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CLINICAL ARTICLE

Evaluation of rectal endometriosis treatment with high-intensity focused ultrasound versus surgery: A clinical retrospective multicenter trial

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Abstract

Objective: We conducted a comparative retrospective bicentric study of rectal endometriosis treatment with high-intensity focused ultrasound (HIFU) and surgery in terms of symptoms and treatment-related morbidity at 6 months.

Methods: All patients with a single symptomatic rectal nodule who had failed hormonal treatment were included in the present study. Patients' symptomatology was assessed using questionnaires: gynecologic and digestive symptoms (visual analog scale [VAS]), health status (MOSSF-36), fecal incontinence (Wexner), constipation (Knowles Eccersley Scott Symptom [KESS] score) and overall sexual health (FSFI). We also assessed the morbidity according to the Clavien–Dindo classification.

Results: A total of 120 patients, 60 in each group, received HIFU or rectal surgery. The characteristics of rectal nodules were similar in both groups. In the HIFU and surgery groups, Clavien–Dindo grades 2 and 3 complication rates were 3.3% versus 21.7% ($P = 0.002$) and 0% versus 10% ($P = 0.01$), respectively. Hospitalization duration was also significantly shorter for the HIFU group (1 vs 3 days; $P < 0.001$). In the HIFU group, significant improvement was observed in acute pelvic pain/dysmenorrhea ($P < 0.001$), dyspareunia ($P < 0.001$), diarrhea ($P < 0.001$), tenesmus/spasms ($P < 0.001$), pain on defecation ($P < 0.001$), and urinary urgency ($P < 0.026$). In the surgical arm, significant improvement was observed in acute pelvic pain/dysmenorrhea ($P < 0.017$), diarrhea ($P < 0.002$), tenesmus/spasms ($P < 0.001$), and pain on defecation ($P < 0.002$). In both groups, an improvement in FSFI, KESS, and Wexner scores and health status was noted at 6 months.

Conclusion: In selected patients with only one rectal location, HIFU treatment enables a similar symptom-related and quality-of-life outcome with a significant reduction in the risk of postoperative complications.

KEYWORDS
disc excision, high-intensity focused ultrasound, rectal endometriosis, rectal shaving, segmental resection

1 | INTRODUCTION

Endometriosis is a benign condition affecting more 190 million women in a reproductive age.[1] With 10% of women affected, intestinal involvement is the third most frequent site of deep infiltrated endometriosis (DIE) nodules, after the uterosacral ligaments and uterine torus.[2] They cause pain during bowel movement, spasms/cramps, alternating diarrhea/constipation, as well as dyspareunia, all of which negatively impact quality of life.

Due to the hormonal sensitivity of the lesions, management of colorectal endometriosis nodules relies on hormonal therapy to initiate amenorrhea.[3] However, this approach only temporarily relieves patients, often with side effects.[4] After failure of hormonal therapy, surgery is considered the standard of care for digestive endometriosis.[5]

Since 2015, high-intensity focused ultrasound (HIFU) treatment has been studied as an alternative to surgery.[6,7] The deep endometriotic lesion is devitalized by the heat generated by the HIFU within minutes and with high precision (Figure 1), without causing injuries to the rectal wall.[8] The aim of our study was to retrospectively compare morbidity and treatment-related improvements in symptoms, for nodules suitable to both approaches, and treated either with HIFU or surgery.

2 | MATERIALS AND METHODS

We conducted a retrospective bicentric comparative study in two endometriosis reference centers in France: the Croix-Rousse University Hospital (Hospices Civils Lyon) and the Franco-European Multidisciplinary Institute of Endometriosis (IFEM Endo)—Clinic Tivoli-Ducos (Bordeaux). All patients included in both study arms were drawn from two independent prospective databases, each approved by their respective ethics committees. Surgical patients were retrospectively selected based on HIFU eligibility criteria, allowing clinically relevant matching by nodule size and location. Surgery was indicated after the failure of hormonal treatment and HIFU treatment proposed as a mini-invasive alternative to surgery.

In the surgical arm, between January 1, 2021, and June 30, 2022, the IFEM Endo database included more than 700 patients treated for deep infiltrating endometriosis (DIE). Among these, 138 patients (19.7%) underwent isolated colorectal surgery either shaving, discoid or segmental resection according to the technic describe by Donnez and Roman.[9] Based on intraoperative findings, we selected 60 (43.5%) patients with rectal lesions deemed suitable for HIFU treatment: the upper margin of the lesion was located less than 15 cm from the anal verge, and there was no associated luminal stenosis greater than 50%. The presence of other endometriotic lesions (e.g., endometriomas, anterior DIE, or superficial endometriosis), or extension of the rectal involvement to adjacent structures (e.g., uterine torus, uterosacral ligaments, and/or vagina), were not considered exclusion criteria. In addition to rectal surgery, all identified endometriotic lesions, including posterior DIE and those at other sites, were excised.

Subjects in the HIFU group were patients older than 25 years, included in the prospective safety study ENDO-HIFU-R1 database.[8] All received HIFU treatment with the Focal One device (EDAP-TMS, France) between August 2020 and March 2022.[8] These patients received HIFU treatment of the rectal nodule and also concomitant posterior DIE lesions when they were visible. They were followed for 6 months without change in their hormonal treatment during the follow-up period.

