High-Intensity Focused Ultrasound for Uterine Fibroids: Advances, Comparative Outcomes, and Clinical Perspectives

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Received: 28 December 2025

Accepted: 2 July 2026

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DOI 10.5001/omj.2028.40

Abstract

Background: Uterine fibroids (leiomyomas) affect up to 80% of women by age 50 and are a leading indication for hysterectomy worldwide. High-intensity focused ultrasound (HIFU) has emerged as a non-invasive, uterus-sparing ablative option delivered under either MRI (MRgHIFU) or ultrasound (USgHIFU) guidance.

Objective: To synthesize current evidence on the biological rationale, technical modalities, clinical effectiveness, safety profile, reproductive outcomes, comparative efficacy, and limitations of HIFU in the management of symptomatic uterine fibroids.

Methods: A narrative review of peer-reviewed literature, systematic reviews, meta-analyses, and health technology assessments was conducted. Evidence was appraised with respect to fibroid volume reduction, symptom severity, quality of life, safety, re-intervention rates, and fertility and pregnancy outcomes.

Results: HIFU achieves mean fibroid volume reductions of 30–65% and symptom severity score improvements of 59.9–71% at 6–12 months. Health-related quality-of-life gains are comparable to surgical approaches. The safety profile is highly favourable, with major complications rare and no reported treatment-related deaths. Achieving a non-perfused volume (NPV) ratio ≥70% at the index procedure is associated with superior symptom control and a significantly lower risk of re-intervention. Re-intervention rates are higher than for myomectomy (5.2–21.6% at 1–2 years depending on modality and fibroid type). Post-HIFU pregnancy rates range from 18.7% to 78.5% across heterogeneous cohorts, ovarian reserve is preserved, and live birth rates are comparable to those after uterine artery embolization (UAE).

Conclusion: HIFU is a clinically effective and safe non-invasive option for symptomatic uterine fibroids, particularly for women desiring uterine preservation or future fertility. Its role should be integrated into individualized, multidisciplinary treatment pathways with transparent patient counselling regarding re-intervention probability and the current limitations of the evidence base.

Keywords: high-intensity focused ultrasound; uterine fibroids; leiomyoma; MRgHIFU; USgHIFU; uterus-sparing treatment; fertility preservation; non-perfused volume

Introduction

Uterine fibroids, also termed leiomyomas, are benign monoclonal smooth-muscle tumors of the myometrium and represent the most common tumors of the female reproductive tract.[1,2]Their true prevalence is difficult to quantify because many lesions remain asymptomatic and undetected; however, widely cited epidemiologic reviews indicate that the cumulative incidence by age 50 reaches approximately 70% in White women and exceeds 80% in Black women.[2] Only a minority of women with fibroids develop symptoms severe enough to require treatment, with most estimates placing the symptomatic proportion at roughly 20% to 30%, although this varies by population and ascertainment method. The clinical burden is disproportionately high among women of African descent, who tend to present at an earlier age and with significantly greater tumor burden and symptom severity than White women.[1]

Clinically significant fibroids are associated with heavy menstrual bleeding, pelvic pain, bulk-related pressure symptoms, impaired fertility, and adverse effects on physical function and quality of life.[2] Heavy menstrual bleeding frequently leads to iron-deficiency anemia, while large or strategically located fibroids can cause rectal or bladder pressure symptoms and chronic pelvic discomfort.[2] From a reproductive perspective, fibroids have been linked to implantation defects, recurrent pregnancy loss, preterm birth, malpresentation, placenta previa, postpartum hemorrhage, and higher rates of cesarean delivery.[2] Socioeconomically, fibroids impose a substantial burden through healthcare utilization, impaired daily functioning, and high direct costs; they remain a primary indication for hysterectomy globally.[1-3]

Historically, hysterectomy and myomectomy have been the definitive treatment options. While curative, both carry risks of operative morbidity, longer recovery times, and, in the case of hysterectomy, the complete loss of reproductive potential. Myomectomy remains the gold standard for uterus-preserving treatment in women desiring pregnancy, yet its clinical utility is often limited by recurrence, postoperative adhesions, and surgical morbidity.[2] Uterine artery embolization (UAE) provides a minimally invasive alternative, but concerns persist regarding its impact on ovarian reserve and long-term reproductive outcomes.[4,5]

Against this background, high-intensity focused ultrasound (HIFU) has emerged as a non-invasive, uterus-sparing treatment that induces localized coagulative necrosis within targeted fibroid tissue using either ultrasound (USgHIFU) or MRI (MRgHIFU) guidance.[6-8] Clinical studies and meta-analyses demonstrate that HIFU effectively improves fibroid-related symptoms and health-related quality of life with a low rate of major complications, making it a highly attractive option for women seeking uterine preservation.[9-11] However, HIFU also has important limitations: pooled analyses report higher re-intervention rates compared to UAE and myomectomy, and its comparative durability remains less certain over long-term follow-up.[6,12,13] Reproductive outcome data after HIFU are encouraging, showing favorable pregnancy and delivery rates, but the evidence remains heterogeneous and largely retrospective.[14,15]

The aim of this narrative review is to synthesize current evidence on the biological rationale, technical modalities, clinical effectiveness, safety profile, reproductive outcomes, and limitations of HIFU in the management of symptomatic uterine fibroids. By clarifying the role of HIFU within individualized, patient-centered treatment strategies, we aim to provide a clearer framework for clinical decision-making, particularly for women desiring future childbearing.[12,14,16]

PRINCIPLES AND MECHANISM OF ACTION OF HIFU

• *Mechanism of Action*

HIFU delivers high-energy ultrasound waves that converge at a precisely defined focal point within the target tissue, where acoustic energy is converted into heat.[7,8,17,18] At this focal zone, tissue temperature can rise to approximately 60–85°C within seconds, producing immediate coagulative necrosis in a sharply confined lesion.[7,18,19] While both thermal and mechanical effects contribute to the treatment, thermal ablation remains the dominant established mechanism in clinical fibroid therapy.[8,18,20]

