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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFECT OF *SPHATIKAYUKTHA RASA SINDOORA* WITH *LODHRA KASHAYA* IN DYSFUNCTIONAL UTERINE BLEEDING

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ABSTRACT

Introduction: Dysfunctional Uterine Bleeding is defined as a state of abnormal uterine bleeding without any clinically detectable organic, systemic and iatrogenic cause. The prevalence varies widely but an incidence of 10% amongst new patients attending the outpatient seems logical. Along with increased susceptibility to iron deficiency, heavy menstrual bleeding can negatively impact physical, emotional and social quality of life and reduce work capacity of females. **Objective:** A clinical study was conducted to evaluate the effect of *Sphatikayuktha Rasa Sindoora* with *Lodhra Kashaya* in Dysfunctional Uterine Bleeding. **Materials and Methods:** This pre-post interventional study was conducted among 20 females in the age group 20-45 years who had the symptoms of Dysfunctional Uterine Bleeding for the past 3 cycles. Drug administration started on the 3rd day of menstruation and was continued till bleeding stopped or upto a maximum of 7 days for 3 consecutive cycles. Follow up was done in the next cycle. The condition of the patient after drug administration in the first, second and third months were separately compared with the condition of the patient before treatment. Outcome variables were change in the amount, duration and frequency of bleeding. **Results and Discussion:** Results were analysed statistically using Wilcoxon signed rank test and Paired t-test. The treatment was effective in reducing the amount of bleeding during treatment period and the follow up period. It was effective in reducing the duration of bleeding during the treatment period as compared to the follow up period and in controlling the cycle interval during the treatment period.

KEYWORDS: Dysfunctional Uterine Bleeding, *Asrigdara*, Ayurveda, *Lodhra, Rasa Sindoora, Sphatika*.

INTRODUCTION

Rhythmic and cyclic menstruation is the crucial indicator of a woman's ability to reproduce which in turn, is brought about by a normal neuroendocrine pathway. Our *Acharyas* described the entire female physiology by the term '*Artava*'. It can be described as that which occurs during a specific period of time. Abnormal Uterine Bleeding (AUB) is one of the most common reasons for women to seek medical care. The prevalence of AUB is estimated at 11-13% in the general population and increases with age, reaching 24% in those aged 36-40 years.[1] In India, the reported prevalence of AUB is around 17.9%[2] and the incidence is pubertal or adolescent DUB 4%, Reproductive DUB 57% Perimenopausal DUB 39% and Postmenopausal DUB 10%.[3]

Dysfunctional uterine bleeding or DUB is defined as a state of abnormal uterine bleeding without any clinically detectable organic, systemic, and iatrogenic cause (Pelvic pathology, e.g. tumor, inflammation or pregnancy is excluded).[4] Upto half of women with AUB in reproductive age will have DUB.[5] The prevalence varies widely but an incidence of 10% amongst new patients attending the outpatient seems logical. The pathophysiology of DUB is largely unknown, but it occurs in both ovulatory and anovulatory menstrual cycles. The endometrial abnormalities that occur in DUB may be primary or secondary to in coordination in the HPO axis. DUB is thus more prevalent in extremes of reproductive period- adolescence and premenopause or following childbirth and abortion. The bleeding may be abnormal in frequency, amount, or duration or combination of any three. As the diagnosis is based with the exclusion of 'organic lesion', so with the care and facilities to exclude such a lesion, the incidence varies. Currently DUB is considered as a state of abnormal uterine bleeding following anovulation due to dysfunction of HPO axis (endocrine origin).[4]

Dysfunctional uterine bleeding (DUB) can be classified as:[6] Ovulatory DUB (10-20%) and Anovulatory DUB (80-90%). Along with an increased susceptibility to iron deficiency, heavy menstrual bleeding can negatively impact physical, emotional and social quality of life and reduce work capacity of females.

