



Faisabilité et sécurité des HIFU dans l'endométriose rectale



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ROBOTIC FOCAL HIFU

Disclosures

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Bringing New Horizons to Therapy



Surgery of rectal endometriosis

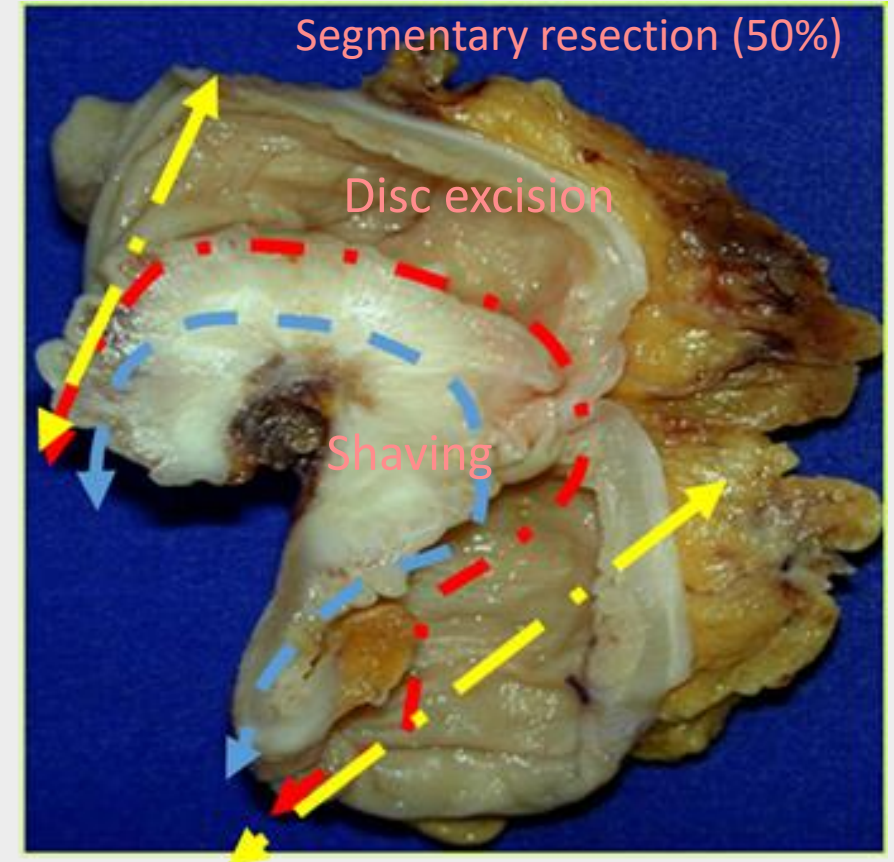
Complications

Rectovaginal fistulae:	14 (3.8%)	
Pelvic abscess requiring second laparoscopy:	19	(5.2%)
Pelvic abscess managed by only antibiotics:	5	(1.4%)
Stenosis of colorectal anastomosis:	8 (2.2%)	
Transitory bladder atony requiring <i>3 weeks to 6 months autocatherization:</i>	30	(8.2%)
Stoma-related early complications:	8 (0.3%)	
Severe abdominal hemorrhage requiring open surgery in emergency:	1 (0.3%)	
Peritonitis after stoma closure:	1 (0.3%)	
Cutaneous abscess:	4 (1.1%)	

Clavien 3 postoperative complications

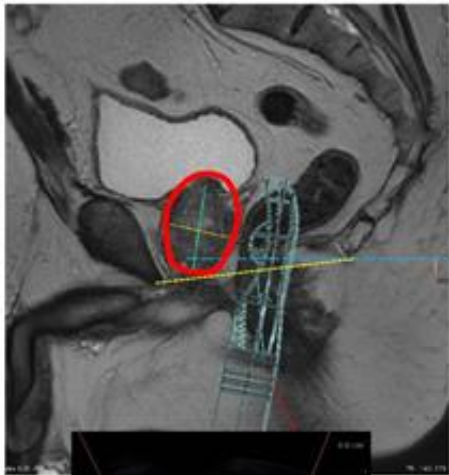
Clavien 3a postoperative complication:	11	(3.0%)
Clavien 3b postoperative complication:	43	(11.8%)

