

A CLINICAL COMPARATIVE STUDY OF DHATAKI CHURNA WITH TRANEXEMIC ACID IN ASRUGDARA WITH SPECIAL REFERENCE TO MENORRHAGIA

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ABSTRACT

Ayurveda, a science of life emphasizes on the maintenance, promotion of health and curing the diseases. Among the eight branches of Ayurveda, Kaumarbhritya Tantra is all about the health of Women and her child. A woman is responsible for progeny and the baby's nourishment after birth. In female, menstruation is a sign of normal uterine bleeding which must be regular for pregnancy. As per Ayurvedic literature, any abnormality in menstrual rhythm leads to excessive and irregular uterine bleeding which is known as 'Asrugdara'. Many herbal drugs & formulations are prescribed in various Ayurvedic literature for the treatment of Asrugdara. Dhataki

(Woodforlia fruticosa) has an astringent, haemostatic and refrigerant properties therefore, comparative experimental study the effect of a Dhataki in the comparison with modern Medicine – 'Tranexemic Acid' For the treatment of Asrugdara revealed that, Dhataki churna along with Tandulodaka is useful in increasing the haemoglobin count without producing any adverse effect & is as effective as Tranexemic Acid.

KEYWORDS: Dhataki, Tandulodak, Asrugdara, Tranexemic Acid.

INTRODUCTION

Ayurveda, a life science has contributed a healthy lifestyle to humanity. It emphasizes on the maintenance, promotion of health and curing the diseases. The Ayurvedic system of medicine advocates a holistic approach to the human health care i.e. a balance between the physical, mental and spiritual functions of the human body. Ayurveda has eight branches, among these Bala i.e. Kaumarbhritya Tantra is all about the health of Women and her child.^[1] As per the

fundamental principal of reproduction i.e. Kshetra Beeja nyaya, Kshetra is one of the four factors which are required for Garbhotpatti (Pregnancy). Female as a Kshetra, one has to consider about the reproductive system, especially Garbhashaya (Tritiya avarta) which is responsible for menstrual flow and embedding of the fertilized ovum.

In female, menstruation is a sign of normal uterine bleeding and this monthly cycle must be regular for pregnancy. Various factors like mental and physical stress, abnormal diet, environmental and emotional influences and suppression of natural urges causes different types of Menstrual disorders e.g. less, heavy, irregular or abnormal uterine bleeding. As per classical Ayurvedic texts, any abnormality in Rutuchakra (Menstrual rhythm) leads to excessive and irregular uterine bleeding which is known as 'Asrugdara'.^[2] It Might be from menarche to menopause & may be life threatening if not treated properly and immediately.

The present study is aimed to find out the effect of a Herbal Drug in the Comparison with modern Medicine – 'Tranexemic Acid' For the treatment of Asrugdara which should prevent the heavy bleeding & irregularity of menstrual cycle due to increased vitiated Doshas without causing any adverse effect. Tranexemic Acid is an antifibrinolytic medication commonly used to treat or prevent excessive blood loss from major trauma, postpartum bleeding, surgery, tooth removal, nose bleeds and heavy menstruation or menorrhagia.^[3] For this study purpose Author has selected 'Dhataki (Pushpa) Churna' along with Tandulodaka for oral administration in the patients of Asrugdara. As Dhataki being an Astringent, Haemostatic, Refrigerant and found to be effective in certain diseases like Menorrhagia, Diarrhoea, Dysentery and bleeding disorders.^[4] Use of Dhataki churna in the treatment of Asrugdara is described in Yogratnakara Pradara chikitsa Adhyaya.^[5] Dhataki Pushpa & Tandulodaka both have properties of Kapha-pitta shamaka, Astringent & Dahashamaka which helps to minimize excessive bleeding and other symptoms of Asrugdara.

MATERIAL AND METHODS

- **Drugs for study**

Dhataki (Pusha) Churna with Tandulodaka & Tab. Tranexemic Acid 500mg.

