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A comparative pharmaceutico-clinical evaluation of boladi vati and kanyalohadi vati W.S.R. to Kashtartava

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Abstract
Women's health is the primary factor to be considered for wellbeing of family, society and culture. Kashtartava is broad term which covers all the problems and ailments that a woman may suffer from pain during menstruation. By analysis one can state this is a result of Vatavruddhi, Apanavata margavarodha, Artava dushti and Dhatukshaya. Kashtartava can be compared with the Dysmenorrhea in Modern medicine. Its prevalence is estimated at 25% of women and up to 90% of adolescents. The majority of cases of Dysmenorrhea are Primary Dysmenorrhea. Today's stressful modern life style, food habits are affecting more to the uterine environment which leads to higher incidence of Dysmenorrhoea. In this scenario Ayurvedic herbal preparations are proved safe and effective than modern therapeutics which may results in some unwanted complications. In the present study Kashtartava is taken for Primary Dysmenorrhea. The whole work was undertaken in three main parts as: pharmaceutical study, analytical study and Clinical study. The Prepared formulations were administered to the patients of Primary Dysmenorrhoea, for a period of 15 days starting from 7 days prior to menstruation for 2 consecutive cycles, 40 volunteers were selected 20 being in each group. As Boladi Vati and Kanyalohadi Vati are mentioned in the classical text of Rasashastra, the ingredients of the both formulations possesses the specific properties like Vatakaphahara, Shoolaghna, Vatanulomana, Dhatuposhaka. Both the trial drugs have shown significant action in relieving primary Dysmenorrhoea but among both, action of Kanyalohadi vati is comparatively superior to Boladi vati.

Keywords: Kashtartava, dysmenorrhea, boladi vati, kanyalohadi vati

Introduction
Menstruation has dual significance for women. From one perspective it defines the start and end of reproductive potential, an affirmation of womanhood. Menstruation, a complex cyclic phenomenon, is an inevitable natural occurrence in women's life. Menstrual disorders form a significant proportion of the adult female population. Dysmenorrhea and pre-menstrual syndrome are the commonest Gynaecological disorders causing great distress to women every month but still are the least reported symptoms.

Primary Dysmenorrhea refers to painful menstruation in the absence of any underlying pelvic pathology. It is most common gynaecological disorder which is now recognized as an important women's health issue with high prevalence. It is a major symptom in many medical conditions, can significantly interfere with a person's quality of life and general functioning. It is the main reason for visiting the emergency department in more than 50% of cases. The prevalence in developing countries revealed that about 25-50% of adult women and about 75% of adolescents experience pain during menstruation, with 5-20% reporting severe Dysmenorrhea or pain that is severe enough to prevent them from carrying out their day-to-day activities. In consequence, it is associated with emotional, social and economic burdens.

Majority of cases of Dysmenorrhea fall in to the group of Primary Dysmenorrhea and it is probable that nearly 50% of adult female population suffer from this. In Ayurvedic classics all gynaecological problems are described under the broad term Yonivyapad. The disease 'Kashtartava' is not described in classics as an individual disease entity. Even then it is a symptom of various Yonivyapads specially Udavarta, Vatala, Sannipatika etc. It is a Tridoshaja Vyādhi with Vata predominance. On analysis, one can make out that it is a result of Vata vruddhi, apana vata margavarodha, arthava dushti and dhathukshaya especially affecting Rasa dhatu.

Kashtartava being painful menstruation is commonly compared with the concept of dysmenorrhoea in conventional sciences. The drugs selected are Kanyalohadi vati and Boladi vati to evaluate their efficacy and safety in Primary Dysmenorrhea. An inference is made on drugs action in Kashtartava based on their properties like Vatakaphahara, Vata anulomana, Garbhashaya shodana, Artava shodaka, Balya, Shulahara etc.

Objectives

1. To evaluate action of Boladi vati on Kashtartava.
2. To assess the efficacy of Kanyalohadi vati in Kashtartava.
3. To evaluate and establish the comparative efficacy between 2 groups in Primary Dysmenorrhea.
4. To analyse Boladi vati and Kanyalohadi vati pharmaceutically, Physico- chemically.

