



Research Article

www.ijrap.net

(ISSN Online:2229-3566, ISSN Print:2277-4343)



A RANDOMIZED COMPARATIVE CLINICAL STUDY OF BHUMYAMALAKI CHURNA AND MADHUKA GHRITA MATRA BASTI IN THE MANAGEMENT OF ASRIGDARA VIS-À-VIS ABNORMAL UTERINE BLEEDING

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Received on: 18/02/22 Accepted on: 24/04/22

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DOI: 10.7897/2277-4343.130352

ABSTRACT

Aim: Asrigdara Vyadhi mentioned as one of the Raktadoshaja Vikara. It manifests as excessive bleeding per vaginum, and its description is widely narrated in almost all the classical texts. In the present study, an attempt has been made to compare the effect of Bhumyamalaki Churna and Madhuka Ghrita Matra Basti in the Management of Asrigdara vis-à-vis Abnormal Uterine Bleeding. The present study aims to find a method of treatment that will impart a permanent cure without any side effects. Bhumyamalaki Churna is taken in present study because of its Raktapitta Shamaka and Yonidosahara property and Madhuka Ghrita Matra Basti because of its Raktapitta Shamaka property. Method: The present study is taken up to evaluate the effect of Bhumyamalaki Churna (Group-A) and Madhuka Ghrita Matra Basti (Group-B) clinically and to compare the effect of both groups (15 in each group) of diagnosed patients of Asrigdara. Results: The study revealed statistically highly significant improvements in both groups but comparing the symptomatic improvement of both groups, it was found that the average percentage of relief was higher in Group B, i.e. 70.09%, followed by 'Group A,' i.e. 66.09%. Conclusion: Madhuka Ghrita Matra Basti is more effective than Bhumyamalaki Churna in Asrigdara.

Keywords: Abnormal uterine bleeding, Asrigdara, Bhumyamalaki Churna, Madhuka Ghrita Matra Basti.

INTRODUCTION

Asrigdara indicates the excessive and irregularity of menses. Asrigdara can be correlated with abnormal uterine bleeding. Acharya Sushruta has explained Raktapitta Shamaka Chikitsa in the management of Asrigdara. Acharya Sushruta indicates Madhuka Ghrita Anuvasana Basti in treating Raktapitta¹. In Samprapti of Asrigdara, Roga Adhithana is Garbhashaya, i.e., Apana Ksetra, and the main vitiated Dosha is Pitta and Vata, i.e. Apana Vayu. Sneha and the Basti are the best Chikitsa for Vata Dosha. Due to "Samskaranuvarti Guna", Ghrita is the best Sneha among Mahasnehas and has Vata-pittashamaka and Yogavahi properties. Madhuka is Vata-pitta Shamaka drug due to its Madhura Rasa-Vipaka, Guru-Snidha Guna and Sheeta Veerya². The drug is haemostatic, good tonic, hepatoprotective, smooth muscle depressant, anti-inflammatory, antioxidant properties etc.

Acharya Yogaratnakar had mentioned Bhumyamalaki Churna in the treatment of Pradara³. Bhumyamalaki is Kapha-Pittashamaka drug due to its Madhur-Tikta-Kasaya Rasa, Laghu-Ruksha Guna, Madhura Vipaka, and Sheeta veerya⁴. Bhumyamalaki has pharmacological actions like Astringent, Antispasmodic, Hepatoprotective, Antifibrotic, Anti-inflammatory, Immunomodulatory and Analgesic properties.

Aims and objectives: Clinical evaluation of Bhumyamalaki Churna and Madhuka Ghrita Matra Basti in Asrigdara.

MATERIALS AND METHODS

Selection of Cases

A total of 36 clinically diagnosed and confirmed cases of Asrigdara were registered for the present clinical trial and randomly divided into two groups for this study. Out of which 30 patients completed the course of treatment. The cases were selected from the O.P.D. / I.P.D. of P.G. Department of Prasuti tantra & Stri Roga, National Institute of Ayurveda (N.I.A.) Hospital, Jaipur, after taking informed written consent.

Criteria for selection of patients

Inclusion criteria

- Patients complaining of Abnormal uterine bleeding have any two of the following symptoms: Excessive bleeding during menstruation (menstrual blood loss > 80 ml in 1-7 days), having a Pictorial blood loss assessment chart (PBLAC) score of more than 100 points for two consecutive cycles/Prolonged menstrual bleeding (With the duration of bleeding >7 days)/Inter menstrual bleeding/Frequent menstrual cycle (interval < 21 days).
- Patients of age group 18 to 45 years.