- **For Preparation of Dhataki Pushpa churna**

Dhataki Pushpa - Shushka (Dried Flowers of Woodfordia fruticosa), Single pan electronic digital balance, Cotton cloth or 100 no. mesh & Grinder.

➤ For Preparation of Tandulodaka

Tandula (Pounded rice), Stainless Steel Pot, Table Spoon & Sieve / Cotton Cloth.

❖ Methods

Raw sample of Dhataki Pushpa (Flowers of *Woodfordia fruticosa*) and Rice were collected from well Known botanical garden and market respectively, where as Authentication & Standardization of study drug were done at well known Botanical Institute & pharmacy.

Preparation of Dhataki Pushpa churna & Tandulodaka were done as per the procedure described in Sharangdhara Samhita.^[6,7]

- **Type of study:** Open Randomized Comparative Experimental Study.
- **No. of patients:** Total 60 (two groups of 30 patients)
One group is Trial and another is Control group.
- **Groups of patients**

Trial group: 30 patients	Control Group: 30 patients
Dhataki Churna 5 gms orally (Apana kale) BD with 20 ml of Tandulodaka as a anupana for 7 days during menstrual period for 3 consecutive cycles.	Oral administration of Tab. Tranexamic Acid 500mg 1 TDS for 7 days during menstrual period for 3 consecutive cycles

• Criteria for selection of patients

Inclusion Criteria	Exclusion Criteria
Age group between 12 to 50 yrs.	Any uterine anatomical abnormalities i.e bleeding from cervical or Endometrial polyps, cervical erosions, cancer, uterine fibroid.
Menstrual flow increase in number of days.	Systemic diseases e.g. Endocrinal Disorders, HTN, & DM.
Excessive menstrual bleeding quantitatively.	Abortional bleeding, Ante partum haemorrhage (APH).
Dysfunctional uterine bleeding (DUB).	History of bleeding from the site other than the uterus.
Reduction in the inter menstrual cycle period.	Anaemia (Hb - less than 8 gms%), HIV/ VDRL / HBsAg positive etc.

Total 60 patients of Asrugdara were selected from daily OPD and divided them into two groups randomly. A case record form was prepared considering the classical description of the disease. To exclude other diseases, confirming and assessing the severity of the disease, systemic examination and investigations were done.

• Methods of evaluation

Changes in signs and symptoms were noted down in C.R.F. after oral administration of Dhataki Churna with Tandulodaka and Tranexemic Acid for Trial & Control group

respectively in each cycle for 3 cycles. 3 follow ups were taken during administration of drug in each cycle for observation of any side effects or for adverse complaint to patient.

According to changes in the symptoms assessment was done. On the basis of severity, all Symptoms were graded into 4 grade scale (0–3).

- **Criteria for Assessment**

A. Subjective Criteria

	Artavati-pravrutti	Adhodarshoola	Grathit-artava	Sarvangmarda
Grade 0	1- 3 Days	Menses not painful	No clots	No pain
Grade 1	4 - 6 Days	Menses painful but daily activities not hampered	1 or 2 clots	Didn't disturbed daily routine, felt only when relaxing
Grade 2	7 - 10 days	Menses painful and daily activities are slightly hampered	3 to 7 clots	Routines were disturbed due to pain
Grade 3	More than 10 Days	Menses painful and daily activities are hampered and oral treatment required	more than 7 clots	Pain disturbs daily routines as well as sleep could not be tolerated by medicated aid.

B. Objective Criteria

1. Ultrasonography -: Endometrial thickness - Before and after treatment
2. Hb gm% before and after treatment

- **Statistical Analysis**

The data generated during the study was subjected to statistical analysis to reach the final result and conclusion. 'Wilcoxon-matched- pairs-signed rank test' and 'Mann-Whitney test' were applied for evaluation of subjective data while 'Paired t – test' and 'Unpaired t – test' were applied for evaluation of objective data. Significance of the results were studied at 5% level of significance.

