

A COMPARATIVE CLINICAL STUDY OF *VARUN SHIGRU GUGGULU* AND *TRIPHALADI GUGGULU* IN THE MANAGEMENT OF *GARBHASHAYA ARBUDA*

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ABSTRACT

Quality of woman's life is dependent on many factors such as the culture and position in society, environment, life-style and changing demands of society towards her. Ayurveda recognize these changes in women's body and provide simple regimen to maintain healthy life throughout. On the basis of pathogenesis, signs and symptoms of uterine fibroid, we can correlate it with *Mansaja Arbuda*. This study is aimed to justify management of uterine fibroid in *Ayurvedic* perspective with an intention to raise awareness and to encourage implementation of *Ayurvedic* therapies in such type of disorders. The treatment approach is directed towards reducing size of fibroids and it's symptoms by using *Shaman Chikista* i.e. *Varun Shigru Guggulu*

vati and *Triphaladi Guggulu vati*. **Methodology:** Research work was a randomized comparative clinical study of 40 patients with cardinal feature of uterine fibroid. Subjects were randomly divided in to 2 Groups of 20 subjects each. Group A, was treated with *Triphaladi Guggulu vati* and Group B, *Varun Shigru Guggulu* for a period of 3 month. **Result:** clinical parameters were assessed statistically. Both the Groups showed statistically significant results. Statistically there was no significant difference between the group in parameter of menstrual abnormalities, pain during menses, pain and heaviness in lower abdomen, back pain, constipation. **Interpretation and conclusion:** Group B, (*Varun Shigru Guggulu*) showed higher response as compare to Group A, (*Triphaladi Guggulu vati*) in the management of *Garbhashaya Arbuda*.

KEYWORDS: *Garbhasayadushtivikara, Yonirogvikara, Mamsa Vridhi, Santarpanajanya vyadhi, uterine fibroid.*

INTRODUCTION

It is the most common hormone dependent benign tumor that is usually found among reproductive aged women.^[1] It is derived from smooth muscle cell either from vessel wall or uterine muscle. It is rarely developed before puberty and after menopause. Uterine fibroids are known to increase in size during pregnancy and with oral contraceptives pills user.^[2] Prevalence of this disease is 20 - 40% among women over the age of 35 years.^[3] The risk factors for fibroids are nulliparity, an early menarche, obesity, family history of fibroids hyper-estrogenic state, high fat diet.^[4] Majority of the time, it remains asymptomatic and is diagnosed accidentally but some time it induces symptoms like heavy p/v bleeding, intermenstrual bleeding, pain during menses, pain and heaviness in lower abdomen, lower backache, pressure symptom, reproductive problems such as infertility and repeated abortion.^[4] About 75% of fibroid are intramural in nature. According to site and size of fibroids the intensity of symptoms varies. Big sized fibroids distort the shape of uterine cavity and may affect the uterine contraction. It is ranked as a major reason for approximately one third of all hysterectomies per year^[6] and hysterectomy does not allow women to preserve their fertility so women prefer conservative treatment.

As per *Ayurvedic* perspective, *Arbuda* is *Vata-Kaphaj* in origin. *Vata Dosha* is responsible for the faulty cell division and *Kapha Dosha* for their growth. Thus vitiated *Vata Dosha* along with *Kapha Dosha* (*Dosha Vaishamya Awastha*) results in tumor formation (benign tumors). Muscular tissue is the most common *Dhatu* affected in tumor. Tumors of muscular origin are slow growing tumors which are caused by *Kapha Dosha*.