Materials and Methods

The whole work was undertaken in three Phases

1. Pharmaceutical study
2. Analytical study
3. Clinical study

Pharmaceutical study

The raw materials were procured from the Jogappa Shanbhag Pharmacy, Udupi. All these materials were authentified before use. The raw materials were air dried for a week under shade and stored in hygienic conditions. In this part of study detailed description regarding various pharmaceutical processes followed in the preparation of trial drugs (Boladi vati and Kanyalohadi vati) will be discussed.

Table 1: Boladi Vati Ingredients[1]

S. No	Ingredients	Quantity
1	Shodita Bola	400 gm
2	Trivrut	200 gm
3	Hingu	200 gm
4	Tankana	200 gm
5	Ela	200 gm
6	Indravaruni	200 gm
7	Kassesa Bhasma	200 gm
8	Jatamamsi Kwatha	Q. S

Table 2: Shodana methods for Boladi Vati Contents

S. No	Drugs	Materials taken	Quantity	Procedure
1	Bola[2]	Khanji- Q. S	500 gm	Bola is taken in khalva yantra crushed and Physical impurities are removed manually. Cleaned bola is powdered well.
				Bola churna is triturated by adding sufficient quantity of Kanji till it attains Subhavita lakshana.
				Obtained paste is spreaded on to a kadali Patra and kept for drying. Dried flakes are collected in airtight container
2	Hingu[3]	Ghruta- Q. S	250 gm	Hingu is fried with sufficient quantity of ghrita till it become crispy.
				Collected in a clean container after it gets cooled.
3	Tankana[4]	-	250 gm	Powdered Tankana is fried in a pan till it becomes free from moisture by continuous stirring.
				Collected in a clean container after it gets cooled

Preparation of Boladi vati

All powdered ingredients were mixed uniformly and gradually part by part, mixture was triturated by adding sufficient quantity of Jatamamsi khwatha. After getting subhavita lakshanas many rolls were made and subjected to tablet cutting machine. Prepared tablets were dried and collected in airtight container

Preparation of Kanyalohadi vati

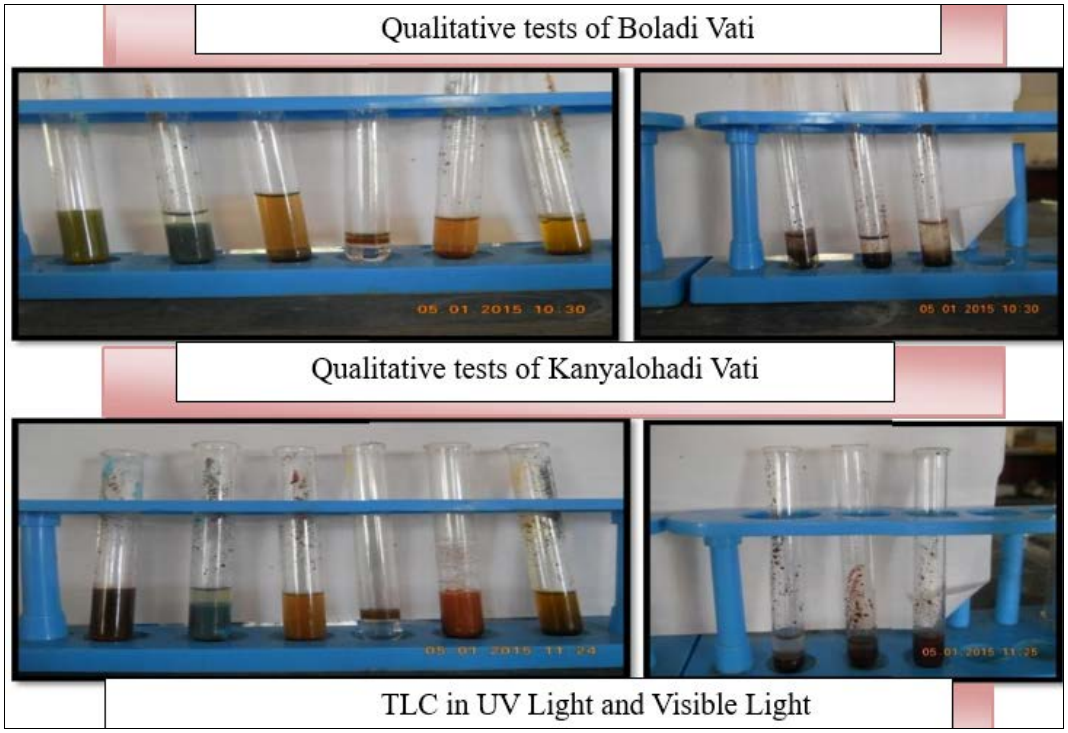
All powdered ingredients were mixed uniformly and gradually part by part mixture was triturated by adding sufficient quantity of Kumari swarasa. After getting subhavita lakshanas many rolls were made and subjected to tablet cutting machine. Prepared tablets were dried and collected in airtight contain

