Research Article

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A CLINICAL STUDY IN THE MANAGEMENT OF GARBHASHAYA GRANTHI WITH SARJADI LEPA WITH SPECIAL REFERENCE TO FIBROID UTERUS

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ABSTRACT

Background: Uterine fibroids are the most common gynaecological disorder, and as such, it should not be surprising that, over the countries. It is also a well-known fact that fibroid is one of the lifestyle disorders that have risen to numbers that never existed before. Uterine fibroid, considered as Garbhashaya Granthi in this study, is one of the forms of current lifestyle disorder. When the fibroid size is small, it may or may not show symptoms. In the presence of symptoms, the patient may suffer from menorrhagia, dysmenorrhea, anaemia, etc. Fibroid is dependent on oestrogen, and therefore, a hyperestrogenic state will be there. It will grow potentially in the childbearing period. An attempt is made to reverse this pathogenesis and reduce the fibroid growth. Aim: To analyse the efficacy of Sarjadi lepa along with oral Chitraka moola churna in the management of Garbhashaya Granthi with special reference to fibroid uterus. Method: A randomised open-labelled controlled clinical study of two groups of 15 patients, the control and trial groups, in each group. Results: Size of fibroid reduction was seen in both the groups, but Group B patients had a little more size reduction compared to Group A. Conclusion: Combined Chitraka moola churna orally along with Sarjadi lepa and alone Chitraka moola churna orally is equally effective in Garbhashaya Granthi with special reference to fibroid uterus.

Keywords: Garbhashaya Granthi, Sarjadi lepa, Chitraka moola churna, uterine fibroid.

INTRODUCTION

One of the most critical aspects of women's health is reproductive health. A woman's health reflects her biological, sociocultural, economic, and physical environment. These factors affect both the duration and quality of her life. Uterine fibroids are one of the most common and yet understudied diseases in women, affecting mainly during reproductive years in about 68.6%.

A fibroid is a non-cancerous tumour of smooth muscle elements; later, it intermingles with fibrous tissue to be called fibromyomata[1]. When the size is small, it may or may not show symptoms. In the presence of symptoms, the patient may suffer from menorrhagia, dysmenorrhea, anaemia, etc. Fibroid is dependent on oestrogen, and therefore, a hyperestrogenic state will be there. It will grow potentially in the childbearing period.[2]

The risk of fibroid decreases with increased parity[3], which occurs before menopause in 80% of cases. In fibroids, intramural fibroids contribute to 75 %, submucosal fibroids contribute to 5%, and subserosal fibroids contribute to 15% of cases[4]. To date, most therapy for fibroids has been surgical, either myomectomy or hysterectomy. Surgical interventions require general anaesthesia, lengthy hospital stays, and long recovery periods. Removal of the uterus is unacceptable to women who desire further childbearing, though it offers a definitive solution to the problem.

Anti-hormonal drugs like progestin or danazol block estrogen to treat fibroids. Uterine fibroid embolisation (UFE) gonadotropin-releasing hormone (GnRH) agonists are other forms of treatment. However, even though the bleeding and dysmenorrhea-related symptoms are treated, the actual myoma size remains unchanged[5].

It is, therefore, highly desirable for the condition to be treated conservatively as much as possible by Ayurvedic interventions with local application and oral medicines.

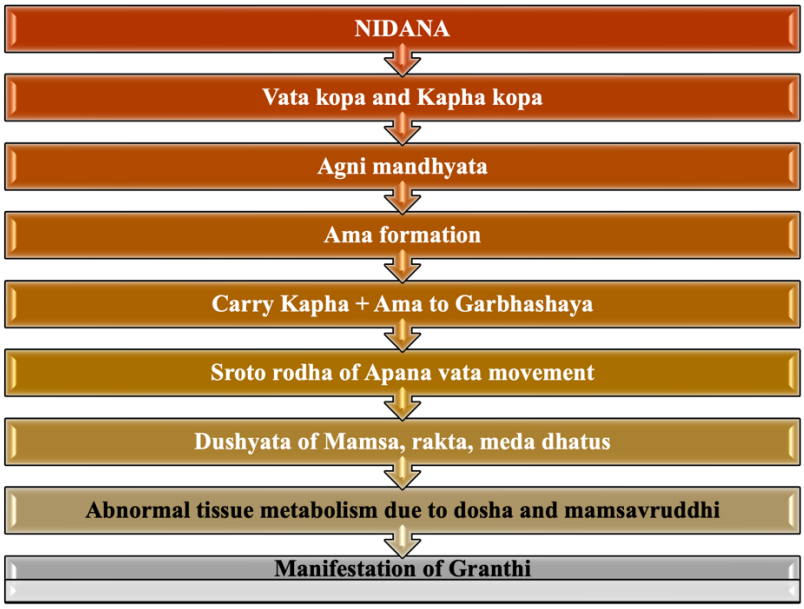
Vitiation of tridosha leads to the formation of a knotty hard swelling. Since it is knotty, it is termed as Granthi [6]. Mamsa granthi is a condition due to the vitiation of mamsa dhatu by consumption of a diet capable of increasing mamsa, which produces big, smooth granthi covered with a network of veins[7]. This can be correlated with uterine fibroids.

