

EFFECT OF NIMBADI KASHAYAM AND KANCHANARA GUGGULU IN UTERINE FIBROIDS: RESEARCH ARTICLE

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ABSTRACT

Uterine fibroids are the commonest benign tumours that arise from the myometrium of uterus. Its prevalence is highest between the age group of 35 – 45 years. The symptoms are rather related to number, size and location of the fibroid and commonly associated symptoms include dysmenorrhoea, menorrhagia, lower abdominal pain etc. In Ayurveda classics there is no direct correlation for uterine fibroids. Two diseases, *granthi* and *arbuda* are similar to that of tumour but specific descriptions of these diseases related to reproductive organ is not available. While going through the etiopathogenesis and symptomatology as per modern science, uterine fibroids can be considered as *mamsavridhijanya vikara* and is correlated to *mamsa granthi*. An attempt was made here to find out the combined effect of *Nimbadi kashayam* and *Kanchanara Guggulu* in fibroids. The study was conducted in Govt Ayurveda College Hospital for women and children, Poojappura Thiruvananthapuram. Married women of age group 25 to 45 yrs. with fibroids were included for the study after confirming by USG. The treatment period was 90 days and two subsequent follow ups were taken, one immediately after the treatment period and other one 90 days post the treatment period. Statistical analysis of the result showed that the combination showed statistically significant effectiveness in reducing the size of fibroid with a P-value <0.01

Keywords *Fibroids; Granthi; Nimbadi Kashayam; Kanchanara Guggulu*

INTRODUCTION: Leiomyomas are benign smooth muscle neoplasms that typically originate from myometrium, commonly encountered in gynaecological practice. They are commonly seen in women of reproductive age group and may remain symptomless in many and get identified only during routine pelvic examination. Symptoms if present, include pain, pressure sensations, dysmenorrhea or abnormal uterine bleeding.

Aetiology of fibroids still remains unknown. Although oestrogen, progesterone, growth hormone and possibly human placental lactogen have been implicated in the growth of myomas, there is growing evidence in support of oestrogen and progesterone dependence for their growth and hence the responsibility of fibroid development and

growth can be attributed to both these steroid hormones.

Although there is no direct description about fibroids in Ayurveda, two disease entities namely, *arbuda* and *granthi* simulate the description of such abnormal growths. The terms *arbuda* and *granthi*, together seems to represent all the tumour forming pathologies that have been described in the earliest text books of Ayurveda. *Granthi* can be better compared to benign neoplasm and *arbuda* to malignant ones as they are harmful to life and fast growing in nature. Vagbhatta differentiates both by saying that only big *granthi* can be considered as *arbuda*. Charaka includes both these conditions under the group of diseases characterized by *sopha*. Garbhashaya being the common site of fibroids and their muscular origin

make them more comparable to *Garbhashayagata Mamsa granthi*¹.

On evaluating the signs and symptoms seen in granthi, it can be considered as a *vata kapha* predominant *tridosha* condition with the involvement of *rasa, rakta, mamsa, and medo dhatu* along with their respective *srotas*. *Nidana* of *Garbhashaya granthi* includes all the factors vitiating the *doshas* and *dhatu*s involved in the *samprapthi*. *Yoni roga nidana* and *Sopha nidana* can also be considered here since (a) *Charaka* has included *sopha* as a main characteristic of *Granthi*, so causative factors of *sopha* can also be reason for *garbhashayagranthi* and (b) the term *yoni* can be considered as the entire reproductive system of female which includes *garbhashaya* also, the major site for fibroids.

In the current scenario hysterectomy remain as the only definitive treatment for uterine fibroids. However this option is associated with substantial complications and is unsuitable for those who wish to preserve their fertility. While other therapies are short-lived, recurrence of both leiomyoma and their symptoms are not uncommon after such therapies. It is high time we find alternative therapies for the same and in an effort to find out an effective combination which can provide long lasting effects without complications, *Nimbadi kashayam* and *KanchanaraGuggulu* which is being used by ayurvedic physicians was found to be effective in reducing the size of fibroids. This study was aimed at statistically evaluating the effect of ayurvedic combination, *Nimbadi Kashaya*² with *Kanchanara guggulu*³, in reducing the size of uterine fibroids.

