

Ayurvedic Insights In The Management Of Uterine Leiomyoma With Shodhana And Shamana Therapies As Non-Surgical Alternatives: A Case Series

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ABSTRACT

Background: Uterine Leiomyoma is the most common benign tumors affecting women of reproductive age with a prevalence rate of 20-40% in a 14-45 years age. Based on pathogenesis and clinical manifestation, Leiomyoma uterus can be correlated with Garbhashaya Granthi as granthi is referred as localized nodular swelling, relative hard in consistency.

Patient information: We report a series of three cases presented to the OPD with AUB, diagnosed with Leiomyoma measuring <5cm on ultrasonography, and seeking non-surgical intervention for the management of the leiomyoma uterus. Per vaginal examination revealed Bulky Uterus in all cases.

Intervention and Results: Management strategy adopted was Shodhana karma -Virechana followed by Shamana therapy with Shigrudi Yoga, Kanchanara Guggulu and Punarnavasava. The primary mechanism of action considered was Lekhana, Shothahara, and Granthihara karma. Cases showed >20% reduction in volume of Uterine Leiomyoma, all three cases with significant improvement in subjective parameters of menstrual abnormalities, abdominal pain, pressure symptoms and backache.

Conclusion:

This case series suggests that combining Virechana with specific Ayurvedic formulations may offer a safe, non-invasive option for small uterine leiomyomas. Larger clinical studies are needed to confirm these findings.

Keywords: Uterine Fibroid, Garbhashaya Granthi, Virechana, Lekhana, Ayurveda.

INTRODUCTION

Uterine Leiomyoma, first identified in 1793 by Matthew Baillie in London are most common benign gynecological tumor. Leiomyomas are benign monoclonal tumors that originate from the smooth muscle of the uterus.[1] Leiomyomas, often known as fibroids, show highest prevalence in premenopausal women.[2] The incidence of uterine fibroids ranges from 20 to 77%, whereas the estimated prevalence among women under 35 is between 40 and 60%, and among women over 50 is between 70% and 80%. [3,4]

The clinical presentation varies from no symptoms to AUB, pressure symptoms, and fertility issues based on the size, localization, and number of fibroids.

Fibroids in women result in significant personal and social expenses, including reduced quality of life, disruption of daily activities, lost work time due to symptoms, and high healthcare costs.[5] The mainstay has been surgical management such as myomectomy, hysterectomy, and uterine artery embolization since there is no definite pharmacological management available. Surgical treatment options are not preferred because of the associated surgical complications such as bleeding, post-operative infection, and poor fertility outcomes.[6] So there is a huge scope for complementary and alternative medicines in the management of Uterine Leiomyoma.

Ayurveda texts specify a number of disease conditions under the categories of Granthi, Arbuda, Gulma, Shopha, Vidradhi that show clinical presentation analogous to Leiomyoma. Granthi, a term for localized nodular swelling or growth that is spherical, elevated above the skin's surface, and resembling a knot[7], is said to arise when pathological body humors localize in tissue in the body.[8] The descriptions of Leiomyoma and Granthi appear to have a similar etiopathogenesis, symptoms, and clinical presentation.[9] Based on the involvement of body tissue (Dushya) and the causative agent (Dosha), nine types of Granthi are mentioned in Ayurvedic literature that have similarities in their etiopathogenesis. Uterine leiomyoma develops in Garbhashaya, one of the root sites of artavavaha srotasa (the channels that carry artava and regulate the reproductive system), and it manifests with symptoms such as menstrual abnormalities and infertility, which are Artavavaha Srotoviddha lakshana[10] (traumatic effects). As a result, uterine leiomyoma can be considered as Garbhashaya Granthi and Granthi management principles can be applied to its treatment.

NEED OF THE STUDY

Globally there was an increase in uterine fibroids from 1990 to 2019 of 67.07%, 78.82%, and 77.34% in incident cases, prevalent cases, and YLDs, respectively.[11] Fibroids have a major impact on healthcare, affecting an estimated 11 million women[12] and costing a significant burden on the global economy every year.[1] An effective non-invasive therapeutic strategy from complementary and alternative medicine that can contribute to lowering the health care burden by addressing the issue and improving the quality of Life of women affected with Uterine Leiomyoma is of merit.

