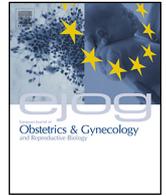




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Full length article

## Technological innovation and personalized surgical treatment for early-stage endometrial cancer patients: A prospective multicenter Italian experience to evaluate the novel percutaneous approach



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### ABSTRACT

**Objective:** To investigate the safety, feasibility and oncological adequacy of the Percutaneous Surgical System - PSS in a consecutive series of low-risk endometrial cancer staging.

**Study Design:** From May 2015 to April 2017, we prospectively performed 30 consecutive percutaneous staging for low/intermediate risk endometrial cancer (FIGO stage IA G1–G2, IB G1–G2, IA G3). All patients were divided in two different groups on the basis of surgical procedure received: Group A included patients submitted to radical Class A hysterectomy and bilateral salpingo-oophorectomy; Group B concerned patients that received a lymph nodal assessment also.

**Results:** The time needed to install percutaneous instruments and suprapubic trocar was 4 min. (range 2–10). The recorded median operative time (OT) was 80 min. (range 65–120) for Gr.A and 143 min. (range 107–190) for Gr.B, in which the median time of lymph nodal assessment was 55 min. (range 20–76). The median time for hysterectomy was 60 min. (range 40–110) in all cases. Lymph nodal assessment was performed in 14 (46.6%) cases: 7 sentinel node mapping, 7 pelvic lymphadenectomy. No intraoperative complications or LPS/LPT conversions were recorded. Median discharge time was 2 days (range 1–4), 5 patients were discharged in 3rd post-op day, and only 1 patient was discharged in 4th day for fever. All patients conveyed high satisfaction with the cosmetic results. A progressive overall reduction of pain perception was observed at 24 h after surgery. Median follow-up was of 14 months (range 12–36), no recurrences have been detected.

**Conclusions:** PSS seems to be a feasible approach for endometrial cancer staging. Larger experiences and prospective comparative studies are important to assess our assumptions and further investigate the real benefits of percutaneous surgical system.

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### Introduction

Multiple studies have shown that minimally invasive endometrial cancer staging reduces blood loss, length of hospital stay, and the incidence and severity of post-operative surgical complications compared with the laparotomic one [1,2]. Subsequently, the gold

standard surgical treatment for endometrial cancer staging rapidly moved from laparotomy to laparoscopy [3] shifting the concept of minimally invasive surgery in the greater dimension of personalized surgical approaches.

Beside the wide diffusion of laparoscopic surgery, ultra-minimally invasive approaches have been proved to further minimize the surgical impact while maintaining safety and efficacy. If on one hand the reduction in number of trocar represented an innovative solution for cosmetic outcome, at the expense of the ergonomics, on the other hand a reduction in trocar size demonstrated the importance of a maintained operative triangulation in operative setting.

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Nowadays, surgical features of both approaches, Single-Port and Minilaparoscopy respectively, are well described in benign and early malignant gynecological diseases [4,5].

In this context, thanks to continuous technological evolution and technique standardization, a new tool was added to ultra-minimally invasive portfolio. Percutaneous instruments (Percuvance™, Percutaneous Surgical System - PSS, TELEFLEX Ltd) represent a new concept of mini-invasive instrumentation that provides a further reduction in size, maintaining the typical surgical efficacy of a 5 mm standard laparoscopic instrument: on a 2.9 mm strength shaft a 5 mm operative tip is installed (Fig. 1).

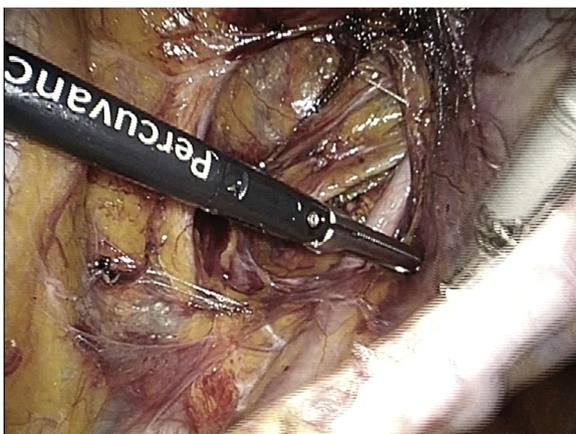
A recently described series of total laparoscopic hysterectomy with bilateral adnexectomy, performed using the PSS, showed such approach to be safe and feasible in terms of median operative time, cosmetic outcomes, postoperative pain, recovery, and length of hospitalization. As reported, to overcome the lack of bipolar energy, surgeons provided a hybrid technique utilizing a multi-functional instrument in a 5 mm suprapubic trocar [6,7].