The classification of rectal locations was made in accordance with the Société Nationale Française de Gastro-Entérologie (SNFGE) classification,[10] based on preoperative magnetic resonance imaging (MRI) in the HIFU group, and on intraoperative description in the surgery group.[11] Respectively, the description of endometriotic

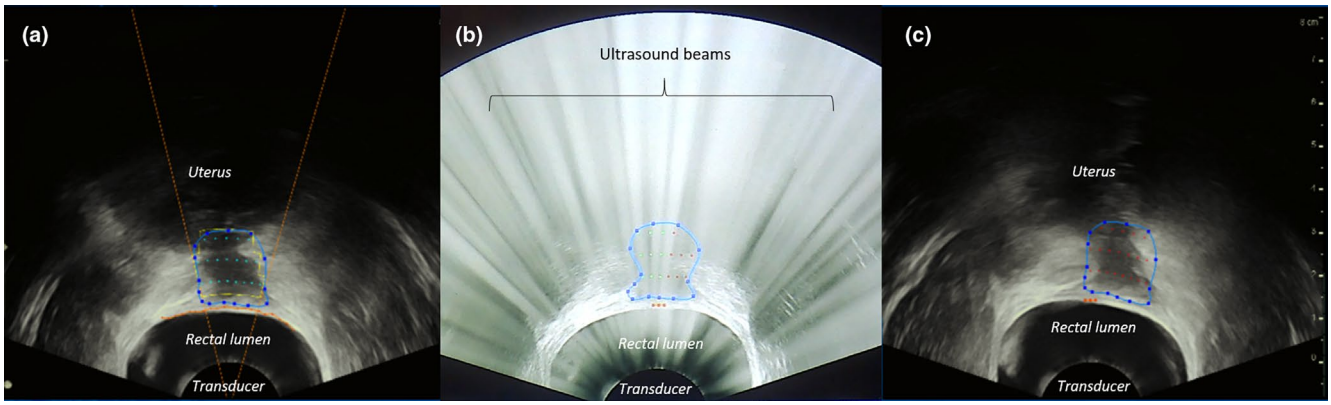

FIGURE 1 Planification of high-intensity focused ultrasound (HIFU) treatment and treatment. The entire volume of the nodule is divided in several slices every 1.7 mm. This figure represents one slice of treatment. (a) The rectal nodule is outlined by the physician (blue dotted line). The software determines the number of thermal lesions required to treat the entire slice (green dots) and the area of thermal diffusion (inside the yellow line). The distance between two vertical points is 5 mm. (b) Shows the ultrasound imaging during the HIFU treatment. The image is blurred by the HIFU shots. When the thermal lesion is formed, the green dot turns red. (c) The treatment of this slice is completed, all the green dots turn red. The probe move to the coming slice 1.7 mm above and so on until the entire nodule is treated.

involvement was conducted in a standardized manner in a preoperative setting using the Enzian classification.[12]

The primary endpoint was the improvement in dysmenorrhea and/or acute pelvic pain at 6 months. Assessment of symptoms was conducted in all patients using the visual analog scale (VAS) and health status, fecal incontinence, constipation and sexual function, respectively using validated self-questionnaires: Medical outcomes study 36-item short form (MOSSF-36) questionnaire,[13] Wexner questionnaire,[14] Knowles Eccersley Scott Symptom (KESS) score,[15] and female sexual function index (FSFI) questionnaire,[16] respectively, that were sent by email before the surgery or HIFU treatment, then 6 months after treatment.

2.1 | Statistical analysis

Patients were appaired one to one according to the size of the nodule. Statistical analyses were conducted with IBM SPSS Statistics (version 28) software. Categorical data are described using number and percentages, while continuous variables with mean and standard deviation, 95% confidence interval (CI), median, interquartile, and range were used. There was no preliminary calculation of the number of subjects required, because no previous study was available to build a hypothesis regarding the difference in terms of main end point. The distribution of each variable was assessed with the Kolmogorov–Smirnov test. For continuous variables, comparisons employed the student's *t*-test and Mann–Whitney test. For categorial variables, we employed the chi-squared and Fisher exact tests. The comparison of variables before and after treatment was conducted using *t*-test or paired-samples Wilcoxon test. Safety analyses included summary tables with the number of adverse events and the corresponding number of patients. For the comparisons, a *P* value less than 0.05 was considered statistically significant. No test for multiplicity adjustment or Bonferroni correction was conducted to control type I error rate.

3 | RESULTS

Patient demographics from both groups are shown in Table 1. Both populations were comparable in terms of age at diagnosis, past surgical management, and obstetric history. Patients in the surgery group were more likely to present with pregnancy intention than patients in the HIFU group (45.0% vs 20.0%, respectively; $P=0.003$). In the HIFU arm, according to the protocol, we did not observe any variation of the hormonal treatment. In the surgical arm, we observed a non-significant reduction of the hormonal treatment ($P=0.172$), mainly explained by the percentage of hysterectomies performed during the surgery. Moreover, according to the Enzian classification (Table 2), the size distribution of the nodules located in the rectum (class C) and uterosacral ligaments (class B) was significantly different between the two arms ($P=0.008$ [class C] and $P=0.002$ [class B], respectively), with a higher proportion of deep nodules in the surgery arm. Likewise, we observed a significant difference in the size distribution of nodules infiltrating the vagina or the rectovaginal space or the retrocervical area (class A, $P<0.001$), with a lower proportion on invasion in the surgery arm.

TABLE 1 Baseline patient and clinical characteristics.

