



Research Article

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EFFECT OF COMBINATION OF FRUIT OF BADARA [*Ziziphus jujuba* (L). Lam] AND PALM JAGGERY IN DYSFUNCTIONAL UTERINE BLEEDING

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ABSTRACT

Dysfunctional uterine bleeding (DUB) is a state of abnormal uterine bleeding. It is a diagnosis of excluding any clinically detectable organic, systemic and iatrogenic cause. Current treatments available have many side effects, including hormonal imbalance. So there exists a lacuna for a safe and effective treatment without side effects for this condition. The present study is an effort to evaluate the combined effect of fruit of Badara [*Ziziphus jujuba*(L). Lam] with Palm jaggery in Dysfunctional uterine bleeding. The study design is interventional with a sample size of 15 subjects within the age group of 16-50 years. The study drug was administered in 6gm in the morning and the evening before food for 90 days. The following 30 days was follow up period without medication. The effect was assessed on subjective and objective parameters before treatment and on the 31st, 61st, 91st and 121st days. The results were statistically analyzed using Paired t-test and Wilcoxon Signed Rank test. The study drug showed the statistically significant result in DUB as reducing the amount and duration of bleeding, an interval of menstruation, number of clots, pain, fatigue, and increasing the Haemoglobin percentage.

Keywords: Abnormal uterine bleeding, Asrigdara, Raktha pradara, Yonivyapath, Guda

INTRODUCTION

Abnormal uterine bleeding (AUB) is a frequent condition met in gynaecological practice. It includes irregularities in the menstrual cycle: frequency, regularity, duration, and volume of menstrual flow. Dysfunctional uterine bleeding (DUB) is the major cause of abnormal menstrual bleeding. It impacts women's health both medically and socially, causing problems such as iron deficiency anaemia and social phobia, for instance. DUB is mainly caused by altered hypothalamic-pituitary-ovarian function and local changes in prostaglandin production. It is thus prevalent in the extremes of the reproductive period, adolescence and pre-menopause or following childbirth and abortion.¹ DUB is reported in 9 % to 14% of women between menarche and menopause. The prevalence varies in each country. In India, the informed majority of DUB is around 17.9%.²

Ayurveda considers Gynaecological disorders comprehensively as "Yonivyapath". One of the conditions in Yonivyapath is Asrigdara, characterized by excessive vaginal bleeding. Based on different signs and symptoms, DUB can be compared to Asrigdara.³ As blood (Rakta) is vital (Jeeva), correction of Asrigdara is significant. The main aim of the treatment is to reduce the menstrual flow, thus reducing morbidity and improving quality of life. Current medications for the management of DUB are likely to produce unwanted side effects, including hormonal imbalance.⁴ Women thus require a safe and effective treatment, without side effects for their menstrual problems. In Ayurveda, various formulations and single drug

remedies are mentioned to manage Asrigdara. The study drug, a combination of the fruit of Badara [*Ziziphus jujuba* (L). Lam] with Palm jaggery (Guda) is mentioned in the 61st chapter of Chakradattam⁵ as a remedy for this condition. It is also said in Vrindamadhava Pradara adhikara⁶ with the same indication. The present study is an effort to evaluate the effect of this combination of the fruit of Badara [*Ziziphus jujuba* (L). Lam] with Palm jaggery (Guda) in Dysfunctional uterine bleeding.

MATERIALS AND METHODS

Preparation of the study drug

Sample Collection: The dried fruit of Badara, [*Ziziphus jujuba* (L). Lam] purchased from the local market was authenticated by a botanist. The accession number given is PHU-H/1400. Its genuineness was assured by preliminary pharmacognostical screening, as well as macroscopical and microscopical evaluation and preliminary physical and phytochemical analysis.

Palm jaggery was collected from a small scale jaggery manufacturing unit at Kuzhithurai near Nagercoil. Its quality standards tested in Drug Standardization Unit, Govt. Ayurveda College, Thiruvananthapuram and were found at par with the Agmark standards.

Method of preparation: The dried fruit of Badara was cleaned thoroughly and pulverized to a fine powder with mesh size 85. Palm jaggery was also made into powder form. The study drug

was packed in airtight zip packets, each containing mixture of 3 gm of Badara fruit powder and 3 gm of Palm jaggery powder to serve as a single dose.

