

# Does Uterine Manipulator Type Affect Surgical Outcomes of Laparoscopic Hysterectomy?

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## Abstract

**Objectives:** Many surgeons use uterine manipulator (UM) during laparoscopic hysterectomy (LH). In this study, we aimed to compare the outcomes of LH operations performed by using partially reusable UM with the articulated system (artUM) and disposable (dUM) UM without articulation. **Materials and Methods:** A total of 99 patients underwent the LH operation. This study was carried out with 35 of those 99 Caucasian patients who met the inclusion criteria. Group I consisted for 7 LH operations using the articulated RUMI®II/KOH-Efficient™ (Cooper Surgical, Trumbull, CT, USA) system (artUM), while Group II consisted of 28 patients using old-type V Care® (ConMed Endosurgery, Utica, New York, USA) dUM as UM.

**Results:** Mean operation time was found to be 157.1 ± 42.0 min. The operation time was found statistically longer in Group I, consisted of artUM used patients ( $P = 0.006$  and  $P < 0.05$ ). No statistically significant difference was found between two groups in terms of surgical results such as, delta hemoglobin value ( $P = 0.483$  and  $P < 0.05$ ), length of hospital stay ( $P = 0.138$  and  $P < 0.05$ ), and postoperative maximum body temperature ( $P = 0.724$  and  $P < 0.05$ ).

**Conclusion:** The UM type did not alter the surgical outcomes except the operating time in our study. According to our results, the surgical technique is a more significant variable than instruments used in LH for normal size uterus. Further prospective, large-scale studies comparing various UM systems are mandatory.

**Keywords:** Laparoscopic hysterectomy, surgical outcomes, uterine manipulator

## INTRODUCTION

In the past two decades, minimally invasive procedures have become extremely popular in all branches of surgery worldwide.<sup>[1]</sup> Laparoscopic hysterectomy (LH) has some superiorities to other hysterectomy types such as less blood loss, minimal risk of wound infection, short hospitalization period, coming back to work in a shorter time, and its popularity has increased rapidly with regard to the surgical wound for LH, positive esthetic outcomes following surgery provide a high level of satisfaction to patients.<sup>[2,3]</sup> In hysterectomy operations

performed due to benign causes, the American Association of Gynecologic Laparoscopists recommends the use of minimally invasive surgical interventions.<sup>[4]</sup> It has been shown that many of comorbidities minimizes via the surgical experience in LH.<sup>[5]</sup> The factors such as the age of the patient, number of parity, and previous pelvic surgery histories have been determined as the parameters affecting the LH outcomes.<sup>[5,6]</sup>

There are certain uterine manipulators (UM) used for manipulating the uterus during LH. The Working group of the

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European Society for Gynaecological Endoscopy reported in 2019 that UM must be placed deep enough in the uterine cavity to allow maximum uterus mobility.<sup>[7]</sup> There are only a few studies about LH without the use of UM.<sup>[8,9]</sup> Many surgeons use UM during the LH. On the other hand, the number of studies comparing various UM is limited.<sup>[10,11]</sup> UM is completely placed on the vaginal fornices and cervix to determine the cervicovaginal borders during the peroperative intraabdominal inspection.<sup>[12]</sup> There are studies reporting that the urethral traumas are decreased with UM.<sup>[13,14]</sup> UM may be totally disposable or reusable. Moreover, there are also UM having certain disposable parts, which are used in vaginal fornices and uterine cavity, and also partially reusable articulated systems. The specific complications can occur depending on the type of UM,<sup>[15]</sup> problems of applying UM to the patient or variable performance of the device during every operation<sup>[10]</sup> make the selection of UM more difficult for the surgeon. It has been reported that the optimal UM could not be found still and gynecologists should select the most appropriate manipulator for their purposes and expectations.<sup>[11]</sup>

In this study, we aimed to compare the outcomes of LH operations performed by using partially reusable UM with articulated system (artUM) and disposable UM without articulation (dUM).

## MATERIALS AND METHODS

The patients operated in Bucak State Hospital's Gynecology and Obstetrics Clinic and Düzce University's Department of Gynecology and Obstetrics between January 2012 and 2014 included in this study. A total of 99 patients underwent the LH operation. This study was carried out with 35 of those 99 Caucasian patients who met the inclusion criteria. The written informed consents of all of the patients were obtained before the operation. The information related to the patients were obtained from the Bucak State Hospital and Düzce University's Medical Faculty Training and Research Hospital records and reviewed retrospectively. Ethics committee approval was received for this study from the Medical Ethical Committee of the Düzce University (approval reference number 2016-33).