In *Susruta Samhita* the clinical feature of *Mamsaja Arbuda* is *Avedana, Snigdha, Ananyavarna, Apakam, Ashmopamam, and Aprachalyam*.^[13] These features are similar with fibroids in the following manner -

- ❖ *Avedna* Generally it is painless tumor, but sometime pain occurs due to its big size.
- ❖ *Snigdha* Outer appearance is glossy
- ❖ *Ananyavarna* Color of tumor is same of the tissue that it grows
- ❖ *Apakam* Non-suppurating
- ❖ *Ashmopamam* Consistency of tumor is hard
- ❖ *Aprachalyam* Immovable

In *Ayurvedic* texts, description and treatment of *Arbuda* is barely mentioned because of the lesser incidence. Most of the diseases in present time are due to consumption of *Mithya Aahar* and *Vihara* so *Nidan Parivarjan*^[18] is considered as first line treatment for all the diseases.

Arbuda Vyadhi can be managed according to the principal of *Samprapti Vighatana* (To break the pathogenesis). *Vata-Kapha* dominating *Tridosha* are involved in the pathogenesis of *Arbuda* hence *Vata-Kaph-har chikitsa* should be done.

AIM AND OBJECTIVES OF STUDY

- ❖ To provided simple, safe, non-hormonal, and non-surgical treatment for uterine fibroid.
- ❖ To evaluate the efficacy of *Triphaladi Gugglu Vati* and *Varun-Shigru Gugglu Vati* in the management of uterine fibroid.

MATERIAL AND METHODS

SOURCE OF DRUG: Raw drugs materials were purchased from *Ayurvedic* drug market of Lucknow and Crude drug of *Guggulu* taken from drug market of Jaipur. All constituent of drug were then authenticated by the Department of *Dravyaguna* State *Ayurvedic* Collage & Hospital, Lucknow.

PREPARATION OF DRUG: Both trial drugs were prepared in the pharmacy of State *Ayurvedic* Collage Lucknow by concerned experts and under the supervision of department of *Rasashashtra* and *Bhaishajakalpana*. Therefore, all the necessary measures regarding the preparation of trial drug had taken by experts.

Types of study: open randomized clinical trial.

Sample size: In present clinical study, total 40 patients were registered from OPD and IPD of State *Ayurvedic* college & hospital and other referred cases.

Group Allocation: The enrolled patients of uterine fibroid for the present clinical study were kept in to two Groups i.e. Group A and Group B.

Treatment Schedule with dose and duration

Group	Drug	Dose	Time	Anupan	Duration
Group A	<i>Triphaladi Guggulu Vati</i>	2 tab twice a daily	After meal	Lukewarm water	3months
Group B	<i>Varun Shigru Guggulu Vati</i>	2 tab twice a daily	After meal	Lukewarm water	3months

FOLLOW UP STUDY

- **During treatment-** one month after clearance of each menstrual cycle during the period of treatment.
- **After treatment-**one month of next menstrual cycle after completion of treatment, to assess the efficacy of trial drug.

(A) INCLUSION CRITERIA

- 1- Patients of age group between 20 to 45 years.
- 2- Patients having fibroid size ≤ 5 cm (largest one) as per USG report
- 3- Single or multiple fibroids
- 4- Patients having clinical signs and symptoms of uterine fibroid.
- 5- Patients willing to participate in this trial therapy.

(B) EXCLUSION CRITERIA

1. Patient below the age of 20 and above the age of 45years.
2. Patient having fibroid size > 5 cm as per usg report.
3. Pregnant women with fibroid.
4. Fibroid with severe menstrual abnormalities like metrorrhagia, menometrorrhagia, polymenorrhea etc.
5. Woman with Hb < 8 gm. %
6. Patient using intra uterine contraceptive device or taking oral contraceptive pills
7. Patients suffering from any other organic pelvic pathology like ovarian tumour, Tubo-ovarian mass, Endometriosis, PID, Malignancy etc.
8. Patient suffering from any systemic illness which may deteriorate her general health like Hypertension, Diabetes mellitus, Tuberculosis, Cardiac disorder, Thyroid dysfunction etc.

(C) DISCONTINUATION CRITERIA

1. Patient not willing to continue trial.
2. Any major illness occurring during trial therapy.

CRITERIA FOR DIAGNOSIS: Diagnosis was done mainly on the basis of USG findings and along with clinical features, sign & symptom, Examination like p/v or p/s findings.