Procedure: Fifteen subjects from OPD of Government Ayurveda College Hospital, Thiruvananthapuram, satisfying the inclusion and exclusion criteria, were selected. Detailed clinical examination and required clinical and laboratory investigations were done before treatment in all subjects. Informed consent was obtained from the subjects. The study was conducted in a single group. The study drug was dispensed with advice to take each packet twice daily before food for 90 days. No medicine was given for the next 30 days of follow up period.

A tabulated chart was given to each subject, and they were asked to evaluate the degree of saturation for each sanitary pad used during each menstrual cycle. The recipient's condition was assessed based on subjective and objective parameters before treatment and on 31st, 61st, 91st and 121st days.

CLINICAL STUDY

Study design: Interventional quasi-experimental study without a control group

Study setting: OPD of Government Ayurveda College Hospital, Thiruvananthapuram.

Sample size: 15

Inclusion criteria: Female patients between 16-50 years, with excessive menstrual bleeding assessed as per PBAC criteria, Prolonged menstrual bleeding (more than seven days), Frequent cycles of less than 21 days apart, Passing of large clots, Hb greater than 8 gm%.

Exclusion criteria: Subjects with organic pathology of the uterus such as ovarian cyst, pelvic inflammatory disease, myomas, endometrial polyp, endometriosis etc., any other causes likely to influence menstrual cycle like pregnancy, abortion, women using IUCD/OCP, subjects with known causes of chronic systemic diseases.

Treatment of subjects

- Dose ⁷: 12 gm of study drug in two equally divided doses.
- Route of administration: oral
- Time of administration: Twice daily before food. (Morning and evening)

Period of study: Total study period - 120 days (including 90 days of intervention and 30 days follow up).

Assessment Criteria

Subjective criteria: Bleeding amount - As per PBAC score, Duration of bleeding, Interval of menstruation, pain in the abdomen/back, Fatigue

PBAC criteria: Based on the scoring criteria depicted below as per the PBAC chart. (Pictorial Blood Loss Assessment Chart.⁸ The scoring is done according to the soaking pattern of sanitary pads.

Table 1: Amount of Bleeding as per PBAC criteria

Criteria	Soaking of sanitary pads	Score
Amount of blood loss per cycle	Lightly stained pad	1
	Moderately stained pad	5
	Completely soaked pad	20
Size of clot	Small	1
	Large	5

Total scores greater than 100/cycle indicates excessive bleeding. Clots were also separately assessed according to the number.

Other Subjective symptoms

Table 2: Other Subjective symptoms

Criteria		Grade
Duration of bleeding	3-5 days	0
	6-7 days	1
	8-9 days	2
	>10 days	3
Interval of Menstruation	25-30 days	0
	20-24 days	1
	15-19 days	2
	<15 days	3
Pain (Pain in abdomen/back)	No pain	0
	Mild pain	1
	Moderate pain	2
	Severe pain	3
Fatigue as assessed by Questionnaire ⁹	Score -10	0
	Score 10-20	1
	Score 20-30	2
	Score 30-40	3

Objective criteria: Hb%

Statistical analysis: Pre-test and post-test comparison of variables was assessed by Paired t-test and Wilcoxon Signed Rank test. All the analyses were carried out with the help of SPSS 22.0 for WINDOWS.

Ethical consideration: Informed written consent was obtained from the subjects. The Institutional Ethical Committee obtained ethical clearance as per letter no IEC 397/2.05.2019.

RESULTS

Effectiveness of treatment: Amount of Bleeding, Number of clots and Haemoglobin percentage were analysed using Paired t-Test.

Table 3: Effectiveness of treatment

Criteria	Mean					SD				
	BT	AT-1	AT-2	AT-3	AT-FP	BT	AT-1	AT-2	AT-3	AT-FP
Amount of Bleeding	532.9	143.0	99.0	85.3	111.0	251.9	56.5	27.6	6.7	32.4
Number of clots	27.6	13.4	9.3	4.2	6.9	23	11.2	8.8	4.2	5.4
Hb	10.5	11.2	11.6	11.8	11.4	1	.6	.3	.1	.2

