



Original Article

## Comparative Evaluation of Ketamine–Dexmedetomidine and Pentazocine Promethazine for Day Care Laparoscopic Tubal Ligation

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### ABSTRACT

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**Background** Ambulatory laparoscopic tubal ligation requires a sedation technique that provides adequate analgesia, haemodynamic stability, and rapid recovery to allow early discharge. Ketamine–dexmedetomidine and pentazocine–promethazine are commonly used sedative combinations, but comparative evidence for this procedure is limited.

**Aim** To compare the efficacy and safety of ketamine–dexmedetomidine versus pentazocine–promethazine for sedation in ambulatory laparoscopic tubal ligation, with propofol used as a rescue agent when required.

**Methods** This prospective, randomized study included 60 ASA I–II patients undergoing ambulatory laparoscopic tubal ligation, allocated into two groups. Group KD received ketamine with dexmedetomidine, while Group PP received pentazocine with promethazine. Haemodynamic parameters, sedation adequacy, requirement of rescue propofol, recovery characteristics, and adverse effects were recorded and compared.

**Results** Both regimens provided acceptable conditions for surgery. However, the ketamine–dexmedetomidine group demonstrated significantly better sedation quality, greater haemodynamic stability, and a lower requirement for rescue propofol compared to the pentazocine–promethazine group. Recovery was significantly faster in the ketamine–dexmedetomidine group, with earlier response to verbal commands and earlier readiness for discharge. Adverse effects, including nausea, vomiting, excessive postoperative sedation, and respiratory depression, were less frequent in the ketamine–dexmedetomidine group.

**Conclusion** Ketamine–dexmedetomidine provides superior sedation compared to pentazocine–promethazine for ambulatory laparoscopic tubal ligation, with better haemodynamic and respiratory stability, reduced need for rescue sedation, faster recovery, and fewer adverse effects. It appears to be a more suitable sedative regimen for day-care laparoscopic procedures.

**Keywords:** Laparoscopy, Ambulatory, Fallopian tube, Ketamine, Dexmedetomidine, Pentozocine, Promethazine.

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### INTRODUCTION

Ambulatory laparoscopic tubal ligation is a frequently performed outpatient gynecological procedure that requires effective sedation and analgesia while ensuring rapid recovery and early discharge. The ideal sedation technique for such procedures should provide adequate pain relief, patient comfort, and hemodynamic stability, with minimal respiratory depression and postoperative side effects (19).

Ketamine has been widely used for procedural sedation because it provides profound analgesia, maintains airway reflexes, and preserves spontaneous respiration (13,15). However, its use alone may be associated with undesirable effects such as tachycardia, hypertension, and emergence reactions. Dexmedetomidine, a highly selective alpha-2 adrenergic agonist, produces dose-dependent sedation and analgesia with minimal respiratory depression (14,18). When combined, dexmedetomidine attenuates ketamine-induced sympathetic stimulation, while ketamine counterbalances dexmedetomidine-related bradycardia and hypotension, making the combination physiologically complementary (12).

Pentazocine–promethazine is a traditional sedative-analgesic combination commonly used for short gynecological procedures, especially in resource-limited settings. Pentazocine, a mixed opioid agonist–antagonist, provides analgesia, while promethazine contributes sedative, antiemetic, and anxiolytic effects (16,17). Despite its widespread use, this combination may be associated with variable analgesia, postoperative sedation, and opioid-related side effects, potentially delaying recovery in ambulatory surgeries (17).

Although both sedation protocols are in clinical use, there is limited comparative evidence evaluating their efficacy, safety, and recovery characteristics specifically in ambulatory laparoscopic tubal ligation. A direct comparison of ketamine–dexmedetomidine with pentazocine–promethazine may help identify a sedation regimen that offers better patient comfort, stable intraoperative conditions, and faster postoperative recovery suitable for outpatient surgical settings (13,18).

Therefore, this study aims to compare the efficacy, safety, and recovery profile of ketamine–dexmedetomidine versus pentazocine–promethazine for sedation in patients undergoing ambulatory laparoscopic tubal ligation.

## **METHODS**

### **Study Design and Setting:**

This prospective, randomized comparative study was conducted in a tertiary care hospital after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants.

