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CLINICAL ARTICLE

Conservative hysteroscopic treatment of endometrial intraepithelial neoplasia and endometrial cancer in patients with high surgical risk with mechanical hysteroscopic tissue removal systems: A retrospective cohort study

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Abstract

Objective: To compare surgical and oncologic outcomes between conventional resectoscopic surgery and mechanical hysteroscopic tissue removal (mHTR) systems in high-risk patients not suitable for standard surgery undergoing conservative treatment for multifocal endometrial atypical hyperplasia/endometrial intraepithelial neoplasia (EAH/EIN) or early-stage low-grade endometrioid endometrial cancer (EEC).

Methods: We conducted a single-center, retrospective cohort study at the Department of Gynecology and Physiopathology of Human Reproduction, S. Orsola-Malpighi Hospital, University of Bologna, Italy. A total of 31 high-surgical-risk patients with EAH/EIN or early-stage low-grade EEC were included: 18 underwent conventional resectoscopic endo-myometrial resection, while 13 were treated with mHTR systems. All patients received a levonorgestrel-releasing intrauterine device (LNG-IUD) postoperatively. After treatment, patients underwent an 18-month follow up with endometrial biopsies every 6 months.

Results: The mHTR group had significantly shorter operative times (mean 12.3 ± 7.7 min) compared with the resectoscopic surgery group (mean 40.6 ± 11.8 min, $P < 0.001$). Additionally, the incidence of intrauterine adhesions was lower in the mHTR group ($P < 0.001$). There were no significant differences between the two groups in terms of disease presence at 6, 12, or 18 months.

Conclusions: Hysteroscopic endo-myometrial resection, with resectoscopic technique or with mHTR systems, combined with LNG-IUD may represent a safe alternative for patients at high surgical risk with EAH/EIN or early-stage low-grade EEC. Moreover, mHTR demonstrated advantages such as shorter operative times and fewer adhesions. A large multicenter prospective study is needed to confirm our study findings.

KEYWORDS
conservative treatment, endometrial cancer, hysteroscopy, resectoscope, tissue removal devices

1 | INTRODUCTION

Endometrial cancer is the most prevalent malignancy of the female genital tract in high-income countries and with its incidence rising due to increasing obesity rates and other risk factors.[1] Most cases are detected at an early stage and the surgical treatment includes total abdominal hysterectomy with bilateral salpingo-oophorectomy, and lymph-node assessment.[2] However, age-related comorbidities and elevated body mass index (BMI; calculated as weight in kilograms divided by the square of height in meters) increase the surgical risks, complicating treatment. For inoperable women with conditions such as endometrial atypical hyperplasia/endometrial intraepithelial neoplasia (EAH/EIN) or early-stage low-grade endometrioid endometrial cancer (EEC) treatment options remain non-standardized because of the absence of clear international guidelines.

Several therapeutic strategies have been explored, including radiation therapy and progestin-based treatments.[3–5] More recently, progestin-releasing intrauterine devices (IUDs) have shown promising results for early-stage EEC, particularly in fertility-preserving cases.[6–8] Furthermore, hysteroscopic resectoscopic removal of endometrial lesions, combined with a levonorgestrel-releasing intrauterine device (LNG-IUD), has been associated with a lower relapse rate than using the LNG-IUD alone.[9]

Mechanical hysteroscopic tissue removal (mHTR) systems have emerged as a safe, minimally invasive option for treating intrauterine conditions, providing high-quality tissue samples without thermal artifacts, and demonstrating a short learning curve for operators.[10–13] Early studies in oncologic settings suggest that mHTR systems, combined with progestin therapy, could offer promising results because of their ability to remove lesions from difficult areas.[14] This study aims to compare the surgical and oncologic outcomes of conventional resectoscopic surgery and mHTR systems for endomyometrial resection in high-risk patients undergoing conservative treatment for EAH/EIN or early-stage EEC. We hypothesize that mHTR could represent a safe and effective alternative to a resectoscopic procedure.

