AYUSHDHARA
ISSN: 2393-9583 (P)/ 2393-9591 (O)
An International Journal of Research in AYUSH and Allied Systems

Research Article

THE STUDY ON THE EFFICACY OF *SUKOSHNA* (LUKE WARM) *YASHTIMADHU GHRITA* IN THE MANAGEMENT OF PAIN DURING APPLICATION OF *KSHARASUTRA* IN *BHAGANDARA* (FISTULA IN ANO)

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KEYWORDS: *Bhagandara*, *Ashta Mahagadas*, *Apamarga Ksharasutra*, *Sukoshna* (Luke warm) *Yashtimadhu Ghrita*, Xylocaine Jelly, Anaesthetic, Non-invasive, Shooting and Scalding Pain.

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ABSTRACT

Bhagandara is one of the oldest diseases which have been described as one of the *Ashta Mahagadas* (Eight grave disorders). *Ksharasutra* application is a successful method and is one of the chief modalities described for the treatment of *Bhagandara* in *Ayurvedic* texts. The local cauterizing pain and prolonged period of treatment causes the agony in few patients and make them to avoid undergoing *Ksharasutra* application. The ability to alleviate pain is one of the most noteworthy goals during change of *Ksharasutra* in *Bhagandara.* The conventional use of 2% xylocaine jelly before changing *Ksharasutra* had local anaesthetic effect up to limited time and also didn't have any other advantages like healing of fistula.30 patients with signs and symptoms of *Bhagandara* who are treated with *Ksharasutra* were selected by simple random sampling method. *Apamarga Ksharasutra* and *Yastimadhu Ghrita* were prepared as per the standard method described in Ayurvedic texts. In the present trial 4 sittings were taken into study and in the 1st sitting 2% xylocaine jelly was applied and in the next three sittings, *Sukoshna* (Luke warm) *Yastimadhu Ghrita* was applied to find out its effectiveness in the management of pain during *Ksharasutra* therapy by comparing 1st and Last sitting. Lastly, it was concluded that the present study was efficacious and non-invasive and it was found to be statistically highly significant in alleviating pain, burning sensation and PRD during and after application of *Ksharasutra* without any side effect.

INTRODUCTION

Ayurveda the ancient and holistic system of Indian Medicine consists of *Ashtangas*[1] and *Shalyatantra* (surgery) which is one among them[2] has been mentioned best of all branches. The disease *Bhagandara* analogous to Fistula-in-ano in the modern surgical terms has been considered under the *Ashta Mahagadas.*[3] The continuous discharge and soiling of the clothes is an essential factor of the disease process and is responsible for the restlessness of the sufferer.

It leads to a stage where physical, psychological and social equilibrium is disturbed. In Modern surgery, this problem is known for its callus nature to get cured and for its high recurrence rate.

According to a recent study conducted by Sainio P. on the prevalence rate of fistula in ano in a London based Hospital Male: Female = 1.8: 1, Mean age of patient is 38.3 years[4]. Surgical treatment of fistula-in-ano required hospilization with a significant risk of recurrence in 0.7% - 26.5% and high risk of impaired continence in 5% - 40% of patients.[5]

Ksharasutra therapy which is one of the chief modalities described for the treatment of *Bhagandara* in Ayurvedic texts[6]. Now days, *Ksharasutra* is the first choice for treating fistula in ano.

AIMS & OBJECTIVES OF THE STUDY

- The main aim of this study was to evaluate the efficacy of *Sukoshna* (Luke warm) *Yashtimadhu*

Ghrita during change of *Ksharasutra* for the management of pain in *Bhagandara.*

- The objective of the present study was to formulate a procedure for alleviation of pain and burning sensation which was major hurdle in *Ksharasutra* therapy.

Importance and Need of Present Study

So far no work was done on management of pain in patients of fistula undergoing *Ksharasutra* application. Hence, to find out an alternative to conventional change of *Ksharasutra*by 2% xylocaine jelly and better pain alleviating feature, *Sukoshna* (Luke warm) *Yashtimadhu Ghrita* was opted for clinical evaluation.

Selection of Drug

In the present clinical study *Sukoshna* (Luke warm) *Yashtimadhu Ghrita* was applied into the fistulous track in fistula patients during the change of *Ksharasutra*. The idea of this study is taken from *Agropaharaneeyaadhyaya* of *Susruta Samhita*[7]. *Yashtimadhu* has *Vedanasthapana, sothahara* and *Vranaropana* properties[8]. Probably application of *Ghrita* externally relieves pain & burning sensation in fistula as it has *Soolahara, Vranaropana* and *Sodhana* properties. The application of *Ghrita* in luke warm state helps in decongesting the fistulous track and lubricates it. Keeping in mind of such advantage it has been planned to use Luke warm *Ghrita* in present study.

