

**Research Article****CLINICAL EVALUATION OF HERBAL COMPOUND DRUGS IN THE MANAGEMENT OF LEIOMYOMA INDUCED MENORRHAGIA****K. Bharathi^{1*}, B. Pushpalatha², C. M Jain³**¹Research Officer (Ayu.), National Institute of Indian Medical Heritage, Revenue Board colony, Gaddiannaram, Hyderabad, Telangana, India.²Lecturer, ³Professor and Ex-head, Dept. of Prasutitantra, National Institute of Ayurveda, Jaipur, India.**Article info**

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ABSTRACT

Leiomyoma is very commonly seen in the present times in Gynecological practice. The incidence is high in women in active reproductive age, especially in nulliparous women. These are commonly known as Fibroids and are composed of fibrous connective tissue. The majority of the small Leiomyomas and some large ones are asymptomatic. Fibroid which are near to endometrial cavity, can cause symptoms like menorrhagia, low-back pain, lower abdomen pain etc. Based on the clinical features this tumour can be compared with the *Mamsajarbuda* type of *Arbuda*, described in Ayurvedic classics. There is no established treatment to control the Menorrhagia induced by Fibroid Uterus. Hence the present study is taken up to evaluate the efficacy of compound formulations viz., *Ashokarishtam* and *Lodhrasava* in controlling excessive bleeding during menses. Study carried out on 30 number of patients, of which, 14 (46.67%) had shown Good response, 03 (10.00%) had shown Fair response, 06 (20.00%) had shown Poor response, and 07 (23.33%) cases did not show any response. On statistical analysis of overall parameters adopted for the study, it is found that the drug efficacy in controlling menorrhagia was highly significant ($P < 0.001$).

INTRODUCTION

Leiomyoma is the commonest of all the benign pelvic neoplasms. The incidence is high during active reproductive age of women; rare before the age of 20 years, but are found in approximately 20% of women over 20 years of age and in 40% of women over the age of 40 years. These tumours are common in nulliparous or relatively infertile women.

Leiomyoma (fibroma or fibroid) is composed of muscle tissue although there is a variable amount of fibrous connective tissue as well, especially in the older and large tumors. Each individual tumor is monoclonal in nature and arises from a somatic mutation in a progenitor myocyte. The tumor is surrounded by a pseudo capsule, consisting of compressed normal uterine wall. The rate of growth is slow and varies from individual to individual. The majority of the small Leiomyoma and some large ones are symptomless. If it is more near to endometrial cavity, more likely it can cause symptoms, especially menstrual symptoms. The characteristic symptom of

Leiomyoma is menorrhagia, that is, an increased blood loss at normally spaced intervals, which is gradual in onset and progressive. The duration of flow may be normal or prolonged and the loss is heaviest on the second and third days¹.

The factors which are causing menorrhagia are; an increase in size of the endometrial cavity, increased vascularity of the uterus, associated with endometrial hyperplasia, compression of veins with consequent dilatation and engorgement of venous plexuses. Fibroid can also interfere with uterine contractions which are alleged to control the blood flow through the uterine wall¹.

Other associated symptoms are pain abdomen, anemia, and sometimes hypoglycemia. Continuous or irregular bleeding is only seen in the following conditions - ulceration of sub-mucous fibroid, polypoidal fibroid, sarcomatous change in tumor or a coincidental carcinoma. Fibroids can cause following complications like dyspepsia, frequency of urination,

retention of urine, edema or varicosities of legs, polycythemia etc.

According to Ayurveda, benign neoplasm can be compared with the clinical condition 'Arbuda'. *Arbuda* is tumour; it is of six types *Vataja*, *Pittaja*, *Kaphaja*, *Siraja*, *Mamsaja* and *Medasaja*². The *Arbuda* which arises from *mamsa dhatu* (muscle tissue) is called *Mamsajarbuda* (tumour arising from muscular tissue). Since fibroid uterus is originating from myocyte and composed of muscle tissue, this can be compared with *Mamsajarbuda*. Main humours involve in the pathogenesis of *Arbuda* are *Vata* and *Kapha*³.

Asrikdara is the condition where *Rajasrava* (menstrual flow) is excess (*Asrikdeeryate yasminneti Asrikdara* - Ca. Ci 30/201 - Cakrapani) and is otherwise known as *Raktapradara*. *Vata* in general and *Apanavata* in particular are the regulating factors of menstrual flow. If there is vitiation of *Vata*, that leads to excessive flow of *rajas* (menstrual blood)⁴. *Arbuda* when occurs in *Garbhasaya* that can cause *Asrikdara* due to vitiation of *Vata*, thereby excessive flow of menstrual blood.