	HIFU ($n=60$)	Surgery ($n=60$)	*P* value
Age, mean ± SD (median) [range]			
Age at diagnosis	31.0 ± 6.1 (30.5) [19; 51]	31.5 ± 6.8 (30.4) [20; 54]	0.95
Age at intervention	35.9 ± 6.2 (35.4) [26; 53]	34.7 ± 7.5 (33.1) [22; 54]	0.22
BMI, mean ± SD (median) [range]	24.2 ± 4.1 (23.8) [17; 36]	23.2 ± 3.9 (22.1) [16; 33]	0.20
Gravidity, mean ± SD (median) [range]	0.95 ± 1.16 (1) [0; 4]	0.83 ± 1.09 (0) [0; 4]	0.55
0	29 (48.3)	33 (55.0)	
1	14 (23.3)	11 (18.3)	
2	11 (18.3)	10 (16.7)	0.71
3	3 (5.0)	5 (8.3)	
4	3 (5.0)	1 (1.7)	
Parity, mean ± SD (median) [range]	0.73 ± 0.90 (0) [0; 3]	0.57 ± 0.87 (0) [0; 4]	0.23
0	31 (51.7)	38 (63.3)	
1	17 (28.3)	12 (20.0)	
2	9 (15.0)	9 (15.0)	0.23
3	3 (5.0)	0 (0.0)	
4	0 (0)	1 (1.7)	
Pregnancy plan	12 (20.0)	27 (45.0)	0.003
Pregnancies	31 (51.7)	27 (45.0)	0.47
Children (including stillborn)	29 (48.3)	22 (36.7)	0.20
Infertility	15 (25.0)	15 (25.0)	1.00
Hormonal treatment to induce amenorrhea			
None	17 (28.3)	29 (48.3)	0.024
Hormonal treatment	38 (63.3)	23 (38.3)	0.006
Estrogen–progestogen	14 (23.3)	15 (25.0)	
Progestin	19 (31.7)	4 (6.7)	
IUD + hormones	4 (6.7)	4 (6.7)	
Add-back therapy	1 (1.7)	0 (0.0)	
Non-hormonal treatment	5 (8.3)	8 (13.3)	0.38
IUD	3 (5.0)	0 (0)	
Other	2 (3.3)	2 (3.3)	
Not specified	0 (0)	6 (10.0)	
Previous endometriosis surgery	15 (25.0)	13 (21.7)	0.67
Previous abdominal surgery	25 (41.7)	19 (31.7)	0.26

Note: BMI, calculated as weight in kilograms divided by the square of height in meters.

Abbreviations: BMI, body mass index; HIFU, high-intensity focused ultrasound; IUD, intrauterine device; SD, standard deviation.

TABLE 2 Size and Enzian classification of the deep infiltrating endometriosis lesions.

	HIFU ($n=60$)	Surgery ($n=60$)	*P* value
Lesion measurements, mm, mean ± SD (median) [range]			
Lesion height (mm)	2.60 ± 0.94 (2.4) [1; 4.8]	2.44 ± 1.23 (2) [0.5; 8]	0.44
Distance from anal margin (upper)	12.1 ± 1.6 (12) [8.7; 15]	10.6 ± 3.4 (11) [4; 25]	<0.001
Enzian classification for deep endometriosis, *n* (%)			
A: Rectovaginal space, vagina, retrocervical area			
None	4 (6.7)	20 (33.3)	
<1 cm	7 (11.7)	11 (18.3)	<0.001
1–3 cm	39 (65.0)	20 (33.3)	
>3 cm	10 (16.7)	9 (15.0)	
B: Sacrouterine ligaments, cardinal ligament, pelvic sidewall			
None	4 (6.7)	3 (5.0)	
<1 cm	25 (41.7)	8 (13.3)	0.002
1–3 cm	25 (41.7)	33 (55.0)	
>3 cm	6 (10.0)	16 (26.7)	
C: Rectum			
<1 cm	4 (6.7)	8 (13.3)	0.008
1–3 cm	40 (66.7)	23 (38.3)	
>3 cm	16 (26.7)	29 (48.3)	
FA: Adenomyosis			
No	53 (88.3)	35 (58.3)	<0.001
Yes	7 (11.7)	25 (41.7)	
FB: Bladder			
No	60 (100)	57 (95.0)	0.122
Yes	0 (0)	3 (5.0)	
FU: Ureter			
No	59 (98.3)	56 (93.3)	0.182
Yes	1 (1.7)	4 (6.7)	
FI: Intestine			
No	60 (100)	56 (93.3)	0.059
Yes	0 (0)	4 (6.7)	

Note: All values are shown as *n* (%), unless otherwise indicated.
Abbreviations: HIFU, high-intensity focused ultrasound; IUD, intrauterine device; SD, standard deviation.

Table 3 shows procedure data and early outcomes. Operating time was significantly lower in the HIFU group than in the surgery group (35 vs 110 min; $P<0.001$). HIFU treatment focused on rectal nodules and also included other posterior deep-infiltrating locations, including the uterine torus (68.3%), uterosacral ligaments (41.7%), and vagina (11.7%). In the surgery group, both deep and superficial locations were removed. Length of hospital stay was significantly lower in the HIFU group (1 day vs 3 days for the surgery group; $P<0.001$). Grade 1 complications (Clavien–Dindo classification) were reported only in the HIFU arm because patients were enrolled in a prospective safety study. As such, all complications were

TABLE 3 Treatment procedure and complications.

