

A CLINICAL EVALUATION OF GOMUTRA HARITAKI ON GARBHASHAYA ARBUDA (UTERINE FIBROID)

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ABSTRACT :

Uterine fibroid (fibromyoma/leomyoma) is the most common benign neoplasm, found approximately 20% to 40% women of reproductive age group. *Garbhashaya Arbuda* is not directly mentioned in *Ayurveda*, but on the basis of etiopathology, *Doshas*, *Dushyas*, *Srotodusti*, symptoms and complication for *Arbuda* can be correlated with uterine fibroid. It is the need of the era that, a secure, less expensive more effective therapy for this sensitive problem should be developed. Patients of reproductive or perimenopausal age with having complaint of menstrual abnormality, dysmenorrhoea, dyspareunia, pressure symptoms, lower abdominal or pelvic pain, abdominal enlargement, infertility etc., investigated with the help of Ultrasonography for confirmation were selected. Total 17 patients were registered, out of them 15 patients completed the course of treatment. *Gomutra Haritaki* (3gm) was given orally before meal for 3months (with *Anupana* of *Madhu*). The drug had shown significant result on symptoms like, Excessive bleeding, dysmenorrhoea, irregular menses, lower abdominal pain, obesity and reducing fibroid size. From the above study it has concluded that the drug *Gomutra Haritaki* is effective to manage symptoms as well as growth of *Garbhashaya Arbuda* (Uterine fibroid) with no apparent evidence of complication.

Key words: *Garbhashaya Arbuda*, *Gomutra Haritaki*, Uterine fibroid.

INTRODUCTION: Uterine fibroid (fibromyoma/leomyoma) is a most common benign neoplasm, found approximately 20% to 40% women of reproductive age group.¹ Approximately 1.6 million women are newly diagnosed with uterine fibroid per year only in US. In India, the prevalence of uterine fibroids among women hovers between 30-50%.² Although many women with fibroid are not aware, the growth may cause symptoms or problems due to their size, number or location. Majority women with fibroids are asymptomatic but in some women it shows many symptoms like menstrual abnormality i.e. menorrhagia,

metrorrhagia, polymenorrhoea, dysmenorrhoea, dyspareunia, pressure symptoms, lower abdominal or pelvic pain, abdominal enlargement, infertility, increase frequency of micturation etc. The incidence is higher in black women, in women with increased body mass index, in nulliparous and in low parity women.³ In *Ayurveda*, context to *Arbuda*, it is mentioned that aggravated *Doshas* vitiating *Mamsa*, getting localized in any body part, produce a local swelling of accumulated *Mamsa*, specially in deeper muscles which is round, gradually increase in size, without pain or associated with mild pain, has deep rooted, and never

suppurates.⁴ On the basis of above description *Arbuda* situated in *Garbhashaya* can be correlated with uterine fibroid. It is also included among disorders of vitiation of *Rakta*, *Mamsa* and *Meda*. The cause of uterine fibroid is unknown. Available treatment protocol in modern are hormonal therapy, hysterectomy, myomectomy, myolysis, endometrial ablation and uterine artery embolization having so many complications in future and do not meet the requirement of Indian population. So many formulations are advised in *Ayurvedic* classics under the *Granthi*, *Arbuda* and *Apachi Chikitsa* along with some specific lifestyle restrictions which have no any complications like modern therapy i.e. *Gomutra*, *Gomutra Haritaki*, *Bhallataka* and its compounds, *Arbudahara Rasa*, *Nityanadrassa* etc. Incidence of this disease is increasing day by day at a fast pace, so there is a need in present era to find out some appropriate and effective solution of the problem. Keeping this point in mind, the present study was planned to find out a reliable and data-based *Ayurvedic* management of Uterine fibroid.

AIMS AND OBJECTIVES:

- To study the etiopathogenesis of *Garbhashayagata Arbuda* (Uterine fibroid)
- To evaluate the effect of “*Gomutra Haritaki*” in *Garbhashayagata Arbuda* (Uterine fibroid)

MATERIALS AND METHODS

:Patients attending the Outdoor Patients Department of *Stree Roga* and *Prasooti Tantra* fulfilling the criteria for selection were incorporated into the study irrespective of caste, religion etc. A detailed history regarding infertility, family history, obstetric history, menstrual history, past illness and clinical finding

pertaining to *Dosha*, *Dushya*, *Agni*, *Srotasa* etc. A special research proforma and a scoring pattern for assessment of efficacy were prepared. Total 17 patients were registered, out of them 15 patients completed the course of treatment. All the patients were examined by TVS to assess size, number and location of uterine fibroid.

