

## A CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF LEKHANA BASTI AND GOMUTRA HAREETAKI ORALLY IN UTERINE FIBROID

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### ABSTRACT

**Background:** Uterine leiomyoma, is a benign neoplasm, has a major impact on women's health physically, mentally and economically if left untreated. In Ayurveda, this disease can be correlated to *mamsaja arbuda* based on symptoms. Since it is seen in *garbhashaya*, it can be coined as *Garbhashaya Arbuda* Even though the incidence and prevalence rate is high, the funding for research works done on uterine fibroid is less compared to malignant cases due to its increased morbidity rate than mortality rate. The women if diagnosed should undergo with necessary interventions. **Aims and Objectives:** To evaluate the therapeutic effect of *lekhana basti* and *gomutra hareetaki* orally in uterine fibroid. **Methodology:** A group of 20 patients suffering from uterine fibroid attending the OPD and IPD of Prasuti Tantra And Stree roga Department are taken for study. The research work is an open label clinical trial where patients diagnosed with uterine fibroid subjected for • Lekhana basti for first 8days • Gomutra hareetaki 1.5gm BD orally with honey before food from 9th day to

81days. Thus for a total of 3 months. The USG report is collected before and after the study to compare the changes. **Result:** In this clinical study, it has significant symptomatic relief. There was improvement in dysmenorrhea, menstrual abnormalities, weakness, pressure symptoms, amount-duration-clots during bleeding. There was significant change in objective

parameters also. There were reduction in bulkiness of uterus, size of fibroid and number of fibroids. **Conclusion:** This clinical study proves that Deepana pachana, vata anulomana, kapha hara, lekhana, arbudahara gulmahara gunas provides significant relief from symptoms and significant reduction in size of uterus and fibroid.

**KEYWORDS:** Uterine fibroids, *Garbhashaya arbuda*, *Lekhana basti*, *Gomutra Hareetaki*, *lekhana*, *Arbudahara*, *Gulmahara*.

## INTRODUCTION

Uterine fibroid is the commonest benign tumour in women of child bearing age and second commonest reason to undergo surgery. It has been estimated that atleast 20% of women at the age of 30 has fibroid in their womb. The prevalence is highest between 35-45 years age group.

Majority women with fibroids remain asymptomatic. But in some women, it shows many symptoms like menstrual abnormality i.e. menorrhagia, dysmenorrhea, dyspareunia, pressure symptoms, abdominal enlargement, infertility and even pregnancy loss.<sup>[1]</sup>

In modern science, the treatment methods usually adopted include hormonal therapy, hysterectomy, myomectomy, myolysis, uterine artery embolization etc. Unfortunately, none of these methods found to be a sole reply for the disease. Mostly it is kept under surgical domain. Management of fibroid has become a global challenge. An effective and safe treatment is a matter of great concern for physicians as well as surgeons.<sup>[2]</sup>

In Ayurveda classics, this disease can be correlated to *arbuda* based on symptoms. There is no direct mentioning of *arbuda* in reproductive organs. Considering the clinical features of *mamsa arbuda*, it can be considered that all relatively big neoplasms developing from muscular and fibrous tissues (Myoma, fibromyoma) can be considered under *mamsa arbuda*. So, *mamsa arbuda* affecting *garbhashaya* can be called as *garbhashaya arbuda*. Main doshas involved are *kapha*, *vata*. These vitiate *mamsa*, produce swelling that is *vritha*, *sthira*, *mandaraja*, *mahantham*, *analpamoola*, *chiravidhi*, *apakam*.<sup>[3]</sup>

Since *vata kapha* dominating *tridoshas* are involved in the pathogenesis of *arbuda* and *dushyas* involved are *Rakta*, *Mamsa* and *Meda*,<sup>[4]</sup> the medications possessing *vatakapahara* and *lekhana* properties are apt in this condition. *Sthanika dosha* involved here is *vata*, hence *basti* is the treatment of choice. Hence *yoga basti*<sup>[5]</sup> with *Lekhananeeya mahakashaya gana*

mentioned in *charaka samhitha sutrasthana*<sup>[6]</sup> is adopted. *Panchatiktakaguggulu ghrtha* mentioned in *Ashtanga hrdaya chikitsasthana vata vyadhi chikitsa*,<sup>[7]</sup> is *vata kapha hara* and *arbudahara*, is taken for *anuvasana basti* and *Gomutra hareetaki* mentioned in *Ashtangahrdaya chikitsasthana arsho roga chikitsa*<sup>[8]</sup> which is indicated in *granthi, apachi, arbuda* has been taken up for study to see the combined effect.