MATERIALS AND METHODS

Materials: *Yastimadhughrita* and *Apamarga Ksharasutra.*

Ingredients required for the preparation of *Yastimadhu ghrita.*

i. Dried roots of *Yashtimadhu*

ii. *Go-Ghrita*

Apamargaksharasutra was prepared as per the standard method described in Ayurvedic texts[9,10].

Method of Preparation of drug was done under aseptic conditions according to *Ghritapaaka* explained in *Sarangadhara samhita, Madhyama khanda[11]. Yastimadhu* roots *Kalka* (paste), *Go Ghrita* and *Kashayam* of roots (decoction) was taken in a ratio of 1:4:16.This combination was kept in a big vessel and heated up on a mild fire till the water and moisture content of the mixture is completely evaporated. The continues stirring was done and the stage of *Phenasanthi*. The prepared *Ghrita* was continuously heated till it attains *Kharapaka* and it was filtered and collected in a glass jar.

Selection of Patients: Patients were selected by simple random sampling method, from the IPD and OPD.

Methods

Design of the study – It was a Randomised Single Blind Study

Place of the study - Department of *Shalya Tantra*, S.V.Ayurvedic College and Hospital, Tirupati.

Sample size: 30 patients

Criteria for selection of cases

Patient with signs and symptoms of *Bhagandara* who are treated with *Ksharasutra* are taken for the present study on the basis of the following inclusion and exclusion criteria.

Inclusion criteria

- Diagnosed cases of *Bhagandara* operated by the method of *Ksharasutra* application.
- Age group of 20 -70 years.
- Patients of either sex were selected.

Exclusion criteria

- Patients suffering with uncontrolled Diabetes Mellitus and Hypertension and patients with immune compromised conditions.
- Fistulae developing secondary to diseases like Tuberculosis, Chronic or acute ulcerative colitis, Crohn's disease, Malignancies etc.

Consent

Patients were well informed about the pros and cons of the treatment and signature on the informed consent form was taken from the patient.

Plan of the study

The clinical study is carried out in 3 phases

Phase - I

All the 30 collected patients who were fit for the selection criteria were selected for the study.

Phase –II For every patient 4 sittings of trial i.e., change of *Ksharasutra* after application of the specially prepared *Yashtimadhu Ghrita* or xylocaine jelly are undertaken.

Phase –III Evaluation of clinical data which was collected and recorded

Administration Procedure

a. Sittings of the trial

1st Sitting: Conventional method of change of *Ksharasutra* without application of trial drug will be taken up and the patient will be asked for his severity of pain felt and report on the 10 point analog scale designed for the study to assess the quantum of pain during the procedure of change of *Ksharasutra* so as

to compare with the pain elicited in subsequent sittings when trial drug is applied.

2nd Sitting: 5 to 10ml of *Sukoshna* (luke warm) *Yashtimadhu ghrita* will be irrigated before 30min of *Ksharasutra* application and the pain felt during the change is recorded on 10 point analog scale and to be compared with the score elicited in first sitting (xylocaine).

3rd Sitting: 5 to 10ml of *Sukoshna* (Luke warm) *Yashtimadhu Ghrita* will be irrigated before 20min of *Ksharasutra* application and the pain felt during the change is recorded on 10 point analog scale and to be compared with the score elicited in second sitting.

4th Sitting: 5 to 10ml of *Sukoshna* (Luke warm) *Yashtimadhu Ghrita* will be irrigated before 10min of *Ksharasutra* application and the pain felt during the change is recorded on 10 point analog scale and to be compared with the score elicited in third sitting.

b. Post Application Procedure

Patients were advised to take sitz bath twice daily. All the patients were advised to take light, easy digestable and non-spicy food**.**

Duration of the treatment: 4 weeks continuously after undergoing surgery for *Ksharasutra* application

Assessment Criteria

Subjective Parameters

Pain

- Intensity of pain (0-10)
- Duration of pain

Burning Sensation

- Intensity of burning sensation(0-10)
- Duration of burning sensation

Intensity of pain and Intensity of burning sensation was recorded on 10 point Analog scale according to the patient's self assessment criteria.

Duration of pain and Duration of burning sensation after *Ksharasutra* change was recorded according to the patient's self assessment criteria.

Pain relief day (P.R.D): This is the day when the patient is totally relived or free from post procedural pain.

Objective Parameters

Unit Cutting Time

$$= \frac{\text{Total No. of days taken to cut through the tract}}{\text{Initial length of the } \textit{Ksharasutra} \text{ in cms}}$$

This is recorded as per routine, to know the general condition and effect of trial on cutting.

