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Randomized single blind controlled clinical study to evaluate the efficacy of *Ashok ghrita* in the management of *Raktapradara* with special reference to Menorrhagia

Research Article

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Abstract

Raktapradara is most common gynaecological problem found in women. According to *Acharya charaka, Raktapradara* is also known as *Asrugdara*. According to modern, *Raktapradara* can be correlated with Menorrhagia. *Ashok* acts as a uterine tonic and improve the muscular tone of uterine musculature which is important to control bleeding. Most of the drugs in *Ashok ghrita* having *rasayan* property and can improve nourishment of all the *dhatus* and reduce the duration of bleeding. Aim: To study the efficacy of *Ashok ghrita* in the management of *Raktapradara*. Materials and Method: A total 80 patients of the age group 16-45 years presenting with signs and symptoms of *Raktapradara* w.s.r to Menorrhagia were selected randomly from OPD of the department of *Stree rog Prasutitantra*. The 40 patients of trial group were treated with *Ashokghrita* and 40 patients of control group were subjected to *Ashok ksheerpak*. Conclusion: *Ashok Ghrita* was found to be more effective than *Ashok ksheerapak* in the management of *Raktapradara* with special reference to Menorrhagia.

Key Words: *Raktapradara*, Menorrhagia, *Asrugdara, Ashok ghrita*, *Ashok ksheerapaka.*

Introduction

Woman is the centre point of the family and health is an important factor. God has gifted woman with rare & unique phenomenon of giving rise to offspring. To effectively fulfil the above aim, nature has conferred special anatomical and physiological characteristics in the woman which are collectively referred to as *"Streekar Bhava."* One among them is the concept of *'Rajapravrutti.'* As human life is constantly influenced by the rhythmic phenomenon operating in this universe, the female menstrual cycle which involves dramatic monthly hormonal changes affecting a woman's emotional and physical state is the broad extension of the well-known '*Lok- Purush Samya Siddhant.'* (1) Menstruation is a natural physical specific property of a female and so, it called as monthly period. *Artava* or menstrual blood is expelled from the uterus through vagina in biological rhythm of women during her reproductive period i.e., from menarche to menopause. Length of *Rutuchakra* (menstrual cycle) is usually twenty-eight to thirty days. A deviation of two to three days from the monthly rhythm is also quite common. The duration of bleeding is about five days and estimated blood loss is 20 to 60 ml. The menstrual rhythm (length of the cycle) depends upon the hypothalamo - pituitary - ovarian function whereas the amount of blood loss depends upon the uterine condition. *Raktapradar* is most common gynaecological problem found in women. According to *Acharya charak, Raktapradar* is also known as *Asrugdar*. Due to *pradirana* of *raja* it is named as *Pradara* and since there is *dirana* of *asruk* it is known as *Asrugdar* in which excessive and prolonged bleeding occurs during menstruation.(2) Excessive consumption of *Lavana*, *Amla* and *Katu* rasa, *Snigdha*, *Guru*, *Vidahi guna ahar, mansa-kshar, payasa, dadhi, shukta, mastu, sura, madya* – all these factors aggravates *Vata dosha* which affects the *Raktadhatu* (*Rajovaha srotas*- i.e. blood volume is increased in blood vessels) that leads to increased quantity of *raja* (*artava*) and hence increasing menstrual flow causing *Raktapradara*.(3) According to modern *Raktapradara* can be correlated with menorrhagia. The term menorrhagia denotes excessive blood loss (increase in duration of bleeding / heavier blood flow) without any change in cycle.

Aim

To study the efficacy of *Ashok ghrita* in the management of *Raktapradara*.