This clinical study is supported by assessing the size of fibroid via ultrasonography before and after the treatment for proper analysis.

## METHODOLOGY

### Objectives of the study

To evaluate the therapeutic effect of *lekhana basti* and *gomutra hareetaki* orally in uterine fibroid.

### Study design

Study type: Interventional, Open label study

Estimated enrolment: 20 participants

Intervention model: Single group

### Intervention

The research work is an open label clinical trial where patients diagnosed with uterine fibroid subjected for

- *Lekhana basti* for first 8days
- *Gomutra hareetaki* 1.5gm BD orally with honey before food from 9th day to 81days
- Review - Once in a month
- Follow-up – Fourth month

### *Lekhana basti* protocol

*Poorvakarma*

Preparation of the medicine- *Basti dravya* is given in the order of

*Makshika*-150ml

*Saindhava*-6gm

*Panchatiktaka guggulu ghrtha*-75ml

*Lekhaneeya gana kalka*-50gm

*Gomutra*-75ml

*Lekhaneeya gana Kashaya-250ml*

Preparation of the patient

- *Sthanika abhyanga*
- *Sthanika swedana* with *ushna jala*
- *Laghu ushna anabhishtandhi bhojana* before *anuvasana basti*

### ***Pradhana karma***

In this study, *niruha basti* will be administered in the dosage of 600ml in yoga basti course wherein three *niruha basti* will be administered on 3rd, 5th and 7th day in the morning, empty stomach. Five *anuvasana basti* with *panchatiktaka guggulu ghrtha* in the dose of 75ml will be administered on 1st, 2nd, 4th, 6th and 8th day in the afternoon immediately after food.

### ***Paschat karma***

*Laghu ushna anabhishtandi bhojana* after *basti*, *Gomutra hareetaki churna* 1.5gm BD orally given with honey before food for 81 days.

### **Inclusion criteria**

- Women aged between 20-45 years
- Married women
- Subjects fit for *Lekhana basti*
- Subjects with USG scan confirmation of uterine fibroid <5cm

### **Exclusion criteria**

- Lactating women
- Hb less than 9 gm%
- Systemic diseases intervening the treatment
- Malignant conditions
- Post menopausal period
- Subjects undergoing hormonal therapy

### **Criteria for assessment**

#### **Subjective parameters**

Menstrual irregularities

Dysmenorrhea

Heaviness of abdomen

Dyspareunia

Weakness

Pressure symptoms

### **Objective parameters**

1. Size of fibroid
2. Number of fibroids
3. Bulkiness of uterus

### **Final assessment**

The result was assessed on the basis of improvement in chief complaints, on the basis of USG. To assess the effects of therapies, a special scoring method was adopted as follows

1. Completely cured (100%relief)
2. Marked improvement (75%relief)
3. Moderate improvement (50%relief)
4. Mild improvement (25%relief)

### **Duration of study**

Duration of treatment – 90days

Duration of basti – 8days

Duration of administration of oral medicine-2 and half months

Follow up -on 4th month

### **OBSERVATIONS**

**Distribution according to chief complaints:** The collected data shows all the patients had dysmenorrhea i.e 100%, 90% patients had Weakness, 80% had Pressure symptoms and only 10% had Dyspareunia.

- ✓ The data of Menstrual abnormalities shows 40% had irregular menstruation, 30% had normal menstruation, 20% had excessive menstruation, 10% had prolonged menstruation.

**Distribution according to size of fibroid:** The collected data shows the size of fibroid in USG as:

There were no fibroids in the range 0-0.5cm, 7% fibroids in the range 0.5-1cm, 14% in the range 1-1.5cm, 10% in the range 1.5-2cm, 17% in the range 2-2.5cm, 7% in the range of 2.5-3cm, 10% in 3-3.5cm, 3% in 3.5-4cm , 17% in 4-4.5cm, 10% in 4.5-5cm.

**Distribution according to no. of fibroids:** The collected data shows 50% had only one fibroid, 33% had 2 fibroids and 17% had 3 fibroids irrespective of type.

**Distribution according to uterine size:** The collected data shows 60% had bulky uterus, 35% had Normal sized uterus and 5% had mildly bulky uterus.