Type of surgeries



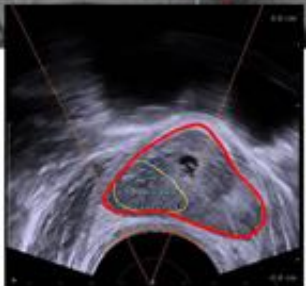
HIFU and Endometriosis

Prostate cancer



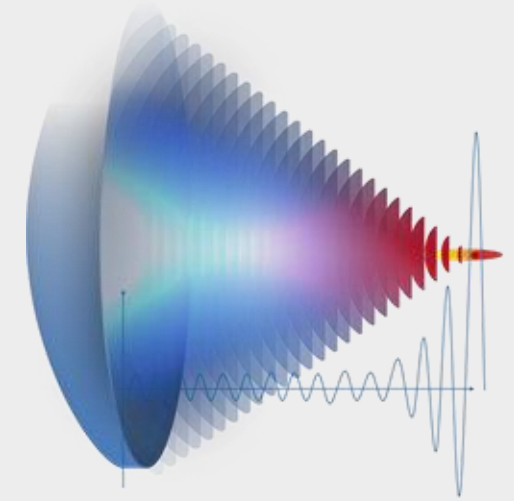
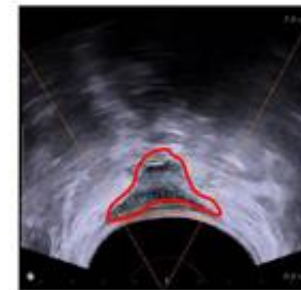
Transrectal approach, similar for both indications

End of the sacrum



The intraoperative US imaging is similar. But the endometriotic nodule is a bit higher than prostate (above the posterior vaginal cuff)

Endometriosis

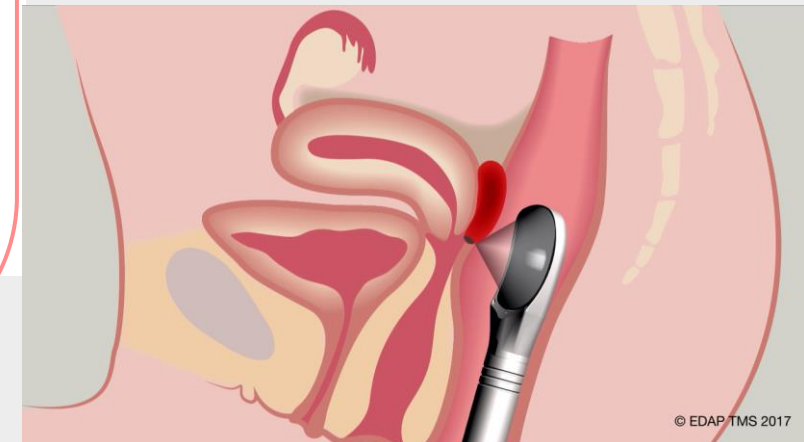


1. Thermal effect

- Heat induction at focus point
- Fast temperature raise
- Max focus temperature : 85°C

2. Mechanical effect

- Generation of gas bubbles
- Cavitation



Robotic HIFU

- **FocalOne**[®] Medical Device cleared for **Prostate Cancer** (CE mark, FDA)
- > 60.000 treatments worldwide, +300 centers

Transrectal approach



Safety multicentric study 60 patients



Inclusion criteria:

- *> 25 years old*
- *Failure of medical treatment → HIFU instead of surgery*
- *No past rectal surgery*
- *One digestive endometriosis location*
- *Rectal (< 15 cm from the anal margin)*
- *No change of hormonal treatment during follow up*
- *No pregnancy during follow-up*

Objectives

Main objective: Safety at 1, 3 & 6 months
(recto-vaginal fistulae, ...)

Secondaries :

Evolution of gynecologic, digestive at 1, 3, 6 months

Evolution of QOL at 1, 3, 6 months

Evolution of nodule volume at 6 months (MRI)

Post procedure analgesic & average pain at 10 days



Protocole of treatment

Location of DIE, based on MRI : RECTAL 100.0% and

Vagina :	75.0%
Torus :	73.1%
Ureterosacral ligament Right:	69.2%
Ureterosacral ligament Left	75.0%
Bladder endometriosis:	1.9%
Endometrioma Right:	7.7%
Endometrioma Left:	15.4%
Adenomyosis:	32.7%

ANESTHESIA, N(%) :

General:	42 (70%)
Spinal:	18 (30%)

Mean nodule volume: **3.0 cc** (0.4-14)

Operating time: **1h26** ± 0h27 (0h40-2h48) / 1h24

In-out probe duration: **0h35** ± 0h13 (0h17-1h29)

HOSPITALIZATION

Discharged after **1 day**: 55 (**91.7%**)

