



Research Article

EFFECT OF YASHTIMADHU GHRITA GUDAPURANA ON POST OPERATIVE PAIN MANAGEMENT IN PATIENTS OF HAEMORRHOIDS AND FISSURE-IN-ANO WITH SPECIAL REFERENCE TO SHASTRANIPATAJA VEDANA: A RANDOMIZED CONTROLLED TRIAL

Yogesh Badwe^{1*}, Sanjay Bhise², Jyoti Shinde³

¹Professor and HOD, ²PG Scholar, ³Professor, Department of Shalyatantra, Shri Ayurved Mahavidyalaya, Nagpur, Maharashtra India.

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ABSTRACT

Modern medical Science has offered many surgical procedures like open and closed haemorrhoidectomy, anal dilatation, Sphincterotomy etc for haemorrhoides and fissure in ano. These operative procedures are associated with unavoidable sequel of symptoms like Pain, Discharge and Inflammation etc. Role of analgesia is vital in the treatment of post-operative pain. The mode of analgesia depends on degree or level of pain which is a subjective criteria. Analgesics routinely used are NSAIDs, opioids and corticosteroids. Side effects includes like Gastritis, Gastrointestinal bleeding etc. Hence, Analgesia has to be supplemented with antacids or H2 Receptor Agonists. Here, quest for knowledge for an alternative treatment to analgesics starts. According to *Sushrutacharya*, these diseases like *Arsha* and *Parikartika* are termed as *Chhedya*, i.e., treatable by surgery and he has indicated *Yashtimadhu Ghrita* in *Shastranipataja Vedana*. **Methodology:** In present study, total 100 postoperative patients of haemorrhoids and fissure in ano, randomly allocated into two groups (50 in each group). In Group A ($n = 50$), *Yashtimadhu Ghrita Gudapurana* was done every day after sitz bath for 5 days. In Group B ($n = 50$), local application of lignocaine jelly every day after sitz bath for 5 days. **Result:** *Yashtimadhu Ghrita* as a local application is clinically as effective as lignocaine jelly in the management of post operative pain in patients of hemorrhoids and fissures in ano. **Conclusion:** it was concluded that *Yashtimadhu Ghrita* is helpful in the management of pain in the post operative patient of haemorrhoids and fissure in ano.

INTRODUCTION

Today “Ageless health through timeless drug therapies in alternative medicine” is the natural step forward as a choice of healthy lifestyle in our society. Pain can be described as any physical or mental suffering or discomfort caused by illness or injury. No matter however mild the pain is anywhere in the body it enables the person to land in state of discomfort and affects day to day activities. Pain can be present in various ways as throbbing pain in toothache, colic pain which comes in spasm as in renal calculi, muscular pain as in sprain, sport injury

and joint pain due to inflammatory condition and many more. Pain is also categorized as acute or chronic on the basis of duration. Our answer to pain is painkiller which on frequent use kills the resistance. Similar is the case with postoperative pain. Hemorrhoids disease is the leading outpatient gastrointestinal diagnosis corresponding to 4.4% of the population seeking treatment under report incidence from age 45 to 65 years^[1]. Anal fissures are most commonly seen in the posterior midline, although 10–20% in women and 1-10% in men are located in the anterior midline^[2]. Haemorrhoids can be correlated to *Arsha* and Fissure in ano to *Parikartika* from the signs and symptoms. *Acharya Sushruta* has stated that *Arsha* and *Parikartika* are *Chhedya Vyadhi*. Modern medical science has offered many surgical procedures like open and closed hemorrhoidectomy, anal dilatation, sphincterotomy etc for these diseases. These operative procedures are associated with unavoidable sequel of symptoms

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like pain, discharge, and inflammation etc^[3]. After Haemorrhoids surgery, pain is reported in the early post-operative period but also after 2-3days, around the time of first defecation. The aetiology of pain is believed to be multi-factorial; some important factors are individual pain thresholds, anaesthetic and analgesic protocols, operative technique, anal sphincter spasm, postoperative inflammation and secondary infections. When two groups were compared for postoperative pain management in surgeries of fissure in ano i.e., lateral anal sphincterectomy and manual anal dilatation. 45% patients complained of persistent pain from all patients. Out of these, 60% belongs to lateral anal sphincterectomy and 40% belongs to manual anal dilatation^[4]. From these references it can be concluded that pain occupies the first and foremost position in post-operative symptomatology of patients. Role of analgesia is vital in the treatment of post-operative pain management. The mode of analgesia depends on degree or level of pain. In routine surgical practice, it is observed that the patient requires topical anaesthetic application for mild to moderate pain and systemic analgesic for severe degree of pain. Analgesics routinely used are NSAIDs, opioids and corticosteroids sometimes. This action is for specific short period of time and need to be taken twice or maximum thrice a day through oral or parenteral route for first 24 to 48 hours of surgery and later as per requirement, still twice daily for minimum 5 days. This increases the cost of surgical protocol by manifold. And side effects include various GI disturbances like Gastritis, GI bleeding etc. Hence, analgesia has to be supplemented with antacids or H2 Receptor Agonists.

