surgeries

MDPI

Article

Transvaginal Ultrasound-Guided Radiofrequency Ablation of Uterine Fibroids: Narrative Literature Review and Exploratory Single-Center Case Series of a Structured Two-Step Technique

Francesco Giuseppe Cannone [1], Martina Billeci [1], Gianfranco Morreale [1], Ilaria Marilli [1], Giulia Roberta Arcidiacono [1] and Ferdinando Antonio Gulino [2,*]

[1] Unit of Gynecology and Obstetrics, Lentini Hospital, ASP Siracusa, 96016 Lentini, Italy; francesco.cannone@hotmail.it (F.G.C.); martinabilleci31@gmail.com (M.B.); gianfrancomorreale13@gmail.com (G.M.); ilariamarilli@virgilio.it (I.M.); ginecologia.lentini@asp.sr.it (G.R.A.)

[2] Unit of Gynecology and Obstetrics, Department of Human Pathology of Adults and Developmental Age "Gaetano Barresi", University of Messina, "G. Martino" University Hospital, 98124 Messina, Italy

* Correspondence: docferdi@hotmail.it

Abstract

Background/Objectives: Radiofrequency ablation (RFA) is a minimally invasive, uterus-preserving treatment for symptomatic uterine fibroids. This study aimed to summarize the current evidence on RFA performed through the vaginal route and to report the early outcomes of a structured two-step technique for transvaginal ultrasound-guided RFA (TV-RFA). **Methods:** A structured narrative review of studies published between January 2010 and May 2025 was performed. In addition, an exploratory, uncontrolled series of consecutive women treated with TV-RFA between June 2024 and March 2025 at a single center was analyzed (data cut-off: January 2026). The procedure consisted of radial "slicing" ablation of the myoma followed by ablation of its vascular base in all patients. The primary outcome was the change in the Uterine Fibroid Symptom and Health-Related Quality of Life (UFS-QOL) symptom severity score (SSS) from baseline to 6 months. **Results:** A total of 22 publications were included (18 on transcervical RFA, largely from two trial programs, and 4 on TV-RFA); they reported short- to mid-term improvements in symptoms, quality of life, and fibroid volume, with reintervention rates ranging from 5–8% in single-arm trials to 27% in a comparative cohort. In the institutional cohort (n = 46; mean fibroid diameter 6.2 cm), 40 women had completed the 6-month assessment. In these women, the SSS decreased from 62.3 ± 15.4 to 29.8 ± 13.1 (mean change −32.5 points; originally reported $p < 0.01$, which could not be independently verified because patient-level data were not retained), and 36 (90%) had a reduction of ≥10 points. One patient (2%) had spontaneous expulsion of necrotic tissue; no major adverse events or reinterventions were recorded. Several procedural and outcome variables were not recorded in the audit database. **Conclusions:** In this exploratory series, two-step TV-RFA was feasible and was followed by short-term symptom improvement. The incremental benefit of vascular-base ablation, comparative effectiveness, long-term safety, and reproductive outcomes remain to be established in controlled studies with longer follow-up and complete procedural reporting.

Academic Editor: Salomone Di Saverio

Received: 27 October 2026
Revised: 19 November 2026
Accepted: 26 November 2026
Published: 28 November 2026

Copyright: © 2026 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license.

Keywords: radiofrequency ablation; uterine fibroids; leiomyoma; transvaginal ultrasound; transcervical fibroid ablation; minimally invasive surgery; uterus-preserving treatment

1. Introduction

Uterine fibroids (leiomyomas) are the most common benign tumors of the female reproductive tract, affecting up to 70–80% of women by the age of 50 years [1,2]. They are composed of smooth muscle and fibrous tissue and may be single or multiple. The International Federation of Gynecology and Obstetrics (FIGO) classification divides fibroids into types 0 to 8 according to their position in the uterus and their relationship with the endometrium and the serosa: submucosal (types 0–2), intramural (types 3–4), subserosal (types 5–7), and fibroids in other locations, such as the cervix (type 8) [3]. Although many fibroids are asymptomatic, approximately one in three women experiences abnormal uterine bleeding, pelvic pain, pressure symptoms, urinary frequency, constipation and, in some cases, infertility or recurrent pregnancy loss [1].

The burden of uterine fibroids extends beyond individual health and represents a substantial economic challenge. Fibroids are among the leading indications for hysterectomy worldwide and contribute to increased healthcare utilization, loss of productivity, and reduced quality of life, underlining the need for less invasive, cost-effective, and uterus-preserving treatment strategies.

Traditional management includes hysterectomy, myomectomy, and uterine artery embolization (UAE) [2,4]. Hysterectomy remains the definitive therapy but is associated with surgical risks, prolonged recovery, and loss of fertility. Myomectomy, whether performed by laparotomy, laparoscopy, or hysteroscopy, preserves the uterus and is effective, but it requires general anesthesia and carries risks of intraoperative bleeding, adhesions, and recurrence. UAE is less invasive and provides satisfactory symptom control, but it involves exposure to ionizing radiation and may compromise ovarian reserve.

Over the past two decades, minimally invasive techniques have been developed to reduce morbidity while preserving the uterus. Among these, radiofrequency ablation (RFA) has emerged as a promising therapy [5]. RFA induces coagulative necrosis through the controlled delivery of thermal energy, resulting in progressive fibroid shrinkage and symptom relief. Initial applications were laparoscopic, but technical developments have enabled incisionless approaches through the vagina, using either a transcervical intrauterine ultrasound-guided device or a needle electrode guided by transvaginal ultrasound.

Incisionless RFA avoids abdominal incisions and has been associated with short hospital stay, rapid recovery, and minimal blood loss, while preserving the uterus [5,6]. Uterine preservation, however, should not be equated with demonstrated preservation of fertility, for which the evidence remains limited to uncontrolled case series [6]. Feasibility studies and multicenter single-arm trials have reported favorable outcomes in terms of bleeding reduction, pain relief, and health-related quality of life, with low complication rates; most adverse events are limited to transient pain, cramping, or minor vaginal discharge [5].

Most of the published evidence concerns transcervical fibroid ablation (TFA) with the VizAblate and Sonata systems, which was evaluated in the single-arm FAST-EU and SONATA trials [7,8]. Transvaginal ultrasound-guided RFA (TV-RFA) is a distinct technique in which a needle electrode is advanced through the vaginal fornix and the myometrium into the fibroid under real-time transvaginal ultrasound guidance, without the need for an intrauterine device [9]. Because the access route, device, and tissue path differ, findings obtained with TFA cannot be directly extrapolated to TV-RFA.

https://doi.org/10.3390/surgeries7040142

Despite encouraging results, RFA has not yet been universally adopted in routine gynecologic practice. This is partly due to the heterogeneity of study designs, the small size of many cohorts, and the limited long-term fertility data. Another important limitation is the lack of standardization of the procedural technique, which may contribute to variability in outcomes: incomplete or partial ablation may result in persistent symptoms or regrowth, underscoring the need for reproducible, systematic approaches.

To address these gaps, our Unit of Gynecology and Obstetrics at Lentini Hospital adopted a structured two-step sequence for TV-RFA, applied in a consecutive series of 46 women with symptomatic fibroids. The aims of this article are (1) to provide an updated structured narrative review of the literature on RFA of uterine fibroids performed through the vaginal route, considering transcervical and transvaginal evidence separately, and (2) to describe our early institutional experience with this procedural strategy as an exploratory, hypothesis-generating case series.

2. Materials and Methods

2.1. Literature Review

2.1.1. Search Strategy

This review was designed as a structured narrative review, without performing a full systematic review. An electronic search of PubMed/MEDLINE, Embase, the Cochrane Library, and Web of Science was performed for full-text articles published from January 2010 to May 2025. The search combined the terms "transvaginal radiofrequency ablation" OR "radiofrequency ablation" [MeSH] AND "fibroids" OR "myomas" OR "leiomyoma", supplemented with "transvaginal", "transcervical", and "ultrasound-guided". The search was limited to human studies published in English. The full database-specific search strings and the exact dates on which the searches were run were not archived; the search therefore cannot be reproduced exactly, which is acknowledged as a limitation.

2.1.2. Eligibility Criteria

Inclusion criteria were as follows:

- Prospective and retrospective clinical studies, randomized controlled trials, systematic reviews, or meta-analyses;
- Studies evaluating transcervical or transvaginal ultrasound-guided RFA of uterine fibroids;
- Studies reporting outcomes such as symptom relief, fibroid volume reduction, safety, or reproductive outcomes;
- Articles published in English.

Exclusion criteria were as follows:

- Case reports or case series with fewer than five patients;
- Studies focusing exclusively on laparoscopic or percutaneous transabdominal RFA;
- Non-peer-reviewed articles, conference abstracts without full text, and animal studies;
- Duplicate publications.