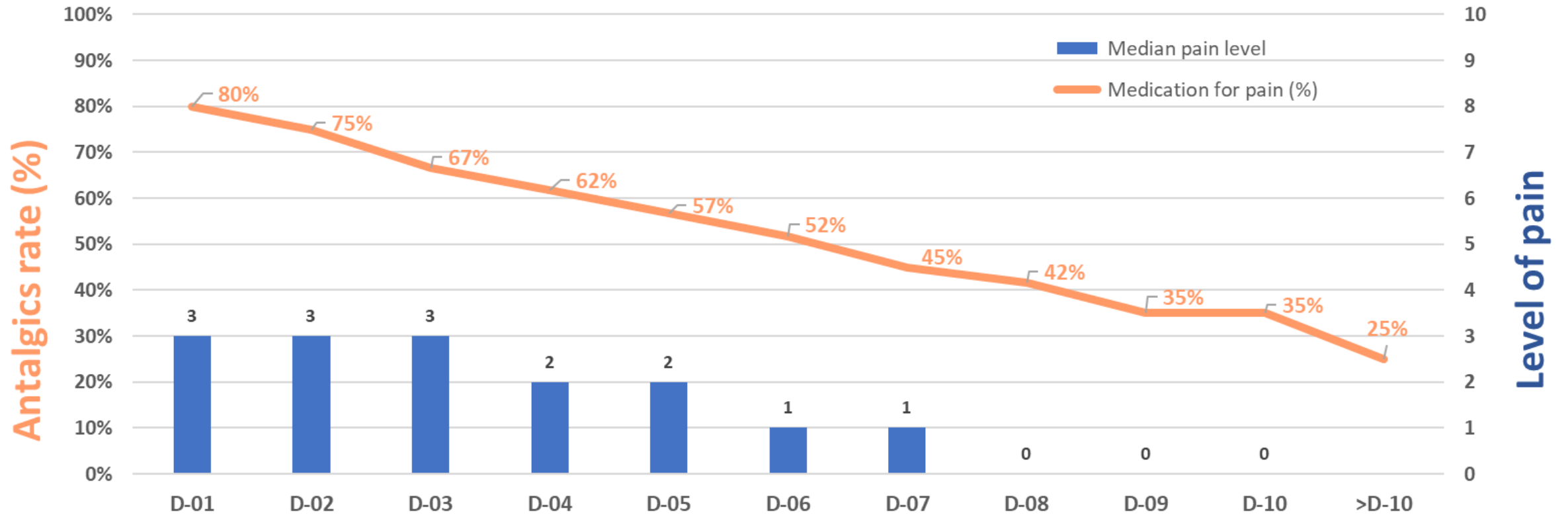
Discharged just after **HIFU**: 4 (**6.7%**)

Discharged after **2 days**: 1 (**1.7%**)

WORK INTERRUPTION, mean ± SD (range)

Duration: **10.2 days** ± 4.9 (4-21)

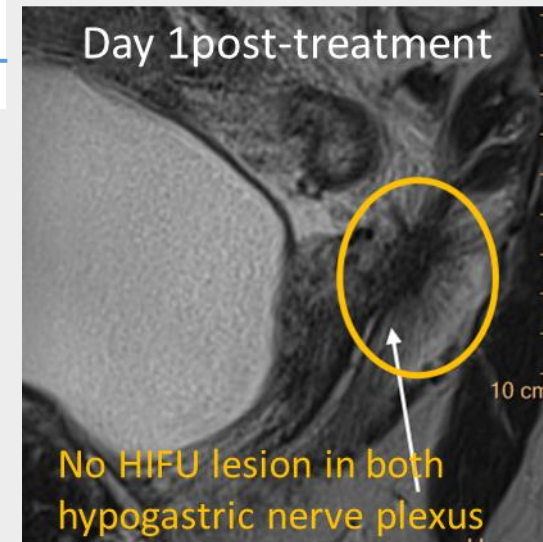
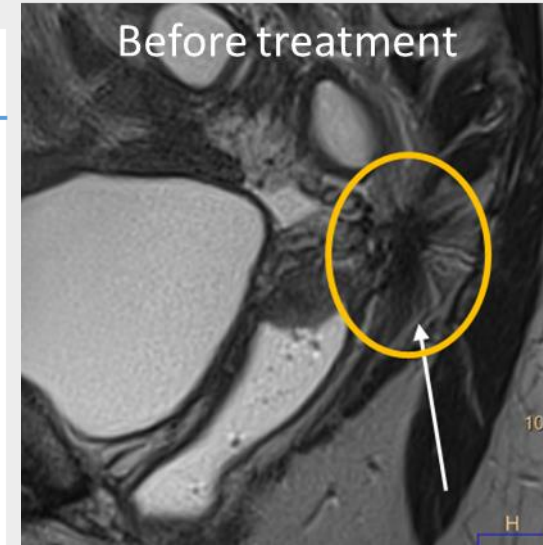
Pain level & medication



- Medication level reduced as soon as Day 1.
- Median pain level reduced starting Day 4
- At 8 days, more than 50% patients reached a pain level of 0.

