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EFFECT OF *BOLA PARPATI* IN *ASRGDARA*

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ABSTRACT

Asrgdara is a type of abnormal uterine bleeding, where the disease is characterized by heavy, prolonged and frequent bleeding. It also includes intermenstrual bleeding associated with body pain and general weakness. In short *asrgdara* refers to all types of abnormal uterine bleeding. The contemporary treatment of AUB consists of medical therapy like antifibrinolytic haemostatic agents and NSAIDS which has many side effects on prolonged use. Surgical interventions like hysteroscopic ablative technique and hysterectomy has limitations in reproductive age group also. Keeping this in view the herbomineral compound *Bola parpati* from *yogaratnākara pradara cikitsa is* selected to conduct the study on most prevalent menstrual disorder in present times called *asrgdara* (Abnormal Uterine bleeding*).* An open label clinical study with pre and post test design was conducted in 30 patients. *Bola parpati* in the form of capsule were provided (375mg). Patients were instructed to take the medicine along with *madhu* twice daily for a period of 3 months. Variables were analyzed using Wilcoxon Signed Rank Test and Chi square test. Administration of *Bola parpati* showed significant improvement in the symptoms like duration of menstrual bleeding, amount of menstrual bleeding, clots passed per day and haemoglobin level. It had no statistical significance in regularizing the cycle. Endometrial thickness which was one of the objective criteria didn't show any remarkable difference even after the administration of the drug.

Keywords: *asrigdara, bola parpati.*

INTRODUCTION: *Asrgdara* refers to all types of abnormal uterine bleeding. Abnormal uterine bleeding (AUB) (a term which refers to menstrual bleeding of abnormal quantity, duration, or schedule) is a common gynecologic complaint, accounting for one-third of outpatient visits to gynecologists. Among women aged 30-49, one in 20 consults their practitioner each year with this problem[1]. AUB is reported to occur in 9 to 14% women between menarche and menopause[2]. In India, it is reported that the prevalence of AUB is around 17.9%[2]

There is an elaborate description of *asrgdara* both in *laghu trayīs* and *brhat trayīs. Acārya Caraka* explained *asrgdara* as a separate disease in *yonivyāpat cikitsādhyāya.* He had also explained as one of *raktapradosaja vikāra* and also

under *pittāvrita apāna vāyu*[3]. *Acārya Susruta* explained it as a separate disease entity and mentioned it under *pittāvrita apāna vāyu* and in *raktapradosaja vikāra*[4]. *Astānga Samgraha* explained *raktayoni* and said *asrgdara* and *pradara* as its synonyms[5]. It was explained by *ācarya Susruta* as a *ghoravyādhi.* This condition is distressing & potentially disabling. It also causes psychological upsets like lack of concentration, discomfort in work place, uneasiness etc. There is sharp increase in the incidence of AUB in modern era hence require solution.

The contemporary treatment of AUB consists of medical therapy like antifibrinolytic haemostatic agents and NSAIDS which has many side effects on prolonged use. Surgical interventions like hysteroscopic ablative technique and hysterectomy has limitations in reproductive age group also. Due to limitation of medical therapy as well as surgical therapy, it becomes necessary to find out a safe and effective ayurvedic management for this condition**.** Even though many ayurvedic researches with herbal formulations were found effective in *asrgdara* there are only a few studies with proper evidence to prove the efficacy of mineral compounds. Keeping this in view the herbomineral compound *Bola parpati* from *yogaratnākara pradara cikitsa* [6] *is* selected to conduct the study on most prevalent menstrual disorder in present times called *asrgdara* (Abnormal Uterine bleeding*)*.

AIM AND OBJECTIVES

To study the effect of *bola parpati* in *asrgdara*.

To assess the symptoms and their association with some socio demographic data.

MATERIALS AND METHODS

Study setting

30 patients were selected as per inclusion criteria from the OPD of Amrita Ayurveda Hospital Vallicavu, Kollam.

Study drug

The study drug was *Bola parpati*, purchased from Uma Ayurvedics, GMP certified company.

Study Duration

Study was done for a period of 18 months.