As in the body, tiryak dhamanis divide into innumerable and form network-like structures. Their openings are attached to hair follicles, which carry sweda and rasa. The viryas of drugs (Sarjadi lepa), which are applied on the skin, transfer into openings of hair follicles and then to the dhamanis and to the particular organ, where the virya of drugs should affect their action.8 Chitraka moola churna, which is ushna, Vatahara, and Shothahara, will reduce the increased Meda dhatu, and Kapha dosha ultimately reduces the Granthi. Hence, the present study is intended to evaluate the efficacy of combined treatment of Sarjadi lepa as an external application along with oral intake of Chitraka moola churna in the uterine fibroid.

Objectives

- To evaluate the effect of Sarjadi lepa and the internal use of Chitraka moola churna in managing fibroid uterus.

- To re-evaluate the effect of internal use of Chitraka moola churna alone in managing fibroid uterus.
- To compare and evaluate the effect of Sarjadi lepa with the internal use of Chitraka moola churna and internal use of Chitraka moola churna alone in the management of fibroid uterus.
- To study the detailed literary review of Garbhashaya Granthi and the fibroid uterus.



Garbhashaya Granthi formation

MATERIALS AND METHODS

Since the present study was a controlled clinical study, two drugs, i.e., a standard and the test drug was selected, they are:
Chitraka moola churna orally
Combined Chitraka moola churna orally and the external application of Sarjadi lepa on the lower abdomen.

Chitraka moola churna was procured from a GMP-certified pharmacy.

Sarjadi lepa ingredients are Sarja kshara, Mulaka kshara, and Shankha churna, which was prepared at the Department of Rasa Shastra and Bhaishajya Kalpana, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.

Sampling Method and Research Design

Source of data: 30 subjects with Garbhashaya granthi were randomly selected from the OPD and IPD of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India. The selected 30 patients were divided into two equal groups of 15 patients. A detailed proforma was prepared considering all points of the study were prepared. The parameters considered for the study were scored based on standard methods and were analysed statistically.

Research Design

A simple randomised open-label controlled clinical study. Thirty subjects fulfilling the diagnostic criteria of Uterine fibroid symptoms were selected and randomly categorised into Group A and Group B using a lottery. Ethical clearance for this study: SSIEC Protocol no: SSIEC/192/2021 Dated 23/07/2021.

Diagnostic Criteria

Diagnosis was made based on the following criteria;
Size of fibroid less than or equal to 5 cm (diagnosed with USG).
Pattern of uterine bleeding.
Clinical presentation, such as pain in the lower abdomen and back.

Lab Investigations

- USG of abdomen and pelvis
- Hb%

Inclusion Criteria

- Subjects are in the age group of 20-45 years, irrespective of their marital status.
- Consent from the subjects
- Fibroid size less or equal to 5 cm.
- Single or multiple fibroids.
- Intramural fibroid and Subserosal fibroid
- Asymptomatic patients with fibroid uterus.
- Hb% more than 8g %.

Exclusion Criteria

- Subjects who had menopause.
- Subjects with degenerative changes in the fibroid.
- Subjects with fibroid size> 5 cm.
- Subjects with submucosal fibroid.
- Subjects who are pregnant and lactating.
- Subjects with a history of malignancy.
- Subjects having uterine prolapse.
- Subjects having the chronic systemic illness.
- Subjects who are non-co-operative.
- Subjects who are undergoing hormonal treatment.
- Subjects who are having metrorrhagia.
- Menorrhagia.

Table 1: Intervention in both the groups

	Group A	Group B
Medicine	Chitraka moola choorna	Chitraka moola churna+ Sarjadi lepa
Dose	2 gm TID with milk	2 gm TID with milk Lepa over the lower abdomen.
Time of administration	After food	After food
Duration of treatment	60 days	60 days Lepa 48 days.
Duration of study	2 months	2 months
Follow-up	Assessment on the 30th day and 60th day	Assessment on the 30th day and 60th day

Assessment Criteria

Subjective parameters

- P/V bleeding
- Pain in the lower abdomen
- Backache

Objective parameters:

- Size of fibroids
- Pads used per/day.

Assessment Schedule

In both, the group assessment was done on the:

- 0th day - 1st assessment before treatment
- 30th day - 2nd assessment after treatment
- 60th day – Follow-up.