BT: Before Treatment, AT: After Treatment

Table 4: Analysis using Paired t-Test

Paired comparison		Amount of Bleeding	Number of clots	Hb
BT vs 31 st day	t	7.417	4.349	5.303
	p	<0.001	0.001	<0.001
BT vs 61 st day	t	7.236	4.656	5.384
	p	<0.001	<0.001	<.001
BT vs 91 st day	t	7.026	4.743	5.22
	p	<0.001	<0.001	<.001
BT vs 121 st day	t	7.161	4.44	3.365
	p	<0.001	0.001	0.005

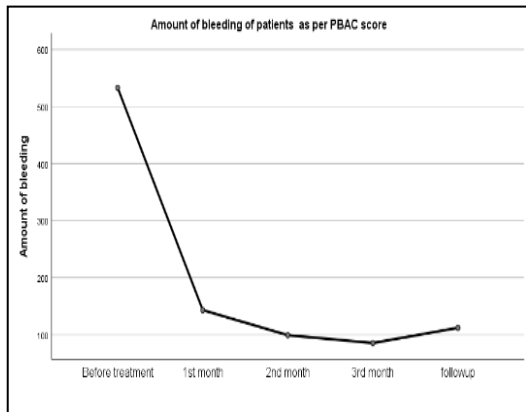
BT: Before Treatment

Other subjective symptoms such as duration of bleeding, menstruation interval, pain and fatigue were analysed using Wilcoxon Signed Rank Test.

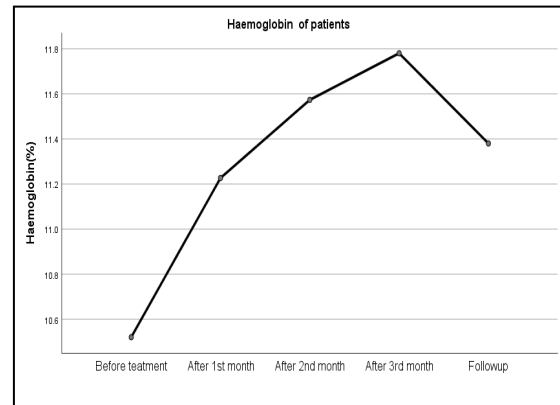
Table 5: Analysis using Wilcoxon Signed Rank Test

Paired comparison		Duration of Bleeding	Interval of menstruation	Pain	Fatigue
BT vs 31 st day	Z	3.207	2	2.859	3.017
	p	.001	0.046	.004	0.003
BT vs 61 st day	Z	3.345	2.07	2.873	3.275
	p	.001	0.038	.004	0.001
BT vs 91 st day	Z	3.36	2.07	2.877	3.499
	p	.001	0.038	.004	<0.001
BTvs121 st day	Z	3.345	1.857	2.807	3.153
	p	.001	0.063	.005	0.002

