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A clinical study to evaluate the efficacy of *Phala Taila Matra Basti* in *Kashtartava* w.s.r. to Primary Dysmenorrhoea

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ABSTRACT

Background: Female health is a primary factor to be considered for the wellbeing and productivity of both family and society. Her menstrual health has a great impact on her educational, social and economic progress. Although dysmenorrhea is not life threatening, it is found to have a profound impact on daily activities resulting in absenteeism.[1] Primary dysmenorrhea prevalence estimates range from 25% to 90% among women and adolescents Studies from India reported the prevalence range between 50% to 87.8% During menstruation, many women experience gastrointestinal upsets which are increased by analgesics and anti-inflammatory drugs, which also cause headache, dizziness, drowsiness and blurred vision. The drugs in this *Taila* are *Vatakaphahara*, *Shoolahara, Udararogahara, Srotovishodana, Garbhashaya Shodana, Balya.* Due to these properties, it helps in reducing symptom of *Kashtartava. Basti* (therapeutic enema) is the ideal treatment option for disorders of *Vata*. *Phala Taila*[2] is a preparation mentioned in *Kashyapa Samhita* for management of aggravated *Vata* in *Prusta* (back of the body), *Uru* (hip), and *Janga Pradesha* (calf muscle). **Aim:** To analyse the effect of *Phala Taila Matra Basti* in the management of *Kashtartava* w.s.r to Primary Dysmenorrhoea. **Method:** "A Randomized controlled clinical study to evaluate the efficacy of *Phala Taila Matrabasti* in *Kashtartava* w.s.r to Primary Dysmenorrhoea." **Result:** Taking all subjective and objective parameter into consideration especially with effect size comparison clearly shows that Group B is much better with respect to most of the parameter in providing clinical relief. **Conclusion:** *Dashamoola Ksheera Yoga Basti* is more effective than *Phala Taila Matra Basti in* the management of *Kashartava* w.s.r. to Primary Dysmenorrhoea.

Key words: *Kashtartava, Primary Dysmenorrhoea, Matra Basti, Yoga Basti.*

INTRODUCTION

Primary Dysmenorrhoea is a condition characterized by severe lower abdominal pain during menstruation associated with other complaints like nausea, vomiting, diarrhea, headache, fatigue. Dysmenorrhoea affects 50% of menstruating women and is found to have a profound impact on the daily activities and may result in absenteeism from work or school. Thereby, it may accentuate the emotional distress brought on by pain. Prevalence of dysmenorrhoea in women of the reproductive age group is 70 - 91%, and severe pain contributes to 2 - 29%.[3] Systematic review of studies in developing countries performed by Harlow and Campbell (2002) has revealed that about 25-50% of adult women and about 75% of adolescents experience pain during menstruation, with 05-20% reporting severe dysmenorrhoea. The treatment of this disorder is still unsatisfactory in modern medicine as the usage of antispasmodic and analgesics drugs may cause many side effects like gastro intestinal upset, headache, dizziness, drowsiness and blurred vision. *Kashtartava* is expressed as "*Kashtenmunchyatiti Kashtartavam*"– *Kashtartava* is the condition where the *Artava* is discharged with great difficulty and pain. It has been compared to dysmenorrhoea based on the symptoms. *Dosha -Vata Pradhana Tridosha*; *Dushya - Rasa, Rakta, Artava Sammurchana* takes place in *Garbhashaya* and due to vitiation of *Vyana* and *Apana Vayu* the

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Aakunchana and *Prasarana Kriya* of *Garbhashaya* does not take place properly, this state resembles with the dysrhythmia of uterine muscles, which will hinder in proper flow of menstrual blood leading to *Kashtartava. Basti* is the ideal treatment option for disorders of *Vata*. It is the treatment modality indicated in all types of *Yonivyapad*. *Phala Taila* is a preparation mentioned in *Kashyapa Samhita Khilasthana*[2] in *Bastiviseshenaniya Adhyaya* for management of aggravated *Vata* in *Prusta, Uru, Janga Pradesha* (calf muscle), *Gulma, Mutraghata* (suppression of urine), *Krimikoshta* (abdominal parasites), and in *Basti Vyapad*. Most of the drug in this preparation contains *Vatakaphahara, Shoolahara, Garbhashaya Shodana*, *Balya, Udararogahara* properties. Due to these properties, it helps in reducing symptom of *Kashtartava.* Here in this study an attempt will be made to evaluate the efficacy of *Phala Taila* as *Matra Basti* in management of *Kashtartava* w.s.r to Primary Dysmenorrhoea.