Mechanical effects include acoustic cavitation and radiation-associated tissue effects, which can enhance heating and tissue disruption; however, uncontrolled cavitation also poses a risk of prefocal injury if not strictly monitored.[7,8,17,21] The resulting focal lesion is typically only a few millimeters in size, which allows for the sparing of tissue along the beam path and surrounding structures when targeting is accurate.[8,18,19] Because it is non-incisional and radiation-free, HIFU is frequently delivered as an outpatient or day-case procedure, facilitating rapid patient recovery.[8,22]

In the management of uterine fibroids, clinical response is closely linked to the achieved non-perfused volume (NPV) immediately following ablation.[20,23,24] Evidence from non-resective treatment studies indicates that MR-guided non-perfused volumes greater than 20% are associated with sustained symptom relief at 24 months, with higher ablation percentages generally correlating with superior clinical outcomes.[20] Under updated MR-HIFU protocols that utilize unrestrictive treatment parameters, the pooled mean NPV is approximately 68.1%, with a corresponding mean symptom reduction at 12 months of 59.9% and a mean fibroid volume shrinkage of 37.7%.[23]

• *Technical Modalities: MRgHIFU vs. USgHIFU*

Two primary HIFU approaches are utilized clinically: MRI-guided HIFU (MRgHIFU/MRgFUS) and ultrasound-guided HIFU (USgHIFU).[18,22,24,25]

MRgHIFU combines focused ultrasound with MRI, which provides superior soft-tissue contrast for precise anatomical localization and real-time MR thermometry for rigorous thermal-dose monitoring.[18,24,25] Early clinical MRgFUS studies demonstrated that 79.3% of treated women reported significant symptom improvement at 6 months, with an initial mean fibroid volume reduction of 13.5%.[24] In a subsequent multicenter trial, 71% of women achieved targeted symptom reduction at 6 months and 51% at 12 months, with a low incidence of adverse events.[20] Long-term follow-up data further reveal that Type 1 and Type 2 myomas (based on T2-weighted signal intensity) show mean volume reductions of 36.5% at 6 months and 39.5% at 24 months. Notably, the 24-month re-intervention rates were 14.0% for Type 1/2 myomas compared to 21.6% for the more resistant Type 3 myomas.[26]

USgHIFU utilizes real-time ultrasound for both targeting and monitoring. Unlike MRgHIFU, treatment feedback is based primarily on grey-scale image changes during ablation rather than quantitative thermometry.[18,22] USgHIFU is generally more accessible and less resource-intensive than MRgHIFU, offering lower costs and broader clinical availability.[18,22] A comparative meta-analysis for fibroids with volumes under 300 cm^3 found mean NPVR values of 81.07% for USgHIFU versus 58.92% for MRgHIFU, with 1-year re-intervention rates of 5.2% and 13.4%, respectively.[11] However, direct head-to-head comparisons between these platforms remain limited, and clinical success continues to depend heavily on the specific protocol, fibroid phenotype, and the completeness of the initial ablation.[21,23,24]

THE HIFU PROCEDURE AND PATIENT SELECTION

• *The Clinical Procedure and Patient Experience*

Understanding the procedural experience is essential for informed consent and for meaningful comparison with alternative uterus-preserving treatments. Prior to the procedure, patients undergo comprehensive pre-procedural imaging—typically MRI—to confirm fibroid dimensions, localization, and technical accessibility, and to ensure a safe acoustic pathway free of intervening bowel or scars.[10,27,28] For both MRgHIFU and USgHIFU, meticulous treatment planning is required to protect adjacent structures, such as the bladder, rectum, and sacral nerves.[17,19,27,28]

HIFU is a non-invasive procedure that generally obviates the need for general anesthesia.[27,29,30] Most clinical protocols utilize conscious sedation and analgesia, although some centers may employ monitored anesthesia care (MAC) to ensure patient immobility and comfort during longer treatment sessions.[19,27,28] During the procedure, energy is delivered in sequential sonications to the planned target volumes under continuous real-time image guidance. Patients are typically awake and able to provide immediate feedback regarding any heat-related discomfort or leg pain, which serves as a critical safety monitor for the adjacent pelvic nerves.[17,27,30]

Procedure duration varies substantially based on the total fibroid volume, number of lesions, and the specific device platform used. While MRgHIFU is often more time-consuming due to the constraints of the MRI environment and thermometry cooling cycles, USgHIFU is generally perceived as more operationally flexible.[11,27,30] Following the procedure, patients undergo a brief period of observation and are typically discharged on the same day. Recovery is remarkably rapid; most patients return to normal daily activities within 24 to 48 hours, significantly faster than the recovery periods associated with myomectomy or hysterectomy.[6,27,29]

• *Operator Qualifications and Learning Curve*

HIFU is a technically demanding, image-guided intervention that requires specialized expertise in patient selection, pelvic imaging interpretation, and real-time targeting strategies.[27,28,30] Clinical outcomes are not merely a function of the technology but are heavily influenced by treatment planning, the thoroughness of the ablation, and institutional experience.[11,13,31] The 2024 HAS assessment underscores that HIFU should be performed in experienced centers with high procedural volumes and strict adherence to standardized selection criteria to optimize patient safety and clinical durability.[28]

• *Patient Selection and Fibroid Characteristics*

Successful outcomes in HIFU are fundamentally rooted in careful patient selection. The ideal candidates are women with symptomatic fibroids that are clearly visualized on pre-treatment imaging and safely accessible via an acoustic window that avoids the bowel, sacral region, and extensive abdominal wall scarring.[10,27,28]