## RESULTS

### Menstrual abnormalities

Parameter	Negative Rank			Positive Rank			Ties	Total	Z Value	P Value	Interpretation
	N	MR	SR	N	MR	SR					
Menstrual Abnormalities_AT Menstrual Abnormalities_BT	0	0	0	7	4	28	13	20	-2.42	0.015	S

There was improvement in Menstrual Abnormalities of 7 patients after treatment which is statistically SIGNIFICANT.

### Dysmenorrhea

Parameter	Negative rank			Positive rank			Ties	Total	Z Value	P Value	Interpretation
	N	MR	SR	N	MR	SR					
Dysmenorrhea_AT Dysmenorrhea_BT	0	0	0	20	10.5	210	0	20	-3.99	0	HS

There was improvement in Dysmenorrhea of 20 patients after treatment which is statistically highly significant.

### Dyspareunia

Parameter	Negative Rank			Positive Rank			Ties	Total	Z Value	P Value	Interpretation
	N	MR	SR	N	MR	SR					
Dyspareunia_AT Dyspareunia_BT	0	0	0	2	1.5	3	18	20	-1.41	0.15	NS

There was improvement in Dyspareunia of 2 patients after treatment which is statistically not significant.

### Weakness

Parameter	Negative Rank			Positive Rank			Ties	Total	Z Value	P Value	Interpretation
	N	MR	SR	N	MR	SR					
Weakness_AT Weakness_BT	0	0	0	15	8	120	5	20	-3.52	0	HS

There was improvement in weakness of 15 patients after treatment which is statistically highly significant.

### Pressure symptoms

Parameter	Negative Rank			Positive Rank			Ties	Total	Z Value	P Value	Interpretation
	N	MR	SR	N	MR	SR					
Pressure Symptoms_AT Pressure Symptoms_BT	0	0	0	17	9	153	3	20	-3.72	0	HS

There was improvement in Pressure symptoms of 17 patients after treatment which is statistically highly significant.

### Usg uterine size

Parameter	Negative Rank			Positive Rank			Ties	Total	Z Value	P Value	Interpretation
	N	MR	SR	N	MR	SR					
USG Uterine Size_AT USG Uterine Size_BT	0	0	0	7	4	28	13	20	-2.46	0.014	S

There was improvement in USG Uterine size of 7 patients after treatment which is statistically significant.

### Usg size of fibroid

Parameters	Mean	N	Std.Deviation	Std.Error Mean	Mean Difference	%	T	P Value	Interpretation
USG Size of Fibroid BT	3.18	20	1.29	0.29	0.8	25%	2.541	0.02	S
USG Size of Fibroid AT	2.38	20	1.58	0.35					

Paired Samples T-test was performed to evaluate the significant difference in mean value of size of fibroid. It was observed that there is SIGNIFICANT difference in mean values of before and after treatment.

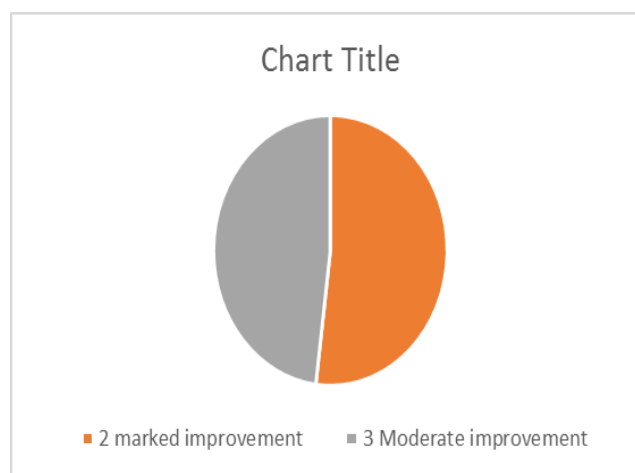
### Usg no. of fibroids

Parameters	Mean	N	Std. Deviation	Std.Error Mean	Mean Difference	%	T	P Value	Interpretation
USG No. of Fibroid BT	1.35	20	0.67	0.15	0.25	19%	2.517	0.02	S
USG No. of Fibroid AT	1.1	20	0.71	0.16					

Paired Samples T-test was performed to evaluate the significant difference in mean value of Number of fibroid. It was observed that there is SIGNIFICANT difference in mean values of before and after treatment.

