ORIGINAL RESEARCH

DOI: 10.5336/jcog.2020-73653

# The Effect of Uterine Manipulator Use in Laparoscopic Tubal Ligation on Operation Duration and Anesthesia Drug Quantity

İsmail BIYIK[a], Mustafa ALBAYRAK[b], Fatih KESKİN[c], Ayşe Nur MUT[d]

[a]Kütahya Health Sciences University Faculty of Medicine, Department of Gynecology and Obstetrics, Kütahya, TURKEY
[b]Private Reyap Hospital, Clinic of Gynecology and Obstetrics, Tekirdağ, TURKEY
[c]Sultan 1. Murat State Hospital, Clinic of Gynecology and Obstetrics, Edirne, TURKEY
[d]Ankara University Faculty of Medicine, Department of Epidemiology, Ankara, TURKEY

**ABSTRACT Objective:** The aim of this study is to compare the duration of surgery and anesthesia, complication rates and the amount of anesthetic drugs used and the cost in laparoscopic tubal ligation cases with and without the use of manipulator. This retrospective case control study included the women who underwent elective interval laparoscopic tubal ligation. **Material and Methods:** The time between intubation and the onset of surgery, duration of surgery (main operation time) and intubation-extubation (total operation time-duration of anesthesia) were recorded in the operating room. **Results:** Demographic datas were similar between the patients with and without manipulators ($p > 0.05$). In the non-manipulator group, intubation to beginning of surgery time, main operation time, total anesthesia time were found to be shorter ($p < 0.001$, $p < 0.001$, $p < 0.001$, respectively). Postoperative hospital stay, the amount of parenteral anesthetic drug used, the need for postoperative parenteral analgesics, the number of laparoscopic ports used and the complication rates were similar between the two groups ($p > 0.05$). Sevoflurane use was found to be less in the non-manipulator group ($p < 0.001$). **Conclusions:** In laparoscopic tubal ligation operation where no uterine manipulator is used, anesthesia and total surgery times are approximately 8 minutes shorter. The use of uterine manipulator increases the duration of surgery and the amount of sevoflurane used. Laparoscopic tubal ligation without uterine manipulator may be considered in cases where severe adhesions are not anticipated and no additional intervention is planned. Besides, avoidance of manipulator use may have the advantage of time and cost savings.

**Keywords:** Tubal ligation; manipulator; sevoflurane; operation duration

Family planning aims having desired number of healthy children and preventing unplanned pregnancies. One of the most effective methods of family planning is tubal ligation, disruption of the integrity of the uterine tubes. Tubal ligation can be performed during cesarean section, in the early postpartum period or as an interval procedure. Interval tubal ligation which is usually performed laparoscopically covers half of all tubal ligation cases.[1]

Laparoscopic tubal ligation is widely used worldwide. In the United States, it is preferred by 20% of women and this is the second most common method of contraception.[2] In the USA, laparoscopic tubal ligation is mostly performed by bipolar coagulation.[1] Surgery is usually performed under general anesthesia. The procedure has risks associated with surgery and anesthesia.[3]

In laparoscopic tubal ligation, the manipulator is inserted into the uterus with the standard method. The placement of the manipulator has the advantage that it makes easier to visualize the tubes.[4] Uterine manipulator, dorsolithotomy placement and positioning of the patient prolongs the operation time. There are also risks such as the risk of uterine perforation, bleeding from the bite of tenaculum, and post-surgical endometrial infection in addition to the cost of manipulator.[5,6] High success rate without the use of uterine manipulator is also reported.[6-8] Lapa-

**Correspondence:** İsmail BIYIK
Kütahya Health Sciences University Faculty of Medicine, Department of Gynecology and Obstetrics, Kütahya, TURKEY/TÜRKİYE
**E-mail:** dribiyik@hotmail.com

Peer review under responsibility of Journal of Clinical Obstetrics & Gynecology.

***Received:*** 19 Jan 2020 ***Received in revised form:*** 02 Mar 2020 ***Accepted:*** 10 Mar 2020 ***Available online:*** 11 Mar 2020

roscopic tubal ligation is a safe, effective and comfortable procedure for the patient, but it is costly depending on the equipment used.[9] However, to the best of our knowledge, there is only one study comparing the duration of surgery and anesthesia, complication rates and the amount of anesthetic drugs used in laparoscopic tubal ligation cases with and without uterine manipulator.[10] And no study compared the cost of procedure with or without the use of manipulator so far.