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Objectives

- To study the review of literature of *Ashok ghrita* and *Ashok ksheerpaka* with its mode of action in *Raktapradara*.
- To study in detail *Raktapradara* and menorrhagia with available *Samhita* & modern literature.
- To compare the effect of *Ashok ghrita* and *Ashok ksheerpaka* in *Raktapradara***.**

Material and methods

A total 80 patients of the age group 16-45 years presenting with signs and symptoms of *Raktapradara* w.s.r to Menorrhagia were selected randomly from OPD of the department of *Stree rog Prasutitantra*. The 40 patients of trial group were treated with *Ashok ghrita* and 40 patients of control group were subjected to *Ashok ksheerpaka.*

Criteria for selection of patients

Diagnostic Criteria

Patients were diagnosed which were having signs and symptoms of *Raktapradar* given in *Ayurveda* and Menorrhagia in modern literature.

Inclusion criteria

- Patient between age group 16 to 45 years.
- Patients having regular menstrual cycle.
- Hb 8 gm % and above.
- Excessive bleeding history for more than 2 to 3 consecutive menstrual cycle.
- More than 3 pads/day 6. Patient is willing to participate in the study.

Exclusion criteria

- Known case of endocrinal disorders.
- Known case of malignant tumour, tubercular cervicitis, HIV.
- Patients having IUCD.
- Patients having irregular menstrual cycle.

Assessment criteria

Parameters	Symptoms	Grade
***Rajastrava Avadhi* (Duration of Bleeding)**	1-3 days	0
	3-5 days	1
	5-7 days	2
	More than 7 days	3
***Rajaswaroop* (Character of bleeding clots)**	No clots	0
	Bleeding with occasional clots	1
	Bleeding with more clots	2
	Only clots	3
***Varna of Raja* (Colour of bleeding)**	Red	0
	Bright red	1
	Reddish brown	2
	Dark brown	3
***Anngamarda, Adhoudar shoola, Katishool* i.e., Associated symptoms**	Normal	0
	Mild (1-3)	1
	Moderate (4-6)	2
	Severe (7-10)	3
***Rajapraman* (Amount of blood loss)**	1-3 pads/day	0
	4-5 pads/day	1
	5-6 pads/day	2
	More than 6 pads/ day	3

Follow ups: 0th day, 1st cycle, 2nd cycle, 3rd cycle.

The graded values were later totally and individually scored and assessed statistically to find out the rate of effect of treatment. The age, occupation, habitat wise distribution of patients with socioeconomic status was also recorded and assessed statistically. The effect of treatment in each group was assessed separately by analysing the pre-treatment and post treatment data, scores and values. The comparison of the effect of therapy of two groups done by statistical analysis.

Ashokghrita

According to *Bhaishajyaratnavali, Ashok ghrita* is indicated in *Raktapradara*. (4)

Ingredients

Sr. No.	Name of drug	Latin name Family	*Rasa*	*Virya*	*Vipaka*	*Guna*	*Doshaghna ta*
1	*Ashoka* (5)	*Saraca asoca (Roxb.)* Caesalpinoidae	*Kashaya Tikta*	*Sheeta*	*Katu*	*Laghu Ruksha*	*Kapha Vata*
2	*Jiraka* (6)	*Cuminum cyminum-Linn* Umbilliferae	*Katu*	*Ushna*	*Katu*	*Laghu Ruksha*	*Kapha Vata*
3	*Jivaka* (7)	*Crepidium AcuminatumD.Don* Orchidaceae	*Madhura*	*Sheeta*	*Madhura*	*Guru Snigdha*	*Vata Pitta*
4	*Rishabhaka* (8)	*Manilkara hexandra (Roxb.)* Sapotacea	*Kashaya Madhura*	*Sheeta*	*Madhura*	*Guru Snigdha*	*Vata Pitta*
5	*Meda* (9)	*Polygonatum cirrhifolium (Wall.)*	*Madhura*	*Sheeta*	*Madhura*	*Guru Snigdha*	*Vata Pitta*
6	*Mahameda* (10)	*Polygonatum verticillatum (Linn.)*	*Madhura*	*Sheeta*	*Madhura*	*Guru Snigdha*	*Vata Pitta*
7	*Kakoli* (11)	*Fritillaria roylei Hook* Liliaceae	*Madhura*	*Sheeta*	*Madhura*	*Guru Snigdha*	*Vata Pitta*
8	*Kshirkakoli* (12)	*Roscoea purpurea Sm.* Zingiberaceae	*Madhura*	*Sheeta*	*Madhura*	*Guru Snigdha*	*Vata Pitta*
9	*Mudgaparni* (13)	*Phaseolus trilobus Michx.* Leguminosae	*Madhura*	*Sheeta*	*Madhura*	*Laghu Ruksha*	*Tridosha*
10	*Mashaparni* (14)	*Teramnus labialis(L.f.) Spreng.* Leguminosae	*Madhura Tikta*	*Sheeta*	*Madhura*	*Laghu Snigdha*	*Vata Pitta*