MATERIALS AND METHODS:

Study Design

- Single group interventional study, pre and post administration of medicine
- Patient's condition after treatment with the status before treatment

Study setting

OPD & IPD, Government Ayurveda College Hospital for Women and Children, Poojappura, Thiruvananthapuram.

Study Population

Patients diagnosed with uterine fibroid, who are coming to the OPD between the age group of 25-45 yrs.

INCLUSION CRITERIA

Married females of age group 25-45 yrs. with uterine fibroids, confirmed by Ultrasonography (USG)

EXCLUSION CRITERIA:

- Post-menopausal women.
- Degenerative changes in fibroid.
- Fibroid size > 6cm.
- Malignancy.
- Pregnancy & Lactation.
- Systemic illness.
- Non co-operative patients.

SAMPLE SIZE

30 patients satisfying the inclusion and exclusion criteria

Sampling technique

Consecutive cases fulfilling all the inclusion and exclusion criteria till attaining mentioned sample size.

Data collection tools

Primary data was collected using the case proforma. General, physical, gynaecological, per vaginal and per speculum examinations was also done.

Study tool

Case proforma, Blood Hb levels, USG report.

Procedure: 30 patients were selected from study setting after evaluating for inclusion and exclusion criteria. Data collection tools were used for collecting the preliminary data and to assess the symptoms of the patient. USG was performed prior to beginning the study to note the size of the fibroid. Ingredients of the kashaya, powdered and made into packets, were given to the patients along with tablets on monthly basis. Instructions regarding mode of preparation and administration of medicines were explained to the patients verbally and also given in writing. Written consent for participation in the study was obtained.

Advices regarding *Pathyaaahara* and *vihaara* were also recommended. The follow-up was done on 30th, 60th, 90th day of drug administration (considering the first day of treatment as day 1) and patients were carefully assessed for their associated symptoms like pain, bleeding etc. A follow-up on 180th day of treatment was also done to assess the persistence of

effects obtained during drug administration. USG assessment to note the variation in size of fibroid was done on 90th day and 180th day.

Outcome Variable

Changes in the size of fibroid, assessed as reduction, progression and persistence through USG.

Table.1 Grading of size of fibroid was done according to following table

No	Size of Fibroid	Grading
1.	No Fibroids	0
2.	<2cm	1
3.	2 – 2.9cm	2
4.	3 – 3.9cm	3
5.	4 – 6cm	4

Statistical analysis

Assessment of fibroid size was done using ‘Paired t test’. Three pairs of data, Before Treatment (BT) - After treatment (AT); after treatment – After follow up (AFU);

before treatment – After follow up; were assessed and the results were evaluated further.

RESULTS:

Table. 2Change in size of fibroid was assessed by USG and percentage distribution according to size is as follows

Size of Fibroid(Grade)	BT		AT		AFU	
	N	%	N	%	N	%
No fibroid	0	0	4	13.33	6	20
<2cm (1)	3	10	8	26.67	10	33.33
2 -2.9cm(2)	11	36.67	7	23.33	7	23.33
3- 3.9cm(3)	7	23.33	10	33.33	6	20
4cm – 4.9(4)	9	30	1	3.33	1	3.33
Total	30	100	30	100	30	100

At the beginning of treatment majority of women had Grade 2 fibroids i.e. in the size range of 2 – 2.9cm. 9 of them had fibroid size greater than 4 cm, 3 had fibroids of size less than 2 cm and 7 had fibroids of size range 3 – 3.9cm.

After the treatment period of 90 days, only one patient had fibroid of size greater than 4 cm, 10 of them had fibroids in the range of 3 – 3.9cm, 7 in the range of 2 -2.9cm, 8 had fibroids of less than 2 cm

and fibroids reported to be absent in 4 of the study patients. After the follow up period of 90 days grade 4 showed no change while number of patients with grade 3 fibroids(3 -3.9cm) reduced to 6. Number of patients with grade 2 (2 - 2.9cm) fibroids remain unchanged. Number of patients with grade 1 and ‘no fibroid’ fibroid went up to 10 and 6 respectively.

