

A RANDOMISED OPEN-LABELLED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF ARBUDAHARA ARKA IN UTERINE LEIOMYOMAS

Dr. Amrut Patil^{*1}, Dr. Savita S. Patil²

¹Post Graduate Scholar, Department of Prasuti Tantra & Stree Roga.

²Professor & Guide, Department of Prasuti Tantra & Stree Roga.

Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru.

Article Received on 24 Sept 2026,

Article Revised on 14 Oct. 2026,

Article Published on 16 Oct. 2026,

<https://doi.org/10.5281/zenodo.23432661>

*Corresponding Author

Dr. Amrut Patil

Post Graduate Scholar, Department of
Prasuti Tantra & Stree Roga.



How to cite this Article: Dr. Amrut Patil^{*1}, Dr. Savita S. Patil² (2026). A Randomised Open-Labelled Controlled Clinical Study To Evaluate The Efficacy Of Arbudahara Arka In Uterine Leiomyomas. World Journal of Pharmaceutical Research, 15(20), 1416–1432.

This work is licensed under Creative Commons Attribution 4.0 International license.

ABSTRACT

Background: Uterine leiomyoma is a common benign smooth-muscle tumour of the uterus and may present with menstrual abnormalities, pelvic pain, pressure symptoms and reproductive problems. In Ayurveda, uterine fibroid may be clinically correlated with Granthi/Arbuda on the basis of its localized, nodular and relatively firm character and with involvement of Kapha-Vata and tissues including Rakta, Mamsa and Meda. The present study evaluated Arbudahara Arka, a distillate formulation described for Arbuda, and compared it with Kasisadi Yoga. **Aim:** To clinically evaluate the efficacy of Arbudahara Arka in uterine leiomyoma and to compare its effects with Kasisadi Yoga on disease-specific subjective and objective parameters. **Methods:** A randomized, open-labelled, controlled clinical study was conducted on 30 participants with

ultrasonographically diagnosed uterine fibroids. Participants were allocated by lottery method into Group A (n=15), receiving Arbudahara Arka 6 ml twice daily before food, and Group B (n=15), receiving Kasisadi Yoga twice daily before food. Treatment was continued for 90 days with assessments at baseline (D0), after 30 days, 60 days and 90 days. Subjective outcomes included pain working ability, pain location, days of pain, pain intensity and menstrual bleeding. Objective outcomes included number and size of fibroids assessed by ultrasonography. Wilcoxon signed-rank and Mann–Whitney U tests were used for non-parametric analysis; clinical effect size was calculated using $r = Z/\sqrt{N}$. **Results:** Both groups

showed improvement in pain-related symptoms and reduction in menstrual bleeding. Group A showed greater percentage improvement in days of pain (40.0% vs 30.0%) and pain intensity (50.0% vs 20.0%), whereas Group B showed greater improvement in working ability (45.5% vs 31.8%) and pain location (42.1% vs 38.9%). Improvement in menstrual bleeding was comparable (26.3% in both groups). The number of fibroids did not show meaningful reduction in either group. Fibroid size showed statistically significant within-group reduction, with large within-group effect sizes: 0.79 for Group A and 0.85 for Group B. No significant adverse drug reaction or rescue medication was reported. **Conclusion:** Both Arbudahara Arka and Kasisadi Yoga produced clinically beneficial changes in uterine leiomyoma. Arbudahara Arka showed comparatively greater improvement in several symptom domains, particularly pain duration and intensity, while Kasisadi Yoga showed greater improvement in working ability and pain location. Both interventions demonstrated significant reduction in fibroid size, and between-group analyses generally indicated comparable efficacy.

KEYWORDS: Uterine leiomyoma, uterine fibroid, Garbhashaya Granthi, Arbuda, Arbudahara Arka, Kasisadi Yoga, Granthi-hara, Lekhana.

INTRODUCTION

Uterine leiomyoma is a benign monoclonal tumour arising from uterine smooth-muscle cells. Its clinical expression varies according to number, size and location of the lesions. Patients may remain asymptomatic or present with heavy menstrual bleeding, dysmenorrhoea, pelvic pain, pressure symptoms, backache and reproductive disturbances. The present study was undertaken in the setting of the recognized clinical burden of uterine fibroids and the need for conservative approaches that can be evaluated systematically.

