was monitored every 5 minutes throughout the procedure, with emphasis on occurrence of hypotension (defined as NIBP values 20% lesser than preoperative measurements), bradycardia (HR <= 48/min or 20% lesser than preoperative measurements, chosen according to preoperative vitals), and apnoea (respiratory rate <6 breaths/min). Postoperatively, recovery time was assessed, and the Aldrete score was recorded to determine readiness for discharge. In the postoperative period, the Visual Analogue Scale (VAS) was employed to assess the extent of postprocedural pain, and rescue medication in the form of Inj. Paracetamol 1g intravenously was administered when VAS scores were ≥ 5 .

Study Data Collection

Data collection was conducted at multiple stages: preoperative baseline parameters, intraoperative hemodynamics at regular intervals, Ramsay sedation scores, and postoperative recovery assessments. Patient comfort, level of sedation, and any adverse events were documented in a proforma. Postoperative pain was evaluated using the Visual Analogue Scale (VAS) at intervals from 30 minutes to 2 hours after the procedure.

Data Analysis

Data were compiled and analyzed using appropriate statistical methods. The primary outcomes (sedation levels, hemodynamics, and recovery profiles) were compared between the two groups using statistical tests such as the t-test or chi-square test where applicable. The significance level was set to p < 0.05 for determining statistical significance between the groups.

Ethical Considerations

The study received approval from the Institutional Ethics Committee before commencement. Written informed consent was obtained from all patients prior to their participation, ensuring they were aware of the study's purpose, procedures, risks, and benefits. The study adhered to the principles of the Declaration of Helsinki, ensuring patient confidentiality and safety throughout the research process.

Result and Analysis

Demographics and Baseline Characteristics

Interpretation: The baseline characteristics, such as age, weight, and initial hemodynamic parameters (systolic BP, diastolic BP, MAP, SpO2, and heart rate), were comparable between the two groups with no significant differences, except for baseline systolic BP, which was slightly higher in the Propofol-Fentanyl (PF) group. The lack of significant differences in most parameters indicates a balanced allocation of participants, ensuring that any effects observed during the procedure can be attributed to the sedative agents used Table 1.

Parameter	Group 1 (KF) Mean ± SD	Group 2 (PF) Mean ± SD	P-value
Age (Years)	26.56 ± 3.78	26.58 ± 3.63	0.7341
Weight (kg)	54.90 ± 3.17	54.48 ± 3.02	0.3281
Systolic BP (Baseline) (mmHg)	118.60 ± 8.48	122.56 ± 5.93	0.0191
Diastolic BP (Baseline) (mmHg)	75.74 ± 7.71	76.80 ± 5.62	0.5211
MAP (Baseline) (mmHg)	88.44 ± 9.94	91.60 ± 5.05	0.3261
SpO2 (Baseline) (%)	98.50 ± 0.61	98.48 ± 0.58	0.9351
Heart Rate (Baseline) (BPM)	79.48 ± 9.62	80.16 ± 8.91	0.5191

 Table 1: Demographics and Baseline Characteristics.

https://academicstrive.com/JCRPA/

Hemodynamic Parameters during Incision

Interpretation: During the incision, Group 1 (Ketofol) demonstrated more stable hemodynamic parameters compared to Group 2 (PF). Systolic BP, diastolic BP, and MAP were significantly higher in the KF group, suggesting that

Ketofol maintains better cardiovascular stability. Group 1 also had higher SpO2 levels and a higher heart rate during incision, indicating better oxygenation and hemodynamic control Table 2.

Parameter	Group 1 (KF) Mean ± SD	Group 2 (PF) Mean ± SD	P-value
Systolic BP (Incision) (mmHg)	122.88 ± 6.85	111.30 ± 14.19	<0.001
Diastolic BP (Incision) (mmHg)	79.12 ± 6.46	70.26 ± 14.31	0.005
MAP (Incision) (mmHg)	93.34 ± 6.13	83.70 ± 14.03	0.001
SpO2 (Incision) (%)	99.28 ± 0.45	98.10 ± 3.81	< 0.001
Heart Rate (Incision) (BPM)	82.60 ± 9.92	74.22 ± 13.23	0.001

Table 2: Hemodynamic Parameters during Incision.

Hemodynamic Parameters after 10 Minutes of Procedure

Interpretation: At 10 minutes into the procedure, there were some significant differences between the groups in

hemodynamic parameters. Group 1 (KF) showed slightly higher systolic BP, MAP, SpO2, and heart rate, indicating a stable cardiovascular status. The diastolic BP was lower but not significantly different between the groups Table 3.