Comparison of Pre and post treatment fibroid size was assessed using Paired t test since the data followed a

normal distribution. Normality was assessed using Shapiro- Wilk's test for normality. (P value = 0.152, >0.05)

Table. 3 Statistical Evaluation:

Pair	Mean	SD	SE	95% CI		T	Df	Sig(2 tailed)
				Upper	Lower			
1	10.967	8.206	1.498	7.902	14.031	7.320	29	.000**
2	2.567	6.897	1.259	-.009	5.142	2.038	29	.051
3	13.533	6.580	1.201	11.076	15.990	11.266	29	.000**

(*P value < .05 – Significant; ** P value < .01- highly significant)

Analysis shows that there is highly significant change in the size of fibroid after treatment and after the follow up period when they are compared to size of fibroid before treatment. (P value of pair 1 and pair 2 <.001). While comparing the reduction of fibroid size noticed after the treatment period and at the end of follow up period there is no significant change as P value is greater than 0.05 which accepts the null hypothesis of 'no significant change between the two pairs of values'. Hence to conclude the treatment is effective in reducing the size of fibroid and the effect was persistent through the follow up period also.

DISCUSSION ON DRUG AND ITS PROBABLE ACTION:

The classical formulation of *Kanchanara Guggulu* was selected here; because it is prescribed in management of *Gandamala* (Goitre), *Apachi* (Lymphadenitis), *Arbuda* (Tumour), *Granthi* (Swelling) etc. The ingredients of *Kanchanara Guggulu* are *Kanchanara twak*, *Triphala*, *Trikatu*, *Varun*, *Ela*, *Twak*, and *Patra*.

The entire ingredients in this formulation have *kashaya*, *madhura* & *tikta rasa*; *ruksha*, *ushna* & *teekshna guna*; *ushna veerya* and *katu vipaka*. *Kanchanara guggulu* has pharmacological

actions like *Agni deepana*, *ama pachana*, *mootrala*, *lekhana*, *shothahara*, *vilayana* and *srotoshodhana* etc. Because of improvement in *jataragni* due to *deepana* & *pachana* effect of drugs, *dhatvagni* also come to normal state which leads to decrease in *kitta bhaga of dhatus* and increase in *prasada bhaga*. Further, due to these actions, *sanga* in the *srotas* due to vitiated *kapha* is reduced which leads to proper functioning and circulation of *dhatus*. Due to normalization of *dhatvagni* there is no further growth of fibroid and due to *lekhana* and *sophahara* action of ingredients there is decrease in the size of fibroid too.

Nimbadi kashayam is mentioned in the *Vidradhi chikitsa of Sahasrayogam*. It has actions like *kapha pitha hara*, *raktaprasadhana*, *lekhana* etc.

Most of the ingredients in this formulation have an anti-inflammatory action, hence can be considered to have *raktaprasada* property and is effective in reducing the symptoms associated with increased *kapha* and *pitha dosha*. Being a *tikta rasapradhana* formulation it helps in the *Shoshana of kleda* and hence removes the *ama* in *dosha* and *dhatus* thereby clearing the corresponding *srotas*

Mean size of fibroid before the treatment was 31.9mm and after treatment

it reduced to 20.93mm and it further reduced to 18.37mm after the follow up. Analysis showed that there was highly significant change in the size of fibroid after treatment and after the follow up period when they were compared to size of fibroid before treatment. This action can be attributed to (a) *deepana* and *pachana* property of the combination. (b) *Vatakaphahara* and *lekhana* property of *Kanchanara Guggulu*. (c) *Kapha pitha hara* and *rakta prasadana* property of the *kashayam*.

CONCLUSION:

The study drug was found to be effective in reducing the size of the fibroid. Albeit small sample size studied, statistically significant results were obtained and the study can be conducted in a large sample to arrive at more precise conclusions.

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