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A CLINICAL EVALUATION OF *HEMAKANDA GHRUTA* ON *GARBHASHAYA ARBUDA* (UTERINE FIBROID)

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ABSTRACT
In India, the prevalence of uterine fibroids (fibromyoma/leomyoma) among women hovers between 30-50%. Special reference of *Arbuda* of female reproductive system is not available in any classics but it can be called as *Garbhashaya Arbuda* on the basis of its origin from *Garbhashaya* and its surroundings and 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 16 patients were registered, out of them 15 patients completed the course of treatment. *Hemakanda Ghruta*(5 ml) was given orally before meal for 3months (with *Anupana* of *Kanchanara Twak Kashaya*). The drug had shown significant result on symptoms like, Menorrhagia, dysmenorrhoea, irregular menses and lower abdominal pain. From the above study it has concluded that the drug *Hemakanda Ghruta*is effective to manage symptoms of *Garbhashaya Arbuda* (Uterine fibroid) with no apparent evidence of complication.

KEYWORD: *Garbhashaya Arbuda*, *Hemakanda Ghruta*, 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 (fibromyoma/leomyoma) among women hovers between 30-50%.[2] Majority women with fibroids are asymptomatic but in some women they show 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. due to their size, number or location. The black women, the women with increased BMI, nulliparous and low parity women have higher incidence.[3] Special reference of *Arbuda* of female reproductive system is not available in any classics but it can be called as *Garbhashaya Arbuda* on the basis of its origin from *Garbhashaya* and its surroundings and can be correlated with uterine fibroid. Available treatment protocol in modern science are costly and having so many complications in future. 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*, *Hemakanda Ghruta*, *Bhallataka* and its compounds, *Arbudahara Rasa*, *Nityanadrasa* etc Due to this disease threat to a fertility at a fast pace, so there is a need in present era to find out some appropriate and effective solution of the problem. 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 "*Hemakanda Ghruta*" 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 16 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

Hemkanda(Cadaba indica Lam.*)* is being used as folklore medicine in various part of the country especially in Gujarat (Una) & Maharashtra (Matunga). Decoction of *Hemkanda* leaves is employed in the treatment of amenorrhea, dysmenorrhoea, and uterine obstruction[4], Graham *et al* explained potential of *Cadaba indica (C. farinose)* against cancer through their survey.[5] *Hemkanda Ghrita* was selected as it is successfully being used for the treatment of fibroid traditionally with effective result. The contents of *Hemkanda* leaves have been reported to have anticancer, antioxidant, wound healing, cytotoxic activity. *Hemakanda* has *Pitta-Kaphahara* Properties, *Ghrita* has *Vata-Pittahara Agnideepana* propeties and *Kanchanara* has *Kapha-Pitta Shamaka* Properties which alleviate *Tridosha.* All three have *Raktadoshahara* effect hence it rectified menorrhagia, duration of blood loss and given relief in anaemia.

Course of treatment

*Hemakanda Ghruta*was given orally 5ml twice a day with *Kanchanar Kashay* (50 ml) in empty stomach for three months. Before starting the treatment, patients were given *Yoga Basti* for *Shodhan* purpose by administrating *Palasha Basti*[6] 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.

OBSERVATION AND RESULT

Table 1: Age wise distribution of 16 patients.

Age	No. of Patients	%
<30 years	3	18.75
>30 to 40 years	9	56.25
>40 to 50 years	4	25.00

Table 2: Site of 18 fibromyomas in 16 patients.

Site of fibromyomas		No. of fibromyoma	%
Intramural	Anterior wall	9	56.25
	Posterior wall	4	25.00
	Fundus	2	12.50
Submucous		1	6.25
Subserous		2	12.50

Table 3: Chief complain wise distribution of 16 patients.

Chief complain		No. of Patients	%
Menstrual abnormalities	Menorrhagia	5	31.25
	Inter menstrual bleeding	1	6.25
	Dysmenorrhoea	12	75.00
	Irregular menses	4	25.00
Dyspareunia		5	31.25
Pain in Lower Abdomen		13	81.25
Abdominal heaviness		8	50.00
Pressure symptom		6	37.50
Increase Frequency of micturation		6	37.50
Infertility	Primary	5	31.25
	Secondary	3	18.75

Table 4: Associated complain wise distribution of 16 patients.

Associated complain		No. of Patients	%
Anaemia	Mild (10-12 gm%)	8	50.00
	Moderate(8-10gm%)	1	6.25
	Severe (<8 gm%)	-	-
White discharge		4	12.50
Backache		10	62.50
Weakness		9	56.25
Constipation		10	62.50

Table 5: BMI wise distribution of 17 patients.

BMI	No. of Patients	%
<18.5	1	6.25
18.5-24.9	6	37.50
25-30	8	50.00
>30	1	6.25

Table 6: Effect of "*Hemakanda Ghruta*" on chief complaints (n= 15).

