

EFFECT OF *SIDDHA GHRITA* FORMULATION ON HORMONAL PROFILE AND ENDOMETRIAL THICKNESS IN *VATAJA-ARTVA-DUSHTI* (HYPOMENORRHOEA OR OLIGOMENORRHOEA)

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ABSTRACT

Introduction: According to *Ayurveda*, normal menstruation is the indicator of healthy and normal reproductive organs. Food and lifestyle habits have the strong relationship with the normal functioning of the menstrual cycle. **Objective:** The study objective was to investigate the effect of *Siddha ghrita* formulation on Endometrial thickness in *Vataja-artava-dushti*. **Methods:** Patients complaining of scanty bleeding and pain during menses with regular cycle were included in the study. Endometrial thickness was measured at 21st day of last menstrual period at initial and at 4th follow up using abdominal ultrasonography. Data analysis was done through SPSS software version 16. **Results:** Mean of increase in endometrial thickness in group A was 9.23 ± 1.25 to 10.23 ± 1.01 . Increase in endometrial thickness, amount, and duration of blood loss, absence of pain during menstruation in group A is better than group B. **Conclusions:** *Vata* aggravating factors or food and lifestyle-related faulty habits have strong relation with menstrual disorders (*Vataja-artava-dushti*). *Vatashamak*, *Triodsh* balancing and *Dhtupushtikar* properties of *siddha ghrita* gives better results in *vataja-artava-dushti*.

Keywords: *Vataja-artava-dushti*, Endometrial thickness, *Siddha ghrita*

INTRODUCTION

Ayurveda since long years back proposed the concept of the ill effect of mal food habits and

lifestyle on human health. *Acharya's* of *Ayurveda* has given it great importance in the patho-

genesis of almost every disease. Menstrual disorders are not exceptions to it. In *Ayurveda* classics menstrual disorders have been given in detail under *Yoni vypada*, *Asht-artava-dushti*, *Asrigdar* and *Jaatharinies*. *Acharya Charak* has mentioned the characters neither of normal menstrual blood and its amount as it should neither be less nor to be excess. It should not be associated with burning and pain 1. Further *AcharayaBhavPrakash* has explained that the slight difference in the character of menstruation could occurs due to *doshik* predominance 2. *Vataja-artava-dushti* based on its prime symptoms of scanty menstrual bleeding can be correlated with oligomenorrhoea or hypomenorrhoea 3. Infrequent scanty menstrual bleeding occurring at the interval more than 35 days oligomenorrhoea and regular scanty menstrual bleeding lost for less than 2 days Hypomenorrhoea. Causes of hypomenorrhoea and oligomenorrhoea are uterine synechiae, or endometrial tuberculosis, oral contraceptive pills, thyroid dysfunction, premenopausal period and mal nutrition4. Menstruation is often irregular among women of early and late reproductive ages, but its variability among women of mid-reproductive age remains unclear5,6. During the follicular phase, endometrial cells proliferate under the influence of estrogen, but following ovulation, progesterone secretion stimulates additional morphologic changes in the endometrium7. After the anovulatory cycle, menstruation is most often a result of progesterone withdrawal, which induces a series of events involving vasoconstriction, cytokine changes in the endometrium, and programmed cell death8. The highest incidence of anovulatory cycles is under age twenty and over age of forty 9. The average volume of blood loss is 30 ml in a normal healthy reproductive women10. Greater than 80

mL is abnormal. Most of the blood loss occurs during the first 3 days of a period11.

Material and methods –

Ethical permission- Proper Ethical permission was obtained from the Institutional ethical committee, Institute of medical sciences Banaras Hindu University.

Selection of patients -Enrolled in the study were 100 patients visited in O.P.Ds PrasutiTantra S.S. Hospital, B.H.U. Varanasi. Patients complaining of scanty bleeding and pain during menses with regular cycle were included in the study.