Asrigdara is the most appropriate correlation of DUB in clinical presentation. It is a disease manifesting as *Artava atipravritti* (excessive bleeding per vaginum). It refers to all types of irregular and abnormal uterine bleeding. Features of *Angamarda* (body ache) and *Vedana* (pain) are also explained.[7] In addition, Dalhana explains symptoms like *Daha* (burning sensation) in *Adhovankshana* (lower part of groin), *Sroni* (pelvic region), *Prishta* (back), *Vrikka* (region of kidneys) and severe pain in *Garbhasaya*.[8]

Because of the diverse etiopathology of DUB in different phases of woman's life, the treatment should be based on the age of the woman, her desire to retain fertility, previous treatment and severity of menorrhagia. The management aims to include control menorrhagia, to prevent or treat anaemia, to prevent recurrence and to treat the cause. General measures, medical management, surgical management are done. Hormone therapy has an important place in the treatment of women of reproductive age but is rarely indicated after the age of 40 years. Women with AUB may become anaemic, and care typically is directed toward bleeding abatement and oral iron replacement. Surgical management includes uterine curettage, endometrial ablation/resection and hysterectomy. This study was an attempt to scientifically evaluate the effect of *Sphatikayuktha rasa sindoora* with *Lodhra kashaya* in DUB.

MATERIALS AND METHODS

OBJECTIVE

To evaluate the effect of *Sphatikayuktha Rasa Sindoora* with *Lodhra Kashaya* in Dysfunctional Uterine Bleeding.

Study Design: Interventional study– Pre and Post

Study Setting: OPD and IPD of Prasuthi Tantra and Streeroga, Govt. Ayurveda College Hospital for Women and Children, Poojappura, Thiruvananthapuram.

Study Population

Females of the age group 20-45 years who came to the OPD and IPD and satisfying the inclusion criteria.

Inclusion Criteria

Female patients complaining of abnormal uterine bleeding (excessive bleeding/ prolonged bleeding/ frequent cycles/intermenstrual bleeding) of the age group 20-45 years for the past 3 cycles without any systemic, organic and iatrogenic causes.

Exclusion Criteria

Bleeding associated with oral contraceptive pills, bleeding associated with IUCD, pelvic pathologies like fibroid, polyp, CIN lesions, PID, adnexal mass PCOS, carcinoma, Patients undergoing prolonged medication for various systemic illnesses like hypertension, diabetes mellitus, renal disease, liver disease, thyroid dysfunction, inherited bleeding disorders, bleeding associated with pregnancy or abortion, postmenopausal bleeding.

Sample Size: Sample size was 20

Data Collection

Clinical observation using a Case Proforma

Study Tool

- Case Proforma
- PBAC (Pictorial Blood Loss Assessment Chart)[9]

Methods

Patients satisfying the inclusion criteria were selected from the OPD and IPD of Women & Children Hospital, Poojappura. History- taking, general physical examination, systemic examination and necessary lab investigations were done. To confirm the diagnosis of DUB, USG abdomen and pelvis was performed. The study was conducted in a single group. Before starting the treatment, the clinical presentation was assessed. An informed consent was taken from the patient prior to the study.

Rasa sindoora was prepared as per classics. Genuine samples of *Sphatika* were collected and purified. Certified samples of *Lodhra twak* were collected from the market and made into coarse powder. 7 small sachets each with 185mg of drug (*Rasa sindoora*- 60mg and *Sphatika*- 125mg were dispensed to the patient. 7 packets of the coarsely powdered drug to prepare *Kashaya* each of 24gm were also dispensed. Mode of administration was well explained to the patients. *Pathya ahara* and *Vihara* were also explained. A general awareness about the assessment of menstrual characteristics was given to the patients and were asked to record the findings. They were instructed to use standard size pads.

Assessment of menstrual blood loss- (Pictorial Blood Loss Assessment Score)[9]

Pictorial blood loss assessment chart (PBAC) was used to assess the amount of bleeding. With a scoring sheet, patients were asked to record daily the number of sanitary products that are lightly, moderately, or completely saturated. The scoring was done according to the soaking pattern of sanitary pads.

Dose of the Drug

Patients were instructed to prepare *Kashaya* by boiling 24gm of the powdered *Lodhra twak* in 16 times of water (384ml), reduced to 1/8th (48ml) and then allowed to cool. They were asked to mix the combination of *Rasa sindoora* (60mg) and *Sphatika* (125mg) making up a total of 185mg with the *Kashaya* and to be consumed in a single dose after food in the morning.

Duration of Drug Administration

The internal administration of the drug started from the day the patient came to the OPD with complaints of abnormal uterine bleeding and was diagnosed as DUB after necessary examinations and investigations. The drug was administered till bleeding stopped or upto a maximum of 7 days. In the next cycle, drug administration started on the 3rd day of menstruation and was continued till bleeding stopped or a maximum of 7 days. The drug was administered for three consecutive cycles.

Follow up: Further follow up was done in the next cycle.