Table 2: Grading of subjective and objective criteria

Parameter	Grading	Findings
Duration of blood loss during menstruation	0	3-5 days
	1	6-10 days
	2	11-15 day
The interval between menstrual cycle	0	Regular: 28-32 days
	1	21 days or less
	2	Intermenstrual: bleeding occurring at 15-16 days cycle
	3	Delayed: menstrual bleeding occurring more than 35 days
Clots during menstruation	0	1 clot
	1	2 clots
	2	3 clots
	3	4 clots
Dysmenorrhea	0	No pain
	1	Mild pain
	2	Moderate pain
	3	Severe pain
Backache	0	Absent
	1	Present
Pain in the lower abdomen	0	Absent
	1	Mild (subsides with rest only)
	2	Moderate (subsides with medicine)
	3	Severe (Pain does not subside with the use of medicine)
Number of pads/day	0	1-2 pads
	1	3-4 pads
	2	5-6 pads
Size of fibroid reduction	0	Reduction in fibroid size 1-1.9 cm
	1	Reduction in fibroid size 2-3.9 cm
	2	Reduction in fibroid size 4-5 cm

OBSERVATIONS

All the 30 patients who approached the OPD and IPD of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru. All the patients were fresh cases and were not initiated on other allopathic and Ayurvedic drugs.

Duration of blood loss during menstruation: Among 15 patients in Group A, 86.66% had mild PV bleeding, 13.33% had moderate PV bleeding, and 00% had heavy bleeding before treatment. After treatment, 100% had mild bleeding. 100% had mild bleeding during follow-up. Among 15 patients in Group B, 73.33% had mild PV bleeding, 26.66% had moderate PV bleeding, and 00% had heavy bleeding before treatment. After treatment, 100% had mild bleeding. 100% had mild bleeding during follow-up.

An interval of the menstrual cycle: Among 15 patients in Group A, 80% had a regular interval between the cycles, 20% had more than 35 days of interval between the cycles, and 00% had < 21 days of interval between the cycles, 00% had intermenstrual bleeding, i.e. <15 days interval between the cycles before treatment. After treatment, 100% had regular cycle intervals, i.e. 28-32 days of interval. 100% had a regular cycle interval, i.e. 28-32 days of interval during follow-up. Among 15 patients in Group B, there was an 80% regular interval between the cycles, 13.33% had more than 35 days of interval between the cycles, 6.6% had < 21 days of interval between the cycles, 00% had intermenstrual bleeding, i.e. <15 days interval between the cycles before treatment. After treatment, 93.33% had regular intervals of the cycle, i.e. 28-32 days of interval, and 6.6% had more than 35 days between the cycles. 100% had regular cycle intervals, i.e. 28-32 days of interval during follow-up.

Dysmenorrhea: Among 15 patients in Group A, 20% had no dysmenorrhea, 20 % had mild, 33.33% had moderate dysmenorrhea, and 26.66% had severe dysmenorrhea before treatment. After treatment, 20% had no dysmenorrhea, 46.66% had mild, 33.33% had moderate, and 00% had severe dysmenorrhea. 33.33% had no dysmenorrhea, 46.66% had mild, 20 % had moderate, and 00% had severe dysmenorrhea during follow-up. Among 15 patients in Group B, 13.33% had no dysmenorrhea, 13.33 % had mild, 40% had moderate dysmenorrhea, and 33.33% had severe dysmenorrhea before treatment. After treatment, 20% had no dysmenorrhea, 26.66% had mild dysmenorrhea, 53.33% had moderate dysmenorrhea, and 6.6% had severe dysmenorrhea. 20% had no dysmenorrhea, 66.66% had mild, 20 % had moderate, and 00% had severe dysmenorrhea during follow-up.

Clots during menstruation: Among 15 patients in Group A, 80% had 1-2 clots per day, 13.33% had 2-3 clots, 6.6% had 3-4 clots per day, 0% had 4-5 clots per day before treatment. After treatment, 86.66% had 1-2 clots per day, 13.33% had 2-3 clots, and 0% had 3-4 and 4-5 clots per day. 33.33% had 1-2 clots, 46.66% had 2-3 clots, and 00% had 3- 4 and 4-5 clots per day during follow-up. Among 15 patients in Group B, 73.33% had 1-2 clots per day, 20% had 2-3 clots, 6.6% had 3-4 clots daily, and 0% had 4-5 clots per day before treatment. After treatment, 93.33% had 1-2 clots per day, 6.6% had 2-3 clots, and 0% had 3-4 and 4-5 clots per day. 93.33% had 1-2 clots, 6.6% had 2-3 clots, and 00% had 3-4 and 4-5 clots per day during follow-up.

Pain in the lower abdomen: Among 15 patients in Group A, 00% had no lower abdominal pain during menstruation, 20% had mild pain in the lower abdomen, 46.66% had moderate pain, 33.33% had severe pain in the lower abdomen during menstruation before treatment. After treatment, 6.6% had no lower abdominal pain during menstruation, 53.33% had mild pain in the lower abdomen, 40% had moderate pain, and 00% had severe pain in the lower abdomen during menstruation. 33.33% had no lower abdominal pain during menstruation, 60% had mild pain in the lower abdomen, 6.6% had moderate pain, and 00% had severe pain in the lower abdomen during menstruation during follow-up. Among 15 patients in Group B, 00% had no lower abdominal pain during menstruation, 20% had mild pain in the lower abdomen, 40% had moderate pain, and 40% had severe pain in the lower abdomen during menstruation before treatment. After treatment, 6.6% had no lower abdominal pain during menstruation, 33.33% had mild pain in the lower abdomen, 53.33% had moderate pain, and 6.6% had severe pain in the lower abdomen during menstruation. 20% had no lower abdominal pain during menstruation, 33.33% had mild pain in the lower abdomen, 46.66% had moderate pain, and 00% had severe pain in the lower abdomen during menstruation during follow-up.