Table 3: Kanyalohadi vati[5] Ingredients

S. No	Ingredients	Quantity
1	Ela	200 gm
2	Khaseesa Bhasma	200 gm
3	Loha Bhasma	200 gm
4	Twak	200 gm
5	Shunthi	200 gm
6	Kumari swarasa	Q. S

Analytical Study

The qualitative and quantitative analysis of the trial formulations, i.e., Boladi and Kanyalohadi vati was evaluated Physico-chemically by the following standard protocol.



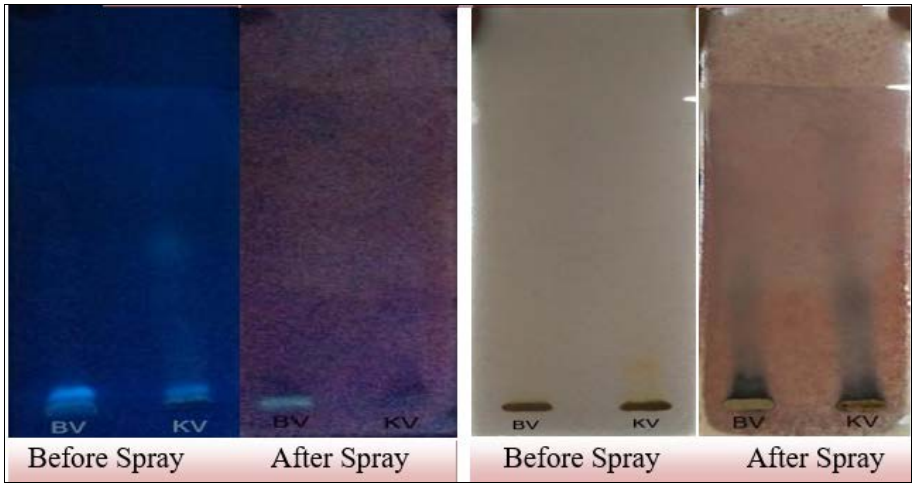


Table 4: Physico-chemical Tests

S. No	Tests	Parameters
1	Physical tests	Total ash Acid insoluble ash Water soluble ash Loss on Drying
2	Qualitative tests	Carbohydrates Tannins Flavonoids Protein Cardiac glycosides
3	Tests for Tablets	Friability test Disintegration test Hardness test
4	TLC	
5	Quantitative estimation of Iron	
6	Quantitative estimation of Sulphur	

Clinical study

To evaluate the Efficacy of Boladi vati & Kanyalohadi vati clinically following methodology was done

Table 5: Methodology for Clinical study

Group	Sample size	Trail drug	Dose	Time & Duration
A	20	Boladi vati	250 mg	15 Days - Starting from 5 days prior to expected date of menstruation for two menstrual cycles.
B	20	Kanyalohadi vati	250 mg	

Table 6: Samples were selected as per inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Patients with in the age group 15 to 30 years. Patients suffering from painful menstruation	Congaenital anomalies
	Any pelvic pathology, acute infection
	Acyclic & excessive bleeding for more than 5day
	Endometriosis
	Adenomyosis
	Uterine fibroid
	Endometrial polyp
	PCOD & other medical, surgical, Neurological conditions resulting in Dysmenorrhea
	Known case of Diabetes mellitus & Hypertension.

Assessment criteria

The patient's response will be assessed on the basis of subjective parameters. Pain will be assessed by using clinical grading starting from 0 (Zero) to 3 (Three).

Table 7: Clinical assessment through Grading

Grade	Subjective parameters
0	Menstruation is not painful
	Daily activities unaffected
1	Menstruation is painful (Mild pain)
	Daily activities unaffected
	No analgesics needed.