Before the operations, all of the patients were examined via bimanual pelvic examination, transvaginal ultrasound, cervicovaginal smear, and underwent endometrial sampling. For all of the patients involved in this study, the diagnostic cystoscopy was performed. All of the operations included in this study were performed by A.Y. with the same method mentioned in the previous publication.<sup>[9]</sup> The patients that underwent surgery with a different surgical method, the cases that underwent laparoscopically assisted vaginal hysterectomy or supracervical hysterectomy, the cases

that underwent nongynecological additional surgery, the patients whose information couldn't be accessed, and the patients whom an invasive malignancy was detected in the preoperative examination, peroperative frozen section examination or histopathologic examination in postoperative period, were excluded from this study. The patients considered to be enlarged uterus, having uterus size of  $\geq 12$  weeks in preoperative physical examination,<sup>[12]</sup> and patients with pelvic organ prolapse were excluded from the study. The procedures were performed using a morcellator and underwent any additional genito-urethral surgical intervention other than diagnostic cystoscopy at the end of the operation, were also excluded. The patients that have received blood transfusion preoperatively were also excluded.

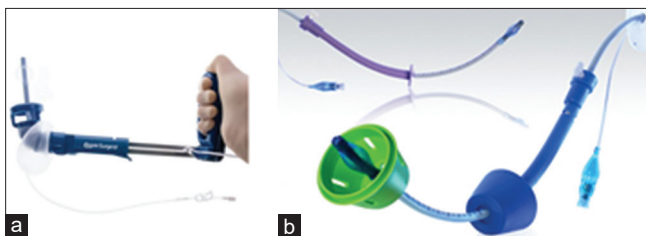
The previous pelvic surgery history was considered positive in case of the presence of cesarian section, hysterotomy, adnexal surgery, urinary system operation, appendectomy, rectosigmoid region surgery, or any surgical intervention in the pelvis. The patients with focal or generalized basic/complex nonatypical hyperplasia in preoperative endometrial sampling results were grouped under endometrial hyperplasia as operation indication. The patients with a preoperative diagnosis of abnormal uterine bleeding (AUB) who were found to have a demonstrable uterine pathology at preoperative evaluation were classified under the relevant uterine pathology as the indication for surgery. The diagnosis of the patients having preoperative diagnosis of abnormal uterine hemorrhage but no obvious reason preoperative was considered AUB. The patients having prediagnosis of ovarian cyst or adnexal mass were gathered under the same group code.

All of the patients received 1 g of cefalosine as preoperative prophylactic antibiotic. Via the oral lactatives given a day before the surgery and the rectal enemas with 8 h of interval, the bowel preparation was performed. The operation time was recorded in accordance with the information in anesthesia follow-up forms. The change between the preoperative hemoglobin (Hb) value and postoperative Hb value was identified as delta Hb.<sup>[9]</sup> The postoperative fever diagnosis was made if the postoperative body temperature of the patient were measured to be  $\geq 100.4^{\circ}\text{F}$  ( $38^{\circ}\text{C}$ ) for 2 times with 4–6 h of the interval within 24 h after the operation or her body temperature was persistently  $\geq 101^{\circ}\text{F}$  ( $38.3^{\circ}\text{C}$ ).<sup>[16]</sup> For patients having no postoperative fever, the maximum level of body temperature measured during the hospitalization was recorded as the maximum postoperative body temperature value. The need for reoperation due to hemorrhage or another reason, urinary system traumas, and bowel and large artery injuries were considered major complications. The patients were examined at least once every 24 postoperative hours. The time of patients' discharge was recorded as 0–24, 24–48 or 48–72 h. The patients having no urinary retention or no need for opioids, being able to mobilize and to wear by herself were discharged.<sup>[17]</sup>

Group 1 consisted of 7 LH operations using the articulated RUMI®II/KOH-Efficient™ (Cooper Surgical, Trumbull, CT, USA) system (artUM), while Group II consisted of 28 patients using old-type V Care® (ConMed Endosurgery, Utica, New York, USA) dUM as UM [Figure 1].<sup>[18,19]</sup>