Treatment and complications	HIFU ($n=60$)	Surgery ($n=60$)	*P* value
Operating time (min), mean ± SD (median) [range]	35 ± 13 (32) [17; 89]	110 ± 58 (100) [30; 300]	<0.001
Type of surgery			
Robotic	–	17 (28.3)	
Laparoscopy	–	43 (71.7)	
Type of digestive surgery			
Shaving (without suture)	–	13 (21.7)	
Shaving (with suture)	–	4 (6.7)	
Discoid resection	–	28 (46.7)	
Segmental resection	–	15 (25.0)	
Others posterior DIE treatment[a] compartment gesture, *n* (%)			
Uterosacral ligament (R or L)	25 (41.7)	57 (95.0)	<0.001
Uterine torus	41 (68.3)	55 (91.7)	0.001
Colpectomy/vagina	7 (11.7)	20 (33.3)	0.004
Other procedure			
Hysterectomy	–	16 (26.7)	
Endometrioma (R)	–	11 (18.3)	
Endometrioma (L)	–	15 (25.0)	
Bladder nodule	–	4 (6.7)	
Parametrial nodule	–	18 (30.0)	
Sacral plexus	–	5 (8.3)	
Sciatic nerve	–	1 (1.7)	
Appendectomy	–	1 (1.7)	
Nights in hospital, mean ± SD (median) [range]	0.95 ± 0.29 (1) [0; 2]	3.05 ± 1.31 (3) [0; 6]	<0.001
Ambulatory	4 (6.7)	1 (1.7)	
1 night	55 (91.7)	6 (10.0)	
2 nights	1 (1.7)	13 (21.7)	<0.001
3 nights	–	18 (30.0)	
≥4 nights	–	22 (36.7)	
Clavien–Dindo complication			
Grade 1	34 (56.7)	NA	NA
Grade 2	2 (3.3)	13 (21.7)	0.002
Grade 3	–	6 (10.0)	0.012
Grade ≥4	–	–	
Recto-vaginal fistulae	0	0	
Bladder voiding dysfunction	1 (1.7)	10 (16.7)	

Note: All values are shown as *n* (%), unless otherwise indicated.
Abbreviations: DIE, deep infiltrating endometriosis; HIFU, high-intensity focused ultrasound; L, left; R, right; SD, standard deviation.
[a]In the HIFU arm, the others posterior DIE locations were treated by HIFU (no combination with a surgical procedure was required).

systematically recorded. No grade 3 complications were observed in the HIFU group, compared with six (10%) in the surgery group ($P<0.001$). No bowel fistulae were recorded in this population. Grade 2 complications arose in 3.3% versus 21.7% ($P=0.002$) in the HIFU versus surgery groups, respectively. One (1.7%) patient in the HIFU group experienced bladder-voiding dysfunction requiring self-catheterization, compared with 10 (16.7%) patients in the surgery group ($P<0.005$).

Table 4 reports assessment of symptoms 6 months after treatment. In the HIFU group, two patients were not assessed at 6 months because they were pregnant. The other 58 patients reported an overall significant improvement in acute pelvic pain/dysmenorrhea, dyspareunia, diarrhea, tenesmus/spasms, pain on defecation, and urinary urgency. In the surgical arm, symptom evaluation questionnaires were available for a limited number of patients. Significant improvement was observed in acute pelvic pain/dysmenorrhea, diarrhea, tenesmus/spasms, and pain on defecation and not in dyspareunia and urinary urgency.

Table 5 compares the evolution of health status based on the MOSSF-36 questionnaire. In the HIFU group, all components of the physical and mental component scales significantly improved at 6 months. In the surgery group, three components out of eight (vitality, emotional well-being, and bodily pain) improved at 6 months. The physical score component showed significant improvement in the HIFU group ($P<0.001$) compared with the surgery group ($P=0.065$). The mental score component was significantly improved in both arms.

Overall evaluation of sexual health (FSFI), constipation (KESS), and fecal incontinence (Wexner) are presented in Table 6. Over half of the patients had a baseline FSFI score <26, indicating compromised sexuality. A slight improvement in FSFI score was observed in both groups but significant only in the HIFU arm ($P=0.012$). Based on the KESS constipation score, a significant improvement was observed in both the HIFU arm and the surgery arm ($P<0.001$ and $P=0.031$, respectively). For the fecal incontinence score (Wexner), an improvement was observed only in the HIFU arm ($P=0.005$). Even if the improvement was significant only in the HIFU arm at 6 months for all the components assessed, no significant difference was observed between the two arms.

4 | DISCUSSION

Here, we report the first study to compare HIFU treatment versus surgical resection for posterior DIE responsible for single digestive infiltration of the rectal wall. The improvement of symptoms 6 months after the procedures was comparable in both groups, with a significant reduction in the rate of postoperative complications as well as the duration of hospital stay after HIFU treatment.

Our study had several limitations. Inclusion criteria limits the extrapolation of our results to patients beyond those presenting with unifocal rectal endometriosis. Given the exploratory nature of this analysis, no correction for multiple testing (e.g., Bonferroni method) was applied. Then comparisons of secondary endpoints should therefore be interpreted in light of their clinical relevance. The comparability of the two arms can also be discussed. The extent of the disease and number of bowel localizations were assessed by preoperative MRI in the HIFU group and by intraoperative assessment in the surgery group. Even if the heights of the lesions were not statistically different in the two arms, the highest lesion sizes were 8 and 4.8 cm in the surgical and the HIFU arm, respectively. As eligibility for HIFU was partly determined by probe geometry and accessibility, more complex nodules were overrepresented in the surgical arm, which may have also contributed to the higher complication rates observed in this group. However, more than the height of the lesion, the protrusion of nodules into the digestive lumen, might have had more significant impact in the eligibility. According to our experience, a lesion of 8 cm with no rectal protrusion would be easier to treat than a smaller one with higher degree of rectal lumen stenosis. In addition, intraoperative assessment is reported to be the most accurate method to identify the number of colorectal nodules.[17] Despite the fact that the description of the lesions was performed based on preoperative MRI, some of the patients enrolled in the HIFU group may have had more than one bowel nodule. However, MRI has demonstrated is sensitivity for the diagnosis digestive endometriosis.[11,18,19] Finally, lower response rate in the surgery group may introduce bias; therefore, only patients with complete follow-up data were included in the symptom and quality-of-life analyses. Our study had several strengths. Data collection was prospective and robust, as patients managed in HIFU groups belonged to a population already enrolled in a prospective study, while patients in the surgical group were enrolled in the IFEM Endo prospective database.[8] Moreover, operators were experienced in each technique.