2	Menstruation is painful (Moderate pain)
	Daily activities affected Back ache
	Analgesics needed.
3	Menstruation is painful (Severe pain)
	Unable to perform daily activities
	Absent for work/classes
	Severe Back ache
	Analgesics show poor effect

Table 8: Showing Scoring Methods for Clinical assessment

Score	Parameters					
	Pain during menses	**Routine activity**	**Area pain**	**Time period**	**Analgesics**	**Total scoring**
0	No pain	Unaffected	No pain	No pain	No need of drugs	No pain
1	Mild	Affect some extent	Limited to Lower abdomen	Pain only for 1-2 hrs just before and during the menstruation	Pain subsided by intake of mild drugs	1-9- Mild pain
2	Moderate	Affect markedly	Limited to Lower abdomen & back	Pain lasting for 5-6 hrs in the first day of menstruation	Pain subsided by intake of strong drugs	10-15- Moderate pain
3	Severe	No activity	Limited to Lower abdomen, back and radiating to thigh region	Pain more than 6 hrs during menstruation	Pain not subsided by such drugs	16 & above- Severe pain

Overall Assessment

1. Cured - relief for 100%
2. Marked improvement - relief from 75% to 100%
3. Moderate improvement - relief from 50% to75%.
4. Mild improvement - relief from 25% to 50%.
5. No relief - below 25%

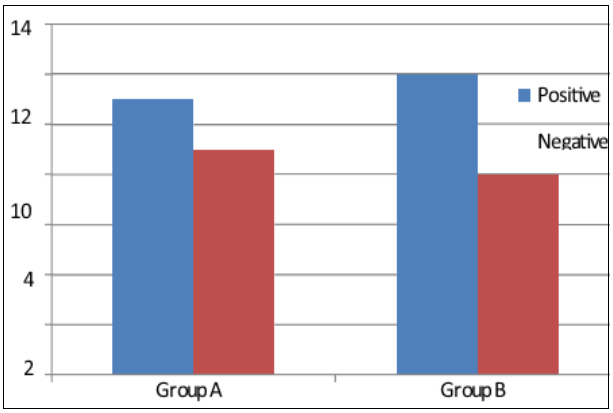
Observation

The observations of the clinical study are represented in tabular forms.

Table 9: Family History wise distributions

Family History	Number of patients		Total	%
	Group A	Group B		
Positive	11	12	23	57.5
Negative	9	8	17	42.5

Thus, 57.5% of the volunteers show positive family history while 42.5% gives negative family history.

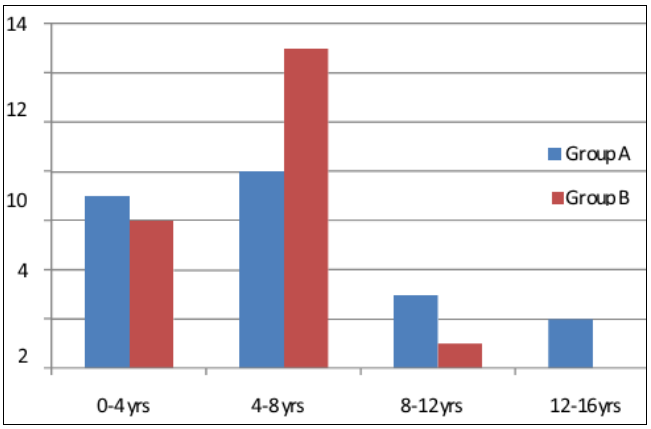


Graph 1: Family History wise distributions

Table 10: Duration of chief complaint wise distribution:

Duration of complaint	Number of patients		Total	%
	Group-A	Group-B		
0-4 yrs.	7	6	13	32.5%
4-8 yrs	8	13	21	52.5%
8-12 yrs	3	1	4	10%
12-16 yrs	2	0	2	5%

Among all 52.5% of patients suffer from the disease since 4-8 yrs.

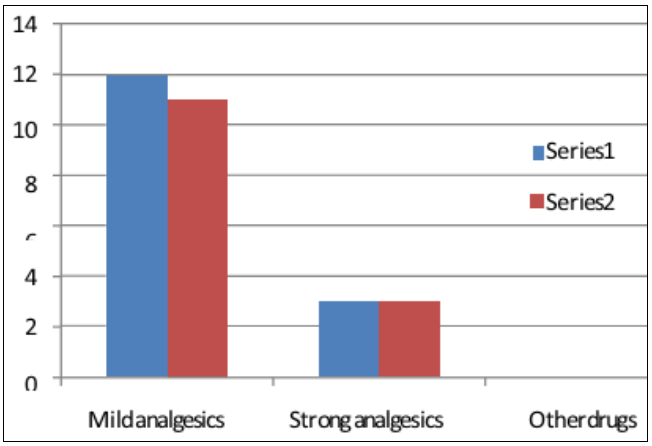


Graph 2: Duration of chief complaint wise distribution

Table 11: Usage of drugs wise distribution:

Drugs	Number of patients		Total	%
	Group-A	Group-B		
Mild analgesics	12	11	23	57.5%
Strong analgesics	3	3	6	15%
Other drugs	0	0	0	0%

57.5% of total patients used mild analgesics and 15% strong analgesics before starting the treatment.

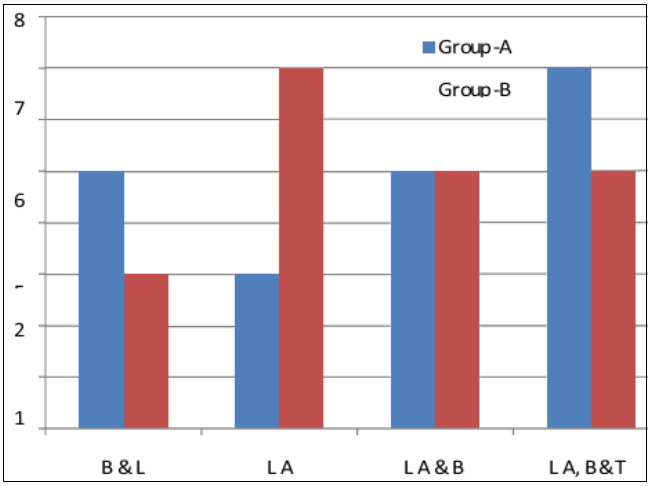


Graph 3: Usage of drugs wise distribution

Table 12: Area of pain wise distribution

Area of pain	Number of Patients		Total	%
	Group -A	Group -B		
B & L	5	3	8	20
L A	3	7	10	25
L A & B	5	5	10	25
L A, B & T	7	5	12	30

30% of the cases had pain in Lower abdomen, back & thigh; 25% each had lower abdomen and Lower abdomen & back; only 20% of them had pain in Back & Legs.



Graph 4: Area of pain wise distribution

Results

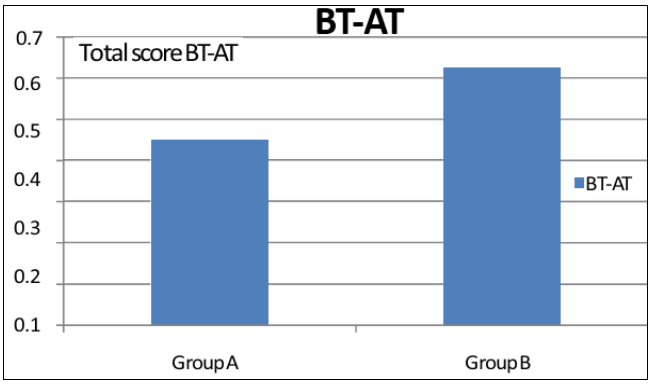
To know the overall effect of the drugs in Dysmenorrhea, the total score based on observation is calculated and subjected to students paired t-test.

Two values are taken in to consideration. One is difference between values before treatment (BT) and after treatment (AT). Second one is difference between values before treatment (BT) and after follow up (AF).

Table 13: Effect of drugs on Dysmenorrhea:

Sl. No.	Groups	Mean Scores						
		B.T	A.T	BT-AT	SD	Degrees of freedom	't' value	'p' value
1.	Group A	1.763	1.313	0.450	0.071	3	12.728	0.001
2.	Group B	1.775	1.150	0.625	0.185	3	6.763	0.007

Both the drugs have proved that they are very effective in treating Dysmenorrhoea. The overall condition of the patient has improved significantly with Kanya lohadi vati as well as Boladi vati.



Graph 5: Effect of drugs on Dysmenorrhea

Table 14: Effect of drugs on on comparison

BT-AT Group A	BT-AT Group B	Degrees of freedom	't' value	'p' value
0.450	0.625	6	1.769	0.127

There is no significant difference between action of Kanya lohadi vati and Boladi vati in Dysmenorrhoea, but Kanya lohadi vati is little superior when the mean values between different groups are compared.