STUDY DESIGN: Open clinical trial.

Ethics Approval: Study started only after obtaining Ethical clearance from the Institutional Ethics Committee. Ref. PGT/7-A/Ethics/2012-13/1964 (dated 21/9/12)

Clinical Trail Registry of India (CTRI) No- REF/2014/03/006576

CRITERIA FOR SELECTION OF CASES:

INCLUSION CRITERIA:

- Age group between 20 to 50 years
- Patients having fibroid size ≤ 5 cm as per USG report
- Single or multiple fibroids
- The patient either asymptomatic or having clinical signs and symptoms of uterine fibroid.

EXCLUSION CRITERIA:

- Patient below the age of 20 years and above the age of 50years
- Patient having fibroid size more than 5 cm as per USG report
- Pregnant women with fibroid
- Women with Hb < 7 gm%
- Ovarian tumour, tubo-ovarian mass and malignant tumours along with fibroid.
- Patient with uncontrolled hypertension, tuberculosis, Diabetis Malitus and any other severe systemic disease.

Parameter of diagnosis and assessment of results:

Patients were selected on the basis of Trans vaginal sonography (TVS).

Other Pathological investigations:

Routine haematological investigations (Hb, TC, DC, ESR, Platelet count, PCV, BT, CT, FBS), Lipid profile, urine were done before and after treatment.

SELECTION OF DRUG:

Gomutra Haritaki is indicated for *Granthi, Arbuda, Apachi*.⁵ *Haritaki (Terminalia chebula Retz)* and *Gomutra* are the constituents in this formulation. *Haritaki* has *Kashaya, Ruksha, Ushna, Anulomana* properties⁶ and *Gomutra* has *Katu, Tikshna, Ushna, Kshara* properties⁷. Due to this property, it breaks the *Samprapti* of *Garbhashaya Arbuda*. As it is *Deepana, Pachana, Lekhana* and *Vatanulomana*, it can do very well in certain *Vata-Kapha* condition like *Garbhashaya Arbuda*.

Course of treatment: *Gomutra Haritaki* was given orally 3 gm twice a day with honey in empty stomach for three months.

OBSERVATION AND RESULT:

Table 1: Age wise distribution of 17 patients

Age	No. of Patients	%
<30 years	4	23.53
>30 to 40 years	4	23.53
>40 to 50 years	9	52.94

Table 2: Site of 22 fibromyomas in 17 patients

Site of fibromyomas	No. of fibromyoma	%	
Intramural	Anterior wall	10	58.82
	Posterior wall	7	41.18
	Fundus	2	11.76
Submucous	0	00	
Subserous	3	17.65	

Table 3: Chief complain wise distribution of 17 patients

Chief complain	No. of Patients	%	
Menstrual abnormalities	Menorrhagia	4	23.52
	Inter menstrual bleeding	3	17.64
	Dysmenorrhoea	14	82.35
	Irregular menses	6	35.29
Dyspareunia	4	23.52	

Before starting the treatment, patients were given *Yoga Basti* for *Shodhan* purpose by administrating *Palasha Basti*⁸ for *Asthapana Basti* and *Tila Taila* for *Anuvasana Basti*.

Advice:

1. To take light meal, warm water, Regular Exercise and to keep fasting once in a week.
2. Sleep early at night and wakeup early in morning.
3. To avoid spicy, over eating, fried food, bakery items, fermented items, cold drinks and Mental Stress etc.
4. Do not suppress natural urge.
5. To avoid hormonal therapy i.e. oral contraceptive pills etc.

Follow-up study:

After completion of treatment, follow up study will be done for 2 months. Any new complaint emerged during follow up period related to study was also noted.