Backache: Among 15 patients in Group A, 40% had no backache during menstruation, and 60% had backache before treatment. After treatment, 60% had no backache during menstruation, and 40% had backache. 66.66% had no backache during menstruation, and 33.33% had backache during menstruation during follow-up. Among 15 patients in Group B, 26.66% had no backache during menstruation, and 73.33% had backache during menstruation before treatment. After treatment, 26.66% had no backache during menstruation, 73.33% had backache. 60% had no backache during menstruation, and 40% had backache during the follow-up.

Pads/Day: Among 15 patients in Group A, 33.33% had used 1-2 pads per day, 53.33% had used 2-3 pads per day, and 13.33% had used 4-5 pads/day before treatment. After treatment, 13.33% had used 1-2 pads/day, 80% had used 2-3 pads/day, and 6.6% had used 4-5 pads/day. 13.33% had used 1-2 pads/day, 86.66% had used 2-3 pads per day, and 00% had used 4-5 pads/day during follow-up. Among 15 patients in Group B, 26.66% had used 1-2 pads per day, 53.33% had used 2-3 pads per day, and 20% had used 4-5 pads/day before treatment. After treatment, 6.6% had used 1-2 pads/day, 80% had used 2-3 pads/day, and 13.33% had used 4-5 pads/day. 6.6% had used 1-2 pads/day, 86.66% had used 2-3 pads per day, and 6.6% had used 4-5 pads/day during follow-up.

Numbers of fibroids: Among 15 patients in Group A, 80% had 1-2 fibroids in the uterus, 6.6% had 2-3 fibroids in the uterus, and 13.33% had more than 3 fibroids in the uterus before treatment. After treatment, 80% had 1-2 fibroids in the uterus, 13.33% had 2-3 fibroids, and 6.6% had more than 3 fibroids in the uterus during follow-up. Among 15 patients in Group B, 86.66% had 1-2 fibroids in the uterus, 13.33% had 2-3 fibroids in the uterus, and 00% had more than 3 fibroids in the uterus before treatment. After treatment, 93.33% had 1-2 fibroids in the uterus, 6.6% had 2-3 fibroids, and 00% had more than 3 fibroids in the uterus during follow-up.

Size of uterine fibroids: Among 15 patients in Group A, 20% of patients had fibroid size less than 10 mm, 20% had 1.1-2 cm fibroid size, 13.33% had 2.1-3 cm fibroid size, 13.33% had 3.1-4 cm of size, 33.33% had 4.1-5 cm of fibroid size before treatment. After treatment of 2 months, 26.66% had less than 10 mm of fibroid size, 26.66% had 1.1-2 cm of fibroid size, 6.6% had 2.1-3 cm, 26.66% had 3.1-4 cm of fibroid size, 13.33% had 4.1-5 cm of fibroid size. Among 15 patients in Group B, 13.33% of patients had fibroid size less than 10 mm, 13.33% had 1.1-2 cm fibroid size, 40% had 2.1-3 cm fibroid size, 20% had 3.1-4 cm size, 13.33% had 4.1-5 cm of fibroid size before treatment. After treatment of 2 months, 26.66% had less than 10 mm of fibroid size, 20% had 1.1-2 cm of fibroid size, 40% had 2.1-3 cm, 6.6% had 3.1-4 cm of fibroid size, 6.6% had 4.1-5 cm of fibroid size.

Table 3: Duration of blood loss at different points in time

Duration of blood loss at different points of time (Data: Median, 25th & 75th percentile)			
Group	**Day 0**	**After 1 Month**	**After 2 Months**
Group A	1.00(1.00-1.00)	1.00(1.00-1.00)	1.00(1.00-1.00)
Group B	1.00(1.00-2.00)	1.00(1.00-1.00)	1.00(1.00-1.00)

Table 4: Interval of loss at different points in time

Interval of loss at different points of time (Data: Median, 25th & 75th percentile)			
Group	**Day 0**	**After 1 Month**	**After 2 Months**
Group A	1.00(1.00-1.00)	1.00(1.00-1.00)	1.00(1.00-1.00)
Group B	1.00(1.00-1.00)	1.00(1.00-1.00)	1.00(1.00-1.00)

Table 5: Dysmenorrhea at different points in time

Dysmenorrhea (Data: Median, 25th & 75th percentile)			
Group	**Day 0**	**After 1 Month**	**After 2 Months**
Group A	3.00(2.00-4.00)	2.00(2.00-3.00)	2.00(1.00-2.00)
Group B	3.00(2.00-4.00)	3.00(2.00-3.00)	2.00(2.00-2.00)

Table 6: Clots on different points of time

Clots (Data: Median, 25th & 75th percentile)			
Group	**Day 0**	**After 1 Month**	**After 2 Months**
Group A	1.00(1.00-2.00)	1.00(1.00-1.00)	1.00(1.00-1.00)
Group B	1.00(1.00-1.00)	1.00(1.00-1.00)	1.00(1.00-1.00)