OBJECTIVES

Primary - To evaluate the efficacy of *Phala Taila Matra Basti* in management of *Kashtartava* w.s.r. to Primary Dysmenorrhoea.

Secondary

1. To re-evaluate the efficacy of *Dashamoola Ksheera Basti* in management of *Kashtartava* w.s.r. to Primary Dysmenorrhoea.
2. To compare the efficacy of *Phala Taila Matra Basti* and *Dashamoola Ksheera Yoga Basti* in management of *Kashtartava* w.s.r. to Primary Dysmenorrhoea.
3. To understand *Kashtartava* in *Ayurvedic* classics w.s.r. to Primary Dysmenorrhoea.

MATERIALS AND METHODS

Since the present study was a controlled study two drugs i.e., a standard and the test drug was selected, they are

1. *Dashamoola Ksheera Yoga Basti*
2. *Phala Taila Matra Basti*

Phala Taila Matra Basti[2]

Ingredients - *Laghu Panchamoola, Madanaphala, Yava, Kola, Kulatta, Jala, Kushta, Satapushpa, Vacha, Yashtimadhu, Kutaja, Madana Beeja, Yavani, Pippali, Devadaru, Rasna, Devapushpa, Musta, Harenu, Bilwa, Priyangu , Ela, Tila Taila* and *Dadhi Mastu*. Raw Drug were identified and approved by Dept. *Dravya Guna*. *Phala Taila was* prepared in pharmacy of *Rasashastra* and *Bhaishjya Kalpana* of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru.

Control drug - *Dashamoola Taila* was procured from GMP certified pharmacy. *Dashamoola Kwatha Choorna,* honey was procured from SSCAS&RH, Bengaluru.

Sampling Method and Research Design

Source of data

A series of 30 subjects with were randomly selected, from the OPD and IPD of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru. The selected 30 patients were divided into 2 equal groups of 15 patients. A detailed Proforma was prepared considering all points pertaining to the study was prepared. The parameters considered for the study was scored on the basis of Standard methods and were analyzed statistically.

Research Design

It is an open labelled controlled clinical study with pre and post-test design, where 30 subjects with *Kashtartava* w.s.r. to Primary Dysmenorrhoea were selected for the study.

Diagnostic Criteria

1. Subjects with painful menstruation
2. Subjects with pain over lower abdomen, thigh or lower back during menstruation
3. Subjects with pain that subsides gradually after the onset of menstruation

Inclusion Criteria

1. Subject with age 18 - 30 years.
2. Subjects with regular menstrual cycle.

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3. Subject suffering with *Kashtartava* for more than 2 consecutive cycles
4. Subjects with scanty or average bleeding during menstruation
5. Subject with history of analgesics during previous cycles

Exclusion criteria

1. Subject suffering from Secondary dysmenorrhoea.
2. Subjects with irregular cycles
3. Subjects with abnormal uterine bleeding
4. Subject using IUCD.
5. Subjects who have undergone major abdominal or pelvic surgery
6. Subjects with HIV, HbSAg or VDRL positive
7. Subjects suffering from systemic diseases, thyroid dysfunction
8. *Basti Ayoga*

Lab investigations

- USG
- Hb%
- ESR
- RBS
- Urine R&M

Table 1: Showing intervention of the study

	Group A	Group B
Medicine	*Phala Taila*	*Dashamoola Ksheera*
Mode of administration	*Matrabasti*	*Yogabasti*
Dose	1½ *Pala* (72ml)[4]	*Dashamoola Ksheera Niruha* - 500ml *Dashamoola Taila Anuvasana* - 60ml
Duration of treatment	8 days	8 days
Duration of study	2 Months	2 Months
Follow up	1 assessment – after 1st cycle 2nd assessment – after 2nd cycle	1 assessment – after 1st cycle 2nd assessment – after 2nd cycle

Assessment Criteria

Subjective Criteria

Table 2: Showing Pain Intensity[5]

Grade	Pain Intensity
0	Absent
1	Mild (pain does not interfere with daily activity
2	Moderate (daily activity hampers, relieves with analgesic)
3	Severe (does not get relieved with analgesics)

Nature of pain site of pain

Table 3: Showing nature of Pain

Grade	Nature of Pain
0	Absent
1	Occasionally (mild)
2	Dull (continuous)
3	Spasmodic (cramp like)

Table 4: Showing site of Pain

Grade	Site of Pain (Abdomen, Lowback, Thigh)
0	No pain
1	One site
2	Two site
3	Three site