Table 15: Effect of drugs after follow up-

Sl. No.	Groups	Mean Scores						
		B.T	A.F	BT-AF	SD	Degrees of freedom	't' value	'p' value
1.	Group A	1.763	0.963	0.80	0.204	3	7.838	0.004
2.	Group B	1.775	0.813	0.962	0.189	3	10.199	0.002

Both of them had shown significant effect after follow up also, which is slightly better than the effect after treatment.

Table 16: Effect of drugs on comparison after follow up

BT-AF Group A	BT-AF Group B	Degrees of freedom	't' value	'p' value
0.80	0.962	6	1.169	0.287

Both the drugs are almost equally effective statistically, after follow up treatment. But Kanyalohadi vati is superior to Boladi vati in effectiveness on Dysmenorrhea in overall observation when the mean values are compared.

Table 17: Comparison of Action of individual drugs on - Activities

BT-AT Group A	BT-AT Group B	Degrees of freedom	't' value	'p' value
0.950	0.700	38	1.344	0.187

Even if not statistically significant, Kanyalohadi vati had better action on correction of daily routines in comparison to Boladi vati when mean values are taken in to consideration.

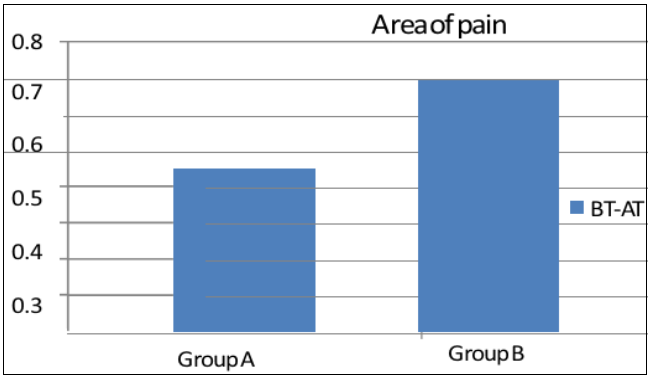
Table 18: Comparison of Action of individual drugs on - Activities

BT-AF Group A	BT-AF Group B	Degrees of freedom	't' value	'p' value
0.950	1.150	38	1.061	0.295

There is not a statistically significant difference between the input groups. The drugs showed a sustained effect after follow up, Kanyalohadi vati being more effective on comparison of means.

Table 19: Action of individual drugs on Area of pain-

Sl. No.	Groups	Mean Scores						
		B.T	A.T	BT-AT	SD	Degrees of freedom	't' value	'p' value
1.	Group A	2.20	1.75	0.450	0.605	19	3.327	$p>0.001$
2.	Group B	2.00	1.30	0.700	0.571	19	5.480	$p<0.001$



Graph 6: Action of individual drugs on Area of pain

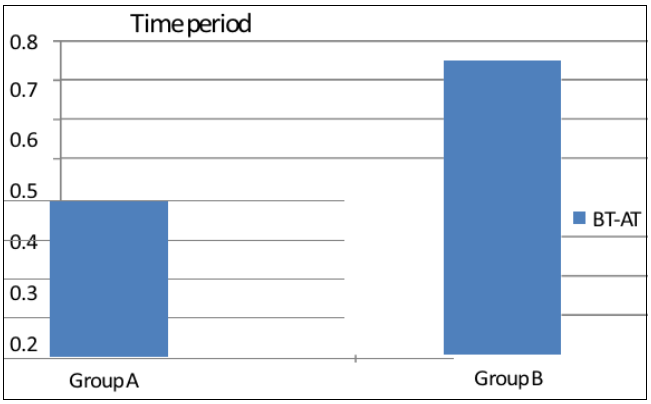
Table 20: Comparison of Action of individual drugs on Area of pain.

BT-AT Group A	BT-AT Group B	Degrees of freedom	't' value	'p' value
0.450	1.00	38	2.463	*p*>0.001

Kanyalohadi vati is more effective when compared with Boladi vati in case of area of menstrual pain.