Table 7: Pain in the lower abdomen at different points in time

Pain in the lower abdomen (Data: Median, 25th & 75th percentile)			
Group	**Day 0**	**After 1 Month**	**After 2 Months**
Group A	3.00(3.00-4.00)	2.00(2.00-2.00)	2.00(1.00-2.00)
Group B	3.00(3.00-4.00)	3.00(2.00-3.00)	2.00(2.00-3.00)

Table 8: Backache at different points in time

Backache (Data: Median, 25th & 75th percentile)			
Group	**Day 0**	**After 1 Month**	**After 2 Months**
Group A	2.00(1.00-2.00)	1.00(1.00-2.00)	1.00(1.00-2.00)
Group B	2.00(1.00-2.00)	2.00(1.00-2.00)	1.00(1.00-2.00)

Table 9: Pads/day at different points in time

Pads/day (Data: Median, 25th & 75th percentile)			
Group	**Day 0**	**After 1 Month**	**After 2 Months**
Group A	2.00(1.00-2.00)	2.00(2.00-2.00)	2.00(2.00-2.00)
Group B	2.00(1.00-2.00)	2.00(2.00-2.00)	2.00(2.00-2.00)

Table 10: Number of fibroids at different points in time

Number of fibroids (Data: Median, 25th & 75th percentile)		
Group	**Day 0**	**After 2 months**
Group A	1.00(1.00-1.00)	1.00(1.00-1.00)
Group B	1.00(1.00-1.00)	1.00(1.00-1.00)

Table 11: Size of fibroids at different points in time

Size of fibroid (Data: Median, 25th & 75th percentile)		
Group	**Day 0**	**After 2 months**
Group A	3.00(2.00-5.00)	2.00(1.00-4.00)
Group B	3.00(2.00-4.00)	3.00(1.00-3.00)

Table 12: Overall Effect of Treatment

Overall Assessment	**Group A**		**Group B**	
	N	%	N	%
No change (<25% changes in size and Symptoms)	4	26.66%	4	26.66%
Mild improvement (26-50%)	8	53.33%	9	60%
Moderate improvement (51-75%)	3	20%	2	13.33%
Marked improvement (More than 76%)	0	0%	0	0%
Complete relief (100% relief in signs and symptoms)	0	0%	0	0%

RESULTS

In the present study, the Mann-Whitney rank sum test was carried out to compare the groups and Freidman's test for within-the-group comparison for repeated measures.

In Group A, no change was observed after one month and 2 months of follow-up in the duration of blood loss. In Group B, no change was observed after one month and 2 months of follow-up in the duration of blood loss. The comparison shows that the difference between the groups was not significant on all points of time, i.e., the 0th day, the 1st month, and the 2nd month of completion.

W= 0.1 in Group B after 1st and 2nd month of follow-up.

The effect size is found to be minor, indicating some improvement in clinical status in Group B. (Table 3)

In Group A, no change could be observed after one month and 2 months of follow-up in the duration of blood loss. In Group B, no change could be observed after one month and 2 months of follow-up in intervals of loss. The comparison shows that the difference between the groups was not significant on all points of

time, i.e., the 0th day, the 1st month, and the 2nd month of completion.
W= 0.05 in Group A after 1st and W= 0.03 after 2nd month of follow-up.
Effect size is found to be marginal, which is clinically indicative of some improvement in Group A. (Table 4)

P<0.05 in comparison to D0 values. It reduced dysmenorrhea symptoms on 1 month and 2nd month follow-ups. (Friedman's test).
In Group A, a significant reduction in dysmenorrhea score was observed within the group after 1 and 2 months of follow-up. In Group B, no change could be observed after one month, but a significant difference was observed in the form of reduced dysmenorrhea symptoms after 2nd month of follow-up within the group. The comparison shows that the difference between the groups was not significant on all points of time, i.e., the 0th day, the 1st month, and the 2nd month of completion.
W= 0.2 in Group A after 1st and 2nd month of follow-up.
W= 0.1 in Group B after 1 month and 0.2 after 2nd month of follow-up.
Effect size is found to be minor, which is clinically significant within the group but higher in Group A for the first month. After that, both groups exhibited equal effect sizes. Though small, the value of 0.20 may represent a 20% improvement in the clinical status and hence may be categorised as moderate efficacy for this parameter. (Table 5)

In Group A, no change in clots could be observed after one month and 2 months of follow-up. In Group B, no change in clots could be observed after one month and 2 months of follow-up. The comparison shows that the difference between the groups was not significant at all points of time on the 0th day, 1 month, and 2nd month of completion.
W= 0.1 in Group B after 1st and 2nd month of follow-up in Group B.
Effect size falls under the lower end of the small category band, which indicates some improvement in this clinical feature in this group. (Table 6)

