



# Total Laparoscopic Treatment of Endometrial Cancer – Pilot Study with a New Model of Uterine Manipulator: Operating Data and Five Years Follow-up in a Reference Center in Southern Brazil

Geraldo Gastal Gomes-Da-Silveira<sup>1</sup>, Cristiane Cruz Nervo<sup>1</sup>, Mila Pontremoli Salcedo<sup>1,2</sup> and Patricia El Beitune<sup>2\*</sup>

<sup>1</sup>Service of Gynecology, Complexo Hospitalar Santa Casa de Porto Alegre (ISCOMPA), Brazil

<sup>2</sup>Department of Obstetrics and Gynecology and Post-Graduate Program, Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA), Brazil

## Abstract

To evaluate operating data, disease-free (DFS) and overall survival (OS) for women with cancer clinically restricted to the uterine corpus underwent to laparoscopy and the effects of the Gomes-da-Silveira manipulator on surgical time and intraoperative complications, sixteen patients treated for endometrial cancer with laparoscopy and followed up for at least 5 years were divided into 2 groups. Group 1, no uterine manipulator; Group 2, with the Gomes-da-Silveira manipulator used during surgery. Mean follow-up was 75 months. Surgery time ranged from 56-230 minutes. Blood loss ranged from 50-250 ml. All patients were discharged before 48 hours after the end of the surgery. Five-year OS and DFS were 100%, and 94%, respectively. Median time was 125 minutes for Group 1 and 63 minutes for Group 2 (p=0.0002). Following the principles of oncologic safety and in the hands of experienced surgeons, laparoscopy is safe, feasible and effective in the treatment of stage I endometrial cancer.

**Keywords:** Endometrial cancer; Laparoscopy; Uterine manipulator

## Background

According to statistics, endometrial cancer is the fourth most common invasive cancer among women in the United States. Current data indicate that 39,080 new cases of endometrial cancer were expected to be diagnosed in 2007, and 7,400 women will die because of this disease. The conventional surgery to treat endometrial cancer is performed by means of laparotomy. However, a growing number of reports that evaluated the selective use of laparoscopy to manage this disease have been published [1-2]. The first randomized study that compared a laparoscopic-vaginal approach with the conventional abdominal approach for treatment of patients with endometrial cancer was carried out by Malur et al. [3]. The authors concluded that laparoscopic-vaginal approach for treatment of endometrial cancer was associated with lower perioperative morbidity compared with the conventional abdominal approach. After this controlled study, several other authors have confirmed these results [4-5].

A device to assist uterine manipulation during laparoscopic hysterectomy is often used, since its invention in 1995 by Arnaud Wattiez in Clermont-Ferrand, France. In 2002, a new device, named Gomes-da-Silveira uterine manipulator was developed in Brazil. Its conception was designed to improve surgical time and decrease technical difficulties in the bladder and cervical dissections.

This study evaluated perioperative morbidity, surgical time, and disease-free and overall survival for women with cancer clinically restricted to the uterine corpus and who underwent treatment using laparoscopy. Moreover, it evaluated the effects of the Gomes-da-Silveira manipulator on surgical time and intraoperative complications in a group of patients that underwent laparoscopic treatment.

## Patients and Methods

Patients with endometrial cancer clinically restricted to the uterine corpus, no contraindications

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### \*Correspondence:

Patricia El Beitune, Department of Gynecology and Obstetrics, UFCSPA, Rua Prof. Annes Dias, 285. Chefia da Maternidade Mario Totta, CEP 90020-090. Porto Alegre – RS – Brazil, Phone/ Fax: +55 51-32148525;

E-mail: pbeitune@yahoo.com.br

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**Table 1:** Median and interquartile range of the social demographic, operatory e follow-up variables of groups according to use or not use of uterine manipulator and in the context of total patients.

Variables	With uterine manipulator (n=8)	Without uterine Manipulator (n=8)	Total (n=16)	p
Age (years)	63(57-69)	63.5(59-71)	63(58-70)	0.79
Weight (kg)	79.5(61.5-86)	79(68.5-89.5)	79.5(64-88.5)	0.72
BMI (kg/m <sup>2</sup> )	31(28.5-33)	31(29.5-33.5)	31(29-33)	0.79
Follow-up time (months)	70.5(64.5-74)	74.5(72.5-92.5)	73.5(68-81)	0.38
DFS (months)	70.5(64.5-74)	73.5(70-82)	73(66.5-74.5)	0.38
Total surgery time (min)	89.5(63-120)	141(107-185)	112.5(87-168.5)	0.08
Hysterectomy time (min)	63(58-69.5)	125(107-145)	87.5(63-125)	0.0002*
Estimated blood loss (ml)	75(50-100)	125(100-175)	100(75-150)	0.02*

DFS: Disease Free Survival; \*(Manipulator used vs. manipulator not used).  
Mann-Whitney test.

for laparoscopic surgery, and uterine size compatible with vaginal removal of the uterus in a single piece without morcellation were followed up in a prospective uncontrolled clinical trial. Surgical staging was performed using laparoscopy with peritoneal lavage, exploration of pelvic and abdominal cavity, and total extrafascial hysterectomy with bilateral salpingo-oophorectomy. Peritoneal material was collected for cytology, Fallopian tubes and infundibulopelvic ligaments were ligated before the placement of the uterine manipulator. Pelvic lymphadenectomy, complementary radiotherapy, or both were used according to FIGO criteria [6].

