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A RANDOMIZED CONTROLLED TRIAL TO STUDY THE EFFECT OF BILWADI CHURNA IN THE MANAGEMENT OF UDAVARTINI YONIVYAPADA WITH SPECIAL REFERENCE TO PRIMARY DYSMENORRHEA

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ABSTRACT

Dysmenorrhea or painful menstruation condition is experienced by majority of adolescent girls with an estimate prevalence 70.2%. it is leading cause of absentism from school & colleges in young girls. Today's stressful life, lack of physical activity, junk food, lack of proper sleep all these are increasing the incidence of dysmenorrhea. According to Ayurveda primary dysmenorrhea may be correlated with Udavartini Yonivyapad. In Udavartini Yonivyapad there is Apanvata Dushti leading to painful menstruation. Thus, the treatment is Vatahara & Vatanulomana. For the present study total 82 patients were selected which were divided into 2 groups- Group A (Trial)- Bilwadi Churna and Group B (Control)- Hingawastaka Churna. The treatment for given from 1st day till 7th day of menstruation for 3 consecutive menstrual cycles. After the completion of clinical trial, it is found that Bilwadi Churna is more effective, well tolerated as compared to Hingwastaka Churna.

KEYWORDS: Dysmenorrhea, Udarvatini Yonivyapad, Bilwadi Churna, Hingwastaka Churna.

INTRODUCTION

In Ayurvedic samhita it is mentioned that the Reproductive period starts from Rajapravrutti (12 years) and ends at Rajo nivrutti (50 years).[1] Menstruation is one of the physiological processes which denotes the healthy state of female reproductive system in the reproductive phase. In Ayurvedic classics all gynecological problems are described under the broad caption of Yonivyapada.[2] Udavartini Yonivyapada, is one of the common gynecological problems. It can be correlated with primary dysmenorrhea in modern science.[3] Dysmenorrhea is defined as painful menstruation of sufficient magnitude to incapacitate day to day activities. [4] Every month majority of women experience various symptoms related to their menstrual cycles amongst them the most common symptom is dysmenorrhea. The prevalence of primary dysmenorrhea in India is 70.2%. [5] It is becoming the leading cause of absentism of young girls from school & colleges.[6]

According to modern medical science, dysmenorrhea is generally treated by OCPs, NSAID'S, antispasmodics, analgesics etc, but long term use of this medicine can cause various side effects.

Hence there is need of Ayurveda which treats the disease from the root cause and brings qualitative life. According to Ayurveda, there is Apanavata Dusti in Udavartini Yonivyapada which leads to painful menstruation. In Ayurveda the line of treatment of Udavartini Yonivyapada is vatahara & vatanulomana. In present research work to achive anuloma in the patients of udavartini yonivyapada 'bilwadi churna'[7] is mentioned in Vangasen Samhita is choosen. All the contents of the drug are easily available, affordable, as well as safe and has shoolprashamana and vatanulomana properties. Bilwadi churna is the one on which there is no studies are done till date while reviewing the literature hence, research work is needed to find out the effect of bilwadi churna in udavartini yonivyapada this drug is selected for the study.

AIMS AND OBJECTIVES

To Study the effect of Bilwadi Churna in the management of Udavartini Yonivyapada with special reference to Primary Dysmenorrhea with the help of subjective criteria after the treatment of 3 consecutive menstrual cycle.

MATERIALS AND METHOD

1) **Type of study-** Randomized control trial (RCT)
2) **Study setting**

- Location of Study- OPD of Prasuti tantra and streeroga Department of SMBT Ayurved College & Hospital, Nashik.
- Duration of Entire study – 18 Months.
- Duration of Treatment – 3 Consecutive Menstrual Cycle

3) **Study population -** For Present Study 82 Patients fulfilling Inclusive criteria of Udavartini Yonivyapada.

- Sampling technique – Simple Randomized Sampling Method by computerized Random Technique.

Method of selection of patients

- **Inclusive criteria**

1) Patients suffering from udavartini yonivyapada for more than 2 consecutive menstrual cycle
2) Patients of age between 16 to 30 years.
3) Patients having Regular menstrual cycle.

- **Exclusion criteria**

1) Patients with systemic diseases.
2) Patients taking contraceptive pills, hormonal therapy.
3) Patients with IUCD.
4) Patients with, Menorrhagia, pelvic pathology like endometriosis, pelvic inflammatory diseases, fibroid, PCOS etc.