Table 21: Effect of drugs on Time period -

Sl. No.	Groups	Mean Scores						
		B.T	A.T	BT-AT	SD	Degrees of freedom	't' value	'p' value
1.	Group A	1.95	1.55	0.40	0.686	19	3.559	*p*>0.001
2.	Group B	2.05	1.30	0.75	0.550	19	6.097	*p*<0.001

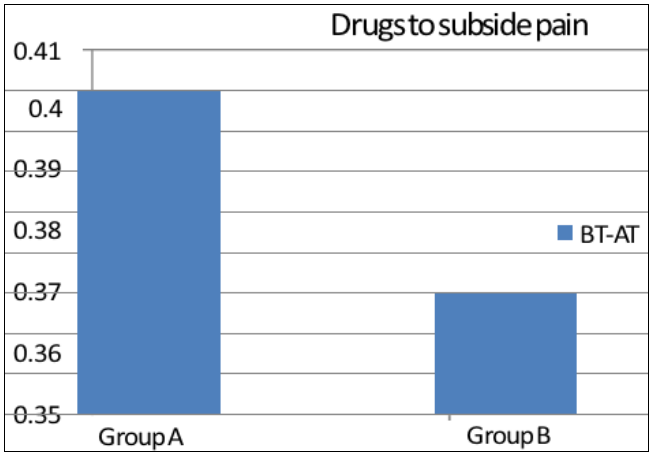


Graph 7: Effect of drugs on Time period

Effects of both the drugs are highly significant on time duration of pain.

Table 22: Effect on Drugs to subside pain:

Sl. No.	Groups	Mean Scores						
		B.T	A.T	BT-AT	SD	Degrees of freedom	't' value	'p' value
1.	Group A	0.85	0.45	0.40	0.503	19	3.559	*p*>0.001
2.	Group B	0.90	0.55	0.35	0.489	19	3.199	*p*>0.001



Graph 8: Effect on Drugs to subside pain

Both the drugs could reduce usage of pain killers or other medicines for pain.

Table 23: Comparison of effect on Drugs to subside pain

BT-AT Group A	BT-AT Group B	Degrees of freedom	't' value	'p' value
0.40	0.35	38	0.319	0.752

Boladi vati appears to be of little higher activity when means are compared. But there is no significant difference between the groups.

Physico-chemical Parameters

Parameters	Boladi vati	Kanyalohadi vati
Moisture Contents	0.02%	0.00%
Total Ash	17.55%	19.34%
Acid Insoluble Ash	2.34%	2.45%
Water Soluble Ash	5.24%	4.80%
Water Soluble Extractives	34.90%	31.80%
Alcohol Soluble Extractives	8.80%	5.70%
Hardness test:	6 N	10 N
Disintegration time (with distilled water) 28 minutes		52 minutes
Friability test	0.86%	1.7%

Qualitative test

	Boladi Vati	Kanyalohadi Vati
Carbohydrate	+++	++
Protein	-	-
Alkaloid	+	-
Cadiac glycoside	+	++
Flavonoid	++++	+
Tannin	++++	++++
Anthraquinone glycoside	+	-
Steroide	+++	++
Triterpinoides	++	-

Quantitative Estimation

	Boladi Vati	Kanyalohadi Vati
Total iron	4.5%	8.8%
Ferric:	1.8%	5.8%
Ferrous:	2.7%	3%
Total sulphur:	8.2%	10.9%

Thin Layer Chromatography
Solvent System: Toluene: Ethyl Acetate: 4: 1
Spraying Agent: Anisaldehyde Sulphuric Acid

Kanyalohadi vati (Before spray)

Table 24: TLC of Kanyalohadi vati (Before spray)

Sl. No.	Rf	U V Light	Visible Light
1	0.04	Yellow	
2	0.08	Fluorescent blue	
3	0.12	Pale orange	
4	0.24	Pale green	
5	0.40	Pale yellow	
6	0.58	Pale Fluorescent green	
7	0.64	Pale blue	

Kanyalohadi vati (After spray)

Table 25: TLC of Kanyalohadi vati (After spray)

Sl. No.	Rf	U V Light	Visible Light
1	0.04	Purple violet	Dark gray
2	0.12	Pale purple	Gray
3	0.64	Pale purple	Creamish gray

Boladi vati (Before spray)

Table 26: TLC of Boladi vati (Before spray)

Sl. No.	Rf	U V Light	Visible Light
1	0.04	Bright Fluorescent Yellow	
2	0.08	Bright Fluorescent blue	
3	0.18	Pale blue	Pale yellow
4	0.28	Pale yellow	
5	0.44	Pale blue	

Boladi vati (After spray)

Table 27: TLC of Boladi vati (After spray)

Sl. No.	Rf	U V Light	Visible Light
1	0.04	Purple violet	Gray
2	0.28		Pale creamish gray

Discussion on analytical study
The prepared Boladi and Kanyalohadi vati were tested on parameters of tablet, proved itself as 0.86% and 1.7% loss in friability test; the average hardness were 6 N and 10 N, disintegration with 28 minutes and 52 minutes respectively.
Based on observation during study:

Family history
57.5% of the cases have positive Family history, which shows that majority of subjects have significant genetic cause for Dysmenorrhea.

