

Clinical Study on *Parikartika* (Fissure-in-Ano) and its Management with *Sindooradyo Malahara*

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Abstract

Parikartika (fissure-in-ano) being a common disease of the ano-rectum is seen extensively in the present society. The present study aims at deriving a standard and easily accessible, cost effective formulation for the management of *Parikartika*. *Sindooradyo Malahara* preparation from *Rasa Tarangini* text had been chosen for the trial purpose. According to the proposed criteria, 45 patients suffering from classical symptoms of *Parikartika* were selected and distributed randomly among three groups. Group-A: 15 patients were treated with local application of the trial drug (*Sindooradyo malahara*). Group-B: 15 patients were treated with local application of *Sindooradyo malahara* with adjuvant therapies such as sitz bath & dietary regimen. Group-C: 15 patients were treated with local application of a modern ano-rectal preparation (Sucralfate + Lignocaine) in ointment form. The improvement in signs & symptoms were assessed by definite scoring method & the result was evaluated mainly on the basis of clinical observations. After the commencement of the whole therapy in Group-A, 80% of the patients got marked improvement w.r.t. their clinical sign and symptom before treatment, 13.3% patients got moderate improvement and 6.67% of the cases got mild improvement. In Group-B, the values found higher than that of other groups i.e., *Sindooradyo Malahara* along with adjuvant therapies had shown marked improvement in 86.6% patients. 13.3% of the patients got moderate improvement and 6.67% of the patients got mild improvement. In Group-C, the effectiveness found at par with the trial Group-A and 80% of the patients got marked improvement, while 10% and 10% of the patients got moderate and mild improvement respectively. Thus, *Sindooradyo Malahara* was found as an effective tool in the management of *Parikartika*.

Keywords: *Parikartika*, *Fissure-in-ano*, *Sindooradyo Malahara*



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INTRODUCTION

In this era, a major portion of people in the society are living with stress & tension in their day-to-day life. In addition to this, unhealthy environment as well as abnormal food habit is playing the key role for their devastating health condition. In this context, ano-rectal diseases are now at a peak occurrence in public, from which *Parikartika* (fissure-in-ano) is a very common disease, whose incidence rate is very high in the community. Irrespective of age and sex it affects all, causing a painful condition, which may lead to deterioration in quality of life. This particular disease has limited references in the classical texts. As like other common diseases, its *panchanidan-lakshana* and *chikitsa* are not found at a single part of any *Ayurvedic* classical texts including *Bruhatrayee* and *Laghutrayees*. It has been described as a complication of *virechan*¹ and *basti*² procedures. *Maharshi Kashyap* described its occurrence in *garbhini*³. Modern science describes *Fissure-in-ano* as the ulcer in the longitudinal axis of the lower anal canal⁴. Although its exact incidence rate is unknown. It has been described with an aetiology of hard stool, inappropriate diet, vaginal child birth, previous anal surgery,

hyper tonicity of anal sphincters and may also associated with some secondary conditions like anal carcinoma, tuberculosis etc. This disease is not life threatening but very painful for the sufferers. Although many times it is self-limiting in nature, still people avoid treatment in fear of social embracement, thus sent the state in to complicacy, and needs surgical intervention. The conventional surgical procedures available for this such as- Lord's dilatation, Fissurectomy, Sphincterotomy etc. also bears the chances of recurrence. The result of all these procedures also causes many complications.

Ayurvedic management procedures in the field of proctology are quite effective and widely accepted globally. Hence, this condition has been attracting *Ayurvedic* surgeons for search of ideal and suitable curative procedures in this field. So far, there have been many researches carried out in different institutions regarding *Parikartika*. The amount of research works which have been done, on this subject is far less in comparison to the agony and urgency it produces. Moreover, there has been no work carried out on clinical management of *Parikartika* with "*Sindooradyo malahara*". Since *Guda* is a *Sadya pranahara marma*⁵

and *Shashtra karma* over this area should not be applied frequently, hence a conservative management attempt was made to see the effect of “*Sindooradyo malahara*” instead of any surgical intervention.

AIMS AND OBJECTIVES

By reviewing the literature related to *Parikartika* as well as Fissure-in-ano, the aim of the study was to derive a standard, easily accessible and cost effective drug for the treatment of *Parikartika*(fissure-in-ano) and prove the hypothesis that- *Bhutaghna* (antimicrobial), *Vranasodhana* (wound debridement), *Vranaropana* (wound healing), *Kandughna* (anti-pruritic) etc. properties are useful in the treatment of *Parikartika*⁶. Objective of the study was to assess the wound healing and analgesic effect of *Sindooradyo Malahara* in the clinical management of *Parikartika*.

MATERIALS AND METHODS

Patients

Patients suffering from *Parikartika* were selected from OPD/IPD of Gopabandhu Ayurved Mahavidyalaya & Hospital, Puri, as deemed fit- irrespective of age, sex, and religion. Under the specified criteria, 45 patients were registered with prior consent

to be included in the study and divided randomly in to three groups (A,B,C) with 15 number of patients in each group. Data collected were interpreted in specialised case sheets with follow up studies. Demographic data were prepared out of 45 cases and statistical evaluations of improvement were made of 40 patients because 5 pts. (Group-C) discontinued the course and not completed the clinical trial. Hence they were dropped out from the study.