- **Withdrwal criteria**

1) If any adverse effect of drug arises on patient.
2) Patient not completing the duration of treatment.
3) Patient who wants to discontinue the treatment.

Treatment details

	Group a	Group b
Type	Trial	Control
No. of patients	41	41

Drug	Bilwadi churna	Hingawastaka churna [8]
Dose	6 gm BD	6 gm BD
Route of administration	Oral	Oral
Time of administration	Prabhakta	Prabhakta
Anupana	Koshna jala	Ghrit
Treatment of duration	3 consecutive menstrual cycles	3 consecutive menstrual cycles
Observation	0th &7th day of 1st, 2nd, 3rd menstrual cycle	0th &7th day of 1st, 2nd, 3rd menstrual cycle
Follow up	7th day of menstrual period for 3 consecutive cycles	7th day of menstrual period for 3 consecutive cycles

Assessment criteria

Assessment was done with the help of subjective parameters based on before and after study.

- **Subjective criteria**

1. **Pain intensity**

Pain Intensity	**Grade**
Absent	0
Mild (Pain do not interfere with daily activities)	1
Moderate (Daily activity hampers, relives with analgesics)	2
Severe (Do not relived by analgesics)	3

2. **Duration of pain**

Duration of pain	**Grade**
Absent	0
Pain for few hours	1
Pain for one whole day	2
Pain for greater than or equal to two days	3

3. **Amount of menstrual flow**

Amount	**Pad**	**Grade**
Spotting	<1 pad/day	0
Scanty menses	1 pad/day	1
Normal	2-3 pads/day	2
Excessive	>3 pads/day	3

4. **Nausea**

Nausea	**Grade**
Absent during menses	0
Present during menses	1

Visual Analog Scale (VAS)

0	1	2	3	4	5	6	7	8	9	10

No pain worst pain

Suprapubic Pain – [VAS scale is used for Grading]

Pain	VAS scale	Grade
No pain	0 cm	0
Mild pain	1-3 cm	1
Moderate pain	4-6 cm	2
Severe pain	7-10 cm	3

5. Lumbosacral Pain – [VAS scale is used for grading]

Pain	VAS scale	Grade
No pain	0 cm	0
Mild pain	1-3 cm	1
Moderate pain	4-6 cm	2
Severe pain	7-10 cm	3

Stastistical analysis

- Wilcoxon Singed Rank test & Mann Whitney's U test for statistical analysis within Group A and Group B.

OBSERVATIONS AND RESULTS

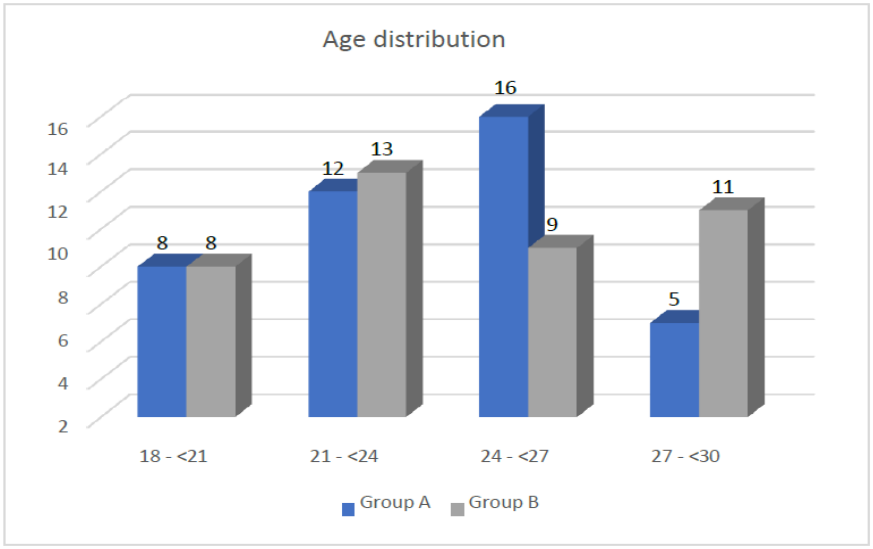
The present study was carried out in total 82 patients in two group as comparative study. The following observations were during the course of present clinical study.