2.1.3. Study Selection and Data Extraction

Two independent reviewers screened titles and abstracts for relevance, and full texts were retrieved for potentially eligible studies. Discrepancies were resolved by consensus. The following data were extracted from each included publication: author, year, and country; study design and sample size; fibroid characteristics (size and FIGO type); intervention details (device, setting, and anesthesia); outcomes, including the symptom severity score (SSS), health-related quality of life (HRQoL), fibroid volume reduction,

reintervention rate, complications, and pregnancy outcomes; and duration of follow-up. Because several publications report different time points or subgroups of the same trial program, each publication was mapped to its parent cohort, so that publications could be distinguished from independent patient cohorts. Data were tabulated, and the narrative synthesis was conducted separately for TFA (feasibility, FAST-EU, SONATA, durability, health utility and economic evidence, fertility, and real-world studies) and for TV-RFA. No formal risk-of-bias tool was applied; the main design limitations of the underlying studies (single-arm design, sample size, attrition, and sponsorship) were appraised narratively.

2.2. Clinical Case Series

2.2.1. Study Design and Ethics

This was a single-center, uncontrolled, exploratory observational case series of consecutive women treated with TV-RFA between June 2024 and March 2025 at the Unit of Gynecology and Obstetrics of Lentini Hospital (ASP Siracusa), Italy. Data were collected prospectively within the hospital's quality-improvement audit program and analyzed retrospectively. The audit database was locked in January 2026, and the present analysis includes all assessments completed by that date. The study was conducted in accordance with the Declaration of Helsinki. TV-RFA was offered as routine clinical care with a commercially available device used within its intended purpose. The two-step sequence described below is a structured way of ordering the ablation passes within this routine procedure; it did not involve any additional device, investigation, visit, or intervention beyond standard care, and no patient was allocated to a treatment for research purposes. Three activities should be distinguished: the procedures, which were routine clinical care; the collection of outcome data, which was part of the unit's internal quality-improvement audit; and the retrospective analysis of the anonymized audit data for publication, which constitutes research. The project was not submitted to an ethics committee, and no formal approval or exemption was issued by an ethics committee or other authorized body. The decision not to seek ethics review was made by the clinical team because the analysis involved no intervention beyond standard care and only anonymized data; it was not based on a formal institutional policy or on a determination by an ethics committee or other authorized body. All patients provided written informed consent to the procedure and to the use of their anonymized clinical data for publication.

2.2.2. Patient Selection

Women were considered eligible for TV-RFA if they met the following criteria:

- Age ≥ 18 years;
- Symptomatic fibroids (e.g., heavy menstrual bleeding, pelvic pain or discomfort, urinary symptoms, or dyspareunia);
- Largest fibroid diameter ≤ 11 cm;
- Fewer than six fibroids;
- FIGO type 3, 4, 5, or 6 fibroids, or hybrid type 2–5 fibroids.

Coexisting adenomyosis was not considered an exclusion criterion, and its presence was not systematically recorded.

Exclusion criteria were as follows:

- Suspected malignancy;
- Severe systemic comorbidity contraindicating anesthesia;
- Active pelvic infection;
- Ongoing pregnancy.

All eligible patients completed the Uterine Fibroid Symptom and Health-Related Quality of Life (UFS-QOL) questionnaire at baseline [10]; the same validated questionnaire was administered at each follow-up visit to evaluate clinical outcomes.

Suitability for TV-RFA was determined by the treating gynecologists on the basis of the type and severity of symptoms; the number, size, FIGO type, and transvaginal accessibility of the fibroids; and the woman's reproductive intentions; a formal multidisciplinary review was not part of the pathway. All women were counseled on the available alternatives (expectant and medical management, hysteroscopic, laparoscopic or open myomectomy, UAE, and hysterectomy), on the limited evidence on the long-term outcomes of TV-RFA, and on the absence of established data on fertility and pregnancy after the procedure. TV-RFA was offered to women who preferred an incisionless, uterus-preserving option or who declined or were considered poor candidates for surgery or UAE. Desire for future pregnancy was discussed during counseling; it was neither a requirement nor an exclusion criterion, and women wishing to conceive were informed that myomectomy remains the reference uterus-preserving treatment in this setting. The series includes all consecutive women who underwent TV-RFA during the study period. The individual reason for choosing TV-RFA, reproductive intentions, and the number of eligible women who did not undergo the procedure were not recorded in the audit database.

2.2.3. Preoperative Work-Up

The preoperative work-up included the following.

- Laboratory tests: complete blood count and coagulation profile;
- Imaging: transvaginal ultrasound, with magnetic resonance imaging (MRI) in cases of diagnostic uncertainty;
- Counseling on alternative treatments (expectant and medical management, myomectomy, UAE, and hysterectomy), as described in Section 2.2.2.

Patients were admitted under a one-day hospital protocol, and most were discharged on the same day or on the following morning.

2.2.4. Surgical Technique

All procedures were performed in the operating theater, with the patient in the lithotomy position and the bladder emptied, under general anesthesia. Ablation was performed with the Myoblate system (RF Medical Co., Ltd., Seoul, Republic of Korea), consisting of the Mygen V-1000 radiofrequency generator (output frequency 480 kHz; maximum output power 140 W), the RFP-300 cooling pump, and an internally cooled, hyperechoic variable-tip electrode (VCTM 35XX series; diameter 1.65 mm, length 35 cm, adjustable active tip of 0.5–4.0 cm controlled by a thumb lever). The same generator and electrode type were used in all patients. Target fibroids were identified with transvaginal ultrasound. The electrode was introduced through a needle guide mounted on the transvaginal probe and advanced through the vaginal fornix and the myometrium into the fibroid, along a path planned with color Doppler to avoid the bladder, bowel, and major vessels, with the electrode tip kept under continuous real-time visualization. A tru-cut biopsy of the target fibroid was obtained through the same access during the same session, immediately before energy delivery. Because histology was not available at the time of ablation, the biopsy served to document the histology of the treated lesion and did not exclude malignancy before treatment; preoperative exclusion of suspected malignancy relied on clinical and imaging assessment (Section 2.2.3). A structured two-step sequence was applied:

- Step 1—myoma slicing. The RF electrode is inserted into the fibroid and ablation is performed in a "slicing" pattern: the electrode is advanced to the far margin of the

fibroid, energy is delivered, and the electrode is then withdrawn and redirected to the adjacent plane, moving radially like the hands of a clock until the entire volume of the myoma has been covered. This systematic sequence is intended to avoid random electrode movements and to reduce the risk of leaving viable tissue untreated;

- Step 2—vascular base ablation. The vascular pedicle or dominant feeding vessel of the fibroid is then targeted. Because the hyperechoic changes produced during Step 1 can obscure the grayscale image, the position of the dominant feeding vessel was mapped with color Doppler before Step 1 and recorded relative to anatomical landmarks; after Step 1, residual flow at the periphery of the fibroid was sought with color/power Doppler from an acoustic window not affected by gas artifacts, and the electrode was repositioned at that site for one or more additional applications. Targeting the blood supply is intended to enhance tissue necrosis. Step 2 was a mandatory part of the technique and was performed in all patients, after Step 1 and in the same session; it was not applied selectively according to residual vascularity or other intraoperative findings. The audit database, however, did not include a dedicated variable documenting the completion of each step in each patient.

This two-step sequence is intended to provide a structured method of covering the fibroid in a single session; because the technical parameters were not recorded (Section 2.2.5), it is not presented as a fully standardized or reproducible protocol. Whether it improves the completeness of ablation or clinical outcomes compared with other TV-RFA techniques was not tested in this study.

To protect the surrounding organs and the endometrial and serosal surfaces, the electrode tip was kept away from the serosa and from the endometrium under continuous ultrasound visualization, and energy delivery was stopped when the hyperechoic area approached the margin of the fibroid. A fixed minimum distance in millimeters was not prespecified or recorded. For FIGO type 6 fibroids, in which the lesion is in contact with the serosa and the risk of thermal injury to the bowel is higher, no additional protocolized precaution was recorded beyond these general measures.