The thesis background notes that fibroids may vary in size, number and location and that intramural, submucosal and subserosal patterns are clinically relevant. The study population was restricted to fibroids measuring ≤ 5 cm. The predominant location in the present sample was intramural, comprising 86.66%, while submucosal and subserosal fibroids comprised 10% and 3.33%, respectively.

Ayurvedic classics do not describe 'uterine leiomyoma' as a separate named disease. The study therefore considered the condition through the broader concepts of Granthi and Arbuda, particularly Mamsaja/uterine growths, together with the symptom complex of abnormal

menstrual bleeding and pain. From this perspective, Kapha contributes to excessive growth and compactness, while Vata contributes to obstruction, pain and disturbed pelvic movement. Rakta, Mamsa and Meda may be involved as Dushya, with Srotorodha and impaired tissue metabolism contributing to the persistence of the lesion.

Arbudahara Arka is a distilled preparation containing Haridra, Lodra, Patanga, Shuddha Manashila, Gruhadhooma and Madhu. The formulation is described in the thesis as possessing predominantly Lekhana, Shothahara, Raktashodhaka, Kapha-Vata shamaka and Arbudahara actions. The Arka dosage form was selected with the intention of providing a relatively small oral dose with rapid and subtle action.

Kasisadi Yoga was selected as the comparator. It contains Varuna Kashaya, Shuddha Shilajatu, Kasisa Bhasma and Saindhava Lavana. The formulation is described in the thesis as having Lekhana, Kapha-Medohara, Granthihara, Shothahara, Raktashodhaka and Srotoshodhaka properties.

The rationale of the comparative study was therefore to assess whether the two interventions, acting through overlapping but pharmacologically distinct pathways, could produce measurable changes in symptoms and ultrasonographic fibroid characteristics.

AIM AND OBJECTIVES

Aim

To clinically evaluate the efficacy of Arbudahara Arka in uterine leiomyoma.

Primary Objective

- To evaluate and compare the clinical efficacy of Arbudahara Arka and Kasisadi Yoga in the management of uterine leiomyoma based on disease-specific subjective and objective parameters.

Secondary Objectives

- To conduct a detailed literary review of uterine leiomyoma.
- To conduct a detailed literary review of Arbudahara Arka.
- To review the individual drugs used in Arbudahara Arka.
- To prepare Arbudahara Arka according to the study protocol.
- To record and report any adverse drug reaction during the study.

Research Question

Whether Arbudahara Arka is effective in uterine leiomyoma?

Hypotheses

- Null hypothesis (H0): There is no significant difference in clinical efficacy between the interventions in uterine leiomyomas.
- Alternative hypothesis (H1): The clinical efficacy of Arbudahara Arka is better than Kasisadi Yoga in uterine leiomyomas.
- Alternative hypothesis (H2): The clinical efficacy of Kasisadi Yoga is better than Arbudahara Arka in uterine leiomyomas.

MATERIALS AND METHODS

Study Design

A randomized, open-labelled, controlled, comparative clinical study was conducted in the institutional clinical setting. Thirty eligible participants were enrolled and randomized into two equal groups by lottery method. There were no drop-outs; all 15 participants in each group completed the study.

Study Population

Participants were women aged 20–55 years with ultrasonographically demonstrated single or multiple uterine fibroids of size ≤ 5 cm. Both symptomatic and asymptomatic participants and those with regular or irregular cycles were eligible when they fulfilled the study criteria.

Inclusion Criteria

- Age 20–55 years.
- Ultrasound showing single or multiple uterine fibroids.
- Fibroid size ≤ 5 cm.
- Regular as well as irregular menstrual cycles.
- Symptomatic and asymptomatic uterine leiomyoma.
- Subject willing to provide informed consent.

Exclusion Criteria

- Subjects not fulfilling the diagnostic criteria or unwilling to participate.
- Patients with conditions requiring immediate surgical or emergency management.

- Pregnancy and other conditions in which study medication was considered unsuitable according to the study protocol.
- Participants unable to comply with treatment or follow-up.

Investigations

- Haemoglobin percentage.
- Ultrasonography of abdomen and pelvis.
- Liver function tests.
- Renal function tests.