Chief complaints	n	Mean		% Relief	S.D. (±)	S.E. (±)	't'	P
		B.T.	A.T.					
Menorrhagia	5	1	0.2	80	0.447	0.2	4	< 0.05
Intermenstrual bleeding	1	1	0	100	-	-	-	-
Duration of blood loss	7	1.29	0.29	77.78	0.577	0.218	4.583	<0.01
Irregular menses	3	1	0.33	66.67	0.577	0.333	2	> 0.05
Dysmenorrhoea	11	1.64	0.73	55.56	0.539	0.163	5.590	<0.001
Scanty memses	6	1	0.67	33.33	0.516	0.211	1.581	> 0.05
Pressure symptom	6	1	0.5	50	0.548	0.223	2.236	>0.05

Table 7: Effect of "*Hemakanda Ghruta*" on associated complaints (n= 15).

Associated complaints	n	Mean		% Relief	S.D. (±)	S.E. (±)	't'	P
		B.T.	A.T.					
Anaemia	8	1.13	0.75	33.33	0.517	0.183	2.049	> 0.05
Weakness	8	1.63	0.5	69.23	0.354	0.125	9.000	<0.001
Backache	9	1.11	0.56	50	0.527	0.176	3.162	< 0.05
Constipation	10	1.6	0.9	43.75	0.483	0.153	4.583	<0.01
Pain in lower abdomen	12	1.17	0.5	57.14	0.492	0.142	4.690	<0.001
Increased frequency of Micturation	6	1	0.33	66.67	0.516	0.211	1.581	<0.05

Table 8: Overall effect of "*Hemakanda Ghruta*" (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)	3	20
Moderate improvement (≥ 50 to 74% relief)	5	33.33
Mild improvement (≥ 25 to 49% relief)	6	40
Unchanged (< 25% relief)	1	6.67

Table 9: Effect of "*Hemakanda Ghruta*" on size of 17 fibromyomas.

Size of Fibromyomas	n	Mean		% Relief	S.D. (±)	S.E. (±)	't'	P
		B.T.	A.T.					
Vertical diameter	17	24.82	24	3.32	1.776	0.431	1.912	> 0.05
Horizontal diameter	17	23.82	22.82	4.20	2.424	0.588	1.701	> 0.05

Table 10: Overall effect of "*Hemakanda Ghruta*" on size of 17 fibromyomas.

Effect of therapy	Total no. of patients	%
Complete remission (100% relief)	0	0
Marked improvement (≥ 75% relief)	0	0
Moderate improvement (≥ 50 to 74% relief)	0	0
Mild improvement (≥ 25 to 49% relief)	4	23.53
Unchanged (< 25% relief)	13	76.47

Table 11: Effect of "*Hemakanda Ghruta*" on obesity.

Obesity	n	Mean		% Relief	S.D. (±)	S.E. (±)	't'	P
		B.T.	A.T.					
BMI (Kg/m^2)	15	24.24	23.66	2.4	0.77	0.2	2.93	< 0.05
Weight (Kg)	15	63.07	61.53	2.43	2.100	0.542	2.828	< 0.05

Table 12: Effect of "*Hemakanda Ghruta*" on mean biochemical values.

Biochemical values	n	Mean		% Relief	S.D. (±)	S.E. (±)	't'	P
		B.T.	A.T.					
S. Cholesterol	15	162.73	159.13	2.21	14.201	3.667	0.982	> 0.05
S. Triglycerides	15	127.27	112.93	11.26	23.823	6.151	2.330	< 0.05
HDL	15	45.53	46.6	2.34	5.203	1.343	0.794	> 0.05
S.G.P.T.	15	12.4	13.33	7.53	3.240	0.836	1.116	> 0.05
S.G.O.T	15	21.13	22.47	6.31	4.952	1.279	1.043	> 0.05

DISCUSSION

The observations of the study are presented in Tables 1 to 5.

The present study supports a study carried out in the USA, showed increasing incidence of fibroid in the late reproductive years and in perimenopausal age[7], As Maximum patients were form the age group of 30-40 years. **[Table 1]** This data support the description about developmental site of fibroid is maximum (75%) in the wall of uterus i.e. intramural.[8] **[Table 2]** Dysmenorrhea and pain in abdomen were found in majority patient because of inappropriate or arrhythmic contraction (low of polarity of uterus). Any type of obstruction in its normal path may lead to pain by aggravating it. 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 cornual 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.[9] **[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/m^2. Women with increased BMI are more prone to develop uterine fibroid. This apparent association between obesity and an increased risk of fibroids may be related to hormonal factor associated with obesity. **[Table 5].**

Effect of "*Hemakanda Ghruta*" on Chief and Associated complain

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

Effect of "*Hemakanda Ghruta*" on size of 17 fibromyomas

No significant relief was given by *Hemakanda Ghruta* in size of fibromyoma, because contents of *Hemakanda*

Ghruta have *Sheeta Veeyra*, *Madhura Rasa* & *Vipaka.* [Table 9, 10]

Effect of "*Hemakanda Ghruta*" on obesity and lipid profile

Statistically significant (P<0.05) effect of *Hemakanda Ghruta*on S.Triglycerides level. [Table 11,12]

CONCLUSION

From the above study it has concluded that *Hemakanda Ghruta* improves quality of life as an effective drug for manage symptoms of *Garbhashaya Arbuda* (Uterine fibroid) rather than fibroid size with no apparent evidence of complication.

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