Study Design

The study was approved by Institutional Ethics Committee. With prior permission and consent from the college, hospital authorities and the patient, an open label clinical study with pre and post test design was conducted in 30 patients. A case proforma was specially designed with details of history taking, signs and symptoms as mentioned in the texts. Patients complaining of abnormal uterine bleeding (excessive, prolonged, frequent, intermenstrual bleeding) of age group 20 - 50 for the past 3 cycles were thoroughly examined for organic, systemic and iatrogenic cause using thorough proper history taking, pelvic examination and relevant investigations. Those patients satisfying above clinical criteria were selected for the study. Every month a detailed enquiry into the menstrual pattern was carried out and drug in the form of capsule were provided (375mg). Patients were instructed to take the medicine along with madhu twice daily for a period of 3 months. The parameters of signs and symptoms and investigations were scored on the basis of standard method and were analyzed statistically after treatment period and after follow up which was 3 months.

Criteria for Inclusion:

- Patients with age group 20 – 50 yrs.
- Patients having classical signs and symptoms of *asrgdara*.

Criteria for Exclusion

- Post menopausal bleeding.
- Bleeding associated with intra-uterine contraceptive devices, oral contraceptive pills and uterine fibroids.
- Systemic illness like hypertension, diabetes mellitus, renal disease, liver disease, inherited bleeding disorders

Investigations: These were carried out before & after treatment and after follow up:- Hemoglobin gm % (Hb %), BT, CT, USG

ASSESSMENT CRITERIA

The subjective and objective parameters were graded for statistical analysis

Subjective parameters

Duration of menstrual bleeding

4-5 days bleeding – 0
6-7 days bleeding-1
8-9 days bleeding-2
10 and above -3

Amount of menstrual bleeding

2-3 pads -0
4-5 pads -1
6-7 pads -2
8 pads and above-3

Number of clots passed per day

0-1 clots-0
2-3clots-1
4-5 clots-2
6 and above-3

Interval of menstruation

The decreased and increased interval were graded
21-35 days-0
36-45 days- 1 11-20-1

Regularity of cycle

Regular -Menstrual cycle with an average interval of 21-35 days for 3 consecutive periods.
Irregular - Menstrual cycle without the above said interval for 3 consecutive periods.

Objective parameters

Hb g%
≥12g%-0
11-10g%-1
9-8g%-2
<8g%-3

Endometrial thickness

5-12mm-0
> 12mm-1

Statistical analysis: The statistical analyses were performed using IBM SPSS software, Version 20. Normality test was performed using Shapiro wilk test**.** Variables were analyzed using Wilcoxon Signed Rank Test and Chi square test with 95% confidence interval .p values ($p<0.05$) were considered statistically significant.

OBSERVATIONS AND RESULTS

A total of 30 patients were enrolled in the study. Out of these, 5 patients didn't complete the study as they were lost to follow up. The remaining 25 patients were evaluated before and after study and during follow up. There was highly significant reduction in the duration ($p<0.001$), amount ($p<0.001$), and number of clots ($p<0.001$)) after treatment and follow up .Regarding interval of menstruation and regularity of cycle, significant results ($p<0.001$) was found after treatment .But it was not statistically significant after follow up period ($p>0.05$). In the study, haemoglobin value showed significant improvement ($p<0.01$).There was no statistically significant difference in the endometrial thickness with p value >0.05.

Table 1: Effect of study drug in the duration of menstrual bleeding

	N	Mean	Std. Deviation	Min	Max	Z	P

BT	25	1.84	.898	0	3	4.25	<0.01
AT	25	.44	.821	0	2		
BT	25	1.84	.898	0	3	4.32	<0.01
FU	25	.20	.408	0	1		

.Table 2: Effect of study drug in the amount of menstrual bleeding

	N	**Mean**	**Std. Deviation**	**Min**	**Max**	**Z**	**P**
BT	25	1.28	.678	0	3	4.56	<0.001
AT	25	.12	.332	0	1		
BT	25	1.28	.678	0	3	4.61	<0.001
FU	25	.16	.374	0	1		

Table 3: Effect of study drug in the interval of menstrual bleeding

	N	**Mean**	**Std. Deviation**	**Min**	**Max**	**Z**	**P**
BT	25	.60	.500	0	1	3.742	<0.001
AT	25	.04	.200	0	1		
BT	25	.60	.500	0	1	1.9	>0.05
FU	25	.40	.500	0	1		