Randomization and Allocation

Group	Participants	Intervention	Dose	Frequency	Duration	Anupana
A – Trial	15	Arbudahara Arka	6 ml	Twice daily, before food	90 days	Equal quantity of water
B – Control	15	Kasisadi Yoga	25 ml Kashaya with prescribed ingredients	Twice daily, before food	90 days	Equal quantity of water

Assessment Schedule

Assessment	Time	Description
BT / D0	Day 0	Pre-treatment baseline
AT / D30	Day 30	First post-treatment assessment
FU / D60	Day 60	Second assessment/follow-up
AF3 / D90	Day 90	Final follow-up assessment

Drug Preparation and Pharmaceutical Details

Arbudahara Arka

The thesis protocol describes Haridra, Lodra, Patanga, Gruhadhooma and Shuddha Manashila as the principal ingredients, with Madhu used in the preparation. Haridra, Lodra, Patanga and Gruhadhooma were taken in coarse form, while Shuddha Manashila was used as fine powder. The ingredients were mixed, soaked in water and subjected to distillation in an Arka Yantra. The distillate was collected and stored in an airtight container.

The preparation record in the thesis describes a laboratory batch in which 500 g each of the principal powdered ingredients were used, followed by soaking and addition of Madhu before distillation. The prepared Arka was dispensed as 360 ml per participant for the treatment period.

Drug Analysis

Parameter	Result
Physical description	Free-flowing liquid with characteristic odour
Specific gravity	0.97 g/ml
pH	4.92
E. coli	Absent
Salmonella spp.	Absent
Staphylococcus aureus	Absent
Shigella spp.	Absent
Pseudomonas aeruginosa	Absent
Total microbial plate count	100 CFU/g
Total yeast and mould	<10 CFU/g

Phytochemical Screening of Arbudahara Arka

Test	Finding
Starch – Iodine test	Negative
Protein – Biuret test	Negative
Steroids – Salkowski test	Positive
Flavonoids – Shinoda test	Positive
Saponins – Foam test	Positive
Alkaloids – Dragendorff test	Positive
Triterpenoids – Salkowski test	Negative
Polyphenols and tannins – Ferric chloride	Positive

Kasisadi Yoga

Kasisadi Yoga was prepared for oral administration using Varuna Kwatha as the decoction base, with Shuddha Kasisa Bhasma, Shuddha Shilajatu and Saindhava Lavana added according to the study protocol. The thesis protocol prescribed 25 ml of Kashaya with the specified powdered/mineral ingredients, twice daily before food, with equal quantity of water as Anupana.

Assessment Criteria

Subjective Parameters

Parameter	Assessment domain
Pain – Working ability	Effect of pain on routine/work
Pain – Location	Site/distribution of pain
Days of pain	Number/duration of painful days
Pain – Intensity	Severity of pain
Assessment of bleeding	Severity of menstrual blood loss

Objective Parameters

Parameter	Grading used in study
Number of fibroids	0 = none; 1 = one; 2 = two–three; 3 = >3
Size of fibroid	0 = none; 1 = 0.1–1 cm; 2 = 1.1–2 cm; 3 = 2.1–3 cm; 4 = >3 cm

Bleeding Severity

Grade	Clinical description
0 – Normal	2 pads/day with complete soaking
1 – Moderate	3–4 pads/day with complete soaking
2 – Severe	5 pads/day or more with complete soaking

Statistical Analysis

Data were recorded at D0, D30, D60 and D90. SigmaStat 32 was used for analysis. Wilcoxon signed-rank testing was used for within-group non-parametric comparisons and Mann–Whitney U testing for between-group comparisons. A p value >0.05 was considered non-significant, p<0.05 significant and p<0.001 highly significant. Clinical effect size was calculated as $r = Z/\sqrt{N}$ and interpreted as small (<0.3), medium (0.3–<0.5) and large (≥ 0.5).

OBSERVATIONS AND RESULTS

Study Flow

Thirty eligible participants were randomized into two equal groups. Group A received Arbudahara Arka and Group B received Kasisadi Yoga. Fifteen participants in each group completed the intervention and follow-up, with no drop-outs. No adverse drug reaction and no rescue medication were reported during the study.

Demographic Profile

Age group	Group A n (%)	Group B n (%)	Total observation
20–28 years	4 (26.66%)	4 (26.66%)	8 participants
29–38 years	7 (46.66%)	6 (40.00%)	13 participants
38–55 years	4 (26.66%)	5 (33.33%)	9 participants

Observation: The 29–38-year age group constituted the largest proportion of the study population. This places most participants in the active reproductive period, when ovarian steroid exposure and reproductive-age risk factors are relevant to leiomyoma development.