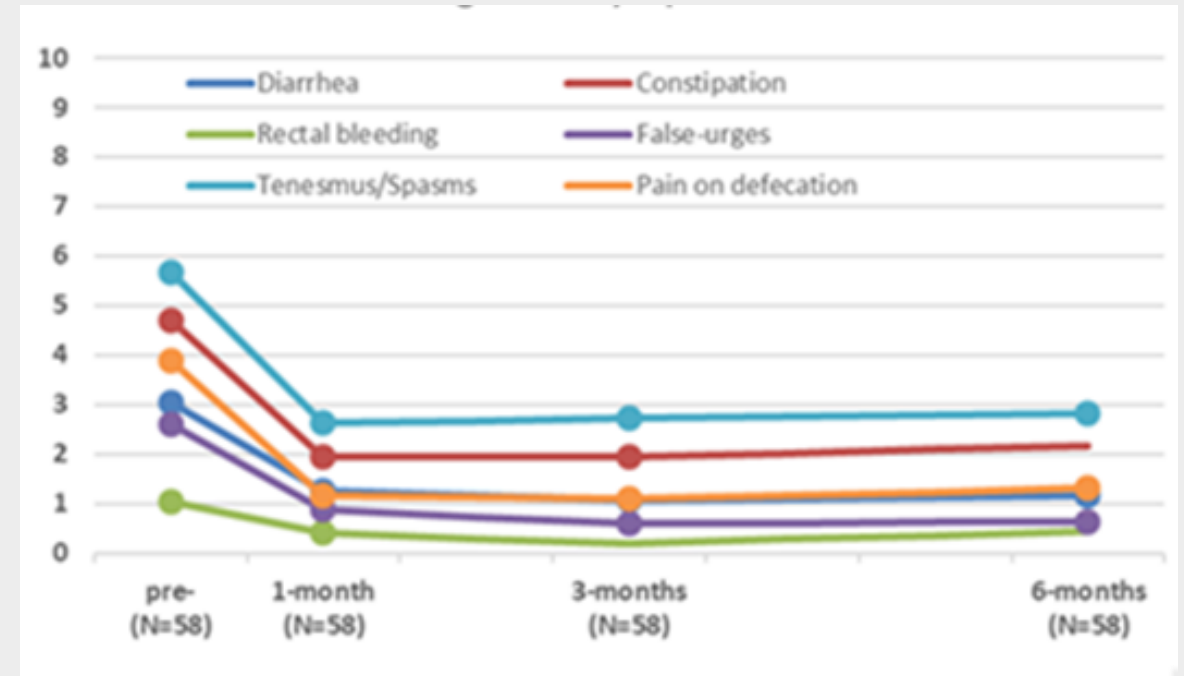
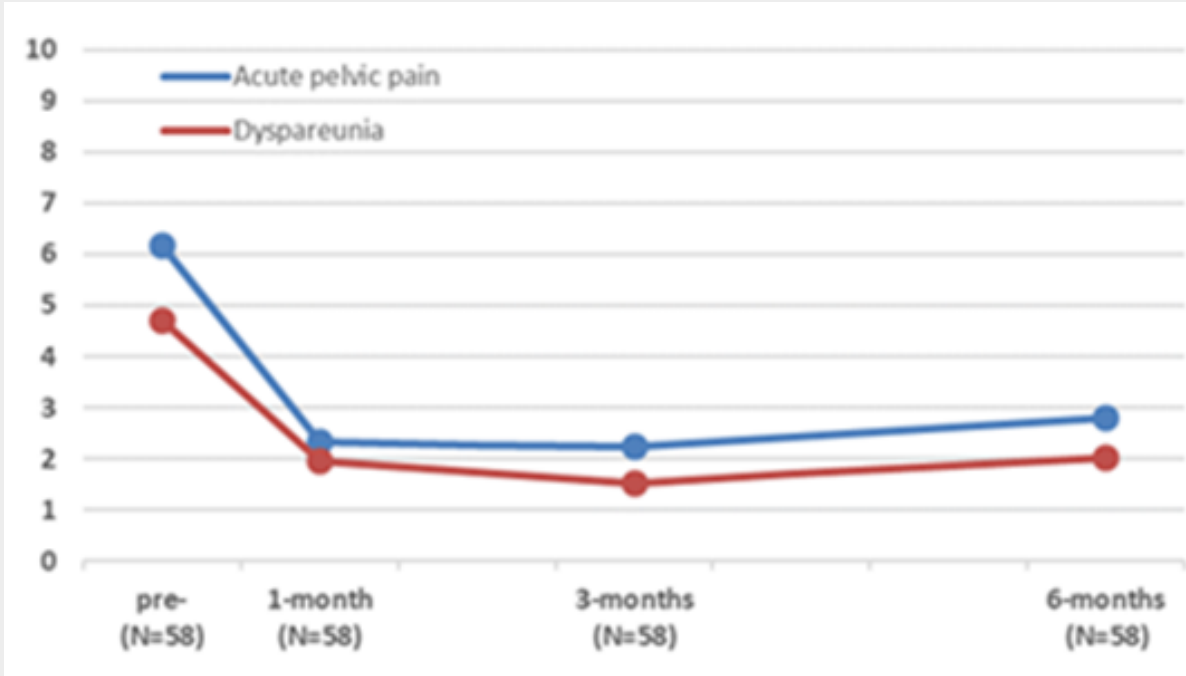
Limited adverse events