MRI is the gold standard for pre-treatment assessment, as it provides critical information on fibroid vascularity and signal characteristics that predict ablation efficiency.[10,31] T2 weighted signal intensity has emerged as a primary predictor of the NPVR. Hypointense fibroids (low T2 signal) generally exhibit the highest response rates, whereas hyperintense fibroids (high T2 signal) often reflect higher vascularity or cellularity, which can lead to "heat-sink" effects, lower ablation efficiency, and a significantly higher risk of long-term re-intervention.[10,13,31] Additionally, while HIFU can be used in patients with coexisting adenomyosis, such cases require cautious management and specialized protocols, as extensive adenomyosis can complicate the assessment of treatment success.[28,30]

CONTRAINDICATIONS TO HIFU

Contraindications to HIFU are primarily categorized into absolute safety exclusions and relative technical limitations. Absolute contraindications consistently identified in evidence-based assessments include known or suspected uterine malignancy, pregnancy, active pelvic inflammatory disease, and clinical scenarios where an adequate acoustic window cannot be established.[17,27,28] Technical contraindications also include the inability to safely protect adjacent organs—such as the bowel, bladder, or sacral nerves—due to intervening structures or extensive abdominal scarring that could lead to thermal injury.[7,19,28]

Relative contraindications, or predictors of poor response, include heavily calcified fibroids and hyperintense (T2-bright) lesions. These are increasingly viewed as technical challenges rather than universal exclusions; while they are associated with reduced ablation efficiency and a higher risk of re-intervention, treatment may still be considered based on individualized patient goals and fibroid location.[10,13,31] Furthermore, while caution is advised in patients with pelvic metal implants or intrauterine devices (IUDs), these are not always absolute contraindications if they do not lie directly within the acoustic pathway or the immediate thermal field.[27,28]

Table 1: Patient Selection Criteria, Predictors of Response, and Contraindications for HIFU

Category	Criteria / Factor	Clinical Implication	References
Ideal Candidate	Symptomatic fibroids (AUB, bulk symptoms); uterus clearly visualized on MRI; safe acoustic window	Best outcomes with hypointense (T2-dark) fibroids and unobstructed beam path	10,27,28
Fibroid Characteristics (Favourable)	Hypointense on T2-weighted MRI (Funaki type I–II); single or few fibroids; volume <500 mL	Higher NPV ratio, greater volume reduction, lower re-intervention risk	10,13,31

Fibroid Characteristics (Poor Response)	Hyperintense on T2-weighted MRI (Funaki type III); heavily calcified lesions	Reduced ablation efficiency; heat-sink effect; higher re-intervention rates	[10,13,31]
Absolute Contraindications	Known/suspected uterine malignancy; pregnancy; active pelvic inflammatory disease; no safe acoustic window	Procedure must not be performed	[17,27,28]
Technical Contraindications	Inability to protect bowel, bladder, or sacral nerves; extensive abdominal scarring in beam path	Risk of thermal injury to adjacent structures	[7,19,28]
Relative Contraindications	Coexisting adenomyosis; pelvic metal implants or IUD not in acoustic path	Requires individualized assessment and specialized protocols	[27,28]
Pre-treatment Assessment	Contrast-enhanced MRI mandatory (MRgHIFU); strongly recommended before USgHIFU	Characterizes fibroid signal, size, location, and acoustic path safety	[10,16]

CLINICAL EFFECTIVENESS

• Fibroid Volume Reduction

Fibroid volume reduction is the most consistently utilized objective measure of HIFU success. Meta-analyses and systematic reviews report a mean volume reduction ranging from 30% to 65% within the first 12 months following treatment.[12,23,29,32] In a systematic review of MRgHIFU under unrestrictive protocols, the mean fibroid shrinkage was 37.7% at 12 months.[23] This reduction typically begins rapidly in the first three months and continues at a more gradual pace through 24 months, significantly contributing to the relief of bulk-related symptoms such as pelvic pressure and urinary frequency.[12,26]

• Symptom Control, Functional Recovery and Quality of Life

Clinical Symptom Relief and the Role of NPV

Clinical symptom relief following HIFU is both substantial and rapid, with significant reductions in heavy menstrual bleeding and pelvic pain typically observed within the first three to six months.[12,23,32] Most clinical series report meaningful symptom improvement in 60% to 75% of patients during the first year of follow-up.[12,23,32] A critical finding across contemporary literature is that clinical success is fundamentally driven by the completeness of the initial ablation; specifically, the achieved NPV serves as the primary predictor of durable symptom control.[20,23,26] Studies suggest that an NPV ratio exceeding 70% is associated with superior clinical outcomes and a significantly lower risk of symptom recurrence or the need for secondary interventions.

Quality of Life Improvements

The improvement in health-related quality of life (HRQoL) is one of the most compelling advantages of the HIFU approach. Studies utilizing validated instruments, most notably the Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire, consistently demonstrate marked and sustained gains across all HRQoL domains.[6,12,20,27]

In a landmark multicenter trial, the mean Symptom Severity Score (SSS) improved significantly, with subjects having a mean decrease of 39% and 36% at 6 and 12 months, respectively.[20] Furthermore, comparative meta-analyses indicate that the HRQoL gains achieved with HIFU are often equivalent to those observed after more invasive surgical options, such as myomectomy, despite the less aggressive nature of the non-invasive ablation.[6,16] This suggests that for many patients, the avoidance of surgical morbidity contributes significantly to overall treatment satisfaction.

Functional Recovery and Socioeconomic Impact

The non-invasive nature of HIFU translates into a superior recovery profile that distinguishes it from all other surgical uterus-preserving treatments. Functional recovery is exceptionally rapid, with the majority of patients resuming normal daily activities and returning to professional work within 24 to 72 hours of the procedure.[6,27,29]

This abbreviated recovery window contrasts sharply with traditional myomectomy and hysterectomy, which typically necessitate an inpatient stay of several days and a total recovery period of four to six weeks before a patient returns to their functional baseline.[1,2,6,33] From a socioeconomic perspective, this rapid return to productivity markedly reduces the indirect costs of fibroid treatment, such as work absenteeism and the need for prolonged post-operative care, making HIFU a potentially cost-effective strategy in the management of symptomatic leiomyomas.[3]

Table 2 summarizes key clinical outcomes.