Preparation of *Ashok Ghrita*

The drugs were collected & authenticated by certified laboratory and *ghrita* was prepared in the pharmacy attached to the institute.

1. The ingredients of *Ashok ghrita* i.e., the *Kwath dravyas* were taken in coarse powdered from and given quantity of water was added to it. It was then heated and reduced to ¼th of its volume and filtered with muslin cloth to obtain *kwath*.
2. The other ingredients (*kalka dravyas*) were taken in fine powder form. These were then transferred to wet grinder and ground with enough water to prepare a homogenous blend (*Kalka*).
3. Then, the *ghrita* was taken in a stainless-steel vessel and heated mildly. Next, the ingredients of *Kalka* were added and the mixture was stirred thoroughly while adding *jeerak Kwath, tandulodaka, maka swarasa* & *Ajaksheer*.
4. It was heated for some time with constant stirring and maintaining the temperature between 500- degree Celsius and 900 degrees Celsius during the first hour of heating. The heating was stopped and it was allowed to stand overnight.
5. Next day, it was heated again and observed for the *sneha siddhi lakshanas*.
6. Finally, it was filtered while hot through a cloth and was allowed to cool.

Preparation of *Ashok ksheerpaka*:

1. *Ashok* powder was taken.
2. 8 times of *Godugdha* was added and 4 times of water to that of *Godugdha.*
3. Then it was heated on low flame till evaporation of whole water and only *Godugdha* remained.
4. It was then kept for cooling and filtered and used for drinking.

Drug Regimen

Group	Group A	Group B
Drug name	*Ashok ghrita*	*Ashok ksheerpaka*
Dose	10ml twice a day	30 ml twice a day
Duration	15 days (3 consecutive cycles)	15 days (3 consecutive cycles)
Route	Oral	Oral
Sevan kala	*Apana Kala* (Before meal)	*Apana Kala* (Before meal)
Anuapana	*Koshna Jala*	

Data thus collected during the study, summarized, and statistically analyzed as per protocol.

Statistical Analysis for Group A (Trial Group) for subjective criteria by Wilcoxon Signed Rank test

Sr. No.	Variables	Number of Pairs (N)	Sum of all Ranks (W)	BT Mean	SD	AT Mean	SD	P
1	*Rajastrava Avadhi*	40	370	1.857	0.8704	0.5433	0.5403	<0.0001 Highly significant
2	*Rajaswaroop*	40	125	0.6663	0.6064	0.1657	0.3710	<0.0001 Highly significant
3	*Varna of Raja*	40	155	1.347	0.4911	0.6343	0.5661	<0.0001 Highly Significant
4	Associated Symptoms	40	181	1.357	0.4911	0.6010	0.5732	<0.0001 Highly Significant
5	*Rajapraman*	40	156	1.236	0.4623	0.6128	0.5321	<0.0001 Highly Significant

Statistical Analysis for Group A (Trial Group) for Objective criteria by Paired "t" test-Hb percentage

Sr. No.	Variables	Number of Pairs (N)	t value	BT Mean	SD	AT Mean	SD	P
1	Hb	40	16.911	9.76	0.4186	10.73	0.5160	<0.0001 Highly significant

