



## LAPAROSCOPIC TUBAL LIGATION - COMPARISON OF DIFFERENT DRUGS FOR SEDATION

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**ABSTRACT**

A study was conducted to compare the sedation given by injection pentazocine with promethazine, inj. ketamine with midazolam and inj. propofol infusion in patients undergoing day care laparoscopic tubal ligation under local anesthesia. 90 patients belonging to ASA I and II, undergoing laparoscopic tubal ligation under local anesthesia were randomly allocated into three equal groups. Group A (n= 30) received inj. pentazocine (fortwin) 0.5 mg/kg with inj. promethazine (phenargan) 0.5 mg/kg intravenously, group B (n =30) received inj. midazolam 0.05mg/kg with inj. ketamine 0.5mg/kg and group C (n =30) received inj. propofol bolus 0.5mg/kg followed by infusion at 50 µg/kg/min. All the patients received local anesthesia with 10ml of 2% xylocaine with adrenaline (1:2,00,000) at the site of incision. Patients were assessed for level of sedation, pain and discomfort during the procedure. Rescue analgesia was given with inj. fentanyl 1 µg/kg bolus intravenously. Results were analysed statistically using MANOVA (Multivariate Analysis of Variance). P value < 0.05 was considered significant.

**Result:** Pain and discomfort was observed in 33% patients in Group A, 6.6% in Group B and 10% in Group C. Time to recovery and discharge was comparable in all the three groups.

**Conclusion:** Minimal pain and discomfort was observed in patients who had received inj. ketamine with midazolam and in patients who received inj. Propofol infusion.

**KEYWORDS :** Laparoscopic tubal ligation, sedation, pentazocine, promethazine, midazolam, ketamine, propofol, local anesthesia.

**INTRODUCTION**

Laparoscopic tubal ligation is a minimally invasive sterilization procedure. It is usually done on a day care basis under local anesthesia. In India, it is a national program for family planning. Most of the cases are done in a government setup or in camps. The turnover of patients is very high and the patients prefer to go home on the same day. We have come across very few recent studies regarding anesthesia or sedation in this surgery. The studies have used both general and local anesthesia. Although the quality provided by local anesthesia is unsatisfactory due to discomfort and contraction of abdominal muscle, it offers the advantage of patient being awake, oriented, breathing spontaneously and fast track recovery.<sup>[1]</sup> Anesthesiologists are usually involved to provide either monitored anesthesia care or sedation. It has been observed that patients do complain of pain and discomfort during the procedure. With this background, this study was conducted with the aim to make the patients comfortable and safe for the procedure and ready to be discharged on the same day.

**MATERIAL AND METHOD**

After approval of the institutional ethical committee and informed written consent, 90 patients scheduled for laparoscopic tubal sterilization were allocated into three equal groups of 30 each in a randomized control manner. All the patients belonged to ASA grade I and II, between 25 -40 years. Patients were within 20% of ideal body weight, had an uncomplicated past surgical history and were at low risk of having pelvic adhesive disease. All the patients were formally counselled for and accepted the use of local anesthesia with intravenous sedation as the method of anesthesia.

Patients were scheduled for day care procedure and were given instruction to fast for 6 hours on the day of procedure. No premedication was given. On arrival in the operating room, monitoring devices were placed and baseline blood pressure, heart rate, and oxygen saturation was recorded. Intravenous access was achieved with 22G iv canula. Group A received inj. pentazocine 0.5 mg/kg with inj. promethazine 0.5 mg/kg, Group B received inj. midazolam 0.05 mg/kg with inj. ketamine 0.5mg/kg and Group C received inj. propofol 0.5mg/kg followed by infusion at 50 µg/kg/min. All the patient received local anesthesia with 10ml 2% lignocaine with adrenaline (1:200000) at the site of incision. Oxygen by face mask was given to all the patient. Surgical procedure was standardised for all the patients. During the surgery, patients were placed in Trendelenburg position and

the abdomen was insufflated with CO<sub>2</sub> after insertion of trocar. Duration of procedure lasted for 21± 5 min. Intraoperative movement which might interfere with surgery, airway obstruction and apnea were noted and were managed accordingly. Vitals were monitored every 5 minutes. Injection fentanyl 0.5 µg/kg bolus intravenously was given to patient who had discomfort during the procedure. Injection ondansetron 4mg was given to prevent postoperative nausea and vomiting. At the end of procedure, inj. diclofenac sodium 1mg/kg was given intramuscularly to all patients for postoperative analgesia. Patients were shifted to recovery room, vitals were monitored in the postoperative ward. To assess the patient's impression of the procedure, we administered a pain questionnaire upon arrival to and departure from postanesthesia care unit. Patients were discharged with an escort when the discharge criteria (Modified Aldrete Score) was fulfilled.