P<0.05 in comparison to D0 values. Reduced pain in the lower abdomen on 1 month and 2nd month follow-up. (Friedman's test).
In Group A, apparent and statistically significant differences in reduction in pain at the lower abdomen have been observed after one month and 2 months of follow-up within the group. In Group B, apparent and statistically significant differences in reduction in pain at the lower abdomen have been observed after one month and 2 months of follow-up within the group. The comparison shows that the difference between the groups was not significant on all points of time, i.e., the 0th day, the 1st month, and the 2nd month of completion.
W= 0.3 in Group A after 1st and W=0.2 after 2nd month of follow-up.
W= 0.3 in Group B after 1st and W=0.1 after 2nd month of follow-up.
Effect size is found to be medium after one month of treatment and minor after 2nd month of follow-up, which is clinically significant. Clinically perceptible moderate improvement was observed in both the groups; it was sustained though a bit less in Group A but tapered to the lower end of the small band in Group B. Thus, Group A may offer the better clinical effect of longer duration. (Table 7)

In Group A, no change could be observed after one month and 2 months of follow-up in reduction of back ache. In Group B, no change could be observed after one month and 2 months of follow-up in reduction of back ache. The comparison shows that the difference between the groups was not significant on all points of time, i.e., the 0th day, the 1st month, and the 2nd month of completion.
W= 0.1 in Group A after 1st and W=0.03 after 2nd month of follow-up.
W=0.1 after 2nd month of follow-up in Group B within the group.
Effect size is found to be small after one month of treatment and marginal after 2nd month of follow-up, indicative of only mild improvement in the clinical status in this parameter. In Group B, the effect size difference was only marginal in the first month and found to have reached 0.1 in 2nd month; this indicates the mild improvement observed has a long latency of onset. (Table 8)

In Group A, no change could be observed after one month and 2 months of follow-up in the group's usage of pads/day during menstruation. In Group B, no change could be observed after one month and 2 months of follow-up in using pads/day during menstruation within the group. The comparison shows that the difference between the groups was not significant on all points of time, i.e., the 0th day, the 1st month, and the 2nd month of completion.
Categorical value basis analysis did not show statistical differences between the groups.
No significant effect size is found within Groups A and B after follow-up. (Table 9)

In Group A, no significant difference could be observed after 2 months of follow-up in the number of fibroids reduced within the group. In Group B, no significant difference could be observed after 2 months of follow-up in the number of fibroids reduced within the group. Comparison shows that the difference between the groups was not significant on all points of time, i.e., the 0th day and the 2nd month completion.
r= 0.1 in Group A after 2nd month of follow-up.
r=0.1 after 2nd month of follow-up in Group B within the group.
The effect size falls under the small band, indicating mild improvement. (Table 10)

P<0.05 in comparison to D0 values. The size of the fibroid was reduced on the 2nd month follow-up. (Wilcoxon signed Rank test).
p=0.004 In comparison to Group A values (Mann Whitney rank sum test)
In Group A, a significant difference in the reduction of fibroid size within the group could be observed after 2 months of follow-up. In Group B, significant differences in reducing fibroid size within the group could also be observed after 2 months of follow-up. The comparison shows that the difference between the groups was significant on the 0th day, and no significant difference was observed on the 2nd month completion in the reduction of fibroid size.
r= 0.3 in Group A after 2nd month of follow-up.
r=0.5 after 2nd month of follow-up in Group B within the group.
Categorical value basis analysis did not show a statistical difference between the groups, though an apparent difference was observed. Fibroid reduction is an important parameter, though statistically, the effect did not reach a statistically significant level- effect size 3 calculation shows that the reduction occurred when observed after follow-up in both groups compared to the initial size. The effect for Group A falls under the medium band, which can be considered a good improvement, and under the large band in Group B, which can be considered an excellent improvement. (Table 11)

Final Result

26.66% had no changes in symptoms in both groups, and 53.33% had mild improvement in reduced fibroid size and subjective parameters. 20% had moderate improvement in the form of a reduction in the fibroid size and subjective parameters in Group

A, 60% had mild improvement, and 13.33% had moderate improvement in the form of a reduction in the fibroid size and subjective parameters in Group B. (Table 12)

Remarks: Despite apparent differences between the groups, they did not match statistically significant levels (p value-0.199).
Chi-square 6.000 with 4 degrees of freedom. (P = 0.199)
ESD calculation for the above (chi-square-based test)- by calculating Cramer's V= Sq rt of X2/nx df
Sq rt of 6/30X 4=6/120=0.05
Sq rt of 0.05= 0.2
Thus, there is no statistically significant difference between the groups. The effect size is found to be medium, which is clinically significant, in favour of group B.

Group A: Chitraka moola churna due to its ushna virya, lekhana property, Kaphavatahara, deepana pachana, shothahara, and granthihara property helped to improve the duration of bleeding, improved appetite, reduced fibroid size to some extent and reduced the bulkiness of uterus due to fibroid.

Group B: Sarjadi lepa, due to its tridoshashamaka, especially Kapha Vatahara, kshara guna, shothahara, lekhana karma, and medohara, helps in the reduction of fibroid size and improved appetite due to Agni deepanakaraka action of kshara.
The effect size difference for Group A falls under the medium band (0.3), which can be considered a good improvement and under the large band (0.5) in Group B, which can be regarded as an outstanding improvement. Hence, the Null hypothesis is accepted.