In clinical practice, few trials have been carried out on cases of fibroid uterus for the reduction of its size through different formulations but encouraging results are not found. Fibroids if asymptomatic can leave untreated. But, when produces symptoms like menorrhagia, it needs immediate treatment. Present trial has been taken up to evaluate *Ashokarishtam* and *Lodhrasavam* in Menorrhagia induced by fibroid uterus.

Rationale for selection of trial drugs

In the existing modern system of medicine, to control bleeding hormonal therapy, haemostatic drugs are available with unsure relief and side effects. Hence finding out alternate therapies to control menorrhagia induced by fibroid uterus, is highly essential in Gynecological point of view.

Ashokarishta and *Lodhrasava* are most common preparations, widely prescribed in almost all sorts of Gynecological diseases. In *Ashokarishta*⁵, *Ashoka* is a main ingredient. *Ashoka* (*Saraca asoca* Roxb) is the drug of choice in diseases that occur from menarche to menopause. It is having stimulative effect on ovarian tissue and on endometrium. It is astringent in taste; especially bark is having strong astringent and sedative effect. It acts directly on the muscular fibres of the uterus. In the classics its actions are described as *Grahi* (binding/constipating), *Raktasangraha* (hemostatic), *Vedanasthapana* (analgesic); useful in clinical conditions like *Kashtartava* (dysmenorrhoea), *Svetapradara* (leucorrhoea), *Raktarshas* (bleeding hemorrhoids), *Raktatisara* (bloody diarrhea) etc and reduce *Garbhasaya sithilata*^{6&7}.

In *Lodhrasava*, *Lodhra* (*Symplocos racemosa* Roxb.) is the main ingredient. *Lodhra* is the best

astrigent drug and well prescribed for Gynecological disorders, since Caraka Samhita period⁸. *Lodhra* is having bitter and astringent taste, coolant in nature. It is containing alkaloids namely *loturine*, *loturidine* and *colloturine*, which may be to be responsible for astringent activity of *lodhra*. On pharmacological study, a crystalline fraction from the bark was found to reduce the frequency and intensity of the contractions in vitro of both pregnant and non-pregnant uteri of some animals. A glycoside isolated from the stem bark, named 3-monoglucufuranoside of 7-o-methyl leucopelargonidin is highly astringent and is reported to be responsible for medicinal properties of the bark⁸.

Many number of clinical studies have been carried out by different investigators on different indications with these drugs like *Raktapradara* (menorrhagia), *Svetapradara* (leucorrhoea), *Strivandhyatva* (female infertility) etc. But very scattered references of studies on Fibroid induced Menorrhagia are available. Hence the present study is taken up with these two well known preparations to evaluate clinically to see their efficacy in fibroid induced Menorrhagia cases.

MATERIALS AND METHODS

Aims: 1). To evaluate the efficacy of trial drugs in controlling bleeding in fibroid induced Menorrhagia

2). To evaluate the efficacy of trial drugs in the reduction of fibroid size.

Sample size and Study design

Design of study – Open trial

Sample size – 30

Trial drug schedule

Dose: *Ashokarishtam* – 10 ml BD

Lodhrasavam – 10 ml BD both drugs are to be taken 30 minutes after food along with equal amount of water.

Duration of therapy: 3 months

Follow-up: 30th day, 60th day and 90th day.

Methods: Total 33 cases were recruited for the study, of which 03 patients were dropped out due to irregular follow-up. All the subjects of trial were drawn from OPD of A. L. Research Centre for Ayurveda, VHS and incorporated according to the criteria of selection. Assessment of clinical parameters was done on initial day, 30th day, 60th day and 90th day. USG abdomen had done before and after treatment. Laboratory parameters were also assessed on initial day and final day of trial.

Source of trial drugs: IMPCOPS, Chennai.

Criteria of Inclusion

1. Woman in active reproductive age i.e., between 20 – 45 years.

- History of heavy or prolonged bleeding with or without clots for minimum 3 cycles.
- Single or multiple fibroids in uterus confirmed on USG.

Criteria of Exclusion

- Woman below the age of 20 and above 45 years.
- History of heavy bleeding during menses due to DUB.
- Menorrhagia due to adenomyoma, ovarian cysts, sarcoma, carcinoma or chorio carcinoma of the uterus.
- Woman with below 7gm/dl haemoglobin.
- Menorrhagia due to Pelvic inflammatory disease or local lesions of cervix /vagina.