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Duration of Pain

Table 5: Showing duration of Pain

Grade	Duration
0	No Pain in menstruation
1	Pain continue for 12 hours
2	Pain continue for 12-24 hours
3	Pain continue more than 24 hours

Objective Criteria

- VAS Scale[6]
- Multi- Dimentional Scoring System[7]
- WaLIDD (Working ability, Location, Intensity, Days of pain)[8]
- Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-SF)

OBSERVATION

The present study revealed the presence of *Kashtartava* **Age** - 56.67% belonged to the age group of 22-25. the incidence rate of Primary dysmenorrhoea is predominantly confined to adolescent girls. **Marital Status** - subject 86.6% were Un married Primary dysmenorrhea is more common in un married girls.[9] Marriage may cure by removing the tension of a long engagement and by providing happiness and security, on the other hand if it proves disharmonious, it can cause dysmenorrhoea. **Education and occupation** - 53% were graduation Students are more prone to Primary dysmenorrhoea due to educational stress, strain, and anxiety over examinations, just before and during menstruation most of the women are efficient physically and more unstable emotionally these factor alone lower the pain threshold. **Family history -** 70% had positive Family history. Thus, this suggests that genetic factor is involved in the pathogenesis. **Socio economic status -** Upper middle class (57%). As Textual reference Dysmenorrhoea common in affluent society study population is not sufficient more study is required.

Subjective Parameter

Non-parametric values like Nature of pain, Intensity of pain, and Site of pain, Duration of pain and Associated symptoms were analyzed using:

- Friedman's test within the groups
- Mann Whitney U test between the groups

Objective Parameter

Parametric values like VAS Scale, Multi-dimensional Scoring, WaLIDD, Q-LES-Q-SF were analyzed using:

- Unpaired T Test Between the Groups
- Repeated Period ANOVA Within the Groups

Effect Size Determination

Table 6: Showing effect size determination nature of pain

Assessment of nature of pain		
	AT (After 1st cycle)	FU (After 2nd cycle)
Group A	1.33 ± 0.61	1.66 ±0.97
Group B	0.8 ± 0.56	1.06 ± 0.73
	MD – 0.53 SD pool- 2.26	MD – 0.59 SD pool- 3.32
ESD	0.11 (S)	0.13 (S)

Table 7: Showing effect size

The effect size after treatment observed for Group A in comparison to Group B is 0.11 and for follow up period 0.13 - both these values fall under small effect size difference hence with respect to this parameter the clinical effect observed for Group B is only marginally better in comparison to Group A.

Table 8: Showing determination pain intensity

Assessment of pain intensity		
	AT (After 1st cycle)	FU (After 2nd cycle)
Group A	1.53 ± 0.91	1.8± 1.73

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Group B	0.8 ± 0.56	1.06± 0.7
	MD – 0.74 SD pool- 5.11	MD – 00.73 SD pool- 5.110
ESD	0.92 (L)	0.125 (S)

Effect size after treatment for Group A in comparison to Group B is 0.92 which falls under higher end of large effect size different; for follow up score the effect size difference was -0.125 which falls under small effect size. Based on this it can be inferred that pain intensity reduction in Group B after treatment is much higher in comparison to the Group A. However, this difference is small with respect to follow up score.

Table 9: Showing Effect Size Determination Site of Pain

Assessment of Site of Pain		
	AT (After 1st cycle)	**FU (After 2nd cycle)**
Group A	1.66± 0.89	1.73± 0.96
Group B	0.8± 0.56	1.13 ± 0.74
	MD – 0.85 SD pool- 2.87	MD – 0.600 SD pool- 3.319
ESD	0.23 (S)	0.123(S)

The effect size difference for Group A in comparison to Group B is 0.23 and for follow up score-0.123-both these values fall under small size band hence the efficacy for this parameter is marginally better in Group B.

Table 10: Showing Effect Size Determination Duration of Pain

Assessment of Duration of Pain		
	AT (After 1st cycle)	**FU (After 2nd cycle)**
Group A	1.06 ± 0.45	1.33 ± 0.61
Group B	0.86 ± 0.51	0.8 ± 0.56
	MD – 0.20 SD pool- 1.86	MD – 0.53 SD pool- 2.26
ESD	0.12(S)	0.112(S)

The effect size difference for group A in comparison to Group B is 0.12 and for follow up score 0.112- both these values fall under the small size band hence the difference in clinical efficacy is small.