From April 2001 to December 2003, 16 patients were surgically treated for endometrial cancer limited to the uterine corpus. The first group of 8 patients was treated using conventional techniques and no uterine manipulator specifically for hysterectomy; for the other 8 patients, the Gomes da-Silveira manipulator was used during surgery.

There was no randomization due to absence of manipulator availability for the first eight cases.

Surgical technique was absolutely the same in both groups, but the group without Gomes-da-Silveira manipulator required greater surgical skills. Both groups were operated by the same surgical team.

We have analyzed the anthropometric parameters of the women included (age, weight, BMI), follow-up time, disease-free survival, surgery duration, estimated blood loss, time of hospitalization. In addition, we looked for intraoperative complications, fever, hematoma, infection, need to convert to laparotomy, need to be hospitalized again, or short- or long-term systemic complications and compare both groups, with and without Gomes-da-Silveira manipulator.

Statistical significance was analyzed according to descriptive results, central distribution and dispersion values, Mann-Whitney test and Kaplan Meyer survival test. The level of significance was set at  $p < 0.05$ .

## Results

Sixteen patients were included in the study. Table 1 shows the median and interquartile range of the social demographic, operatory e follow-up variables of groups according to use or not use of uterine manipulator and in the context of total patients. Median age was 63 years, and median BMI was 31 kg/m<sup>2</sup>. Staging results were: Ia = 3; Ib = 10; and IIa = 3. Pelvic lymphadenectomy was performed in 8 cases. Overall surgery time ranged from 56 to 230 minutes (median, 112.5). Blood loss ranged from 50 to 250 ml (median, 100). No patient

needed a blood transfusion. All patients were discharged before 48 hours after the end of the surgery. Median follow-up in May 2009 was 73.5 months. All patients were followed up for at least 5 years. There was one recurrence four years after surgery in the lower third of the vagina of a patient with stage IIa disease who had previously undergone postoperative radiotherapy; this patient underwent rescue surgery with colpotomy. Overall survival up to May 2009 was 100%, and five-year disease-free survival was 94%. The analysis of surgical time and intraoperative complications revealed that median time for hysterectomy only was 87.5, and median time was 125 minutes in the group in which the conventional technique without a manipulator was used; in the group in which the Gomes da-Silveira manipulator was used, median time was 63 minutes; the difference between groups was significant (Mann Whitney,  $p=0.0002$ ). No intraoperative complications were found in the group of patients in which the manipulator was used, but there was one case of bladder injury, corrected using laparoscopy, in the group in which this instrument was not used. Despite this lesion, postoperative progression was uneventful; the patient was discharged home with a catheter in less than 48 hours and did not require another hospitalization.

None of the patients had fever, hematoma, infection, need to convert to laparotomy, need to be hospitalized again, or short- or long-term systemic complications. During follow-up, no clinical signs compatible with distant metastases were found.

## Discussion

Laparoscopic staging has been recommended and adopted in studies since 1992. In tumors limited to the uterine corpus (stage I), treatment results similar to those obtained with the use of standard procedures have been reported. Moreover, laparoscopy makes it possible to explore the peritoneal surface more carefully, which results in lower postoperative morbidity, earlier hospital discharge and no delay in the initiation of radiotherapy indicated as adjuvant treatment. The laparoscopic technique is similar to the technique used for laparotomy, and does not violate the oncologic principles of procedural safety [1,5].

Some positive aspects of our study were the facts that all patients were operated on by a surgeon specialized in gynecologic oncology and trained in laparoscopy, and that patients were followed up for at least 5 years after surgery.

Although the literature is rich in studies that demonstrate the benefits of laparoscopy over conventional laparotomy [3,7-8], few studies evaluated the benefits of exclusive laparoscopy in the

management of endometrial cancer [4,5,9] in patients followed up for at least five years [10]. The study conducted by Zullo et al. [10] followed up their patients for 19 to 84 months, whereas follow-up in our series ranged from 63 to 97 months.

In our study, mean surgery time was 123 minutes, which is acceptable according to usual standards; when the Gomes da-Silveira manipulator was used, a significant reduction in surgical time was found, as seen in Graph 1. Our surgery duration was similar to the time of 136 minutes reported by other authors [5], and significantly lower than the 236 minutes reported in previous studies [7].

A device to assist uterine manipulation during laparoscopy is often used, which shows that there does not seem to be a risk of tumor cell dissemination in peritoneal lavage when standard procedures are adopted [11].

The use of a manipulator seems to have made surgery safer and faster, which is supported by the results reported here. Because of that, we decided to use it in all cases treated in our study after its development.

Although mean BMI was 30.5 kg/m<sup>2</sup> in this study, there was no increase in perioperative morbidity. These results support the suggestions made by some authors that laparoscopy reduces surgical morbidity, with lower rates of wall infection and paralytic ileus in overweight and obese women [2,7]. Laparoscopy is usually associated with lower immediate postoperative morbidity rates, and studies suggest that overall and disease-free survival rates are comparable to those found when laparotomy is used [2,8,12].

In our study group, only one case of recurrence in a site other than the surgical site was found in a patient with stage IIa disease. No case of recurrence was found among patients with stage I disease, in agreement with findings in the literature, which describes low recurrence rates, similar to those found in cases of laparotomy [6,12].

## Conclusion

Finally, the laparoscopic management of endometrial cancer resulted in the achievement of surgical aims, low perioperative morbidity, prompt return to activities of daily living, and no delay in the initiation of adjuvant therapy when indicated. Our results confirm data in the literature that indicate that, following the principles of oncologic safety and in the hands of experienced surgeons,

laparoscopy is safe, feasible and effective in the treatment of stage I endometrial cancer.

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