Exclusion criteria

- Patients having bleeding due to abortion
- Patients having coagulation disorders
- Patients having bleeding after menopause
- Any type of malignancy

- Puberty menorrhagia
- Patients having STDs
- Patients having any systemic diseases
- Hb% < 7 gm%
- Women using IUCD or Pill

Study design

A Randomized Open Clinical study

Study type: Interventional

Intervention model: Two group assignment

Allocation: Randomized (by Lottery method)

Masking: Open-label

Primary Purpose: Efficacy and Safety

Timing: 2 Months

Endpoint: Treatment

Sample size (number of subjects): 15 in each group, i.e. 30 in the centre.

Level of study: I.P.D. & O.P.D. Level.

Ethical committee clearance: As this was clinical research, Institutional Ethics Committee (IEC) approval was taken before initiation of research & its letter No. IEC/ACA/2018/32.

Administration of drugs

Clinically diagnosed and registered patients of Asrigdara were divided randomly into the following two groups:

Group A: Bhumyamalaki Churna, 5gm twice daily before food along with Tandulodaka (200 ml). Starting from seven days

before the due date of the menstrual cycle and continuing for two consecutive cycles.

Group B: Madhuka Ghrita Matra Basti, 60 ml Just after food. Seven days each in 2 successive cycles from seven days before the due date of the menstrual cycle.

Duration of clinical trial: 60 days/2 consecutive menstrual cycles

Criteria of assessment: All the patients registered for the present trial will be assessed based on subjective parameters, objective parameters, laboratory investigations and a Pictorial blood loss assessment chart (PBLAC).

Subjective parameters

- Amount of flow/bleeding
- Duration of menstrual bleeding
- Intermenstrual Period
- Pain during menses
- Body Ache
- Burning Sensation
- General weakness
- Giddiness

Objective parameters

- Pallor
- Blood Pressure
- Pulse Rate

RESULT

Clinical Improvement

Table 1: The pattern of clinical recovery in various ‘Subjective Parameters’ of Asrigdara in Group-A by Wilcoxon matched-pairs signed-ranks test (n=15)

Symptom	Mean		Mean Diff.	Percentage of Relief	SD	SE	P	Significance of Results
	BT	AT						
Amount of bleeding	1.667	0.3333	1.333	79.96	0.8165	0.1594	0.0005	E.S.
Duration of bleeding	1.733	0.2000	1.5333	88.47	0.7432	0.1919	0.0001	E.S.
Inter-menstrual period	0.9333	0.2000	0.73330	78.57	0.7037	0.1817	0.0039	V.S.
Pain during menses	1.000	0.2000	0.8000	80.00	0.6761	0.1746	0.0020	V.S.
Body ache	1.267	0.4667	0.8000	63.14	0.8619	0.2225	0.0078	V.S.
Burning sensation	1.400	0.6667	0.7333	52.38	0.7037	0.1817	0.0039	V.S.
General weakness	1.333	0.8000	0.5333	40	0.5164	0.1333	0.0078	V.S.
Giddiness	1.133	0.7333	0.4000	35.30	0.5071	0.1309	0.0313	S.
PBLAC	2.133	0.4000	1.733	81.25	0.4577	0.1182	0.0001	E.S.

SD = Standard Deviation, SE = Standard Error, ES= extremely significant, VS= Very Significant, S= Significant, BT: Before Treatment, AT: After Treatment

Table 2: The pattern of clinical recovery in various ‘Subjective Parameters’ of Asrigdara in ‘Group B’ by Wilcoxon matched-pairs signed-ranks test (n=15)

Symptoms	Mean		Mean Diff.	Percentage of Relief	SD	SE	P	Results
	BT	AT						
Amount of bleeding	1.667	0.2667	1.400	83.98	0.7368	0.1902	0.0002	E.S.
Duration of bleeding	1.667	0.1333	1.5333	91.97	0.9155	0.2364	0.0001	E.S.
Inter menstrual period	1.267	0.1333	1.1333	89.45	0.9155	0.2364	0.0010	E.S.
Pain during menses	0.9333	0.1333	0.8000	85.71	0.5606	0.1447	0.0010	E.S.
Body ache	1.000	0.5333	0.4667	46.67	0.5164	0.1333	0.0156	S.
Burning sensation	1.067	0.3333	0.7333	68.73	0.5936	0.1533	0.0020	V.S.
General weakness	1.200	0.8000	0.4000	33.33	0.5071	0.1309	0.0313	S.
Giddiness	1.067	0.6667	0.4000	37.49	0.5071	0.1309	0.0313	S.
PBLAC	2.067	0.1333	1.933	93.51	0.2582	0.06667	0.0001	E.S.