OBSERVATIONS AND RESULT

After completion of three months tenure, Effect or adverse effect of the study drug with status of signs & symptoms in all the patients were observed. After applying Wilcoxon-matched-pairs-signed-rank statistical test to the subjective criteria, it is observed that both drugs have a extremely significant effect in all symptoms of asrugdara (Table no. 1 & 2) and in comparison, after applying Mann-Whitney Test, there is no significant difference found between Trail & Control group.(Table no.3)

In case of objective criteria, after applying statistical paired 't' test, it is observed that, both drugs have extremely significant effect on endometrial thickness where as *Dhataki* shows significant & Tranexemic Acid shows extremely significant effect on Hb%. (Table 4&5). At last, comparison of results of parametric (objective) data between two Groups by unpaired - 't' Test shows that, p value of each subjective criteria is > 0.05 which is statistically not significant. (Table no.6) which suggests that, there is no significant difference in the two groups with respect to the total effect of therapy.

Table 1: Statistical analysis of effects of therapy on subjective parameters in - Group A (Trial Group) By Wilcoxon- matched-pairs-signed-rank test.

Sr. no.	Symptom		Mean	SD	SE	W	P
1	Aartavati pravrutti	BT	2.867	0.3457	0.06312	465	<0.0001 Extremely Significant
		AT	0.4667	0.5074	0.09264		
		DIFF.	2.400	0.5632	0.1028		
2	Adhodara shoola	BT	2.533	0.5074	0.09264	465	<0.0001 Extremely Significant
		AT	0.4000	0.4983	0.09097		
		DIFF.	2.133	0.7303	0.1333		
3	Grathit artavata	BT	1.933	0.5208	0.09509	435	<0.0001 Extremely Significant
		AT	0.4333	0.5040	0.09202		
		DIFF.	1.500	0.6297	0.1150		
4	Sarvangama-rda	BT	2.067	0.6397	0.1168	378	<0.0001 Extremely Significant
		AT	0.4000	0.4983	0.09097		
		DIFF.	1.667	0.8442	0.1541		

Table 2: Statistical analysis of effects of therapy on subjective parameters in Group- B (Control group) By Wilcoxon- matched-pairs-signed-rank test.

Sr. No.	Symptom		Mean	SD	SE	W	P
1	Aartavati-pravrutti	BT	2.767	0.4302	0.07854	465	<0.0001 Extremely Significant
		AT	0.4333	0.5683	0.1038		
		DIFF.	2.333	0.6065	0.1107		
2	Adhodara-shoola	BT	2.633	0.5561	0.1015	457	<0.0001 Extremely Significant
		AT	0.6000	0.5632	0.1028		
		DIFF.	2.033	0.9279	0.1694		
3	Grathit-artavata	BT	2.200	0.4842	0.08841	435	<0.0001 Extremely Significant
		AT	0.6667	0.5467	0.09981		
		DIFF.	1.533	0.8193	0.1496		
4	Sarvanga-marda	BT	2.400	0.6747	0.1232	465	<0.0001 Extremely Significant
		AT	0.5333	0.5074	0.09264		
		DIFF.	1.867	0.6814	0.1244		

Table 3: Showing comparison between two Groups with respect to symptoms score by Mann-Whitney Test.

Symptoms	Mean		SD		SE		U	U'	Sum of rank A	Sum of rank B	P
<i>Artavati-pravrutti</i>	0.4667	0.4333	0.5074	0.5683	0.09264	0.1038	427	473	938	892	0.7001
<i>Adhodarshoola</i>	0.4000	0.6000	0.4983	0.5632	0.0909	0.1028	369	531	834	996	0.1724
<i>Grathitartava</i>	0.4333	0.6667	0.5040	0.5467	0.0920	0.0998	353.50	546.5	818.5	1011.5	0.1037
<i>Sarvanga-marda</i>	0.4000	0.5333	0.4983	0.5074	0.09097	0.09264	390	510	855	975	0.3088

Table 4: Showing effect on objective parameters of 30 patients of AsruIIIgdara in group-A (Trial group) by paired -'t' test.