**RESULT**

All the patients in the three groups were comparable according to age, body weight and height (Table I). Mean age was 31.3±5.8, 30.4±5.1 and 32.6±5.36 respectively. Body Mass Index (BMI) was 22.66±2.24, 23.55±1.8 and 22.43±2.26. There was significant increase in heart rate at skin incision in Group A as compared to Group B and Group C (Table II). Similarly, there was significant increase in mean systolic and diastolic blood pressure at skin incision as compared to Group B and Group C (Table III). Incidence of pain and discomfort was 33% in Group A, 6.6% and 10% in Group B and Group C respectively. 10% of patients in Group A and 3.2% patient in Group B had experienced nausea and vomiting. Movement of leg was observed in 33% patient in group A, 16.6% in Group B and 10% in Group C for which rescue analgesia was given (Table IV). Duration of procedure was more or less comparable in all the three study groups. (Table II). Operative time in group A was 21.53±4.86 min, group B 21.48±6.65 min, and group C 22.34±5.64 min.

Time to meet discharge criteria was 10.23± 4.35, 11.67±5.67 and 11.24± 4.57 in group A, group B and group C respectively. (Table V). Result was both clinically and statistically significant <0.05.

**DISCUSSION**

Laparoscopic tubal ligation is a minimally invasive method of contraception and is widely accepted. It was introduced by Palmer in 1963. The ideal anaesthetic for laparoscopic tubal ligation should

produce a rapid and smooth onset of action, intraoperative analgesia, good surgical condition and a short recovery period without side effects. Local anesthesia was used as a means of lowering anesthetic risk, decreasing cost, reducing operation and recovery room times as well as postoperative discomfort and convalescence.<sup>[3,3]</sup> Both general and regional anesthesia has been used for the procedure, but they are associated with complications.<sup>[4]</sup> Bordahl et al reported higher incidence of abdominal pain in general anesthesia group (85% vs 35% in local anesthesia and sedation group). Peterson et al reported at least one-third of death from laparoscopic tubal ligation related to general anesthesia.<sup>[5]</sup> Laparoscopic tubal ligation with intravenous sedation reduces the risk as well as the other complications of general anesthesia such as nausea and vomiting and so forth.<sup>[6,7,8,9]</sup>

Lipscomb et al compared the cost of tubal ligation performed under local versus general anesthesia in an operative room setting and found that 76% of cost saving per case could attribute to anesthesia related drugs and equipment.<sup>[10]</sup> Pentazocine is a potent analgesic and has wide application in clinical medicine. Pentazocine can provide analgesia but does not have effect on mood. It provides less CNS depression in particular with regard to respiratory depression and nausea and vomiting. Parenteral administration of pentazocine produces rapid strong analgesia. An informed survey revealed that the combined administration of pentazocine with promethazine is widely used. The technique is easy to apply, encourages rapid turnover of cases. However, patients acceptance is poor as pain and discomfort is very common. Promethazine at a dose of 0.5 -1 mg/kg is given along with pentazocine to prevent postoperative vomiting and also has anxiolytic effect. Hook et al compared the efficacy and safety of nalbuphine or pentazocine with midazolam in patients undergoing minor oral surgery under local anesthesia.<sup>[11]</sup>

Ketamine, a phencyclidine derivative, in a dose of 0.5mg /kg intravenously produces good analgesia in 2-5 min without loss of consciousness. Emergence reaction including vivid dream and illusion can occur in some patients. The incidence is higher in females. This can be minimized by use of benzodiazepines.<sup>[12]</sup> Midazolam was given in group B patients to allay anxiety and prevent emergence delirium. It exhibits a greater margin of safety. In our study, none of the patient in group B had emergence delirium.

Propofol produces a pleasant sedation which is easily controlled. The pharmacologic profile results in easy titration and rapid recovery. Continuous infusion provides a more consistent degree of sedation than repeated dosing for prolonged period. It produces both antiemetic and mood elevating effects. At very low infusion rate 25-50µg/kg/min, sedation is achieved without addition of opioid or benzodiazepine, thereby facilitating more rapid recovery.<sup>[13,14]</sup>

Fentanyl is a rapid acting and short lasting opioid with no active metabolite. Its peak effect occurs in 3-5 min after intravenous use and duration last for 30 min. During short gynecological procedures, the addition of fentanyl (50µg) does not affect recovery from propofol nitrous oxide anesthesia.

**CONCLUSION**

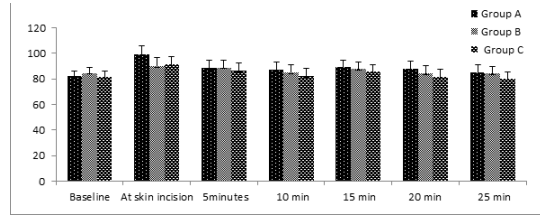
Our study suggests that laparoscopic tubal ligation can be performed under local anesthesia with sedation. Low dose Ketamine in combination with midazolam provides good sedation but delirium may occur in some patient and may delay discharge. Use of pentazocine with promethazin is a technique most commonly practiced by obstetrician but patient comfort is compromised. Low dose propofol infusion along with local anesthesia is the preferred technique with excellent patient acceptance and early recovery. Apart from patient comfort and safety, we have also considered the cost of the procedure, since laparoscopic tubal ligation is a national program. Newer drugs like dexmedetomidine can also be tried but its cost effectiveness is questioned.