Criteria of Withdrawal

- Not showing any improvement
- Development of any side effects
- Irregular intake of drug and irregular follow-up

Criteria of Assessment of Results

- Good Response:** Complete normalcy of menstrual flow, and complete relief from associative symptoms like pain abdomen, low back pain and cases with >75 -100% relief.
- Fair Response:** Normalcy of menstrual flow, but no relief in associated clinical symptoms and percentage of relief between 51 -74%.
- Poor Response:** Reduction in heavy menstrual flow and no relief in associated symptoms and percentage of relief between 25% -50%.
- No Response:** No reduction in heavy menstrual flow and associated symptoms and percentage of relief less than 25% are considered under this group.

PARAMETERS ADOPTED FOR ASSESSMENT:

Parameter	Gradation
1. Duration of menstrual flow	
Severe – excessive bleeding p/v for >7 days	20
Moderate – excessive bleeding p/v for >5 days	10
Mild - excessive bleeding p/v for >3 days	05
2. Amount of Menstrual flow	
Severe – Soakage of >4 diapers in day & > 2 in night	20
Moderate – Soakage of >3 diapers in day & > 1 in night	10
Mild - Soakage of >2 diapers in day & > 1 in night	05
3. Pain abdomen	
Severe pain abdomen, needs analgesics /anti-spasmodics	20
Moderate – Pain abdomen, forced to take rest	10
Mild – Dull colic pain in abdomen, patient is able to carry out routine	05

works

4. Low back pain

Severe – excruciating low back pain, needs analgesics	20
Moderate – intense low back pain, force the patient to take rest	10
Mild – dull pain and patient is able to carry out routine works	05

5. Hemoglobin

Hemoglobin between 7-8 gms/dl	20
Hemoglobin between 8-9 gms/dl	10
Hemoglobin between 9-10 gms/dl	05

OBSERVATIONS

Demographic data

Table I: Showing the incidence of age

Age in years	No of cases	Percentage
20 -25	00	00.00
25-30	04	13.33
30 -35	06	20.00
35 - 40	11	36.67
40 -45	09	30.00
Total	30	100.00

Table II: Showing the incidence of Parity

Type	Number	Percentage
Nullipara	07	23.33
Primipara	05	16.67
Multipara	18	60.00
Total	30	100.00

Table III: Showing the Incidence of Prakriti

	Vata	Pitta	Kapha	Vata Pitta	Pitta Kapha	Vata Kapha	Sama	Total
No	-	-	-	11	09	10	-	30
%	-	-	-	36.67	30.00	33.33	-	100.00

Table IV: Incidence of Occupation

	House wife	Desk work	Field work	Field work intellectual	Physical Labour	Total
No	16	07	00	03	04	30
%	53.33	23.33	00.00	10.00	13.34	100.00

CLINICAL DATA

Table V: Changes in duration of menstrual flow before & after treatment

Duration of menstrual flow	Before treatment		After treatment	
	No	Percentage	No	Percentage
> 7 days	08	26.66	02	06.67
5-7 days	11	36.67	05	16.66
3-5 days	11	36.67	06	20.00
< 3 days	00	00.00	17	56.67
Total	30	100.00	30	100.00

Table VI: Changes in amount of menstrual flow before & after treatment

Amount of menstrual flow	Before treatment		After treatment	
	No	Percentage	No	Percentage
Severe	19	63.33	01	03.33
Moderate	11	36.67	14	46.67
Mild	00	00.00	07	23.33
Normal	00	00.00	08	26.67
Total	30	100.00	30	100.00

Table VII: Changes in pain abdomen during menstruation before & after treatment

Pain Abdomen	Before treatment		After treatment	
	No	Percentage	No	Percentage
Severe	01	03.33	01	03.33
Moderate	23	76.67	05	16.67
Mild	02	06.67	12	40.00
No pain	04	13.33	12	40.00
Total	30	100.00	30	100.00

Table VIII: Changes in Fibroid on USG before and after treatment

Fibroid size	Before treatment		After treatment	
	Number	%	Number	%
Seedling	04	13.33	04	13.34
2-3 cm	10	33.33	10	33.33
3-4cm	08	26.67	06	20.00
>4 cm	08	26.67	10	33.33
Total	30	100.00	30	100.00

Table IX: Results of the study

	GR	FR	PR	NR	Total
Number	14	03	06	07	30
Percentage	46.67	10.00	20.00	23.33	100.00

Table X: Statistical analysis of efficacy of trial drug on overall parameters

	Before treatment	After treatment	Difference
Mean	54	23.16	30.63
SD	±8.16	±11.87	±12.67
SE	1.51	2.20	2.35
-t			13.11
P			<0.001