Drug

The selected research medicine “*Sindooradyo Malahara*^{7,8}” was taken from *Rasatarangini* text. It is a herbo-mineral *malahara* (ointment) preparation with *Siktha taila* as base. There are two separate *malahara* preparations mentioned in the same context (*Rasa Tarangini*, Ch-21) and among them, first *Sindooradyo malahara* contains *Tankana* (Borax) and second *Sindooradyo Malahara* contains *Rala* (resin of Sal tree) as extra component. Whereas *Siktha taila* and *Sindoor* are found in both the preparations. Here, the second *Sindooradyo Malahara* has been selected by the DRC (Departmental research committee) of the institution for research trial. Necessary amount of the medicine needed for the study was prepared in the Pharmacy attached to *RSBK Dept., GAM, Puri* with the following ingredients as per the reference. For clinical study

Sindooradyo Malahara prepared using *Sikthataila*⁹, *Rala*¹⁰ and *Sindoor*^{11,12} in a proportion 6:1:1 respectively as per reference⁷ (Figure-1). The Control drug was procured from the market and it is a modern ointment preparation which is used for treating anal fissure having mixture of two medicinal ingredients i.e. Sucralfate & Lignocaine.

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Selection Criteria-

Patients were selected randomly irrespective of age & sex with the clinical features-viz. pain in the anal region during and after defecation, H/O constipation, burning sensation around the anus and bleeding may be present or not etc. Diagnosis was carried out with routine procedures i.e., inspection, P/R exam etc. as required and the patient's data was collected & interpreted in a specialised case sheet.

Inclusion Criteria-

- ❖ Patients presenting with classical symptoms of *Parikartika*.
- ❖ Patients suffering from acute & chronic anal fissure with no other ano-rectal abnormalities.
- ❖ Patients having anal fissure with sentinel tag were also included.

Exclusion Criteria-

- ❖ Anal Fissure associated with Piles or Fistula in ano.
- ❖ Patients with prolapsed rectum, Ca rectum and systemic diseases like tuberculosis, diabetes were not included.
- ❖ **Assessment Criteria-**
- ❖ The result was evaluated mainly based on clinical observations¹³.

| S. No. | Character | Score | Score details |
|--------|-------------------|-------|------------------------------------------------------------------------|
| 1 | Pain | 0 | Absence of pain |
| | | 1 | Tolerable pain |
| | | 2 | Intolerable pain |
| 2 | Ulcer | 0 | Absence of ulcer |
| | | 1 | Mild ulcer |
| | | 2 | Marked ulcer |
| 3 | Bleeding P/R | 0 | Absence of bleeding |
| | | 1 | Slight bleeding |
| | | 2 | Severe bleeding |
| 4 | Skin tag | 0 | Absence of skin tag |
| | | 1 | Skin tag present |
| | | 2 | Prominent skin tag |
| 5 | Constipation | 0 | Normal defecation |
| | | 1 | One defecation per day with straining |
| | | 2 | One defecation in alternate day with straining or severely constipated |
| 6 | Burning sensation | 0 | Absence of Burning sensation |
| | | 1 | Mild Burning Sensation |
| | | 2 | Severe Burning Sensation. |
| 7 | Itching | 0 | No itching |
| | | 1 | Occasional itching |
| | | 2 | Regular itching |

Application of medicine and follow up-

Both the trial as well as control medicine was administered locally, 2 gm twice daily for 3 weeks in respective group of patients

and observations were recorded every 7th day in the specified case sheet. During local application of the respective medicines with finger, gradual anal dilatation done during the course of study on a daily basis. In Group-B patients warm sitz bath & dietary regimen were also applied with the therapy as adjuvant therapy.

Plan of Study-

Forty five patients were divided in to 3 groups randomly and routine pathological tests of the patients were done to rule out other systemic diseases. Treatment applied as follows:

Group-A: Trial group1 (T.G.1)-

Fifteen patients were treated with local application of the trial drug i.e., *Sindooradyo Malahara* with gradual anal dilatation done on a daily basis.

Group-B: Trial group2 (T.G.2)-15 patients were treated with local application of *Sindooradyo Malahara* with adjuvant therapies such as warm sitz bath, anal dilatation& dietary regimen.

Group-C: Control group (C.G.)- 15 patients were treated with local application of a modern ano-rectal preparation i.e., Sucralfate+ lignocaine in ointment form with gradual anal dilatation done on a daily basis.