### Operation method

All of the operations were performed under general anesthesia. UM was placed on vaginal fornices. Pneumoperitoneum was applied from the umbilicus or Palmer point via the Veress needle. Ten millimeters (mm) telescope was placed through the sheath of trocar applied to the umbilicus and then a 25° Trendelenburg position achieved. A 5 mm trocar sheaths were placed in both of hypochondriums.<sup>[12]</sup> A tissue fusion device was placed on the 5 or 10 mm trocar placed on the Palmer's point. Through the 5 mm trocar arms placed on both of lower quadrants, dissector, and holder forceps with 5 mm diameter were placed [Figure 2].<sup>[12]</sup> Considering the points where the ureter may pass below the peritoneum and by utilizing UM, the operations were performed by uplifting the uterus from the pelvic floor. Hemostasis was ensured in round ligaments, uteroovarian, or infundibulopelvic ligament on both sides by performing tissue dissection by using a device running via tissue fusion technology. All of the operations were performed at the point closest to the uterus. Frontal and posterior parts of the peritoneum were dissected, and uterine artery traces were revealed. By using tissue fusion technology device, the uterine arteries were coagulated. Vesico uterine peritoneal fold and bladder were separated from the uterus and the upper vagina dissected. At the level of vaginal fornices determined through the cervical cup of UM, all of the vaginal walls were circularly separated from the cervix by using L-form monopolar needle or ultrasonic thermal scalpel. The specimens were through the vagina. The vaginal cuffs were closed vaginally or laparoscopically with delayed absorbable sutures. Then the diagnostic cystoscopy was performed via rigid cystoscope. All of the bladder walls were systematically examined. The jet flows were detected from both of urethral gaps in cystoscopy.



**Figure 1:** The picture depicting the uterine manipulators. (a) RUMI®II/KOH-Efficient™ (Cooper Surgical, Trumbull, CT, USA) system (artUM), (b) old-type V Care® (ConMed Endosurgery, Utica, New York, USA) disposable uterine manipulator (dUM)

### Statistical analysis

Descriptive statistics included mean, standard deviation, and ratio. Data from the Mann–Whitney U test performed on the independent samples were used in the analysis of the quantitative data. Wilcoxon test was used in the analysis of dependent quantitative data. Chi-square test and Fisher's exact test were used to compare the qualitative data between both the groups. SPSS version 26.0 (IBM® SPSS® Statistics for Windows, Version 19.0, IBM Corporation; New York, USA) software package was used in the statistical analysis.  $P < 0.05$  considered statistically significant.

### RESULTS

The mean age of the patients participating in our study was found to be  $49.9 \pm 6.3$  years. Operation indication of 17 patients was myoma uteri (48.6%) and that of 6 patients was AUB (17.2%). The mean parity of the patients was found to be  $2.9 \pm 1.6$ . In 7 (20%) of the patients that underwent LH, there were previous pelvic surgery history. Mean operation time was found to be  $157.1 \pm 42.0$  min. The mean preoperative Hb value of the patients was found to be  $12.5 \pm 1.3$  g/dl. Major complication was observed in only 1 patient (2.9%), and ureter stent was peroperatively placed. One patient (2.9%) received 2 units of erythrocyte suspension in postoperative period. No postoperative febrile morbidity was observed. General characteristics of the patients are presented in Table 1.

The operation time was found statistically longer in group 1, consisted of artUM used patients ( $P = 0.006$  and  $P < 0.05$ ). No statistically significant difference was found between two groups in terms of surgical results such as, delta Hb value ( $P = 0.483$  and  $P < 0.05$ ), length of hospital stay ( $P = 0.138$  and  $P < 0.05$ ), and postoperative maximum body temperature ( $P = 0.724$  and  $P < 0.05$ ) [Table 2].



**Figure 2:** Location of four trocars

**Table 1: General characteristics of the patients**

	<i>n</i> =35; 100%	Mean±SD	Minimum–maximum
Age (year)	49.9±6.3	41	69
Parity	2.9±1.6	0	9
Preoperative Hb (g/dl)	12.5±1.3	10,00	14,30
Postoperative Hb (g/dl)	11.1±1.4	7,8	13,9
Past history of pelvic surgery (+)	7 (20)		
Mean operation time (minimum)	157.1±42.0	70	240
Major complication	1 (2,9)		
Indications			
Leiomyoma	17 (48,6)		
Endometrial hyperplasia	4 (11,6)		
Adnexal mass	7 (20,3)		
Adnexal mass + leiomyoma + cystocele	1 (2,9)		
AUB	5 (14,5)		
Endometrial polyp	1 (2,9)		

AUB: Abnormal uterine bleeding, SD: Standard deviation, Hb: Hemoglobin

**Table 2: Comparison of surgical outcomes of two groups**

	Group 1 ( <i>n</i> =7; %100)	Group 2 ( <i>n</i> =28; %100)	<i>P</i>
Operation time (min) <sup>a</sup>	196.4±30.5	147.3±38.9	0.006*
Delta Hb (g/dl) <sup>a</sup>	1.6±1.2	1.3±0.9	0.483
Length of hospital stay (days) <sup>a</sup>	4.0±0.6	3.5±1.1	0.138
Postoperative maximum body temperature (°C) <sup>a</sup>	37.1±0.7	36.9±0.4	0.724

<sup>a</sup>Mean±SD, \**P*<0.05 was considered statistically significant. SD: Standard deviation, Hb: Hemoglobin

## DISCUSSION

LH needs equipment required to perform that differs from the abdominal or vaginal hysterectomy. During LH, significant upward traction must be applied to the cervix and uterus.<sup>[7]</sup> A proper UM can make surgery easier and ensures a successful operation.