Even if the 6-month follow-up limits the ability to assess recurrence and late complications, interestingly, the improvement of gynecologic and digestive symptoms was similar in women managed with HIFU treatment of their rectal nodule only versus those managed with complete excision of all pelvic and abdominal endometriosis lesions. It may be tempting to conclude that all endometriosis lesions except rectal nodules have a negligible impact on pelvic pain, sexual function, and digestive disorders, so surgeons could focus solely on management of rectal endometriosis. Countless studies demonstrated that complete excision of all endometriosis lesions is associated with better postoperative improvement of symptoms.[20] That could be partially explained by the fact that the number of patients who completed the assessment of symptoms in the two groups was not comparable. Moreover, in this study, the assessment of the symptoms was focused on gynecologic and digestive symptoms and thus does not highlight the benefits of the surgery for others locations of deep endometriosis excised by surgery. Interestingly, in the HIFU population, based on MRI, 98.3% of patients presented with endometriosis lesions outside of the digestive tract. As HIFU treatment is carried out under

TABLE 4 Evolution of symptoms (VAS)—paired results.

	HIFU	Surgery	
VAS symptoms	Mean ± SD (median) [IQR] (95% CI)		*P* value
Gynecologic symptoms			
Acute pelvic pain/dysmenorrhea	*n* = 58	*n* = 19	
Preoperative	6.2 ± 3.1 (7) [5; 8.3] (5.4; 7.0)	4.5 ± 3.3 (6) [0; 7] (2.9; 6.1)	0.052
6 months	2.8 ± 3.0 (2) [0; 5] (2.0; 3.6)	1.9 ± 2.3 (0) [0; 4] (0.8; 3.0)	0.27
Difference	−3.4 ± 3.8 (−3.0) [−7; 0] (−4.4; −2.4)	−2.6 ± 4.1 (−2) [−7; 0] (−4.5; −0.6)	0.5
P value	<0.001	0.017	
Dyspareunia	*n* = 58	*n* = 16	
Preoperative	4.7 ± 3.3 (6) [0; 7.3] (3.8; 5.6)	4.3 ± 2.9 (5) [1.3; 6.8] (2.7; 5.8)	0.6
6 months	2.0 ± 2.9 (0) [0; 3.3] (1.3; 2.8)	3.3 ± 2.7 (4) [0; 5.8] (1.9; 4.7)	0.045
Difference	−2.7 ± 3.3 (−3.0) [−5.3; 0] (−3.5; −1.8)	−0.9 ± 2.9 (0) [−2; 0.8] (−2.5; 0.6)	0.06
P value	<0.001	0.28	
No colpectomy		*n* = 11	
Preoperative		4.3 ± 2.5 (5) [2; 6] (2.6; 6.0)	
6 months		4.0 ± 2.5 (4) [2; 6] (2.3; 5.7)	
Difference		−0.3 ± 2.0 (0) [−2; 1] (−1.6; 1.0)	
P value		0.67	
Colpectomy		*n* = 5	
Preoperative		4.2 ± 4.0 (5) [0; 8] (−0.8; 9.2)	
6 months		1.8 ± 2.7 (0) [0; 4.5] (−1.5; 5.1)	
Difference		−2.4 ± 4.3 (−2) [−6.5; 1.5] (−7.7; 2.9)	
P value		0.27	
Digestive symptoms			
Diarrhea	*n* = 58	*n* = 29	
Preoperative	3.0 ± 3.3 (2.5) [0; 6.0] (2.2; 3.9)	5.2 ± 2.9 (6) [4; 7] (4.1; 6.3)	0.007
6 months	1.2 ± 2.3 (0) [0; 1.3] (0.6; 1.8)	2.8 ± 2.3 (2) [0; 5] (1.9; 3.7)	<0.001
Difference	−1.9 ± 3.1 (0) [−4; 0] (−2.7; −1.1)	−2.3 ± 3.6 (−2) [−5.5; 0.5] (−3.7; −1.0)	0.5
P value	<0.001	0.002	
Tenesmus/spasms	*n* = 58	*n* = 19	
Preoperative	5.7 ± 3.0 (6) [4.8; 8] (4.9; 6.5)	5.7 ± 2.4 (6) [5; 7] (4.5; 6.9)	0.7
6 months	2.8 ± 2.9 (3) [0; 5] (2.1; 3.6)	2.8 ± 2.4 (3) [0; 5] (1.7; 3.9)	0.9
Difference	−2.8 ± 3.3 (−2.5) [−6; 0] (−3.7; −2.0)	−2.9 ± 2.8 (−3) [−5; 0] (−4.2; −1.6)	1.0
P value	<0.001	0.001	
Pain on defecation	*n* = 58	*n* = 18	
Preoperative	3.9 ± 3.7 (4) [0; 7] (2.9; 4.9)	5.9 ± 2.1 (6) [4.8; 8.0] (4.8; 7.0)	0.053
6 months	1.3 ± 2.1 (0) [0; 2.3] (0.8; 1.9)	2.9 ± 2.2 (3) [1.5; 5.0] (1.9; 4.0)	0.002
Difference	−2.6 ± 3.1 (−2.0) [−5; 0] (−3.4; −1.7)	−2.9 ± 3.0 (−3) [−5.3; 0] (−4.5; −1.4)	0.6
P value	<0.001	0.002	
Urinary symptoms			
Dysuria	*n* = 58	*n* = 17	
Preoperative	0.6 ± 1.8 (0) [0; 0] (0.1; 1.1)	2.7 ± 3.0 (2) [0; 5] (1.1; 4.2)	<0.001
6 months	0.5 ± 1.8 (0) [0; 0] (0.0; 1.0)	1.1 ± 1.4 (0) [0; 2.5] (0.3; 1.8)	0.002
Difference	−0.1 ± 1.4 (0) [0; 0] (−0.5; 0.3)	−1.6 ± 3.0 (0) [−4.5; 0] (−3.1; −0.0)	0.032
P value	0.611	0.055	
Urgency	*n* = 58	*n* = 17	

