A COMPARATIVE CLINICAL STUDY OF DURVADI GHrita AND TANKan KShara IN THE MANAGEMENT OF GUDA-PARIKartIKA (FISSURE-IN-ANO)

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ABSTRACT

Anal fissure is second most common condition seen in an ano rectal clinic and by far the most common cause of anal ulceration. According to Ayurveda, it can be compared with guda-parikartika. The present study was conducted on 30 patients of Guda-parikartika (Fissure-in ano) with an objective to compare the efficacy of Durvadi Ghrita and Tankan Kshara on Guda-parikartika patients. The patients were divided into two groups of 15 patients in each group. Patients of Group A were recommended Durvadi Ghrita application, while patients of Group B were treated by Tankan Kshara. The patients were assessed per week for continuous one month according to the assessment criteria. After observing the overall therapy, it was found that in most of the parameters, Durvadi Ghrita have much better results than the Tankan Kshara like pain in ano, bleeding per anum, tenderness and anal sphincter tone.

KEYWORDS: Fissure-in-ano, guda-parikartika, durvadi ghrita, tankan kshara.

INTRODUCTION

Guda-parikartika is very common and painful condition. The factors responsible for causation of guda-parikartika are found in various texts as Vaman-virechana Vyapada, Basti Karma Vyapada and Upadrava of Atisara, Grahan, Arsha, Udavarta etc. The contributory factors are constipation, spasm of internal sphincter, surgical catastrophe during operation for hemorrhoids followed by anal stenosis, ulcerative colitis, Crohn's disease, syphilis and tuberculosis. On the basis of symptoms, the disease fissure-in-ano can be compared to the guda-parikartika described in Ayurveda. Acharya Sushruta has described the term ‘Parikartika’ as a condition of Guda (anus) where cutting and burning pain in anus, penis, umbilical region and neck of urinary bladder with cessation of flatus is there. Acharya Daudhana and Jejita have also clearly described Parikartika as a condition which results into cutting pain in anus. Acharya Kashyapa has also described three types of Parikartika viz. Vataja, Pittaja and Kaphaja. Whereas, Acharya Charaka has mentioned the features like pricking pain in groins and sacral region, scanty constipated stools and bleeding per anum.

In acute fissure-in-ano treatment is painkiller, stool softener and soothing ointment. In chronic fissure treatment is anal dilatation, sphincterotomy, fissurectomy are in vague but these procedures have complications like recurrence, incontinence and pruritus ani.

Its chikitsa aims at pacifying Vata and Pitta dosha and in classics is pichha basti, anuvasana basti, pichu, parisheka and lepa with sneha dravya. Durvadi Ghrita is having ingredients with Vrana Ropana properties which can help the Vrana (wound) to heal rapidly. It’s base is Ghrita which itself is having Samskara Anuvartan and healing properties. Ghrita kalpana is made as described in Sharangdhar Samhita.

Kshara Karma (Potential Cauterizing Application): It is a milder procedure compared to Shastra Karma (surgery) and Agnikarma (Thermal cautery). Kshara is described as one among the Anushastras or Upayantras. Kshara Karma is useful as the substitute of surgical treatment.

Tankan Kshara has been selected for clinical evaluation as it has wound healing property and stops bleeding after local application as mentioned in Rasatarangini.
OBJECTIVES
1. To evaluate the efficacy of the Durvadi Ghrita in Guda-parikartika
2. To evaluate the efficacy of the Tankan Kshara in Guda-parikartika
3. To compare the efficacy of Durvadi Ghrita and Tankan Kshara in Guda-parikartika (Fissure-in-ano).

MATERIAL AND METHODS
Selection of Patients
After making the diagnosis of the Guda-parikartika (Fissure-in-ano), the patients were selected for the study. The patients were registered and grouped by simple random method from OPD/IPD of PG department of Shalya Tantra, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University Hospital, Jodhpur, irrespective of age, gender, occupation, religion and casts.

Inclusion Criteria
1. The patients who were having classical signs and symptoms of fissure-in-ano were selected for the present clinical study.
2. Patients will be selected irrespective of age, sex, religion and socioeconomic status.

Exclusion Criteria
1. Patients suffering from fissure-in-ano, due to any secondary cause.
2. Patients with other systemic illness like uncontrolled Diabetes Mellitus, Hypertension, malignancy, HBsAg requiring concurrent treatment

Investigations
In all the patient’s general systemic and local examination along with laboratory investigations were carried out before treatment to rule out other diseases. Blood investigations done were Hb, TLC, DLC, BT, CT, ESR, Random Blood Sugar, HIV, HBsAg, VDRL.

Grouping of Patients
A clinical study in which 30 patients were selected on the basis of simple random sampling procedure and were divided into two groups of 15 patients each and clinical trail was be conducted as follows:

Group A: Per anal application of Durvadi Ghrita once daily.
Group B: Per anal application of Tankan Kshara (with honey) once daily.