System Class Organ (SOC)	Clavien 1	Clavien 2	Overall
Overall	50.0%	3.3%	53.3%
Gastrointestinal disorders ⁽²⁾	36.7%	-	36.7%
Reproductive system disorders ⁽³⁾	18.3%	-	18.3%
General disorders	15.0%	-	15.0%
Renal and urinary disorders ⁽⁴⁾	3.3%	1.7%	3.3%
Injury, and procedural complications	na	na	-
Infections	-	1.7%	1.7%
Skin and subcutaneous disorders	1.7%	-	1.7%
Nervous system	1.7%	-	1.7%
Muskuloskeletal and connective tissue disorders	1.7%	-	1.7%



- **No Clavien grade 3**
- **No rectovaginal fistulae observed**
- **One severe adverse event (grade 2): bladder atony requiring autocatheterization (> 6 months)**
 - ➔ Independent safety committee didn't find any relationship with HIFU treatment but both hypogastric nerve plexus were involved by DIE and procedure was performed under spinal anesthesia

Improvement of symptoms



EVA (paired results)	pre-op (N=58)	1-mo (N=58)	3-mo (N=58)	6-mo (N=58)	p-value (1-mo)	p-value (3-mo)	p-value (6-mo)
Acute pelvic pain	6.17	2.33	2.22	2.79	0.000	0.000	0.000
Dyspareunia	4.69	1.95	1.52	2.03	0.000	0.000	0.000
Diarrhea	3.03	1.26	1.07	1.16	0.000	0.000	0.000
Constipation	4.69	1.95	1.95	2.16	0.000	0.000	0.000
Rectal bleeding	1.03	0.4	0.19	0.43	0.011	0.002	0.035
False-urges	2.59	0.88	0.59	0.64	0.000	0.000	0.000
Tenesmus/Spasms	5.67	2.62	2.72	2.83	0.000	0.000	0.000
Pain on defecation	3.88	1.16	1.09	1.31	0.000	0.000	0.000
Posterior Pelvic Pain	3.6	1.62	1.41	2.09	0.000	0.000	0.004
Asthenia	6.38	4.31	3.76	4.24	0.000	0.000	0.000