Comparison between the group for clinical efficacy based on statistical analysis showed that there is no significant difference between the two groups with respect to the effect observed on *Arthava Pramana, Praseka, Swedadhikyata, Chardi, Vankshanashoola, Kati Shoola, Janu Shoola* and *Shirasoola*. Further the apparent difference between the groups for effect size was also not remarkable hence it was not calculated. Hence no clinical effect size was calculated.

Objective Parameter

Table 11: Showing Effect Size Determination VAS Scale

Assessment of VAS Scale		
	AT (After 1st cycle)	**FU (After 2nd cycle)**
Group A	5.33 ± 1.07	5.73 ± 1.28
Group B	4.83 ± 1.06	1.28± 1.33
	MD – 0.5 SD pool- 4.12	MD – 0 SD pool- 5.50
ESD	0.12(T)	0 (T)

The effect size value for VAS scale on AT is 0.12 for FU day – 0, both fall under Trivial band. This indicates that in this Group B has clinically marginally effective in comparison to Group A.

Table 12: Showing Effect Size Determination Multi Dimensional Scoring System

Assessment of Multi Dimensional Scoring System		
	AT (After 1st cycle)	**FU (After 2nd cycle)**
Group A	4.67 ± 1.29	5.27 ± 0.96
Group B	3.47 ± 1.76	4.33 ± 1.83
	MD – 1.19 SD pool- 5.97	MD – 0.93 SD pool- 5.65
ESD	0.20(S)	0.166 (S)

The effect size value scoring multi-dimensional scoring system on AT is 0.20 for FU day – 0.166, both fall under small band. This indicates that in this Group B has clinically effective in comparison to Group A.

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Table 13: Showing Effect Size Determination WaLIDD

Assessment of WaLIDD		
	AT (After 1st cycle)	FU (After 2nd cycle)
Group A	1.2 ± 0.41	1.6± 0.63
Group B	0.8 ± 0.41	1.0± 0.53
	MD – 0.399 SD pool- 1.58	MD – 0.60 SD pool- 2.25
ESD	0.25 (S)	0.266 (S)

The effect size value WaLIDD scoring scale on AT is 0.25 for FU day – 0.266, both fall under small band. This indicates that in this Group B has clinically effective in comparison to Group.

Table 14: Showing Effect Size Determination Q-LES-Q-SF

Assessment of Q-LES-Q-SF		
	AT (After 1st cycle)	FU (After 2nd cycle)
Group A	69.4 ± 10.22	61.47 ± 10.49
Group B	73.6 ± 9.17	70.6± 16.18
	MD – 4.199 SD pool- 37.60	MD – 9.12 SD pool- 52.80
ESD	0.11(S)	0.17(S)

DISCUSSION

Discussion on Drug Review

Phala Taila is a preparation mentioned in *Kashyapa Samhita Khila Sthana* in *Bastiviseshenaniya Adhyaya* for management of aggravated *Vata* in *Prusta, Uru, Janga Pradesha, Gulma, Mutraghata, Krimikoshta,* and in *Basti Vyapad*. It contents 26 drugs, most of the drug in this preparation acts as *Vatakaphahara, Vedanastapana* (anodynes), *Garbhashaya Shodana, Balya* (strength promoters), *Udararogahara, Kashtartava (Rajorodha), Kashtartava - Kulattha, Kushta, Kantakarai, Yavani, Madanaphala; Shiroshoola* (headache), *Deepana* (appetizer), *Pachana* (digestives), *Vatanulomana.* Among 28 drugs in *Phala Taila*; *Rasa - Madura* - 13; *Katu* - 13; *Tikta* - 14; *Kashaya* - 9; *Veerya - Ushna* - 15; *Sheeta* - 11; *Vipaka - Katu* -16; *Amla* - 1; *Madura* - 9; *Dosha - Vatakaphahara* - 16; *Tridoshashamaka* - 3; *Vatapitta Shamaka* - 2; *Vatahara* - 1; *Pittakaphashamaka* - 4.

Discussion on drug probable mode of action of *Phala Taila*

Based on *Rasa*

- *Tikta Rasa* is having property of *Kaphaghna, Lekhana, Shodana.*
- *Katu Rasa* is having properties like *Kapha Shamaka* acts *Agni Deepana, Srotovivarana* property acts as vasodilation which in turn reduces the pain.
- *Madhura Rasa: Vata-Pitta Samaka*. Acts as *Dhatu Vardhana, Balya, Jeevaniya, Ayusha, Sandhanadara, Kantya, Murchaprashamana, Indriya Prasadana* all this properties help in reducing associated symptoms like *Srama, Aruchi, Tamodarshana*, etc.