2 | MATERIALS AND METHODS

2.1 | Selection criteria

The present study, approved by protocol no. 301/2020/Sper/AOUBo, was designed as a single-center, observational, retrospective cohort study conducted at the Department of Gynecology and Physiopathology of Human Reproduction, S. Orsola—Malpighi Hospital, University of Bologna, Italy. It adheres to the STROBE guidelines. Medical records were reviewed to identify patients who underwent hysteroscopic surgery followed by LNG-IUD placement between January 1, 2018, and March 31, 2023, for EAH/EIN and/or early-stage low grade EEC. Patients treated between 2018 and 2020 were retrospectively enrolled, while from 2020 onward, data were prospectively collected, using consistent procedures for data collection and assessment throughout the entire study period. The study was approved by the Institutional Review Board of the IRCSS Azienda Ospedaliero-Universitaria di Bologna (approval number 301/2020/Sper/AOUBo).

2.2 | Inclusion criteria

Women were included in the study if they had a histologic diagnosis of EAH/EIN or early-stage low-grade EEC; hysteroscopic findings indicative of multifocal endometrial involvement; a multidisciplinary assessment of high surgical risk; hysteroscopic follow up of 18 months; no evidence of metastasis or deep myometrial infiltration; and an absence of contraindications to IUD placement.

All patients provided informed consent for the anonymous use of their data for research purposes.

2.3 | Exclusion criteria

Patients lost during follow up or whose medical reports were unavailable were excluded from the study.

2.4 | Outcomes of the study

The primary outcome of the study was the difference in oncologic outcomes between the two groups, assessed by disease presence at 6, 12, and 18 months.

Secondary outcomes were the comparison between hysteroscopic resection and mHTR systems in terms of mean total operative time, intraoperative complications, and presence of intrauterine synechiae at hysteroscopic follow up.

2.5 | Preoperative evaluation

In our routine clinical practice, all patients diagnosed with EAH/EIN or early-stage low-grade EEC via endometrial sampling underwent a clinical and radiologic evaluation, including medical history collection, bimanual examination, and transvaginal ultrasound with color Doppler, following international guidelines.[15] Tumor size, myometrial invasion, and potential disease spread to adnexal or cervical

areas were assessed. Myometrial invasion was evaluated sonographically using the Karlsson index.[16,17] For patients with a histologic diagnosis of early-stage low-grade EEC, computed tomography was performed to confirm the absence of pelvic, para-aortic, or distant metastases.

Patients underwent multidisciplinary evaluation to determine the most appropriate therapeutic options and surgical risk was assessed using Shoemaker's method (adapted by Boyd) and the American Society of Anesthesiologists physical status classification.[18,19] A detailed overview of the clinical conditions that supported the high surgical risk assessment is presented in Table 1.

For high-surgical risk patients with EAH/EIN or early-stage low-grade EEC the proposed diagnostic-therapeutic approach included endo-myometrial resection combined with the placement of an LNG-IUD (Mirena®; Bayer Healthcare Pharmaceuticals, Pittsburgh, PA, USA).

Hysteroscopic endo-myometrial resection was performed using either resectoscopic hysteroscopy or mHTR systems, introduced at our tertiary center in 2022 for conservative treatment using a combined technique with miniresectoscope.

According to the definitions provided by Carugno et al.,[20] resectoscopic hysteroscopy was conducted in an operating room environment, whereas mHTR resection was carried out in an outpatient clinic setting. Both surgical interventions were administered under an outpatient care model, enabling patients to be discharged on the same day as the procedure.[20] Following the introduction of mHTR systems, almost all patients were treated using this method to facilitate outpatient clinic procedures. However, the choice of technique was ultimately determined by the surgeon's preference.