On this preface, the aim of this pilot study was to evaluate the safety, feasibility, and oncological adequacy of the percutaneous approach in a consecutive series of low-risk endometrial cancer staging.

## Material and methods

In this multicenter prospective study we present collected data from a series of consecutive percutaneous staging of early-stage endometrial cancer patients. From May 2015 to April 2017, 176 endometrial cancer patients were considered eligible for minimally invasive surgical staging either robotic or laparoscopic. 96 patients (54.4%) met inclusion criteria and were enrolled in the study. Among them, 66 patients received standard laparoscopic approach due to the limited availability of involved surgeons and experimental instrumentation. Finally, 30 patients (31.2%) with preoperative suspicion of low/intermediate risk endometrial cancer (FIGO stage IA G1-G2, IB G1-G2, IA G3) received the planned treatment of percutaneous surgical staging.

13 patients were enrolled by the Coordinator center was the Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, Fondazione Policlinico Universitario A. Gemelli IRCCS. Other participating centers were Pineta Grande Hospital, Castel Volturno, Italy (6 patients enrolled); Department of Medicine and Aging Sciences, University "G. D'Annunzio" of Chieti-Pescara, Chieti, Italy (4 patients enrolled); Division of Gynecology, San Carlo di Nancy Hospital, Rome, Italy (7 patients enrolled).



**Fig. 1.** 5 mm operative tip installed on percutaneous instrument during the left pararectal space development.

An experience of 5 percutaneous and 100 laparoscopic hysterectomies were considered as minimum amount to be involved in the study. On these criteria, 4 surgeons were selected among the four Centers. Exclusion criteria were BMI > 40, ASA Score > III, preoperative suspicious of cervical or lymph nodal involvement. No specific exclusion criteria were identified in terms of uterine size and previous major abdominal surgery with respect to that commonly applied for standard laparoscopic approach. IRB approval was obtained and all the patients signed informed consent. The preoperative workup included: bi-manual pelvic examination; endometrial biopsy; transvaginal ultrasound; and magnetic resonance imaging or computed tomography scan.

Perioperative data and pathological features were prospectively collected in an electronic database. All enrolled patients were divided in two different groups on the basis of surgical procedure received: Group A included patients submitted to radical Class A hysterectomy [8] and bilateral salpingo-oophorectomy; Group B concerned patients that received a lymph nodal assessment also. For both Groups total operative time (OT, calculated skin to skin) was recorded. In addition to this, procedure-specific times were separately recorded (instruments placement, hysterectomy and vaginal cuff closure). For Group B, time for lymph nodal assessment was also collected. Intra-operative complications were defined as blood loss (EBL > 500 ml), bladder, and ureteral, vascular and bowel injuries.

For each patient, post-operative pain was evaluated using Visual Analog Pain Scale (VAS) 24 h after the surgical procedure. Patients were discharged fully mobile, without bladder catheter and without fever. Postoperative complications, within 30 days after surgery, were defined as fever (>38 °C, excluding the first day after surgery), vaginal dehiscence, bowel occlusion, post-operative infection, and secondary surgical procedure.

## Surgical technique

While under general anesthesia, the patient was positioned in the dorsal lithotomy position, with both legs supported in Allen stirrups with a Trendelenburg tilt, and arms along the body. In the same way as in standard laparoscopy, the surgeon stands on the left of the patient, the first assistant on the right side and the second assistant is seated between the legs to manipulate the uterus. A 5-mm Hasson balloon trocar was inserted at the umbilicus for the telescope. Once pneumoperitoneum (12 mmHg) was achieved, intra-abdominal visualization was obtained with a 0° 5 mm HD telescope (ENDOYEYE, Olympus Winter & Ibe, Hamburg, Germany). One additional standard 5-mm port was placed in suprapubic position under direct visualization. Two PSS instruments were used as side graspers for both surgeon and first assistant. The Percuvance™ shaft was percutaneously inserted by using the introducer tip. After that, the percutaneous instrument was pulled out through the 5 mm suprapubic port, and an interchangeable 5 mm tip was placed instead of the introducer. An atraumatic grasper (grripper grasper tip) and an alligator tip were installed on both Percuvance. A 5 mm port was used for suction/irrigation, monopolar hook, 5 mm endoclip, and multi-functional instrument (Thunderbeat, Olympus Winter & IBE GMBH, Hamburg, Germany). After bilateral cauterization of the fallopian tubes, in some cases intrauterine manipulator (Clermont Ferrand uterine manipulator, Karl Storz, Tuttlingen, Germany) was positioned.