DISCUSSION

Fibroids are common phenomenon during active reproductive phase. In some cases these are asymptomatic, but when these are present as submucous fibroids, they can cause Menorrhagia. Hence the present study is taken up to evaluate the efficacy of *Ashokarishta* and *Lodhrasava*, two Ayurvedic herbal liquids in the management of fibroid (s) induced Menorrhagia. Study carried out in 30 cases, of which, 14 (46.67%) cases had shown Good response, 03 (10.00%) cases had shown Fair response, 06 (20.00%) cases had shown Poor Response, and 07 (23.33%) cases did not show any response.

Out of 30 total cases, majority of the women i.e., 11(36.67%) were seen under 35-40 years age group and 09 (30.00) under 40-45 years of age group. All the women were observed under *Dvanda prakrities*, and equally distributed under *Vatapitta*, *Vatakapha*, *Pittakapha*. Most of the women were multiparous 18 (60.00) women, and are House wives 16 (53.33%).

Analysis of two import parameters, duration of menstrual flow and amount of menstrual flow shown that; Before treatment, more than 7 days duration was seen in 26.66% of women, 5-7 days excessive flow was seen in 36.67% of women, and 3-5 days excessive flow was seen in 36.67% women. After treatment more than 7 days flow was seen only in 06.67% and 5-7 days excessive flow was seen in 16.66%, 3-5 days excessive flow was seen in 20.00% of women.

Before treatment; amount of flow was severe in 63.33% and moderate in 36.67% and after treatment the flow was observed severe in 03.33% and moderate in 46.67%, mild in 23.33% and bleeding was normal in 26.67%.

Another important symptom i.e., pain abdomen was severe in 03.33%, moderate in 76.67% and mild in 06.67% and pain was not there in 13.33%, before treatment. After treatment pain was severe in 03.33%, moderate in 16.67%, mild in 40.00% and 40.00% become pain free.

Pelvic USG carried out before and after treatment, before treatment to confirm the diagnosis and after treatment to see the change in size. However, there are no significant changes observed in the size of the fibroids.

On statistical analysis of overall parameters adopted for the study, it is found that the drug efficacy in controlling Menorrhagia was highly significant ($P < 0.001$). Out of 30 completed cases 14 (46.67%) had shown Good response, 03 (10.00%) had shown Fair response, 06 (20.00%) had shown Poor response, and 07 (23.33%) cases did not show any response.

Modus Operandi of trial drugs

In *Ashokarishta*, *Ashoka* (*Saraca indica*) is the main ingredient, having *Kashaya*, *Tikta rasa*. Bark is highly astringent and uterine sedative may be due to the presence of hemotoxin. It is having *Rakta sangraha*, *Vedanasthapana* properties. It is containing phenolic-glycoside and non-phenolic glycoside. Pure phenolic glycoside is non-toxic in nature. It is having pharmacological activities like astringent, anti-tumor, anti-fungal, antifertility, spasmodic action in uterine affections etc.

In *Lodhrasava*, *Lodhra* (*Symplocos racemosa*) is the main ingredient. It is having *Tikta*, *Kashaya rasa*, *Sita virya*. It is also highly effective astringent,

and this astringent action can be attributed to an alkaloid present in *Lodhra* bark called loturodine.

These two drugs might have acted in synergy in controlling fibroid induced menorrhagia. Dysmenorrhoea was also relieved effectively after treatment in Good number of patients; this may be due to uterine sedative action of *Ashoka*.

CONCLUSIONS

1. Leomyomas are the commonest among all the benign pelvic neoplasms.
2. These can induce menstrual symptoms like menorrhagia, dysmenorrhoea etc.
3. Menorrhagia can be compared with '*Asrikdara*' based on cardinal feature of excessive bleeding per vaginum during menstruation, as per Ayurveda.
4. Fibroid induced menorrhagia can be compared with *Mamsajarbudaja Asrikdara*, since tumour from soft muscle origin is called *Mamsajarbuda*.
5. Hormonal and all other haemostatic medicines are not effective in controlling excessive menstrual flow.
6. *Ashokarishta* and *Lodhrasava* are age old classical preparations found effective in controlling excessive uterine and vaginal discharges.
7. The present study is taken up to evaluate the haemostatic effect of both the drugs in fibroid induced menorrhagia.
8. From this study total 56.67% of patients got benefited.
9. On statistical analysis these drugs are found highly significant ($P < 0.001$).

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