Parameter	Group 1 (KF) Mean ± SD	Group 2 (PF) Mean ± SD	P-value
Systolic BP (10 Minutes) (mmHg)	115.64 ± 5.11	112.86 ± 6.07	0.022
Diastolic BP (10 Minutes) (mmHg)	72.74 ± 5.17	70.64 ± 5.52	0.075
MAP (10 Minutes) (mmHg)	86.74 ± 4.78	84.46 ± 5.31	0.044
SpO2 (10 Minutes) (%)	99.42 ± 0.61	98.88 ± 0.48	<0.001
Heart Rate (10 Minutes) (BPM)	78.56 ± 10.29	71.14 ± 5.08	<0.001

Table 3: Hemodynamic Parameters after 10 Minutes of Procedure.

Sedation and Recovery Time

Interpretation: The total sedation time was significantly longer in the KF group compared to the PF group, suggesting a more prolonged sedative effect of Ketofol. Recovery time was also notably longer in Group 1 (KF), indicating that patients in the Ketofol group took more time to return to baseline consciousness and activity Table 4.

Parameter	Group 1 (KF) Mean ± SD	Group 2 (PF) Mean ± SD	P-value
Total Sedation Time (minutes)	17.72 ± 1.28	16.46 ± 0.81	<0.001
Total Recovery Time (minutes)	8.74 ± 1.12	6.34 ± 1.38	<0.001

 Table 4: Sedation and Recovery Time.

VAS Scores at Various Time Points

Interpretation: Postoperative pain scores, as measured by the Visual Analogue Scale (VAS), were consistently lower in Group 1 (KF) at all measured time points. This suggests better pain control in the Ketofol group compared to the PF group. The difference was significant at all-time points, with the most notable difference in the initial 15 to 30 minutes post-procedure Table 5.

Journal of Clinical Research in Pain and Anaesthesia

Time Point	Group 1 (KF) Mean ± SD	Group 2 (PF) Mean ± SD	P-value
Post-Op 0 min	3.36 ± 0.63	3.98 ± 0.96	0.001
Post-Op 15 min	2.80 ± 0.76	3.76 ± 1.04	< 0.001
Post-Op 30 min	2.60 ± 0.73	3.42 ± 1.25	0.001
Post-Op 60 min	2.40 ± 0.67	3.36 ± 1.27	< 0.001
Post-Op 90 min	2.22 ± 0.51	3.08 ± 1.28	< 0.001
Post-Op 120 min	2.04 ± 0.35	2.90 ± 1.22	< 0.001
Post-Op 150 min	1.96 ± 0.35	2.50 ± 0.86	< 0.001
Post-Op 180 min	1.74 ± 0.44	2.08 ± 0.63	0.003

Table 5: VAS Scores at Various Time Points.

Adverse Effects

Interpretation: Adverse effects were significantly more prevalent in Group 2 (PF). Group 1 (KF) had fewer cases

of hypotension and none reported in Group 1. There was a small incidence of apnea and bradycardia in both groups, but these were not significantly different Table 6.

Adverse Effect	Group 1 (KF) n (%)	Group 2 (PF) n (%)	P-value
None	42 (84%)	26 (52%)	< 0.001
Hypotension	0 (0%)	14 (28%)	< 0.001
Apnea	6 (12%)	7 (14%)	0.5
Bradycardia	2 (4%)	3 (6%)	0.5

Table 6: Adverse Effects.

Need for Rescue Analgesia

Interpretation: A significantly higher proportion of patients in Group 2 (PF) required rescue analgesia compared to Group 1 (KF). The type of rescue analgesia used was IV paracetamol, which was administered more frequently in the PF group. This indicates that patients in the Ketofol (KF) group experienced less postoperative pain and required fewer additional analgesics Table 7.

Parameter	Group 1 (KF) n (%)	Group 2 (PF) n (%)	P-value
Need for Rescue Analgesia (%)	6 (12%)	16 (32%)	0.037
Type of Rescue Analgesia (IV Paracetamol)	6 (12%)	16 (32%)	0.037

Table 7: Need for Rescue Analgesia.

Discussion

This study aimed to compare the efficacy and safety of two sedative regimens – Ketofol (a combination of ketamine and propofol) and a propofol-fentanyl combination – for sedation and analgesia during tubal sterilization procedures. The main focus was to evaluate hemodynamic stability, sedation and recovery times, pain control, and the incidence of adverse effects. A total of 100 patients, all classified as ASA physical status I or II, were randomized into two groups of 50 each: Group 1 (KF), which received Ketofol, and Group 2 (PF), which received propofol-fentanyl. The results demonstrated that Ketofol was superior to the propofol-fentanyl combination in terms of hemodynamic stability, better postoperative analgesia, fewer adverse effects, and reduced need for rescue analgesia.