After coagulation and section of round ligaments, we approached the retroperitoneal space, where the ureters were visualized, and a hemostatic clip was positioned at the origin of the uterine artery bilaterally. To be safely, we dissected and cauterized the ovarian vessels by using a window opened between the left ovarian pedicle above and below the ureter. The vesico-uterine and

**Table 1**  
Patients Baseline Characteristics.

Patients Baseline Characteristics	
Number of patients	30
AGE (year), median (range)	59 (45–80)
BMI, median (range)	27 (22–37.9)
Menopause, n (%)	23 (76.6)
Nulliparous, n (%)	10 (33.3)
Previous Cesarean Section, n (%)	6 (20)
Previous Abdominal Surgery, n (%)	14 (46.6)
Indication for surgery, n (%)	4 (13.3%)
• Endometrial Hyperplasia	26
• Early Stage Endometrial Cancer	(86.6%)

vesico-vaginal peritoneum were dissected until the pubo-cervical fascia (Halban's fascia), starting from lateral to medial. These surgical steps allow an excellent skeletonization of the uterine vessels, which can be easily recognized, cauterized, and sectioned close to the uterus walls. The vagina was incised circumferentially with monopolar hook, following the porcelain-valve of the uterine manipulator as a guide. Uterus and adnexa were extracted through the vagina. The vaginal vault was closed with a running suture by laparoscopic or vaginal approach with 0 Vicryl. A frozen section analysis was performed for all patients.

After this, we decided whether to perform or not the lymph-nodal assessment, according to NCCN Guidelines. As the same way as in standard laparoscopy, we extracted lymph nodes introducing an endobag (Memobag by Teleflex) through the transumbilical trocar: the camera is removed, the endobag is pushed into the peritoneal cavity and, after the reintroduction of the camera the lymph node is placed inside the endobag and removed. We excluded from our series the cases with positive pelvic lymph nodes at frozen section, which required aortic lymphadenectomy: in these cases, the procedure was converted to standard laparoscopy to maintain a good control of retroperitoneal aortic anatomy by using bipolar grasper, multifunctional instrument and 5 mm suction/irrigation system.

Video 1 briefly shows the main steps of the explained surgical procedures.

## Results

Our study included 30 early stage endometrial cancer patients who underwent surgical staging between May 2015 and April 2017.

**Table 2**  
Perioperative outcomes divided in two different Groups. Group A: Hysterectomy with bilateral salpingo-oophorectomy. Group B: Hysterectomy with bilateral salpingo-oophorectomy and lymph nodal assessment.

Perioperative outcomes	Group A	Group B	Total
Number of cases	16	14	30
Operative Time (min), median (range)	80 (65–120)	143 (107–190)	110 (65–190)
Instruments placement time (min), median (range)	–	–	4 (2–10)
RH time (min), median (range)	56 (40–90)	75 (45–110)	60 (40–110)
Lymph nodal assessment time(min), median (range)	–	55 (20–76)	–
Manipulator, n (%)	10 (62.5)	13 (92.8)	24 (80)
EBL (ml), median (range)	50 (10–200)	50 (50–200)	50 (10–200)
Uterus weight (gr) median (range)	146 (60–350)	130 (76–230)	145 (60–350)
Vaginal cuff closure time (min), median (range)	10 (5–15)	10 (7–15)	10 (5–15)
Drainage positioning, n (%)	3 (18.75)	8 (57.14)	11 (36.6)
Conversion to Laparoscopy, n (%)	0 (0)	0 (0)	0 (0)
Conversion to Laparotomy, n (%)	0 (0)	0 (0)	0 (0)
Intraoperative complications, n (%)	0 (0)	0 (0)	0 (0)
Ileus (h), median (range)	12 (8–24)	24 (12–24)	12 (8–24)
30-days complications	1 (6.25)	0 (0)	1 (3.3)
Discharge time (days), median (range)	2 (1–4)	2 (2–3)	2 (1–4)

In order to stratify the perioperative outcomes, we divided all patients in two Groups, in accordance with the surgical procedures received: Group A included patients who received radical hysterectomy (Class A sec Querleu-Morrow) and bilateral salpingo-oophorectomy only; Group B included patients who also underwent to a lymph nodal assessment.