Table 2: Summary of Key Clinical Outcomes Following HIFU.

Outcome	**Evidence-Based Summary**	**References**	**Follow-up**
Fibroid Volume Reduction	Mean reduction 30–65%; shrinkage plateaus at 12–24 months.	12,23,29,32	6–24 months
Symptom Improvement	Mean symptom reduction of 59.9% at 12 months (MR-HIFU unrestrictive protocols); 71% of patients achieved symptom response at 6 months in multicenter trial.	20,23	6–24 months
Quality of Life (HRQoL)	Significant improvements comparable to surgical outcomes on validated scales (SSS).	6,16	Up to 24 months
Re-intervention Rate (MRgHIFU, by Funaki type)	14.0% for Type 1–2 (Funaki) myomas; 21.6% for Type 3 myomas.	26	24 months
Re-intervention Rate (by modality, fibroids <300 cm^3)	5.2% (USgHIFU) vs. 13.4% (MRgHIFU).	11	1 year

SAFETY PROFILE AND COMPLICATIONS

• *General Safety Profile*

HIFU is associated with a highly favorable safety profile, particularly when compared to invasive surgical alternatives. Systematic reviews and clinical trials consistently demonstrate that serious complications are rare, with the vast majority of adverse events being mild and transient in nature.[12,19,27,29] The incidence of major complications has significantly declined over the last decade, a trend attributed to refined treatment protocols, improved real-time thermometry, and the accumulation of institutional operator experience.[19,28]

• *Common and Transient Adverse Events*

The most frequently reported side effects include post-procedural pelvic pain or a "heavy" sensation, lower abdominal wall tenderness, and transient skin erythema at the transducer entry site.[8,19] These symptoms typically resolve within 24 to 72 hours with conservative management or over-the-counter analgesics.[19] A small proportion of patients may experience a low-grade fever or vaginal discharge (sloughing of necrotic tissue), which are generally self-limiting and do not require formal intervention.[19,23]

• *Rare but Clinically Significant Complications*

Although rare, certain complications require specific clinical attention:

Skin Burns: While early studies reported higher rates of thermal skin injury, modern cooling protocols and the use of degassed water systems have reduced this risk to well below 1% in most recent series.[6,19,29]

Nerve Irritation: Transient irritation of the sacral nerves or sciatic nerve can occur if the thermal field extends beyond the posterior uterine wall. When protocols are strictly followed, permanent nerve injury is exceedingly rare, with most cases resolving fully within weeks.[19,27]

Bowel Injury: This represents the most serious potential complication of HIFU. It is typically avoided through meticulous pre-procedural planning and the use of mitigation maneuvers. Current data suggest the incidence of bowel injury is extremely low (<0.1%) in experienced centers.[19,28]

Table 3: Summary of the Safety Profile and Complications of HIFU.

Complication Domain	Evidence-Based Clinical Summary	Estimated Incidence	References
Pain/Discomfort	Mild pelvic or lower back pain; typically resolves within 48 h.	Common (10–25%)	19,20
Skin Erythema	Superficial redness at the entry site; Grade 1 burns are rare.	Uncommon (<3%)	19,29
Nerve Irritation	Transient leg pain or paresthesia; usually self-limiting.	Rare (1–2%)	19,27
Bowel/Bladder Injury	Major adverse event; avoided by strict acoustic windowing.	Very Rare (<0.1%)	19,28
Post-ablation Fever	Mild inflammatory response to tissue necrosis.	Rare (<1%)	19

RE-INTERVENTION AND DURABILITY

A recognized limitation of HIFU is its higher cumulative re-intervention rate when compared with definitive surgical treatments. Systematic reviews and long-term follow-up studies report that re-intervention rates for HIFU increase over time, typically exceeding those of myomectomy and, in several series, surpassing those of UAE.[6,13,34] The necessity for secondary treatment is often linked to incomplete initial ablation (NPV <70%) or the regrowth of existing or new fibroids. However, it is clinically significant that re-intervention after HIFU is generally not associated with increased surgical morbidity; repeat HIFU or subsequent surgery remains technically feasible and safe.[6,34]

Table 4: Comparative Re-Intervention Patterns.

Treatment	Relative Durability Pattern	References
HIFU	Higher re-intervention; cumulative rates increase over 3–5 years.	6,13,34
Myomectomy	Lower re-intervention than HIFU; considered the gold standard for durability.	2,34
UAE	Intermediate; often lower than HIFU but higher than surgery.	5,25
Hysterectomy	Definitive treatment; zero re-intervention for fibroids.	1,5

Fertility and Pregnancy Outcomes

Fertility preservation is a key consideration for many women undergoing fibroid treatment. Cumulative evidence indicates that HIFU does not preclude subsequent pregnancy and may support favorable reproductive outcomes. In a single-center retrospective study of 189 nulliparous women who were actively attempting conception, the pregnancy rate was 69.3%, with 95.4% of these being spontaneous and 74.0% conceiving within one year.[35] In a larger multicenter comparison of 676 women, the pregnancy rate was 68.4% after USgHIFU versus 66.7% after laparoscopic myomectomy, with a significantly shorter mean time to pregnancy in the HIFU group (13.6 ± 9.5 vs. 18.9 ± 7.3 months; $p<0.05$).[36] A 2023 systematic review and meta-analysis reported a wide range of post-HIFU pregnancy rates (18.69%–78.53%), reflecting heterogeneity in study populations and follow-up periods.[37] A more recent cohort study observed an overall pregnancy rate of 40.4%, with 88.1% of these being natural conceptions.[38]