TABLE 4 (Continued)

VAS symptoms	HIFU Mean ± SD (median) [IQR] (95% CI)	Surgery	*P* value
Preoperative	1.8 ± 3.0 (0) [0; 5] (1.0; 2.6)	3.7 ± 3.2 (4) [0; 6.5] (2.1; 5.3)	0.018
6 months	1.1 ± 2.5 (0) [0; 0] (0.4; 1.7)	1.9 ± 1.7 (2) [0.5; 3] (1.1; 2.8)	<0.001
Difference	−0.8 ± 2.7 (0) [−0.3; 0] (−1.5; −0.0)	−1.8 ± 3.6 (−1) [−6; 1] (−3.6; 0.1)	0.6
P value	0.026	0.104	

Abbreviations: CI, confidence interval; HIFU, high-intensity focused ultrasound; IQR, interquartile range; SD, standard deviation; VAS, visual analog scale.

TABLE 5 Evolution of health status (MOSSF-36)—paired results.

Health status SF-36	HIFU (*n* = 58) Mean ± SD (median) [IQR] (95% CI)	Surgery (*n* = 47)	*P* value
PF: Physical functioning			
Preoperative	80.6 ± 21.4 (90) [70; 95] (75; 86)	77.4 ± 21.9 (85) [60; 95] (71; 84)	0.4
6 months	89.1 ± 14.1 (93) [85; 100] (85; 93)	79.3 ± 22.2 (90) [70; 95] (73; 86)	0.014
Difference	8.5 ± 16.2 (5) [−5; 15] (4.3; 12.8)	1.8 ± 19.0 (0) [−10; 10] (−3.8; 7.4)	0.056
P value	<0.001	0.68	
RP: Role limitation due to physical health			
Preoperative	51.3 ± 40.9 (50) [0; 100] (41; 62)	53.2 ± 36.7 (50) [25; 100] (42; 64)	0.8
6 months	70.7 ± 40.3 (100) [25; 100] (60; 81)	54.8 ± 42.6 (75) [0; 100] (42; 67)	0.028
Difference	19.4 ± 48.0 (0) [0; 50] (6.8; 32)	1.6 ± 47.6 (0) [0; 25] (−12.4; 15.6)	0.22
P value	0.004	0.95	
RE: Role limitation due to emotional problems			
Preoperative	43.7 ± 37.0 (33) [0; 67] (34; 53)	50.4 ± 41.6 (67) [0; 100] (38; 63)	0.4
6 months	74.1 ± 38.5 (100) [33; 00] (64; 84)	57.4 ± 42.1 (67) [33; 100] (45; 70)	0.042
Difference	30.5 ± 44.3 (33) [0; 67] (18.8; 42.1)	7.1 ± 35.4 (0) [0; 33] (85; 93)	0.004
P value	<0.001	0.2	
Vitality: Energy/fatigue			
Preoperative	34.1 ± 17.8 (30) [20; 45] (29; 38)	32.8 ± 20.3 (30) [15; 45] (27; 39)	0.6
6 months	48.8 ± 19.7 (50) [50; 65] (44; 54)	38.9 ± 20.9 (35) [20; 60] (33; 45)	0.013
Difference	14.7 ± 16.8 (15) [0; 25] (10.3; 19.2)	6.2 ± 18.8 (5) [−5; 20] (0.7; 11.7)	0.033
P value	<0.001	0.02	
MH: Emotional well-being			
Preoperative	50.6 ± 19.5 (52) [36; 64] (46; 56)	46.3 ± 20.2 (48) [28; 64] (40; 52)	0.33
6 months	65.0 ± 18.2 (68) [52; 80] (60; 70)	54.5 ± 20.4 (52) [40; 68] (48; 60)	0.006
Difference	14.3 ± 18.7 (10) [0; 25] (9.4; 19.3)	8.2 ± 14.8 (4) [−4; 16] (85; 93)	0.11
P value	<0.001	<0.001	
SF: Social functioning			
Preoperative	52.4 ± 24.2 (50) [38; 63] (46; 59)	53.5 ± 27.9 (50) [25; 75] (45; 62)	0.7
6 months	76.5 ± 21.3 (75) [63; 100] (71; 82)	61.4 ± 27.7 (63) [50; 88] (53; 70)	0.004
Difference	24.1 ± 21.3 (25) [13; 38] (18.5; 29.7)	8.0 ± 27.3 (0) [0; 25] (−0; 16.0)	0.004
P value	<0.001	0.072	
BP: Bodily pain			
Preoperative	49.2 ± 23.7 (45) [34; 68] (43; 55)	50.0 ± 26.4 (58) [35; 68] (42; 58)	0.7
6 months	71.9 ± 20.0 (74) [58; 90] (67; 77)	61.2 ± 26.2 (66) [45; 90] (54; 69)	0.037

(Continues)

TABLE 5 (Continued)