Patients' baseline characteristics are shown in Table 1. The median age was 59 (range 45–80), and 23 (76.6%) patients were in menopause. The median BMI was 27 kg/m<sup>2</sup> (22–37.9). Fourteen (14) patients (46.6%) had undergone previous abdominal surgeries. Preoperative indication for surgery was a hysteroscopic diagnosis of endometrial cancer in 26 (86.6%) patients, and atypical hyperplasia in 4 (13.3%) ones. The definitive pathology report revealed endometrial cancer for all cases. Perioperative outcomes are shown in Table 2. The time needed to install percutaneous instruments and suprapubic trocar was 4 min. (range 2–10). PSS placement was successfully executed in all cases without any complication. The recorded median operative time (OT) was 80 min. (range 65–120) for Group A and 143 min. (range 107–190) for Group B, in which the median time of lymph nodal assessment was 55 min. (range 20–76). Furthermore, the median time for hysterectomy was 60 min. (range 40–110) in all cases. Lymph nodal assessment was performed in 14 (46.6%) cases. In particular, 7 patients underwent to sentinel node mapping, 7 patients received pelvic lymphadenectomy: among them, the median number of retrieved lymphnodes was 16 (13–45). No intraoperative complications or LPS/LPT conversions were recorded. The vaginal cuff was closed by laparoscopy or by the vaginal route in 20 (66.6%) and 10 (33.3%) cases respectively. The median uterus weight was 145 g (range 60–350). With an overall median discharge time of 2 days (range 1–4), 24 patients (80%) were discharged within the 2nd postoperative day, 5 patients were discharged in 3rd post-op day, and only 1 patient was discharged in 4th post-op day for fever. More in depth, the prolonged hospitalization (range 2–3 days) was recorded in Group B due to a prudential waiting for adequate postoperative observation after advanced laparoscopic procedures in an experimental setting.

Table 3 reports the VAS score results and cosmetic outcome. All patients conveyed high satisfaction with the cosmetic results. Starting from a very low median recorded value of 2 for each measurement at 2, 4, 12 and 24h after surgery, a progressive overall reduction of pain perception was observed at 24h after surgery (range 0–4).

With a median follow-up of 14 months (range 12–36) no recurrences have been detected.

**Table 3**

Post operative pain evaluation and cosmetic outcome.

VAS score and Cosmetic outcome	Total
VAS 2h	2 (0–5)
VAS 4h	2 (0–6)
VAS 12h	2 (0–6)
VAS 24h	2 (0–4)
30-day cosmetic result (Patient's opinion)	10 (8–10)

## Discussion

It has been thoroughly demonstrated that minimally invasive surgery is adequate and effective in terms of surgical outcomes in the staging of endometrial cancer (ref. [9–13]). Furthermore, many reports in literature assessed the role of ultra minimally invasive approaches like mini-laparoscopy and single port in this subset of patients [14–17]. Despite this, in a recent survey of members of the Society of Gynecology Oncology, Conrad et al. revealed that while the indications for laparoscopy have expanded beyond endometrial cancer staging, the use of ultra-MIS, like single port, have been further reduced [18]. On this preface, considering laparoscopic surgical setting as the most advantageous approach, we investigated whether the percutaneous surgical system could be an alternative tool for surgical staging of endometrial cancer.

In this scenario, percutaneous technology is an emerging solution in gynecological surgery. In a recently published paper, we demonstrated that percutaneous approach could improve surgical and cosmetic outcomes in hysterectomy patients, when compared with other ultraminimally invasive solutions [19].

To the best of our knowledge, this is the only series that introduces these instruments in gynecological oncological field. The instrument triangulation and the presence of 5-mm operative tip on the percutaneous shaft keep the main principles of laparoscopy. With this concern, our proposed operative solution - 2 Percutance on both sides of the pelvis and one 5 mm suprapubic trocar - is a hybrid technique: while the use of a 5 mm instrument is mandatory to overcome the lack of bipolar energy, a multifunctional instrument inserted through the trocar represents instead an added value in performing advanced laparoscopic procedures, such as lymph nodal assessment, and in improving efficacy of surgical maneuvers. The possibility to maintain our standardized surgical technique without increasing surgical complexity, represents an important issue with good promises in terms of safety and oncological adequacy. Recorded operative outcomes and complication rate of our results reinforce these assumptions even if the small sample size doesn't allow driving definitive conclusions. More in depth, operative times were superimposable to those reported in previously published experiences [4,7,19].