In Ayurveda, Uterine Leiomyoma can be correlated with Granthi, and Virechana is the shodhana Chikitsa mentioned for the management of Granthi. A combination of Shigrudi Yoga, a anubhoota yoga, a proven Granthihara drug- Kanchanar Guggulu, and a potent shothahara drug - Punarnavasa are thought to further improve the outcomes in the management of Granthi w.s.r. to Uterine Leiomyoma. As a result, an intervention with the Ayurveda Therapeutic strategy of Virechana along with the aforementioned indigenous intervention, was planned in three cases of Uterine Leiomyoma, and encouraging results were obtained, which are presented in this study.

PATIENT INFORMATION AND CLINICAL FINDINGS

The clinical presentations of all the five cases are highlighted in Table 1.

Case 1: A 43-year-old married Hindu housewife from Middle Socioeconomic background whose abdominal examination revealed a soft, no mass palpable. Her per speculum examination revealed a cervix with parous os, bulky, fullness, and tenderness in the posterior fornix. She had previously visited a gynecologist and was advised of a Myomectomy. As she was not willing to surgical intervention, she visited the PTSR OPD of the institute and was treated with the intervention as per protocol. Her serum tumor markers were within normal limits.

Case 2: A 38 years old Hindu woman, married, from an upper socio-economic background banker by profession visited PTSR OPD. Her abdominal examination revealed a soft ill-defined mass with no tenderness on palpation. Her per speculum examination revealed a cervix with a nulliparous os, whereas an enlarged uterus and bulky cervix, fullness of fornices, and Cervical motion tenderness on per vaginal examination. The serum tumor markers (CA 125, CA 19.9, CEA, AFP, Inhibin and LDH) were within normal limits.

Case 3: A 33-year-old, married Hindu woman from a lower socio-economic background presented to OPD whose vaginal examination revealed a uterus of normal size but a bulky cervix while per speculum examination revealed three small nabothian cysts at 12 o'clock, 1 o'clock, and 7 o'clock, respectively. Her cervical Pap smear was performed which reported to be negative for intraepithelial lesion/malignancy.

Table 1: Clinical presentation and imaging findings.

Case	Parity	Presenting Complaints	USG Findings
Case 1	P2L2	Painful and heavy menstrual bleeding x 1 year Back pain x 6 months H/O Constipation and urinary retention x 6 months	Bulky uterus: 9.1*5.7*4.8 cm, Intramural Posterior wall fibroid: 42*42 mm, Thickened endometrium:12.5 mm.
Case 2	Nulligravida	Pain in lower abdomen, Irregular and painful period, Constipation, and urinary retention x 3 years Primary infertility x 8 years H/O Myomectomy for multiple uterine leiomyoma 6 years back H/O Bowel disturbance and frequent micturition H/O Interrupted sleep	Bulky uterus: 82*54*60 mm Multiple fibroids in uterus – a subserosal fibroid in fundus: 25*26 mm, Four intramural fibroids in from anterior wall, largest measuring 14*12 mm, Two fibroids arising from posterior wall, with larger measuring 8*7mm. Submucous fibroid of 12*13 mm in posterior wall in sub endometrial zone, Endometrial thickness: 8.5mm Grade-I Fatty liver.
Case 3	P3L3A2	Pain in the abdomen and back before and after periods, irregular and heavy menstrual cycle x 3 years Whitish discharge per vagina on and off. X 1 year H/O two Spontaneous Abortion. N/H/O Bowel or bladder Disturbance	Subserosal fibroid:17*14 mm in the anterior wall of the myometrium, Two anterior wall intramural fibroid measuring 6*5 mm and 20*19 mm respectively, Endometrial thickness of 12.5 mm Bulky cervix with multiple nabothian cyst, largest measuring 13 mm

Table 2: Dashvidha Atura Pariksha Findings

	Case 1	Case 2	Case 3
1. Prakriti (Body type)	Kaphapradhana Vata	Kaphapradhana Pitta	Vatapradhana Kapha

2. Vikruti (Pathology type)			
3. Sara (Essence)	Mansasara	Medasara	Asthisara
4. Samhanan (compactness)	Madhyama	Madhyama	Avara
5. Pramana (physical anthropometry)	Madhyama	Madhyama	Avara
6. Satmya (congenial things)	Pravara	Madhyama	Madhyama
7. Satva (Psychic factor)	Pravara	Avara	Avara
8. Aharashakti (Digestive capacity)	Madhyama	Madhyama	Madhyama
9. Vyayamashakti (Exercise capacity)	Madhyama	Madhyama	Avara
10. Vaya (Age)	Madhya	Madhya	Madhya

DIAGNOSTIC ASSESSMENT

Ultrasonography imaging was used for the confirmation of the diagnosis of uterine fibroid in this case series. On analysis of signs and symptoms based on Ayurveda principles, the patients were diagnosed with Granthi, and its management principles were adopted in this study.