Statistical Analysis for Group B (Control Group) by Wilcoxon Signed Rank test- (subjective criteria)

Sr. No.	Variables	Number of Pairs (N)	Sum of all Ranks (W)	BT Mean	SD	AT Mean	SD	P
1	*Rajastrava Avadhi*	40	286	1.857	0.5174	1.110	0.4126	<0.0001 Highly significant
2	*Rajaswaroop*	40	75	0.7100	0.5960	0.3667	0.4901	0.0020 significant
3	*Varna of Raja*	40	120	1.333	0.4795	0.8333	0.6477	<0.0001 Highly Significant
4	Associated Symptoms	40	190	1.400	0.4883	0.7000	0.5960	<0.0001 Highly Significant
5	*Rajapraman*	40	210	1.654	0.4996	1.012	0.4543	<0.0001 Highly Significant

Statistical Analysis for Group B (Control Group) for Objective criteria by Paired "t" test-Hb percentage

Sr. No.	Variables	Number of Pairs (N)	t value	BT Mean	SD	AT Mean	SD	P
1	Hb	40	5.607	9.91	0.5918	10.75	0.6254	<0.0001 Highly significant

Statistical analysis in between the trial and control group subjective parameters (by Mann Whitneys U test)

Parameters	Group	Mean	SD	U	P
Rajastrava Avadhi	Trial	1.3031	0.8023	236	0.0003 S
	Control	0.7567	0.4302		
Rajaswaroop	Trial	0.5000	0.5075	375	0.2949 NS
	Control	0.3333	0.4795		
Varna of Raja	Trial	0.7343	0.7397	382.5	0.2590 NS
	Control	0.5000	0.5085		
Associated Symptoms	Trial	0.7667	0.7179	435.5	0.8409 NS
	Control	0.7000	0.5960		
Rajapraman	Trial	0.7667	0.7179	435.5	0.8409 NS
	Control	0.7000	0.5960		

Statistical analysis in between the trial and control group objective parameters (by unpaired "t" test) Hb

Group	No of patients	Mean	SD	t value	P
Trial	40	0.9700	0.7279	0.6017	0.5497 NS
Control	40	0.8400	0.5467		

Efficacy Evaluation of the therapy in Group A (Trial Group) and Group B (Control Group)

Sr. No	Parameters of Assessment	Number of patients	Group A % Change	Group B % Change
1	*Rajastrava Avadhi*	40	60.20	47.42
2	*Rajaswaroop*	40	61.42	45.94
3	*Raja varna*	40	63.21	54.94
4	Associated symptoms	40	63.33	56.52
5	*Rajapraman*	40	65.26	58.16
6	Hb%	40	10.01	8.29

Overall Assessment criteria

Sr.No	Assessment	Trial	%	Control	%
1	Unchanged	0	0	0	0
2	Least Improvement	1	2.5	4	10
3	Mild Improvement	37	92.5	36	90
4	Moderate	2	5	0	0
5	Excellent	0	0	0	0
5	Total	30	100	30	100

Observations

Age

In Group A, 40 patients were selected for the study. Out of them, 22.5% of patients were in the age group of 16-20 years, 27.5% of patients were in the age group of 21-25 years, 30% of patients were in the 26-30 age group of years, 17.5% of patients were in the 31-35 age group of years, 2.5% of patients were in the 36-40 age group of years. In Group B, 40 patients were selected for the study. Out of them, 15% of patients were in the age group of 16-20 years, 37.5% of patients were in the age group of 21-25 years, 27.5% of patients were in the 26-30 age group of years, 15% of patients were in the 31-35 age group of years, 5% of patients were in the 36-40 age group of years.

Occupation

In Group A, out of 40 patients most of the patients were housewives i.e.,47.5%. Students were 25% while 17.5% were labor and 10% patients were doing service. In Group B, out of 40 patients most of the patients were housewives i.e., 50%. Students were 25% while 7.5% were labor and 17.5% patients were doing service.