DISCUSSION

Granthi (fibroid) can take many different shapes. Different authors have different opinions on the kinds. Vataja, Pittaja, Kaphaja, Mamsaja, Medaja, Siraja, Asthija, Vranaja, and Rakata are the names of these people. Acharyas discusses all of the nidana, lakshana, and samprapti. Mamsa, rakta, and medas are also impacted by the vitiated Vatadi doshas in this situation, which results in the growth of a protuberant, hard swelling called Granthi. The fibroids and Mamsaja granthi could be associated since they have comparable structural explanations after taking the lakshanas and performing a general analysis. Since Mamsaja granthi calls fibroids Siraanadham, it is also clear they are extremely vascular structures.

The drugs used in this study to prepare lepa are Sarja kshara, Mulakak kshara, and Shankha churna.

Sarja is having katu-kshara rasa, ushna virya, laghu-tikshana guna, deepana, chedana, Kaphahara, vidarana, kledi. Used in diseases like Gulma, Adhmana, Krimi, Shula, Medojathara, and Mutrakrichra Kasa rogas.

Mulaka is having katu-tikta rasa, laghu-teekshna guna, ushna virya, katu vipaka, tridoshashamaka. It is used in Shotha, Granthi, Visarpa, Vatavyadhi, Arsha, Kasa, Swasa, Mootrakrichra, Arbuda, Kushta, Shola and Arsha.

Shankha is having katu rasa, kshara guna, grahi, snigdha, sheeta virya, Madhura vipaka, tridoshaghnata used in Ajirna, Agnimandya, Grahani, Parinamashoola, Visa and Yakritplihavrddhi.

Chitraka moola churna, which is ushna, Vatahara, and shothahara, will reduce the increased meda dhatu, and Kapha dosha ultimately reduces the Granthi.

Probable mode of action of drug based on Guna and Karma

The disease has Vata Kapha dominating tridoshas involvement in the pathogenesis of Granthi roga. Dushyas are rakta, medas and mamsa. All the drugs discussed above are either tridoshaghna or Kapha Vata shamaka.

They possess qualities like medohara, chedana, bhedanakaraka, rakta vardhaka, and yogavahi. So, the drug's action on the disease could be substantiated based on virya, prabhava, and doshaghnata.

All of the drugs are ushna virya. Thus, Kapha shamaka reduces Granthi. The trial drug Sarjika possesses kshariya and lekhana properties with medohara quality, as they have laghu, ruksha, tikshna, and ushna guna. These qualities will reduce the increased meda dhatu and Kapha dosha, ultimately reducing the Granthi[8].

Mulaka also has katu rasa, ushna virya, tridoshahara and shothahara, which helps reduce the Granthi size; as Charaka said, Granthi can be treated as the same shotha line of treatment[9].

Shankha has katu rasa, grahi property, and trisodhahara balances the vitiated doshas like Kapha, Vata and breaking down, the Granthi formed due to Vata and Kapha dosha[10].

Mode of action of chemical constituents

Although the actual cause of fibroids in the uterus is unknown, they might be thought of as a lifestyle disorder because they are caused by hormonal elements that change based on a person's mental state. Therefore, they may also be brought on by stress.

Anti-tumour Activity
Alkaloids, flavonoids, triterpene, and ferulic acid are chemical components of the experimental medications that have been shown to have anti-tumour activity, which aids in stopping the growth of fibroids.
Mulaka is rich in vitamin C, folic, and anthocyanins, so they can be used for treating many types of cancer, particularly uterine, colon, kidney, intestinal, stomach, and oral cancer. The Isothiocyanates found in radishes have a major impact on the genetic pathways of cancerous cells. It helps in reducing the tumour size.
Glycosides present in Mulaka act as antioxidants and anti-inflammatory activities. Ferulic acid helps remove the free radicals and reduces the oxidative stress of tissue repair.
Sapogenins have a hypocholesterol effect and anti-carcinogenic, anti-oxidative, and anti-tumour properties.
The iron content of Mulaka helps to improve haematological changes in the fibroid.
Vitamin C also contributes to reducing weight. Due to their rechana, deepana, pachana, and laghu guna are easily digested in the body and can act on abnormal medas.
Shankha is mentioned in Rasashastra as a mineral under Sudha Varga, which is rich in carbonate of calcium, iron, and magnesium; studies suggested that by calcium magnesium supplementation, fibroid growth can be presented and due to magnesium dysmenorrhea can be managed. Iron helps in the improvement of Hb in cases of excess bleeding. It possesses various properties, such as anti-inflammatory, antioxidant, etc.

Antioxidant Activity
An impaired antioxidant cellular enzymatic system characterises uterine fibroids. Drugs like Shankha, Mulaka, and Sarjika have chemical constituents which act as anti-oxidative stress, which in turn helps to reduce the fibroid size.

Effect on the duration of blood loss: Chitraka moola and Sarjadi lepa ingredients have agneya guna- along with Vata Kapha hara action, which does srotoshodhana and does Pittakara action also, thus maintains the regular flow during menstruation.