ASSESSMENT CRITERIA

The results of the intervention are assessed using the following subjective and objective parameters in this case series. Assessment of subjective parameters was done at the end of each month of treatment whereas

A) Subjective parameters

1. Menstrual parameters such as Duration of flow, interval between two cycles, Amount of flow, Dysmenorrhea, Pain in lower abdomen, Backache, Constipation, Increased frequency of urine (Table 3)

Table 3: Assessment criteria for Subjective parameters

Subjective Parameter	Grade 0	Grade 1	Grade 2	Grade 3
1. Menorrhagia	<5 pads/day without clots	5-6 full soaked pads/day without clots	5-6 pads/day with clots	>6 pads/day with or without clots
2. Irregular Menses	Once in 21-35 days	Once in 15-20 days	Once in 10-15 days	Less than 10 days
3. Dysmenorrhea	No pain	Painful, no analgesic required	Painful, daily activity affected, analgesic required	Analgesic required but have no effect
4. Duration of bleeding	1-3days	4-6 days	7-10 days	>10 days
5. Lower abdominal Pain	Absent	Mild(Local tolerable pain, subsides with rest only)	Moderate (Local tolerable pain at rest also, subsides with medicine)	Severe (Pain does not subside with medicine)
6. Backache	No pain	Painful, no analgesic required	Painful, daily activity affected, analgesic required	Analgesic required but have no effect

7. Frequent micturition	More than every 2 hours	Every 2 hours	Every hour	Less than every hour
8. Constipation	No constipation	Passes hard & soft stool regularly	Passes hard stool all the time but no need of laxative	Needs laxative to pass stool

B) Objective parameters

An assessment of objective parameters was performed at two intervals i.e. before treatment and on completion of treatment after 90 days and % improvement was measured in each parameter.

1. Volume of Fibroid

The Volume of the largest fibroid was measured by transvaginal ultrasound scan at two intervals -1. Initial screening, 2. Completion of therapy after 12 weeks by expert sonologist. The prolate ellipsoid method [formula $V = 0.5233 (D1 \times D2 \times D3)$] was applied to measure the volume of the fibroid.[13]

2. Number of Fibroids

A number of Uterine Leiomyomas irrespective of site and size was reported before treatment and compared with the number of Uterine leiomyomas post-treatment using Ultrasound imaging after the 12th week to assess the reduction in the number following treatment.

THERAPEUTIC INTERVENTION

The cases were treated with the Ayurveda therapeutics strategy in two phases: I. Shodhana therapy (detoxification) followed by II. Shamana therapy. The treatment was initiated with Purvakarma—Deepana, Pachana, and Rukshana for 7 days to attain Aamapachana and Agnidipati. It was followed by Shodhana and Sansarjana Krama. Shamana medicines were advocated for 2 months after completion of Sansarjana Krama. (Table 4 and Table 5)

Table 4: Interventions used

I. Shodhana Therapy				
1. Deepana (carminative)	Ajmodadi churna[14] (Sharangdhar Samhita, Madhyama Khanda 6/113- 117)	3gm Apana Kala (Just before meal twice in a day with warm water	5 to 7 days till the appearance of Agni deepti lakshana and Rukshana	
	Abhayarishta[15] (Charak Samhita, Chikitsa sthana 14)	15ml with equal amount of water after food twice in a day		
	Chirubilwadi Kashaya[16] (Sahasrayoga)	15 ml with 45 ml with warm water empty stomach twice in a day		
2. Pachana (digestive)	Udvartana with Triphala Churna[17]	Q.S Before bath once in a day		
	Takrapana	Q.S.		
3. Rukshana	Sukumara Ghritam (Sahasrayoga)	30 to 210 ml	5 days to 7 days (Based on snehasiddhi lakshana)	
4. Snehapana				