Sr. no.	Objective parameters in respective unit		Mean	SD	SE	t	P
1	Endometrial Thickness	BT	7.966	2.579	0.4708	5.839	<0.0001
		AT	5.690	2.445	0.4463		
		DIFF	2.276	2.135	0.3897		
2	Hb %	BT	10.260	1.298	0.2370	3.348	0.0023
		At	10.548	1.224	0.2234		
		DIFF	-0.2883	0.4717	0.08612		

Table 5: Showing effect on objective parameters of 30 patients of Asrugdara in group-B (Control group) By paired -'t'test.

Sr. no.	Objective parameters in respective unit		Mean	SD	SE	t	P
1	Endometrial Thickness	BT	9.877	3.744	0.6836	8.810	<0.0001
		At	7.070	3.315	0.6052		
		DIFF	2.807	1.745	0.3186		
2	Hb %	BT	10.127	1.234	0.2252	3.158	0.0037

Table 6: Comparison of results of parametric data between two groups by unpaired -‘t’ Test.

Sr. no.	Objective parameters in respective unit		Mean	SD	SE	t	P
1	Endometrial Thickness	Group- A	2.276	2.135	0.3897	1.055	0.2959 Not significant
		Group- B	2.807	1.745	0.3186		
2	Hb %	Group- A	-0.2883	0.4717	0.08612	0.746	0.4583 Not significant
		Group- B	-0.4033	0.6995	0.1277		

DISCUSSION

In present study before starting the treatment, patients were observed for each sign and symptom & status of the symptoms was recorded as well as investigation were done as per criteria of assessment. Therapy was given for 3 menstrual cycles. Follow up of each cycle was taken and change in sign and symptoms were noted. According to CRF mentioned in earlier part detailed history was also recorded. All patients were examined with respect to Ayurvedic contention of Rugna Parikshana.

The result and observation obtained are discussed here under - General discussion & discussion on Subjective & Objective parameters.

- **General discussion:** Under this study maximum Patients of age group 26-38 years were found in both groups, among them 75% women were house wives. As housewives have tendency of laziness, Diwaswap, negligence of proper diet i.e. consumption of Katu, Lavana, Amla rasa, Ushna, Tikshana, Ruksha gunatmaka Ahara, lack of exercise which causes vitiation of doshas & it may increase vaginal bleeding. Out of 60 patients, maximum patients were found having middle socioeconomic status followed by lower class. Also Most of the patients were non vegetarian & of Pitta-Vatajprakriti, so this data can support the responsible factor of Asrugdara.
- **Effect on Subjective parameters:** Both drugs have a extremely significant effect in all symptoms of Asrugdara & there was no significant difference found in Trial and Control group. Comparison of results of non-parametric (subjective) data between two groups By Mann-Whitney test shows that Trial group is as effective as Control group in symptoms like Artavatipravrutti, Adhodarshoola, Grathitartava and Sarvangamarda.
- **Effect on Objective parameters:** both drugs have extremely significant effect on endometrial thickness where as Dhataki shows significant & Tranexemic Acid shows

extremely significant effect on Hb%. At last, comparison of results of parametric (objective) data between two groups by unpaired -'t' test shows that there is no significant difference in the two groups with respect to the total effect of therapy.

CONCLUSION

Based upon the results of the clinical study displayed in the form of tables and graphs following conclusions are drawn:-

1. Incidence of Asrugdara is highest in Pitta-vata Prakruti between the age group 26-38 years.
2. Dhataki churna is useful in increasing the Haemoglobin count, so it proves the better effectiveness in patient of Asrugdara having symptoms of Anaemia.
3. There was no any adverse effect found after administration of Dhataki Churna in the patients of Asrugadra.
4. Oral administration of Dhataki churna with Tandulodaka is as effective as Tranexamic acid.

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