Based on *Gunas*

- *Laghu Guna* possess *Pachana, Lekhana* properties
- *Tikshna Guna* acts *Kapha Vatahara*, which will expel the *Dosha* completely.
- *Snigdha* and *Guru Guna* possess *Vatahara.*

Based on *Virya*

Ushna Virya possess *Vatahara* & *Kaphahara* properties acts *Deepana, Pachana Karma.*

Based on *Karma*

All dugs of *Phala Taila* have the actions like *Vatakaphahara, Vedanastapana, Garbhashaya Shodana, Balya, Udararogahara, Kashtartava (Rajorodha), Shiroshoola, Deepana, Pachana, Vatanulomana*. The properties of *Phala Taila* such as *Snigdha, Guru, Ushna* are opposite to the properties of *Vata*. Thus, these properties of *Phala Taila* acts against *Vata* and help in subsiding the *Shoola.*

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By *Kaphavataharatva, Ushnatva* & *Katutva* removes *Sanga* of *Artavavaha Srothas*, thereby it avoids *Sanga* and *Vimarga* of *Artavavaha Srothas*, By *Vataghnata* and *Shulaghnata* effect it directly acts on pain. *Margavarodha* and *Dhatukshaya* are *Nidana* of *Vataprakopa.* In this disease of *Kashartava Margavarodha* can be taken as obstruction in normal pathway of menstruation. The property of *Vatanulomana* corrects the path of *Apana Vata* and help in *Artava Niskramana Kriya* without causing pain.

Mode of action of *Basti* - *Acharya Vagabhata* says the *Virya* of *Basti* is conveyed to *Apana* and then to *Samana Vata*, which may regulate the function of *Agni*. It then goes to *Udana, Vyana*, and *Prana*, thus providing its efficacy all over the body. *Basti* therapy is considered as prime among all the therapeutic measures, especially for management of *Vatavyadi*, and some physicians accept it as a complete therapeutic measure. *Basti Dravyas* can act as *Vatahara, Shulahara, Shothahara, Srotoshodhaka, Yogavahi, Agnideepaka*, and *Rasayana*. Our *Acharyas* have considered the rectum (*Guda*) as the root of the body (*Mula* of *Sharira*). At the same time *Basti* by pacifying *Vata*, restores the disturbed *Kapha* and *Pitta* at their original seats and thus helps in breaking the pathogenesis. Thus, according to *Ayurveda*, the *Veerya* (active principle) of the ingredients used in the *Basti* gets absorbed and then, through the general circulation, reaches at the site of the lesion and relieves the disease.

Modern pharmacokinetic studies have also proved that drug administration via the rectum can achieve higher blood levels of the drug than administration through the oral route due to partial avoidance of hepatic first-pass metabolism. The rectum has a rich blood and lymph supply and drugs can cross the rectal mucosa as they can other lipid membranes. Thus, un-ionized and lipid-soluble substances are readily absorbed from the rectum. The portion absorbed from the upper rectal mucosa is carried by the superior hemorrhoidal vein into the portal circulation, whereas that absorbed from the lower rectum enters directly into the systemic circulation via the middle and inferior hemorrhoidal veins. Thus, administration of drugs in the *Basti* form has faster absorption and provides quicker results.

Overall Assessment

Table 14: Showing Overall Assessment

Parameter	Group A	Group B	Clinical Effect size
Duration of pain	33%	48%	B>A
Site of Pain	38%	72%	B>A
Working ability	27%	51%	B>A
Q-LES-Q-SF	22%	32%	B>A
Total	35%	67.66%	

CONCLUSION

The present study was done to evaluate the efficacy of *Phala Taila Matra Basti* (Study group) and *Dashamoola Ksheera Yoga Basti* (Control group) in *Kashartava* w.s.r. to Primary Dysmenorrhoea. Objectives were statistically analyzed using repeated measure Anova and Paired t test. Each medicine was found to be effective within the group with a highly significant p value <0. 001 and mean difference. But percentage of improvement were high in Group B. Taking all subjective and objective parameter into consideration especially with effect size comparison clearly shows that Group B is much better with respect to most of the parameter in providing clinical relief. Thus, Alternate hypothesis (H2) is accepted. *Dashamoola Ksheera Yoga Basti* is more effective than *Phala Taila Matra Basti* in the management of *Kashartava* w.s.r. to Primary Dysmenorrhoea.

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