5. Abhyanga	Sarshapa Taila (Bhavaprakasha, Purva Khanda)	Q.S.	3 days
6. Swedana	Bashpa sweda	Q.S.	
7. Virechana	Trivritavaleha (Ashtangahrdaya Kalpasthana 2/9)	70 -120 gm	1 day
8. Sansarjana Krama	Mentioned below		5 to 7 days based on the type of shuddhi
II. Shamana medicines			
1. Granthihara	Shigrudi Yoga (Anubhoota yoga)	Kwatha Empty Stomach in Morning (Preparation: 10gm medicine with 4 cups of water boiled and reduced to 1 cup)	8 weeks (Started following Sansarjana Krama till completion of 12 weeks)
2. Lekhana	Kanchanara Guggulu	2 tabs Just before meal twice a day with warm water	
3. Shothahara	Punarnavasava (Bhaisajyaratnavali, Sotharogadhikara: 197–201)	25 ml after food with an equal amount of water twice in a day	

Table 5: Details of shodhana

Cases	Deepana-pachana & Rukshana	Snehana	Virechana Aushadha	Virechana Vega Dose	Shuddhi prakara
Case I	7 days	6 days		16	Madhyama Shuddhi
Case II	7 days	5 days		18	Madhyama shuddhi
Case III	6 days	7 days		24	Pravara shuddhi

FOLLOW-UP AND OUTCOMES

After shodhana, the menstrual cycle was reported to be regular in all three cases, whereas menorrhagia was persistent after shodhana on the first assessment of subjective parameters in the fourth week. (Table 6) In all three cases, measurable (>20%) reduction was noted in leiomyoma size in all three cases after completion of treatment. (Table 7)

Infertility in Case II was consistent even on follow-up at 3 months after the completion of treatment. Abnormal vaginal discharge and other visible changes due to cervicitis reduced considerably per speculum examination in case 3.

Table 6: Assessment of Subjective Parameters

Subjective Parameters		Case I				Case II				Case III			
		Day 0	4 wk	8 wk	12 wk	Day 0	4 wk	8 wk	12 wk	Day 0	4 wk	8 wk	12 wk
Menstrual Abnormalities	Menorrhagia	2	2	1	1	0	0	0	0	2	2	1	0
	Irregular menses	1	1	0	0	2	1	1	0	2	2	1	0
	Dysmenorrhea	3	2	2	1	3	2	2	2	1	1	1	1
	Pain in lower abdomen	0	0	0	0	2	2	1	1	2	1	1	0

Backache		1	1	0	0	0	0	0	0	2	1	1	1
Pressure symptoms	Frequency of micturition	2	2	1	1	3	2	1	2	0	0	0	0
	Constipation	1	1	1	0	3	2	2	1	0	0	0	0

Table 7: Assessment of Objective Parameters

Objective Parameter	Case I			Case II			Case III		
	Day 0	12 wks	% reduction	Day 0	12 wks	% reduction	Day 0	12 wks	% reduction
1. Volume of largest Leiomyoma (mm ³)	35077.84	10952.67	68.78	7483.19	5651.64	24.48	2386.25	1524.0	100
2. Number of Leiomyoma	1	1	0	8	2	75.00	3	2	63.86

DISCUSSION

Uterine fibroids are the most prevalent benign tumor of the uterus and a leading cause of morbidity among women. The worldwide burden of uterine fibroids continues to rise in the middle, low-middle, and low SDI quintiles. The growing trend of uterine fibroids in India has a significant impact across the globe owing to its vast population and rapid economic development.[18] Almost one-third of women with leiomyomas will seek treatment due to their symptoms. The majority of current therapeutic approaches require surgical procedures; however, patients' age and desire to avoid radical surgery, like a hysterectomy, influence the course of treatment.[19] There is a clear need for non-surgical alternatives to surgical intervention, particularly for women from lower socio-economic backgrounds and those who desire to preserve fertility.

The pathogenesis of Granthi (tumor/cystic growth) states that Rakta (blood), Medo Dhatu (adipose tissue), and Mansa (muscle fibers) are vitiated. According to Acharya, when Mansa (muscle tissue) becomes vitiated, it produces smooth, massive, and hard Mansaja Granthi (tumor of muscular origin), a type of granthi, which is usually enormous and painless.[20] Vaghbata asserts that Mansaja Granthi is Yanya (manageable but incurable), but tends to relapse.[20] This feature is quite comparable to that of uterine fibroids, which similarly tend to recur. As a result, the uterine fibroid can be identified as Garbhashayagata Mansaja Granthi (intrauterine encapsulated growth of muscular origin).