1) Distribution of patients

In the present study, 41 no. of patient's were included Group A and 41 no. of patient's were included Group B.

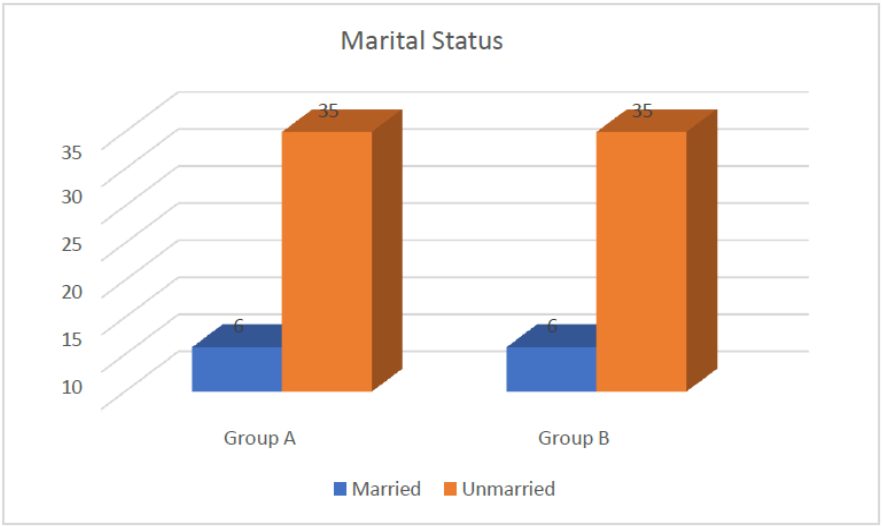
2) Age distribution

Age	No. of patients				Total
	Group A	%	Group B	%	
18 - <21	8	19.51%	8	19.51%	16
21 - <24	12	29.27%	13	31.71%	25
24 - <27	16	39.02%	9	21.95%	25
27 - <30	5	12.20%	11	26.83%	16
TOTAL	41	100.00%	41	100.00%	82



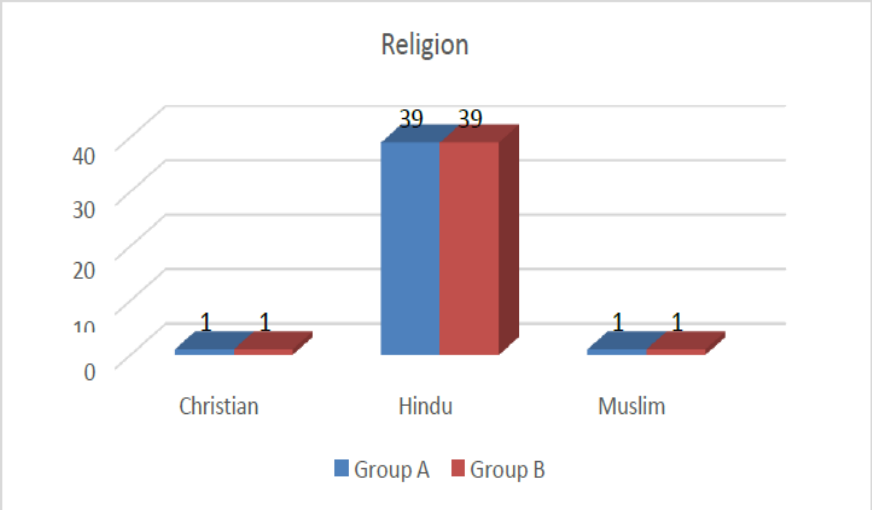
3) Marital status

Marital Status	No. of patients				Total
	Group A	%	Group B	%	
Married	6	14.63%	6	14.63%	12
Unmarried	35	85.37%	35	85.37%	70
Total	41	100.00%	41	100.00%	82