The demographic characteristics of both groups were comparable, with no significant differences in age, weight, and baseline hemodynamic parameters, ensuring the internal validity of the study. The mean age was 26.56 ± 3.78 years in the Ketofol group and 26.58 ± 3.63 years in the propofol-fentanyl group, with a p-value of 0.7341, indicating no significant difference. Similarly, the baseline weight (54.90 ± 3.17 kg in Group KF and 54.48 ± 3.02 kg in Group PF, p = 0.3281) and other vital parameters such as diastolic BP, MAP, SpO2, and heart rate were similar across the two groups. However, there was a slight but significant difference

in baseline systolic BP (118.60 \pm 8.48 mmHg in Group KF vs. 122.56 \pm 5.93 mmHg in Group PF, p = 0.0191). The absence of significant baseline differences in most parameters facilitated a balanced comparison of the effects of the two sedation protocols.

One of the primary outcomes was the hemodynamic stability during various phases of the procedure, particularly during the incision. Patients in Group 1 (KF) demonstrated significantly more stable hemodynamics compared to those in Group 2 (PF). During the incision phase, the systolic BP was significantly higher in the KF group (122.88 \pm 6.85 mmHg) compared to the PF group (111.30 ± 14.19 mmHg, p < 0.001), indicating a better cardiovascular response. A similar pattern was observed for diastolic BP (79.12 ± 6.46 mmHg in Group KF vs. 70.26 ± 14.31 mmHg in Group PF, p = 0.005) and MAP (93.34 ± 6.13 mmHg in Group KF vs. 83.70 \pm 14.03 mmHg in Group PF, p = 0.001). The KF group also maintained significantly better oxygen saturation levels (SpO2) during incision (99.28 ± 0.45% in Group KF vs. 98.10 ± 3.81% in Group PF, p < 0.001), and heart rate (82.60 ± 9.92 BPM in Group KF vs. 74.22 ± 13.23 BPM in Group PF, p = 0.001). These findings highlight the superiority of Ketofol in preserving hemodynamic stability during periods of surgical stress.

At 10 minutes into the procedure, the stability in hemodynamic parameters remained in favor of the Ketofol group. The systolic BP remained significantly higher in Group KF (115.64 ± 5.11 mmHg) than in Group PF (112.86 ± 6.07 mmHg, p = 0.022). Although the difference in diastolic BP (72.74 ± 5.17 mmHg in Group KF vs. 70.64 ± 5.52 mmHg in Group PF) was not statistically significant (p = 0.075), the trend still favored the Ketofol group. MAP was also significantly better maintained in Group KF (86.74 ± 4.78 mmHg) than in Group PF (84.46 ± 5.31 mmHg, p = 0.044). Notably, SpO2 levels were consistently higher in Group KF (99.42 ± 0.61%) compared to Group PF (98.88 ± 0.48%, p < 0.001). The heart rate followed a similar pattern, with Group KF having a significantly higher rate (78.56 ± 10.29 BPM) than Group PF (71.14 ± 5.08 BPM, p < 0.001).

The sedation and recovery times were important endpoints of the study, reflecting the efficiency and duration of the sedative effects. The total sedation time was significantly longer in Group KF (17.72 ± 1.28 minutes) than in Group PF (16.46 ± 0.81 minutes, p < 0.001). This suggests that Ketofol has a more prolonged sedative effect, which can be advantageous in ensuring adequate sedation throughout the procedure. Conversely, the total recovery time was also significantly longer in Group KF (8.74 ± 1.12 minutes) compared to Group PF (6.34 ± 1.38 minutes, p < 0.001). The longer recovery time with Ketofol may be attributed to the effects of ketamine, which is known to provide a more

prolonged sedation but can also result in a more gradual recovery.

Pain control, assessed using the Visual Analogue Scale (VAS), was another crucial parameter. The VAS scores were consistently lower in the Ketofol group across all postoperative time points, indicating superior pain control. At 0 minutes postoperatively, the VAS score was 3.36 ± 0.63 in Group KF versus 3.98 ± 0.96 in Group PF (p = 0.001). This trend continued across all measured time points, with significant differences observed at 15 minutes (2.80 ± 0.76 in Group KF vs. 3.76 ± 1.04 in Group PF, p < 0.001), 30 minutes $(2.60 \pm 0.73 \text{ in Group KF vs. } 3.42 \pm 1.25 \text{ in Group PF, } p = 0.001),$ 60 minutes (2.40 ± 0.67 in Group KF vs. 3.36 ± 1.27 in Group PF, p < 0.001), and so on up to 180 minutes postoperatively (1.74 ± 0.44 in Group KF vs. 2.08 ± 0.63 in Group PF, p = 0.003). This significant reduction in postoperative pain in the Ketofol group likely reflects the analgesic properties of ketamine, contributing to reduced pain perception and enhanced patient comfort.