All the patients have been given adjuvant drugs as mentioned below.
- Eranda Bhishtha Haritaki Churna : 5 g at bed time
- Triphala Guggula : 2 vati twice daily
- Panchawalkal Kwatha for sitz bath : 20g twice a day

Duration of Trial: 4 weeks

Assessment Criteria
The assessment was made by adopting numeric gradation method of symptoms and signs of the patients of Fissure-in-Ano:

Subjective parameters
1. Pain in ano
2. Bleeding per anum

Objective parameters
1. Tenderness in anal region
2. Anal sphincter tone

Score Pattern
Following score-pattern has been fixed for the assessment of the effect of therapy in the case of Fissure-in-Ano selected for the research study and the details are as below:

Pain in ano
0 : No pain
1 : Localised feeling of pain during bowel movement only but no feeling during rest
2 : Localised tolerable pain even during rest but completely relieved by hot sitz bath
3 : Intolerable pain relieved by oral or local medicine but no disturbed sleep
4 : Intolerable radiating and continuous pain with sleep disturbance and patient seek medical help as earlier possible

Bleeding per anum
0 : No bleeding
1 : Bleeding along with defecation streakwise only over the stool
2 : Drop wise bleeding during or after defecation 0-10 drops occasionally
3 : Drop wise bleeding during or after defecation 11-20 drops
4: Profuse bleeding drop wise or stream wise amounting more than 20 drops in each defecation.

Tenderness in anal region
0: No tenderness
1: Tenderness on deep palpation
2: Tenderness on light pressure
3: Tenderness on touch
4: Patient is rigid & doesn’t allow to touch

Anal Sphincter Tone
0: Easy DRE
1: DRE with discomfort
2: Painful DRE
3: DRE is not possible

Overall Assessment
The overall assessment of the results was done during 4 weeks (28 Days) after completion of treatment as per the following criteria.

Criteria For Overall Assessment
Overall effect of the therapy was assessed by adopting the following criteria:
Complete relief: 100% relief in subjective and objective parameters
Marked relief: 76-99% relief in subjective and objective parameters
Moderate relief: 51-75% relief in subjective and objective parameters
Mild relief: 25-50% relief in subjective and objective parameters
No relief: <25% relief in subjective and objective parameters.

Follow-Up Period: After the completion of treatment, the patients were asked to come weekly for three months for checkup. It was to be noted whether the relief provided by therapy was permanent or there was any recurrence.

Statistical Analysis
The information collected on the basis of observation were analyzed using appropriate statistical test as following:
- The Wilcoxon matched-pairs signed rank test was used in intra group for statistical analysis of result.
- The Mann-Whitney Test was used for inter group comparison.

The obtained results were interpreted to evaluate the significances at different levels i.e. at 0.05, 0.01 and 0.001 levels as following:
- Insignificant or Not significant (NS) - p > 0.05
- Significant (S) - p < 0.05
- More or very Significant (VS) - p < 0.01
- Highly or Extremely Significant (ES) - p < 0.001

OBSERVATIONS
Maximum 40% patients were in the age group 31-40 years, followed by 26.66% patients were in the age group of 18-30 years, 23.33% patients were in the age group of 41-50 years, 6.66% patients were in the age group of 51-60 years and 3.33% patient was in the age group of 61-70 years. 63.33% patients were males and 36.66% patients were females. 33.33% patients were housewives followed by 26.66% businessmen, 13.33% patients were doing service, 13.33% were students and 13.33% patients were labourers. 43.33% patients were of lower class family, 33.33% patients were recorded from middle class family whereas 23.33% patients were from upper class family. 60% patients were vegetarian and 40% patients were non-vegetarian. 93.33% of patients had given history of irregular bowel habit while 6.67% of patients were having regular bowel habit.

RESULTS
Table No. 1: Showing Effect of Therapy in Subjective and Objective Parameters in 15 patients of Group A.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean decrease</th>
<th>% relief</th>
<th>SD</th>
<th>SE</th>
<th>P value</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain in ano</td>
<td>2.333</td>
<td>0.4000</td>
<td>1.933</td>
<td>82.86</td>
<td>0.2582</td>
<td>0.06667</td>
<td>&lt;0.001</td>
<td>ES</td>
</tr>
<tr>
<td>Bleeding per annum</td>
<td>1.200</td>
<td>0.06667</td>
<td>1.133</td>
<td>94.44</td>
<td>0.6399</td>
<td>0.1652</td>
<td>&lt;0.001</td>
<td>ES</td>
</tr>
<tr>
<td>Tenderness</td>
<td>1.400</td>
<td>0.1333</td>
<td>1.267</td>
<td>90.48</td>
<td>0.4577</td>
<td>0.1182</td>
<td>&lt;0.001</td>
<td>ES</td>
</tr>
<tr>
<td>Anal sphincter tone</td>
<td>2.267</td>
<td>0.2000</td>
<td>2.067</td>
<td>91.18</td>
<td>0.2582</td>
<td>0.6667</td>
<td>&lt;0.001</td>
<td>ES</td>
</tr>
</tbody>
</table>

(BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error, P = Probability, S = Significance).