Table 4: Effect of study drug in the regularity of menstrual bleeding

	N	**Mean**	**Std. Deviation**	**Min**	**Max**	**Z**	**P**
BT	25	.60	.500	0	1	3.606	<0.001
AT	25	.08	.277	0	1		
BT	25	.60	.500	0	1	.816	<0.05
FU	25	.52	.510	0	1		

Table 5: Effect of study drug on number of clots

	N	**Mean**	**Std. Deviation**	**Minimum**	**Maximum**	**Z**	**P**
BT	25	1.28	.891	0	3	3.85	<0.001
AT	25	.28	.458	0	1		
BT	25	1.28	0.891	0	3	4.03	<0.001
FU	25	0.08	0.277	0	1		

Table 6: Effect of study drug on hemoglobin

	N	**Mean**	**Std. Deviation**	**Minimum**	**Maximum**	**Z**	**P**
BT	25	1.04	1.020	0	3	3.35	<0.01
AT	25	.40	.645	0	2		
BT	25	1.04	1.020	0	3	2.42	<0.05
FU	25	.48	.510	0	1		

Table 7: Effect of study drug on endometrial thickness

	N	Mean	Std. Deviation	Min	Max	Z	P
BT	25	.08	.277	0	1	1.00	>0.05
AT	25	.04	.200	0	1		
BT	25	.08	.277	0	1	1.414	>0.05
FU	25	.00	.000	0	0		

Table 8: Statistical data showing the relationship between asrgdara and sociodemographic variables

Demographic variables	p-value
Age	**0.476**
Domicile	**0.146**
Religion	**0.446**
Educational qualification	**0.363**
Occupation	**0.363**
Socio-economic status	**0.930**
Marital status	**0.103**

The relationship between asrgdara and demographic variables were not statistically significant at p>0.05

DISCUSSION: On the individual assessment of cases it was found that 24% patients had bleeding for more than 10 days,44% had 8-9 days bleeding, 24% with 6-7 days bleeding and 8% with 4-5 days bleeding .This indicates that a woman approaches a physician only when the condition becomes unbearable. And it was said that heavy menstrual blood loss had significant impact on woman's quality of life. So intervention should be mainly focusing on this. [7]In this study the duration got reduced in each cycle .After the treatment period 76% attained normal duration with 4-5days bleeding, statistically significant at p<0.001 and after the follow up period 80% patients had attain 4-5 days bleeding with p value <0.001.

In the *samprāpti* of *asrgdara rakta pramāna utkrāmana* is explained ie, the *ārtava* increases in its amount. Here in this study we assessed the amount of bleeding by counting the number of pads used per day and it was found that 8% of study population had been using more than 8 pads per day, 16% were using 6-7 pads per day,72% with 4-5 pads per day and 4% with 2-3 pads per day. After treatment period 88% came to normal amount ,ie 2-3 pads per day and 12% were using 4-5 pads per day ,statistically significant at p<0.001. After follow up period also the results were statistically significant at p<0.001.

On assessing the number of clots passed per day during menstruation, 16% had no clots, 52 % presents with 2-3 clots per day, 20% with 4-5 clots and 12% with above 6 clots. This indicates the normal tendency to approach a physician only when the disease becomes severely disturbing to the patient. Passage of more clots indicates increased bleeding .After treatment 72 % of the patients presented with no clots with highly significant statistical results (p<0.001) and after

follow up 92% got complete cure ($p<0.001$).

The study drug had effect in both short and prolonged cycles. But it was found only after study period and not in the follow up period. In the study group 36% had short cycles, 24% had prolonged cycles and remaining had regular interval cycles. The interval of 21-35 were considered normal. After treatment period interval became normal with statistically significant results. But after follow up period, there were no statistically significant results in the interval of cycles with $p>0.05$.

The average score of regularity of menstrual bleeding changed from 0.6 ± 0.5 to 0.04 ± 0.2 after treatment, statistically significant at $p<0.001$ and to 0.4 ± 0.5 after follow up ,which was not statistically significant with $p >0.05$.Before treatment 60% of the study population had irregular cycles .After treatment period which was 3 months,71% of the cases become regular. But after follow up period which was the next 3 months 52% again become irregular cycles and the results were not statistically significant with p value >0.05.

