Ambulatory Laparoscopic Tubal Ligation: A Comparison of General Anaesthesia with Local Anaesthesia and Sedation

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ABSTRACT

Background: To compare the anaesthetic techniques for laparoscopic tubal ligation using either general anaesthesia with LMA or a combination of local anaesthetic and intravenous sedation, this study was conducted on 60 ASA-1/2 patients in the age group of 20-40 years.

Patients & Methods: 60 ASA grade I & II female patients undergoing laparoscopic tubal ligation on a day care basis were randomly divided in two groups- group I (GA using LMA, n=30), group II (Local anaesthesia, n=30). Both groups received similar premedication. General anaesthesia in group I was induced with propofol 2-3 mg kg\(^{-1}\) and following LMA insertion, the anaesthesia was maintained with 0.5-1.5% halothane. In group II the incision site was infiltrated with 10 ml of 1.5% lidocaine with adrenaline and patients were sedated with intravenous midazolam 0.07mg kg\(^{-1}\) and ketamine 0.5 mg kg\(^{-1}\). A rescue dose of 0.15 mg kg\(^{-1}\) of ketamine was given in group II if the patient complained of pain or discomfort during the procedure. Diclofenac sodium 1 mg kg\(^{-1}\) was used for postoperative analgesia in both the group s. All patients were observed in the PACU until they met the discharge criteria.

Results: The demographic profile was similar in both the groups. The induction to skin incision time was significantly more in group I (5.13 ±0.93 min vs 3.01 ±1.86 min in group II). The decrease in pulse rate and blood pressure (systolic and diastolic) was also significant in group I. The incidence of intraoperative bradycardia was 16.7% and 10% in group I & group II respectively. The changes in SpO\(_2\) during the procedure, recovery time and time to meet discharge criteria were comparable in both the groups. The incidence of PONV was 20% & 3.3% in group I and 10% & 6.6% in group II respectively . All patients in both the groups required postoperative analgesics.

Conclusions: Both the techniques were found to be comparable for laparoscopic sterilization, however a longer induction to skin incision time and higher incidence of PONV and shivering in GA group makes LA with sedation a better choice.

KEYWORDS: Laparoscopy, Tubal ligation, Propofol, Ketamine, Local anestheisa.
measurement. In group I, GA was induced with intravenous propofol 2-3 mg kg\(^{-1}\), followed by insertion of a size 3 or 4 classic LMA. Anaesthesia was maintained with halothane (0.5-1.5%) delivered in oxygen and nitrous oxide. Halothane and N\(_2\)O were discontinued after ligation of the fallopian tubes and the LMA was removed following completion of skin suturing, allowing patients to breathe room air.

Group II patients received intravenous midazolam 0.07 mg kg\(^{-1}\) and ketamine 0.5mg kg\(^{-1}\). The incision site was also infiltrated with 10 ml of 1.5% lignocaine with adrenaline (1:200,000). Oxygen (FIO\(_2\)-0.3) was given to all patients using a ventimask. A second dose (rescue dose) of intravenous ketamine 0.15mg kg\(^{-1}\) was given if the patients complained of discomfort or pain. The data recorded during the procedure included induction to skin incision time, number of attempts of Verres needle insertion, total volume of CO\(_2\) insufflated, maximum intra-abdominal pressure, besides the vital signs. The duration of surgery, recovery time, intraoperative and postoperative complications were also recorded.

Postoperative pain was treated with intravenous diclofenac sodium 1mg kg\(^{-1}\) in all patients. The patients were monitored every five minutes in the post anesthesia care unit discharge.

The data was recorded as mean±SD. Student ‘t’ test was used for comparison between the groups and paired t test was applied for intra-group comparison. A p value of <0.05 was taken as significant. The data was analysed using SPSS (Statistical Package for the Social Sciences) version 12 software.

### RESULTS

Both the groups were comparable with regard to age, weight, period of gestation and hemoglobin levels (table 1). Induction to skin incision time was significantly more in group I (5.13 ± 0.93 min) compared to Group II (3.01 ± 1.86 min). Although there was a decline in pulse rate from baseline in both the groups, it was significant only in Group I (5, 10, 15, 20, 25min) but without any clinical consequence.

There was a decline in systolic blood pressure from baseline in Group I, and an increase in Group II. The difference in systolic blood pressure between two groups was statistically significant at 5, 10, 15, 20 and 30 minutes, whereas the difference in diastolic blood pressure was statistically significant only at 5, 10 and 15 minutes. These changes in blood pressure did not have any clinical effects. The SpO\(_2\) was maintained in both the groups throughout the procedure. The volume of CO\(_2\) used was similar in both the groups (1.98 ± 0.29L and 1.95 ± 0.32L in Group I and Group II respectively). The difference in the mean intra-abdominal pressure was statistically significant, 13.20 ± 1.45 mm Hg in Group I and 14.07 ± 1.62 mm Hg in Group II, without any clinical effects.