### **Study Population:**

Adult female patients scheduled for ambulatory laparoscopic tubal ligation for contraception were included in the study.

### **Inclusion Criteria:**

- Age 18–45 years
- American Society of Anesthesiologists (ASA) physical status I or II
- Elective ambulatory laparoscopic tubal ligation

### **Exclusion Criteria:**

- Refusal to participate
- ASA physical status III or higher
- Known allergy to study drugs
- Significant cardiovascular, respiratory, hepatic, or renal disease
- Psychiatric illness or chronic opioid use
- Pregnancy or suspected pregnancy

### **Randomization and Group Allocation:**

Patients were randomly allocated into two equal groups using a computer-generated randomization table and sealed opaque envelopes.

Group KD: Received ketamine and dexmedetomidine for sedation

Group PP: Received pentazocine and Promethazine for sedation

### **Anaesthetic Technique:**

Standard fasting guidelines were followed. On arrival in the operating room, baseline heart rate, blood pressure, oxygen saturation and respiratory rate were recorded. All patients received standard monitoring including ECG, non-invasive blood pressure, ET<sub>CO</sub>2 and pulse oximetry. Supplemental oxygen was administered via nasal cannula.

Group KD: Ketamine and dexmedetomidine were administered intravenously to achieve adequate sedation and analgesia. Group KD received injection ketamine 0.5 mg/kg + Dexmedetomidine 1 µg/kg IV over 10 minutes intravenously followed by 0.5 µg/kg/min, stopped after trocar removal.

Group PP: Pentazocine and Promethazine were administered intravenously to achieve adequate sedation and analgesia. Group PP received Injection pantozocine 0.5 mg/kg + Promethazine 0.3mg/kg over 10 minutes followed by normal saline infusion via infusion pump, stopped after trocar removal.

Supplemental dose of IV anaesthetic 0.5mg /kg propofol was given if sedation level was inadequate measured by Ramsay sedation score <4. Intravenous propofol was used as a rescue agent if sedation or analgesia was inadequate RSS <4, defined by patient movement, discomfort, or increase in heart rate or blood pressure greater than 20% from baseline.

Local anaesthetic infiltration at port sites was provided in all patients.

### **Outcome Measures:**

Primary outcome was the requirement of rescue propofol. Secondary outcomes included haemodynamic parameters, sedation adequacy, respiratory events, recovery time, nausea and vomiting, and other adverse effects.

## RESULTS

A total of 60 patients were included in the study, with 30 patients in each group. Demographic characteristics and surgical variables were comparable between Group KD and Group PP. There were no statistically significant differences in age, body weight, ASA physical status distribution, or duration of surgery between the two groups ( $p > 0.05$  for all), indicating adequate baseline comparability (Table 1).

Sedation quality was assessed using the Ramsay Sedation Score, with a score 4-5 considered adequate for the procedure. A significantly higher proportion of patients in Group KD achieved and maintained adequate sedation throughout surgery compared to Group PP (86.7% vs 60%,  $p = 0.03$ ) (Table 2).

Recovery parameters were superior in Group KD. Time to response, defined as the time taken to respond appropriately to verbal commands, was significantly shorter in Group KD than in Group PP ( $9.4 \pm 2.1$  minutes vs  $12.8 \pm 3.4$  minutes,  $p < 0.001$ ). Readiness for discharge was also significantly earlier in Group KD ( $82.6 \pm 10.4$  minutes) compared to Group PP ( $95.3 \pm 12.1$  minutes), and this difference was statistically significant ( $p = 0.002$ ) (Table 2).

Intraoperative haemodynamic stability was better maintained in Group KD. The mean intraoperative heart rate was significantly lower in Group KD compared to Group PP ( $68.4 \pm 6.8$  vs  $82.6 \pm 8.9$  beats/min,  $p < 0.001$ ). The incidence of tachycardia (HR  $> 100$  bpm) was significantly lower in Group KD (3.3%) than in Group PP (20%) ( $p = 0.04$ ). Bradycardia (HR  $< 50$  bpm) occurred in two patients (6.7%) in Group KD and in none of the patients in Group PP; however, this difference was not statistically significant ( $p = 0.15$ ) (Table 3).