Study Period: 4 months

Assessment

The patients were advised to report on the 7th day of drug administration during each month of the study period and the menstrual pattern was assessed. The condition of the patient after drug administration in the first, second and third month separately was compared with the condition of the patient before drug administration. Similar assessment was made after the follow up period also.

Selection of drug

Rasa sindoora- Sphatika prayoga is explained in *Rasa Tarangini, Talakadi Vijnaniya Taranga* in the context of *Sphatika.*[12]

Lodhra kashaya is mentioned as *Anupana* for *Rasa sindoora* in the treatment of *Asrigdara* in *Rasa Tarangini*.[13]

Outcome Variables

- Change in the amount of bleeding (assessed by the number of pads used per day and PBAC score).
- Duration of bleeding (assessed by the number of days of bleeding).
- Frequency of bleeding (assessed by the interval of menstrual bleeding i.e., the interval between 1st day of LMP (Last menstrual period) of a cycle to the 1st day of LMP of the subsequent cycle).

Assessment Criteria

Interval of Blood Loss

Menstrual interval was calculated in days. Normal menstrual interval was taken as 21-35 days. For the purpose of categorization, grading was done as follows:

21 – 35 days - Grade 0

> 35 days - Grade 1

< 21 days - Grade 2

Duration of Blood Loss

Menstrual duration or the number of days of bleeding was calculated in days. An average of 3-5 days bleeding was considered as normal. Grading was done as follows:

3 – 5 days - Grade 0

5 – 7 days - Grade 1

7 – 10 days - Grade 2

>10 days - Grade 3

Amount of Blood Loss (Pictorial Blood Loss Assessment Score)[9,10,11]

The standard scores are as follows

Light soaking of pads -1

Moderate soaking of pads - 5

Complete soaking of pads - 20

Clots were also included in assessing the amount of bleeding. Considering clots, scoring was done according to the size of clots. The standard scoring is as follows.

Absent - 0

Small clots - 1

Large clots - 5

Flooding was also included in the assessment. It indicates the overflowing/ staining of clothing/ undergarments. Each episode of flooding was given a score of 5. Points are then tallied for each day. Total score greater than 100 per cycle indicates menorrhagia. Clots were also separately assessed according to their number.

Changes in the haemoglobin percentage were also included in the study. Assessment of associated complaints like pain, dizziness, fatigue and anorexia were also done.

Statistical Analysis

Change in main parameters i.e., menstrual interval and duration of bleeding was analysed statistically using Wilcoxon signed rank test. Amount of bleeding and clots were analysed using Paired t test.

Change in haemoglobin percentage was analysed statistically using Paired t test. Changes in the associated complaints were analysed statistically using Wilcoxon signed rank test.

OBSERVATIONS AND RESULTS

Table 1: Percentage distribution according to presenting complaints

Presenting complaints	Frequency	Percentage
Excessive bleeding	20	100
Prolonged bleeding	9	45
Passing of clots	16	80
Frequent cycles	3	15
Intermenstrual bleeding	0	0

Data Related to Effectiveness of Treatment

BT – Before treatment, WT1 – Within treatment (1st month), WT2 - Within treatment (2nd month), WT3 - Within treatment (3rd month), AF – After follow up

Table 2: Effectiveness of treatment on the cycle interval

Wilcoxon signed rank test	Z	p
BT-WT1	1.73	.084
BT-WT2	2.251	.024
BT-WT3	2.251	.024
BT-AF	1.127	.260

Considering the effectiveness of treatment in normalizing the cycle interval, statistically significant improvement was found in the interval of cycle in the 2nd (p value <0.05) and 3rd months (p value <0.05) within treatment comparing to before treatment as per Wilcoxon signed rank test. Before treatment- within treatment in the first month (p- 0.084), and before treatment- after follow up (p 0.260) results were not found to be statistically significant. The results show that the study drug was effective in normalizing the cycle interval (21-35 days) during the 2nd and 3rd months of treatment period as compared to the 1st month of treatment. Thus the study was statistically significant normalizing the cycle interval within the treatment period.

Table 3: Effectiveness of treatment on the duration of bleeding

Wilcoxon signed rank test	Z	p
BT-WT1	3.704	<0.001
BT-WT2	3.834	<0.001
BT-WT3	4.021	<0.001
BT-AF	3.477	.001

Statistically significant results were found in the duration of bleeding during the treatment period as per Wilcoxon signed rank test. Before treatment-within treatment in the 1st, 2nd and 3rd months (p<0.001) results were found to be highly significant. Before treatment-after follow up (p - 0.001) comparison was found to be statistically significant. Thus the study drug was effective in reducing the duration of bleeding during the treatment period compared to the follow up period.