2.2.5. Technical Parameters and Completion Criteria

Radiofrequency energy delivery was adjusted according to fibroid size and tissue response, following the manufacturer's recommendations. The generator was used in automatic mode in all procedures. The active tip length selected for each application, the power and temperature reached, and the duration and number of individual applications were not recorded for each procedure and therefore cannot be reported, which limits the reproducibility of the technique. Each application was continued until the treated area showed homogeneous hyperechogenicity on grayscale ultrasound, and Doppler ultrasound was used to assess the reduction or absence of intralesional flow. Both findings were used as intraprocedural surrogate markers of thermal coverage; they do not confirm complete ablation, which would require contrast-enhanced imaging and was not assessed in this series. The procedure was considered technically complete when circumferential coverage of the myoma had been obtained during the slicing phase and the dominant vascular base had been ablated. Active ablation time was defined as the cumulative time of energy delivery per fibroid, excluding electrode positioning; total procedure time and anesthesia time were not recorded. The cases treated during the initial familiarization phase with the device are not included in this series; the two-step sequence was applied consistently throughout the study period without major modifications.

2.2.6. Follow-Up and Outcomes

Patients were scheduled for clinical review and transvaginal ultrasound at 1, 3, 6, and 12 months, with completion of the UFS-QOL questionnaire at each visit. For each time

point, visits were classified as completed or not completed at the data cut-off. The UFS-QOL SSS ranges from 0 to 100, with higher values indicating more severe symptoms [10].

The primary outcome was the change in SSS from baseline to 6 months. Two response endpoints were defined separately: (1) SSS response, defined as a reduction of ≥10 points in the SSS from baseline to 6 months, a threshold commonly used to indicate a clinically meaningful change on this scale, although it is not a formally validated minimal clinically important difference; and (2) patient-reported symptom improvement at the 3-month visit, defined as the woman reporting, at clinical review, that her presenting symptoms had improved, without the use of a standardized instrument. SSS values at 1 and 3 months and the HRQoL subscale scores were not retained in the audit database and are not reported.

Imaging outcomes were summarized at the patient level, using the dominant (largest) treated fibroid as the index lesion. Fibroid volume was calculated from the three orthogonal diameters measured on transvaginal ultrasound with the ellipsoid formula (volume = 0.523 × D1 × D2 × D3), and volume reduction was expressed as the percentage change from baseline. Doppler evaluation of the vascularity of the largest fibroid was performed in selected cases at the operator's discretion, without predefined selection criteria, and was assessed qualitatively as reduced or not reduced compared with baseline.

Adverse events were recorded intraoperatively, at discharge, and by direct questioning at each follow-up visit and were classified as minor (requiring no treatment or pharmacological treatment only) or major (requiring surgical, endoscopic, or radiological intervention, readmission, or transfusion, or life-threatening). Reintervention was defined as any further surgical, interventional, or ablative treatment for fibroid-related symptoms. Pregnancies occurring during follow-up were recorded.

2.3. Statistical Analysis

Data were analyzed using SPSS version 31 (IBM Corp., Armonk, NY, USA). Continuous variables are reported as means ± standard deviations (SD) or medians (range), and categorical variables as numbers and percentages with 95% confidence intervals (CI) calculated using the Wilson score method. Clinical outcomes were analyzed at the patient level; imaging outcomes were also summarized at the patient level using the index fibroid, so that multiple fibroids from the same patient were not treated as independent observations. Analyses were based on available cases: patients without an assessment at a given time point (visit not completed) were excluded from the analysis of that time point, no imputation was performed, and the number of patients analyzed is reported for each outcome. Baseline and 6-month SSS were originally compared using the paired *t*-test in women with both assessments. The original statistical output, the patient-level paired differences, and the source questionnaires were not retained in the audit database and could not be retrieved; consequently, the assumptions of the paired t-test could not be assessed, the original result could not be independently verified and is reported as originally obtained, a non-parametric alternative (Wilcoxon signed-rank test) could not be applied, and the SD of the within-patient change, a standardized effect size, and the exact *p*-value could not be reported. Separately from this original analysis, an approximate 95% CI for the mean change was reconstructed from the aggregate summary statistics (means and SDs at baseline and at six months) under the assumption of zero correlation between baseline and follow-up scores. This is an assumption rather than a conservative approach: the reconstructed interval is wider than the true interval if the within-patient correlation is positive, as is usual for repeated measurements, but narrower if it is negative. Given the exploratory nature of the series, no sample size calculation was performed, and no adjustment was made for multiple comparisons. A two-tailed p-value < 0.05 was considered statistically significant.

3. Results

3.1. Literature Review

3.1.1. Study Selection

The database search identified 256 records. After the removal of 48 duplicates, 208 titles and abstracts were screened, and 143 were excluded as irrelevant or not meeting the inclusion criteria. Of the 65 full-text articles assessed, 43 were excluded because of incomplete data or unrelated outcomes; the number of articles excluded for each individual reason was not recorded. This left 22 publications for inclusion (Figure 1). The study by Kim et al. [9], which had been cited in the Introduction but omitted from the original tabulation, meets the eligibility criteria and is now included. The characteristics of the included publications are summarized in Table 1.

Table 1. Characteristics and main findings of the 22 publications included in the literature review. Publications arising from the same trial program (FAST-EU or SONATA) report overlapping populations.

Main Findings	Follow-Up	Patients (n)	Design	Study
Transcervical fibroid ablation (TFA)				
Safety and tolerability; procedures of ~30 min	Periprocedural	19	Prospective feasibility study	Garza-Leal et al., 2011 [11]
↓ bleeding, SSS and volume (~68% ↓ perfused volume at 3 months); safety confirmed	6 months	50	Multicenter prospective, single-arm (FAST-EU)	Bongers et al., 2015 [12]
~67% ↓ perfused volume; SSS −55%; reintervention ~8%	12 months	50	Multicenter prospective (FAST-EU)	Brölmann et al., 2016 [7]
EQ-5D ↑ from ~0.75 to ~0.91	12 months	49	Prospective, health utility (FAST-EU)	Huirne and Brooks, 2018 [13]
Clinically significant SSS/HRQoL gains; few AEs	12 months	147	Multicenter prospective, single-arm (SONATA)	Chudnoff et al., 2019 [8]
Replicated SSS/HRQoL improvements; favorable safety	12 months	125	Prospective cohort analysis (SONATA, US cohort)	Hudgens et al., 2019 [14]
Cumulative reintervention ~5–6%; durable benefit	24 months	147	Multicenter prospective (SONATA)	Miller and Osman, 2019 [15]
Preserved uterine wall integrity after TFA	12 months	29	Prospective, MRI core laboratory	Bongers et al., 2019 (INTEGRITY) [16]
No de novo intrauterine adhesions (0/34 assessed)	6 weeks (hysteroscopy)	37	Multicenter post-market prospective	Bongers et al., 2019 (OPEN) [17]
Durable symptom control; few further procedures	Mean 64.4 months	17	Retrospective long-term follow-up of FAST-EU participants (single site)	Garza-Leal, 2019 (VITALITY) [18]
Reintervention ~8%; sustained HRQoL/EQ-5D	36 months	147	Multicenter prospective (SONATA)	Lukes and Green, 2020 [19]
Efficacy in FIGO 1–2 and >5 cm fibroids	12 months	197	Pooled subgroup analysis (FAST-EU and SONATA)	Shifrin et al., 2021 [20]
Registry protocol; preliminary results	Up to 5 years (planned)	Ongoing	Post-market registry (ongoing)	Christoffel et al., 2021 (SAGE) [21]
High term-delivery rate; no uterine rupture or placenta accreta	NR	28 women (36 pregnancies)	Multicenter case series	Christoffel et al., 2022 [22]
Higher reintervention in mixed practice; satisfaction 69%	Median 36 months	53	Retrospective cohort	van der Meulen et al., 2022 [23]
Sustained generic and fibroid-specific HRQoL gains to 3 years	36 months	147	Prospective follow-up (SONATA)	Roy and Robinson, 2022 [24]

No uterine rupture, placenta accreta spectrum or stillbirth	NR	72 women (89 pregnancies)	Case series (pregnancy outcomes); update including [22]	Hansen-Lindner et al., 2024 [25]
Return to work: median 3 days (TFA) vs. 47 (myomectomy) and 45 (hysterectomy); SSS change at 12 months −22.2, −24.9 and −47.2; surgical reintervention at 18 months 27.3% (TFA) vs. 6.3% (myomectomy); TFA cost-effective vs. myomectomy	18 months (economic evaluation at 12 months)	96	Prospective comparative cohort, patient-preference allocation (TFA vs. myomectomy vs. hysterectomy)	Cooijmans et al., 2025 (ESONATA) [26]
Transvaginal ultrasound-guided RFA (TV-RFA)				
Reduced dominant myoma volume; improved menorrhagia and SSS at 1–12 months; no major complications; 3 deliveries	12 months	69	Prospective, single-arm (outpatient)	Kim et al., 2011 [9]
Volume −78%; ↑ symptom and QoL scores; no complications	12 months	51 (62 fibroids)	Prospective	Wu et al., 2016 [27]
65.5% assisted conception; miscarriage 15.9%; preterm birth 4.1%; no uterine rupture	NR	226 pregnant women	Retrospective (pregnancy outcomes)	Rey et al., 2025 [28]
Volume ↓ >80% at 12 and ~60% at 24 months; further surgery 7.7%	24 months	65	Prospective	Santalla-Hernández et al., 2025 [29]

NR, not reported; QoL, quality of life; AEs, adverse events; EQ-5D, EuroQol five-dimension questionnaire; HRQoL, health-related quality of life; MRI, magnetic resonance imaging; QALY, quality-adjusted life year; SSS, symptom severity score; TFA, transcervical fibroid ablation; WPAI, work productivity and activity impairment; ↓, decrease; ↑, increase. Publications labeled FAST-EU [7,12,13,18] or SONATA [8,14,15,19,24] report the same patient cohorts; reference [20] pools both; reference [25] is an update that includes reference [22].