Prakriti

In Group A, out of 40 patients enrolled for the study, *Vatapitta* and *Kaphapitta prakriti* was observed in 27.5% of patients each while *Pittavata prakriti* was observed in most of the patients i.e.,35% and *Pittakapha* in 10% of patients. In Group B, out of 40 patients enrolled for the study, *Vatapitta prakriti* was noted in 42.5% of patients while *Kaphapitta prakriti* was observed in 15% of patients. *Pittavata prakriti* was observed in 32.5% of patients and *Pittakapha* in 10% of patients.

Agni

In Group A, *Teekshagni* was observed in most of the patients i.e.,40% followed by *Vishamagni* in 30%, *Mandagni* in 20% and *Samagni* in 10% of the total patients. In Group B, *Teekshagni* was observed in most of the patients i.e.,45% followed by *Vishamagni* in 35%,

Mandagni in 7.5% and *Samagni* in 12.5% of the total patients.

Results

Statistically significant results were observed in *Rasastrava avadhi* in both the groups. Duration of bleeding was decreased after treatment in both the groups. Both the group A and B showed statistically significant results in *Rajaswaroop*. Number of clots in bleeding got decreased after treatment. Statistically significant results were obtained in both the groups in *Raja varna*. In most of the patients, brownish colour of bleeding turned to normal red colour. Both the drugs *Ashok ghrita* and *Ashok ksheerpaka* showed statistically Significant results on *raja praman* as quantity of bleeding was decreased after treatment. Both the groups showed statistically significant results in associated symptoms Like *Katishoola, Adoudara shoola and Angamarda*.

Discussion

Duration of bleeding was decreased after treatment in both the groups. This may be due to *Raktastambhak* property of *Ashok* by its *Kashaya rasa* dominancy. Also, may be due to *Vatapittashamak* properties of most of the drugs in *Ashok ghrit* like *Shatavari, Meda, Mahameda, Kakoli* etc. *Ashok* act as uterine tonic and improved the muscular tone of uterine musculature which is important to control bleeding. Most of the drugs in *Ashok ghrita* having *rasayan* property and may improve nourishment of all *dhatus* and reduce the duration of bleeding. Number of clots in bleeding get decreased after treatment. *Granthi raja* is mainly due to *Vatakapha dosha* dominancy. Most of the drugs in *Ashok ghrita* having *Vatashamak* property and may reduce formation of Clots. Also, some drugs by virtue of their laghu and *ruksha guna* leads to *Kaphashaman* and may reduce *granthi raja*.

Shatavari, Bhringaraj, Rasanjana, Ashok having *tikta rasa* which is *amapachana, Deepana, srotoshodhana* may reduce *granthi raja*. *Vivarnata* mainly causes by vitiation of *Pitta dosha*. Most of the drugs in *Ashok ghrita* having *Pittashamak* property by virtue of their *Madhura rasa, Sheeta virya, Guru and snigdha guna, Madhur vipaka*. Also, *ghrit*a itself possess *Pittashamak* property. Indulgence of *Pittaprakopaka* food leads to vitiation of *Pitta* mainly by its *drava and ushna guna. Pittashamaka* property of drug reduces its vitiation and thus decreased quantity. Also, *laghu and ruksha guna* drugs absorption of excess *dravata* as well as *kashay rasa* having *stambhana* property leads to reduction on quantity of *raja.* Both the groups showed statistically significant results in associated symptoms Like *Katishoola, Adhodara shoola and Angamarda*. All the associated symptoms are mainly aroused due to vitiation of *vata dosha*. *Ashok ghrita* contains drugs having *vatashamak* properties may reduce *vata* or *Anulomana* of *vata dosha* may reduce *shoola*. (15)

Mode of action of the Drug: (16)

Action by virtue of its *Rasa*:

Most of the drugs in *Ashok Ghrita* having *Madhura* and *Kashaya rasa*.