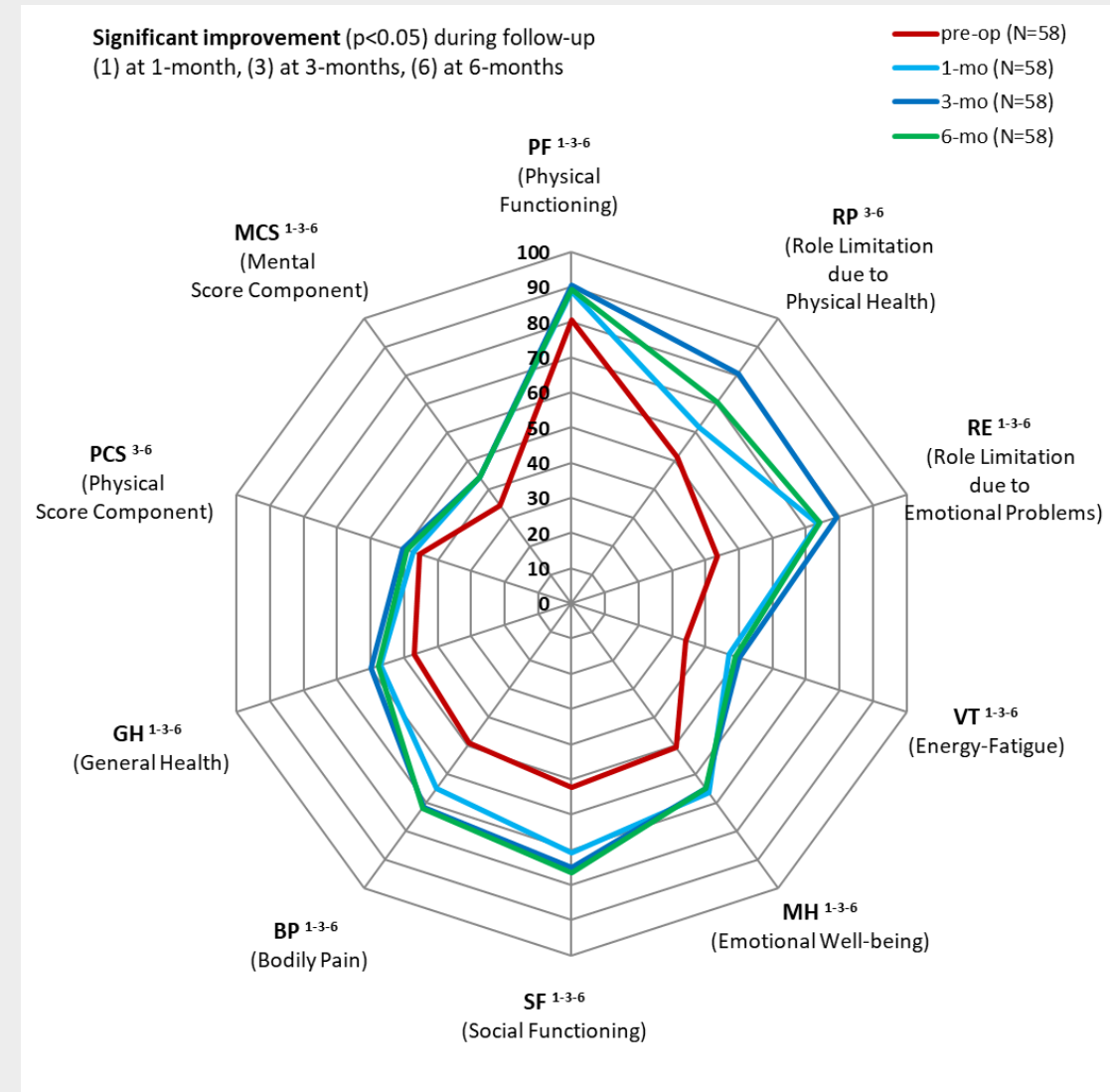
No significance difference between 2 consecutive follow-up visits (1 after 3-months and 3 after 6-months)

Improvement of Health Status (SF-36 questionnaire)

- Quality of Life was significantly improved at 1 month and & remained improved at 3 and 6 months

EVA (paired results)	pre-op (N=58)	1-mo (N=58)	3-mo (N=58)	6-mo (N=58)	p-value (1-mo)	p-value (3-mo)	p-value (6-mo)
PF (Physical Functioning)	80.6	88.7	90.5	89.1	0.000	0.000	0.000
RP (Role limitation due to Physical Health)	51.3	61.6	80.6	70.7	0.136	0.000	0.004
RE (Role limitation due to Emotional Problems)	43.7	73.6	79.3	74.1	0.000	0.000	0.000
VT (Energy/Fatigue)	34.1	47	50.3	48.8	0.000	0.000	0.000
MH (Emotional well-being)	50.6	66.3	65	65	0.000	0.000	0.000
SF (Social functioning)	52.4	70.9	75	76.5	0.000	0.000	0.000
BP (Bodily Pain)	49.2	65.1	71.6	71.9	0.000	0.000	0.000
GH (General Health)	46.8	57.1	59.8	57.8	0.000	0.000	0.000
PCS (Physical Score Component)	45.3	47.2	50.5	49.2	0.062	0.000	0.000
MCS Mental Score Component)	34.5	44.4	44.5	44.3	0.000	0.000	0.000
SF-36	409	530	572	554	0.000	0.000	0.000

