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CLINICAL EVALUATION OF MADHUYASHTYADI GHrita AND ANAL DILATATION IN THE MANAGEMENT OF PARIKARTIKA (FISSURE-IN-ANO)

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ABSTRACT: Anal Fissure is very common condition in Ano-Rectal Clinics due to its agonising pain. Its prevalence rate is higher than Haemorrhoids. The disease Fissure-in-Ano can be compared to the disease Parikartika according to Ayurveda. Acharya Dalhana has described the term Parikartika as a condition of Guda. The condition has been mentioned as complication of Vamana and Virechana procedures in Ayurvedic classics. Even though there are many modalities of treatments in modern but none of them are complete and satisfactory.


INTRODUCTION:-

- Fissure-in-Ano is very common and painful condition; fissure occurs most commonly in the midline posteriorly. In males fissures usually occur in the midline posteriorly- 90%, and much less commonly anterior 10%. In females fissures on the midline posteriorly are slightly commoner than anteriorly (60:40).¹⁰,¹⁷,¹⁸
- Predominant cause has been explained as posterior angulation of the anal canal, relative fixation of the anal canal posteriorly, divergence of the fibers of the external sphincter muscle posteriorly and the elliptical shape of the anal canal. In addition to it, the other contributory factors are constipation, spasm of the internal sphincter, surgical catastrophe during operation for haemorrhoids followed by anal stenosis, which may ultimately result into anal fissure.¹⁵,¹⁰,¹⁷
- Similarly, secondary causes like Ulcerative Colitis, Crohn’s disease, Syphilis and Tuberculosis have also
been held responsible for the formation of the disease Fissure-in-Ano.\textsuperscript{10,15,16,17,18}

- Fissure-in-Ano has been classified into two varieties; viz. **Acute Fissure-in-Ano** and **Chronic Fissure-in-Ano**. Either acute or chronic, pain and bleeding are the two main symptoms of this condition. Pain is sometimes intolerable. In long standing cases it may be associated with Haemorrhoids or a Sentinel tag. Pruritis ani may be another symptom of this condition.\textsuperscript{10,15,17}

- The disease **Fissure-in-Ano** can be compared to the disease **Parikartika** according to Ayurveda. Acharya Dalhana has described the term Parikartika as a condition of Guda in which there is cutting and tearing pain. Similarly Jejjata and Todara have clearly described Parikartika as a condition which causes cutting pain in Ano-rectum.\textsuperscript{1,2,3}

- The factors responsible for causation of Parikartika as found in various texts are Vamana-Virechana-Vyapada, Bastikarma Vyapada, Atisara, Grahani, Arsha, Udavarta etc. In the similar manner it has been described of three types; viz. Vataja, Pittaja and Kaphaja.\textsuperscript{1,2,3,4,5,6,7,8}

- Sushruta while describing the symptoms of the disease speaks of the features like: cutting or burning pain in anus, penis, umbilical region and neck of urinary bladder with cessation of flatus. Whereas, Charaka has described the features like: pricking pain in groins and sacral area, scanty constipated stools and frothy bleed per anum.\textsuperscript{1,2,3,4,5,6}

- The present trend in the treatment of Fissure-in-Ano depends on the type of the disease: e.g. in cases of acute variety with short history of the problem can be treated on the conservative lines, which include oral pain killing medication to be taken before anticipated bowel movement. Stool softener may be used to make the stool soft enough, weak bulk laxative or cathartics are the best. Soothing ointment, self dilatation etc. are considered to be beneficial. Whereas, injection of long acting Anaesthetics solution though promotes relief but not free from complications. Whereas in chronic ulcer anal dilatation, posterior Sphincterotomy and Fissurectomy and excision of the anal ulcer along with skin graft has not been successful.\textsuperscript{10,17,18}
An alarming rise in the incidence of the disease Fissure-in-Ano and no known satisfactory remedies evolved so far has given an impetus to find out a suitable solution, with altogether better effects, from amongst the treatments advocated by the ancient Ayurvedacharyas, a set of treatment principles were selected and tried over the cases of Parikartika vis-a-vis Fissure-in-Ano. Hence, from the repeated advocacy of Sushruta and other ancient Acharyas, Madhuyashtyadi Ghrita (ingredients-Yashtimadhu, Devadaru, Haridra, Tagara, Nirgundi, Udumbara, Ghrita) for local application and Anal Dilatation under suitable anaesthesia separately and in combination along with laxative and local soothers and anti-inflammatory drugs in the selected cases of Fissure-in-Ano.