Inference: The distribution was broadly comparable between the two treatment groups, supporting baseline comparability for age.

The study also recorded predominance of Hindu, married and upper-middle socioeconomic participants, with most participants being graduates. Intramural fibroids were predominant (86.66%), followed by submucosal (10%) and subserosal (3.33%) lesions.

Overall Percentage Improvement

Parameter	Group A – Arbudahara Arka	Group B – Kasisadi Yoga	Comparative observation
Working ability	31.8%	45.5%	Greater improvement in Group B
Pain location	38.9%	42.1%	Greater improvement in Group B
Days of pain	40.0%	30.0%	Greater improvement in Group A
Pain intensity	50.0%	20.0%	Greater improvement in Group A
Menstrual bleeding	26.3%	26.3%	Comparable
Number of fibroids	Minimal change	Minimal change	No meaningful change
Size of fibroids	Significant reduction	Significant reduction	Comparable; slightly larger effect size in B

RESULTS – SUBJECTIVE PARAMETERS

1. Pain – Working Ability

Both groups showed improvement in the effect of pain on working ability during treatment and follow-up. The within-group effect size for Group A increased from 0.00 between baseline and the first post-treatment assessment to 0.52 by follow-up and 0.70 at the final assessment. Group B showed corresponding effect sizes of 0.00, 0.52 and 0.70 in the study record. Between-group effect sizes remained small, indicating that the two interventions were broadly comparable for this parameter.

Inference: Both interventions contributed to improvement in functional limitation caused by pain. The overall percentage improvement was 31.8% in Group A and 45.5% in Group B.

2. Pain – Location

Pain-location scores improved in both groups. Group A showed within-group effect sizes of 0.00, 0.45 and 0.73 for BT–AT, AT–FU and BT–AF3, while Group B showed 0.26, 0.58 and 0.77 respectively. These findings indicate that meaningful clinical improvement became more evident toward the later follow-up period.

Inference: Group B showed a higher percentage improvement in pain location (42.1%) than Group A (38.9%), although the difference between the interventions was not large.

3. Days of Pain

The number of days with pain decreased over the study period in both groups. Group A demonstrated within-group effect sizes of 0.00, 0.58 and 0.79, whereas Group B demonstrated 0.00, 0.52 and 0.73. The larger final effect size in Group A corresponds with the higher percentage improvement of 40.0% compared with 30.0% in Group B.

Inference: Both interventions reduced the duration of pain, with the study data showing a comparatively greater clinical change in Group A.

4. Pain Intensity

Pain intensity improved in both groups. Group A showed within-group effect sizes of 0.00, 0.45 and 0.68; Group B showed 0.26, 0.52 and 0.73. The overall percentage improvement was 50.0% in Group A and 20.0% in Group B.

Inference: A clinically meaningful reduction in pain intensity was observed in both groups, with the percentage improvement favouring Group A.

5. Menstrual Bleeding

Menstrual bleeding showed gradual improvement. Within Group A, effect sizes were 0.00, 0.58 and 0.73 for BT–AT, AT–FU and BT–AF3. Group B showed 0.00, 0.58 and 0.77. At the final assessment, both groups showed statistically significant improvement within the study record, while the overall percentage improvement was identical at 26.3%.

Inference: Both formulations demonstrated comparable clinical benefit in controlling menstrual bleeding, and the between-group comparison did not establish a meaningful superiority.

Results – Objective Parameters

1. Number of Fibroids

The median number of fibroids remained stable from baseline to the final assessment in both groups. The between-group p value was 0.983 at baseline and 0.983 at the final assessment. Within-group analysis did not demonstrate significant change. The within-group effect size was 0.00 in both groups.

Inference: Neither intervention demonstrated a clinically or statistically significant reduction in the number of fibroids during the 90-day study period.

2. Size of Fibroids

Fibroid size demonstrated the most consistent objective response. Within Group A, the BT–FU effect size was 0.79, classified as large. Group B showed a BT–FU effect size of 0.85, also large. Between-group analysis showed no significant difference at baseline or at the relevant comparison point, indicating comparable baseline status and broadly comparable reduction in fibroid size.