- *Madhura rasa* –It is having *Balya, Rasayan* properties, enhances nourishment to *dhatus*, improves quality of *Rasa dhatu* and ultimately all *dhatus*. *Madhura rasa* having *Vata and Pittashamak* property and thus play an important role in *Raktapradara*.
- *Kashaya rasa-Ashok* having *Kashaya rasa* which poessess *raktastambhak* property and thus it causes cessation of bleeding.
- *Tikta rasa* -Some of the drugs like *Shatavari* and *Bhringraja* have *tikta rasa* which is having *agnideepana, amapachan, srotoshodhan* properties and effective in *Pradara*. Also, *tikta rasa* is best *Pittashamak rasa* and may reduce *drava guna of Pitta* and reduces bleeding.

Action by virtue of its *Guna*

Ashok ghrita contains drugs having combination of many gunas like *laghu, ruksha, guru, snigdha, mrudu* etc. In *Raktapradara*, Pitta increases by its *drava guna* and as *Rakta* and *Pitta* having *Ashrayashrayi bhava* it increases *dravata of Rakta dhatu* also. *Laghu and ruksha guna* drugs having *shoshana* property which absorbs excess of water content in *rakta dhatu* and reduces its quantity. Also, *laghu and ruksha guna* have *Vayu mahabhut* dominancy which absorbs *dravata* of *rakta dhatu*.

Action by virtue of its *Virya*

Ashok ghrita is a best combination of *sheeta* and *ushna virya* drugs. *Sheeta virya* having *Pittashamak, Raktastambhak, Raktaprasadhan* properties. *Sheeta virya* having *balya, rasayan* properties which give strength to uterine muscles and improves its tone.

Ushna virya drugs having *deepana, pachana, srotoshodhan* properties and thus reduces the symptoms.

Action by virtue of *Vipaka*

In *Ashok ghrita* most of the drugs having *Madhura vipaka* and few having *Katu vipaka*.

Madhura vipaki drugs having *Vatapittashamak* properties and reduces symptoms as there is dominance of *Vata* and *Pitta* in *Raktapradara*.

Importance of *Vatashaman* in *chikitsa*

Acharya Charak explained *Asrigdara or Pradar* as a separate disease with its management in *Yoni Vyapad Chikitsa* and mentioned it as symptoms of *Pittavrita Apanavayu*. As it is known that without the influence of *Vata Dosha, Yoni Vyapads* never occurs. In *Asrigdara* dominant causative factor or *Dosha* is '*Vayu*' and *Dushya* is *Rakta Dhatu.* The main ingredient is *Ashoka* which is a uterine tonic and haemostatic in nature and thus a cardinal herb in treating *Asrigdar*. *Ashoka ghrita* is a uterine tonic which improves uterine functions, modulates uterine contractions, stabilizes hormonal imbalance and is hemostatic in nature. It

gives strength to the uterus which helps in easier dislodging of the uterine lining during menstruation and prevents ischemia. Thus, it reduces menstrual cramps. It also corrects the aggravated *Pitta*. Its *Vipaka* acts as *vatapittahara, sthambana, raktashodhaka*. It corrects *rasa*. The constituents of *Ashoka* include glycosides, flavonoids, tannins, saponins, and sterols. Research has shown that it has antibacterial, anti-fungal, oxytocic, uterotonic, anticancer, antiprogesterone, anti-estrogenic, anti-inflammatory, and anti-oxidant Phytoestrogens which are also present in *Ashoka* bark modulate the raised levels of hormones in cases of primary dysmenorrhea.

Ghrita is prepared by *Ghrita Kalpana* described in *Sharangdhar Samhita.* It has *Madhura rasa, Sheeta virya* having *Vata-pittahara* qualities. It is *Balya* and is beneficial for *Rasa dhatu* and does *Preenana* of *Garbhashaya.*

Conclusion

Thus, from above study it can be concluded that *Ashok Ghrita* is found to be more effective than *Ashok ksheerapak* in the management of *Raktapradara* with special reference to Menorrhagia.

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