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A RANDOMIZED OPEN LABELLED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF *KSHARA GUDIKA* AND *PANCHATIKTA GHRITA UTTAR BASTI* IN THE MANAGEMENT OF *GARBHASYA ARBUDA* W.S.R. UTERINE FIBROID

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ABSTRACT

Background- Uterine fibroids are the most common benign tumour of the pelvic area found mainly in the reproductive age group. They range from tiny, undetectable seedlings to large, bulky masses that can distort the cavity and enlarge the uterus. Uterine fibroids are classified into various types as per location, are mainly asymptomatic, and few individuals have symptoms such as irregular cycles with flow and patterns, pressure symptoms, and lower abdominal pain. The growth of fibroids is tied to reproductive hormones like Estrogen & progesterone. Allopathy has options regarding treatment ranging from wait & watch to surgical removal. But as per a study to improve the quality of life of women, Ayurvedic approaches case *Arbuda* differently. As *Kapha* predominance is central in its pathogenesis along with *Rasa, rakta, mamsa & meda* involved in its *samprapti, Uttar Basti Chikitsa* is considered for the treatment. *Acharya Yogaratnakar* has indicated *Panchatikta Ghrita* in *arbuda* management. Chapter: Similarly, *Acharya Charaka* mentioned *Kshara Gudika* in Shoth Chikitsa-12 for the management of granthi, indirectly for *Arbuda* treatment. A combined and individual comparative study was performed for its management to avoid the surgical option until much needed.

KEYWORDS: *Arbuda*, Fibroid, Tumor, Hysterectomy.

AIM: Evaluate the efficacy of *Kshara Gudika* and *Panchatikta Ghrita Uttar Basti* combination in the management of *Garbhasya Arbuda* w.s.r Uterine Fibroid.

OBJECTIVES

Primary Objective: To clinically compare the efficacy of Kshara Gudika and Panchatikta Ghrita Uttara Basti in combination & Panchatikta Ghrita Uttarabasti individually in the management of Garbhasya Arbuda w.s.r. Uterine Fibroid.

Secondary Objective

1. To study in detail *Garbhasya Arbuda* in modern and Ayurvedic literature. To find out an *Ayurvedic* approach for the management of *Garbhasya Arbuda*.
2. To investigate how the medicine affects the subjective and objective clinical parameters related to *Garbhasya Arbuda*.
3. To standardize an *Ayurvedic* course of therapy, including the medication and dosage, which may play a vital role in the treatment of *Garbhasya Arbuda*.

Methodology: 60 patients fulfilling the inclusion criteria of the study will be selected and randomized into 2 groups (30 in each group).

- Group A - 30 patients will be receiving both *Kshara Gudika* and *Panchatikta Ghrita Uttar Basti*.

- Group B - 30 patients will be receiving *Panchatikta Ghrita Uttar Basti* only.

Observations will be done on the basis of before and after subjective and objective parameters and clinical investigations.

KEYWORD: *Arbuda*, Fibroid, Hysterectomy, *Uttarbasti*, Hysterectomy.

INTRODUCTION

Women's health should be a big focus in any woman's life. Owing to complicated female body structure, women are subject to a large number of complaints & surrounded with various kinds of disease. Among them, uterine fibroid/fibromyoma/leiomyoma has an important place in present time. Regarding its treatment, surgical intervention has historically been mainstay of uterine fibroid treatment. Major modern approaches, at the expense of future fertility loss, have unwelcome side effects. As the economic burden due to uterine fibroids increases, these benign tumors are a major health concern. Women looking for non-invasive methods. Due to modern science limitations, Ayurveda has great scope in the field to find out effective & non-invasive approach to manage the disease.

On exploring *Samhita*, study revealed that symptomatology of disease entity *"Arbuda"* correlated to tumor. In classical texts, special reference of *Arbuda* of the female reproductive system is not available, but on basis of the origin in *Garbhasya* (uterus), it is compared with *Garbhasya Arbuda*.

Aggravated *doshas* vitiating *Mamsa, Rakta, and Meda* getting localized in *garbhasya* (uterus) produce local swelling[3] in deep muscles, which is round, fixed, small, big associated with pain, deep-seated roots, and increasing gradually.

The principle of *Samprapti Vighatan* i.e. to break the pathogenesis used for the management of uterine fibroid. The protocol for the treatment of *Garbhasya Arbuda* is to dissolve/reduce the size. Here is an attempt on *Kshara Gudika* described by *Acharya Charaka* and *Panchatikta Ghrita Uttar Basti* mentioned in *Yog Ratnakar*.

AIMS AND OBJECTIVES

Aim: To evaluate the efficacy of *Kshara Gudika* and *Panchatikta Ghrita Uttar Basti in* combination in the management of *Garbhasya Arbuda* w.s.r. Uterine Fibroid.

Primary Objective: To clinically compare the efficacy of *the Kshara Gudika* and Panchatikta Ghrita Uttara Basti combination & Panchatikta Ghrita Uttarabasti individually in the management of *Garbhasya Arbuda* w.s.r. Uterine Fibroid.