### Overall effect of treatment

1. Completely cured – Nil
2. Marked improvement – 52%
3. Moderate improvement – 48%
4. Mild improvement -Nil



### DISCUSSION

*Vata* is the foremost *Dosha* who controls the other *Doshas*, when it gets vitiated, disturbs the normal physiology of reproductive tract as the *Adhodara Pradesha* is the main site of *Vata Dosha*.

Vitiated *Kapha* causes *Apakti*-indigestion leads to *Ama* formation which is responsible for *Srotorodha*. Moreover, *Kapha Dosha* also causes *Vata Prakopa* by *Margavarodha* of *Vata*. It also vitiates its *Ashraya Rasa Dhatu* and thus also it's *Upadhatu Artava*. All the three *Doshas* are involved but *Kapha* and *Vata* play prime role in pathogenesis of *Garbhashaya Arbuda*. *Kapha* and *Vata*, because of their *Karma upachaya* and *sarvasareeradhatuvyuhakara*, *sthulaanusrotasam bhetha*, *samyoga vibhage Karanam paramanunam* respectively regulates growth of uterine fibromyoma.

*Arbuda* being a *mamsa pradoshaja vyadhi*, the improper nourishment and *kha vaigunya* effect the *mamsa dhatu* in *garbhashaya*; *medo dhatu* which is in *ashrayashrayi bhava* with



*kapha dosha* and have same *panchaboutika* properties, the vitiation of *kapha dosha* will result in *medodhatu dushti*. Thus vitiation of *vata*, *kapha doshas*, *mamsa*, *medho dhatus* localises in *garbhashaya* results in *garbhashaya arbuda*.

### Probable mode of action

#### ➤ *Mode of action of basti*

Amongst *tridosha vata dosha* has been given prime importance because according to *Ashtanga hrdaya shareerasthana* it is *vibhutwat*, *ashukaritwat*, *balitwat* and *anyakopanat*. When the seat of origin of the disease is concerned, it is purely in the *apana kshetra* and has significant connection with the *pakwashaya*. Since it is the *udbhava sthana* of the *vyadhi*, this route is favouring the *samprati vighatana* of the *vyadhi*. In this context the disease uterine fibroid has been approached with the administration of *lekhana basti* (*pakwashayagata basti*). The mode of action can be understood based on the method of administration of *basti*. According to *Ashtanga sangraha kalpasthana 5<sup>th</sup> adhyaya*, it is mentioned that the effect of *basti* is immediately transferred to *apana vata*, then to *samana vata*, then to *vyana vata* followed by *udana* and *prana vata*. Thus, the action of *basti* helps in regulating the *pancha vata* just not only *apana vata*. Also, it keeps *pitta* and *kapha* in its *swasthana* *Yoga basti* was selected in the present study. Since *niruha basti* is *lekhana* and *Sneha basti* is *brmhana*, administering in *yoga basti* pattern helps in counteracting the *agnimandhya* and *vata prakopa*. Also, the *anuvasana basti* is given with *ghrtha* prepared with *tikta Kashaya rasa drugs* which also helps in achieving *kapha medohara* action. The mode of action depends on the *kwatha dravya* and *kalka dravya* along with *avapa dravya* which is selected in the study. The properties of these drugs which were already discussed in the drug chapter that *ushna veerya*, *teekshna* and *lekhana gunas* of drugs in *lekhaneeya mahakashaya gana*, *lekhana guna* of *gomutra* added as *avapa dravya* and *ushna teekshna arbudahara gunas* in *panchatiktaka guggulu ghrtha* is helping in acting towards *kapha* and *medo dhatu*, thereby the size of the fibroid mass was reduced significantly which was even proved through the statistics.

#### ➤ *Mode of action of gomutra hareetaki*

*Gomutra Haritaki* causes *Kapha-Vata Shamana* and *Vatanulomana*. By normalizing *Vata*, restore normal function of HPO axis and normalize *Vibhajana Karma* of *Vata* and *Upachaya Karma* of *Kapha* leading to reduction in size of fibromyoma.

*Gomutra Haritaki* have *Deepana*, *Pachana* properties which stimulate *Jatharagni* along with *Dhatvagni* as well as it digests *Ama*, clears *Srotorodha*, decreases *Rasa Dhatu Dushti* and

alleviates *Kapha Prakopa*. All these promote normal function of *Dhatu* and decrease in accumulation of *Mamsa* and *Medo Dhatu*. These entire acts have combined effect on *Garbhashaya Arbuda* and decrease the size & symptoms of *Garbhashaya Arbuda*.