Criteria for selection of drugs- Authentic classical reference of disease condition and its treatment. *Siddhaghrita* formulation composed of *Bharangi* (Clerodendrum serratum), *Bhadradaru* (Cedrus deodar) are *Vata – Kaphashamak* and *Madhuk* (Glycyrrhizaglabra) *vata – pitta shamak*. *Ghrita* is *rasayana*, *medhya*, *agnivardhak* and *dhatupushtikar* acts synergistically to pacify the principle *doshavata* as well as balance the rest *doshas* by its *tridosha* balancing properties12.

Preparation and standardization of drug- Drug preparation was done by standard methods given in Ayurvedic Formulary of India, Part 2. Standardization of drug was done in Captain Srinivasamurti Research Institute for *Ayurveda* and *Siddha* Drug Development, Chennai13, 14.

Inclusion criteria- Patients suffering from *Vataja-artava-dushti* (scanty menstrual bleeding and pain) since more than 3 cycles between the age group 20-36 years.

Exclusion criteria- Patients with Hb < 9gm/dl, Thyroid disorders, any chronic general illness. Patients suffering from any organic pathology like Fibroids, Congenital anomaly, Polyp, PCOD, Myoma, Adenomyosis and who were

taking medications that could affect endometrial thickness were excluded.

Methods of Assessment amount of menstrual blood loss- was assessed on the basis of statements given by the patient. All the patients were advised to use a Stay Free secure pads (Johnson & Johnson) having average pad weight 12.5 gm. Patients were asked to change the pad when it gets fully soaked and to note the count of the pad used per day during menstruation. Soakage of 1 to 1½ pad per day (Normal), Soakage of 1 pad per day(Average), Soakage of 1/2 of pad per day (Scanty), Soakage of 1/3 of pad per day (Very scanty), Presence 2 to 3 spots per day (Spotting).

Methods of Assessment duration of menstrual blood loss-Duration of bleeding was categorized according to bleeding occurring in the total number of days. 4 days (Normal), 3 days (Average), 2 days (Short), 1day (Very short).

Methods of Assessment of pain intensity during menstruation-Pain is a subjective feeling hence, pain intensity was assessed on the basis of the statement given by the patients about difficulties in her routine daily work and need of

analgesic drugs. Does routine work without medication feels discomfort (mild pain), Mild analgesic required, able to do work after medication (moderate pain), Unable to do routine work, even after medication (severe pain) no pain (absent).

Grouping of cases- Total100 selected patients randomly divided in to two groups, Group A (50 patients) Group B(50 patients).Group A was treated with *Siddha ghrita* in a dose of 6 gm BD with milk after the meal for 3 months starting from 1st day of menses for three cycles. Group B was treated with *Rajah pravartinivati* 250 mg BD with warm water after the meal from the 1st day of menses for three cycles 24.

Follow-ups - Total 4 follow-ups were done at the regular interval of one month after clearance of menses, three follow-ups with medication and fourth follow up without medication.

Investigations- sr. FSH, sr. LH, and sr. PRL were assessed before treatment and at 4th follow-ups on 2nd or 3rd day of menses. Endometrial thickness was measured by abdominal ultrasonography on the 21st day of menses.

Tables -

Table 1: Showing incidence of age, married life, gravidity, parity in total cases and both the groups

Variables	Total (N=100)	Group A (N=50)	Group B (N=50)	unpaired t test
	Mean± S.D.	Mean± S.D.	Mean± S.D.	
Age	24.65±4.06	24.56±4.26	24.74±3.90	p=0.111
Married life	3.57±2.43	3.38±2.46	3.76±2.40	p=0.144
Gravidity	2.44±2.00	2.40± 1.95	2.46±2.09	p= 0.138
Parity	1.74±1.39	1.76±1.36	1.72±1.42	p=0.136

Table 2: Showing incidence of personal history in total cases and both the groups.