The average score of haemoglobin changed from 1.04 ± 1.02 to 0.4 ± 0.64 after treatment, statistically significant at $p< 0.01$, and to 0.48 ± 0.51 after follow up, which was statistically significant at $p<0.05$. The high statistical significance obtained during the treatment period might be due to the effect of drug in controlling the excessive bleeding by acting directly on the haemostatic mechanism at the endometrium

Management of AUB based on endometrial thickness is an effective approach to control acute uterine bleeding. In our study endometrial thickness didn't show any remarkable difference even after the administration of the drug and one of the main findings of this study is that endometrial thickness of most of the patients was within the normal range. Even though the most common endometrial pathology seen in abnormal uterine bleeding was endometrial hyperplasia, in a study conducted in Chennai the most common age group presented was 41–50 years (33.5%) and the commonest pattern in these patients was normal cycling endometrium (28.4%)[8] The incidence of endometrial hyperplasia in this study was less as compared to others. In another study conducted in rural Bihar there was no definite relationship found between endometrial patterns & bleeding pattern.

The study drug *Bola Parpati* is composed of *rasa, gandhaka* and *bola. Bola* is *rakta dosanut*. *Ācarya Caraka* explains *asrgdara* as one among the *raktapradosaja vikāra*. So *bola* might directly act at the *dhātu* level itself and lead to proper formation of *ārtava*. *Bola* is specially indicated in *pradara*. It can stimulate the uterus for mucus secretions and facilitates drainage. It is *garbhāśaya śodhaka* in nature. Bola having *tikta rasa* as its prominent *rasa* can produce *dosa pācana, agni dīpana and rakta samgrahana*. By its *kasāya rasa* it can produce *rakta stambhana* action. It contains compounds like β sitosterol, campestrol etc which are anti-inflammatory in nature. Due to its anti-inflammatory nature it might act at the level of prostaglandins. Research works have proven the cytotoxicity activity of extracts and compound of *bola* against human gynaecologic cancer cells[9].*Gandhaka* is *dīpana*, *pācana, rasāyana* and *yogavāhi* . Due to its *yogavāhi* nature it helps to carry the *vīrya* of *Bola.* Sulphur helps in wound healing via keratin. By this action it might help in

tissue repair by which menstrual bleeding gets arrested.

Pārada is tridosahara ,rasāyana and *yogavāhi.* As both *pārada* and *gandhaka* are *rasāyana* in nature it may act at the level of *dhātu parināma* and helps in the formation of *rakta dhātu*. The study drug is in *parpati* form. *Parpati* itself is *dosa pācana* in nature. As *parpati* is found as flakes, it may have specific action at uterus which is a muscle layered organ.

The *rasa bhāva* told in the *samprāpti* of *asrgdara* can again be considered as the factors for vasoconstriction and tissue repair which is needed for arrest of menstrual bleeding. Prostaglandins which are the vasoconstrictors are products of arachidonic acid metabolism through the cyclo-oxygenase path way. The endometrium and to some extent myometrium synthesize prostaglandins from arachidonic acid. The drugs might regulate this metabolism by correcting this path way and thus helps in the *samprāpti vighatana*.

Madhu is *agnidīpana, lekhana, tridosahara.*and *vrana ropaka.* Due to its particular *vrana ropaka* action it can act at the level of endometrial vasculature and can attain haemostasis. *Madhu* is used as *anupāna* here, hence acts as catalyst for *bola parpati* and enhances the action of it. The enzyme glucose oxidase present in honey produces hydrogen peroxide (which provides antimicrobial properties) along with gluconic acid from glucose, which helps in calcium absorption. It was proved that calcium is essential for arrest of menstrual bleeding

CONCLUSION: Administration of *Bola parpati* showed significant improvement in the symptoms like duration of menstrual bleeding, amount of menstrual bleeding, clots passed per day and hemoglobin level. It had no statistical significance in regularizing the cycle. Endometrial thickness which was one of the objective criteria didn't show any remarkable difference even after the administration of the drug. This may be due to the reason that most of the patients were within the normal endometrial range. Thus it can be concluded that the study drug is effective in controlling the excessive bleeding during menstruation which may become a life threatening factor if not properly managed. But it was not effective in regularity and interval of cycle. Further studies can be suggested in *asrgdara* patients with regular cycles, where the effect of treatment in endometrial thickness can be assessed

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