Inference: Both Arbudahara Arka and Kasisadi Yoga were associated with significant reduction in fibroid size within their respective groups. The slightly larger numerical effect size in Group B should be interpreted as a within-group effect and not as proof of between-group superiority.

Overall Grading

Group	Highly significant	Significant	Non-significant
Group A – Arbudahara Arka	0%	57.14%	42.85%
Group B – Kasisadi Yoga	0%	42.85%	57.14%

The overall grading indicates that a larger proportion of assessed outcomes reached statistical significance in Group A. However, the principal objective comparison should be interpreted together with the parameter-specific between-group analyses, which generally showed comparable efficacy.

DISCUSSION

Discussion on Disease

Uterine leiomyoma is a benign uterine tumour characterized by variable size, number and anatomical location. Clinically, its manifestations are closely related to the location and size of the lesion. In the present study, intramural fibroids predominated. This is clinically relevant because intramural lesions may produce pain, altered uterine contractility and menstrual abnormalities depending on their size and relationship to the endometrial cavity.

From an Ayurvedic perspective, the present study approached uterine leiomyoma through the concepts of Granthi and Arbuda rather than claiming a direct one-to-one textual equivalence. The nodular, localized, firm growth can be interpreted within the spectrum of Granthi/Arbuda, while the involvement of Kapha may explain the compact and persistent mass and Vata may contribute to pain, obstruction and disturbed movement in the pelvic region.

The thesis discussion considers Rakta, Mamsa and Meda among the involved Dushya and Srotorodha as an important component of the disease process. Dhatvagni impairment, particularly disturbance of Mamsa and Meda metabolism, may be understood as contributing to abnormal tissue accumulation. Thus, treatment principles such as Lekhana, Shoshana, Granthi-hara, Srotoshodhana and Kapha-Vata shamana become relevant.

Discussion on Chikitsa Siddhanta

- Kapha shamana addresses the compact, stable and proliferative component of the lesion.
- Vata shamana and Vatanulomana may reduce pain and improve pelvic physiological movement.
- Lekhana and Shoshana are directed toward reduction of excessive tissue accumulation.
- Srotoshodhana aims to address obstruction and improve local tissue circulation.
- Shothahara action may reduce inflammatory and oedematous components associated with symptomatic fibroids.
- Rakta-prasadana and supportive Rakta-related actions are relevant when menstrual blood loss accompanies fibroid disease.

Discussion on Arbudahara Arka

Arbudahara Arka is the trial formulation of the present study. Its therapeutic rationale can be understood by integrating the Ayurvedic properties of its ingredients with the pharmacological actions reported in the thesis.

Probable Ayurvedic Mode of Action

- Haridra, Lodra and Patanga possess Tikta/Kashaya predominance and are described with Lekhana, Shothahara and Raktashodhaka actions. These properties may help in reducing abnormal Mamsa-Meda accumulation and associated inflammatory changes.
- The formulation as a whole predominantly expresses Kapha-Vata shamaka, Deepana, Pachana, Lekhana, Shoshana, Granthi-hara and Arbudahara actions. These actions may help address Srotorodha and abnormal tissue metabolism.
- Ushna Virya, Tikta/Katu Rasa and Katu Vipaka in selected ingredients may support Srotoshodhana and metabolic correction.
- Lodra, with Kashaya Rasa and Rakta-stambhaka relevance, may contribute to control of excessive menstrual bleeding.

- Patanga and Haridra contribute antioxidant and anti-inflammatory potential, which may be relevant to oxidative stress and inflammatory pathways associated with fibroid biology.
- Shuddha Manashila and Gruhadhooma are considered in the thesis for Tikshna, Lekhana, Chedana and Kapha-Medohara actions.
- Madhu is considered Yogavahi and may facilitate the delivery and action of the formulation.

Modern Correlation

The thesis relates the phytochemical profile of the preparation to steroid, flavonoid, saponin, alkaloid and polyphenolic constituents. Haridra is known for curcuminoids and turmeric volatile constituents; Patanga contains characteristic phenolic compounds such as brazilin/brazilein. These constituents provide a plausible pharmacological basis for antioxidant and anti-inflammatory activity. Such mechanisms should be regarded as supportive hypotheses rather than proof of a direct anti-leiomyoma molecular effect in humans.