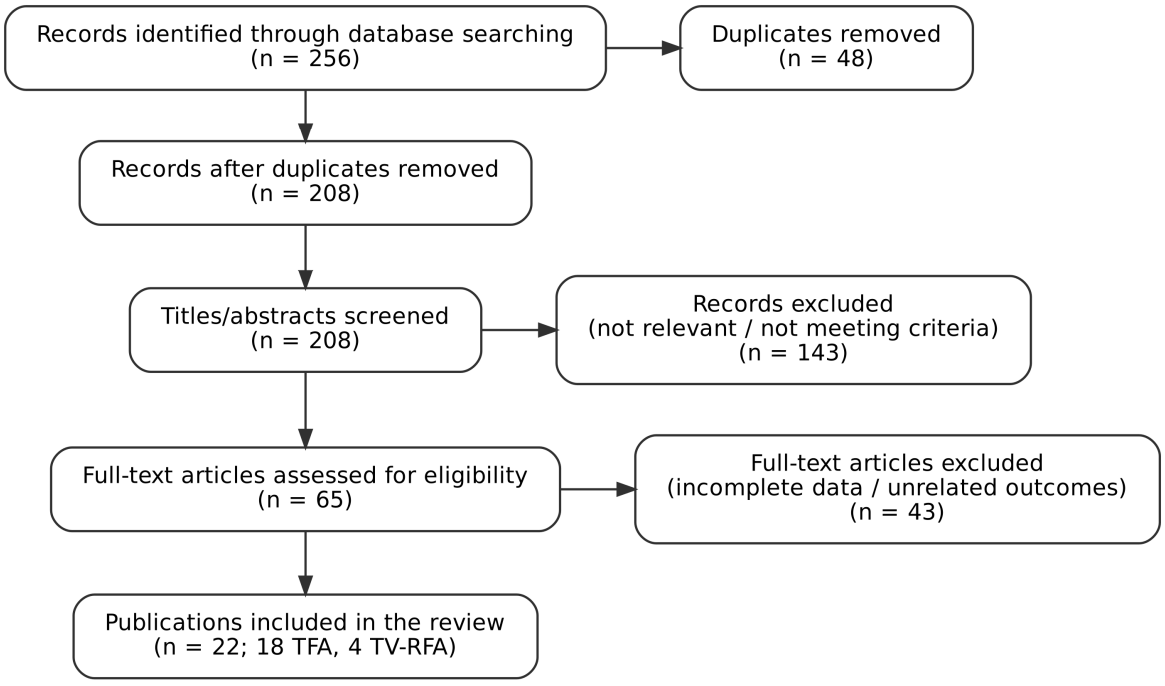

Figure 1. Flow diagram of the study selection process for the literature review.

Over the past 15 years, RFA performed through the vaginal route has progressed from feasibility studies to multicenter single-arm trials and real-world cohorts. Most of this evidence concerns TFA (18 publications), whereas 4 publications specifically addressed TV-RFA. The 22 publications do not correspond to 22 independent cohorts. Among the TFA publications, three report the FAST-EU cohort (n = 50) at different time points or for different outcomes [7,12,13], and the VITALITY study is a long-term follow-up of FAST-EU participants treated at a single site [18]; five report the SONATA cohort (n = 147) or its US subgroup [8,14,15,19,24]; one is a pooled subgroup analysis of FAST-EU and SONATA [20]; and the two pregnancy series overlap, the second being an update of the first [22,25]. The TFA evidence therefore rests largely on two manufacturer-sponsored single-arm trial programs, complemented by small substudies (INTEGRITY and OPEN), one registry, one retrospective cohort, and one non-randomized comparative cohort. The TFA evidence is organized below into five clusters: (1) early feasibility studies and the FAST-EU program; (2) the SONATA pivotal trial and its extensions; (3) durability and safety substudies (VITALITY, INTEGRITY, and OPEN); (4) health utility and economic evidence; and (5) fertility and pregnancy outcomes, together with real-world cohorts. Evidence on TV-RFA is presented separately in Section 3.1.8.

3.1.2. Early Feasibility Studies and FAST-EU

The feasibility study by Garza-Leal et al. established the safety of a closed-abdomen, transcervical, intrauterine ultrasound-guided approach, reporting short procedure times and good tolerability [11]. The FAST-EU program then provided prospective multicenter evidence of symptom and volume reduction at 3–6 months [12], subsequently confirmed at 12 months, when the mean reduction in perfused fibroid volume approached two-thirds and the SSS decreased by more than 50% [7]. Collectively, these studies defined the patient-selection window (FIGO types 1–6), the recovery profile (often outpatient), and the low rate of perioperative complications. Both were single-arm studies of limited size (19 and 50 women) without a comparator.

3.1.3. SONATA Pivotal Trial and Longitudinal Outcomes

The SONATA pivotal IDE trial reported clinically significant improvements in SSS and HRQoL at 12 months in 147 women, with a low reintervention rate and no device-related serious adverse events [8]. An analysis of the US cohort of the same trial reproduced these outcomes [14]. At 24 months, Miller et al. reported sustained symptom relief with a cumulative reintervention rate of approximately 5–6% [15], and at 36 months, Lukes et al. found durable benefit with a reintervention rate of approximately 8% [19]. These estimates derive from a single-arm trial with attrition over time and contrast with the higher reintervention rates observed in a retrospective real-world cohort and in a comparative cohort [23,26].

3.1.4. Durability and Safety Substudies

Durability beyond three years was explored in the VITALITY study, a long-term follow-up of 17 FAST-EU participants from a single site, which showed symptom control and a low need for further procedures beyond five years [18]. Procedure-specific safety questions were addressed by focused substudies: the INTEGRITY study used core-laboratory MRI to document preserved uterine wall integrity after TFA [16], and the OPEN study performed routine post-procedural hysteroscopy and found no de novo intrauterine adhesions at six weeks [17]. These data are reassuring with respect to uterine wall integrity and the endometrial cavity after TFA, although the small numbers (17, 29, and 37 women) limit the precision of the estimates.

3.1.5. Health Utility, Quality of Life, and Economic Evidence

Patient-reported health utility improved after TFA. In FAST-EU, Huirne and Brooks reported an increase in mean EQ-5D utility from 0.745 at baseline to 0.914 at 12 months [13]. In the SONATA population, improvements in generic and fibroid-specific HRQoL were sustained through 36 months [24]; these are single-arm quality-of-life data and do not constitute a comparative cost-effectiveness analysis. Further SONATA-based analyses documented improvements in work productivity and activity impairment, consistent with short recovery [8,15,19]. Comparative economic evidence is limited to the ESONATA study, a single-center prospective cohort of 96 women who chose TFA, myomectomy, or laparoscopic hysterectomy, with 18 months of clinical follow-up and an economic evaluation at 12 months [26]. Return to work was faster after TFA (median 3 days) than after myomectomy (47 days) or hysterectomy (45 days). At 12 months, the SSS had decreased by 22.2 points after TFA, 24.9 after myomectomy, and 47.2 after hysterectomy; TFA was cost-effective compared with myomectomy, whereas hysterectomy produced the largest HRQoL gain at the highest cost. These advantages must be weighed against a surgical reintervention rate at 18 months of 27.3% after TFA compared with 6.3% after myomectomy, and against the non-randomized, preference-based allocation of treatment.

3.1.6. Fertility and Pregnancy Outcomes

Pregnancy after TFA is increasingly reported. A multicenter case series described 36 pregnancies in 28 women, with a high term-delivery rate and no uterine ruptures [22], and an updated series, which includes the former, described 89 pregnancies in 72 women, with no uterine ruptures, placenta accreta spectrum disorders, or stillbirths [25]; nonetheless, the literature highlights small numbers, potential reporting bias, and the need for prospective registries [6]. These series include only women who conceived and provide no denominator of women attempting pregnancy; they therefore indicate that pregnancy is possible after TFA and that serious obstetric complications have not so far been reported, but they do not establish that fertility is preserved or improved. Women desiring future pregnancy should be counseled accordingly.