Regarding live birth and miscarriage, the same 2023 meta-analysis reported pooled live birth rates of 73.5% for USgHIFU, 70% for MRgHIFU, 70.8% for UAE, and 75% for transcervical radiofrequency ablation.[37] Miscarriage rates after HIFU are generally comparable to those following myomectomy and lower than those reported after UAE; for instance, studies have reported HIFU miscarriage rates of 14.9%[35] and 17.8%,[39] whereas UAE has been associated with higher rates, such as 19.2%.[37]

When comparing fertility outcomes to laparoscopic myomectomy, systematic reviews indicate that women undergoing HIFU may achieve higher rates of spontaneous pregnancy, spontaneous delivery, and full-term delivery, though some data suggest potential risks of miscarriage or postpartum complications.[16] Wu et al. reported a lower cesarean delivery rate after USgHIFU compared to laparoscopic myomectomy (41.6% vs. 54.9%; $p<0.05$).[36] While the incidence of complications such as placenta increta, placenta previa, and postpartum hemorrhage is relatively low after HIFU, some studies have noted a higher incidence of preterm birth, fetal distress, fetal growth restriction, and puerperal infection compared to laparoscopic myomectomy.[36] Clinicians should counsel patients regarding these findings, particularly the need for close obstetric surveillance regarding placental implantation.[37]

Ovarian reserve is preserved following HIFU. In a study of 84 women of reproductive age, median anti-Müllerian hormone (AMH) concentrations showed no significant change six months post-treatment (1.26 ng/mL before to 1.27 ng/mL after).[40] Similarly, MR-HIFU has been shown to have no negative impact on ovarian reserve regardless of fibroid location or total acoustic energy delivered.[41] Prospective cohorts confirm stable AMH levels up to six months post-treatment,[42] and randomized controlled trials have even demonstrated higher AMH levels six months after HIFU compared to laparoscopic myomectomy (2.39 ng/mL vs. 2.15 ng/mL; $p<0.05$).[43]

Table 5: Reproductive Outcomes After HIFU.

Outcome	Reported Range / Value	References
Pregnancy rate (actively attempting)	69.3%; 68.4% vs. 66.7% LM	[35,36]
Pregnancy rate (mixed intent, larger cohorts)	40.4%; pooled range 18.7–78.5%	[37,38]
Spontaneous pregnancy proportion	95.4%	[35]
Time to pregnancy	13.6 months vs. 18.9 months (LM)	[36]
Live birth rate	73.5% (USgHIFU); 70% (MRgHIFU)	[37]
Miscarriage rate	14.9–17.8%; comparable to myomectomy; lower than UAE (19.2%)	[35,37,39]
Cesarean delivery rate	41.6% vs. 54.9% (LM)	[36]
Preterm birth	Higher with HIFU than LM in some series	[36]
Placental abnormalities	2.8% (USgHIFU) vs. 1.6% (UAE)	[37]
Uterine rupture	Rare but documented; no cases in large 281-delivery cohort	[37]
Ovarian reserve	Preserved at 6 months and 1–2 years	[40-43]

COMPARISON WITH OTHER TREATMENTS

A comprehensive evaluation of uterine fibroid management requires a critical assessment of the trade-offs between definitive surgical debulking and non-invasive, organ-preserving modalities. High-intensity focused ultrasound is frequently benchmarked against myomectomy, uterine artery embolization, and, less frequently, hysterectomy, necessitating a tailored approach to patient selection.

• HIFU Versus Myomectomy

Myomectomy remains the standard uterus-preserving surgical approach, particularly for women with symptomatic fibroids for whom fertility preservation is a priority. Laparoscopic, abdominal, and hysteroscopic myomectomy techniques achieve immediate and substantial reduction of tumor burden, often resulting in symptom improvement in 85–90% of patients.[1,2] Long-term data suggest re-intervention or recurrence rates of approximately 10–20% at five years following myomectomy.[1,2] However, myomectomy incurs the risks inherent to surgery, including significant intraoperative blood loss (estimated >500 mL in 10–25% of procedures), transfusion requirements (2–10%), adhesion formation (up to 55%), and hospital stays typically ranging from 2–5 days or longer depending on approach.[2,34]

HIFU, by contrast, offers a non-invasive alternative, with meta-analyses documenting clinically meaningful fibroid volume reduction and symptom severity score improvements comparable to surgical approaches.[11,27,29]

Recovery times after HIFU are significantly shorter, with rapid functional recovery and a favorable safety profile (see Safety Profile and Complications, above). However, re-intervention rates with HIFU tend to be higher over the long term.[6,11,32] While myomectomy generally demonstrates superior durability, the less invasive nature of HIFU and its favorable morbidity profile make it appealing, particularly for women who are poor surgical candidates, those with contraindications to anesthesia, or those prioritizing rapid recovery.

• *HIFU Versus Uterine Artery Embolization*

UAE is a minimally invasive radiologic technique that occludes uterine arteries to induce ischemic fibroid necrosis and symptom resolution. Symptom improvement following UAE ranges from 70–90%, with mean fibroid volume reductions of 40–60% at 6–12 months and sustained benefits in many patients.[4,5,28] UAE typically requires short hospital admission with recovery over 1–2 weeks and is associated with post-embolization syndrome (pain, fever, nausea) in up to 30–40% of cases.[4,5]

Comparative meta-analyses indicate that HIFU may have a higher re-intervention rate than UAE (relative risk [RR] ≥4.06) and offers similar or somewhat less pronounced symptom burden reduction, but may confer advantages in pregnancy and ovarian function outcomes.[13,14,16] A network meta-analysis further showed that HIFU exhibits the lowest incidence of major complications within one year compared with surgery and UAE, along with shorter hospital stays and quicker recovery times.[11,28]

In summary, while UAE remains an effective minimally invasive option, especially for women not seeking future fertility, HIFU may be preferable for those prioritizing preservation of ovarian function and rapid convalescence, though patients should be counseled about potentially higher re-treatment probabilities.