Health status SF-36	HIFU ($n=58$) Mean ± SD (median) [IQR] (95% CI)	Surgery ($n=47$)	*P* value
Difference	22.7 ± 25.2 (20) [7; 43] (16.1; 29.3)	11.2 ± 31.9 (13) [−10; 33] (1.9; 20.6)	0.045
P value	<0.001	0.013	
GH: General health			
Preoperative	46.8 ± 19.4 (45) [35; 65] (42; 52)	51.0 ± 20.6 (50) [40; 60] (45; 57)	0.27
6 months	57.8 ± 18.4 (60) [44; 70] (53; 63)	56.8 ± 23.4 (60) [35; 75] (50; 64)	1.0
Difference	10.9 ± 14.3 (10) [0; 25] (7.2; 14.7)	5.9 ± 18.2 (0) [−10; 15] (0.5; 12.2)	0.052
P value	<0.001	0.076	
PCS: Physical score component			
Preoperative	45.3 ± 8.9 (47) [24; 61] (43; 48)	45.6 ± 9.3 (48) [39; 52] (43; 48)	1.0
6 months	49.2 ± 7.0 (51) [33; 63] (47; 51)	46.8 ± 9.4 (48) [39; 55] (44; 50)	0.26
Difference	3.9 ± 7.5 (4) [−9; +21] (2; 6)	1.1 ± 10.6 (1) [−6; 7] (−2.0; 4.3)	0.098
P value	<0.001	0.65	
MCS: Mental score component			
Preoperative	34.5 ± 10.4 (35) [27; 40] (31; 37)	34.4 ± 12.2 (35) [23; 44] (31; 38)	1.0
6 months	44.3 ± 11.2 (48) [38; 52] (41; 47)	38.4 ± 12.4 (37) [28; 48] (35; 42)	0.013
Difference	9.8 ± 10.2 (10) [2; 16] (1.4; 6.6)	4.0 ± 8.9 (3) [−1; 10] (1.4; 6.6)	0.004
P value	<0.001	0.004	

Abbreviations: CI, confidence interval; HIFU, high-intensity focused ultrasound; IQR, interquartile range; MOSSF-36, Medical Outcomes Study 36-item short form; SD, standard deviation.

TABLE 6 Evolution of FSFI, KESS, and Wexner—paired results.

FSFI, KESS, and Wexner	HIFU Mean ± SD (median) [IQR] (95% CI)	Surgery	*P* value
Sexual function			
FSFI	$n=58$	$n=42$	
Preoperative	19.1 ± 11.1 (23.1) [4.1; 28.4] (16.2; 22.1)	20.3 ± 10.3 (22.8) 16.3; 28.3] (17.1; 23.5)	1.0
6 months	21.3 ± 12.1 (25.8) [3.9; 31.3] (18.1; 24.5)	21.1 ± 10.1 (24.1) [16.5; 29.2] (18.0; 24.3)	0.7
Difference	2.2 ± 9.8 (1.8) [−0.1; 5.2] (−0.4; 4.8)	0.8 ± 7.8 (−0.6) [−2.5; 4.4] (−1.6; 3.2)	0.5
P value	0.012	0.9	
Constipation			
KESS	$n=58$	$n=44$	
Preoperative	13.3 ± 6.5 (14.0) [8.0; 18.0] (11.6; 15.0)	12.9 ± 6.0 (13.0) [8.3; 17.0] (11.1; 14.7)	1.0
6 months	9.6 ± 6.1 (8.5) [4.8; 13.3] (8.0; 11.2)	11.3 ± 6.1 (11.0) [7.0; 16.8] (9.5; 13.2)	0.7
Difference	−3.7 ± 4.7 (−2.0) [−7.0; −1.0] (−4.9; −2.5)	−1.6 ± 4.5 (−1.0) [−5.0; 1.0] (−3.0; −0.2)	0.17
P value	<0.001	0.031	
Anal continence			
Wexner	$n=58$	$n=45$	
Preoperative	2.0 ± 2.2 (1.5) [0.0; 3.0] (1.4; 2.5)	1.3 ± 1.9 (0.0) [0; 2.5] (0.7; 1.9)	1.0
6 months	1.2 ± 1.6 (1.0) [0.0; 2.0] (0.8; 1.6)	1.4 ± 1.9 (0.0) [0; 3.0] (0.9; 2.0)	0.068
Difference	−0.7 ± 2.0 (0.0) [−2.0; 0.0] (−1.2; −0.2)	0.1 ± 2.0 (0.0) [−0.5; 1.0] (−0.5; −0.7)	0.9
P value	0.005	0.6	

Abbreviations: CI, confidence interval; FSFI, female sexual function index; HIFU, high-intensity focused ultrasound; IQR, interquartile range; KESS, Knowles Eccersley Scott Symptom score; SD, standard deviation.

general anesthesia, it seems likely that HIFU management of rectal nodules could be combined with laparoscopic or robotic excision of other endometriotic lesions. This result could also be explained by the fact that the treatment, in the HIFU arm, was not limited to rectal nodule but extended to uterosacral ligaments, uterine torus and vagina in 41.7%, 68.3% and 11.7%, respectively of the patients (Figure 2). Moreover, a placebo effect on overall symptoms cannot be completely ruled out during the first few months postoperatively, as observed in a randomized trial on laparoscopy where endometriotic lesions were left in place,[21] and more recently with GnRH antagonists.[22] However, the thermal effect of HIFU[23] confirmed by the significant reduction of the rectal nodule volume following HIFU[8] confirmed the physical effect of HIFU on endometriosis tissue.