RUMI®II/KOH-Efficient™ (Cooper Surgical, Trumbull, CT, USA), a kind of (artUM) is the new generation of RUMI system.<sup>[18]</sup> The RUMI system consists of the RUMI manipulator, the KOH cervical cup, and the KOH colpo-pneumo-occluder.<sup>[11,18]</sup> It has a wide range of motion, about 140° in the anterior-posterior plane.<sup>[11]</sup> The insertion of RUMI®II/KOH-Efficient™ (Cooper Surgical, Trumbull, CT, USA) system is more complex than the old type V Care® manipulator (ConMed Endosurgery, Utica, New York, USA). The old type V Care® manipulator (ConMed Endosurgery, Utica, New York, USA) is a lightweight, dUM.<sup>[11,19]</sup> It has advantages as good delineation and to maintain the pneumoperitoneum well.<sup>[11]</sup> Handling the old type V Care® manipulator is easy.<sup>[11,19]</sup> It is provided with an inflatable intrauterine balloon apparatus and it is aimed to be stable in the uterus.<sup>[20]</sup> The RUMI system consists of the RUMI manipulator, the KOH cervical cup, and the KOH colpo-pneumo-occluder.<sup>[11]</sup> It has a wide range of motion, about 140° in the anterior-posterior plane.<sup>[11]</sup> RUMI®II/KOH-Efficient™

(Cooper Surgical, Trumbull, CT, USA), a kind of (artUM) is the new generation of RUMI system. The insertion of RUMI®II/KOH-Efficient™ (Cooper Surgical, Trumbull, CT, USA) system is more complex than the old type V Care® manipulator (ConMed Endosurgery, Utica, New York, USA).

An artUM, may provide a wide range of movement and positioning of the uterus.<sup>[11]</sup> Furthermore, artUM particularly helpful in displaying the uterine artery by flexing the uterus laterally flexed with some degree of ante-version.<sup>[11]</sup> Major complications by indication were most common with endometriosis in LH.<sup>[6]</sup> The artUM makes the uterus to be elevated, and ante-flexed, which exposes the posterior fornix, and traction allows dissection of the rectum, especially in patients with recto-vaginal endometriosis.<sup>[11,21]</sup>

The old type V Care® (ConMed Endosurgery, Utica, New York, USA), a kind of dUM was accepted as user friendly.<sup>[11]</sup> But it was reported that the lightweight design can be less suitable for larger uteri.<sup>[10]</sup> van den Haak *et al.* claimed that dUM does not offer independent motion of the intrauterine tip, rather it uses leverage to manipulate the uterus.<sup>[11]</sup> The dUM has also a wide range of motion,<sup>[11]</sup> but it has a rigid body and cannot make flexion movements.

There are a few reviews about the different type of UM and their capabilities,<sup>[10,11,22]</sup> but there is no review or study that makes a comparison between RUMI®II/KOH-Efficient™ (Cooper

Surgical, Trumbull, CT, USA) (artUM) and V Care® (ConMed Endosurgery, Utica, New York, USA) (dUM). Husslein *et al.* compared Colpo-Probe Vaginal Fornix Delineator (Cooper Surgical, Inc, Trumbull, CT) and Hohl manipulator (KARL STORZ AG, Tuttlingen, Germany) in their study in 2017 and found Hohl manipulator results in a shorter operative time.<sup>[23]</sup> Misirlioglu *et al.* claimed that LH assisted with the Vectec (VECTEC, Hauterive, France) UM is associated with shorter operation time. They also added that the movements of the uterus, visualization of the vaginal fornices, and maintenance of pneumoperitoneum were significantly better with Vectec (VECTEC, Hauterive, France) compared to the Clermont-Ferrand (Karl Storz GmbH and Co., Tuttlingen, Germany) manipulator.<sup>[24]</sup> There are many types of UM, but V Care® (dUM) and RUMI®II/KOH-Efficient (artUM) are more commonly used than any others and it was reported in a recent review that they have similar disadvantages as excessive bleeding, disintegration inside the patient and uterine rupture in RUMI®I (artUM) and V Care® (dUM).<sup>[22,25,26]</sup> We performed this study in patients with normal size uterus and we did not detect any difference between RUMI®II/KOH-Efficient™ (Cooper Surgical, Trumbull, CT, USA) (artUM) and V Care® (ConMed Endosurgery, Utica, New York, USA) (dUM) with regard to the range of uterine manipulation, vaginal fornix delineation, and the operative difficulty of vesicouterine fold dissection.