3.1.7. Real-World Cohorts and Special Populations

Real-world series complement trial evidence. A Dutch single-center retrospective cohort reported higher reintervention rates at mid-term follow-up than the pivotal trials and highlighted learning-curve and case-mix effects, underscoring the importance of rigorous technique and structured postoperative surveillance [23]. Subgroup analyses of the pooled trial populations suggest efficacy in submucous (FIGO 1–2) and large (>5 cm) fibroids [20]. Ongoing post-market registries, such as SAGE, will be important in defining performance across centers, indications, and levels of operator experience [21]. The ESONATA comparative cohort (Section 3.1.5) likewise found a higher surgical reintervention rate after TFA than after myomectomy, and randomized head-to-head trials remain a key unmet need [26].

3.1.8. Transvaginal Ultrasound-Guided RFA

Evidence specific to TV-RFA, in which a needle electrode is advanced through the vaginal fornix under ultrasound guidance, is more limited and consists of four publications from independent single-center cohorts, all without a comparator [9,27–29]; an earlier day-care series published before the search period is cited for context [30]. Kim et al. treated 69 premenopausal women as outpatients and reported a reduction in the volume of the dominant myoma and significant improvements in menorrhagia and SSS at 1, 3, 6, and 12 months, with no major complications and three uneventful deliveries within 12 months [9]. In a prospective study of 51 women with 62 fibroids, Wu et al. reported a

mean volume reduction of 78% at 12 months, significant improvement in symptom and quality-of-life scores, and no complications [27]. In a prospective series of 65 women, Santalla-Hernández et al. observed volume reductions of more than 80% at 12 months and of approximately 60% at 24 months, with 7.7% of patients requiring further surgery [29]. Regarding reproductive outcomes, a retrospective analysis of 226 women who became pregnant after TV-RFA, 65.5% of them with assisted reproductive technologies, reported a miscarriage rate of 15.9% and a preterm birth rate of 4.1%, with no uterine ruptures [28]; because only women who conceived were included, this study cannot inform on the probability of conception after TV-RFA. None of these publications describes a prescribed order of electrode passes or deliberate targeting of the vascular base, and none compares procedural techniques.

3.1.9. Safety and Technical Completeness

Across studies, adverse events were uncommon and generally minor (transient cramping, light bleeding, and discharge), and outpatient treatment with rapid convalescence was the norm. Most of these safety data, including the imaging (INTEGRITY) and hysteroscopic (OPEN) substudies [16,17], were obtained with TFA and cannot be directly extrapolated to TV-RFA, in which the electrode crosses the vaginal fornix and the myometrium. A plausible, although not directly tested, principle is that the result of RFA depends on the thermal coverage of the myoma, and that incomplete or eccentric ablation may leave viable tissue, with persistence of symptoms or regrowth. None of the included studies evaluated ablation completeness as a function of the pattern of electrode placement. This rationale, rather than direct evidence, motivated the structured two-step sequence (slicing followed by vascular base ablation) adopted in our unit.

3.2. Institutional Case Series

3.2.1. Patient and Fibroid Characteristics

Between June 2024 and March 2025, 46 consecutive women underwent TV-RFA of uterine fibroids at our institution; the number of eligible women who did not undergo the procedure was not recorded. The median age was 42 years (range 26–52); the mean age and its SD were not available. Some 29 women (63%) were parous and 17 (37%) were nulliparous. Reproductive intentions were not recorded in a structured way, so the number of women who desired future pregnancy cannot be reported. The main presenting complaints were heavy menstrual bleeding (37/46, 80%), pelvic pain or pressure (28/46, 61%), bulk-related symptoms (13/46, 28%), and dyspareunia (6/46, 13%). The prevalence of coexisting adenomyosis was not systematically recorded. Up to four fibroids were treated per patient (median three); the total number of fibroids treated was not recorded. The mean diameter of the dominant fibroid was approximately 6.2 cm (range 3–11 cm). According to the FIGO classification of the largest fibroid in each patient, 32 (70%) were intramural or subserosal fibroids of type 3, 4, or 5, grouped for reporting (the breakdown by individual type was not recorded); 9 (20%) were hybrid type 2–5 fibroids; and 5 (11%) were type 6.

3.2.2. Procedural Outcomes

All procedures were completed as planned under general anesthesia, without intraoperative complications. A tru-cut biopsy was obtained in every case; histology became available after the procedure, and the individual histology reports were not collected in the audit database, so the biopsy findings cannot be summarized here. Both steps, including vascular-base ablation, were performed in all patients; the completion of each step was not documented as a separate variable in the audit database. The mean active ablation time was 4.2 min per fibroid; its variability, its relationship with fibroid size, the total

ablation time per patient, the total procedure time, and the anesthesia time were not recorded. Thirty-nine patients (85%) were discharged on the same day and seven (15%) after an overnight stay. The median time to return to normal activities was 2.5 days (range 1–4).

3.2.3. Clinical Outcomes

At the data cut-off (January 2026), the 1-month assessment had been completed by all 46 women, the 3-month assessment by 43, and the 6-month assessment by 40. Three women did not attend the 3-month visit or any later visit and are considered lost to follow-up. Of the six women without a 6-month assessment, three were these women and three had not attended the 6-month visit by the data cut-off, although the visit was due. No 12-month assessments had been completed at the data cut-off. The baseline characteristics of patients with and without a completed 6-month assessment are reported in Table 2, and the number of women assessed and the available SSS values at each time point are reported in Table 3. Women without a 6-month assessment had smaller fibroids (mean diameter 4.0 vs. 6.5 cm). These six women completed the UFS-QOL questionnaire at baseline, but their scores were not retained in the audit database.

Table 2. Baseline characteristics of patients with and without a completed six-month assessment.

Six-Month Assessment Not Available (n = 6)	Six-Month Follow-Up Completed (n = 40)	Characteristic
38	42	Age, years, median
2 (33%)	15 (37%)	Nulliparous, n (%)
4.0	6.5	Fibroid diameter, cm, mean
3	3	Number of fibroids treated, median
Not available	62.3 ± 15.4	Baseline UFS-QOL SSS, mean ± SD

SD, standard deviation; SSS, symptom severity score; UFS-QOL, Uterine Fibroid Symptom and Health-Related Quality of Life questionnaire.

Table 3. Follow-up completeness and available UFS-QOL symptom severity scores at each scheduled time point (available-case analysis).

SSS Response (≥10-Point Reduction), n/N (%)	SSS, Mean ± SD	Not Assessed, n (Reason)	Assessed, n	Time Point
—	62.3 ± 15.4	—	40	Baseline (6-month completers)
—	Not available	—	6	Baseline (women without 6-month assessment)
Not available	Not available	0	46	1 month
Not available	Not available	3 (lost to follow-up)	43	3 months
36/40 (90%)	29.8 ± 13.1	6 (3 lost to follow-up; 3 visit not attended by data cut-off)	40	6 months
—	—	46 (3 lost to follow-up; 43 no visit completed by data cut-off)	0	12 months

SD, standard deviation; SSS, symptom severity score; UFS-QOL, Uterine Fibroid Symptom and Health-Related Quality of Life questionnaire. The SSS ranges from 0 to 100; higher values indicate more severe symptoms. Not available: value not retained in the audit database.

The primary analysis included the 40 women with paired baseline and 6-month questionnaires; the baseline SSS of 62.3 ± 15.4 refers to these 40 women, and the baseline SSS of the six women without a 6-month assessment was not available. In the paired analysis, the SSS decreased from 62.3 ± 15.4 at baseline to 29.8 ± 13.1 at six months, a mean within-

patient change of −32.5 points ($p < 0.01$, paired *t*-test, as originally reported and not independently verifiable; approximate 95% CI reconstructed from aggregate data assuming zero correlation, −39.0 to −26.0; see Section 2.3). An SSS response (reduction of ≥10 points) was observed in 36 of 40 women at six months (90%; 95% CI 77–96%). Patient-reported symptom improvement at three months was recorded in 35 of 43 women (81.4%; 95% CI 67–90%). SSS values at one and three months, HRQoL subscale scores, and results stratified by fibroid size were not available. Because the six women without a 6-month assessment had smaller fibroids than those included, the 6-month estimates predominantly reflect women with larger fibroids and may be affected by attrition bias; because the baseline SSS of these six women was not retained, the direction of any resulting selection bias cannot be determined.