The aim of this study is to compare the duration of surgery and anesthesia, complication rates and the amount of anesthetic drugs used and the cost in laparoscopic tubal ligation cases with and without the use of manipulator

## MATERIAL AND METHODS

This retrospective case control study included women who underwent elective interval laparoscopic tubal ligation between June 2018 and June 2019 at Karacabey State Hospital, Karacabey, Bursa, Turkey. Ethical approval was obtained from Trakya University Faculty of Medicine Scientific Research Ethics Committee (TUMF-SREC 2019/301) and informed written consent was obtained form each participants. The operations in the study were performed by a single surgeon (İsmail Bıyık). Data were extracted from the operation files and recorded on a pre-prepared sheet including the demographic data, operation time, anesthesia time, complications, amount of drug, intraoperative and early postoperative complications. All eligible cases whose operation records were complete and those except having factors that may prolong the surgery or /anesthesia duration or amount of drug use (and hence the cost) were included. Those who underwent laparoscopic tubal ligation in addition to the other surgical procedures, who required adhesiolysis due to widespread adhesion in the abdomen, and those who had comorbidities prolonging the duration of surgery (pulmonary, cardiac disease, etc.) were excluded from the study.

ASA (Physical Status Classification System) I-II patients were included in the study. Anesthesia induction was made with 2 mg/kg propofol, 1 µg/kg intravenous fentanyl (Talinat® 0.5 mg ampoule, Vem Pharmaceutical Industry) and 0.6 mg/kg intravenous rocuronium (Esmeron® 50 mg/5 ml, Merck Sharp Dohme Pharmaceuticals Ltd.). After muscle relaxation, autotracheal intubation was performed with an appropriate tube (no. 7 and no. 7.5). Following orotracheal intubation without complications, anesthesia was maintained with 50% $O_2$ and 50% dry air with 2.5% sevoflurane (Sevorane®, Abbott Lab, North Chicago, USA).

All operations were carried out by an experienced European Society for Gynaecological Endoscopy (ESGE) certified laparoscopic surgeon. Following the completion of preparation of surgical equipments, the induction of intravenous general anesthesia was started. After endotracheal intubation, patients were put in dorsolithotomy position if they were planned to be operated with the manipulator. HUMI (Harris-Kronner) Uterine Manipulator® was inserted into the uterus after biting upper cervical rim with teneculum. Cases without manipulator were operated in the supine position. Following the antisepsis, Veress needle was applied from the sub-umbilical area. $CO_2$ insufflation was performed to the abdomen at a rate of 1 lt/min. Following insufflation of gas that ensures 14 mmHg intrabdominal pressure, a 5 mm trocar and laparoscope were applied subumbilically. An auxiliary port 5 mm trocar was inserted through the 2 cm upper-inner part of the anterior superior of the left spinal iliac. Tubes were cauterized from the middle with bipolar energy. Then, the cauterized area was cut with the laparoscopic scissors at two separate areas. At the end of the surgical procedure, tenoxicam (Tilcotil® 20 mg/2 mL vial containing I.M./IV. lyophilized powder, Deva Holding) was given for postoperative analgesia. Then anesthesia was terminated. At the extubation stage, 1 mg atropine (Atropine Sulphate Biofarma® 0.25 mg/1 ml ampoule, Biofarma Pharmaceutical Industry) and 2 mg neostigmine (Plantigmin®, Polifarma İlaç Sanayi) were administered intravenously for decuration, and the patients were extubated. Diclofenac sodium 75 mg IM (Diclomec ampul® , Abdi Ibrahim Pharmaceutical Industry) was administered to the patients in the postoperative period. The patient was extubated after the operation. The patients were discharged on the same day.

In order to determine the amount of anesthetic agent inhaled during the operation, the calculation formula recommended by Drager Cato anesthesia device was used.[11] Sevoflurane administration rate was calculated as 4 ml/minute. Consumption of the inhaled anesthetic agent (ml /h) was calculated by the formula of: 3 x fresh gas flow (L / min) x percentage of inhaled anesthetic used (%).

The time between intubation and the onset of surgery, duration of surgery (main operation time) and intubation-extubation (total operation time-duration of anesthesia) were recorded in the operating room.