LH may be slower than open surgery because of the smaller instruments used and their striction of movement caused by operating through fixed trocar sleeves.<sup>[21]</sup> To save time, it is accepted that unnecessary steps, such as avoidable instrument changes, should be kept to minimum.<sup>[21]</sup> The perioperative complications and the operating time are the main variables studied in the literature similar to our study.<sup>[23,24]</sup> Brummer *et al.* reported that operation time is primarily related to the experience of the surgeon.<sup>[6]</sup> Furthermore, a surgeon seems to need performing at least 20–40 total LH (TLH) with or without an UM to decrease the rate of surgical complications.<sup>[27]</sup> All of the operations were performed by the same fashion described by the same surgeon in our study. On the other hand, the perioperative outcomes of the first 30 LH performed with V Care® (dUM) and RUMI®II/KOH-Efficient (artUM) were analyzed in our study. According to our results; operative times were found longer in RUMI®II/KOH-Efficient (artUM) group ( $P = 0.006$  and  $P < 0.05$ ). It was reported that the operation time may be longer in artUM used surgeries in previous reports similar to our study.<sup>[10,11,22]</sup>

At present, some new instruments and techniques were introduced for both vessel sealing and cutting properties in laparoscopic surgery.<sup>[28]</sup> It was found that novel bipolar platforms, including tissue fusion devices, used in TLH were not determined to be independent predictors of the amount of blood loss in patients having a uterus  $\leq 12$  weeks of

gestation.<sup>[28]</sup> Twijnstra *et al.* declared that surgical experience predicts the successful outcome of LH with respect to blood loss.<sup>[5]</sup> Furthermore, it was demonstrated that the blood loss may be higher in cases of large uteri.<sup>[29]</sup> We excluded the cases having uterus size of  $\geq 12$  weeks in preoperative physical examination. All of the operations were performed with the uniform technique and the same kind of device was used for achieving hemostasis. We did not find any difference between the two groups in terms of delta Hb value ( $P = 0.483$  and  $P < 0.05$ ) in our study.

A fast recovery and short hospitalization is often possible for patients underwent TLH.<sup>[30]</sup> This has made TLH particularly fashionable in developing countries that do not have enough staffed personnel.<sup>[20]</sup> There is a wide variation between studies in terms of hospital stay. Kang *et al.* used RUMI® System in their study and they found the mean hospitalization duration of 4.1 days.<sup>[31]</sup> On the other hand, Mitri *et al.* found the mean length of hospital stay 1 day.<sup>[32]</sup> The mean length of hospital stay was found  $4.0 \pm 0.6$  days in the artUM group and  $3.5 \pm 1.1$  days in the dUM group, but the difference was not statistically significant in our study ( $P = 0.138$  and  $P < 0.05$ ).

LH has lower rates of postoperative fever because of infection when compared to open surgical approaches.<sup>[33]</sup> The rate of postoperative fever after LH varies widely, but it was found between 0 and 1% of patients in most of the recent studies.<sup>[5,12]</sup> The rate of febrile morbidity decreases with surgical experience.<sup>[6]</sup> We did not have any patients with postoperative fever in our study. All of LH operations were performed with the technique used by the same surgeon in this study, it may be a potential reason. Therefore, we compared the postoperative maximum body temperature between the two groups. No statically significant difference was found in our study ( $P = 0.724$  and  $P < 0.05$ ).

LH may still be the best choice for eligible patients when performed by experienced surgeons.<sup>[34]</sup> It was found that the surgeon experience was associated with many perioperative outcomes.<sup>[6,27]</sup> The UM type did not alter the surgical outcomes except the operating time in our study. The possible reason for the long operation time in the artUM group is the longer time of insertion of RUMI®II/KOH-Efficient™ (Cooper Surgical, Trumbull, CT, USA) system. The number of patients is limited in our retrospective study. However, according to our results, the surgical technique is a more significant variable than instruments used in LH for normal size uterus. Further prospective, large-scale studies comparing various UM systems are mandatory.

## CONCLUSION

The uterine manipulator type did not alter the surgical outcomes except the operating time in our study. According to our results, the surgical technique is a more significant

variable than instruments used in LH for normal size uterus. Further prospective, large-scale studies comparing various uterine manipulator systems are mandatory.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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