Table 4: Effectiveness of treatment on the amount of bleeding (As per PBAC score)

Amount of bleeding	N	Mean	sd
BT	20	376.6	111.7
WT1	20	167.2	53.2
WT2	20	117.1	50.6
WT3	20	71.3	28.9
AF	20	114.0	43.1

Table 5: Comparison of effectiveness of treatment on the amount of bleeding

Paired comparison	Paired difference		Paired t test	
	mean	Sd	t	P
BT- WT1	209.4	95.1	9.844	<0.001
BT- WT2	259.5	100.2	11.588	<0.001
BT- WT3	305.3	106.5	12.823	<0.001
BT- AF	262.7	106.0	11.077	<0.001

Statistically significant results were found in the amount of bleeding throughout the study period as per Paired t test. Before treatment-within treatment in the 1st, 2nd and 3rd months results were found to be highly significant (p<0.001). Before treatment-after follow up (p<0.001) comparison was also found to be highly significant. Thus the study drug was effective in reducing the amount of bleeding throughout the study period.

Table 6: Effectiveness of treatment on number of clots

Number of clots	N	Mean	sd	Paired comparison	Paired difference		Paired t test	
BT	20	16.6	10.5		Mean	sd	T	P
WT1	20	10.4	7.8	BT- WT1	6.2	4.5	6.142	<0.001
WT2	20	7.2	5.5	BT- WT2	9.5	6.5	6.542	<0.001
WT3	20	4.9	3.8	BT- WT3	11.7	8.3	6.268	<0.001
AF	20	6.8	4.6	BT- AF	9.8	7.9	5.526	<0.001

Statistically significant results were found in the number of clots throughout the study period as per Paired t test. Before treatment-within treatment in the 1st, 2nd and 3rd months results were found to be highly significant (p<0.001). Before treatment-after follow up (p<0.001) comparison was also found to be highly significant. Thus the study drug was effective in reducing the number of clots throughout the study period.

Table 7: Effectiveness of treatment on haemoglobin percentage

Haemoglobin	N	Mean	sd
BT	20	10.12	0.95
WT1	20	10.64	0.90
WT2	20	11.62	0.73
WT3	20	11.89	0.57
AF	20	10.88	0.78

Table 8: Comparison of effectiveness of treatment on haemoglobin percentage

Paired comparison	Paired difference		Paired t test	
	mean	sd	t	P
BT- WT1	.52	.30	-7.66	<0.001
BT- WT2	1.50	.66	-10.15	<0.001
BT- WT3	1.77	.66	-12.04	<0.001
BT- AF	.76	.45	-7.61	<0.001

Anaemia of varying degrees was present in the cases. This is attributed to the amount and duration of blood loss. Other haematological values were found to be within normal limits. Before treatment, the mean Hb percentage was 10.12 ± 0.95gm%. The mean values after the 1st, 2nd and 3rd months of treatment were 10.64 ± 0.90 gm%, 11.62 ± 0.73 gm%, 11.89 ± 0.57gm%. After the follow up period, the mean Hb was 10.88 ± 0.78gm%. According to Paired t test, the results were statistically significant.

As the amount and duration of blood flow was reduced considerably due to the treatment, Hb percentage showed an increase concurrently.

Effectiveness of treatment on associated symptoms

Most of the cases presented with associated symptoms like pain, dizziness, fatigue, anorexia etc. Though associated symptoms were not included under outcome variables, patients had statistically significant relief from some of those symptoms after administration of the study drug for three consecutive cycles.

Table 9: Effectiveness of treatment on pain

Wilcoxon signed rank test	Z	p
BT-WT1	2.121	.034
BT-WT2	2.233	.026
BT-WT3	2.144	.032
BT-AF	1.408	.159

Statistically significant results were found in the intensity of pain during the treatment period as per Wilcoxon signed rank test. Before treatment-within treatment in the 1st, 2nd and 3rd months results were found to be significant ($p<0.05$). Before treatment-after follow up ($p>0.05$) comparison was not significant.