3.2.4. Imaging Outcomes

Fibroid volume and Doppler vascularity were assessed at follow-up as part of routine care, but the individual measurements, their variability, the number of paired observations, and the numerators and denominators of the Doppler assessment were not retained in the audit database. These observations could therefore not be verified and are reported only qualitatively: a reduction in the size and intralesional Doppler flow of the dominant fibroid was generally observed at six months. No quantitative estimate is provided, and these unverified observations should not be interpreted as evidence of treatment efficacy or ablation completeness.

3.2.5. Complications and Safety

Adverse events were recorded in all 46 women up to the data cut-off. No intraoperative complications occurred (0/46). One woman (1/46, 2.2%; 95% CI 0.4–11.3%) experienced spontaneous transvaginal expulsion of necrotic fibroid tissue four months after the procedure; this was classified as a minor postprocedural adverse event and required no intervention. No major adverse events (0/46; 95% CI 0–7.7%) and no reinterventions were recorded during the observation period. No pregnancies were recorded during follow-up.

4. Discussion

In this exploratory, uncontrolled series, TV-RFA performed with a structured two-step sequence was feasible and was followed by short-term improvement in fibroid-related symptoms, in line with the literature on RFA as a minimally invasive, uterus-preserving treatment for symptomatic fibroids. The series was not designed to test, and cannot establish, whether the addition of vascular-base ablation or the slicing sequence improves the completeness of ablation or clinical outcomes compared with other TV-RFA techniques; this remains a hypothesis for comparative studies.

4.1. Comparison with Published Outcomes

The short-term symptom improvement observed in our series is of the same order as that reported in single-arm trials of TFA, such as FAST-EU and SONATA [7,8], and in previous TV-RFA series [9,27,29]. In our series, 36 of the 40 women assessed at six months (90%) had a reduction of at least 10 points in the SSS. These figures should not be read as evidence of equivalence: the access route, device, patient selection, and definitions of response differ between studies, most of the comparative literature concerns TFA rather than TV-RFA, and our series has no comparator. Before–after changes in a patient-reported score in an unblinded, uncontrolled series are also susceptible to regression to the mean and to placebo effects. Likewise, the same-day discharge rate, the short time to return to normal activities, and the short active ablation time are encouraging but, without

a control group, do not demonstrate superiority over myomectomy, UAE, or other ablative techniques.

Because the individual ultrasound measurements were not retained, fibroid volume reduction in our series cannot be quantified or compared with the reductions in perfused volume reported at 12 months in TFA trials [7] or with the reductions of more than 75% reported in TV-RFA series [27,29], and no inference on treatment efficacy or ablation completeness can be drawn from our imaging observations. Fibroids larger than 6 cm are recognized as more difficult to treat with RFA and may respond less favorably; our data could not be stratified by fibroid size, so we cannot determine whether outcomes differed in larger fibroids. A marked symptomatic improvement despite a modest reduction in volume has been described after thermal ablation, but in an uncontrolled series it cannot be attributed with confidence to the treatment. Coexisting adenomyosis, which was not systematically recorded, may also have contributed to bleeding and pain independently of the treated fibroids and may have influenced the symptom scores in either direction.

4.2. Safety Profile

Adverse events were recorded in all 46 women, and no intraoperative complications or major adverse events were recorded. These observations must be interpreted with caution: with no events among 46 women, the upper limit of the 95% confidence interval is approximately 8%, so uncommon but serious complications cannot be excluded, and the observation period was short. This applies in particular to thermal injury of the bowel or bladder, which is the main concern for fibroids in contact with the serosa (FIGO type 6, five women in our series), for which no protocolized precaution beyond continuous ultrasound visualization was adopted, and to the additional vascular-base ablation step, the specific safety of which cannot be assessed in a series of this size. One woman (2%) had spontaneous vaginal expulsion of necrotic fibroid tissue at four months. Tissue expulsion is a recognized event after thermal ablation of fibroids, particularly those with a submucosal component; we report it as a postprocedural adverse event rather than as a therapeutic endpoint, because it can be associated with pain, discharge, infection, or the need for hysteroscopic removal, although none of these occurred in our patient.

The low complication rates reported for TFA in FAST-EU and SONATA [7,8], the absence of de novo intrauterine adhesions in the OPEN study [17], and the preserved uterine wall integrity documented in the INTEGRITY study [16] were obtained with a different device and access route and cannot be assumed to apply to TV-RFA. With regard to preoperative pathological evaluation, the tru-cut biopsy in our protocol was taken during the same session, immediately before ablation, and its result was not available when energy was delivered; it was therefore intended to document the nature of the treated lesion and did not exclude malignancy before treatment; in addition, the histology reports were not collected for this analysis. Moreover, needle biopsy samples only a small part of the lesion and has limited sensitivity for leiomyosarcoma and other uterine mesenchymal tumors, so a benign result does not rule out malignancy. As with all ablative treatments, no surgical specimen is available for definitive histology; careful preoperative selection on clinical and imaging grounds and structured follow-up of lesions that do not regress remain essential.

4.3. Reintervention and Durability

No patient required repeat treatment or surgery during the observation period, but outcome assessment was limited to six months, which is insufficient to assess the durability of symptom relief, fibroid regrowth, or the need for reintervention. In the TFA literature, reintervention rates vary widely with study design: approximately 8% at 36 months in the single-arm SONATA trial [19], with sustained benefit beyond five years in the small

VITALITY cohort [18], but higher rates in a retrospective real-world cohort [23] and 27.3% at 18 months, compared with 6.3% after myomectomy, in the ESONATA comparative cohort [26]. For TV-RFA, further surgery was required in 7.7% of women at 24 months in one series [29]. These data cannot be directly extrapolated to our technique, and longer follow-up of our cohort is needed.

4.4. Fertility Considerations

TV-RFA preserves the uterus, but uterine preservation is not equivalent to demonstrated preservation of fertility. The available evidence consists of uncontrolled case series of women who conceived after RFA: 36 and 89 pregnancies after TFA, with no uterine ruptures or abnormal placentation reported [22,25], and 226 women who became pregnant after TV-RFA, about two-thirds with assisted reproductive technologies, with no uterine ruptures [28]. These series lack a denominator of women attempting conception and are subject to reporting bias; they do not show that fertility is maintained or improved, nor do they allow reliable estimates of the risks of miscarriage, preterm birth, abnormal placentation, or uterine rupture. Our series does not add evidence on this point: nulliparity (37% of the cohort) is not a measure of reproductive intention, the number of women who desired pregnancy or attempted to conceive was not recorded, and no pregnancies were recorded during the available follow-up. Consequently, time to pregnancy, mode of conception, miscarriage, ectopic pregnancy, preterm birth, live birth, and obstetric complications could not be assessed. Women who wish to conceive should be counseled that reproductive outcomes after TV-RFA are uncertain.

4.5. Technical Standardization

Previous reports of TV-RFA describe multiple overlapping electrode passes guided by ultrasound but do not prescribe the order of the passes or the deliberate targeting of the feeding vessels [9,27,29,30]. The approach described here differs in two respects: the passes are ordered radially so that each plane of the fibroid is treated in sequence, and the vascular base is ablated in all cases as a separate final step. The rationale is that incomplete thermal coverage may leave viable tissue, with persistent symptoms or regrowth. This rationale is plausible but unproven: our study did not include a comparison group treated with a different technique, did not verify the extent of ablation with contrast-enhanced imaging, and relied on hyperechogenicity and reduced Doppler flow, which are surrogate markers and not a confirmation of complete ablation. The two-step sequence should therefore be regarded as a description of how the procedure is performed in our unit, not as a fully standardized, reproducible protocol or as a technique with demonstrated advantages; because the energy delivered, the active tip length used for each application, the application duration, and the number of applications were not recorded, it cannot be reproduced exactly from this report. The treatment also has limitations and risks that patients should be aware of, including incomplete ablation, persistence of symptoms, fibroid regrowth, the need for repeat intervention, expulsion of necrotic tissue, the lack of a surgical specimen for histology, and uncertainty about long-term uterine and reproductive outcomes. Future studies should compare procedural algorithms and explore the role of contrast-enhanced ultrasound or MRI in verifying ablation completeness.

4.6. Health-Economic Impact

Economic considerations are relevant to the adoption of any treatment. Follow-up of the SONATA cohort showed sustained improvements in generic and fibroid-specific quality of life through three years [24], but these single-arm data are not a comparative cost-effectiveness analysis. The ESONATA study compared TFA with myomectomy and hysterectomy, not with UAE, in a patient-preference cohort of 96 women: TFA was associated

with a much faster return to work and was cost-effective compared with myomectomy at 12 months, whereas hysterectomy gave the largest improvement in quality of life at the highest cost; at 18 months, however, surgical reintervention was more frequent after TFA (27.3%) than after myomectomy (6.3%) [26]. The favorable recovery and economic profile must therefore be balanced against a higher probability of further treatment, and the economic horizon of 12 months does not capture later reinterventions. No economic evaluation of TV-RFA is available, and no economic data were collected in our series.