Similarly, mean intraoperative mean arterial pressure was significantly lower in Group KD ( $76.8 \pm 7.2$  mmHg) compared to Group PP ( $88.9 \pm 9.1$  mmHg) ( $p < 0.001$ ). An increase in mean arterial pressure greater than 20% from baseline was observed in significantly fewer patients in Group KD (6.7%) than in Group PP (30%) ( $p = 0.02$ ) (Table 3).

Adverse effects were less frequent in Group KD. Nausea and vomiting were significantly lower in Group KD (10%) compared to Group PP (30%) ( $p = 0.05$ ). Excessive postoperative sedation occurred significantly less often in Group KD (3.3% vs 20%,  $p = 0.04$ ). Respiratory depression was observed only in Group PP (6.7%), though the difference was not statistically significant ( $p = 0.15$ ). Emergence reactions were rare and comparable between the two groups (Table 4).

The requirement for rescue propofol was significantly higher in Group PP. Rescue propofol was required in 5 patients (16.7%) in Group KD compared to 15 patients (50%) in Group PP ( $p = 0.008$ ). A significantly higher proportion of patients in Group PP required two or more rescue boluses (23.3% vs 3.3%,  $p = 0.02$ ). Among patients requiring rescue sedation, the mean total propofol dose was significantly higher in Group PP than in Group KD ( $46.2 \pm 9.3$  mg vs  $28.4 \pm 5.1$  mg,  $p < 0.001$ ) (Table 5).

Statistical analysis was performed using SPSS software version 20. Continuous variables were expressed as mean  $\pm$  standard deviation and analyzed using Student's t-test. Categorical variables were compared using the Chi-square test or Fisher's exact test, as appropriate. A p-value of less than 0.05 was considered statistically significant.

**Table 1 Demographic Data and Surgical Characteristics**

Parameter	Group KD (n = 30)	Group PP (n = 30)	p value
Age (years)	$28.6 \pm 3.2$	$29.1 \pm 3.4$	0.54
Weight (kg)	$54.2 \pm 5.8$	$55.0 \pm 6.1$	0.63
ASA physical Status (I / II)	19 / 11	18 / 12	0.79
Duration of Surgery (minutes)	$12.4 \pm 1.1$	$12.6 \pm 1.2$	0.48

**Table 2: Sedation Quality and Recovery Profile**

Parameter	Group KD	Group PP	p value
Adequate sedation throughout surgery RSS(4-5)	26 (86.7%)	18 (60%)	0.03
Time to response (minutes)	$9.4 \pm 2.1$	$12.8 \pm 3.4$	$< 0.001$
Readiness for discharge (minutes)	$82.6 \pm 10.4$	$95.3 \pm 12.1$	0.002

**Table 3: Intraoperative Haemodynamic Parameters**

Parameter	Group KD (Ketamine–Dexmedetomidine) n = 30	Group PP (Pentazocine–Promethazine) n = 30	p value
Mean intraoperative heart rate (beats/min)	68.4 ± 6.8	82.6 ± 8.9	<0.001
Patients with tachycardia (HR > 100 bpm), n (%)	1 (3.3%)	6 (20%)	0.04
Patients with bradycardia (HR < 50 bpm), n (%)	2 (6.7%)	0	0.15
Mean intraoperative mean arterial pressure (mmHg)	76.8 ± 7.2	88.9 ± 9.1	<0.001
Patients with MAP increase >20% from baseline, n (%)	2 (6.7%)	9 (30%)	0.02

**Table 4: Adverse Effects**

Adverse effect	Group KD	Group PP	p value
Nausea / vomiting	3 (10%)	9 (30%)	0.05
Respiratory depression Spo2<90%, RR<8	0	2 (6.7%)	0.15
Excessive postoperative sedation	1 (3.3%)	6 (20%)	0.04
Emergence reaction	1 (3.3%)	0	0.31

**Table 5: Requirement of Rescue Propofol**

Parameter	KD (Ketamine–Dexmedetomidine)	PP (Pentazocine–Promethazine)	P value
Patients requiring rescue propofol, n (%)	5 (16.7%)	15 (50%)	0.008
Rescue propofol bolus dose	0.5 mg/kg	0.5 mg/kg	—
Patients requiring ≥2 rescue boluses, n (%)	1 (3.3%)	7 (23.3%)	0.02
Mean propofol dose among patients requiring rescue (mg)	28.4 ± 5.1	46.2 ± 9.3	<0.001

**DISCUSSION**

The present study demonstrates that the ketamine–dexmedetomidine (KD) combination provides superior procedural sedation compared to the pentazocine–promethazine (PP) combination, as evidenced by better sedation quality, improved haemodynamic stability, reduced need for rescue propofol, faster recovery, and fewer adverse effects.