4) Religion

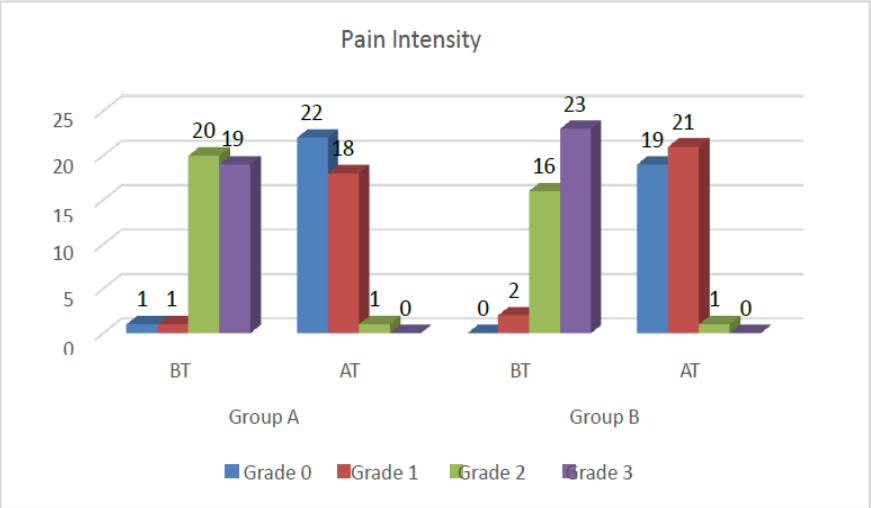
Maximum number of patients Hindu by religion in both the groups



Changes in Subjective Parameters Before and After treatment

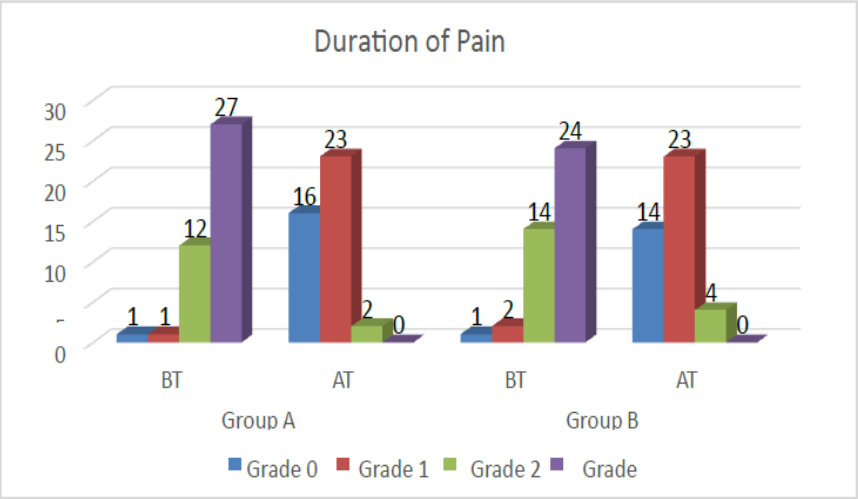
1) Pain intensity

Pain intensity	Group A		Group B	
	BT	AT	BT	AT
Grade 0	1	22	0	19
Grade 1	1	18	2	21
Grade 2	20	1	16	1
Grade 3	19	0	23	0
Total	41	41	41	41



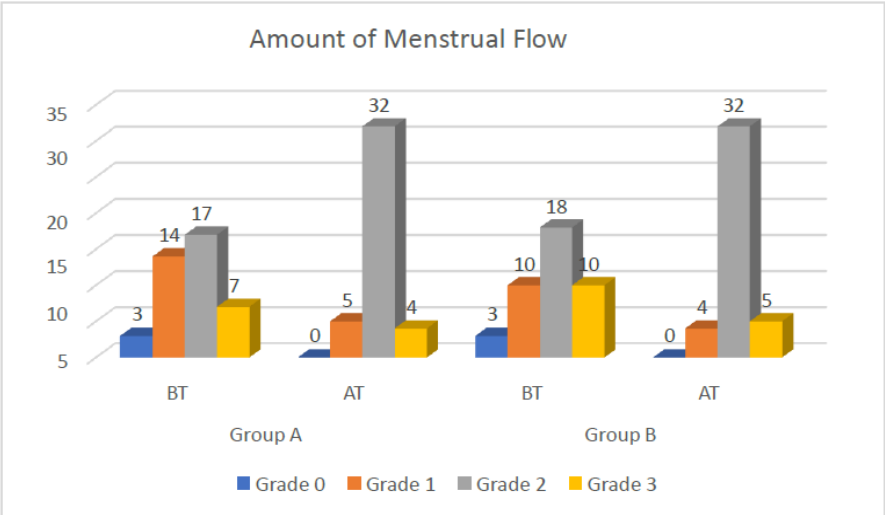
2) Duration of pain

Duration of Pain	Group A		Group B	
	BT	AT	BT	AT
Grade 0	1	16	1	14
Grade 1	1	23	2	23
Grade 2	12	2	14	4
Grade 3	27	0	24	0
Total	41	41	41	41