### STATISTICAL ANALYSES

Alpha significance level was taken as 0.05 and variance coefficient was taken as 0.5. The minimum sample size that could determine the ratio of 1.5 units between the two groups' mean duration of surgery with 81% power was calculated as 46 (23+23) in the PASS 11 program. All statistical analyses were performed with the SPSS 21 programme. Data were expressed as numeric variables given as median (semi interquartile range) and categorical variables given as n (row %). The variables between two groups were compared by Mann Whitney U Test, Fisher Exact Test, Chi-Square Analysis. A value of $p < 0.05$ was considered statistically significant.

## RESULTS

Age, weight, height, body mass index (BMI) values, demographic data and previous abdominal surgical history rates were similar between the patients with and without manipulators ($p>0.05$). Demographic data of the cases are given in Table 1.

In the non-manipulator group, intubation to beginning of surgery time, main operation time, total anesthesia time were found to be shorter ($p<0.001$, $p<0.001$, $p<0.001$, respectively). Postoperative hospital stay, the amount of parenteral anesthetic drug used, the need for postoperative parenteral analgesics, the number of laparoscopic ports used and the complication rates were similar between the two groups ($p>0.05$). Sevoflurane use was found to be less in the non-manipulator group ($p<0.001$). Surgical and anesthetic data of the cases are given in Table 2.

There was minimal superfical cutaneous bleedings from the trocar site in 1 case without manipulator and 3 cases with the manipulator which needed to be controlled by simple superfical sutures on the skin. In one patient with the manipulator, uterine perforation developed during the depth measurement of the uterine cavity with hysterometer before uterine manipulator placement. The bleeding stopped without suturing or using cautery.

**TABLE 1:** Demographic data of the cases.

| | Without manipulator (n:25) | With manipulator (n:20) | p value |
|---|---|---|---|
| **Age (years)** | 34 (3.5) | 34.5 (4) | 0.900[a] |
| **Gravida** | 2 (1) | 3 (0.5) | 0.150[a] |
| **Parity** | 2 (0.5) | 3 (0.5) | 0.250[a] |
| **Number of vaginal deliveries** | 2 (1) | 3 (0.75) | 0.380[a] |
| **Number of caesarean sections** | 0 (0) | 0 (0.25) | 1.000[a] |
| **Number of live births** | 2 (0.5) | 3 (0.5) | 0.185[a] |
| **Weight (kg)** | 68.50 (7) | 70.30 (4.62) | 0.451[a] |
| **Height (cm)** | 158 (5.50) | 159.5 (2.75) | 0.308[a] |
| **Body mass index (kg/m$^2$)** | 27.79 (2.98) | 27.42 (2.27) | 0.664[a] |
| **Abdominal surgery history** | | | |
| No | 9 (36%) | 8 (40%) | 0.783[b] |
| Yes | 16 (64%) | 12 (60%) | |

[a]MannWhitney U Test, [b]Chi-Square Analysis, numeric variables given as median (semi interquartile range) and categorical variables given as n (row%).

**TABLE 2:** Surgical and anesthetic data of the cases.

| | Without manipulator (n:25) | With manipulator (n:20) | p value |
|---|---|---|---|
| **Entubation to beginning of surgery time (min)** | 3 (0.5) | 9 (0.5) | **< 0.01**[a] |
| **Main operation time (min)** | 9 (1.5) | 12.5 (1.5) | **<0.01**[a] |
| **Total operation time (min)** | 17 (3) | 25 (2.5) | **<0.01**[a] |
| **Postoperative hospital stay (hour)** | 6 (0) | 6 (0) | 0.110[a] |
| **Fentanyl (mcg)** | 100 (0) | 100 (0) | 0.597[a] |
| **Rocuronium (mg)** | 40 (5) | 40 (1,25) | 0.649[a] |
| **Propofol (mg)** | 200 (15) | 200 (20) | 0.897[a] |
| **Sevoflurane (ml)** | 6.8 (1.2) | 10 (1) | **<0.001**[a] |
| **Parenteral postoperative analgesic requirement** | | | 0.192[b] |
| 1 time | 25 (58.1) | 18 (41.9) | |
| 2 times | 0 (0) | 2 (100) | |
| **Port number** | | | 0.444[b] |
| 2 | 25 (56.8%) | 19 (43.2%) | |
| 3 | 0 (0%) | 1 (100%) | |
| **Complications** | | | 0.386[b] |
| Port site bleeding | 1 (4%) | 3 (15%) | |
| Uterine perforation | 1 (4%) | - | |

[a]MannWhitney U Test, [b]Fisher Exact Test p value, numeric variables given as median (semi interquartile range) and categorical variables given as n (row%).