Adequate procedural sedation, defined as a Ramsay Sedation Score greater than 5, was achieved in a significantly higher proportion of patients in the KD group. This finding can be explained by the synergistic sedative and analgesic actions of ketamine and dexmedetomidine. Dexmedetomidine produces sedation by activating  $\alpha_2$ -adrenergic receptors in the locus coeruleus, resulting in a sleep-like, cooperative sedation, while ketamine provides dissociative anesthesia and analgesia through NMDA receptor antagonism [1,2].

Importantly, despite deeper sedation, patients in the KD group demonstrated faster recovery, as shown by shorter time to response to verbal commands and earlier readiness for discharge. This is consistent with previous studies showing that dexmedetomidine produces sedation that closely resembles natural sleep and allows rapid arousal on stimulation, unlike conventional sedative–opioid combinations that may cause prolonged residual sedation [3,4].

Intraoperative haemodynamic parameters were significantly more stable in the KD group. Lower mean heart rate and mean arterial pressure, along with fewer episodes of tachycardia and hypertensive responses, suggest effective sympatholysis with dexmedetomidine. Dexmedetomidine reduces central sympathetic outflow and circulating catecholamine levels, thereby attenuating stress responses to surgical stimulation [5].

Although ketamine alone is known to cause sympathetic stimulation, its combination with dexmedetomidine balances this effect, resulting in haemodynamic stability without clinically significant hypotension or bradycardia [6]. The low incidence of bradycardia observed in the KD group was not statistically significant and did not require intervention, indicating a favorable safety profile.

In contrast, the PP group showed higher heart rate and blood pressure values, likely due to inadequate suppression of stress responses and the limited sedative depth provided by pentazocine–promethazine [7].

The significantly higher requirement of rescue propofol in the PP group reflects suboptimal baseline sedation and analgesia. Pentazocine, a mixed agonist–antagonist opioid, has a ceiling effect for analgesia, while promethazine provides sedation primarily through antihistaminic action, which may be unpredictable and prolonged [8]. This explains the higher number of patients requiring rescue sedation, multiple boluses, and higher cumulative propofol doses in the PP group.

Reduced propofol requirement in the KD group is clinically important, as it minimizes risks of respiratory depression, delayed recovery, and post-procedural sedation [9].

The incidence of adverse effects was lower in the KD group. Nausea and vomiting were significantly more common in the PP group, likely related to opioid use and promethazine’s anticholinergic properties [10]. Excessive postoperative sedation was also more frequent in the PP group, reflecting the longer and less titratable sedative effects of promethazine.

Respiratory depression occurred only in the PP group, consistent with the known respiratory depressant effects of opioid-based sedation regimens. In contrast, dexmedetomidine is well recognized for preserving respiratory drive even at deeper levels of sedation [11]. Emergence reactions were rare and comparable between groups, possibly due to the mitigating effect of dexmedetomidine on ketamine-induced psychomimetic effects [12].

Overall, the ketamine–dexmedetomidine combination offers a balanced sedative regimen that provides adequate depth of sedation, haemodynamic stability, rapid recovery, and improved safety, making it particularly suitable for short surgical procedures requiring monitored anesthesia care.

## CONCLUSION

Both ketamine–dexmedetomidine and pentazocine–promethazine can be used to provide sedation for ambulatory laparoscopic tubal ligation. However, the ketamine–dexmedetomidine combination offers clear clinical advantages, including more consistent sedation, improved haemodynamic stability, reduced requirement for rescue propofol, faster postoperative recovery, and a lower incidence of adverse effects. These findings suggest that ketamine–dexmedetomidine is a more effective and reliable sedative regimen for monitored anesthesia care in short ambulatory laparoscopic procedures.

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