Pain in Lower Abdomen	15	88.24
Abdominal heaviness	15	88.24
Pressure symptom	10	58.82
Increase Frequency of micturation	7	41.18
Infertility	Primary	6
	Secondary	2

Table 4: Associated complain wise distribution of 17 patients

Associated complain		No. of Patients	%
Anaemia	Mild (10-12 gm%)	9	52.90
	Moderate(8-10gm%)	1	5.88
	Severe (<8 gm%)	-	-
White discharge		2	11.77
Backache		11	64.70
Weakness		11	64.70
Constipation		12	70.59

Table 5: BMI wise distribution of 17 patients

BMI	No. of Patients	%
<18.5	1	5.88
18.5-24.9	7	41.17
25-30	6	35.3
>30	3	18

Table 6: Effect of "Gomutra Haritaki" on chief complaints (n= 15)

Chief complaints	n	Mean		% Relief	S.D. (±)	S.E. (±)	't'	P
		B.T.	A.T.					
Menorrhagia	4	1	0.5	50	0.577	0.289	1.732	> 0.05
Intermenstrual bleeding	3	1	0	100	-	-	-	-
Duration of blood loss	8	1.25	0.63	50	0.744	0.263	2.376	< 0.05
Irregular menses	5	1	0.2	80	0.447	0.2	4	< 0.05
Dysmenorrhoea	12	1.67	0.42	75	0.452	0.131	9.574	<0.001
Scanty menses	6	1	0.17	83.33	0.408	0.167	5	< 0.01
Pressure symptom	9	1	0.33	66.67	0.500	0.167	4	< 0.01

Table 7: Effect of "Gomutra Haritaki" on associated complaints (n= 15)

Associated complaints	n	Mean		% Relief	S.D. (±)	S.E. (±)	't'	P
		B.T.	A.T.					
Anaemia	9	1.11	0.89	20	0.441	0.147	1.512	> 0.05
Weakness	11	1.36	0.27	80	0.539	0.163	6.708	<0.001
Backache	10	1	0.3	70	0.483	0.153	4.583	<0.01
Constipation	11	1.82	0.27	85	0.522	0.157	9.815	<0.001
Pain in lower abdomen	14	1.36	0.36	73.68	0.784	0.209	4.770	<0.001

Increased frequency of Micturation	6	1	0.5	50	0.548	0.224	2.236	>0.05
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Table 8: Overall effect of “Gomutra Haritaki” (n=15)

(On the basis of effect on chief complaints, associated complaints and BMI)

Effect of therapy	Total no. of patients	%
Complete remission (100% relief)	0	00
Marked improvement (≥ 75% relief)	6	40
Moderate improvement (≥ 50 to 74% relief)	6	40
Mild improvement (≥ 25 to 49% relief)	2	13.33
Unchanged (< 25% relief)	1	6.67

Table 9: Effect of “Gomutra Haritaki” on size of 20 fibromyomas

Size of Fibromyomas	N	Mean		% Relief	S.D. (±)	S.E. (±)	‘t’	P
		B.T.	A.T.					
Vertical diameter	20	27.48	24.33	11.46	3.675	0.822	3.834	< 0.05
Horizontal diameter	20	25.2	22.12	12.22	3.610	0.807	3.815	< 0.05

Table 10: Overall effect of “Gomutra Haritaki” on size of 20 fibromyomas

Effect of therapy	Total no. of fibroid	%
Complete remission (100% relief)	0	0
Marked improvement (≥ 75% relief)	0	0
Moderate improvement (≥ 50 to 74% relief)	2	10
Mild improvement (≥ 25 to 49% relief)	9	45
Unchanged (< 25% relief)	9	45

Table 11: Effect of “Gomutra Haritaki” on obesity

Obesity	N	Mean		% Relief	S.D. (±)	S.E. (±)	‘t’	P
		B.T.	A.T.					
BMI (Kg/m ²)	15	25.61	23.97	6.41	1.31	0.34	4.84	<0.001
Weight in Kg	15	62.73	58.73	6.38	3.162	0.816	4.899	<0.001

Table 12: Effect of “Gomutra Haritaki” on mean biochemical values

Biochemical values	N	Mean		% Relief	S.D. (±)	S.E. (±)	‘t’	P
		B.T.	A.T.					
S. Cholesterol	15	179.6	161.33	10.17	22.324	5.764	3.169	< 0.01
S. Triglycerides	15	174.53	138.86	20.44	48.596	12.547	2.843	< 0.05
HDL	15	49.67	49	-1.34	5.912	1.526	-0.437	> 0.05
S.G.P.T.	15	12.73	10	-21.46	6.029	1.557	-1.756	> 0.05
S.G.O.T	15	20.13	18.07	-10.26	4.008	1.035	-1.997	> 0.05