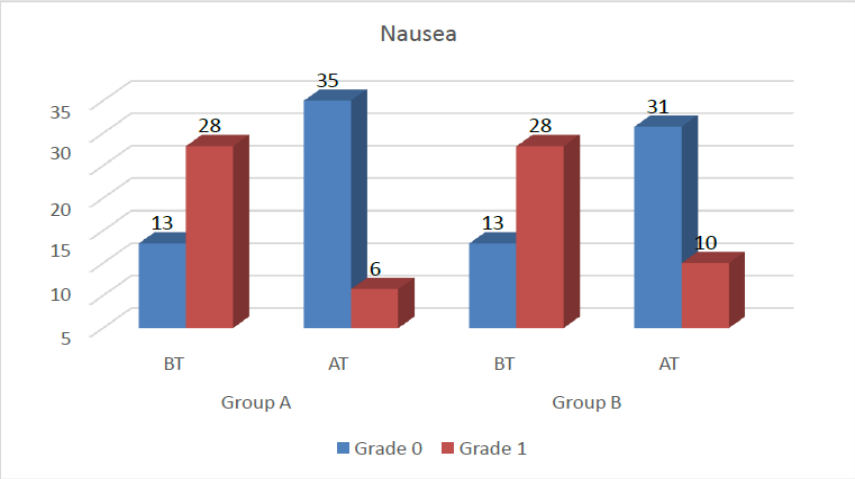
3) Amount of menstrual flow

Amount of Menstrual Flow	Group A		Group B	
	BT	AT	BT	AT
Grade 0	3	0	3	0
Grade 1	14	5	10	4
Grade 2	17	32	18	32
Grade 3	7	4	10	5
TOTAL	41	41	41	41



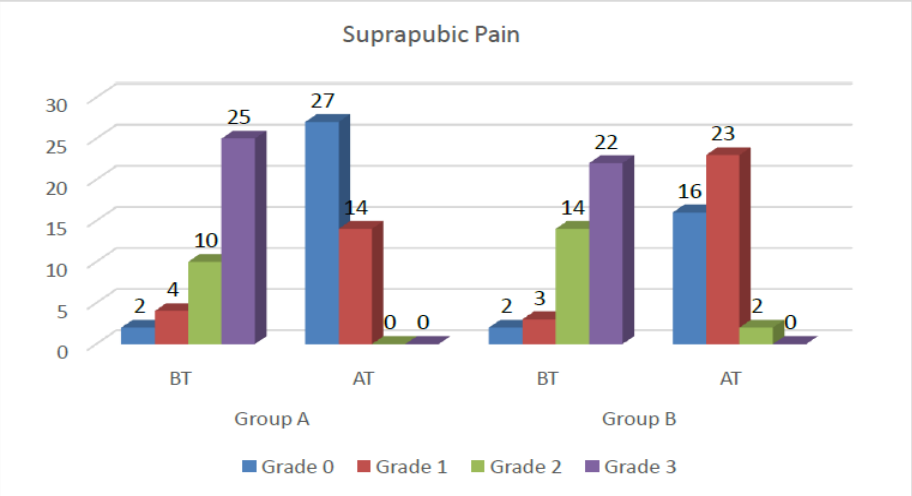
4) Nausea

Nausea	Group A		Group B	
	BT	AT	BT	AT
Grade 0	13	35	13	31
Grade 1	28	6	28	10
Total	41	41	41	41