AIMS AND OBJECTIVES:
1. To explore Ayurvedically the basic idea of the disease Fissure-in-Ano.
2. To assess the efficacy of Anal Dilatation and Madhu Yashtyadi Ghrita separately and in combination in the management of Fissure-in-Ano.
3. To know the pre-disposing factors like Ahara, Vihara, Dosha, Dushya of different types of Fissure-in-Ano from Ayurvedic View Point.
4. To assess the level of effectiveness of the Ayurvedic drugs.

MATERIALS AND METHODS:
A) The Patients:
Patients will be selected from the OPD & IPD of Shalya Tantra Dept. of JGCHS Ayurvedic medical College Hospital and J.G.Co-Op Hospital & Research Institute Ltd. Ghataprabha, Karnataka for the present study.

B) The Drugs:
The formulation with their respective ingredients was prepared in the pharmacy section of JGCHS Ayurvedic medical College & Hospital, Ghataprabha (Karnataka).

CRITERIA OF SELECTION OF THE PATIENTS:
The patient suffering from fissure-in-ano and also having the associated symptoms like sentinel tags, pain and bleeding per rectum, etc. were selected for the present study. Patients were randomly selected irrespective of age, sex, religion, caste etc.

EXCLUSION CRITERIA:
1. Patients suffering from systemic diseases like Diabetes mellitus, Tuberculosis will be excluded from the study.
2. Patients found associated with HbsAg and HIV / AIDS will be excluded from the study.

3. Patients associated with Prolapse Rectum, Fistula-in-Ano, Ca Rectum, Ulcerative colitis, Crohn’s Disease and 2nd, 3rd & 4th degree Haemorrhoids will also be excluded from the study.

**CRITERIA FOR DIAGNOSIS:**

For the purpose of clinical evaluation, following parameters were adopted –

1. Guda Daha.
2. Kartanavat Vedana.
3. Rakta Srava.
4. Vibhandata.

For all these parameters, a special score sheet was prepared and was used for the assessment of the effect of the therapy.

**Laboratory Investigations:**


**Plan of the Clinical Study:**

The selected patients were randomly distributed in to three groups as below-

1. **Group-A: Madhuyashtyadi Ghrita Group.**  
   {Madhuyashtyadi Ghrita 10 gms BD for local application for 4 weeks.}

2. **Group B: Anal Dilatation Group.**  
   {One sitting under suitable anesthesia by Lord’s Method}

3. **Group C: Combined Group.**  
   [Anal Dilatation followed by Madhuyashtyadi Ghrita 10 gms BD Local application.]

➢ Informed, written consent was obtained from all the patients before admitting them in to the treatment schedule.

➢ Patients were managed at OPD level unless they need to be admitted.

➢ Weekly follow-up was done for the duration of 3 months.

➢ Patients of all the groups were administered – Tab. Triphala Guggulu 1 tab. TDS, Panchavalkala Kashaya Avagaha sweda & Haritaki Churna 5 gms HS for analgesic, soothing & Anulomana effects during the treatment regimen and in post-operative period.

➢ In the event of any other illness, the patients are advised to report the scholar immediately.

**CRITERIA FOR ASSESSMENT:**

Effect of the Treatment was assessed as under mentioned –
1. **Curative:** - Complete healing of the Fissure and subsidence of the presenting complaints.

2. **Effective:** - Relief in Signs and Symptoms of Fissure-in-Ano and improvement in the physical and mental status of the patient and non-healing of the Fissure.

3. **Unchanged:** - No positive effect in the signs and symptoms.

The results of the therapy were assessed on the basis of clinical signs and symptoms followed in Ayurvedic classics as well as followed by investigations and overall improvement.

**OBSERVATIONS:**

- Out of 105 patients, maximum 42% of patients were in between the age group of 31 to 40, followed by 40% was between 41 to 50 age group.
- 58% patients were Females and 47% patients were Males.
- 74% patients were Hindu and 26% patients were Muslim.
- maximum 37% patients were found without education.
- Education, 21% were graduates and 20% patients were having primary education.
- maximum 37% patients were housewives, followed by 21% businessmen and 19% were doing labour work.
- 43% patients were found of lower class family.
- 87% patients were married and 13% patients were unmarried.
- 61% patients were found Non-vegetarian & 39% patients were vegetarian.
- 42% patients were addicted to Tobacco & 25% patients were addicted to Tea/Coffee.
- 64% patients were found Vata Pittadhika Prakruti, followed by 22% patients of Kapha Pitta prakruti.
- Out of 105 patients, 100% patients were found having Guda Daha and Aniyata Vibandhata, 58% patients were having cutting pain and 57% patients were found having Rakta Srava.
- Out of 105 patients, 57% patients were having Agni Vaishamya and 38% were having Avipaka.
- 59% patients were having fissure in midline posterior position of anal canal. 23% patients were having fissure in midline anterior and 17% Patients were having in both the positions.
80% patients were found sphincter spasm and 20% patients were found normal tone.