Diet habits	Total (n=100)		Group A (n=50)		Group B (n=50)		χ ² test
	No.	%	No.	%	No.	%	
Irregular and Spicy food	53	53	28	56	25	50	p=0.746
Irregular and non spicy food	12	12	7	14	5	10	
Regular and spicy food	26	26	11	22	15	30	

Regular and non spicy food	9	9	4	8	5	10	
Appetite							
Poor	78	78	40	80	38	76	
Good	22	22	10	20	12	24	p=0.700
Bowel habits							
Regular	13	13	6	12	7	14	p=0.766
Irregular	87	87	44	88	43	86	
Hygienic condition							
Good	39	39	18	36	21	42	p=0.174
Poor	61	61	32	64	29	58	

Table 3: Follow up study amount of blood loss

Groups	Grade	Amount of blood loss (Number and (%) of cases)				
		Initial No.(%)	I st follow up No.(%)	II nd follow up No.(%)	III rd follow up No.(%)	IV th follow up No.(%)
Group A	Normal	0	0	0	36(72)	36(72)
	Average	0	0	0	6(12)	6(12)
	Scanty	7(14)	7(14)	7(14)	2(4)	2(4)
	Very scanty	20(40)	20(40)	20(40)	4(8)	4(8)
	Spotting	23(46)	23(46)	23(46)	2(4)	2(4)
Group B	Normal	0	0	0	12(24)	12(24)
	Average	0	0	0	19(38)	19(38)
	Scanty	10 (20)	10 (20)	10 (20)	12(24)	12(24)
	Very scanty	19(38)	19(38)	19(38)	3(6)	3(6)
	Spotting	21(42)	21(42)	21(42)	4(8)	4(8)
Chi square Test		P=0.724	P=0.724	P=0.724	P=0.00	P=0.00

Table 4: Follow up duration of blood loss

Groups	Grade	Duration of blood loss (in days) Number and (%) of cases				
		Initial No.(%)	I st follow up No. (%)	II nd follow up No. (%)	III rd follow up No. (%)	IV th follow up No. (%)
A	Normal	0	0	0	16(32)	16(32)
	Average	0	0	0	19(38)	19(38)
	Short	23(46)	23(46)	23(46)	9(18)	9(18)
	Very Short	27(54)	27(54)	27(54)	6(12)	6(12)
	B	Normal	0	0	0	6(12)
	Average	0	0	0	16(32)	16(32)
	Short	20(40)	20(40)	20(40)	19(38)	19(38)
	Very Short	30(60)	30(60)	30(60)	9(18)	9(18)
Chi square Test		P=0.545	P=0.545	P=0.545	P=0.030	P=0.030

Table 5: Follow up Intensity of pain during menstruation

Groups	Grade	Intensity of pain Number and (%) of cases)				
		Initial No.(%)	I st follow up No.(%)	II nd follow up No.(%)	III rd follow up No.(%)	IV th follow up No.(%)
Group A	Absent	0(0)	0(0)	18(36)	43(86)	43(86)
	Mild pain	10(20)	10(20)	5(10)	0	0
	Moderate Pain	14(28)	14(28)	19(38)	3(6)	3(6)
	Severe	26(52)	26(52)	8(16)	4(8)	4(8)
Group B	Absent	0	0	10(20)	13(26)	13(26)
	Mild pain	12(24)	12(24)	14(28)	28(56)	28(56)
	Moderate Pain	17(34)	17(34)	15(30)	8(16)	8(16)
	Severe	21(42)	21(42)	21(42)	14(28)	14(28)
Chi square Test		P=0.108	P=0.841	p=0.085	P=0.00	P=0.00

Table 6: Follow up study Sr. FSH, sr. LH, sr. PRL and Endometrial thickness

Groups	Sr. FSH (mIU/ml) (Initial)	Sr. FSH (mIU/ml) (4th flw.up)	Sr. LH (mIU/ml) (initial)	Sr. LH (ng/ml) (4th flw. up)	Sr. PRL (ng/ml) (initial)	Sr. PRL (ng/ml) (4thFlw.up)	E.T.(m.m) (initial)	E.T.(m.) (4thflw. up)
Group A	7.41±2.27	7.36±1.53	5.07±1.11	4.85±0.96	11.37±2.07	11.29±1.30	9.23±1.25	10.23±1.01
Group B	7.73±1.77	7.08±0.91	4.96±1.10	4.90±0.76	11.98±1.24	11.68±1.24	9.49±1.22	9.63±1.07
	P=0.088	P=0.078	P=0.085	P=0.081	P=0.077	P=0.064	P=0.076	P=0.00