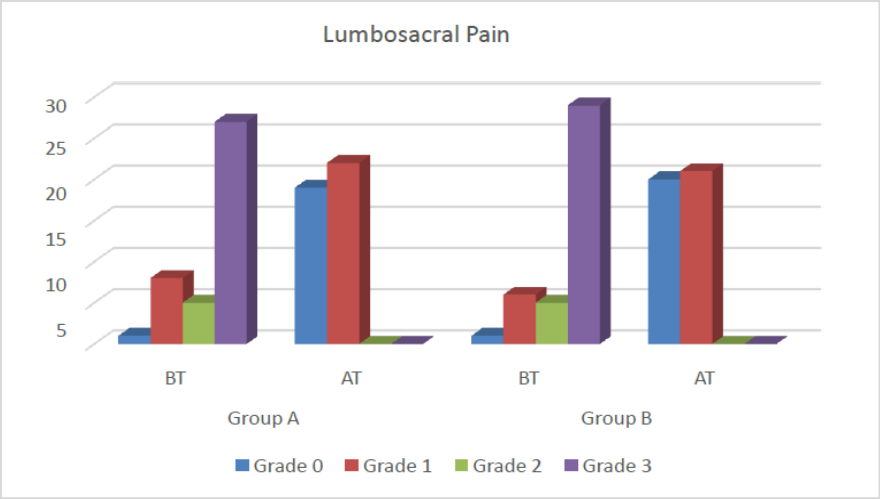
5) Suprapubic pain

Suprapubic Pain	Group A		Group B	
	BT	AT	BT	AT
Grade 0	2	27	2	16
Grade 1	4	14	3	23
Grade 2	10	0	14	2
Grade 3	25	0	22	0
Total	41	41	41	41



6) Lumbosacral pain

Lumbosacral Pain	Group A		Group B	
	BT	AT	BT	AT
Grade 0	1	20	1	19
Grade 1	6	21	8	22
Grade 2	5	0	5	0
Grade 3	29	0	27	0
Total	41	41	41	41



Statistical Analysis subjective parameters (By Wilcoxon Singed Rank Test)

1. **Null Hypothesis H0:-** There is no significant difference between median ranks of score before treatment and after treatment. That is "treatment is not effective"
2. **Alternative Hypothesis H1:-** There is significant difference between median ranks of score before treatment and after treatment. That is "treatment is effective"

1) Pain Intensity

Group	BT/AT	Mean	SD	Median	W-Wilcoxon statistics	P-value
Group A	BT	2.39	0.666	2	5.817	< 0.001
	AT	0.49	0.553	0		
Group B	BT	2.51	0.597	3	5.749	< 0.001
	AT	0.56	0.55	1		

2) Duration of pain

Group	BT/AT	Mean	SD	Median	W-Wilcoxon test statistics	P-value
Group A	BT	2.59	0.67	3	5.523	< 0.001
	AT	0.66	0.575	1		
Group B	BT	2.49	0.711	3	5.454	< 0.001
	AT	0.76	0.624	1		

3) Amount of menstrual flow

Group	BT/AT	Mean	SD	Median	W-Wilcoxon test statistics	P-value
Group A	BT	1.98	0.851	2	4.604	< 0.001
	AT	1.07	0.648	1		
Group B	BT	1.95	0.74	2	4.786	< 0.001
	AT	1.12	0.678	1		

4) Nausea

Group	BT/AT	Mean	SD	Median	W-Wilcoxon test statistics	P-value
Group A	BT	0.68	0.471	1	4.69	< 0.001
	AT	0.15	0.358	0		
Group B	BT	0.68	0.471	1	4.243	< 0.001
	AT	0.24	0.435	0		

5) Suprapubic pain

Group	BT/AT	Mean	SD	Median	W-Wilcoxon test statistics	P-value
	BT	2.41	0.865	3		
Group A	AT	0.34	0.48	0	5.344	< 0.001
Group B	BT	2.37	0.829	3	5.333	< 0.001
	AT	0.66	0.575	1		

6) Lumbosacral pain

Group	BT/AT	Mean	SD	Median	W-Wilcoxon test statistics	P-value
Group A	BT	2.41	0.894	3	5.328	< 0.001
	AT	0.54	0.505	1		
Group B	BT	2.51	0.84	3	5.235	< 0.001
	AT	0.51	0.506	1		

Statistical Analysis in between the Group A and Group B Subjective Parameters (BY Mann Whitney's U Test)

Symptom	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U Statistics	P-Value
Pain Intensity	A	41	31.55	1720	822	0.8644
	B	41	33.45	1683		
Duration of Pain	A	41	31.83	1600	739	0.3457
	B	41	33.17	1803		
Amount of Menstrual Flow	A	41	35.5	1664.5	803.5	0.7327
	B	41	29.5	1738.5		
Nausea	A	41	34.66	1619.5	758.5	0.4419
	B	41	30.34	1783.5		
Suprapubic Pain	A	41	34.47	1501.5	640.5	0.627