Discussion on Arka Kalpana

Arka is a liquid preparation obtained through distillation. The thesis attributes Sukshma, Tikshna, Vyavayi and Ashukari qualities to the Arka form. From the Ayurvedic pharmaceutical perspective, these qualities are considered to facilitate rapid and subtle action. The small administered dose of 6 ml twice daily may also improve acceptability and reduce the quantity of formulation required.

Discussion on Kasisadi Yoga

Kasisadi Yoga was selected as the comparative formulation because its ingredients are described as having Lekhana, Kapha-Medohara, Granthihara, Shothahara, Raktashodhaka and Srotoshodhaka properties.

Probable Therapeutic Action

- Varuna is described as Katu-Tikta and Ushna and is considered useful for Kapha-related accumulation and Srotoshodhana. The thesis associates its phytochemicals, including triterpenoid and flavonoid fractions, with anti-inflammatory and antiproliferative potential.

- Shuddha Shilajatu is considered Yogavahi and Rasayana and may support tissue metabolism. Fulvic/humic fractions are discussed in the thesis in relation to antioxidant and immunomodulatory activity.
- Kasisa Bhasma provides an iron-containing component and is considered relevant to Rakta Dhatu and anaemia associated with excessive menstrual loss. Its Lekhana action is also considered relevant to abnormal tissue accumulation.
- Saindhava Lavana possesses Sukshma and Vyavayi qualities and is considered to facilitate penetration, improve Srotoshodhana and enhance the action of other ingredients. Thus, Kasisadi Yoga may act through a combined Lekhana–Kapha–Medohara–Granthihara–Shothahara–Srotoshodhaka pathway. In modern terms, the formulation may plausibly influence inflammatory and oxidative pathways and tissue metabolism, although direct molecular mechanisms were not measured in the present trial.

Discussion on Demographic Profile

Factor	Observation	Inference
Age	Majority belonged to 29–38 years	Predominance in active reproductive age is compatible with the hormone-responsive nature of leiomyoma.
Religion	Hindu participants predominated	Reflects the study population rather than a disease-specific association.
Marital status	Married participants predominated	Likely reflects the demographic composition of the institutional population.
Socioeconomic status	Upper-middle group predominated	May reflect accessibility and characteristics of the institutional study population.
Education	Graduates formed the major educational category	Indicates relatively high educational representation in the sample.
Fibroid location	Intramural 86.66%; submucosal 10%; subserosal 3.33%	Intramural fibroids were the predominant anatomical pattern in the study.

The demographic profile of the two groups was broadly comparable. The predominance of intramural lesions is an important observation because symptom severity and menstrual manifestations can vary according to fibroid location.

Integrated Probable Mechanism of Action

Ayurvedic action	Probable clinical relevance	Modern correlate
Lekhana	Reduction of excessive tissue accumulation	Potential modulation of proliferative/metabolic pathways
Kapha-Medohara	Reduction of compact, excessive growth	Alteration of tissue lipid/metabolic environment
Shothahara	Reduction of inflammatory symptoms	Anti-inflammatory activity
Srotoshodhana	Reduction of obstruction/congestion	Improved microcirculatory environment
Raktashodhaka/Rakta-prasadana	Support of menstrual and blood-related manifestations	Antioxidant/haematinic supportive effects
Vatanulomana / Vata shamana	Reduction of pain and functional disturbance	Analgesic/anti-inflammatory correlation
Yogavahi	Facilitation of formulation action	Potential enhancement of delivery/availability

The clinical results provide support for symptom improvement and reduction in measured fibroid size, but they do not establish a specific biochemical mechanism. Hormonal assays, molecular markers and advanced imaging were not included; therefore, mechanistic explanations remain interpretive.

Comparative Discussion of Both Groups

The study demonstrated that both interventions produced clinically beneficial outcomes. Group A showed greater percentage improvement in days of pain and pain intensity, while Group B showed greater improvement in working ability and pain location. Menstrual bleeding improvement was comparable. Both groups demonstrated significant reduction in fibroid size, while the number of fibroids remained essentially unchanged.

The within-group effect sizes provide an additional dimension to the statistical findings. Group A demonstrated large final effects for days of pain (0.79), pain intensity (0.68), bleeding (0.73) and fibroid size (0.79). Group B demonstrated large final effects for pain location (0.77), days of pain (0.73), pain intensity (0.73), bleeding (0.77) and fibroid size (0.85).