4.7. Limitations

This study has several limitations. It is a single-center, uncontrolled case series of limited size (n = 46), and the absence of a comparison group precludes any conclusion on comparative effectiveness or on the incremental contribution of vascular-base ablation. Follow-up was short. Outcomes are reported up to 6 months, and no 12-month data were available, so that long-term durability of symptom relief, fibroid regrowth, reintervention, and late adverse events could not be assessed. Three women (7%) were lost to follow-up after the 1-month visit, and a further three had not attended the 6-month visit by the data cut-off, so that six women (13%) had no 6-month assessment; the analysis was restricted to available cases, these women had smaller fibroids than those included, and their baseline SSS was not retained, so attrition or selection bias of unknown direction cannot be excluded. A major limitation is that the data derive from a quality-improvement audit that was not designed as a research database, and several variables requested for a complete report were not recorded or were not retained: the active tip length, the energy delivered and the duration and number of applications, the safety margins, the documentation of the completion of each step in each patient, procedure and anesthesia times, and the biopsy findings; the mean age, reproductive intentions, the prevalence of adenomyosis, and the reasons for choosing TV-RFA; the total number of fibroids, absolute fibroid volumes, and the denominators of the Doppler assessment; and SSS values at intermediate time points, HRQoL subscale scores, and the patient-level differences needed to verify the assumptions of the paired *t*-test and to report the variability of the change. The technique therefore cannot be reproduced from this report alone, results could not be stratified by fibroid size or FIGO type, and the statistical results should be regarded as descriptive. The primary outcome was a patient-reported score collected without blinding. Ablation completeness was not verified with contrast-enhanced imaging, and ultrasound measurements were not independently reviewed. The sample size is too small to exclude uncommon serious complications. No pregnancies occurred, and reproductive outcomes could not be evaluated. The study was not reviewed by an ethics committee and had no prospectively registered protocol. Finally, the literature review was narrative rather than systematic, the full search strings, search dates, and itemized reasons for full-text exclusion were not archived, no formal risk-of-bias assessment was performed, and most of the available evidence concerns TFA, largely from two manufacturer-sponsored single-arm trial programs, and cannot be directly extrapolated to TV-RFA.

4.8. Future Directions

Several steps are needed to strengthen the evidence base:

- Randomized controlled trials comparing vaginal-route RFA with laparoscopic myomectomy and UAE;
- Prospective fertility registries to clarify reproductive outcomes and neonatal safety;
- Long-term multicenter cohorts documenting durability beyond five years;
- Standardized reporting of technical parameters (energy dosing, coverage mapping, and intraoperative ultrasound criteria) to improve reproducibility and cross-study comparison;

- Comparative studies of the two-step sequence versus conventional TV-RFA, with verification of ablation completeness by contrast-enhanced imaging;
- Technological refinements integrating real-time imaging and artificial intelligence for ablation mapping;
- Health-economic studies to guide inclusion in national guidelines and reimbursement frameworks.

5. Conclusions

In this exploratory single-center case series, TV-RFA performed with a structured two-step sequence was feasible and was followed by short-term improvement in fibroid-related symptoms and a no major adverse events recorded among 46 women during a short observation period. These preliminary observations, which are limited by incomplete recording of procedural and outcome variables, do not establish the incremental benefit of vascular-base ablation, superior ablation completeness, comparative effectiveness, long-term safety, or preservation of fertility. Controlled multicenter studies with longer follow-up, complete reporting of technical parameters, imaging verification of ablation, and prospective recording of reproductive outcomes are required.

Author Contributions: Conceptualization, I.M.; investigation, G.M. and G.R.A.; resources, M.B.; data curation, F.A.G.; writing—original draft preparation, M.B.; writing—review and editing, F.G.C. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki. All procedures were performed as part of routine clinical care, and outcome data were collected within an internal quality-improvement audit of the Unit of Gynecology and Obstetrics, Lentini Hospital (ASP Siracusa), without any change in patient management or allocation of patients to treatment for research purposes. The retrospective analysis of the anonymized audit data for publication was not submitted to an ethics committee, and no formal approval or exemption was issued. The decision not to seek ethics review was made by the clinical team because the analysis involved no intervention beyond standard care and only anonymized data; it was not based on a formal institutional policy or on a determination by an ethics committee or other authorized body.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patients to publish this paper.

Data Availability Statement: The data presented in this study are available on request from the corresponding author due to privacy restrictions.

Acknowledgments: During the preparation of this manuscript, the authors used Claude (Opus 5.5, Anthropic) for the purposes of restructuring and editing the text, checking the reference list, formatting the manuscript according to the journal template, and drawing the flow diagram in Figure 1 from the authors◎data. During the revision, the authors used Claude (Fable 5.2, Anthropic) to restructure and edit the text in response to the reviewers◎comments, to draft the point-by-point response letter, to check the details of cited studies against the published sources, to update Figure 1, and to calculate the approximate confidence interval for the mean change in symptom score from the summary statistics. During the second revision, the authors used Claude (Opus 5.5, Anthropic) to edit the text in response to the reviewer◎s comments, to draft the response letter, and to update the graphical abstract. No patient-level data were provided to the tool. The authors have reviewed and edited the output and take full responsibility for the content of this publication.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

AEs	adverse events
CI	confidence interval
EQ-5D	EuroQol five-dimension questionnaire
FIGO	International Federation of Gynecology and Obstetrics
HRQoL	health-related quality of life
IDE	investigational device exemption
MRI	magnetic resonance imaging
QALY	quality-adjusted life year
RF	radiofrequency
RFA	radiofrequency ablation
SD	standard deviation
SSS	symptom severity score
TFA	transcervical fibroid ablation
TV-RFA	transvaginal ultrasound-guided radiofrequency ablation
UAE	uterine artery embolization
UFS-QOL	Uterine Fibroid Symptom and Health-Related Quality of Life questionnaire
WPAI	work productivity and activity impairment

References

1. Stewart, E.A.; Laughlin-Tommaso, S.K.; Catherino, W.H.; Lalitkumar, S.; Gupta, D.; Vollenhoven, B. Uterine Fibroids. *Nat. Rev. Dis. Primers* **2016**, *2*, 16043. https://doi.org/10.1038/nrdp.2016.43.
2. Khan, A.T.; Shehmar, M.; Gupta, J.K. Uterine Fibroids: Current Perspectives. *Int. J. Womens Health* **2014**, *6*, 95–114. https://doi.org/10.2147/IJWH.S51083.
3. Munro, M.G.; Critchley, H.O.; Broder, M.S.; Fraser, I.S.; FIGO Working Group on Menstrual Disorders. FIGO Classification System (PALM-COEIN) for Causes of Abnormal Uterine Bleeding in Nongravid Women of Reproductive Age. *Int. J. Gynaecol. Obstet.* **2011**, *113*, 3–13. https://doi.org/10.1016/j.ijgo.2010.11.011.
4. Havryliuk, Y.; Setton, R.; Carlow, J.J.; Shaktman, B.D. Symptomatic Fibroid Management: Systematic Review of the Literature. *JSLS* **2017**, *21*, e2017.00041. https://doi.org/10.4293/JSLS.2017.00041.
5. Bradley, L.D.; Pasic, R.P.; Miller, L.E. Clinical Performance of Radiofrequency Ablation for Treatment of Uterine Fibroids: Systematic Review and Meta-Analysis of Prospective Studies. *J. Laparoendosc. Adv. Surg. Tech. A* **2019**, *29*, 1507–1517. https://doi.org/10.1089/lap.2019.0550.
6. Polin, M.; Hur, H.-C. Radiofrequency Ablation of Uterine Myomas and Pregnancy Outcomes: An Updated Review of the Literature. *J. Minim. Invasive Gynecol.* **2022**, *29*, 709–715. https://doi.org/10.1016/j.jmig.2022.01.015.
7. Brölmann, H.; Bongers, M.; Garza-Leal, J.G.; Gupta, J.; Veersema, S.; Quartero, R.; Toub, D. The FAST-EU Trial: 12-Month Clinical Outcomes of Women after Intrauterine Sonography-Guided Transcervical Radiofrequency Ablation of Uterine Fibroids. *Gynecol. Surg.* **2016**, *13*, 27–35. https://doi.org/10.1007/s10397-015-0915-3.
8. Chudnoff, S.; Guido, R.; Roy, K.; Levine, D.; Mihalov, L.; Garza-Leal, J.G. Ultrasound-Guided Transcervical Ablation of Uterine Leiomyomas. *Obstet. Gynecol.* **2019**, *133*, 13–22. https://doi.org/10.1097/AOG.0000000000003032.
9. Kim, C.H.; Kim, S.R.; Lee, H.A.; Kim, S.H.; Chae, H.D.; Kang, B.M. Transvaginal Ultrasound-Guided Radiofrequency Myolysis for Uterine Myomas. *Hum. Reprod.* **2011**, *26*, 559–563. https://doi.org/10.1093/humrep/deq366.
10. Spies, J.B.; Coyne, K.; Guaou Guaou, N.; Boyle, D.; Skyrnarz-Murphy, K.; Gonzalves, S.M. The UFS-QOL, a New Disease-Specific Symptom and Health-Related Quality of Life Questionnaire for Leiomyomata. *Obstet. Gynecol.* **2002**, *99*, 290–300. https://doi.org/10.1016/S0029-7844(01)01702-1.
11. Garza-Leal, J.G.; Toub, D.; León, I.H.; Saenz, L.C.; Uecker, D.; Munrow, M.; King, D.; Bajor, J. Transcervical, Intrauterine Ultrasound-Guided Radiofrequency Ablation of Uterine Fibroids with the VizAblate System: Safety, Tolerability, and Ablation Results in a Closed Abdomen Setting. *Gynecol. Surg.* **2011**, *8*, 327–334. https://doi.org/10.1007/s10397-010-0655-3.
12. Bongers, M.; Brölmann, H.; Gupta, J.; Garza-Leal, J.G.; Toub, D. Transcervical, Intrauterine Ultrasound-Guided Radiofrequency Ablation of Uterine Fibroids with the VizAblate® System: Three- and Six-Month Endpoint Results from the FAST-EU Study. *Gynecol. Surg.* **2015**, *12*, 61–70. https://doi.org/10.1007/s10397-014-0873-1.
13. Huirne, J.; Brooks, E. Improvement in Health Utility after Transcervical Radiofrequency Ablation of Uterine Fibroids with the Sonata System: Health Utility after Radiofrequency Ablation. *Eur. J. Obstet. Gynecol. Reprod. Biol.* **2018**, *224*, 175–180. https://doi.org/10.1016/j.ejogrb.2018.03.053.
14. Hudgens, J.; Johns, D.A.; Lukes, A.S.; Forstein, D.A.; Delvadia, D. 12-Month Outcomes of the US Patient Cohort in the SONATA Pivotal IDE Trial of Transcervical Ablation of Uterine Fibroids. *Int. J. Womens Health* **2019**, *11*, 387–394. https://doi.org/10.2147/IJWH.S201912.