SD = Standard Deviation, SE = Standard Error. ES= extremely significant, VS= Very Significant, S= Significant, BT: Before Treatment, AT: After Treatment

Table 3: Inter Group Comparison in Subjective Parameters by Mann Whitney Test (n=30, group A=15, group=15)

Symptoms	Group	Mean	S.D.±	S.E.±	P	Result
Amount of bleeding	A	1.267	0.7988	0.2063	0.6662	N.S.
	B	1.400	0.7368	0.1902		
Duration of bleeding	A	1.533	0.7432	0.1919	0.9631	N.S.
	B	1.533	0.9155	0.2364		
Inter menstrual period	A	0.7333	0.7037	0.1817	0.2311	N.S.
	B	1.133	0.9155	0.2364		
Pain during menses	A	0.8000	0.6761	0.1746	0.9620	N.S.
	B	0.8000	0.5606	0.1447		
Body ache	A	0.8000	0.8619	0.2225	0.3374	N.S.
	B	0.4667	0.5164	0.1333		
Burning sensation	A	0.7333	0.0.7037	0.1817	0.4851	N.S.
	B	0.5333	0.5164	0.1333		
General weakness	A	0.5333	0.5164	0.1333	0.4867	N.S.
	B	0.4000	0.5071	0.1309		
Giddiness	A	0.4000	0.5071	0.1309	0.9805	N.S.
	B	0.4000	0.5071	0.1309		
PBLAC	A	1.733	0.4577	0.1182	0.1578	N.S.
	B	1.9333	0.2582	0.06667		

SD = Standard Deviation, SE = Standard Error, NS = Not significant
In Inter Group comparison, statistically, no significant changes are observed in all Parameters.

Table 4: Percentage of improvement of Subjective Parameters in Both Groups

Parameters	Result In Percentage	
	Group A (n=15)	Group B (n=15)
Amount of bleeding	75.77	83.98
Duration of bleeding	88.47	91.97
Inter Menstrual Period	78.57	89.45
Pain during menses	80.00	85.71
Body ache	63.14	46.67
Burning sensation	52.38	68.73
General weakness	40.00	33.33
Giddiness	35.30	37.49
PBLA Chart	81.25	93.51
Average percentage of Relief	66.09%	70.09%

DISCUSSION

Asrigdara is to be treated on the lines of Raktapitta, Raktarshas and Rakta-atisara.

According to line of treatment of Raktarsha; Deepana, Pachana, Agni Vardhana, Rakta Sangrahana and Dosha Pachana Should be done by Tikta & Kashaya Rasa Pradhana Dravya⁵.

In the present study, “Bhumyamalaki Churna” and “Madhuka Ghrita Matra Basti” have evaluated their efficacy in the management of Asrigdara. The instinctive properties of the drugs have been enlisted in these drugs.

In keeping with theories proposed so far, we can safely conclude that all the drugs taken in the present study can act at all the levels of the Samprapti, thus satisfying “Samprapti vighatanam eva chikitsa”.

Action on samprapti ghataka

Dosha: Predominant Dosha responsible for the disease are, vitiated Vata and Pitta. Pitta is pacifying due to Tikta-Kashaya Rasa and Sheeta Veerya. Vata is pacifying due to Madhura rasa and guru Snigadha Guna.

Dushya: Most of the components are Dahashamak, Pitta-Rakta Samaka and Raktasangrahi which helps in Shodhana of Dushita Pitta and Rakta. Further, this has Deepana and Pachana

properties which played a role in Ama Pachana of Rasa Dhatu by their action on Jatharagni. It is useful in bleeding disorders.

Adhithana and Srotasa: Most of the components are Shothahar and vranaropana properties, which help in Srotoshodhana and Garbhashaya Shodhana, thereby reducing inflammation and uterine congestion. The presence of Vrana-ropana property mitigates the fragility of endometrial capillaries and thus helps in their toning.

CONCLUSION

Comparing the symptomatic improvement in both groups, the average percentage of relief was higher in ‘Group B,’ i.e., 70.09%, followed by ‘Group A,’ i.e., 66.09%. It shows that the effect of therapy was more in Group B than in Group A. This study overall concluded that both drugs Bhumyamalaki churna and Madhuka Ghrita Matra Basti are effective, but Madhuka Ghrita Matra Basti is comparatively better at curing the subjective and objective parameters of Asrigdara.

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Cite this article as:

Sanju Rao *et al.* A randomized comparative clinical study of bhumyamalaki churna and madhuka ghrita matra basti in the management of asrigdara vis-à-vis abnormal uterine bleeding. *Int. J. Res. Ayurveda Pharm.* 2022;13(3):27-30
<http://dx.doi.org/10.7897/2277-4343.130352>

Source of support: Nil, Conflict of interest: None Declared

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