LABORATORY INVESTIGATION

- ❖ Haematological investigation- Hb%, TLC, DLC, ESR, Platelet count, CT & BT.
- ❖ Blood Sugar- Fasting and postprandial.
- ❖ USG (Trans vaginal / lower Abdomen)-To measure the size of fibroid.

ASSESSMENT CRITERIA: The effect of therapy was analysed on different parameter before and after treatment.

SUBJECTIVE CRITERIA

- a. Menstrual abnormalities (menorrhagia)
- b. Pain during menses
- c. Pain and heaviness in lower abdomen
- d. Backache
- e. Constipation

OBJECTIVE PARAMETER: The effect of trial therapy was analysed on different parameter before and after treatment.

- a. USG (Trans vaginal / lower Abdomen)- To measure the size of fibroid.

RESULT

- Majority of the cases belong to the age range 40-44 years (30%) followed by the age group 30-34 years (25%).
- 65.0% patients were of *Vata-Kapha prakriti* followed by 32.5% *Vata-Pittaj prakriti* and 2.5%, *Pittaj-Kapha prakriti*.
- Bulky size uterus was found in 92.5% cases.
- 37.83% patients were having nulliparous os cervix. 62.16% cases were having parous os cervix

% Improvement in various Parameters within Group A & Group B

Parameter	Group A		Group B	
	% change	p-value	% change	p-value
Duration of bleeding	25.0	0.014	15.0	0.083
Amount of bleeding	100.0	0.008	100.0	0.083
Interval between cycle	100.0	0.317	NA	1.000

Pain during menses	75.9	<0.001	76.9	<0.001
Pain in lower abdomen	78.1	<0.001	81.5	<0.001
Back Pain	62.1	<0.001	77.8	<0.001
Constipation	66.7	<0.001	68.2	<0.001
Size of Fibroid	47.2	<0.001	47.5	<0.001

Final Improvement Status and its Intergroup Comparison between Group A & Group B

Final Status	group A		group B	
	No.	%	No.	%
Marked improvement (75 % - 100%)	6	33.3%	5	29.4%
Moderate improvement (50 % - 75%)	11	61.1%	12	64.7%
Mild improvement (25 % - 50%)	1	5.6%	1	5.9%

DISCUSSION

- Specific illustration of *Arbuda* of female reproductive system is not available in any classics but it can be correlated to *Garbhashaya Arbuda* on the basis of its origin from *Garbhashaya* and its surrounding structures.
- As per Ayurvedic perspective, *Arbuda* is *Vata-Kaphaj* in origin. The causative factors for formation of *Arbuda* are *Mithya Aahar* (*Gramya Mamsa*, *Ajeerna Aahara*, *Dusta Bhojana*, *Abhishyandhi Bhojana*), *Mithya Viharas* (*Divaswapna*, *Avyayama*) etc. which lead to *Agni Vaishamya* and vitiated *Kapha - Vata Dosha*. *Agni Vaishamya* causes *Pitta Dosha* vitiation and produce *Ama*. This *Ama* (Toxins) accelerates the *Kapha Dosha* vitiation, and move to *Garbhashaya* (uterus) by *Apana Vata*. Formation of *Ama* and accumulation of vitiated *Kapha* block the movement of *Apana Vata* in susceptible individuals (*Kha-Vaigunya* occurs in *Garbhasaya*). Ultimately causes vitiation of *Mamsa Dhatu* which leading to *Arbuda* formation in *Garbhasaya*.
- Now- a- days the prevalence of uterine fibroid among women is between 30-50% due to inappropriate changes in lifestyle.
- If we look towards modern medicinal system for treatment of fibroid, we found out the hormonal therapy or surgical interventions as a solution. Hormonal therapy causes many side effects and surgical therapy especially hysterectomy does not allow to preserve her fertility.
- *Arbuda Vyadhi* can be managed according to the principal of *Samprapti Vighatana* (To break the pathogenesis). *Vata-Kapha* dominating *Tridosha* are involved in the pathogenesis of *Arbuda* hence *Vata-Kapha-chikitsa* may be administered. *Tikshna Ushna*, *Lekhan*, *Chedana*, *Shrotoshodhan Dravya* can be used to reduce the symptoms and size of uterine fibroid.