These findings indicate that both interventions were associated with clinically meaningful changes within their respective groups. However, effect size within a group does not by itself establish superiority between groups. The between-group analyses generally showed no

statistically significant differences for the principal parameters, supporting the interpretation that the two formulations had comparable overall efficacy within the limits of this study.

CONCLUSION

- The randomized open-labelled comparative clinical study included 30 participants, with 15 participants in each group and no drop-outs.
- Both Arbudahara Arka and Kasisadi Yoga produced improvement in pain-related parameters and menstrual bleeding.
- Group A showed greater percentage improvement in days of pain (40.0%) and pain intensity (50.0%).
- Group B showed greater percentage improvement in working ability (45.5%) and pain location (42.1%).
- Improvement in menstrual bleeding was comparable in both groups (26.3%).
- No meaningful reduction in the number of fibroids was demonstrated during the 90-day period.
- Both interventions produced statistically significant reduction in fibroid size within the respective groups, with large effect sizes of 0.79 in Group A and 0.85 in Group B.
- No significant adverse drug reaction or rescue medication was reported during the study.
- Overall, the findings indicate that Arbudahara Arka and Kasisadi Yoga were both clinically beneficial and statistically comparable in the management of uterine leiomyoma.
- The study data do not establish a statistically significant overall superiority of either intervention; therefore, the null hypothesis of comparable efficacy is retained in the final interpretation of the thesis.

Further Scope of the Study

- Future studies should include a larger sample size to improve statistical power and generalizability.
- Longer follow-up should be undertaken to determine persistence of fibroid reduction and recurrence rates.
- Multicentric studies may help determine whether the findings are reproducible in different populations.
- MRI or standardized volumetric ultrasonographic assessment may provide more precise measurement of fibroid regression.

- Hormonal assays and relevant molecular/inflammatory biomarkers may help clarify the mechanism of action.
- Dose-escalation studies of Arbudahara Arka may be considered; the present study used 6 ml twice daily, and the thesis identifies 12 ml as a possible dose for future evaluation subject to safety assessment.
- Future studies should include detailed safety monitoring, especially for formulations containing mineral ingredients, with appropriate quality-control and toxicological assessment.

Limitations of the Present Study

- The study was open-label and therefore observer and participant bias cannot be excluded.
- The study was conducted at a single centre, limiting wider population representation.
- Advanced imaging modalities such as MRI and hormonal assays were not included.
- The sample size was small.
- The study duration and follow-up period were limited to 90 days.

REFERENCES

1. Tiwari PV. Ayurvediya Prasutitantra Evam Streeroga. 2nd ed. Vol. 2. Varanasi: Chaukhambha Orientalia, 2017; p. 139.
2. Shastri K, Chaturvedi G. Vidyotini Commentary on Charaka Samhita, Chikitsa Sthana. Varanasi: Chaukhamba Bharati Academy; Reprint, 2017.
3. Tripathi B. Dipika Hindi Commentary on Sharangadhara Samhita, Purva Khanda, Kaladi Adhyaya, Chapter 5, Verse 28. Varanasi: Chaukhambha Surbharati Prakashan; Reprint, 2011.
4. Acharya YT, editor. Sushruta Samhita with Nibandhasangraha Commentary. Varanasi: Chaukhambha Surbharati Prakashan.
5. Charaka Samhita of Agnivesha with Ayurveda Dipika Commentary. Varanasi: Chaukhambha Krishnadas Academy.
6. Arka Prakasha. Classical reference for Arbudahara Arka as cited in the thesis.
7. Standard Ayurvedic pharmaceutical literature describing Arka Kalpana and Arka Yantra.
8. Ayurvedic materia medica references for Shuddha Manashila.
9. Ayurvedic materia medica references for Patanga.
10. Ayurvedic materia medica references for Lodra.
11. Ayurvedic materia medica references for Haridra.

12. Ayurvedic materia medica references for Madhu.
13. Contemporary gynecology literature on uterine leiomyoma and hormone-responsive growth.
14. Contemporary literature on clinical manifestations and diagnosis of uterine leiomyoma.
15. Contemporary gynecology literature describing intramural, submucosal and subserosal fibroids.
16. Contemporary clinical literature on ultrasound assessment of uterine fibroids.