Intraoperatively 25 patients (83.3%) in Group I and 27 (90%) in Group II had no complication. Bradycardia (heart rate < 60/minute) occurred in 5 patients (16.7%) in Group I and 3(10%) patients in Group II, necessitating the use of atropine. The duration of surgery (21.53 ± 5.56 min. in Group I and 21.56 ± 6.33 min. in Group II), recovery time (4.60 ± 2.95 min. in Group I and 3.23 ± 3.78 minutes in Group II) and time to meet discharge criteria (10.00 ± 4.08 minutes in Group I and 11.53 ± 7.15 minutes in Group II) were comparable in the two groups.

The haemodynamic parameters in the postoperative period were stable and comparable in both the groups. Six patients (20%) in group I and 1 (3.3%) in group II had nausea. 10 patients (33.3%) had vomiting in group I and 2 (6.6%) in group II. Shivering occurred in 3 patients(10%) in group I and 1 (3.3%) in group II, where as 3 patients complained of discomfort or pain. The data recorded during the procedure included induction to skin incision time, number of attempts of Verres needle insertion, total volume of CO\(_2\) insufflated, maximum intra-abdominal pressure, besides the vital signs. The duration of surgery, recovery time, intraoperative and postoperative complications were also recorded.

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### Table 1

Comparison of Patient Data in the Two Groups: Mean ± SD

| Group | Group I | Group II | P Value |
|-------|---------|----------|--------|
| Age (years) | 27.00 ± 3.56 | 28.07 ± 4.21 | 0.426 |
| Weight (Kg) | 45.53 ± 5.84 | 46.87 ± 6.67 | 0.359 |
| POG* | 54.83 ± 8.62 | 57.67 ± 9.49 | 0.358 |
| Haemoglobin (gm %) | 9.67 ± 0.80 | 9.59 ± 0.78 | 0.990 |

P significant<0.05, POG: Period of gestation in days

### Table 2

Comparison of induction time, duration of surgery, between Group I and Group II: Mean (SD)

| Group | Group I GA with LMA | Group II LA with Sedation | P Value |
|-------|---------------------|--------------------------|--------|
| Induction Time \(t\) (in minutes) | 5.13(0.93) | 3.01(1.86) | 0.00* |

*significant value

### Table 3

Comparison of Pulse Rate Between Two Groups at Different Time Intervals Intraoperatively: Mean (SD)

| Time Interval | Group I | Group II | P Value |
|---------------|---------|----------|--------|
| Baseline      | 95.60±10.56 | 98.23±10.81 | 0.344 |
| 5 Minutes     | 85.63±9.63  | 96.43±9.61  | 0.000* |
| 10 Min        | 82.30±10.20 | 94.20±14.06 | 0.000* |
| 15 Min        | 79.03±10.94 | 95.53±14.37 | 0.000* |
| 20 Min        | 80.00±12.47 | 93.29±15.85 | 0.002* |
| 25 Min        | 80.05±14.70 | 92.57±12.90 | 0.015* |
| 30 Min        | 88.00±17.61 | 89.50±14.25 | 0.845 |
| 35 Min        | 95.60±24.57 | 96.00±10.44 | 0.980 |

P significant<0.05, *significant value
(10%) in group I and 2 (6.7%) in group II complained of pain/discomfort in the postoperative period (table 5). Mean time to first dose of analgesic was 24.3 ± 3.9 minutes & 29 ± 2.4 minutes in group I and II respectively.

**DISCUSSION**

Since the introduction of laparoscopic sterilization by Palmer in 1963, there have been attempts to develop a safe anaesthetic technique that facilitates early ambulation. Most anaesthetic studies focus on postpartum tubal ligation, but in our hospital such procedures are done either as elective interval procedures or following medical termination of pregnancy.

Although tubal ligation can be performed under local anesthesia with sedation, its effectiveness has been questioned and it has been suggested that the anaesthetic technique (i.e., regional versus general) should be individualized, based on anesthetic and/or obstetric risk factors and patient preference. General anaesthesia has been recommended for tubal ligation to reduce the complications, but it is not a very safe technique. The case-fatality rate for tubal sterilization procedures has been reported to be 3.6/100,000 procedures. Out of 29 reported deaths, 11 were attributed to complications of general anesthesia, including hypoventilation in non intubated women, remaining were due to cardiorespiratory arrests of unknown cause.