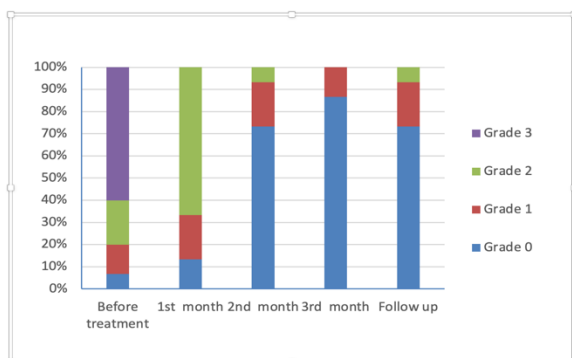
BT: Before Treatment



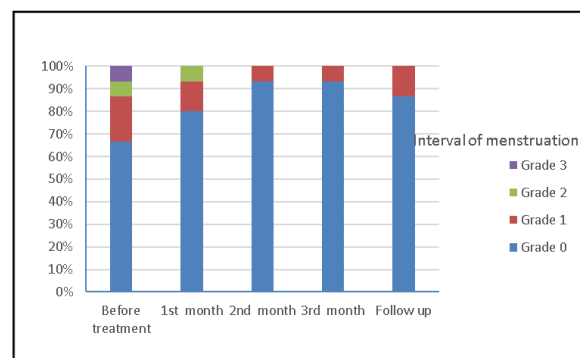
Graph 1: Amount of Bleeding



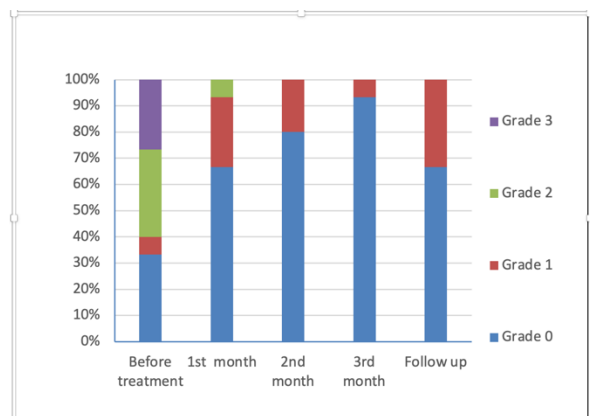
Graph 2: Haemoglobin %



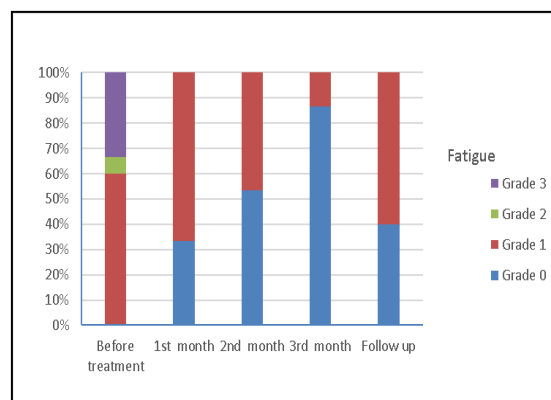
Graph 3: Duration of bleeding



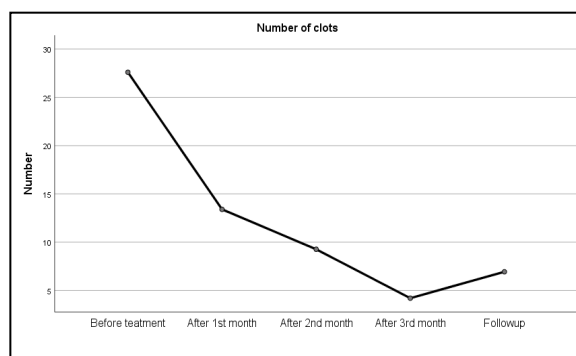
Graph 4: Interval of menstruation



Graph 5: Pain



Graph 6: Fatigue



Graph 7: Number of clots

DISCUSSION

The present study attempts to clinically evaluate the effect of a combination of the fruit of Badara [*Ziziphus jujuba* (L). Lam] with Guda (Palm jaggery) in Dysfunctional uterine bleeding. The data on symptoms of DUB before the intervention and after 1st, 2nd and 3rd months of intervention and after the follow up was statistically analysed using Paired t-test and Wilcoxon Signed Rank test. The results were found to be statistically significant.

The study drug was found effective in reducing the significant DUB symptoms. The amount and duration of bleeding decreased significantly after the treatment period of 90 days, and it was sustained after the follow-up period ($p < .001$). The drug was found effective in normalizing the interval of menstruation. The p-value after 1st month was $p .0046$, 2nd and 3rd months $-p.038$. There was also a gradual reduction of clots in the 1st, 2nd and 3rd months and after follow up ($p < .001$). There was a significant reduction in pain intensity after treatment ($p .004$), sustained after follow up ($p .005$). The decline in fatigue after treatment and after follow up was also significant (1st month- $p .003$, 2nd month- $p.001$, 3rd month- $p < .001$, Follow up- $p.002$). Haemoglobin % also showed significant changes after treatment ($p-.001$), which continued during follow-up ($p.005$).

Thus, the combination of fruit of Badara [*Ziziphus jujuba* (L). Lam] with Palm jaggery is proved effective in Dysfunctional uterine bleeding.

CONCLUSION

The combination of fruit of Badara [*Ziziphus jujuba* (L). Lam] with Palm jaggery is found effective in reducing the cardinal symptoms of Dysfunctional uterine bleeding as amount and

duration of bleeding, an interval of menstruation and number of clots in the menstrual blood. The study drug also significantly reduced the associated complaints such as pain and fatigue and increased the Haemoglobin percentage. Thus, the study drug was an effective remedy for Dysfunctional uterine bleeding.

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