2.6 | Types of endo-myometrial resection

Resectoscopic surgery for endo-myometrial resection was carried out in the operating room under spinal anesthesia; a 10-mm cervical dilatation was achieved using Hegar dilators, followed by the introduction of a 26-Fr resectoscope (Karl Storz) with a 0° lens. The uterus was distended with Mannitol 0.54%-Sorbitol 2.7% 3000 mL (Baxter Healthcare Corporation, Rome, Italy). Intrauterine pressure was automatically controlled (80–100 mm Hg) by an electronic irrigation and suction device (Hamou Endomat Irrigation Suction Pump; Karl Storz). The entire endometrium (uterine walls, tubal ostia, and uterine fundus) and the first 5 mm of the underlying myometrium were cautiously resected with a 5-mm cutting loop electrode and 100 W of pure cutting output power by minimally invasive techniques.

For endo-myometrial resection with an mHTR system, we used the TruClear™ Elite Mini hysteroscope (6.15 mm). Patients received paracervical anesthesia with ropivacaine 7.5% in an outpatient clinic setting.[20] The uterus was distended with saline solution. As a result of the smaller diameter of the mHTR systems, cervical dilation was usually not required. A 15-Fr Miniresectoscope (Karl Storz) with a 0° lens was initially used to remove the main lesion and the first 5 mm of the underlying myometrium. Following this, the mHTR system was introduced into the uterine cavity to complete the resection of the pathologic endometrium. The mHTR systems adopt automated fluid management systems that measure the distending media input and output, the intrauterine pressure, and the fluid deficit volume.

During the hospital stay, before discharge to home, an LNG-IUD was inserted and we controlled the correct insertion by ultrasound evaluation using a Voluson E8 system (GE Healthcare, Little Chalfont, UK).

TABLE 1 Main comorbidities considered by the multidisciplinary team in determining high surgical risk status.[a]

Characteristics	Total patients ($n = 31$)	RES group ($n = 18$)	mHTR group ($n = 13$)
Age at diagnosis >70 years	12 (38.7%)	9 (50%)	3 (23.1%)
BMI >40	19 (61.3%)	10 (55.6%)	9 (69.2%)
Hypertension	18 (58.1%)	12 (66.7%)	6 (46.2%)
Previous myocardial infarction	6 (19.4%)	4 (22.2%)	2 (15.4%)
Previous pulmonary embolism	2 (6.5%)	1 (5.6%)	1 (7.7%)
Previous stroke	3 (9.7%)	2 (11.1%)	1 (7.7%)
Respiratory failure/COPD	5 (16.1%)	5 (27.8%)	/
Diabetes	11 (35.5%)	7 (38.9%)	4 (30.8%)
Active venous thrombosis	3 (9.7%)	2 (11.1%)	1 (7.7%)
OSAS	4 (12.9%)	2 (11.1%)	2 (15.4%)
Chronic renal failure	1 (3.2%)	/	1 (7.7%)
Two risk factors	10 (32.3%)	6 (33.3%)	4 (30.8%)
Three or more risk factors	15 (48.4%)	10 (55.6%)	5 (38.5%)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); COPD, chronic obstructive pulmonary disease; mHTR, mechanical hysteroscopic tissue removal; OSAS, obstructive sleep apnea syndrome; RES, resection.

[a]Data are presented as number (percentage).

TABLE 2 Demographics table.[a]

Characteristics	Total patients ($n=31$)	RES group ($n=18$)	mHTR group ($n=13$)	P value
Age at diagnosis, y	64.4 ± 13.5	66.5 ± 14.1	61.5 ± 12.5	0.320
Menopausal status	24 (77.4%)	14 (77.8%)	10 (76.9%)	0.957
Hormone replacement therapy use	0 (–)	0 (–)	0 (–)	
Tamoxifen use	0 (–)	0 (–)	0 (–)	
BMI	40.2 ± 10.8	37.8 ± 10.4	43.5 ± 11.1	0.150
Parity ≥1	22 (70.9%)	15 (83.3%)	7 (53.8%)	0.074
Previous dilation and curettage	3 (9.6%)	2 (11.1%)	1 (7.6%)	0.760
EAH/EIN	17 (54.8%)	9 (50.0%)	8 (61.5%)	0.540
EEC G1	14 (45.1%)	9 (50.0%)	5 (38.5%)	0.540
Myometrial infiltration ≤3 mm	2 (6.5%)	1 (5.5%)	1 (7.7%)	0.819

