Research Article

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A CLINICAL STUDY FOR THE EVALUATION OF THE EFFECT OF BALA MOOLA CHURNA IN ASRIGDARA

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ABSTRACT

Menstruation is a physiological function that denotes a healthy reproductive system in a woman. A normal menstrual cycle is vital for every woman's physical and psychological well-being. Asrigdara is a condition where there is excessive or prolonged bleeding. Considering the symptoms, it can be related to Dysfunctional Uterine Bleeding, a state of abnormal bleeding without any clinically detectable organic, systemic or iatrogenic causes. It is common in multiparous women than in nulliparous women. Bala Moola mentioned in Chakradutta is undertaken for the present study to evaluate its efficacy in Asrigdara. A randomized clinical study consisting of two groups, with 20 patients in each group were selected. Group A was given trial drug Bala Moola Churna with milk and honey in the dose of 6 gms twice daily after food for three consecutive cycles. Group B was given Tranexamic acid one tablet twice after food for three-cycle. Both the drugs were given till the bleeding stopped or a maximum of 15 days. The study showed that both the drugs, Bala Moola Churna and Tranexamic acid, were equally effective in reducing the symptoms of Asrigdara at the end of treatment.

Keywords: Asrigdara, Dysfunctional uterine bleeding, Bala Moola Churna, Tranexamic acid

INTRODUCTION

Menstruation is a physiological function that denotes a healthy reproductive system in a woman. The female menstrual cycle involves dramatic monthly hormonal changes affecting a woman's emotional and physical state. An interplay of hypothalamo-pituitary-ovarian axis coordinates menstrual rhythm. Change in lifestyle, food, habits, mental stress etc., can disturb this rhythm and cause menstrual irregularities. Menstrual problems acquire significance, as reproduction depends on a normally-functioning menstrual cycle. .

In Ayurveda, Artava represents the element produced following a rhythm and cyclicity in female genital physiology. Asrigdara is characterized by the Pradirana (excessive excretion) of Raja[1]. Acharya Charaka considers it one of the Rakta Pradoshaja Vikara[2] and diseases due to Pittaavrita Apana Vayu[3]. Ashtanga Sangraha has described Raktayoni and mentioned Asrigdara and Pradara as their synonyms[4]. According to Acharya Susrutha, excessive or prolonged blood loss during menstruation with or without intermenstrual bleeding[5]. Considering the above view, Asrigdara can be understood as Dysfunctional Uterine Bleeding. DUB is defined as heavy menstrual bleeding in the absence of any recognizable pelvic pathology, pregnancy or generalized bleeding disorders which interferes with a woman's physical, social, emotional or material quality of life[6].

DUB affects 10-30% of women in the overall population, and heavy menstrual bleeding is a common condition, accounting for about 30% of all cases attending a Gynecology OPD[7,8]. The diagnosis is based on the exclusion of organic lesions, so the incidence varies. Within five years of referrals, 60% of women will have undergone hysterectomy, making it the most familiar major gynaecological operation. Currently, DUB is defined as a state of abnormal uterine bleeding following anovulation due to dysfunction of the hypothalamo-pituitary-ovarian axis that is of endocrine origin. It is more prevalent in extremes of the reproductive period, adolescence and premenopausal age or following childbirth and abortion. The commonest age group affected by DUB is 31-40 years (45.6%) and seen primarily on multiparous women (71.58%)[9]. If not treated properly, it may lead to further complications like anaemia, weakness, infertility, mental distress etc. DUB's medical management includes hormonal therapy, prostaglandin synthetase inhibitors, anti-fibrinolytic agents, oral contraceptive pills, etc[10]. All these have significant and minor side effects like nausea, hypertension, GIT disorders, liver diseases, etc. Surgical management includes uterine curettage, endometrial resection and hysterectomy, which also have other complications[11]. Hence it is essential to find an effective cure for this disease without any adverse reaction.

Our Acharyas have mentioned that the treatment principle of Raktatisara, Raktapitta and Raktarsha can be adopted in Asrigdara[12]. The general principles to be followed in treating excessive bleeding include Nidana Parivarjana, Dosha Shodhana, Dosha Shamana, Rakta Sangrahana and Rakta Sthapana. Here a yoga of Balamoola, indicated for Asrigdara, mentioned in Chakradutta, Pradara Chikitsa· is selected to access its action. Hence, an attempt is made to evaluate the Rakthasthambaka property of Balamoola Churna and compare its efficacy with a

standard drug, Tranexamic acid, an anti-fibrinolytic that competitively inhibits the activation of plasminogen to plasmin, thereby controlling bleeding.