Table 10: Effectiveness of treatment on dizziness

Wilcoxon signed rank test	Z	p
BT-WT1	2.236	.025
BT-WT2	2.828	.005
BT-WT3	3.317	.001
BT-AF	3.317	.001

Statistically significant results were found in the intensity of dizziness throughout the study period as per Wilcoxon signed rank test. Before treatment-within treatment in the 1st, 2nd and 3rd months results were found to be significant ($p<0.05$). Before treatment-after follow up comparison was also significant.

Table 11: Effectiveness of treatment on fatigue

Wilcoxon signed rank test	Z	p
BT-WT1	1.414	.157
BT-WT2	3	.003
BT-WT3	3.742	<0.001
BT-AF	2.646	.008

Statistically significant results were found in the intensity of fatigue during the study period as per Wilcoxon signed rank test. Before treatment- within treatment in the 2nd month result was found to be significant ($p<0.05$). Before treatment- within treatment in the 3rd month result was found to be highly significant ($p<0.001$). Before treatment- after follow up comparison was also significant ($p<0.05$).

Table 12: Effectiveness of treatment on anorexia

Wilcoxon signed rank test	Z	p
BT-WT1	1.414	.157
BT-WT2	1.897	.058
BT-WT3	3.317	.001
BT-AF	2.111	.035

Statistically significant results were found in the intensity of anorexia during the study period as per Wilcoxon signed rank test. Before treatment-within treatment results in the 2nd and 3rd months were found to be significant ($p<0.05$). Before treatment- after follow up comparison was also significant ($p<0.05$).

An attempt to identify the type of *Asrigdara* was made on the basis of the perception by the patient about the colour and characteristics of menstrual blood. From these, it was found that 50% of the cases suffered from *Pittaja asrgdara*. This shows a relationship of *Prakrithi* to the *Dosha* predominance

of the disease. The drug showed results in all types of *Asrigdara*, especially in *Pittaja* type.

DISCUSSION

Abnormal uterine bleeding (AUB) has negative impacts on women's health and well-being inducing anaemia, impacting their quality of life by impairing sexuality, and leads to absenteeism and social embarrassment. Dysfunctional uterine bleeding (DUB) is the diagnosis given for the presentation of abnormal uterine bleeding with no clinically identifiable etiology. The incidence is high among both reproductive and perimenopausal age groups. *Asrigdara* is the most appropriate correlation of DUB, and is characterised by *Artava atipravritti* (excessive, prolonged and even intermenstrual bleeding). All types of irregular and abnormal uterine bleeding can be included in *Asrigdara*. The treatment principles of *Asrigdara* can be employed in the management of DUB.

Sphatika has *Kashaya rasa* mainly which has the property of *Sthambhana* (astringent/styptic action). It is also *Grahi*, and *Rudhirasrava rodhini*. Thus it can constrict the capillaries of uterine vasculature and cause haemostatic action. *Lodhra* is included in *Sonithasthapana gana*, *Sandhaniya gana*, and *Kashaya skandha*. It has *Laghu guna*, *Seetha veerya* and *Kashaya rasa*. Thus it is an effective haemostatic drug. It is also *Garbhasaya sothahara*, *Sankochaka* and *Rakthasoshaka*. Thus it can cause constriction of capillaries of the endometrium to control bleeding. *Rasa sindoora* acts as *Yogavahi dravya*. The catalyst action of *Rasa sindoora* enhances the properties of other drugs along with it so that their efficacy is ensured and augmented. It is *Sarvarogahara* by its *Prabhava*. It is also a potent *Rasayana* that helps in tissue repair and clearing any damage to any part of the body system. On the basis of the innumerable *Gunas*, in curing DUB, *Rasa Sindoora* can evidently augment the haemostatic properties of *Sphatika* and *Lodhra*. When the amount and duration of blood loss is controlled, the haemoglobin percentage will be normalised accordingly. Also, the associated symptoms related to blood loss can be controlled. Thus the selected combination of drugs was effective in reducing the symptoms of DUB.

CONCLUSION

Sphatikayuktha Rasa Sindoora with *Lodhra Kashaya* is effective in DUB by reducing the amount and duration of bleeding. The drug showed significant results in reducing the number of clots and increasing the haemoglobin level. PBAC scoring system was efficient in assessing the amount of blood loss. Results show that *Sphatikayuktha Rasa Sindoora* with *Lodhra Kashaya* is a safe and cost-effective remedy in Dysfunctional Uterine Bleeding by reducing the amount and duration of bleeding.

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