- The ingredients of drug have *Ushna Virya*, *Kashaya*, *Tikta Rasa*, *Ushna*, *Ruksha*, *Teekshna Guna*, and *Katu Vipak*. *Guggulu* possesses *Laghu*, *Ruksha*, *Tikshna*, *Vishad Sara*, *Vata- anuloman*, *Lekhana*, *Medohar* and *Raktaprasadana guna*. With these properties, the formulation drugs act like *Deepan*, *Amapachana*, *Lekhana*, *Shothahara*, *Vilayana*, and *Srotoshodhana* etc. thus due to *Deepana- Pachana* effect of drugs, improves *Jatharagni*. *Jatharagni* act *Mamsa* and *Medo Dhatvaagni*.
- Besides *Deepan- Pachan*, *Lekhana*, *Shothahara*, *bhedan*, and *kshar Guna* also present which causes *Apchaya* of *Mamsa* and *Medo Vriddhi*, gradually removed *Avarodha* (in the form of *Aghata* or *Avarana*) and normalized the physiology of *Apana Vayu*, thus decrease proliferation of cell and ultimately leads to reduction in size of fibroid.
- *Triphaladi Guggulu Vati* drug in group A was selected from classical text book of *Yog Ratnakar* indication of drug is *Granthi*, *Arbuda*, *Gandmala* & *Apachi nasak* and content of drug have been reported as anticancer agent, antiproliferative, antioxidant, antispasmodic. As it is *Deepana*, *Pachana*, *Vatanulomana* and *Srotoshodhana Guna*, it can do very well work on vitiated *Vata-Kapha Dosha* originated *Vyadhi* like *Garbhashaya Arbuda*.
- *Varun Shigru Guggulu Vati* drug in Group B, *Anubhut yog*. Drug has *Kashaya*, *Ruksha*, *Ushna*, *Tikshna*, *Katu*, *Anulomana*, *Lekhana*, *Vilayana* etc. *Guna* and the contents of drug also have been reported to as anticancer, antioxidant, wound healing, cytotoxic activity.

CONCLSION

- ❖ On the basis of specific clinical features of *Arbuda* and *Mamsaja Arbuda*, it can be correlated with uterine fibroid due to its origin from muscular and fibrous tissues of uterus.
- ❖ In present era changes in lifestyle, food habits, obesity, early menarche, late marriages, OCPs, mental stress, environmental exposure to toxins are predisposition factors for growth of uterine fibroid.
- ❖ Trial drugs have *Kashaya*, *Tikta Rasa*, *Ushna*, *Teekshna Guna*, *Ushna Virya*, *Katu Vipak*, with these properties, drug act like *Deepan*, *Ama Pachana*, *Lekhana*, *Shothahara*, *Vilayana*, and *Srotoshodhana* and break the pathogenesis of disease.
- ❖ On the relief of pain during menses both the group showed statistically highly significant, where Group B, showed 1.06% more effective than Group A.
- ❖ On the duration of bleeding both the group showed statistically significant, where Group A, showed 15% more effective than Group B.

- ❖ On the relief of pain in lower abdomen both the group showed statistically highly significant, where Group B, showed 3.35% more effective than Group A.
- ❖ On the relief of back pain both the group showed statistically highly significant, where Group B, showed 15.71% more effective than Group A.
- ❖ Size of fibroid was found to reduce in both the group. In Group B, 44.50% while Group A, 44.22% improvement was seen which statically highly significant. Action of trial drug in both Groups is observed to almost same.

So it is concluded that the response of treatment in group B (*Varun Shigru Guggulu*) is higher as compare to Group A (*Triphaladi Guggulu*).

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