Secondary Objective

1. To study in detail *Garbhasya Arbuda* in modern and Ayurvedic literature. To find out an *ayurvedic* approach for the management of *Garbhasya Arbuda.*
2. To investigate how the medicine affects the subjective and objective clinical parameters related to *Garbhasya Arbuda*.
3. To standardize an *Ayurvedic* course of therapy, including the medication and dosage which may play a vital role in the treatment of *Garbhasya Arbuda*.

Research Question

Is there any efficacy of *Kshara Gudika* and *Panchatikta Ghrita Uttar Basti* combination in the management of *Garbhasya Arbuda* w.s.r. Uterine Fibroid?

RESEARCH HYPOTHESIS

Kshara Gudika and *Panchatikta Ghrita Uttar Basti* in combination is significantly effective in the management of *Garbhasya Arbuda*.

NULL HYPOTHESIS

There is no efficacy of *Kshara Gudika* and *Panchatikta Ghrita Uttar Basti* in combination in the management of *Garbhasya Arbuda*.

Experimental Source: It will be a pure Human Clinical trial; no animal experiment will be done.

MATERIALS AND METHODS

To fulfill the aim and objectives, the study plan is divided into 2 sections.

- Literary review
- Clinical study.

Study design

- Type of Trial – Interventional
- Design- Randomized clinical trial
- Purpose – Treatment
- Masking- No, Open Label
- Timing- Prospective
- End Point- Efficacy
- Duration of trial- 18 months
- Phase of trial- phase 2
- Subjects- 60 (30 in each group)
- Statistical tool—The appropriate tool will be apply

Selection of patients: The patients fulfilling the criteria and attending PTSR OPD and IPD of the Prasuti Tantra Evam Stree Roga department of the I.A.S.R Kurukshetra Haryana will be selected for research study.

Inclusion Criteria[5]

- ❖ Patients having an age group from 20 to 50 years old.
- ❖ Patients having fibroid size < or = 5 cm as per USG (TVS) Report.
- ❖ A single or multiple fibroid.

- ❖ Patients either asymptomatic or having clinical sign and symptoms of uterine fibroid.
- ❖ Patient willing to participate in trial.

Exclusion criteria

- ❖ Patients below age of 20yrs. and above age of 50yrs.
- ❖ Patients having fibroid size > 5cm as per USG report.
- ❖ Pregnancy cases
- ❖ Ovarian tumor, Tubo-ovarian mass, any Malignant tumors.
- ❖ Patient with HTN, TB, uncontrolled DM and any other severe systemic diseases.
- ❖ Patients with CA-125>50 units/ml
- ❖ Patients with BMI less than 18.5 / Hyperacidity/ ulcers/ (for oral drug)
- ❖ Unmarried girl (For Uttara Basti only)
- ❖ Postmenopausal stage
- ❖ Patient who have developed sarcomatous changes in fibroids.
- ❖ Fibroid with Adenomyosis.

Investigations

For assessing the general condition of patient and exclusion of other pathogenesis the following investigation may be performed: Blood and Serological test -

1. CBC
2. ESR
3. RBS
4. CA-125

MATERIAL AND METHODS

Clinical study materials: Patients indicated as fit for trial were selected from outpatient & inpatient departments of Prasuti Tantra Evam Stree Roga, I.A.S.R., Kurukshetra, Haryana.

Conceptual study materials: Literary references are collected from Ayurvedic Samhitas and their commentaries, modern literature, research journals, and online portal like PubMed, Ayush research portal, Google scholar are analysed to frame the conceptual work.

DRUG REVIEW

INTERVENTIONS FOR EACH GROUP

GROUP A:- Comparative group

1. *Kshara Gudika* (GMP certified) - 500 mg, BD with *Sukhoshan Jala*, after meals given to potential patients for 90 days (cessation during menses). Route of administration: Oral route.

2. *Panchatikta Ghrita* (GMP certified) - 4 ml (intrauterine) for 3 days after cessation of menses – 3 consecutive cycles.

GROUP B: Comparative group

1. *Panchatikta Ghrita* (GMP certified) - 4 ml (intrauterine) for 3 days after cessation of menses—3 consecutive cycles.

INTERVENTION PERIOD - PROCEDURE FOR TRIAL DRUG

S.NO.	GROUP	GROUP	MEDICATIONS	DOSE	NO. OF PATIENTS	Duration
1.	Group A	Trial group	*Kshara Gudika + Panchtikta Ghrita Uttar Basti*	2 Tab. BD (1 Tab.= 250mg) after meal, with lukewarm water + 4 ml (Intra uterine) for 3 days after cessation of menses	30	3 months
2.	Group B	Trial group	*Panchtikta Ghrita Uttar Basti only*	4 ml (Intra uterine) for 3 days after cessation of menses	30	3months

Method of administration of Basti[4]

Poorva Karma - Local mridu *abhyanga and swedana are* to be given before *Uttar Basti* administration.

Pradhana Karma - A Sims speculum and retractor are used to visualize the cervix, and Allis forceps are applied to the anterior lip.