Table No. 2: Showing Effect of Therapy in Subjective and Objective Parameters in 15 patients of Group B.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean decrease</th>
<th>% relief</th>
<th>SD</th>
<th>SE</th>
<th>P value</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain in ano</td>
<td>2.467</td>
<td>1.067</td>
<td>1.400</td>
<td>56.76</td>
<td>0.6325</td>
<td>1.633</td>
<td>&lt;0.001</td>
<td>ES</td>
</tr>
<tr>
<td>Bleeding per annum</td>
<td>1.467</td>
<td>0.1333</td>
<td>1.333</td>
<td>90.91</td>
<td>0.6172</td>
<td>0.1594</td>
<td>&lt;0.001</td>
<td>ES</td>
</tr>
<tr>
<td>Tenderness</td>
<td>2.000</td>
<td>0.5333</td>
<td>1.467</td>
<td>73.33</td>
<td>0.5164</td>
<td>0.1333</td>
<td>&lt;0.001</td>
<td>ES</td>
</tr>
<tr>
<td>Anal sphincter tone</td>
<td>2.067</td>
<td>0.3333</td>
<td>1.733</td>
<td>83.87</td>
<td>0.4577</td>
<td>0.1182</td>
<td>&lt;0.001</td>
<td>ES</td>
</tr>
</tbody>
</table>

(BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error, P = Probability, S = Significance).
Table No. 3: Inter Group Comparision in 30 Patients.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group</th>
<th>Sum of Rank</th>
<th>Diff.</th>
<th>% Relief</th>
<th>SD</th>
<th>SE</th>
<th>U value</th>
<th>P value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain in ano</td>
<td>A</td>
<td>285.5</td>
<td>1.933</td>
<td>82.86</td>
<td>0.2582</td>
<td>0.6667</td>
<td>59.5</td>
<td>0.0267</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Bleeding per anum</td>
<td>B</td>
<td>179.5</td>
<td>1.40</td>
<td>56.76</td>
<td>0.6325</td>
<td>0.1633</td>
<td>94.0</td>
<td>0.4475</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Tenderness</td>
<td>A</td>
<td>214.0</td>
<td>1.133</td>
<td>94.44</td>
<td>0.6399</td>
<td>0.1652</td>
<td>79.9</td>
<td>0.3512</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>251.0</td>
<td>1.333</td>
<td>90.91</td>
<td>0.6172</td>
<td>0.1594</td>
<td>90.0</td>
<td>0.3512</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Pain in ano</td>
<td>A</td>
<td>210.0</td>
<td>1.267</td>
<td>90.48</td>
<td>0.4577</td>
<td>0.1182</td>
<td>88.9</td>
<td>0.3512</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Bleeding per anum</td>
<td>B</td>
<td>255.0</td>
<td>1.467</td>
<td>73.33</td>
<td>0.5164</td>
<td>0.1333</td>
<td>94.0</td>
<td>0.3512</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Tenderness</td>
<td>A</td>
<td>268.0</td>
<td>2.067</td>
<td>91.18</td>
<td>0.2582</td>
<td>0.0667</td>
<td>77.0</td>
<td>0.1314</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>197.0</td>
<td>1.733</td>
<td>83.87</td>
<td>0.4577</td>
<td>0.1182</td>
<td>94.0</td>
<td>0.3512</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

(\(SD = \text{Standard Deviation}, \ SE = \text{Standard Error}, \ P = \text{Probability}, \ S = \text{Significance}\))

DISCUSSION

The discussion has been made under the following headings:
1) Discussion on overall effect of therapy.
2) Probable Mode of Action of Drug.

Overall effect of therapy

- The effect of therapy in the subjective parameter of “Pain in ano” reveals 82.86 % relief in group A and 56.76 % relief in group B.
- The effect of therapy in the subjective parameter of “Bleeding per anum” reveals 94.44 % relief in group A and 90.91 % relief in group B.
- The effect of therapy in the objective parameter of “Tenderness” reveals 90.48 % relief in group A and 73.33 % relief in group B.
- The effect of therapy in the objective parameter of “Anal sphincter tone” reveals 91.18 % relief in group A and 83.87 % relief in group B.