Effect on the interval of the menstrual cycle: Chitraka moola and Sarjadi lepa ingredients have agneya guna, tridoshahara, and medohara, along with Vata Kapha hara action which does srotoshodhana, does Pittakara action also, thus helping in regularising the menstruation monthly.

Effect on dysmenorrhea: Vata dosha is the causative factor for pain in the body. Tridoshahara, anulomana karaka, and shothahara (anti-inflammatory) action of Sarjadi lepa and Chitraka moola and antioxidant action help reduce dysmenorrhea symptoms.

Effect on pain in the lower abdomen and backache: Because of Vata shamaka, Vatanulomana properties and the anti-spasmodic and anti-inflammatory action of Chitraka moola helped reduce pain during menstruation and backache.
Sarjadi lepa has ingredients such as shothahara, tridoshahara, and agneya nature helps in Vata anulomana and helps in pain reduction and backache.

Effect on pads/day: Due to agneya, Vatahara property of Chitraka moola and Mulaka, Sarja kshara helps in artava pravrutti and improves the menstruation flow.

Effect on size of fibroids: All drugs are ushna virya. Thus, Kapha shamaka reduces Granthi. The trial drug Sarjika possesses kshariya, and lekhana properties with medohara quality, as they have laghu (light), ruksha, tikshna, and ushna guna. These qualities, along with Chitraka moola churna, which is ushna, Vatahara, and shothahara (anti-inflammatory), will reduce the increased meda dhatu and Kapha dosha ultimately reducing the Granthi (fibroid).

CONCLUSION

The present study was completed with 30 patients randomised into 2 groups comprising 15 subjects in each group - Subjects in control group (Group A) were treated with Chitraka moola churna orally, and subjects in trial group (Group B) were treated with Chiraka moola churna along with Sarjadi lepa externally. After the completion of the study, a conclusion can be made based on the observations. Most of the fibroids are asymptomatic and diagnosed accidentally. They show symptoms based on their location: PV Bleeding, menstrual abnormalities, lower abdominal pain, backache, pressure symptoms, etc. The maximum number of patients (80%) had regular cycles in the study. After the administration of the combined treatment of Chitraka moola churna and Sarjadi lepa, it was observed that significant symptomatic relief was seen in the patient. There is some significant difference in the size of fibroids in the USG. The size of fibroid reduction was seen in both groups, but Group B patients had a little more size reduction compared to Group A. A significant decrease in dysmenorrhea score was observed in both groups after 2 months of follow-up. 20% clinical improvement in both groups after 2 months. Significant differences in pain in the lower abdomen have been observed in both groups. Group A may be considered to offer better clinical effects of longer duration. No changes were seen in the number of fibroids in both groups. Thus, there is no statistically significant difference between the groups. The effect size is found to be medium, which is clinically significant in favour of Group B.

Hence, the Null hypothesis (H0) is accepted.

Scope for future studies

- Though Sarjadi lepa is potent due to difficulty in absorption via dermal microcirculation to reach the deeper organs, we suggest modulating the intervention for a longer duration in future studies.
- Further study for different formulations in the form of external applications for managing uterine fibroid is needed in future studies.
- Sarja kshara, Mulaka kshara, and Shankha churna, each separate drug, can be analysed for their chemical constituents, and the effect of each drug on the fibroid uterus can be studied in future studies.

REFERENCES

1. Dutta D C. Benign lesions of uterus. 6th Ed. New Delhi: Jaypee Brothers; 2013. p. 259.
2. Berek J. Uterine fibroid. 15th Ed. New Delhi: Wolters Kluwer India; 2012.
3. Dutta D C. Benign lesions of uterus. 6th Ed. New Delhi: Jaypee Brothers; 2013. p. 260.
4. El-Balat A, De Wilde R, Schmeil I, Tahmasbi-Rad M, *et al.* Modern Myoma treatment in the last 20 years: A review of the literature. Biomed Research International. Hindai. 2018[cited 2018 January 24]; 2018(10):6.
5. Tewari P V. Granthi Adhyay. 2nd ed. Volume 2, Varanasi: Chaukhamba Orientalia; 2000. p. 370.
6. Sharma S, editor. Granthyarbudashlipadaapachinadi pratishedha adhyay. 1st Ed. Ashtanga Samgraha of Vruddha Vagbhata, Uttara tantra; Varanasi: Chaukhamba Sanskrit series, 2003. p. 804.
7. Sharma P V. Dhamani vyakarana sariradhyaya. 1st Ed. Varanasi: Chaukhamba Visvabharati Oriental; 2013. p. 219.
8. Reddy K. Lavana and kshara varga. Rasa Shastra. Edition 1. Varanasi: Chaukhamba Sanskrit Bhavan; 2007. p. 566.
9. www.WebMD.com/vitamins-supplements/ingredients Mono-502-Radish.
10. Reddy K. Sudha varga. Rasa Shastra. Edition 1. Varanasi: Chaukhamba Sanskrit Bhavan; 2007. p. 530-531

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