In terms of adverse effects, the study found a significantly lower incidence in Group KF. The proportion of patients without any adverse effects was significantly higher in Group KF (84%) compared to Group PF (52%, p < 0.001). Notably, hypotension, a common side effect of propofol, was observed in 28% of patients in Group PF, whereas none of the patients in Group KF experienced this complication (p < 0.001). The occurrence of apnea was slightly higher in Group PF (14%) compared to Group KF (12%), but this difference was not statistically significant (p = 0.500). Similarly, the incidence of bradycardia was low in both groups (4% in Group KF and 6% in Group PF), with no significant difference (p = 0.500). Overall, the Ketofol combination demonstrated a favorable safety profile with fewer adverse events, potentially due to the stabilizing effects of ketamine on hemodynamics and respiratory function.

A significant finding of the study was the reduced need for rescue analgesia in the Ketofol group. Only 12% of patients in Group KF required additional analgesia in the form of IV paracetamol, compared to 32% in Group PF (p = 0.037). The reduced requirement for rescue analgesia in the Ketofol group further emphasizes the superior analgesic properties of ketamine when used in combination with propofol, contributing to more effective postoperative pain control.

Conclusion

In conclusion, the study found that the Ketofol combination was associated with better hemodynamic stability, as evidenced by more stable systolic and diastolic BP, MAP, SpO2, and heart rate during the surgical procedure. The prolonged sedation and slightly longer recovery times with Ketofol were offset by superior pain control, as indicated by consistently lower VAS scores and a reduced need for rescue analgesia. Additionally, the Ketofol group had a significantly lower incidence of adverse effects, particularly hypotension, which is a known side effect of propofol and fentanyl. These findings suggest that Ketofol is a superior choice for sedation and analgesia during tubal sterilization procedures, providing both effective sedation and enhanced patient comfort with a favorable safety profile.

The results of this study support the use of Ketofol as a preferable alternative to the propofol-fentanyl combination, particularly in settings where hemodynamic stability and postoperative pain control are crucial. The addition of ketamine to propofol not only enhances sedation but also provides a more stable hemodynamic profile and analgesic effect, making it a valuable combination for various clinical procedures requiring sedation.

References

- 1. World Health Organization (2016) Contraceptive Sterilization: Global Overview. Geneva: WHO.
- 2. Khurana G, Sharma S (2019) Monitored Anesthesia Care: Techniques and Trends. Anesth Clin Pract 12(3): 224-229.
- Stoelting RK, Hillier SC (2011) Opioids: Pharmacology and Clinical Use. Basics of Anesthesia. In: 6th (Edn.), Philadelphia: Elsevier.
- 4. Chau-In W, Kyaw W (2018) Fentanyl-Induced Respiratory Depression. Anesth Int J 10(1): 50-55.

- David H, Shipp J (2011) Ketofol for Procedural Sedation: A Systematic Review and Meta-Analysis. Emerg Med J 28(8): 654-661.
- 6. Willman EV, Andolfatto G (2007) A Prospective Evaluation of Ketofol (Ketamine/ Propofol Combination) for Procedural Sedation and Analgesia in the Emergency Department. Ann Emerg Med 49(1): 23-30.
- Aouad MT, Moussa AR (2015) A Comparison of Ketofol Versus Propofol-Fentanyl Combination for Sedation During Colonoscopy: A Randomized Double-Blind Clinical Trial. Anaesthesia 70(7): 711-717.
- 8. Shah A, Mosdossy G (2011) Comparison of Ketamine and Ketofol in Procedural Sedation: A Double-Blind Randomized Controlled Trial. Acad Emerg Med 18(5): 522-529.
- 9. Vuyk J, Sitsen E, Reekers M (2015) Intravenous Anesthetics. In: Miller's Anesthesia. 8th (Edn.), Philadelphia: Elsevier.
- 10. Demiraran Y, Korkut E (2008) The Use of Ketamine-Propofol Combination in Procedural Sedation. Anesth Analg 107(1): 87-91.
- 11. Dal D, Kose A (2009) Efficacy of Low-Dose Ketamine in Reducing Postoperative Pain After Laparoscopic Procedures. Surg Endosc 23(11): 2477-2483.
- 12. Andolfatto G, Willman E (2010) A Prospective Case Series of Single-Syringe Ketamine-Propofol (Ketofol) for Procedural Sedation in the Emergency Department. Ann Emerg Med 56(1): 41-47.