Comparison of Both the Therapies in Group A and Group B

- **Durvadi Ghrita** showed better results on all subjective and objective parameters. It was statistically very significant on subjective parameter Pain in ano and not significant on all the rest subjective and objective parameters.
- Out of 15 patients of Group A, complete relief was seen in the 11 patients, marked relief in 2 patients, moderate relief in 2 patients, no patient was seen with mild relief and no relief.
- Out of 15 patients of Group B, complete relief was seen in the 5 patients, marked relief in 4 patients, moderate relief in 6 patients, no patient was seen with mild relief and no relief.

Probable Mode of Action of Drugs

(1) **Durvadi Ghrita**

*Durvadi Ghrita* has constituents: *Durva*, *Kampillaka*, *Daruharidra* and *Ghrita*.

The *Anurasa* of *Durva* grass which are *Tikta* and *Kashaya* are *Pittashamaka* with *Krimivishhara* (may be antibiotic) and *Ropana* (healing) properties respectively. *Cynodon dactylon* (*Durva*) is *tridoshashamak* especially *kapha-pitta shamak* and known antimicrobial, antiviral and antulcer drug. The flavanoid present in durva facilitate the healing process by increase in collagen and protein and decrease in lipid peroxide in granulation tissue (Wound healing). It has inhibitory activity against increased amount of peroxides found during the inflammation (Anti-inflammatory). It increase pain threshold. Durva promotes angiogenesis probably through stimulating VEGF (vascular endothelial growth factor) expression. Durva is anti-allergic by antiphylactic and mast stabilization mechanism.

**Kampillaka** has *krimighna-kriminiskasaka* and rakta-shodhaka activity. It contains an alkaloid called rottellerin which produces analgesic effects by mechanisms affecting the production of endogenous opioids, prostaglandins, histamine and other mediators important for pain production and sensitizers. It showed a significant reduction in the exudative fluid. It possesses a significant anti-inflammatory and anti-nociceptive activity. Fruit extract shows strong antibacterial activity against *Pseudomonas aeruginosa*, *E. coli* and *Staphylococcus aureus*.

**Daruharidra** is kapha-pitta shamak. Berberine alkaloid has haemostatic action by inducing platelet aggregation activity by inhibiting PAF. This alkaloid has anti-inflammatory activity by inhibiting release of arachidonic acid and vascular permeability. It possess
antimicrobial activity against gram positive and gram-negative bacteria.

**Ghrita** is the medium of combination. It possesses vrsna sodhana and ropana property and is vata-pitta shamana. Therefore, ghrita enhances the action of the drug. It also reduces the rakshata of vayu and maintains the normal tone of muscles. Cow ghee is considered to be extremely useful for treating wounds, inflammatory swellings and blisters for promotion of quick healing. It is a rich sources of essential fatty acids, such as Omega-3 and Omega-6 which regulate prostaglandin synthesis and thus has anti-inflammatory property. It also also has a soothing property. It form a thin film over them and that allows early epithelization of wound. It also protects wound from invasion of any microbes.

The disease is vata-pitta dominant. Drugs used to prepare Durvadi Ghrita are having dominantly Madhura Rasa, Sheeta Virya and Madhura Vipaka. Because of these properties it is Vata Pittashamana property. Madhura Rasa is Sandhanarakara. This drug has haemostatic, anti-inflammatory, anti-microbial activity and are having vrana sodhana and ropana properties.

**(II) Tankan Kshara**

As the definition of kshara says, it removes the unwanted tissue from the body. The fibroses in the edges of fissure hampers the healing process.

When tankan kshara is applied after drying the site the fibroed edges become very dry and thus the kshara is very much effective there. The caustic kshara, chemically cautzerizes the site of fibrosis. The changes occurring will be described in observations. Thus when fibrosis is sloughed out the process of healing becomes faster.

The kshara is deepana and pachana, so local dhatvagni is boosted and so is process of regeneration. Kshara is shoshaka, the mucoid discharge that gets collected in fissure bed is dried and granulation promoted.

There is temporary local inflammatory response after kshara application. The prostaglandins and histamine secured, and also add to the process of granulation tissue formation. This is how the kshara works in treatment of Charaka parikartika (a dusha vrana).

**Madhu** is a very good Vrana Shodhaka. Due to its sukshmata, it enters very small pores around the wound site and does not allow any infection to enter the site. When cleansed it also does desloughing of the wound.

**CONCLUSION**

On the basis of the entire study, the following points are selected that should be concluded:

- On the basis of causes and pain dominant symptoms of Guda-parikartika described by Sushruta, this disease resembles with disease fissure-in-ano.
- According to chief complaints of the patients, Guda-parikartika is found as Vata-pitta Pradhana disease which is as similar to classics.
- Fissure-in-ano was present at 6 o’clock position in about 59.26% cases and most of the time it is a single fissure only. However the fissure at 12 o’clock or at other site may also be found either alone or in combination.
- The Durvadi Ghrita and Tankan Kshara both are significant, though Durvadi Ghrita shows better results in pain in ano, bleeding per anum, tenderness and on anal sphincter tone.

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