15. Miller, C.E.; Osman, K.M. Transcervical Radiofrequency Ablation of Symptomatic Uterine Fibroids: 2-Year Results of the SONATA Pivotal Trial. *J. Gynecol. Surg.* **2019**, *35*, 345–349. https://doi.org/10.1089/gyn.2019.0012.
16. Bongers, M.; Gupta, J.; Garza-Leal, J.G.; Brown, M.; Felberbaum, R. The INTEGRITY Trial: Preservation of Uterine-Wall Integrity 12 Months after Transcervical Fibroid Ablation with the Sonata System. *J. Gynecol. Surg.* **2019**, *35*, 299–303. https://doi.org/10.1089/gyn.2019.0033.
17. Bongers, M.; Quinn, S.D.; Mueller, M.D.; Krämer, B.; Tuschy, B.; Sütterlin, M.; Lasmar, R.B.; Chudnoff, S.; Thurkow, A.; De Wilde, R.L. Evaluation of Uterine Patency Following Transcervical Uterine Fibroid Ablation with the Sonata System (the OPEN Clinical Trial). *Eur. J. Obstet. Gynecol. Reprod. Biol.* **2019**, *242*, 122–125. https://doi.org/10.1016/j.ejogrb.2019.09.013.
18. Garza-Leal, J.G. Long-Term Clinical Outcomes of Transcervical Radiofrequency Ablation of Uterine Fibroids: The VITALITY Study. *J. Gynecol. Surg.* **2019**, *35*, 19–23. https://doi.org/10.1089/gyn.2018.0051.
19. Lukes, A.; Green, M.A. Three-Year Results of the SONATA Pivotal Trial of Transcervical Fibroid Ablation for Symptomatic Uterine Myomata. *J. Gynecol. Surg.* **2020**, *36*, 228–233. https://doi.org/10.1089/gyn.2020.0021.
20. Shifrin, G.; Engelhardt, M.; Gee, P.; Pschadka, G. Transcervical Fibroid Ablation with the Sonata™ System for Treatment of Submucous and Large Uterine Fibroids. *Int. J. Gynaecol. Obstet.* **2021**, *155*, 79–85. https://doi.org/10.1002/ijgo.13638.
21. Christoffel, L.; Römer, T.; Schiermeier, S. Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE): Study Protocol and Preliminary Results. *Med. Devices (Auckl.)* **2021**, *14*, 77–84. https://doi.org/10.2147/MDER.S301166.
22. Christoffel, L.; Bends, R.; Toub, D.; Schiermeier, S.; Pschadka, G.; Engelhardt, M.; Quinn, S.; Hartmann, M.; Habiba, M.; Felberbaum, R.; et al. Pregnancy Outcomes after Transcervical Radiofrequency Ablation of Uterine Fibroids with the Sonata System. *J. Gynecol. Surg.* **2022**, *38*, 207–213. https://doi.org/10.1089/gyn.2021.0136.
23. van der Meulen, J.F.; Cooijmans, T.H.; van Zutven, V.J.; Leemans, J.C.; Verhoeven, C.J.; Bongers, M.Y. Long-Term Results of Transcervical, Intrauterine Ultrasound-Guided Radiofrequency Ablation of Uterine Fibroids with the Sonata System: A Retrospective Follow-Up Study. *AJOG Glob. Rep.* **2022**, *2*, 100087. https://doi.org/10.1016/j.xagr.2022.100087.
24. Roy, K.; Robinson, J.K. Durable Improvement in Generic and Fibroid-Specific Quality of Life in Women Treated with Transcervical Fibroid Ablation with the Sonata System after Three Years. *J. Gynecol. Surg.* **2022**, *38*, 143–148. https://doi.org/10.1089/gyn.2021.0073.
25. Hansen-Lindner, L.; Schmid-Lossberg, J.; Toub, D. Transcervical Fibroid Ablation (TFA): Update on Pregnancy Outcomes. *J. Clin. Med.* **2024**, *13*, 2892. https://doi.org/10.3390/jcm13102892.
26. Cooijmans, T.H.; Dujardin, Z.; van der Meulen, J.F.; Geomini, P.M.A.J.; Coppus, S.F.P.J.; Koks, C.A.M.; Leemans, J.C.; Bongers, M.Y. Evaluation of the Clinical and Cost-Effectiveness of Transcervical Ultrasound-Guided Radiofrequency Ablation of Leiomyomas (ESONATA): A Prospective Comparative Cohort Study. *Eur. J. Obstet. Gynecol. Reprod. Biol.* **2025**, *311*, 114062. https://doi.org/10.1016/j.ejogrb.2025.114062.
27. Wu, X.-J.; Guo, Q.; Cao, B.-S.; Tan, L.-X.; Zhang, H.-Y.; Cai, Y.-R.; Gao, B.-L. Uterine Leiomyomas: Safety and Efficacy of US-Guided Suprapubic Transvaginal Radiofrequency Ablation at 1-Year Follow-Up. *Radiology* **2016**, *279*, 952–960. https://doi.org/10.1148/radiol.2015142537.
28. Rey, V.E.; Falcon, M.M.; Ferrara, I.; Yanes, G. Pregnancy Outcomes after Transvaginal Radiofrequency Ablation of Leiomyomas. *Obstet. Gynecol.* **2025**, *145*, 346–353. https://doi.org/10.1097/AOG.0000000000005826.
29. Santalla-Hernández, Á.; Naveiro-Fuentes, M.; López-Criado, M.S.; Naveiro-Flores, R.; Fernández-Parra, J. Clinical Outcomes after 2-Year Follow-Up of Transvaginal Radiofrequency Ablation of Symptomatic Uterine Fibroids. *J. Obstet. Gynaecol. Res.* **2025**, *51*, e16216. https://doi.org/10.1111/jog.16216.
30. Cho, H.H.; Kim, J.H.; Kim, M.R. Transvaginal Radiofrequency Thermal Ablation: A Day-Care Approach to Symptomatic Uterine Myomas. *Aust. N. Z. J. Obstet. Gynaecol.* **2008**, *48*, 296–301. https://doi.org/10.1111/j.1479-828X.2008.00855.x.

Disclaimer/Publisher's Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.