



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 conceptual study

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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 and side effects includes like Gastritis, Gastrointestinal bleeding etc. Hence, Analgesia has to be supplemented with Antacids or H₂ Receptor Agonists. This is common story of post-operative patients. The modified release of trial drug at this level can be achieved by instillation of medicated ghee with Glycyrrhiza Glabra (*Yashtimadhu Ghrita*) through anus which can be referred as "*Gudapurana*" in "*Shastranipataj Vedana*" in surgical wounds of *Arsha* and *Parikartika* mentioned by *Acharya Sushruta*. It will be a prospective conceptual study, comprising of total 102 Postoperative patients of haemorrhoids and fissure in ano, randomly allocated into two groups (52 in each group). In Group A ($n = 52$), local application of *Yashtimadhu Ghrita* twice a day after sitz bath for 5 days will be given. In Group B ($n = 52$), local application of lignocaine ointment twice a day after sitz bath for 5 days will be given along with 5 gram triphala churna at bed time. A standard case record form will be used for data collection which will also be elaborating the minimalised requirement of modern analgesics in the trial group. After completion of trial, collected data will be subjected to statistical tests like paired t test, chi square test and p value will be calculated at 0.0001 level of significance. Thus effect size will be calculated In this way an Ayurveda base analgesia as an alternative to modern analgesics can be established at the end of the clinical trial.

Keywords: hemorrhoids, fissure in ano, analgesics, side effects, effect size

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 categorised as acute or chronic on the basis of duration. our answer to pain is painkiller which on frequent use kills the resistance. similar in 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 haemorrhoidectomy, anal dilatation, Sphincterotomy etc for these diseases. These operative procedures are associated with unavoidable sequel of symptoms 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 parental 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. 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 is selected.

Criteria for Inclusion of Patient

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

Criteria for exclusion of Patients

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

Selection of patients

Post-operative Patients of *Parikartika* (fissure in ano) and *Arsha* (hemorrhoids) will be 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.

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

: Institutional Ethics Committee clearance- MUHS/E-3//PG/31/08/2350 dated 27/10/2017 Clinical trial register of India registration number:-CTRI/2020/03/024243

Materials

Among 104 registered patient in group A (n=52), postoperative patients of *Arsha* and *parikartika* will be treated with *Yashtimadhu Ghrita*, and in group b (n=52), patients of *H/arsha* and *parikartika* were treated with local application of lignocaine jelly. Methodology

- **Group A:** Local application of *Yashtimadhu Ghrita* will be done in Post-operative patients of *Arsha* and *Parikartika* twice a day after sitz bath for 5 days.
- **Group B:** Local application of lignocaine gelly will be done in Post-operative patients of *Arsha* and *Parikartika* twice a day after sitz bath for 5 days

Trial Drug

Trial drug i.e. *Yashtimadhu Ghrita* was prepared and analysed on parameters like morphological evaluation, rancidity, weight /ml, refractive index at 25 degree celsius, 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 will be done.

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

Procedure of Gudapurana Demonstrated



Fig 1

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

Duration of treatment

5 DAYS

Follow up period

0th, 1st, 2nd, 3rd, 4th, 5th day

Statistical tests

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

Comparison: Before and after treatment will be done by paired t test in each group separately. P value <0.05 will be 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

Scale for observations

Pain

Table 1

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.

Anal Sphinctor Musclespasm

Table 2

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

Result

Result will be drawn according to observation and discussion.

Discussion

Yashtimadhu has madhura rasa, madhura vipak, 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 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 Amarprakash *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 divoides of any side effects. This treatment can be used as supportive treatment modality for early recovery [16]. Latest article dwivedi *et al* has concluded that *yashtimadhu* has got bactericidal and antiseptic property which aids in wound healing. 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. More study is necessary on large scale, as this limited study has not covered all aspects, but clinical trial shows encouraging results. Study conducted on 10 post-operative patients of hemorrhoids and fissure in ano (two of each category) revealed significant pain relief, relaxation of anal sphincter spasm after 5 days *gudapurana* treatment with *yashtimadhu ghrita*. The effect was appreciable immediately after treatment on day 1 and gradual increase in effect size till day 5.

Conclusion

It can be concluded that *Yashtimadhu Ghrita* is helpful in the management of pain after completion of this clinical study it will be helpful to understand the effect of *Yashtimadhu Ghrita Gudapurana* in post-operative pain management in the patient of haemorrhoids and fissure in ano.

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