Duration of complaint
While Dysmenorrhea is less common during the first 2-3 years after menarche, when most of the menstrual cycles are anovulatory, it becomes more prevalent during mid and late adolescence, with the establishment of ovulatory menstrual cycles. More number of patients (52.5%) & age of patients more than 20 have a history of pain for the duration of 4-8 yrs. This may be due to apprehensive & partial knowledge of physiological response of genitourinary system.

Drugs on subside
Since severity of pain taken into trial 57.5% of patients was dependent on analgesics for relief from pain this signifies the extent of morbidity cause due to dysmenorrhoea. This also shows the dire need for alternative medicine in the field concerned.

Duration
Majority of patients have normal range of menstruation (3-6days) indicating that duration of menses probably does not alter in Dysmenorrhea.

Site of pain
Majority (30%) of the patients having pain in Lower abdomen, back and thigh region which is the prime symptom of Dysmenorrhea. It probably indicates the origin of pain which corresponds to anatomical structure of uterus and its appendages. 9, 12, 13 In Primary dysmenorrhoea, it is thought that the muscles of the uterus (womb) squeeze and contract harder than normal to dislodge the thickened lining of endometrium. These contractions might also reduce blood flow to the uterus, making the pain worse[15/16]

Discussion on Result
On analysis of the reduction in the signs and symptoms of the Dysmenorrhea of all the two groups, it can be inferred that Boladi vati (Group A) and Kanyalohadi vati (Group B) were highly effective.
In all the four factors considered here, Kanyalohadi vati is better in improving the ‘daily routine activities’, ‘Area of pain’ and ‘Time period’. Only with ‘Drug to subside’ Boladi vati shows a better result.
As pain is the cardinal symptom of Dysmenorrhea which is going to hamper the daily activities of the women, the Group B showed significant reduction in the pain and activities were improved which can be inferred that among two groups, Group B is highly effective in treating Dysmenorrhea. During follow up it was found that Group B was effective in reducing the intensity of pain and recurrence of the signs and symptoms of Dysmenorrhea.

Probable mode of drug action
Majority of the drugs have Laghu, Ruksha, Tikshna gunas, Ushna Virya and Katu Vipaka acts on Ama and reduces Kapha. Snigdha guna of Hingu & Shunthi acts as vata hara and Ushna Virya acts as both Deepana and Pachana. Both Hingu & Bola possess Vedana sthapana property.
By the Anulomana action of Trivrut, Hingu & Ela; the morbid Vata is going to be corrected and brought back to the normal state. Once Vata attains normal condition the pain is going to be subsided in the Dysmenorrhea Both Tankana & Khaseesa have the property of subsiding kapha & vata, resulting in the samprapti vighatana of Kashtartava.
Garbha sravaka property of Kumari helps in the easy evacuation of the Artava there by reducing the pain. Upalepa of the srotas is removed by Lekhana property along with the sara guna of Loha Artava flows out very easily.

Conclusion

The present clinical study entitled "A comparative pharmaceutico-clinical evaluation of Boladi vati and Kanyalohadi vati w.s.r. to Kashtartava" was undertaken to evaluate the efficacy and safety of the trial drugs.

Both the trial groups were significant in treating Primary Dysmenorrhoea. Group-B showed better result in improving the daily routine activities, in reducing the Area of pain, Time period of pain in comparison to group-A. Group-A showed better results in improving 'drugs to subside pain' parameter. Both the groups showed better result after treatment and after follow-up. There is no any notable harmful effect found during the study, hence they can be considered as a safer remedy for Kashtartava.

The further scope of the Study should be carried out in larger number of samples, as the disease is much influenced by psychological factors. The mode of action, rate and site of absorption can be studied. The pharmaceutical standardization of the formulation can be concentrated. Studies can be conducted along with the combination of other drugs for getting better results.

Conflict of Interest

Not available

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