The digestive complaints were higher in the surgical arm. This could be explained by a significantly lower number of patients under hormonal treatment at the inclusion in the surgical arm and by a lower number of patients who responded to the questionnaire in this arm at 6 months. This higher pain level and more extensive disease in the surgical arm may have led to more extensive resections, potentially contributing to the greater severity of complications. Given that endometriosis is a benign condition in young women, conservative surgery is recommended in view of the lower rate of complications and satisfactory improvement of symptoms.[9] On a spectrum of the most conservative to the most radical approaches to treating rectal nodules, HIFU treatment appears as a less invasive procedure than rectal shaving with a low rate of complications.

Although surgery significantly improves symptoms, it does not definitively prevent recurrences.[24] In women treated by HIFU, the symptoms were improved and the progression of the rectal nodule seemed to be halted[8] but assessing the risk of progression after HIFU requires long-term follow-up. All the patients treated by HIFU are currently included in a long-term follow-up study. As with surgery, and in order to prevent the risk of recurrences after HIFU, using hormonal treatment to induce continuous amenorrhea seems a reasonable strategy.[25]

5 | CONCLUSION

In the present study we report encouraging data concerning the management of deep endometriosis nodules involving the rectum by HIFU compared with surgical excision, in terms of health improvement, rate of complications, operating time, and length of hospital stay. Postoperative complications were statistically less frequent after HIFU treatment. These findings suggest that HIFU treatment could be an alternative to surgery in patients with a single rectal nodule. However, further studies are required to refine selection criteria for patients who can benefit from this treatment, as well as to assess long-term outcomes and recurrence rate.

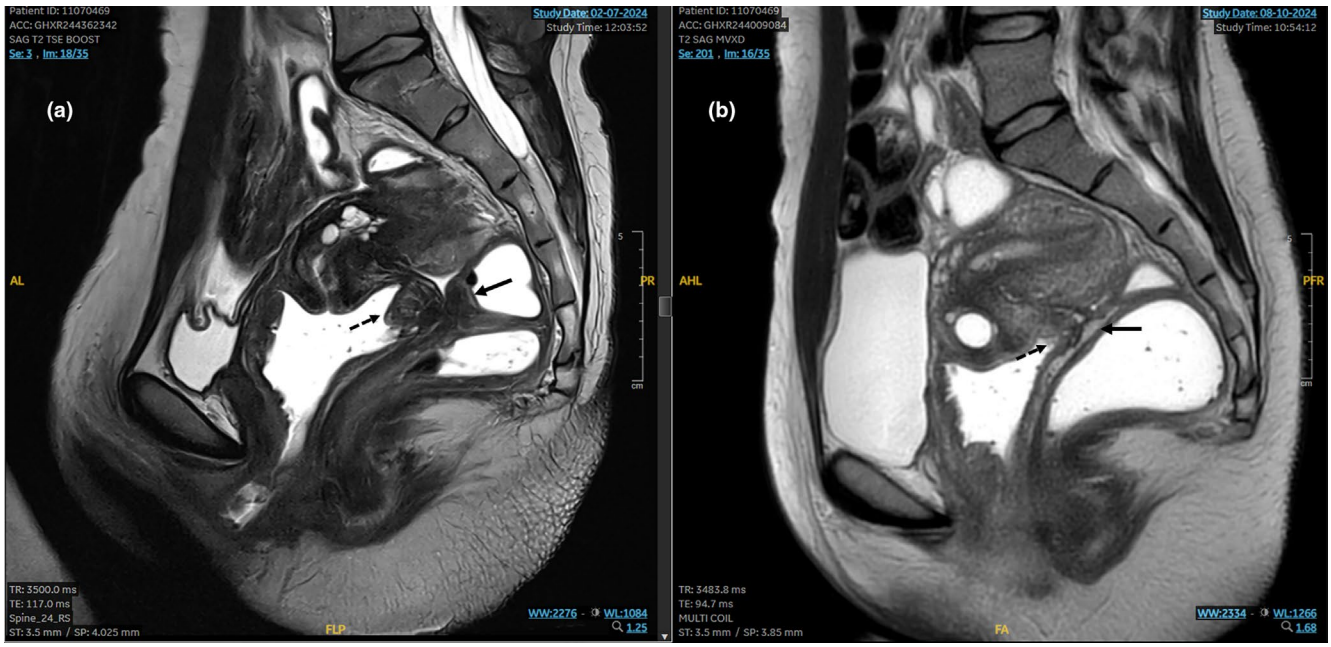

FIGURE 2 Pre- and 3 months post high-intensity focused ultrasound (HIFU) treatment magnetic resonance imaging (MRI) (T2 sequences) of a rectal endometriosis with vaginal involvement, No hormonal treatment. (a) Preoperatively. Sagittal T2-weighted MR image performed 15 days before HIFU treatment shows a consequent rectal lesion of the junction of the mid and high rectal anterior wall (arrow), with invasion of both the recto-vaginal septum and the posterior vaginal fornix (dotted arrow). (b) Three months after HIFU, no hormonal treatment since the treatment for a desire of pregnancy. Sagittal T2-weighted MR image shows a complete regression of both the rectal lesion and recto-vaginal septum involvement (arrow). An important decrease in size of the posterior vaginal cuff lesion (volume reduction >80%) (dotted arrow).

AUTHOR CONTRIBUTIONS

Gil Dubernard and Horace Roman: Design of the study, inclusion and treatments of patients and redaction of the manuscript. **Chloé Devantay**: collection of clinical data and redaction of the manuscript. **Charles-André Philip, Sophie Warembourg, Emilie Nguyen-Ba, Thomas Dennis and Benjamin Merlot**: Treatment of patients.

CONFLICT OF INTEREST STATEMENT

Professor Dubernard is a consultant for EDAP TMS company. However, the authors declare no conflict of interest for this study.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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