MATERIALS AND METHODS

Study Design: A randomized comparative clinical study consisting of 40 patients suffering from Asrigdara fulfilling the inclusion criteria were selected for the study. They were assigned into two equal groups, A and B.

Ethical clearance: The study was carried out as per the International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP) or as per the declaration of Helsinki guidelines. Written and informed consent was taken from each patient willing to participate in the trial before their registration for the study. The institutional clinical ethical committee approved this study as proposal number ICEC/PTSR/03 Dated 29/03/2019.

Sample source: Forty patients attended the Prasoothi Tantra and Streeroga OPD of Alva's Ayurveda Medical College and Hospital Moodbidri and other available sources.

Method of preparation of drug: A sufficient quantity of Bala moola was taken, and fine powder was prepared in a pulverizer. This sukshma churna was sieved in a thin cloth and packed in sterile, airtight containers.

Diagnostic Criteria

- Raja atipravarthi – Excessive bleeding
- Deergakalanubandhi – Prolonged duration
- Anruthavalpamapi – Inter menstrual scanty bleeding
- Vedana – Pain

Inclusion Criteria

- Patients were fulfilling the diagnostic criteria.
- Age group –25 to 40 years
- Patients with Hb >8gm%

Exclusion Criteria

- Patients with a history of bleeding disorders, DM, HTN and other systemic diseases.
- Endocrinal disorders like Thyroid dysfunction, PCOS.
- IUCD and OCP
- Any benign or malignant growth in the reproductive tract
- Pelvic pathologies like Endometriosis, Uterine fibroids.
- Pregnancy.
- Patients with post abortal bleeding

Assessment Criteria

Subjective criteria

- Intermenstrual Bleeding
- Body ache
- Pain during menstruation

Objective Criteria

- Duration of menstrual flow
- Amount of menstrual blood loss

Table 1: Intervention

Groups	Dosage	Administration	Duration of Treatment	Anupana
Group A Bala Moola Churna (trial)	6 gm (½ Karsha) BD	After food	From the 3rd day of menstruation till bleeding stops or maximum up to 15 days for three consecutive cycles.	Ksheera Madhu
Group B Tranexamic acid (standard)	500mg BD	After food	From the 3rd day of menstruation till bleeding stops or maximum up to 15 days for three consecutive cycles.	Water

Assessment Parameters

Table 2: Duration of bleeding

No. of days	Scoring	Grading
<5 days	0	Normal
6-7 days	1	Mild
8-9 days	2	Moderate
>9 days	3	Severe

Table 3: Amount of blood loss

No. of pads/day	Scoring	Grading
Two pads moderately soaked	0	Normal
2-3 pads thoroughly soaked	1	Mild
4-5 pads thoroughly soaked	2	Moderate
> 6 pads thoroughly soaked	3	Severe

Table 4: Interval between menstrual cycles

Length of cycle	Scoring	Grading
28- 30 days	0	Normal
20- 27 days	1	Mild
15- 19 days	2	Moderate
<15 days	3	Severe

Table 5: Pain

Pain scale	Scoring	Grading
0	0	No pain
1-3	1	Mild
4-6	2	Moderate
7-8	3	Severe
9-10	4	Worst

Assessment

The assessment was done on the 3rd day,10th day and 17th day during the treatment period for three consecutive cycles and follow up was done on the 5th day of the next menstrual cycle after the treatment.
The parameters were scored based on gradation and analyzed statistically.

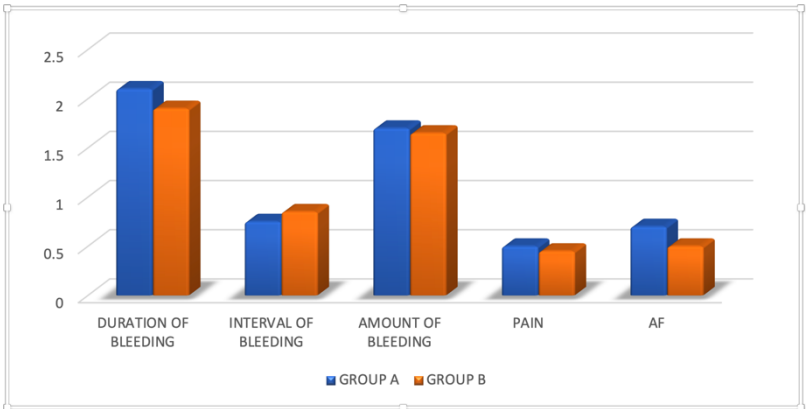
Statistical Analysis

The assessment was done based on the detailed proforma adopting standard scoring methods of subjective and objective parameters. Both groups were statistically analyzed using Wilcoxon signed Rank Test for within-group comparison and Mann-Whitney U Test.