**TABLE I: DEMOGRAPHIC PROFILE OF PATIENTS. MEAN ± SD**

	Group A (n = 30)	Group B (n = 30)	Group C (n = 30)
Age (years)	31.3 ± 5.82	30.4 ± 5.12	32.6 ± 5.36
Weight (kg)	51.8 ± 5.93	53 ± 5.48	51.4 ± 6.08
Height (cm)	155.8 ± 4.23	152.46 ± 3.95	154.78 ± 4.59

**TABLE II: MEAN HEART RATE AT VARIOUS TIME INTERVALS. (MEAN ± SD)**

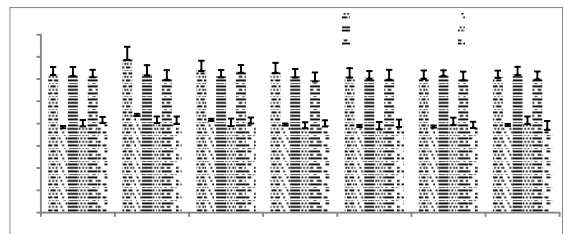
Time Interval	Group A	Group B	Group C
Baseline	82.5 ± 3.35	84.7 ± 4.13	81.77 ± 4.18
At skin incision	99.33 ± 6.75	90.23 ± 6.58	91.25 ± 6.18
5minutes	88.36 ± 6.36	88.9 ± 5.35	86.2 ± 6.24
10 min	87.54 ± 5.54	85.2 ± 5.59	82.1 ± 5.84
15 min	89.34 ± 5.58	87.6 ± 5.64	85.6 ± 5.48
20 min	87.6 ± 6.43	84.32 ± 6.23	81.33 ± 6.32
25 min	85 ± 5.8	84.24 ± 5.76	80.36 ± 5.32



**Table III: Mean systolic and Diastolic Blood Pressure at different time intervals (mmHg). Mean ± SD**

**SYSTOLIC BLOOD PRESSURE                      DIASTOLIC BLOOD PRESSURE**

Time Interval	Group A	Group B	Group C	Group A	Group B	Group C
Baseline	124.6 ± 6.43	123.7 ± 7.24	122.6 ± 5.78	76.8 ± 4.48	78.5 ± 4.67	81.45 ± 4.58
At skin incision	138.2 ± 10.84	124.33 ± 8.23	120.4 ± 7.69	87.84 ± 5.68	81.5 ± 4.95	80.66 ± 5.68
5minutes	128.21 ± 8.34	122.57 ± 5.53	126.7 ± 5.95	83.4 ± 5.46	78.7 ± 5.76	80.97 ± 4.57
10 min	126.53 ± 8.12	122.45 ± 6.68	118.8 ± 7.23	79.2 ± 4.57	76.8 ± 4.35	78.32 ± 4.58
15 min	122.23 ± 7.54	121.24 ± 5.98	120.45 ± 7.95	77.87 ± 5.12	75.8 ± 5.58	77.79 ± 5.78
20 min	121.22 ± 6.56	123.68 ± 4.2	119.86 ± 6.94	77.35 ± 3.95	79.65 ± 5.78	76.98 ± 4.67
25 min	122.15 ± 5.47	124.56 ± 6.57	120.58 ± 6.32	78.69 ± 4.56	80.54 ± 5.87	75.43 ± 6.82



**TABLE IV: COMPARISON OF COMPLICATION AMONG THE GROUPS**

Complication	Group A (%)	Group B (%)	Group C (%)
Pain and discomfort	33	6.6	10
Nausea and Vomiting	10	3.2	0
Movement of leg	33	16.6	10
Apnea/ Hypoxemia	0	0	0

**TABLE V: DURATION OF SURGERY AND TIME TO MEET DISCHARGE CRITERIA**

	Group A	Group B	Group C
Duration of Surgery (minutes)	21.53 ± 4.86	21.48 ± 6.65	22.34 ± 5.64
Time to meet discharge criteria (minutes)	10.23 ± 4.35	11.67 ± 5.67	11.24 ± 4.57

Duration of surgery -: from skin incision to end of skin stitching

Time to meet discharge criteria-: from the end of procedure to the time when patient modified Aldrete score was = 9.

**TABLE V: MODIFIED ALDRETE SCORE**

Parameters	Description of Patient	Score
Activity Level	Moves all extremities	2
	Moves 2 extremities	1
	Cannot move extremities	0
Respiration	Breaths deeply and coughs freely	2
	Is dyspneic with shallow limited breathing	1
	Is apneic	0
Circulation	Is 20 mmHg $\leq$ Preanesthetic level	2
	Is 20- 50 mmHg $\leq$ Preanesthetic Level	1
	Is 50 mmHg $\leq$ Preanesthetic level	0
Consciousness	Is fully awake	2
	Is arousable on calling	1
	Is not responding	0
Oxygen Saturation as determined by Pulse oximetry	Has level > 90% when breathing room air	2
	Requires supplemental oxygen to maintain >90 %	1
	Has level <90% with oxygen supplementation	0

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