80% patients were found with indurated edges and 20% patients were found with soft edges.

80% patients were found with tenderness whereas, tenderness was absent in 20% patients.

chronicity wise 33% patients were observed between 1 to 6 months duration and 28% were observed more than 1 year of duration.

38% patients were found having sentinel pile (Tag) and 62% patients were not having tag.

Table No:1: Effect of the Treatment on cardinal symptoms of Parikartika in 35 patients of ‘A’ group:-

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Mean Score</th>
<th>Mean decrease</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>“t”</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guda Daha</td>
<td>2.8</td>
<td>0.4</td>
<td>2.4</td>
<td>85.71</td>
<td>0.75</td>
<td>0.16</td>
<td>14.23</td>
</tr>
<tr>
<td>Cutting pain</td>
<td>1.65</td>
<td>0.05</td>
<td>1.6</td>
<td>96.96</td>
<td>1.50</td>
<td>0.33</td>
<td>4.76</td>
</tr>
<tr>
<td>Rakta Srava</td>
<td>1.20</td>
<td>0.05</td>
<td>1.15</td>
<td>95.83</td>
<td>1.22</td>
<td>0.27</td>
<td>4.19</td>
</tr>
<tr>
<td>Aniyata Vibandhata</td>
<td>2.95</td>
<td>0.35</td>
<td>2.6</td>
<td>88.13</td>
<td>0.68</td>
<td>0.15</td>
<td>17.08</td>
</tr>
</tbody>
</table>

Table No:2: Effect of the Treatment on cardinal symptoms of Parikartika in 35 patients of ‘B’ group:-

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Mean Score</th>
<th>Mean decrease</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>“t”</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guda Daha</td>
<td>2.75</td>
<td>0.45</td>
<td>2.3</td>
<td>83.63</td>
<td>0.73</td>
<td>0.16</td>
<td>14.03</td>
</tr>
<tr>
<td>Cutting pain</td>
<td>1.15</td>
<td>0.2</td>
<td>0.95</td>
<td>82.60</td>
<td>1.19</td>
<td>0.27</td>
<td>3.57</td>
</tr>
<tr>
<td>Rakta Srava</td>
<td>0.9</td>
<td>0.1</td>
<td>0.8</td>
<td>88.88</td>
<td>0.89</td>
<td>0.2</td>
<td>4.0</td>
</tr>
<tr>
<td>Aniyata Vibandhata</td>
<td>2.85</td>
<td>0.55</td>
<td>2.3</td>
<td>80.70</td>
<td>0.65</td>
<td>0.14</td>
<td>15.65</td>
</tr>
</tbody>
</table>
Table No:3: Effect of the Treatment on cardinal symptoms of Parikartika in 35 patients of ‘C’ group:

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Mean BT</th>
<th>Score AT</th>
<th>Mean decrease</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>“t”</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guda Daha</td>
<td>2.75</td>
<td>0.15</td>
<td>2.6</td>
<td>94.54</td>
<td>0.50</td>
<td>0.11</td>
<td>23.13</td>
<td>&lt;0.00</td>
</tr>
<tr>
<td>Cutting pain</td>
<td>2.2</td>
<td>0.2</td>
<td>2</td>
<td>90.90</td>
<td>1.16</td>
<td>0.26</td>
<td>7.6</td>
<td>&lt;0.00</td>
</tr>
<tr>
<td>Rakta Srava</td>
<td>1.25</td>
<td>0.05</td>
<td>1.2</td>
<td>96</td>
<td>1.00</td>
<td>0.22</td>
<td>5.33</td>
<td>&lt;0.00</td>
</tr>
<tr>
<td>Aniyata Vibandhat a</td>
<td>2.9</td>
<td>0.2</td>
<td>2.7</td>
<td>93.10</td>
<td>0.47</td>
<td>0.10</td>
<td>25.68</td>
<td>&lt;0.00</td>
</tr>
</tbody>
</table>