- The vaginal canal and cervix are swabbed with antiseptic, and the uterus is measured using a uterine sound.
- The cervical os is gently dilated with Hegar's dilators to admit the uterine canula.
- The medicated oil or decoction is then injected slowly into the uterus using a syringe while the patient is in a head-low position.

Paschat Karma—The expelled medicated substance is observed, and a sterile gauze is placed in the vagina.

- The instruments and towels are removed carefully.
- The patient remains in a head-low position for 15 minutes in the operating room and is advised to rest for 2-3 hours.

- Vital signs, such as pulse and blood pressure, are monitored for two hours.

Route of administration: Vaginal route.
Follow-up - 30th, 60th, and 90th days.

DIAGNOSTIC CRITERIA

- All routine laboratory investigations and relevant clinical examinations to rule out systemic illnesses and ensure the fitness of the patient for the proposed intervention were conducted.

- **Laboratory Investigations**: CBC, ESR, RBS, CA125.
- **Radiological Investigation**: USG (Pelvis).

ASSESSMENT CRITERIA
All these symptom assessments will be done by using the Symptom Rating Scale as following.

❖ **Subjective Criteria**	**Objective criteria**
❖ Lower Abdominal Pain ❖ Constipation ❖ Backache ❖ Urine incontinence ❖ Menstrual	❖ Size of fibroid

Subjective Parameters Grade

1. Lower Abdominal Pain

Nopain	0
Painful, no analgesic Required	1
Painful, daily activity affected, analgesic required	2
Analgesic required but no effect	3

2. Constipation

No constipation	0
Passes hard/soft stool regularly	1
Passes hard stool all time, but no need of laxatives	2
Need laxatives to pass stool	3

3. Backache

No pain	0
Painful, no analgesic required	1
Painful, daily activity affected, analgesic required	2
Analgesic required but no effect	3

4. Urine incontinence

No urine loss found	0
Urine loss in droplets, while standing	1
Urine loss in a stream, while standing	2
Urine loss in a stream, while lying down	3

5. Menstrual

Sr. No.	Assessment Criteria	Grading 0	Grading 1	Grading 2	Grading 3
1.	Intervals between menstrual cycles	25-28 days	20-25days	15-20days	Up to 15 days or irregular
2.	Duration of menstrual bleeding	3-5days	6-8days	9-11days	<11 days
3.	Quantity of menstrual bleeding	<5pads/day without clots	5-6 full soaked pads/day without clots	5-6pads/day with clots	>6pads/day with or without clots
4.	Pain during menses	No Pain	Mild	Moderate	Severe with sleep disturbance

Objective Parameters **Size of fibroid**

SIZE	GRADING
Below 2cm	0
>2cm&<4cm	1
4cm-5cm	2

OVERALL ASSESSMENT OF THERAPY

No improvement	<25%
Mild improvement	26%-50%
Moderate improvement	51-75%
Marked improvement	76-99%
Cured	100%

OUTCOMES

- **PRIMARY OUTCOME -** To resolve or reduce the size of uterine fibroids.
- **SECONDARY OUTCOME -** Changes in other associated clinical features related to uterine fibroid.

SAMPLE SIZE

The sample size is calculated on the basis of maximum and minimum expected cure rate among the study groups using the formula:

$$n = \frac{\left(z_{\alpha} + z_{\beta}\right)^{2}}{\left[\ln\left(1 - e\right)\right]^{2}} \left[\frac{1 - p_{1}}{p_{1}} + \frac{1 - p_{2}}{p_{2}}\right]$$

Where p_1 = 0.2115 (21.15%) maximum expected cure rate among the study groups.
p_2 = 0.1739 (17.39%) minimum expected cure rate among the study groups.
(Ref: Rajput, Shivshankar & Mata, Shweta & Dei, Laxmipriya. (2020). COMPARATIVE CLINICAL STUDY OF AYURVEDIC THERAPY AND INTERVENTION IN THE MANAGEMENT OF UTERINE FIBROID: AN OPEN LABEL, PROSPECTIVE RANDOMIZED PARALLEL GROUP STUDY. International Journal of Research in Ayurveda and Pharmacy. 11. 128-133. 10.7897/2277-4343.1104102.)
e = 1.05(p_2 / p_1), the proportion ratio considered to be clinically significant
Type I error, α=5%
Type II error β=10% for detecting results with power of study 90%
The sample size is **n = 28 each group round off 30.**

Statistical Analysis

The observations and results will be analyzed and presented on the basis of respective and applicable statistical tests.

Ethical Clearance & CTRI Registration

- Study was started after obtaining ethical clearance from the Institutional Ethics Committee, I.A.S.R. Kurukshetra. **SKAU/Acad/2024/11575**
- Study was registered in CTRI: - **CTRI/2024/11/077505**

OBSERVATION AND RESULT

The observations and results will be analyzed statistically with relevant tests, and the level of significance will be reported.

DISCUSSION

The obtained results will be discussed on the basis of Ayurvedic concepts and modern parameters.

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