	B	41	30.53	1901.5		
Lumbosacral Pain	A	41	33.05	1781	761	0.4603
	B	41	31.95	1622		

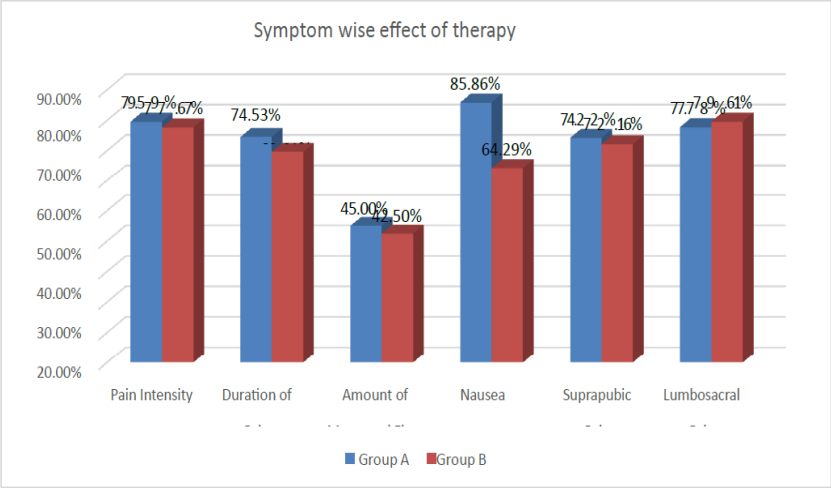
For comparison between Group A and Group B, we have used Mann Whitney U test. From above table we can observe that P-Value is greater than 0.05 hence we conclude that there is no significant difference in effect of Group A and Group B. Treatment is equally effective in both groups for all the symptoms but the percentage relief in group A is more than group B for all the symptoms.

Effect of therapy according to % relief in symptoms -Group A

Sr. No.	Symptom (Group A)	BT	AT	Relieved	% Relief
1	Pain Intensity	98	20	78	79.59%
2	Duration of Pain	106	27	79	74.53%
3	Amount of Menstrual Flow	35	64	29	45.00%
4	Nausea	99	14	85	85.86%
5	Suprapubic Pain	97	25	72	74.22%
6	Lumbosacral Pain	99	22	77	77.78%

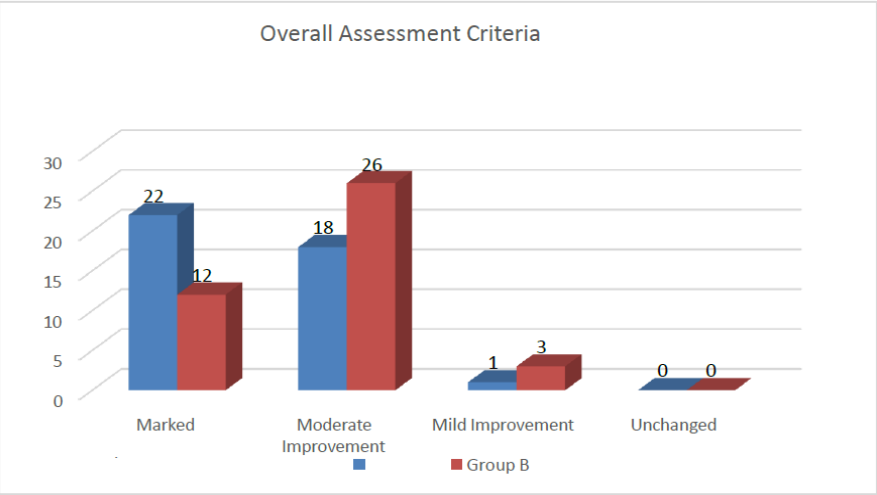
Effect of therapy according to % relief in symptoms -Group B

Sr. No.	Symptom (Group B)	BT	AT	Relieved	% Relief
1	Pain Intensity	103	23	80	77.67%
2	Duration of Pain	102	31	71	69.61%
3	Amount of Menstrual Flow	80	46	34	42.50%
4	Nausea	28	10	18	64.29%
5	Suprapubic Pain	97	27	70	72.16%
6	Lumbosacral Pain	103	21	82	79.61%