Results - Mean age of the patients was 24.65±4.06 (p>0.05). mean of Married life 3.57±2.43(p>0.05) mean of gravidity 2.44±2.00 (P>0.05). mean of Parirty1.74±1.39 (p>0.05)(Table 1). 53% had Irregular and spicy food in their diet (p>0.05). Appetite was poor in 78% (p>0.05), irregular bowel habits 87% (p>0.05). The hygienic condition were poor in 61 % (p>0.05) (Table 2).72% patients had the Normal amount of menstrual blood loss in group A and 24% in group B (P<0.05) (Table 3). Duration of blood loss was normal and average in 70% patients in group A and 24% patients in group B(P<0.05) (Table 4). Pain during menstruation was absent in 86% patients in group A and 26% in group B (P<0.05) (Table 5).The changes in the mean of FSH (N<14.4 mIU/ml), mean of LH (N< 11.6 mIU/ml) and mean of PRL(N< 25 ng/ml) were within the limit(Table 6). mean of increase in endometrial thickness in group A

was 9.23±1.25 to10.23±1.01(P<0.05).Increase in endometrial thickness, amount, and duration of blood loss and absence of pain during menstruation in group A was better than group B.

DISCUSSION

Younger patients (24 yrs.) were more sufferer than older ones. The maximum patients had married life 3 years with gravidity and parity more than one. Speroff et al., 1999, have shown in their study that menstrual disorders are more common in younger patients whereas atrophy and organic lesion become more frequent in older individuals¹⁵.Our results show that those factors responsible for aggravating the *vata-dosha* viz. Irregular and spicy food habits, poor appetite, irregular bowel habits and poor hygienic condition were present in maximum cases suffering from *vataja-artava-dushti* (scanty menstrual bleeding).The study result is also

supported by Nanzip. Et al. 2014., Lifestyle disorders, food habits and stress have the serious impact on human health, especially menstrual disorders in females^{16,17}. Increase in amount of blood loss (Table 3) and duration of blood loss (Table 4) can be explained on the basis of *Tridoshashamaka* and *dhatupushtikar* action of *siddha ghrita* that promotes the endometrial thickness (Table 6). As the existing methods of assessment of blood loss during menstruation are not accurate hence we adopted objective and subjective criteria both because definitive diagnosis alone is not accurate ^{18,19}. Average amount of blood loss during menstruation in healthy women is about 30 ml²⁰. Results of our study is supported by the study done by Ghose A et al., 2010 *Shatpushpa* (Anthem sowa) have better results in *artavakshaya* (Oligomenorrhoea)²¹. Pain during menstruation was relieved due to *vatahamak* action of *siddha ghrita*, recent researchers have also proved Analgesic and anti-inflammatory action of *Bharangi* (Clerodendrum Serratum) (Narayan et al., 1999) and Anti-spasmodic activity of *Bhadradaru* (Cedrus deodar) (Kar et al., 1975). Increase in endometrial thickness and changes in sr. FSH, LH and PRL level within the physiological limit can be explained on the basis of *Tridosha balancing* action of *siddha ghrita*. Although our study is showing the significant effect of *siddha ghrita* formulation on endometrial thickness in *vataja-artava-dushti* clinically, but the exact mechanism action is still obscured. This study opens the new horizon for the further research at molecular level to justify the exact mode of action.

CONCLUSION

Our *siddha ghrita* formulation showing significant Improvement than the *Rajah*

pravartainivati over endometrial thickness which is associated with improvement in complaint of *Vataja-artava-dushti*. *Siddha ghrita* formulation can be implicated for the better management of *Vataja-artava-dushti* (scanty menstrual bleeding). This study opens the new way to implicate the *siddha ghrita* formulation in other scanty bleeding related menstrual disorders.

Limitation of study –

- No methods of assessment of blood loss are accurate. Hence, use objective and subjective criteria for assessment of menstrual blood loss during each menstrual cycle.
- Pain is subjective criteria and it is hard to assess the intensity of pain hence subjective explanation about the difficulty in routine work and use of analgesic drugs were taken as the parameter.

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