In the present case series, 3D ultrasound was used for the baseline diagnosis of uterine leiomyoma as it is the gold standard test for its diagnosis, inexpensive, and widely available. Based on Ayurveda correlation, the Granthi management protocol was initiated in the cases.

Ayurveda explains the therapeutic use of Shodhana (purificatory therapy) and Shamana (palliative therapy) in treating various diseases. The Shodhana procedure increases the potency of the Shamana medicines. While detailing the management aspects of Granthi (tumor/cystic growth), Acharyas have recommended employing management principles of Shotha (inflammatory swelling), whereas they advocate treating Mansaja Granthi (tumor of muscular origin) like that recommended for Kaphaja Granthi (growth arising from Kapha imbalance).[21] As a result, the treatment strategy was designed as Shodhana followed by Shamana with Lekhana (scraping therapy), Shothahara (anti-inflammatory), and Granthihara (anti-tumor) drugs with appropriate dietary modifications.

Prior to the Shodhana procedure, Niramavastha (state of complete digestion and absence of ama) was attained with Deepana-Pachana (appetite-stimulating and digestive) medicines administered for five to seven days till Agni Deepti Lakshanas (signs of kindled digestive fire) appear. Along with Deepana-Pachana, Rukshana (drying/lightening therapy) was performed taking into consideration the Kapha-Meda Samprapti (pathogenesis involving Kapha and adipose tissue) of the disease prior to Snehapana (internal oleation therapy). Ajamodadi Churna is a polyherbal combination indicated in ama-dominant conditions and Kapha-Vataja diseases to restore digestive fire.[22] Abhayarishta is Sharaka (purgative), Malamutra Vibandhahara (relieves constipation and urinary retention) in action and acts as Pachakagni Pradipana (enhancer of digestive fire). Chirubilwadi Kashaya has Jatharagni Vivardhaka (enhances primary digestion) effect.

Following 5–7 days, Niramavastha was observed and Accha Snehapana (pure ghee oleation therapy) was initiated with Sukumara Ghrita at an initial dose of 30 ml. Sukumara Ghrita[23] is mentioned as a drug of Snehapana and indicated in Shopha (edema), Yonishula (gynecological pain), Gulma (abdominal lump), and Vidradhi (abscess). It is a Yamaka Sneha (dual oleation formulation) containing Ghrita (ghee) and Eranda Taila (castor oil) which contribute to Snehana as well as Anulomana (downward regulation of Apanavata). It took 6 days to observe the ideal signs and symptoms (Samyak Snigdha Lakshana – proper signs of oleation) expected after Accha Snehapana. This was followed by Bahya Abhyanga (external oil massage) and Bashpa Sweda (steam fomentation) for three days with dietary regimen of Mudga Yusha (green gram soup) and rice. Sarshapa Taila (mustard oil) possesses Lekhana (scraping) action due to its Ushna (hot) and Tikshna (sharp) qualities and alleviates the vitiation of Kapha, Meda, and Vata, whereas Bashpa Sweda eliminates morbid waste from the microchannels.

Virechana (therapeutic purgation) is the choice of Shodhana indicated in Granthi[24,25]. Hence, following Purvakarma (preparatory procedures), Virechana was administered as per Standard Operating Procedure[26] on the 3rd day morning after Kaphakala (Kapha-dominant time) in the present case. A dose of 50–100 g of Trivritavaleha was given based on the Koshta type (nature of bowel). Trivritavaleha[27] is a Hridya Virechana (cardiac-friendly purgative) containing Trivrit (Operculina turpethum), the supreme drug for Sukhavirechana (safe purgation) and indicated in Kapha-Pitta dominant conditions. Virechana purifies the Dhatus (body tissues) and restores their health.[28] According to the type of Shodhana (Pravara, Madhyama, Avara – excessive, moderate, and mild purification), 7/5/3 Annakala (meals) of Sansarjana Karma (post-therapy dietary regimen for recovery) was followed, after which a normal diet was resumed as per classical texts.