## DICUSSION

Tubal ligation is applied to 700,000 women annually in the USA.[12,13] Half of the tubal ligations are applied in the postpartum period and the other half is used as an interval.[1]

The majority of interval tubal ligations are performed laparoscopically. The standard method of laparoscopic tubal ligation is performed in the dorsolithotomy position using uterine manipulator. The use of the manipulator has the advantage of making the tubes easily visible and accessible.[4] However, following general anesthesia, the patient needs be placed in the dorsolithotomy position for placement of the manipulator necessitating extra time. During insertion of the manipulator, there are risks of uterine perforation, bleeding from the bite area of the tenaculum and the risk of post-operative infection.[5,6] In this study, only one uterine perforation occured by hysterometer before uterine manipulator placement, but no intervention was required.

There are publications describing successful laparoscopic tubal ligation without using a manipulator.[6-8] To the best of our knowledge, only one study compared the cases with and without uterine manipulators so far.[10] However, in this retrospective study, the two groups with and without direct uterine manipulator were compared only in terms of operative times. The use of uterine manipulator was found to increase the duration of surgery significantly. The amounts of anesthetic drugs used were not compared. In addition, cases with pathologies such as ovarian cyst removal that prolonged duration of surgery were not excluded. Positioning the patient and inserting the uterine manipulator prolongs the operation time. In the present study, the total operation time (i.e. anesthesia time) with the use of uterine manipulator was found to be 8 minutes longer. The group using the uterine manipulator was given inhalation anesthesia with an additional 3.2 ml of sevoflurane. Sevoflurane is sold in a 250 ml solution and costs $108/min. The cost of 3.2 ml of sevoflurane was calculated as $1.38/min. In a study conducted in Serbia, the ml price of sevoflurane was calculated as 0.78 euro/min.[14] The cost of sevoflurane, for 8 minutes, is calculated as 7 US dollars. Avarage laparoscopic tubal ligation operation costs 116 dollars in Turkey. Therefore, using manipulator corresponds to at least 6% of the total cost of surgery which excludes the

cost of operating room, cost of manipulator sterilization and non-reusable parts. In a US publication in 2017, the cost of laparoscopic tubal ligation was reported to be $ 5163.[9] If the operation is performed in the USA, it can be assumed that the cost difference will be higher.

There are publications that calculate the cost of the use of the operating room. There are no data indicating the cost per minute of the operating room in laparoscopic tubal ligation. Data are from the other laparoscopic gynecological and non-gynecologic operations. In an article published in the USA in 2018, the cost of operating room usage was calculated as 36-37 dollars/min.[15] In another US-based study, the cost of operating room use was reported to be 22-133 dollars/min with an average of 62 dollars/min, depending on the complexity of the operation.[16,17] Cost for laparoscopic hysterectomy in Europe was calculated as 14-26 dollars/minute. In our study, the difference in operation time between the two groups was 8 min. Anesthesic drugs used in other studies, additional cost of sterilization of manipulator, surgical material prices and personnel expenses are not fully specified. Operating room cost and expenses such as staff costs are not calculated according to the time or per incident in Turkey. Therefore, we cannot make a direct comparison of the cost of other studies. However, it is evident that operations without manipulator seems more cost-effective because it is completed in a shorter time with smaller doses of sevoflurane even if other costs such as operating room and staff expenses were not included. For instance, the cost of the manipulator in our study is not taken into account because it is obvious that it would add higher costs to manipulator group besides indirect costs of manipulator cost usage such as the anesthesia drug use due to prolongation of operation time require to place it. Even if we used an reusable one sterilization costs would be very hard to calculate.

## CONCLUSION

In laparoscopic tubal ligation operation where no uterine manipulator is used, anesthesia and total surgery times are approximately 8 minutes shorter. The use of uterine manipulator increases the duration of surgery and the amount of sevoflurane used. Laparoscopic tubal ligation without uterine manipulator may be considered in cases where severe adhesions are not anticipated and no additional intervention is planned. Besides, avoidance of manipulator use may have the advantage of time and cost savings.