OBSERVATIONS

The present study reveals that the incidence of *Bhagandara* is more among male patients, with mixed diet, mainly of *Vata pitta prakriti*, most of the patients are with pus discharge and pain with gradual onset, 0-12 months chronicity, 6-8cms initial length of tract, *Parisravi* type of *Bhagandara* and low anal type of Fistula.

Table 1: Sex wise distribution of patients

Sex	No. of patients	%
Male	27	90
Female	3	10

Table 2: Diet habit of patients

Diet	No. of patients	%
Vegetarian	2	6.66
Mixed	28	93.33

Table 3: *Prakriti* wise distribution of patients

Types of *Prakriti*	No. of patients	%
Vata Pitta	12	40
Pitta Kapha	11	36.66
Vata Kapha	7	23.33

Table 4: Chief complaints of patients

Chief Complaints	No of Patients	%
Discharge	28	93.33
Pain	27	90
Induration	18	60
Burning Sensation	14	46.66
Itching	9	30
Tenderness	8	26.66

Table 5: Chronicity of the disease in the patients

Chronicity of disease in months	No. of patients	%
0-12	20	66.66
13-24	10	33.33
25-36	0	0
37-48	0	0

Table 6: Initial length of the tract in cms

Initial length	No. of patients	%
0-2cms	0	0
2-4cms	1	3.33
4-6cms	8	26.66
6-8cms	11	36.66
8-10cms	7	23.33
10-12cms	3	10

Table 7: Type of *Bhagandara* in the patients

Type of *Bhagandhara*	No. of patients	%
Sataponaka	3	10
Ustragriva	5	16.66
Parisravi	20	66.66
Sambukavarta	0	0
Unmargi	2	6.66

Table 8: Type of Fistula in the patients

Type of fistula	No. of patients	%
Submucosal/Subcutaneous	5	16.66
Low Anal	21	70
High Anal	4	13.33

Table 9: Showing mean of subjective and objective parameters in all the sittings among all the patients

Mean of parameter	1st sitting	2nd sitting	3rd sitting	4th sitting
Intensity of Pain	10	7.767	5.867	4.46
Intensity of burning sensation	10	7.567	5.6	4.167
PRD	2.5	1.51	0.95	0.78

Table 10: Showing mean of subjective parameters in 1st and 4th sitting among all the patients

Mean of parameter	1st sitting	4th sitting
Duration of pain	39.266	4.033
Duration of burning sensation	5.833	1.741

Comparison of Average UCT of present study with earlier works

- Present study - 7.09 days
- Deshpande et al - 6 to 7 days
- Dattatreya Rao et al - 4.46 days

The UCT was also studied and compared with earlier research works which shows no interference of present trial procedure with the UCT.

Table 11: Showing Average UCT according to type of Fistula

Type of fistula	Average UCT
Submucosal/Subcutaneous	7.6
Low Anal	7.06
High Anal	6.57

Table 12: Showing Average PRD (in days) according to type of Fistula

Type of fistula	Average PRD
Submucosal/ Subcutaneous	1.25
Low Anal	1.44
High Anal	1.46

RESULTS

Statistical Analysis

The parameters are subjected for statistical analysis of Paired t test and One way anova with multiple comparisons at 1% level of significance. All the subjective and objective parameters were found to be highly significant with significant difference between 1st sitting with baseline conventional method of thread change and 4th sitting with irrigation of *Sukoshnayashtimadhughrita*10min before change of *Ksharasutra* with 55.33%, 58.4%, 89.73%, 70.15% and68% of relief for intensity of pain, intensity of burning sensation, duration of pain, duration of burning sensation and PRD respectively.

Subjective Parameters

Intensity of pain

Table 13: Showing one way anova test for intensity of pain

Source of variance	SS	df	M S	F value
Between Groups	518.6	3	172.9	3.847***
Within Groups	100.2	29	3.454	
Total	618.8	32	176.354	

Table 14: Showing one way anova multiple comparisons for intensity of pain

Comparison	A_1vs B_1	A_1vs C_1	A_1vs D_1
M.D.	2.233	4.133	5.533
S.E of diff	0.2699	0.2432	0.2701
% of relief	22.33%	41.33%	55.33%

Intensity of burning sensation

Table 15: Showing one way anova test for intensity of burning sensation

Source of variance	SS	df	M S	F value
Between Groups	575.9	3	192	3.953***
Within Groups	106.2	29	3.661	
Total	682.1	32	195.661	

Table 16: Showing one way anova multiple comparisons for intensity of burning sensation

Comparison	A_2vs B_2	A_2vs C_2	A_2vs D_2
M.D.	2.433	4.4	5.833
S.E of diff	0.2568	0.2519	0.292
% of relief	24.34%	44%	58.4%