Our study enrolled 60 ASA I & II with similar demographic profile. The significantly higher induction to skin incision time in group I (5.13±0.93min versus 3.01±1.86 min in Group II) (table 2) was attributable to the time required for induction of general anaesthesia and insertion of LMA and was similar to the observations of Swann et al. The decline in heart rate in group I can be attributed to propofol, which blunts the pressor response to surgical stimulation and causes a reduction in blood pressure without a compensatory increase in heart rate. Subsequent fluctuations in blood pressure in group I can be attributed to propofol and substantiation of its depressant effect on baroreceptor reflex and sympathetic over activity by fentanyl & halothane. Similarly the rise in blood pressure in group

### Table 4
Comparison of Systolic Blood Pressure (in mmHg) Between Two Groups at Different Time Intervals Intraoperatively: Mean±SD

| Time Interval | Group I GA with LMA | Group II LA with Sedation | P Value |
|--------------|---------------------|---------------------------|---------|
| SBP DBP SBP DBP SBP DBP |
| Baseline     | 122.73± 72.33± 120.77+ 73.20 0.449 0.172 |
| 5 Min        | 98.80± 58.80± 122.00± 75.93 0.000* 0.000* |
| 10 Min       | 101.70± 60.87± 125.93± 77.33 0.000* 0.000* |
| 15 Min       | 108.40± 68.40± 126.33± 77.97 0.000* 0.001* |
| 20 Min       | 115.24± 72.86± 126.57± 78.29 0.018 0.109 |
| 25 Min       | 120.00± 73.60± 125.43± 76.57 0.413 0.487 |
| 30 Min       | 118.55± 76.72+/- 130.63± 78.63 0.043 0.658 |
| 35 Min       | 118.40± 69.60± 129.67± 74.67 0.248 0.344 |

P significant<0.05
*significant value

### Table 5
Comparison of Complications Between the Two Groups

| Complication | Group I GA with LMA | Group II LA with Sedation | P Value |
|--------------|---------------------|---------------------------|---------|
| None         | 25(83.3%)           | 27(90%)                   |         |
| Bradycardia  | 5(16.7%)            | 3(10%)                    |         |
| Nausea       | 6(20%)              | 1(3.3%)                   |         |
| Vomiting     | 10(33.3%)           | 2(6.6%)                   |         |
| Shivering    | 3(10%)              | 1(3.3%)                   |         |
| Pain/Discomfort | 3(10%)               | 2(6.7%)                   |         |

(in Immediate Post OP)

### Table 6
Comparison of duration of surgery and time to meet discharge criteria modified aldrete scoring between two groups postoperatively at different time intervals

| Group | Group I GA with LMA | Group II LA with Sedation | P Value |
|-------|---------------------|---------------------------|---------|
| Duration of surgery | 21.53±5.56 | 21.56±6.3 0.983 |
| Time To Meet | 10.00±4.08 | 11.53±7.15 0.325 |

Discharge Criteria

P significant<0.05
Duration if surgery -from skin incision to end of skin stitching
time to meet discharge criteria from the end of procedure to the
time when patients’ modified Aldrete score was =9.

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 patients’ modified Aldrete score was =9.
IlI can be attributed to ketamine.

The fall in $\text{SpO}_2$ to 90% in group I could be due to coughing and breath-holding during insertion of LMA in light plane. The incidence of intraoperative bradycardia requiring atropine was more in group I (16.7% vs. 10%) possibly due to vagal mediated reflex bradycardia due to the stretching of peritoneum as well as the use of propofol, fentanyl and halothane.

The time to recovery and discharge were comparable in both the groups and were similar to the observations by Raeder et al. Postoperative nausea and vomiting was one of the main complaints after the procedure. The higher incidence of nausea and vomiting in group I could be due to gastric insufflation with volatile anaesthetic agent. Earlier studies have implicated the use of nitrous oxide in gynecologic procedures for the higher incidence of postoperative vomiting by 33%. More patients complained of pain in group I (10% vs. 6.7%) requiring analgesia early (24.3±3.9 min vs. 29±2.4 min). Bordahl et al have reported a higher incidence of abdominal pain in the general anaesthesia group (83% vs. 35% in LA & sedation group). The preoperative administration of parenteral ketorolac or oral ibuprofen has not been found to decrease postoperative pain or side effects when compared to placebo in this outpatient population.

The lower incidence of pain the LA & sedation group could be due to bupivacaine spray of fallopian tube. Both the techniques were found to be safe as there were no major complications with either technique and the patients could be discharged to home within 20 minutes of the procedure.

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