Health Technology Assessment and Guidelines

Health technology assessments synthesize clinical evidence and contextualize it within healthcare systems. The 2024 report by the French Haute Autorité de Santé (HAS) concluded that the published evidence regarding the efficacy of USgHIFU compared to myomectomy is of a low level of evidence and does not allow for a conclusion of equivalent, inferior, or superior efficacy of USgHIFU compared to myomectomy.[28]

International consensus documents reiterate similar findings. A comparative narrative review and meta-analysis by Liu et al. demonstrated higher quality-of-life improvements and lower complication rates with HIFU compared with surgery, though differences in re-intervention and pregnancy outcomes were not statistically significant in some analyses.[14] HAS and other expert bodies emphasize that HIFU is not universally superior to established surgical interventions, but represents an important option within a shared decision-making framework, particularly for women with moderate fibroid burden, a desire for non-invasive therapy, or contraindications to surgery.[28]

Emerging guidelines from radiologic and gynecologic societies support incorporating HIFU into multidisciplinary fibroid clinics, encouraging robust informed consent that includes discussion of long-term data limitations, reproductive goals, and comparative risks of other modalities.[6,10,28]

Limitations of Current Evidence

Despite its increasing use, the evidence base for HIFU has notable limitations. First, the literature is dominated by cohort studies, retrospective analyses, and observational trials; high-quality randomized controlled trials (RCTs) comparing HIFU directly with myomectomy or UAE are limited, and existing RCTs often lack sufficient power for key outcomes such as fertility or long-term re-intervention.[6,10,12]

Second, study heterogeneity is a consistent challenge. Differences in fibroid characteristics (size, number, location, imaging signal intensity), treatment modality (US-guided vs. MR-guided HIFU), and outcome definitions complicate pooling of data. Fibroid signal intensity on T2-weighted MRI, for example, has been shown to significantly affect re-intervention risk, with hyperintense fibroids exhibiting a 3.45-fold higher re-intervention risk compared to hypo-/isointense lesions.[32]

Third, reproductive outcome data after HIFU remain variably reported and subject to substantial heterogeneity. A 2023 systematic review and meta-analysis of 25 original articles reported that post-HIFU pregnancies ranged widely from 18.69% to 78.53%, reflecting differences in inclusion criteria, fibroid characteristics, treatment modality, and ascertainment of pregnancy intent.[37] Pooled live birth rates were comparable across modalities (USgHIFU 73.5%, MRgHIFU 70%, UAE 70.8%, TFA 75%), while miscarriage was highest in the UAE group (19.2%).[37] These results contrast indirectly with the Chen et al. 2024 meta-analysis reporting substantially lower pooled pregnancy (~23%) and live birth (~17%) rates after HIFU than after myomectomy (~57% pregnancy, ~44% live birth),[15] although methodological differences (criteria, populations, comparison groups) likely explain the divergence. This variability highlights the need for standardized reporting — pre-pregnancy counseling, fertility intent documentation, fibroid phenotyping, and minimum follow-up windows — to enable meaningful comparison across studies and modalities.

Fourth, long-term follow-up is variable, often limited to 1–3 years, and may underestimate later re-interventions or symptom recurrence. More robust longitudinal research with standardized outcome reporting is needed to clarify durability.

Finally, many studies lack standardized definitions for key endpoints such as symptom resolution, quality of life, fertility metrics, and re-intervention, impeding direct comparison across modalities and centers.[10-12]

Future Directions

Future research should focus on addressing the current evidence gaps through well-designed, multicenter RCTs that compare HIFU with myomectomy and UAE across meaningful endpoints including symptom burden, quality-of-life improvements, fertility outcomes, obstetric outcomes, and long-term re-intervention rates. Harmonized definitions of success and failure, standardized follow-up intervals, and stratification by fibroid characteristics will enhance comparability.[6,10,12]

Technological innovation remains a key area of advancement. Enhancing real-time imaging and thermometry accuracy, incorporating automated targeting systems, and optimizing energy delivery algorithms may improve non-perfused volume and reduce re-treatment rates. Artificial intelligence (AI) and machine learning tools could assist in treatment planning, predicting outcomes based on pre-treatment imaging, and identifying patients who are most likely to benefit.[11,32]

Reproductive outcomes require particular emphasis. Prospective registries and fertility-focused studies should measure not only pregnancy and live birth rates, but also time to conception, miscarriage, preterm birth, placental abnormalities, and uterine rupture risk. A 2023 meta-analysis pooled the following HIFU-associated pregnancy outcomes: USgHIFU live birth rate **73.5%**, MRgHIFU **70%**, miscarriage rate highest after UAE (**19.2%** vs UAE/HIFU-specific values ranging 14.9–17.8% across primary series), placental abnormalities **2.8% with USgHIFU vs 1.6% with UAE**, and elevated preterm birth, fetal distress, and fetal growth restriction in some direct comparisons with myomectomy.[35-37,39] Comparative analyses that adjust for age, baseline fertility status, fibroid phenotype, and pregnancy intent will be essential to disentangle treatment effects from underlying patient factors.[36,37]

Finally, health economic evaluations and quality-of-life assessments will inform cost–benefit considerations, helping to clarify HIFU's role within diverse healthcare systems and patient populations.[3]

Conclusion

In the context of symptomatic uterine fibroids, HIFU represents a clinically meaningful non-invasive treatment option that provides significant symptomatic relief, rapid recovery, and a favorable safety profile. It is associated with substantial fibroid volume reduction and quality-of-life improvement and serves as a valuable option for women seeking uterus preservation or those for whom surgery carries elevated risk. However, HIFU generally exhibits higher long-term re-intervention rates compared with myomectomy and may yield lower reproductive outcomes in some cohorts, underscoring the necessity of individualized counseling and careful patient selection. Although observational data suggest comparable fertility potential and obstetric safety in many cases, the current evidence base would benefit from additional high-quality comparative studies and standardized outcome reporting. With ongoing technological refinement and rigorous research, HIFU is poised to play an increasingly prominent role in personalized uterine fibroid management pathways.[28]

Disclosure

The authors declared no conflicts of interest. Written consent was obtained from the patient/kin of the patient.