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); EAH/EIN, endometrial atypical hyperplasia/endometrial intraepithelial neoplasia; EEC G1, endometrioid endometrial cancer Grade 1; mHTR, mechanical hysteroscopic tissue removal; OSAS, obstructive sleep apnea syndrome; RES, resection.

[a]Data are presented as mean ± standard deviation or number (percentage).

TABLE 3 European Society of Hysteroscopy intrauterine adhesions classification (1989).

Grade	Extent of intrauterine adhesions
I	Thin or filmy adhesions easily ruptured by hysteroscope sheath alone. Cornual areas normal.
II	Singular filmy adhesions connecting separate parts of the uterine cavity. Visualization of both tubal ostea possible. Cannot be ruptured by hysteroscope sheath.
IIa	Occluding adhesions only in the region of the internal cervical os. Upper uterine cavity normal.
III	Multiple firm adhesions connecting separate parts of the uterine cavity. Unilateral obliteration of ostial areas of the tubes.
IIIa	Extensive scarring of the uterine cavity wall with amenorrhea or hypomenorrhea.
IIIb	Combination of Grades III and IIIa.
IV	Extensive firm adhesions with agglutination of uterine walls. Both tubal ostial areas occluded.

2.7 | Follow up

Follow-up hysteroscopy with endometrial sampling was scheduled every 6 months for the first 18 months. All samples obtained from resection and biopsies were sent to the same expert pathologist, who had access to every patient's complete histologic records.

For each patient, demographic, anthropometric, clinical, histopathologic, and operative data—including total operative time—were collected. Age, menopausal status, use of hormone replacement therapy and/or tamoxifen, parity, BMI, and history of dilation and curettage were recorded (Table 2). Postoperative outcomes, such as the evaluation of intrauterine synechiae using the European Society of Hysteroscopy intrauterine adhesion classification[21] (Table 3) and the presence of disease at 6, 12, and 18 months, were systematically assessed during office follow-up hysteroscopies.

The presence of disease was defined as a persistently positive biopsy at 6, 12, or 18 months, with no disease-free interval during office hysteroscopic follow ups.

2.8 | Statistical analysis

Continuous data were expressed as mean ± standard deviation or median (interquartile range), as appropriate. Categorical variables were expressed as numbers and percentages. Student t test or Mann–Whitney U test and χ^2 or Fisher exact test were used for continuous and categorical data, respectively, as appropriate. A P value less than 0.05 was considered significant for all tests. Statistical analysis was carried out using the SPSS software version 29.0.2.0 (IBM Corp., Armonk, NY, USA).

3 | RESULTS

Between January 2018 and March 2023, 75 women were diagnosed with EAH/EIN or early-stage EEC without evidence of deep infiltration or metastatic disease and were considered inoperable based on multidisciplinary evaluation. We excluded 29 patients with focal disease and 15 patients who were lost to follow up.

Based on the selection criteria, 31 patients were included in the study: 18 (58%) patients in the resection group (RES group) and 13 (42%) in the mHTR group.

Baseline characteristics of the two groups are presented in Table 2. No significant difference between the two groups was found in terms of previous pregnancies and tamoxifen therapy. The average age at diagnosis was 66.5 ± 14.1 years for the RES group and 61.5 ± 12.5 years for the mHTR group ($P = 0.320$), with 14 (78%) patients from the RES group and 10 (77%) from the mHTR group already postmenopausal. None had undergone previous hormonal replacement therapy, and the mean BMI was 37.8 ± 10.4 for the RES group and 43.5 ± 11.1 for the mHTR group ($P = 0.150$).