Assessment

Subjective Criteria

Table 1. Pain

Scale reading	Pain level
0	No pain
I	Mild Pain (Annoying interfering in daily activities) which last for 1 hour after defecation
II	Moderate pain (Interferes significantly with regular activities) which last for 1 to 3 hrs.
III	Severe pain (Unable to perform daily activities) More Than 3 hrs.

Objective Criteria

Table 2. Anal Sphincter Muscle spasm

Grade	Symptoms
0	Normal (1 finger can pass)
I	Finger can be pass with severe pain
II	No finger can be passed

Overall Assessment Criteria: Criteria of assessment was based on improvement in subjective and objective parameters after the treatment. The results were categorized as,

Complete relief -- 75% and above

Need of Study

Here, quest for knowledge for an alternative treatment to analgesics starts. Here Ayurveda offers a ray of hope in the form of a treatment option mentioned by *Acharya Sushruta*. According to him, these diseases like *Arsha* and *Parikartika* are termed as *Chhedya*, i.e., treatable by surgery and he has indicated *Yashtimadhu Ghrita* in *Shastranipataja Vedana*. Hence the modified release of trial drug at this level can be achieved by installation of medicated ghee with *glycyrrhiza glabra* (*Yashtimadhu Ghrita*) through anus which can be referred to as "*Gudapurana*" in "*Shastra Nipataja Vedana*" in surgical wounds of *Arsha* and *parikartika*^[5]. Ghee boiled with *Yashtimadhu Ghrita* and applied on wound^[6]. The abundant knowledge in the Ayurveda texts needs validation in the form of clinical trials and evaluation on scientific parameters. Hence, with the purpose of validation of *Yashtimadhu Ghrita* instillation through anus as "*Gudapurana*", and considering all the conceptual and practical aspects of most prevalent ano-rectal disorders, post-operative pain stigma, limitations and drawbacks of mandatory analgesic use, this study was selected.

MATERIALS AND METHODS

Inclusion Criteria

1. Post-operative patients of Haemorrhoids and fissure in ano.
2. Patient above 18 year of age, irrespective of gender and socio economic status.

Exclusion Criteria

1. Anorectal surgeries for diseases other than Haemorrhoids and Fissure in ano.
2. Patients with immuno-compromised diseases.

Moderate relief -- 50% to 74% improvement

Mild relief -- 25 to 49% improvement

No relief -- Below 24% improvement

Selection of Patients

Post-operative Patients of *Parikartika* (fissure in ano) and *Arsha* (hemorrhoids) was selected from OPD or IPD of *Shalya Tantra* department, Shri Ayurved Mahavidyalaya, Nagpur. Irrespective of gender, occupation, religion etc., the registered patients were randomly allocated into two groups.

The study was approved by Institutional Ethics committee (IEC), before starting the clinical trial.: Institutional Ethics Committee clearance- MUHS/E- 3//PG/31/08/2350 dated 27/10/2017

Clinical study was also registered in Clinical trial register of India.

Trial register of India registration number: CTRI/2020/03/024243

MATERIALS

Among 100 registered patient in group A (n=50), postoperative patients of *Arsha* and *Parikartika* were treated with *Yashtimadhu Ghrita*, and in group B (n=50), patients of *Arsha* and *Parikartika* were treated with local application of lignocaine jelly.

Methodology

- **Group A:** Local application of *Yashtimadhu Ghrita* was done in post-operative patients of *Arsha* and *Parikartika* every day after sitz bath for 5 days.
- **Group B:** Local application of lignocaine jelly was done in Post-operative patients of *Arsha* and *Parikartika* every day after sitz bath for 5 days.

Group A

Trial Drug

Trial drug i.e., *Yashtimadhu Ghrita* was prepared and analysed on parameters like morphological evaluation, rancidity, weight/ml, refractive index at 25°C, viscosity, iodine value, saponification value, acid value, peroxide value, free fatty matter and total fatty acids in the pharmacy of Shri Ayurved Mahavidyalaya, Nagpur^[7].

Standard Operating Procedure (Validated)

Under all aseptic precautions and patient in lithotomy position, painting and draping was done.