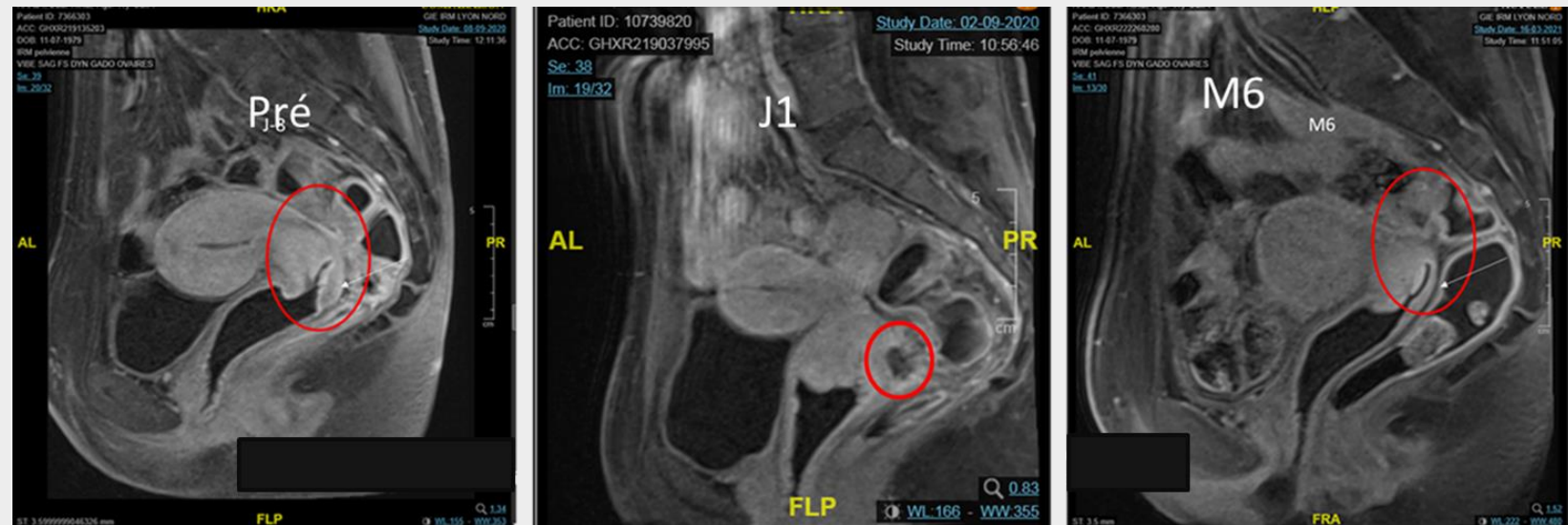
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Assessment of the nodule volume at 6 months

Volume decreased for **77%** patients

Methodology: an Independent & randomized review of pre- and 6 months post-treatment MRI was performed by a radiologist (N=57).



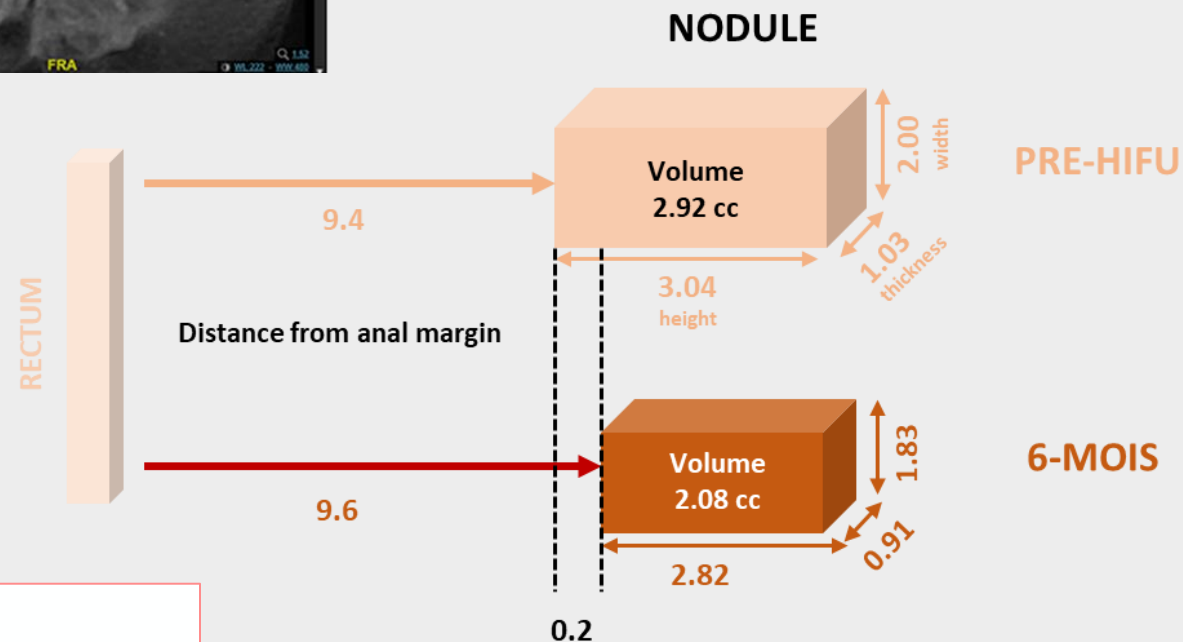
THICKNESS

Mean variation: **-11%** ($p < 0.001$)