The RES group included nine women diagnosed with EAH/EIN and nine women diagnosed with early-stage low-grade EEC. In the mHTR group, eight women had a diagnosis of EAH/EIN, while five were diagnosed with early-stage low-grade EEC. All diagnoses were confirmed through histologic analysis after resection. Among the early-stage EEC cases, two patients—one from each group—exhibited minimal myometrial invasion (<3 mm) upon definitive histologic evaluation, which was considered clinically insignificant.

All patients in the RES group underwent hysteroscopic surgery in the operating room under spinal anesthesia, whereas all patients in the mHTR group received local anesthesia.

The mean operative time was 40.6 ± 11.8 min for the RES group, whereas it was 12.3 ± 7.7 min for the mHTR group, showing a statistically significant difference ($P < 0.001$). No intraoperative complications or LNG-IUS displacements at the sonographic control before discharge were reported in the two groups.

Intrauterine adhesion grades were assessed during follow-up hysteroscopies using the European Society of Hysteroscopy classification. The RES group had a median score of 4.5 (interquartile range 4), indicating intermediate adhesions between grades III and IV. In contrast, the mHTR group had a median score of 0 (interquartile range 0), reflecting the substantial absence of adhesions. This difference was statistically significant, with the mHTR group showing fewer adhesions ($P < 0.001$).

All 31 patients completed a follow-up period of 18 months, during which no adverse effects related to local hormonal therapy were observed, and none experienced abnormal uterine bleeding.

Comparative analysis of the two groups revealed no statistically significant differences in disease presence at 6 months ($P = 0.81$), at 12 months ($P = 0.81$), and at 18 months ($P = 0.38$) (odds ratio 1.417, 95% confidence interval 0.08–24.95).

In the RES group, one patient showed persistent presence of disease at 6, 12, and 18 months. During follow up, she experienced pulmonary embolism and acute pulmonary edema, requiring aortic valve prosthesis implantation. Considering her comorbidities, an endometrial resection was repeated, and the LNG-IUD was replaced. She did not undergo radiotherapy, remained asymptomatic throughout the follow-up period, and subsequent sampling results were negative.

In the mHTR group, one patient exhibited the presence of early-stage endometrial cancer at 12 months. As a result of her severe multiple comorbidities, she underwent a second ablation with a following negative biopsy and then she continued clinical follow up, remaining asymptomatic.

4 | DISCUSSION

Hysteroscopic endo-myometrial resection, with resectoscopic technique or with mHTR systems, combined with LNG-IUD offers a safe alternative for patients at high surgical risk with EAH/EIN or early-stage low-grade EEC.

Both techniques demonstrated comparable oncologic outcomes with no significant differences in terms of disease presence during follow up. Moreover, mHTR systems showed several advantages, including shorter operative times and a lower incidence of intrauterine adhesions.

Endometrial carcinoma remains the most common gynecologic malignancy and approximately 10% of early-stage cases are inoperable because of factors such as advanced age, high BMI, and comorbidities.[22] For these patients, currently, there is no standardized treatment and progestin therapy could be considered in cases of small tumors, confined to the uterus, without myometrial invasion.

Conservative treatment for EAH/EIN and early-stage EEC is considered appropriate for patient groups who seek fertility-sparing options or for those with contraindications to standard treatment.