1. With gloved hand and with proper lubrication 15ml of *Yashtimadhu Ghrita* was instilled into anal canal with help of 20ml disposable syringe and sterile rubber catheter no.9
2. After instillation of *Yashtimadhu Ghrita* Pain was assessed with VAS (visual analogue scale) scale after every 2 hours for next 8 hours.
3. Requirement of analgesics was noted and action was taken likewise.



Pics no 1, 2, 3 revealing *Yashtimadhu Ghrita* prepared, dressing tray (instruments and procurements) and procedure of *Gudapurana* respectively.

Group B

Lignocaine Jelly

Application of lignocaine jelly

1. Lignocaine 2% jelly will be taken on applicator.
2. Informed patient about procedure and tell to take deep breath.
3. It will be applied per rectally with help of applicator.

Duration of treatment: 5 Days

Follow up period: 0th, 1st, 2nd, 3rd, 4th, 5thday

Statistical Tests

Two independent samples are there, hence t test will be used and chi square test was used to access the significance of the proportion between the two groups. Within the group

Comparison: Before and after treatment was done by paired t test in each group separately. P value <0.05 was considered statistically significant for all comparisons Formula: for sample size

$$N = \{Z_{1-\alpha} \sqrt{2P(1-P)} + Z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)}\}^2 / (p_1 - p_2)^2$$

Where, p=mean of two proportion, p₁=Group A, p₂=Group B

OBSERVATIONS AND RESULT

Effect of Therapy for Group A

Pain

In assessment criteria of pain, in control group mean score before treatment was 3.00 and after treatment it was reduced to 0.96. The pain score in lignocaine jelly got 68% relief occurs. P value is <0.05 means result is highly significant. Lignocaine jelly Stabilizes the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses, thereby effecting local anaesthetic action. The onset of action is 3 to 5 minute.

Spasm

In this study, criteria of sphincter spasm in control group mean score before treatment it was 1.98 and after treatment it was reduced to 0.02. P value is <0.05 means result is highly significant. 98% result was observed in criteria of sphincter spasm.

Effect of Therapy for Group B

Pain

In assessment criteria of pain, in experimental group mean score before treatment is 2.94 and after treatment 0.94 and P value is <0.05 means results is significant. *Yashtimadhu Ghrita* doesn't have any anaesthetic action but as per Ayurveda, reduces *Vata* (which was vitiated after the surgical procedure). It also included in *Vedanasthapaka Gana* i.e., reducing pain mentioned by *Acharya Charaka*. *Yashtimadhu* contains Glycyrrhizine and asparagine as active ingredients. Glycyrrhizine is a saponin widely used as an anti-inflammatory agent. Asparagine is a type of amino acid and act as analgesic (natural painkiller) and anti-inflammatory.

Spasm

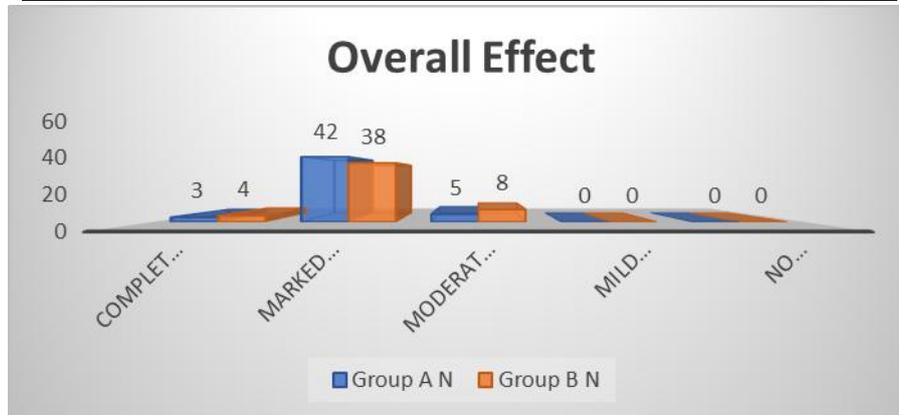
In this study, secondary objectives were anal spasm. In criteria of spasm, mean score before treatment was 2.0 and after treatment it was reduced to 0.08. P value is <0.05 means result is highly significant. 96% relief was occurred due to *Gudapurana* of *Yashtimadhu Ghrita*. Throughout digital examination maximum number of patients after treatment one finger easily admitted on 2nd day follow up. *Sankocha* i.e., spasm is one of the *Karma* of *Vata* and *Yashtimadhu Ghrita* pacify *Vata* and *Ghrita* reduces *Pitta* which ultimately causes relief in anal spasm.