For medicinal management of Garbhashaya Granthi (uterine tumor), the use of Katu-Tikta Dravya (pungent and bitter substances), Shothahara, Lekhana, and Ksharana Dravya (corrosive substances) was employed as they directly act on Kapha Dosha, the main causative factor of Granthi.

Shigurdi Yoga, an Anubhoota Yoga (empirical formulation) consisting of equal parts of Shigru (Moringa oleifera Linn.), Kanchanara (Bauhinia variegata L.), Haridra (Curcuma longa Linn.), and Varuna (Crataeva nurvala Buch.-Ham.), plays a pivotal role in ameliorating cystic growths (Granthi) through multifaceted mechanisms. Shigru, rich in quercetin and antioxidants, induces apoptosis, inhibits abnormal cell proliferation, and neutralizes oxidative stress, a key driver of tumorigenesis.[29] Kanchanara, a key Ayurveda herb to manage glandular swellings, exerts cytotoxic and anti-inflammatory effects while reducing lymphatic blockages and promoting normal tissue architecture.[30] Haridra, enriched with curcumin, acts as a potent anti-angiogenic, epigenetic modulator, and immunomodulator, effectively starving neoplastic cells of nutrients, promoting apoptosis, and enhancing immunity.[31,32] Varuna complements these actions through its component stachydrine, which shows anti-fibrotic and uterine-regulating characteristics, targeting abnormal cellular growths.[33] Synergistically, these herbs regulate

cellular and systemic responses, reducing inflammation, preventing oxidative damage, regulating immune responses, and inhibiting fibrotic changes, thereby addressing the root causes of leiomyoma formations.

Kanchanara Guggulu is a classical Ayurvedic formulation used in Granthi (extra growth) and Arbuda (tumors) owing to its cytotoxic potential.[34] It inhibits cell division and thus reduces cell proliferation.[35] It helps break the pathogenesis of Granthi as it works on accumulated hardened Kapha in the tissues, which may manifest as Kaphaja Granthi. It also helps improve lymphatic drainage and eliminates inflammatory toxins. Overall, the ingredients in the formulation exhibit Vata-Kaphashamaka (pacifying Vata and Kapha), Shothahara (anti-inflammatory), Lekhana (bioscraping), and Bhedi (purgative) properties, which could have helped the reduction in the volume of leiomyoma, alleviating its cardinal symptoms.

Punarnavasava has been indicated in various diseases, including abdominal lumps and Shotha (inflammatory swelling).[36] Its Shothahara (anti-inflammatory) activity, as reported in several studies, may help reduce the accumulation of Dosha in uterine tissue, further preventing leiomyoma growth in this study.[37] This action is complemented by Punarnava, a key ingredient in the formulation that exhibits anti-proliferative, anti-fibrotic, and anti-estrogenic properties, suggesting its inhibitory role in estrogen-dependent leiomyomas.[38,39] Its Shothahara (anti-inflammatory) property might have helped in reducing the cervicitis changes in Case III.

Thus, it is clear that Shodhana (purificatory therapy) resulted in expelling the vitiated Dosha, destroying the pathogenesis of the disease. Shamana therapy (palliative treatment), which included Kapha-Vata Dosha Shamana (pacification of Kapha and Vata), Lekhana Karma (bioscraping action), and Granthi-Arbudahara Karma (tumor-resolving action), was offered to treat fibroids. This treatment prevented further growth. The therapy demonstrated relief in the symptoms of uterine fibroids, as well as a reduction in the number and volume of fibroids to some extent. Thus, the treatment protocol may prove beneficial in patients seeking medicinal intervention for the management of fibroid, as well as in patients unfit for surgical intervention.

Conclusion

The present case series highlights the potential role of Ayurvedic interventions in the conservative management of uterine leiomyoma. Administration of Shodhana Karma (Virechana) followed by Shamana Chikitsa with Shigrudi Yoga, Kanchanara Guggulu, and Punarnavasava resulted in normalization of menstrual cycles, reduction in abnormal vaginal discharge, and symptomatic relief in all three cases, along with a measurable (>20%) reduction in leiomyoma size. While these outcomes suggest that Ayurveda therapies may provide a safe, non-invasive alternative for the management of small uterine fibroids, the evidence from this limited case series cannot be generalized. Well-designed clinical trials with larger sample sizes, longer follow-up, and objective outcome measures are essential to validate efficacy, safety, and long-term benefits.

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