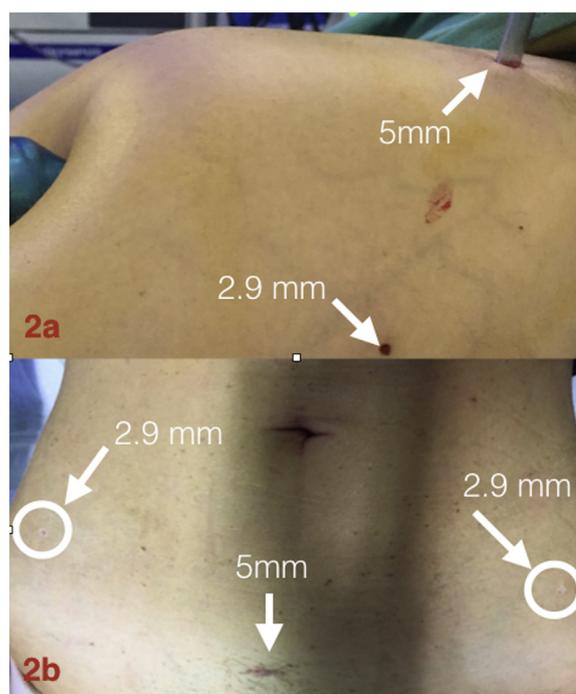
Patients' baseline characteristics show that no specific case selection was made in terms of previous abdominal surgery and BMI. Moreover, the recorded time of 4 min. to install percutaneous instruments and suprapubic trocar represents another important element to take in consideration. All these aspects let assume the potential reproducibility of the proposed technique.

Among 14 patients who underwent to lymph nodal assessment, 7 patients received sentinel node mapping, in place of pelvic lymphadenectomy: the difference in treatment was due to the evolution in technology and concept of endometrial cancer staging. In order to simplify the data interpretation, we preferred to consider the lymph nodal assessment time as a unique operative time rather than dividing Group B in two different sub-groups. Although this aspect could be considered as a bias, it does not influence the main substance of our results. Differently, it further testifies the good surgical confidence that can be achieved with

percutaneous instruments in different surgical procedures. With this regard, surgeons notified a minimal reduction of sensitivity at the tip of the percutaneous instruments: this characteristic could be ascribed to the absence of a trocar. Indeed, whereas the trocar represents a constantly open path, an instrument directly introduced through the abdominal wall receives on its shaft the friction of direct contact with skin, fascia, and muscles. By the interposition of this factor between the surgeon's hand and the instrument's tip derives a reduction in feeling of managing tissues. However, despite this factor does not increase the fatigue for the surgeon, we can assume that this characteristic could be considered a limiting factor in manipulating soft and fragile lymphatic tissues that require a prolonged learning curve for safety issue. On the other hand, none increase of the percutaneous instruments incisions' outer diameter after the surgical procedure (Fig. 2a) has been recorded. This aspect has an important value that overcomes the clinical aspect of the postoperative pain, as reported in Table 3. In fact, considering 30 days cosmetic outcomes (Fig. 2b) as a "scarless" outcome, it is demonstrated that reduction of surgical scars in oncological patients significantly improves their body image and subsequently quality of life [20].

Despite the median follow-up of 14 months is not enough to drive definitive conclusions regarding the oncological aspect, on the basis of the presented data we can speculate that PSS allows the surgeon to maintain oncological adequacy in performing staging surgical procedures. Moreover, we can also hypothesize that by using 2.9 mm instruments, the reduced in size parietal defect with respect a standard 5/10 mm one facilitates the approximation of the parietal surfaces. Thus, with the oncological concern we could probably assume that a reduced peritoneal incision after PSS removal could theoretically reduce the risk of port-site metastases [21].

In conclusion, PSS seems to be a feasible approach for endometrial cancer staging. On the basis of our results, it is worth to be further improved with technological advancement, in order to provide a full-percutaneous surgical treatment. Due to the small sample size, the present study can be considered as result from a



**Fig. 2.** a: post-operative 2.9 percutaneous incision outer diameter b: 30-days 2.9 percutaneous cosmetic outcome.

discovery cohort to investigate safety, feasibility and oncological adequacy of percutaneous approach in an oncological setting. Larger experiences and a prospective comparison with standard technique are important future steps to assess our assumptions and definitively confirm the real benefits of percutaneous surgical system.

### Conflict of interest statement

The authors declare that there are no conflicts of interest.

### Authors contribution section

Conception and design of the study: Gueli Alletti S, Rossitto C, Scambia G. Patients recruitment: Gueli Alletti S, Rossitto C, Fanfani F, Vascone C, Cianci S. Operations: Gueli Alletti S, Rossitto C, Fanfani F, Fagotti A, Vascone C. Data Collection: Perrone E, Monterossi G, Gallotta V. Data Analysis: Vizzielli G, Uccella S. Manuscript Preparation: Gueli Alletti S, Perrone E, Scambia G.

### Funding informations

Nothing to disclose.

### Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.ejogrb.2019.01.024>.

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