### *Source of Finance*

*During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.*

### *Conflict of Interest*

*No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.*

### *Authorship Contributions*

***Idea/Concept:*** *İsmail Bıyık, Mustafa Albayrak, Ayşe Nur Mut;* ***Design:*** *İsmail Bıyık, Mustafa Albayrak, Ayşe Nur Mut;* ***Control/Supervision:*** *Mustafa Albayrak, Fatih Keskin;* ***Data Collection and/or Processing:*** *İsmail Bıyık;* ***Analysis and/or Interpretation:*** *İsmail Bıyık, Fatih Keskin, Ayşe Nur Mut;* ***Literature Review:*** *İsmail Bıyık, Mustafa Albayrak, Fatih Keskin;* ***Writing the Article:*** *İsmail Bıyık, Mustafa Albayrak, Fatih Keskin;* ***Critical Review:*** *Mustafa Albayrak, Ayşe Nur Mut;* ***References and Fundings:*** *İsmail Bıyık.*

## REFERENCES


1. Pollack A. ACOG practice bulletin. Clinical management guidelines for obstetrician-gynecologists. Number 46. Obstet Gynecol. 2003;102(3):647-58. [Crossref] [PubMed]
2. Centers for Disease Control and Prevention (CDC). National Survey of Family Growth. Accessed: October 12, 2011. [Link]
3. Jamieson DJ, Hillis SD, Duerr A, Marchbanks PA, Costello C, Peterson HB. Complications of interval laparoscopic tubal sterilization: findings from the United States Collaborative Review of Sterilization. Obstet Gynecol. 2000;96(6):997-1002. [Crossref] [PubMed]
4. van den Haak L, Alleblas C, Nieboer TE, Rhemrev JP, Jansen FW. Efficacy and safety of uterine manipulators in laparoscopic surgery: a review. Arch Gynecol Obstet. 2015;292(5):1003-11. [Crossref] [PubMed]
5. Akdemir A, Cirpan T. Iatrogenic uterine perforation and bowel penetration using a Hohlmanipulator: a case report. Int J Surg Case Rep. 2014;5(5):271-3. [Crossref] [PubMed] [PMC]
6. Mehta PV. Laparoscopic sterilizations (16,803) without vaginal manipulation. Int J Gynaecol Obstet. 1982;20(4):323-5. [Crossref] [PubMed]
7. Banerjee AK, Emembolu JO. Plastic suction curette as uterine manipulator at combined laparoscopic sterilization: a prospective study of 531 cases. Eur J Contracept Reprod Health Care. 2006;11(4):310-3. [Crossref] [PubMed]
8. Khandwala SD. Development of a simplified laparoscopic sterilization technique. J Reprod Med. 1984;29(8):586-8. [PubMed]
9. Carney PI, Yao J, Lin J, Law A. Comparison of healthcare costs among commercially ınsured women in the united states who underwent hysteroscopic sterilization versus laparoscopic bilateral tubal ligation sterilization. J Womens Health (Larchmt). 2017;26(5):483-90. [Crossref] [PubMed]
10. Prasad P, Agochiya J, Hecht RM. Uterine manipulation during laparoscopic sterilization-can we do without it? Austin J Womens Health. 2014;1(1):1-3.
11. Yildirim A, Goksu H, Toprak GC, Kılıc R, Yasar MA. [The safety and quality of low flow anaesthesia with isoflurane, sevoflurane and desflurane]. Fırat Med J. 2006;11(3):170-4.
12. Westhoff C, Davis A. Tubal sterilization: focus on the U.S. experience. Fertil Steril. 2000;73(5):913-22. [Crossref] [PubMed]
13. MacKay AP, Kieke BA Jr, Koonin LM, Beattie K. Tubal sterilization in the United States, 1994-1996. Fam Plann Perspect. 2001;33(4):161-5. [Crossref] [PubMed]
14. Stevanovic PD, Petrova G, Miljkovic B, Scepanovic R, Perunovic R, Stojanovic D, et al. Low fresh gas flow balanced anesthesia versus target controlled intravenous infusion anesthesia in laparoscopic cholecystectomy: a cost-minimization analysis. Clin Ther. 2008;30(9):1714-25. [Crossref] [PubMed]
15. Childers CP, Maggard-Gibbons M. Understanding costs of care in the operating room. JAMA Surg. 2018;18(4):e176233. [Crossref] [PubMed] [PMC]
16. Shippert RD. A study of time-dependent operating room fees and how to save $100 000 by using time-saving products. The American Journal of Cosmetic Surgery. 2005;22:25-34. [Crossref]
17. Macario A. What does one minute of operating room time cost? J Clin Anesth. 2010;22(4):233-6. [Crossref] [PubMed]