References

1. Stewart EA, Laughlin-Tommaso SK. Uterine fibroids. N Engl J Med 2024 Nov;391(18):1721-1733. .

2. Bulun SE. Uterine fibroids. N Engl J Med 2013 Oct;369(14):1344-1355. .

3. Borah BJ, Carls GS, Moore BJ, Gibson TB, Moriarty JP, Stewart EA. Cost comparison between uterine-sparing fibroid treatments one year following treatment. J Ther Ultrasound 2014 Mar;2:7. .

4. Pron G, Mocarski E, Bennett J, Vilos G, Common A, Vanderburgh L; Ontario UFE Collaborative Group. Pregnancy after uterine artery embolization for leiomyomata: the Ontario multicenter trial. Obstet Gynecol 2005 Jan;105(1):67-76. .

5. de Bruijn AM, Ankum WM, Reekers JA, Birnie E, van der Kooij SM, Volkers NA, et al. Uterine artery embolization vs hysterectomy in the treatment of symptomatic uterine fibroids: 10-year outcomes from the randomized EMMY trial. Am J Obstet Gynecol 2016 Dec;215(6):745.e1-745.e12. .

6. Wang Y, Geng J, Bao H, Dong J, Shi J, Xi Q. Comparative effectiveness and safety of high-intensity focused ultrasound for uterine fibroids: a systematic review and meta-analysis. Front Oncol 2021 Mar;11:600800. .

7. Haar GT, Coussios C. High intensity focused ultrasound: physical principles and devices. Int J Hyperthermia 2007 Mar;23(2):89-104.

8. Bachu VS, Kedda J, Suk I, Green JJ, Tyler B. High-intensity focused ultrasound: a review of mechanisms and clinical applications. Ann Biomed Eng 2021 Sep;49(9):1975-1991. . Published online 10 Aug 2021.

9. Fennessy FM, Tempany CM, McDannold NJ, So MJ, Hesley G, Gostout B, et al. Uterine leiomyomas: MR imaging-guided focused ultrasound surgery–results of different treatment protocols. Radiology 2007 Jun;243(3):885-893. .

10. Zheng S, Rong Y, Zhu H, Zhang X, Liu X, Wu Y, et al. Role of magnetic resonance-high intensity focused ultrasound (MR-HIFU) in uterine fibroids management: an updated systematic review and meta-analysis. Wideochir Inne Tech Maloinwazyjne 2022 Mar;17(1):83-94. .

11. Yu L, Zhu S, Zhang H, Wang A, Sun G, Liang J, et al. The efficacy and safety of MR-HIFU and US-HIFU in treating uterine fibroids with the volume <300 cm^3: a meta-analysis. Int J Hyperthermia 2021;38(1):1126-1132. .

12. Yan L, Huang H, Lin J, Yu R. High-intensity focused ultrasound treatment for symptomatic uterine fibroids: a systematic review and meta-analysis. Int J Hyperthermia 2022;39(1):230-238. .

13. Li S, Ma WW, Yang MJ, Deng YB, Hu L, Chen JY. Long-term re-intervention after USgHIFU and prediction of NPVR in different ages of patients with uterine fibroids. Int J Hyperthermia 2024;41(1):2304264. .

14. Anneveldt KJ, van 't Oever HJ, Nijholt IM, Dijkstra JR, Hehenkamp WJ, Veersema S, et al. Systematic review of reproductive outcomes after high intensity focused ultrasound treatment of uterine fibroids. Eur J Radiol 2021 Aug;141:109801. .

15. Chen Y, Yi J, Lin S, Xie X, Liu X, Guo SW. Reproductive outcomes of high-intensity focused ultrasound ablation and myomectomy for uterine fibroids: a systematic review and meta-analysis. Reprod Biomed Online 2025 Jan;50(1):104436. .

16. Hu Y, Song X, Xu L, Zhou Z. High-intensity focused ultrasound is a better choice for women with fertility desire: a systematic review and meta-analysis of the comparison between high-intensity focused ultrasound and laparoscopic treatment of uterine fibroids. Gynecol Minim Invasive Ther 2023 Oct;13(2):79-89. .

17. Izadifar Z, Izadifar Z, Chapman D, Babyn P. An introduction to high intensity focused ultrasound: systematic review on principles, devices, and clinical applications. J Clin Med 2020 Feb;9(2):460. .

18. Zhou YF. High intensity focused ultrasound in clinical tumor ablation. World J Clin Oncol 2011 Jan;2(1):8-27. .

19. Ali MM, Raphael Mpehle C, Olusola E, Ratshabedi PK, Ragab Shehata A, Ashraf Youssef M, et al. A systematic review of the side effects of high-intensity focused ultrasound ablation of uterine fibroids. Proc (Bayl Univ Med Cent) 2024 Aug;37(6):947-956.

20. Stewart EA, Rabinovici J, Tempany CM, Inbar Y, Regan L, Gostout B, et al. Clinical outcomes of focused ultrasound surgery for the treatment of uterine fibroids. Fertil Steril 2006 Jan;85(1):22-29.

21. Coussios CC, Farny CH, Haar GT, Roy RA. Role of acoustic cavitation in the delivery and monitoring of cancer treatment by high-intensity focused ultrasound (HIFU). Int J Hyperthermia 2007 Mar;23(2):105-120.