Table 3: Showing comparison of pain and anal spasm in both groups in 100 post operative patients of Arsha (Hemorrhoids) and Parikartika (Fissure-in-ano)

Subjective Parameter		N	Mean Rank	Sum of Ranks	Mann-Whitney U	P - value
Pain	Group A	50	51.42	2571.00	1204.000	.599
	Group B	50	49.58	2479.00		
	Total	100				
Anal Spasm	Group A	50	50.50	2525.00	1250.000	1.000
	Group B	50	50.50	2525.00		
	Total	100				

For comparison between Group A and Group B, we have used Mann Whitney U Test. From above table we can observe that, P-Value the parameters are greater than 0.05. Hence we conclude that, there is no significant difference observed in Group A and Group B.

Overall Effect	Group A		Group B	
	N	%	N	%
Complete Relief	3	6.00	4	8.00
Marked Improvement	42	84.00	38	76.00
Moderate improvement	5	10.00	8	16.00
Mild Improvement	0	0.00	0	0.00
No Change	0	0.00	0	0.00
TOTAL	50	100.00	50	100.00



DISCUSSION

Yashtimadhu has *Madhura Rasa*, *Madhura Vipaka*, *Sheet Virya* and *Vata Pittashamak* property^[8]. *Yashtimadhu* also has *Vranaropana* and *Vrana Shodhana* properties^[9]. *Go Ghrita* has a soothing property and form thin film layer over them and then that allows early epithelization of skin. *Yashtimadhu* has proven healing, anti ulcerogenic, anti-inflammatory and skin regeneration activity^[10]. Sodium glycyrrhizate possessed anti-ulcer activity and stimulation of regeneration of skin^[11]. *Yashtimadhu* contains Glycyrrhizine and asparagine as active ingredients. Glycyrrhizine is a saponin widely used as an anti-inflammatory agent and Asparagine is a type of amino acid and act as analgesic (natural painkiller) and anti-inflammatory agent. Pain is stated to be also reduced due to *Vednashamak* effect of *Yashtimadhu Ghrita* local application without using. It doesn't only controls the pain but also act as *Vatahara*, *Pitta Shamak*, *Ropaka*, *Dahashamak*, *Stambhak* in *Vrana*^[12].

Previous study on *Yashtimadhu ghrita* also concluded as follows

Jigna Ratilal Patel *et al* stated that *Yashtimadhu ghrita* as well as lignocaine- nifedipine ointment both are equally effective in symptomatic relief in the management of *Parikartika* (acute fissure in ano). In lignocaine -nifedipine ointment minor complications were noted^[13].

Waghmare Dinesh *et al* concluded that most evident symptoms present i.e., pain and bleeding, burning sensation, itching can be relieved much earlier and fistula can heal much rapidly by the

application of *Yashtimadhu Ghrita* rather than *Tiktaadi Ghrita*^[14].

Dwivedi Amar prakash *et al* concluded that Symptoms present i.e., pain and bleeding, burning sensation, itching can be relieved much earlier and fissure can heal much rapidly by the application of *Yashtimadhu Ghrita* rather than *Shatadhauta Ghrita*^[15].

Gadhari Anup Bhimrao *et al* stated that *Yashtimadhu Ghrita* with *Madhu* as a local application is clinically effective in post-operative haemorrhoidectomy patients. This treatment is devoid of any side effects. This treatment is devoid of side effects. This treatment can be used as supportive treatment modality for early recovery^[16].

The previous work done with *Yashtimadhu ghrita* as trial drug are conclusive of its analgesic and wound healing properties. Also, *Yashtimadhu Ghrita* having various properties might be working on factors as pain and anal sphincter spasm and wound healing as well. *Yashtimadhu Ghrita* work as antiseptic and bactericidal on non-infected surgical wounds.

CONCLUSION

- Yashtimadhu Ghrita* as a local application is clinically as effective as lignocaine jelly in the management of post operative pain in patients of hemorrhoids and fissures in ano.
- Reduction in the level of pain and anal spasm was equal when comparing effect of *Yashtimadhu Ghrita* with lignocaine jelly in post operative patients of hemorrhoids and fissure in ano.

3. Overall both therapies are equally effective in the management of postoperative pain in the patients of hemorrhoids and fissures.
4. This treatment is devoid of any side effects.

Future Scope of the Study

1. Multicentric study can be carried out with large sample size.
2. In future, it can be used as an alternative option to modern topical application.
3. There is a scope for the study of *Yashtimadhu Ghrita* in combination with other Ayurvedic analgesic drugs for local application for post operative pain management

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*Address for correspondence

Dr. Yogesh Badwe
Professor and HOD,
Department of Shalyatantra,
Shri Ayurved Mahavidyalaya,
Nagpur, Maharashtra, India.
Email: dryogesh.badwe@gmail.com
Mob: 9011060498

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