VARIATION OF VOLUME

Mean variation: **-27%** ($p < 0.001$)

Volume variation was not correlated with symptom evolution



Conclusion

HIFU treatment of rectal endometriosis appears as :

- ✓ **A safe procedure compared with surgery** (no Clavien type 3 complication, no fistulae),
- ✓ **Low pain & medication level**
- ✓ **Efficient with a significant improvement of Digestive/Gynecologic symptoms and Health status, since the first month**
- ✓ **Cost-effective:** potential for outpatient procedure and fast recovery

2015-2018

Faisability study
(20 patients)



2019

Attenuation
study
(14 patients)



2019 - 2020

Safety study
(60 patients)

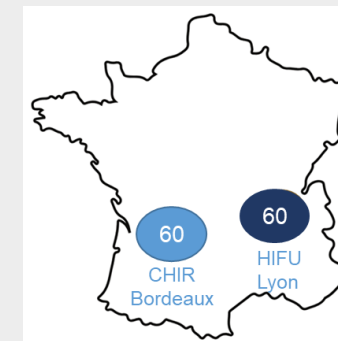


2023

Double blind
ttt vs sham study
(53/60 patients)



Comparative
retrospective study



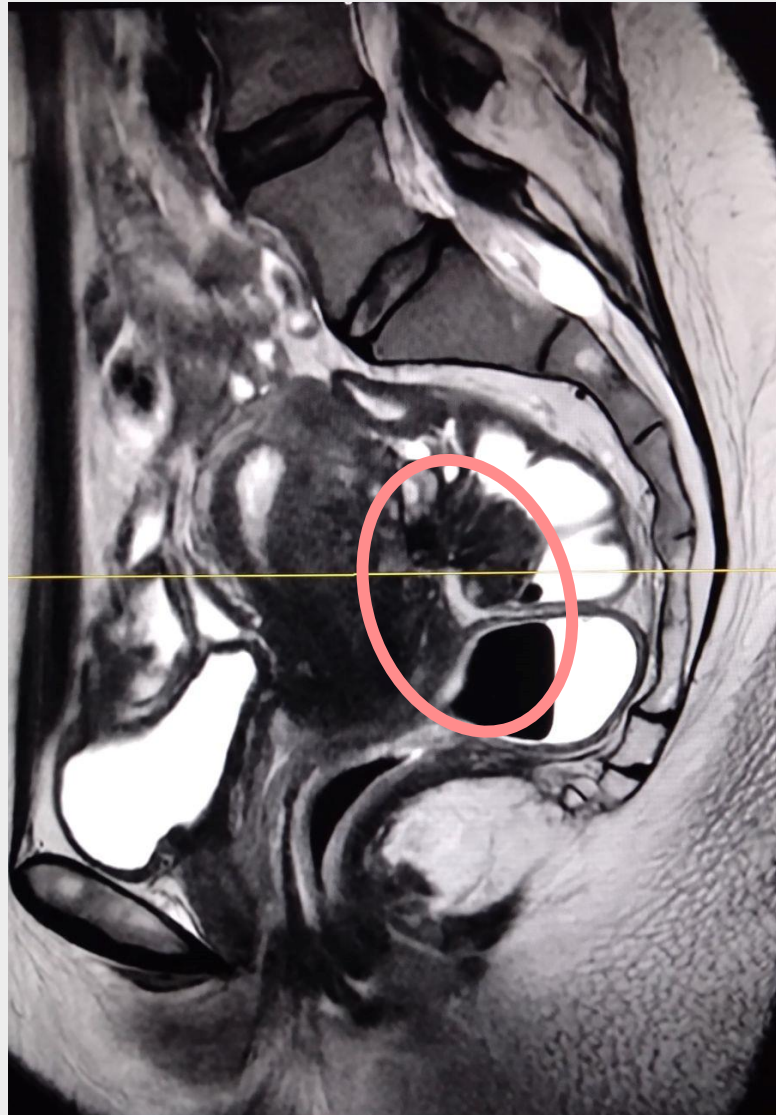
2024



Preclinical
study

Long term follow-up

53^{ème} / 60 Clermont Ferrand ce matin



Equipe clinique endométriose – Croix-Rousse



<https://www.brut.media/fr/health/un-traitement-par-ultrasons-contre-l-endometriose-au-chu-de-lyon> Brut.



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ET APPLICATIONS ULTRASONORES



8 HIFU Baby

SCGP

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