By its *Lekhana* property *Gomutra Haritaki* with Honey replenish stored amount of *Medas* and scrap *Garbhashaya Arbuda* eventually decreasing its size.

#### ➤ **Mode of action of *panchatiktaka guggulu ghrtha***

The ingredients are: Nimba, Guduchi, Patola, Kantakari, Vasa, Patha, Vidanga, Devadaru, Gajapippali, Swarjika Kshara, Yavakshara, Shunti, Haridra, Misi, Chavya, Kushta, Tejovati, Maricha, Kutaja, Jeeraka, Chitraka, Katuki, Bhallataka, Vacha, Pippali, Manjishta, Atasi, Haritaki, Vibheetaki, Amalaki, Ajamoda, Ativisha, Guggulu, Goghrtha. Most of the drugs are having *kashaya tikta guna*, *snigdha*, *vishada gunas* and are *vata kapha hara*, *tridosahara*.

*Snigdha guna* which inhibits *ruksha guna* of *vata* and *vishada guna* pacifies *pichila guna* of *kapha*. This reduces vitiation of *kapha*. Thus, clears *srotorodha* caused due to vitiated *kapha*, thereby pacifies *vata prakopa*. As there is an *ashrayashrayi* relation between *kapha* and *rasa dhatu*, pacifying *kapha dosha* will also pacifies *rasa dhatu dushti*.

*Tikta rasa* present in *nimba*, *guduchi*, *vasa*, *patola* and other main drugs pacifies vitiation of *pitta* and thus normalizes bleeding. It also acts as *amapachana* and *lekhana*.

Ingredients like *amalaki*, *haritaki*, *guduchi* have *rasayana guna* chemical constituent Gallic acid, Ellagic acid, Chebulagic acid in *amalaki* and *hareetaki* have an anti-cancerous and anti-neoplastic properties which help in reducing the size of fibroid.

Since, *guggulu* is one of the main ingredients, its *Sukshma guna* helps to reach *srotas* and remove *rodha*. *Guggulu* is also *granthighna*, *lekhana* hence can act on fibroid. Its anti-spasmodic action along with *Vibhitaki*, *Amalaki* and *Vasa* will help in symptomatic relief.

Also drugs like *patha*, *vidanga*, *nagara*, *pippali*, *gajapippali*, *maricha*, *misi* are *sulahara*, *vata anulomana* which gives good relief in dysmenorrhea like symptoms.

And *Ghrtha* having *samskarasyanuvarthana* property enhances all the *gunas* of ingredients further promoting its actions. Along with this *arbudahara*, *gulmahara* indications of *panchatiktakaguggulu ghrtha* helps in reducing size of fibroid and bulkiness of uterus.

➤ **Mode of action of *lekhaneeya gana***

*Lekhana dravyas* have the capacity to remove abnormally increased *dhatu*s and to clear the blocks in minute channels and *srotas* in the body. The drugs include *Musta*, *Kushta*, *Haridra*, *Daruharidra*, *Vacha*, *Ativisha*, *Katurohini*, *Chitraka*, *Chiruvilwa*, *Haimavathi*. Most of the drugs in *dasemani gana* have *katu*, *tikta* and *kashaya rasa*, *ruksha* and *laghu guna* and hence are *vata kapha* and *tridoshahara*

Most of the drugs are *ushna veerya* and hence *vata kapha shamana*.

Five drugs are *anulomana* and so net effect is *vata shamana*, *kapha shamana* and normalising *pitta*, and also *mamsa medo hara* through *ashrayashrayibhava* with *kapha dosha*.

## CONCLUSION

After the study, it shows that giving *lekhana basti* in *yoga basti* pattern and oral administration of *gomutra hareetaki* has *Deepana*, *pachana*, *vata anulomana*, *kapha hara*, normalizing *pitta*, *lekhana*, *arbudahara gulmahara gunas* that provides symptomatic relief and significant reduction in size of uterus and fibroid. The study was done for a total of 3 months and could attain satisfying results more symptomatically on comparing before treatment and after treatment.

No other side effects of drugs except gastritis in some patients were observed during treatment. The duration of study is small to draw a proper conclusive action on uterine fibroid even though it provides significant symptomatic relief. Hence following this treatment protocol for a course of 6 months can give more fruitful results as per the changes noted within 3 months.

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