22. Taheri M, Galo L, Potts C, Sakhel K, Quinn SD. Nonresective treatments for uterine fibroids: a systematic review of uterine and fibroid volume reductions. Int J Hyperthermia 2019;36(1):295-301.

23. Verpalen IM, Anneveldt KJ, Nijholt IM, Schutte JM, Dijkstra JR, Franx A, et al. Magnetic resonance-high intensity focused ultrasound (MR-HIFU) therapy of symptomatic uterine fibroids with unrestrictive treatment protocols: a systematic review and meta-analysis. Eur J Radiol 2019 Nov;120:108700.

24. Hindley J, Gedroyc WM, Regan L, Stewart E, Tempany C, Hynyen K, et al. MRI guidance of focused ultrasound therapy of uterine fibroids: early results. AJR Am J Roentgenol 2004 Dec;183(6):1713-1719.

25. Yerezhepbayeva M, Terzic M, Aimagambetova G, Crape B. Comparison of two invasive non-surgical treatment options for uterine myomas: uterine artery embolization and magnetic resonance guided high intensity focused ultrasound-systematic review. BMC Womens Health 2022 Mar;22(1):55.

26. Funaki K, Fukunishi H, Sawada K. Clinical outcomes of magnetic resonance-guided focused ultrasound surgery for uterine myomas: 24-month follow-up. Ultrasound Obstet Gynecol 2009 Nov;34(5):584-589.

27. Pron G. Magnetic resonance-guided high-intensity focused ultrasound (MRgHIFU) treatment of symptomatic uterine fibroids: an evidence-based analysis. Ont Health Technol Assess Ser 2015 Mar;15(4):1-86.

28. Haute Autorité de Santé. Evaluation of high-intensity focused ultrasound (HIFU) for the treatment of symptomatic uterine fibroids [INAHTA Brief]. Saint-Denis La Plaine: HAS; 2024.

29. Zhang L, Zhang W, Orsi F, Chen W, Wang Z. Ultrasound-guided high intensity focused ultrasound for the treatment of gynaecological diseases: a review of safety and efficacy. Int J Hyperthermia 2015 May;31(3):280-284. .

30. Kim YS. Clinical application of high-intensity focused ultrasound ablation for uterine fibroids. Biomed Eng Lett 2017 Jan;7(2):99-105.

31. Zhou Y, Zhang J, Li C, Chen J, Lv F, Deng Y, et al. Prediction of non-perfusion volume ratio for uterine fibroids treated with ultrasound-guided high-intensity focused ultrasound based on MRI radiomics combined with clinical parameters. Biomed Eng Online 2023 Dec;22(1):123. .

32. Ji Y, Hu K, Zhang Y, Gu L, Zhu J, Zhu L, et al. High-intensity focused ultrasound (HIFU) treatment for uterine fibroids: a meta-analysis. Arch Gynecol Obstet 2017 Dec;296(6):1181-1188. .

33. Sarli VG, Vogiatzoglou AL, Charalampos T, Sioutis D, Panagopoulos P, Machairiotis N. Laparoscopic myomectomy and pregnancy outcomes: a narrative review. Cureus 2025 Jul;17(7):e87268. .

34. Liang D, Li J, Liu D, Zhao H, Lin Y. Comparison of thermal ablative methods and myomectomy for the treatment of fibroids: a systematic review and meta-analysis. Int J Hyperthermia 2021;38(1):1571-1583. .

35. Li JS, Wang Y, Chen JY, Chen WZ. Pregnancy outcomes in nulliparous women after ultrasound ablation of uterine fibroids: a single-central retrospective study. Sci Rep 2017 Jun;7(1):3977. .

36. Wu G, Li R, He M, Pu Y, Wang J, Chen J, et al. A comparison of the pregnancy outcomes between ultrasound-guided high-intensity focused ultrasound ablation and laparoscopic myomectomy for uterine fibroids: a comparative study. Int J Hyperthermia 2020;37(1):617-623. .

37. Akhatova A, Aimagambetova G, Bapayeva G, Laganà AS, Chiantera V, Oppelt P, et al. Reproductive and obstetric outcomes after UAE, HIFU, and TFA of uterine fibroids: systematic review and meta-analysis. Int J Environ Res Public Health 2023 Mar;20(5):4480. .

38. Briones DA, Ma R, Zhou W, Xiong Y, Zhang L, Zou M, et al. Analysis of pregnancy outcomes and influencing factors in patients with uterine fibroids after high-intensity focused ultrasound ablation. Gynecol Minim Invasive Ther 2026 Feb;15(1):44-51. .

39. Bohlmann MK, Hoellen F, Hunold P, David M. High-intensity focused ultrasound ablation of uterine fibroids--potential impact on fertility and pregnancy outcome. Geburtshilfe Frauenheilkd 2014 Feb;74(2):139-145. .

40. Qu K, Mao S, Li J, Wang J, Ouyang G, Wang Z, et al. The impact of ultrasound-guided high-intensity focused ultrasound for uterine fibroids on ovarian reserve. Int J Hyperthermia 2020;37(1):399-403. .

41. Otonkoski S, Sainio T, Mattila S, Blanco Sequieros R, Perheentupa A, Komar G, et al. Magnetic resonance guided high intensity focused ultrasound for uterine fibroids and adenomyosis has no effect on ovarian reserve. Int J Hyperthermia 2023;40(1):2154575. .

42. Gu W, Yuan J, Zhou Y, Li Y, Wang Y. Impact of ultrasound-guided high-intensity focused ultrasound for the treatment of uterine fibroids on ovarian reserve and quality of life: a single-center prospective cohort study. BMC Womens Health 2024 Aug;24(1):470. .

43. Wang M, Zhu Q, Guan H, Zhao J, Gu P, Tang L. The impact of high-intensity focused ultrasound ablation and laparoscopic myomectomy on ovarian function in patients with uterine fibroids. Int J Womens Health 2025 Nov;17:4239-4245. .