RESULTS AND DISCUSSION

Table 6: Comparative results between Group A and Group B

Signs and symptoms	Group a (median)	Group b (median)	S.d (±)	Mann-Whitney test			Remarks
				U Value	Z Score	P-Value	
Duration of bleeding	2.10	1.90	0.934	174.00	0.741	0.495	NS
Interval of bleeding	0.75	0.85	0.758	180.00	0.582	0.602	NS
Amount of bleeding	1.70	1.65	0.616	191.00	0.281	0.820	NS
Pain	0.50	0.45	0.640	185.00	0.453	0.698	NS



Graph 1: Comparative results between Group A and Group B

Discussion on the probable mode of action

Based on Rasa: Bala Moola predominantly possesses Madhura Rasa and also Tikta Rasa, according to Raja Nighantu. The Anupana Ksheera and madhu are also Madhura Rasa Dravyas. Madhura Rasa has the property of Vatapittahara, and Tikta is Pittahara which in turn eliminates the Raktha Dushti, thereby controlling the bleeding. Madhura also does Brimhana and Jeevana, which helps cure the general debility caused by this disease. Kashaya, Anurasa of Madhu, has Sthambana action, which may also help reduce the bleeding.

Based on Guna: The drug Bala possesses Guru, Snigdha and Picchila Gunas, which helps in reducing the Vata and Pitta doshas which are the main doshas involved in Asrigdara. The Anupana Ksheera also possesses Guru and Snigdha Gunas.

Based on Virya: Bala has Sheeta Virya, by which it acts as Raktapitta Shamaka and Raktha Sthambhaka, which is the primary action by which the disease Asrigdara is controlled. The Anupana Ksheera and Madhu also possess Sheetha Virya. Acharya Susrutha mentions Skandana, i.e., coagulation, as one among the four measures to prevent blood loss which Sheeta Guna Pradhana Dravyas achieve

Based on Vipaka: Bala possesses Madhura Vipaka, which helps in Vata Pitta Shamana, which helps in maintaining the normalcy of Pitta and thereby regulating the Rakta Dhatu and regularising the menstrual cycle. Also, the Anupanas Ksheera and Madhu undergoes Madhura Vipaka

Based on Karma: Considering the Karma, drugs predominantly possess the properties of Vata-Pittahara, Raktapittahara, Grahi, balya and brihmana. The anupanas, ksheera and madhu also have the property of Raktapitta Shamana. Ksheera is Jeevaniya, Balya, Rasayana and Vatapitta Shamaka.

Based on Pharmacological action: The chemical constituent choline in plant Bala has a haemostatic effect that helps control the bleeding. Bala also contains betaine, hypaphorine ecdysterone, phytosterol, beta-sitosterol, and indole alkaloids which possess anti-oxidant, anti-inflammatory and immunomodulatory action, preventing oxidative stress and inflammation responsible for fibrinolysis, thereby reducing the bleeding.

Overall Effect Of Therapy

Group A: The overall response of therapeutic effect at the end of treatment in group A showed that 15% of the patients had mild improvement, 40% had moderate improvement, and 45% had marked improvement.

Group B: The overall response of therapeutic effect at the end of treatment in group B showed that 25% of the patients had mild improvement, 45% had moderate improvement, and 30% had marked improvement.

Comparison between both the groups showed a reduction in symptoms as the curative rate in all parameters were statistically significant. But the percentage of cure of all the symptoms were more in Group A when compared to Group B even though the difference between the groups were statistically not significant.

CONCLUSION

Bala Moola Churna possesses Madhura Rasa, Sheeta Virya, Raktapittahara, Raktasthambhaka, Balya, Vatapittahara and Brihmana properties, and Tranexamic acid is an anti-fibrinolytic agent. In the present study, the effects of both drugs were statistically analyzed. Both groups attained a $P<0.001$ when tested for all the parameters, which is statistically significant. Between the group for all parameters, $P>0.05$, which is statistically insignificant and shows that both the drugs have only negligible differences in curing the disease. But on clinical evaluation, the percentage of relief was more significant in Group A than in Group B patients. So we can consider that Bala Moola is more effective than Tranexamic acid in controlling bleeding. Also, it was found that there was no significant difference on all parameters on comparing after treatment and follow up period in

both the groups with P>0.05. Hence, the null hypothesis is accepted, and the alternate hypothesis is rejected, i.e., there is no significant difference between the effect of Bala Moola Churna and standard drug in Asrigdara.

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