Table No:4: Overall effect on Parikartika in 105 patients:

<table>
<thead>
<tr>
<th>Effect</th>
<th>No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td>74</td>
<td>70</td>
</tr>
<tr>
<td>Improved</td>
<td>31</td>
<td>30</td>
</tr>
<tr>
<td>Unchanged</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

DISCUSSION:

Anatomical smiley for the Guda in modern science is the anus; since the Valies told are the ring like projections of the sphincter muscles and Levator ani muscles. The site of Parikartika is Guda Vartma or Guda twak which is similar to the site of Fissure-in-Ano i.e. anoderm. Sedentary life as well as very hard work and stressful life play important role in predisposition to the
About 41% of the patients who suffer from Fissure-in-Ano belong to the age group of 31-40 years and 40% patients were in between 41 to 50 years, majority of which are female patients. Vata and Pitta Dosha seem to play a vital role in the development of fissure and similarly on further analysis it appears that the persons belonging to Vatic and Paittika temperament have a tendency of development of fissure. 6 O’clock is always a fixed position for Fissure-in-Ano in about 63% cases and most of the time it is single fissure only. However, the fissures at 12 o’clock or the other odd site may also be found either alone or in combination.

Stressful life, untimely and unlawful dietary habits excessive consumption of Lavana, Katu, Tikta, Ruksha, Ushna, Guru Ahara etc., are the main precipitating factors of this condition.

Clinical history and tightly puckered anus or presence of a sentinel tag is confirmatory of an acute or chronic fissure respectively. Similarly a streak of blood on the side of a hard faecal column is a specific for a fissure in most of the cases however excessive bleeding and abscess and fistulae formation are rare complication. The presence of a sentinel tag is confirmatory of a chronic fissure and unless it is removed the treatment is not successful. Pain which is the most evident and presenting symptom of fissure-in-ano can be relieved much earlier completely by the application of Madhuyashtyadi Ghrita or by Anal Dilatation or with both. Anal Dilatation followed by local application of Madhuyashtyadi Ghrita will be an excellent less invasive approach in this condition.

Anal Dilation was done under suitable anaesthesia, either Local, or Short General Anaesthesia or spinal. The spasm of anal sphincters
The follow up study of these cases shows that the results achieved in all the groups are effective and stable for a long time. No recurrence was noticed in three groups during the follow up the period of which extended from 6 months. The use of Madhuyashtyadi Ghrita has a definite advantage in the treatment of Fissure-in-Ano in terms of earlier relief of cardinal symptoms; and spasm, quick healing of the ulcer is achieved with Anal Dilation and on the whole, inducing a cure of the lesion when the treatment is combined and with other oral medicament for improving the digestive function and regular bowel movement of the patients.

Lastly, the trial management was found to be very effective in this disease. These modalities may be chosen singly or with combination on the basis of the severity of the condition in clinical practice.
Ayurveda has rich source of time tested medicines which can be utilized in the management of Fissure-in-Ano in a non-invasive or less invasive methods.

**CONCLUSIONS:-**

After completion of whole research work, following conclusions can be drawn:-

- All the modalities viz, Local application of Madhuyashtyadi Ghrita, Anal Dilation and Anal Dilation followed by local application of Madhuyashtyadi Ghrita are effective in the management of Parikartika vis-à-vis Fissure-in-Ano.

- As a conservative line of management Fissures can be treated effectively with Madhuyashtyadi Ghrita as local application.

- Anal dilation relaxes the sphincters thereby enhance and accelerates the healing of the ulcer.

- Anal Dilation followed by local application of Madhuyashtyadi Ghrita will cure the disease completely.

- Use of Triphala Guggulu, Haritaki Churna and Panchavalkala Kwatha Avagaha Sweda will give Analgesic, Anulomana and Soothing effect respectively during and in post-operative period.

   Hence, it can be concluded without any hesitation that even though all the treatment modalities are effective over the condition Fissure-in-Ano but Anal Dilation followed by local application of Madhuyashtyadi Ghrita in the post-operative period will be better in comparison with Madhuyashtyadi Ghrita application alone as a conservative measure or Anal Dilation alone. There is need of few more research works regarding this concept on larger samples of study.

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PHOTOGRAPHS:

**Madhuyashtyadi Ghrita**

**Posterior Fissure-in-Ano**

**Application of Madhuyashtyadi Ghrita**

**Manual Anal Dilation**

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