Available data for a fertility-sparing approach are more conclusive,[6,7,9] but evidence for this treatment in inoperable patients remains limited. The hysteroscopic tumor resection associated with progestin therapy has been found to achieve quicker complete responses and longer relapse-free intervals compared with progestin therapy alone.[9] A pilot study conducted at our center demonstrated that hysteroscopic endo-myometrial resection with LNG-IUD placement can represent an effective alternative for women with early-stage EEC who are either inoperable or unsuitable for standard treatments.[23]

The introduction of mHTR systems represents a notable advancement, offering precise and minimally invasive tissue removal.[10–13] Initial evidence regarding the application of mHTR systems for fertility-preserving approaches suggests that the combination of progestin therapy with hysteroscopic resection using mHTR systems may result in higher rates of complete response.[14] Moreover, Evans-Hoeker et al.[24] reported that mHTR systems can effectively penetrate the underlying myometrium during polypectomy: this evidence suggests that mHTR systems may be a safe option, potentially minimizing the risk of disease downstaging.

Nonetheless, a current limitation is the lack of a standardized surgical technique for mHTR systems in the oncologic context, despite initial promising results with experimental techniques.[14]

Our data align with previous studies, supporting the evidence that mHTR systems are associated with shorter operative times, probably because of their ability to simultaneously cut and aspirate tissue fragments, thereby eliminating the need for multiple device removals and reinsertions into the uterine cavity.

Previous studies on mHTR devices for benign intracavitary pathologies have reported a reduced risk of intrauterine adhesions, possibly resulting from to the use of mechanical rather than electrical energy.[25] Our findings confirmed the lower incidence of intrauterine synechiae during hysteroscopic follow up, enhancing the ability to adequately evaluate the uterine cavity and improving the accuracy of endometrial sampling. This aspect is relevant for our patients, who cannot undergo standard treatments, as regular endometrial biopsies are essential for early detection of malignancy or disease recurrence.[25]

In the present study, the lack of significant intraoperative complications and the avoidance of spinal anesthesia during the mHTR procedure highlight its safety, especially for high-risk patients. These systems are both time-efficient and can be performed in outpatient settings, reducing costs and hospital stays.

The present study's strengths include its setting in a tertiary care center with skilled operators, ensuring consistent surgical treatment, and its novel research question. However, several limitations impact the generalizability: the retrospective design may introduce selection bias, though baseline characteristics between study groups were comparable. Single-center results may not extend to non-tertiary settings, but complex procedures like endo-myometrial resection are typically managed in specialized centers. Moreover, given our unpowered sample size, larger studies with extended follow up are needed to better evaluate oncologic outcomes. Future studies incorporating molecular classification could further optimize risk stratification and help personalize treatment approaches.

In conclusion, mHTR systems for endo-myometrial resection demonstrate comparable oncologic outcomes to resectoscopic hysteroscopy for patients with pre-neoplastic or early-stage endometrial lesions ineligible for standard surgery. They may also reduce total operative time and decrease the incidence of intrauterine synechiae, enhancing safety and accuracy in follow-up sampling. A large multicenter prospective study is needed to confirm our study findings.

AUTHOR CONTRIBUTIONS

In accordance with the ICMJE authorship criteria, all authors have made significant contributions to the study as outlined: Camilla Franceschini, Eugenia Mantovani, Agnese Virgilio, Attilio di Spiezio Sardo, and Renato Seracchioli contributed to the conceptualization and study design; Camilla Franceschini, Eugenia Mantovani, Erika Bettiol, and Agnese Virgilio contributed to data collection; Alessandro Arena, Eugenia Mantovani, Attilio di Spiezio Sardo, Renato Seracchioli, Paolo Casadio, Manuela Guerrini, and Maria Chiara De Angelis contributed to data analysis and interpretation; Alessandro Arena, Camilla Franceschini, Eugenia Mantovani, Maria Chiara De Angelis, Agnese Virgilio, Erika Bettiol, Paolo Casadio, Renato Seracchioli, Attilio di Spiezio Sardo, and Manuela Guerrini contributed to the original draft and to review and editing; and Alessandro Arena, Manuela Guerrini, Maria Chiara De Angelis, Attilio di Spiezio Sardo, Paolo Casadio, and Renato Seracchioli contributed to supervision and project administration. All authors have read and approved the final manuscript and have agreed to be accountable for the accuracy and integrity of the entire work.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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