DISCUSSION: The observations of the study are presented in Tables 1 to 5. In the present study, Maximum patients were from the age group of 40-50 years, A study carried out in the USA showed that the incidence of uterine fibroids by age 35 was 60%, increasing to >80% by age 50 As

increasing incidence of fibroid in the late reproductive years and in perimenopausal age⁹. [Table 1] Site of fibromyoma was maximum in the wall of uterus i.e. intramural this data support the description about developmental site of fibroid is maximum (75%) in the wall of uterus i.e.

intramural¹⁰. [Table 2] Majority patients had dysmenorrhoea and pain in abdomen, the cause of inappropriate or arrhythmic contraction (low of polarity of uterus) leading to pain. Any type of obstruction in its normal path may lead to pain by aggravating it. Irregular menses is due to the age factor because most of the patients were from perimenopausal period. Menorrhagia is due to increase in surface area of endometrial cavity and increased vascularity of the uterus associated with endometrial hyperplasia Probable reasons for infertility are Large intramural tumours located in the crnual regions may obstruct the tubes, Continuous bleeding in patients may impede implantation, increased incidences of abortion and premature labour, and excess estrogen which lowers the level of FSH hormone by negative feedback results in anovulation.¹¹ [Table 3] Backache is due to a feeling of pelvic heaviness that can radiate to the back or lower extremities. A posterior leiomyoma may produce rectal pressure causing a sense of rectal fullness, pain during defecation, tenesmus constipation. [Table 4] Majority of fibroids remain asymptomatic. But the data obtained here are just reverse to this assumption. All patients were symptomatic, the reason may be due to the patients don't come to the hospital for check up until they suffer from sign and symptom of disease. Present study shows that patients were belongs to Overweight i.e. BMI was >25-30 kg/m² and Obese class 1 (BMI was >30-35 kg/m²). Obese women are more prone to develop uterine fibroid while compared to thin. This apparent association between obesity and an increased risk of fibroids may be related to hormonal factor associated with obesity. [Table 5]

Effect of “Gomutra Haritaki” on Chief and Associated complain

Gomutra Haritaki has shown marked as well as moderate improvement in Chief and Associated complain, is due to *Ushna*, *Tikshna*, *Kshara*, *Deepana*, *Pachana* and *Vatanulomana* properties of *Gomutra Haritaki*. For dysmenorrhoea, scanty menses *Vata* and *Kapha* are main culprit while irregular menses, backache, constipation, pain in lower abdomen and pressure symptom *Vata* are main culprit. *Gomutra Haritaki* having *Kapha-Vata Shamaka* property, therefore it alleviate *Kapha Prakopa*, remove *Ama*, clears *Srotorodha*, subside *Avaranajanya Vata* and bring harmony of menstruation quantitatively and qualitatively. [Table 6, 7, 8]

Effect of “Gomutra Haritaki” on size of 20 fibromyomas

Mild and moderate relief is given by *Gomutra Haritaki* in size of fibromyoma, because contents of *Gomutra Haritaki* have better *Deepana*, *Pachana*, *Anulomana* and *Lekhana Karma*. [Table 9, 10]

Effect of “Gomutra Haritaki” on obesity and lipid profile

Statistically highly significant (P<0.01) and significant (P<0.05) effect of *Gomutra Haritaki* on S.Cholesterol and S.Triglycerides level respectively. Properties of *Gomutra Haritaki* which are key activity required for *Samprapti Vighatana* of *Sthaulya*. Preparation of *Gomutra Haritaki* includes *Agni Samsakara* which increases *Tikshanata* (Potency) of compound hence it has better *Kapha-Vata Shamaka Guna*, may again it clears *Srotorodha* and break the pathology of obesity. [Table 11,12]

CONCLUSION: From the above study it has concluded that *Gomutra Haritaki* is an

effective drug for management of *Garbhashaya Arbuda* (Uterine fibroid) with no apparent evidence of complication. It has shown effective result for reducing body weight so it may be utilized in obesity also.

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