Overall Assessment criteria

Relief of symptoms	Percentage	Group A	Group B
Marked Improvement	Above 75% relief	22	12
Moderate Improvement	50% <75% relief	18	26
Mild Improvement	25% <50% relief	01	3
Unchanged	< 25% relief	00	0



DISCUSSION

In the classics of Ayurveda painful menstruation is the symptom in Udavartini yonivyapada, Charaka while describing the features of Udavartini says that "arthave sa vimukthe tu tat kshanam labhate sukham". which implies an immediate relief of pain following the discharge of menstrual blood, which clearly denotes spasmodic type of dysmenorrhoea. Vata is responsible for the pain. According to Acharyas no yonivypada occurs without involvement of vata dosha. For production of Artava, Vyan Vayu and Apana vata work in co-ordination with each other. Contraction and Relaxation of uterus and its related organ is the function of Vyan vayu. Vyan vayu has control over the muscles which bring about the actions such as contraction, relaxation after which Artava is expelled out by Anulomana kriya of Apana vayu.

Vegodavarthana leading to Pratiloma gati of Apana vata and Rajas is the pathology behind Udavartha yonivyapath. The aim of management is to bring balance of vitiated Doshas, especially Apana Vayu through Agnideepaka (Improving appetite), Grahi (Controlling of excessive outflow), Vata anulomana (Normalizing any type of abnormal flow) and Pakvashaya Shuddhikara (Purification of large intestine) methods.

According to modern aspect, during a women's menstrual cycle, the endometrium thickens for preparation for pregnancy. But, if after ovulation, ovum is not fertilized and there is no pregnancy and thus the thickened endometrium sheds. Prostaglandins are released during menstruation due to the destruction of the endometrial cells. Release of prostaglandins and other inflammatory mediators in the uterus cause the uterus to contract. These substances are thought to be a major factor in primary dysmenorrhea. When the uterine muscles contract, they constrict the blood supply to the tissue of the endometrium, which in turn, breaks down and dies. These uterine contractions continue as they squeeze the old, dead endometrial tissue through the cervix and out of the body through the vagina. These contractions and the resulting oxygen deprivation to nearby tissues are responsible for the pain or cramps experienced during menstruation.

Almost all the contents of Bilwadi churna have Antiprostaglandin, Spasmolytic, Analgesic, Antioxidant Activity. Due to antiprostagladin activity there is inhibition cyclooxygenase & Lipooxygenase pathways which leads to inhibition of prostaglandin synthesis and thus pain is relieved. Due to antioxidant property there is production of Inreactive oxygen free radical which relieves pain. According to Ayurveda, most of contents of Bilwadi Churna are Katu Rasa, Katu Vipaka and Ushna Virya which leads to Vatakaphahara and removes Srotorodha which pacifies Vata Dosha. As Vata Dosha is pacified it leads to Vatanulomana thus reducing Yonivedana.

Study shows maximum patients of primary dysmenorrhea are between age group 21-27 years due to their food habits including junk foods and sedentary lifestyle. Maximum number of patients in both the group were unmarried. Due to anti spasmodic, analgesic and vatanulomana properties of bilwadi churna Group A is more effective than Group B i.e The mean % of relief of Pain Intensity in group A is 79.59% and in group B it is 77.67%. The mean % of relief of Duration of Pain in group A is 74.53% and in group B it is 69.61%. It was found that amount of menstrual flow is more increase in Group A i.e 45% than in Group B i.e 42.50%. The mean % of relief of Nausea in group A is 85.86% and in group B it is 64.29%. The mean % of relief of Suprapubic Pain in group A is 74.22% and in group B it is 72.16%. The mean % of relief of Lumbosacral Pain in group A is 77.78% and in group B it is 79.61%. Based on Assessment criteria, the percentage relived in Trial Group is 74% and control group is 69%. Bilwadi churna is more effective in patients having nausea and pain. As it has anti emetic, antispasmodic, antiprostaglandin activity. Due to its deepan pachana properties it

reduces nausea and increases appetite.

CONCLUSION

The present clinical study clearly indicates that the Bilwadi churna is more effective, well tolerated and clinically safe formulation for management of udavartini yonivyapada.

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