Table 17: Showing paired two sample t test for subjective parameters

Parameter	1st sitting	4th sitting	% Relief	Mean	S.D.	S.E.	't'	P	Inference
Duration of pain	39.26	4.03	89.73%	35.23	30.98	5.657	6.229	< 0.0001	***
Duration of burning sensation	5.83	1.74	70.15%	4.100	2.589	0.472	8.675	< 0.0001	***

OBJECTIVE PARAMETER

Pain Relief Day (PRD)

Table 18: Showing one way anova test for PRD

Source of variance	SS	df	M S	F value
Between Groups	54.68	3	18.23	3.352***
Within Groups	13.34	29	0.4601	
Total	68.02	32	18.6901	

Table 19: Showing one way anova multiple comparisons for PRD

Comparison	A_3vs B_3	A_3vs C_3	A_3vs D_3
M.D.	0.9833	1.55	1.733
S.E of diff	0.09123	0.1299	0.1285
% of relief	39.6%	62%	68%

Note: *** Highly significant

Overall effect of Therapy

Overall effect of therapy shows that there is good response in 56.66% patients, moderate response in 43.33% patients and nil percentage of patients were seen under poor response and no response categories

Table 20: Overall effect of Therapy

Relief	No. of patients	% of patients
Good response	17	56.66%
Moderate response	13	43.33%
Poor response	0	0%
No response	0	0%

UNTOWARD or SIDE EFFECTS

No side effects were observed during the course of the study.

Fig No 1 - 4 Showing before and during treatment of present trial (Pt No. SJ0802)

Pic 1: Before Change of Ksharasutra

Pic 2: During change of Ksharasutra

Pt No. SJ0330

Pic 3: Before Change of Ksharasutra

Pic 4: During change of Ksharasutra

DISCUSSION

All the parameters were subjected to statistical analysis of one way anova multiple comparison test and paired t test and were found to be highly significant with significant difference between 1st sitting and 4th sitting with 55.33%, 58.4%, 89.73%, 70.15% and 68% of relief for intensity of pain, intensity of burning sensation, duration of pain, duration of burning sensation and PRD respectively. The UCT was also studied and compared with earlier research works and was infered that the procedure of the *Sukoshna* (Luke warm) *Yashtimadhu Ghrita* application does not interfere with the UCT of the fistula patients undergoing *Ksharasutra* treatment. In this clinical study it is observed that there is good response in 56.66% patients, moderate response in 43.33% patients and no patient is under poor response and no response categories.

Probable mode of action of *Yashtimadhu Ghrita*

Probably the trial drug may work as TRPV1 antagonist on the cell membrane and may block the transduction channel of the receptors of pain sensation in the lining membrane of the fistulous tract because of flavonoids and isoflavonoids[12] present in the dried roots of *Yashtimadhu* which was proved by earlier study on *Anthocephalus chinensis* (Lam)[13]. Further the inclusion of luke warm *Ghrita* which felicitates the penetration of the drug in to the deeper planes of the lining membrane and underneath tissue may enhance the action of *Yashtimadhu*. Thus the comprehensive overall action of *Yashtimadhu* as pain controlling agent can be understood.

The presence of *Vatapittahara* and *Vedana-sthapana*[8], analgesic and anti-inflammatory[12] properties in *Yashtimadhu* and the presence of *Vatapittahara, Soolahara*[14] and sedative[15] properties in *Ghrita* may have helped the trial drug in alleviating pain and burning sensation. The advantage of *Vranaropana* and *Vranasodhana* properties in *Yashtimadhu* and *Ghrita* will enhance the efficacy of drug not only in relieving the pain and burning sensation but also healing of the wound.

CONCLUSION

In the disease *Bhagandara* (Fistula in ano) the pain felt by the patient during *Ksharasutra* maneuvers was the prime thrust area for the present research work. The application of *Sukoshna Yashtimadhu Ghrita* was found to be significantly efficacious in alleviating pain, burning sensation and PRD during and after the maneuvers with *Ksharasutra.*

Though the limitations of the study are manifold but it is a beginning in a right direction to establish in perfect way of pain control during the *Ksharasutra* therapy with the indigenous drugs and procedures. It is recommended to start a bigger study to pave the way for active analgesia through indigenous techniques.

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Cite this article as:
Sri Jyothsna P M, S.Dattatreya Rao, T.Udaya Kiran. The Study on the Efficacy of Sukoshna (Luke Warm) Yashtimadhu Ghrita in the Management of Pain During Application of Ksharasutra in Bhagandara (Fistula in Ano). AYUSHDHARA, 2017;4(5):1338-1344.