Study Design-(Control Comparative Study)

Single group design-

| | | |
|-------------------------------------|----|----------------------------------------------|
| T ₁ G ₁ (B.T) | Vs | Effectiveness of T ₁ was assessed |
| T ₁ G ₁ (A.T) | | |
| T ₂ G ₂ (B.T) | Vs | Effectiveness of T ₂ was assessed |
| T ₂ G ₂ (A.T) | | |
| T ₃ G ₃ (B.T) | Vs | Effectiveness of T ₃ was assessed |
| T ₃ G ₃ (A.T) | | |

Where T₁=Treatment 1-*Sinduradyo Malahara* application (Trial group1)

T₂=Treatment 2-*Sinduradyo Malahara* application with adjuvant therapies (Trial group2)

T₃= Treatment 3-Sucralfate+lignocaine ointment. (Control group)

B.T= Before Treatment A.T= After Treatment

T₁G₁, T₂G₂, T₃G₃ are the treatment groups.

Statistical analysis-

In order to prove the effectiveness scientifically, all the assessment has been statistically analysed and the derived mean value has been shown. In the statistical analysis the Mean \pm S.D. of each sign and symptom before treatment has been compared with Mean \pm S.D. after treatment. The effectiveness of the Trial drug w.r.t. each sign & symptom has been assessed

through the *p-value* applying student's t-test (paired).

RESULTS AND DISCUSSION

The clinical assessments of results were noted after treatment based on the cardinal clinical features. The results in view of percentage of improvement were classified as follows and presented in tabular form (Table-1).

Table 1 Table showing the overall Clinical assessment of result in Gr-A, Gr-B & Gr-C patients after treatment.

| Overall Effect | Group A | | Group B | | Group C | |
|--------------------------------|---------|-------|---------|-------|---------|----|
| | F | % | f | % | f | % |
| Maximum Improvement (75%-100%) | 12 | 80 | 13 | 86.66 | 8 | 80 |
| Moderate improvement (50%-75%) | 2 | 13.33 | 1 | 6.67 | 1 | 10 |
| Mild Improvement (25%-50%) | 1 | 6.67 | 1 | 6.67 | 1 | 10 |
| Unsatisfactory (<25%) | 0 | 0 | 0 | 0 | 0 | 0 |

DISCUSSION

Parikartika as an independent disease is not found in any of the *Ayurvedic* texts. But the term *Parikartika* has been mentioned at various contexts such as complication of *Virechana karma*¹⁴, *Basti karma*¹⁵ and also as *Bastinetrayapad*¹⁶. If *rukshavasti* containing *teekshna and lavana dravyas* are

administered in heavy dose, it may produce *Parikartika*². *Charaka & Bagbhatta* opine that, *Parikartika* is a symptom in *Vataja Atisara* due to trauma by hard stools¹⁷. In *Kashyap Samhita*, this disease has been described as a complication of pregnancy in women and again *doshic* involvement were also traced out by him. As has already been observed, this disease is particularly *vatic* in nature¹⁸. Burning however is also associated which suggests that, the *paittika* involvement is also not very rare¹⁴. But the presence of *kaphaja* symptoms is very rarely seen in these cases suggesting the minimal *kapha* vitiation. It seems that majority of the cases who suffered from *Parikartika* did also suffer from constipation even in those days. And that may be a reason enough that they were advised *Bastikarma*. However, the development of fissure due to enemas nozzle is a common sequel even in the modern days. Therefore, this observation described in the ancient books is very much justified and correct. Various treatment modalities regarding the diseases were described in many classical texts. Moreover, no surgical advice was found regarding the management of *Parikartika*. Modern science also describes the specific aetiology of the disease as constipated stool and other

secondary conditions¹⁹. Its signs & symptoms are noticed with a distinct nature of pain and other associated conditions like blood striking the stool, burning sensation and discharge, *etc.*²⁰. A sentinel tag always represents a repeated and chronic fissure²¹. The disease also has several treatment options described like stool softeners along with local application, injection method and surgery. Sometimes anal fissures can be an extremely painful condition. The primary reason for severe pain is spasm of the anal sphincter. This spasm causes ischemia, which both produces pain and interferes with healing^{22, 23}. Thus the goals of the treatment lie behind the relaxation of the sphincter and relieve the pain.

From the demographic data it was found that, the incidence of Fissure-in-ano was more in 21-40 years of age group (66.67%), and also male were more prone to this disease (56%). A higher incidence was observed in the Hindu patients (97.78%), married persons (80%) and in persons having business occupation (37.88%) & Urban population (66.67%). The incidence

of the patients consuming non-vegetarian or mixed (93.33%) diets and patients with less water intake habit (66.67%) were also found to be very high. Irregular bowel habits were also in the higher range of suffering (77.78%) from this disease. People with more active life style (46.67%), *Vishamagni* (73.33%) and disturbed sleep habit (64.44%) were noticed as sufferers from this disease. Demographic data had shown more acute cases (71.11%) of Fissure-in-ano with mid-line posterior (71.11%) position.

RESULTS

The effectiveness of the trial and control medicines in three groups was assessed on the basis of fixed criteria. After completion of treatment, on statistical evaluation, it was observed that, with respect to the improvement of the clinical sign & symptoms, better result was obtained in Group-B in comparison to the results obtained in Group-A & Group-C (Table-2 & Table-3).

Table 2 The average clinical progress of three treatment groups w.r.t. The sign & symptom after treatment at1, at2 & at3 (n=40)

| Sign & symptom | AT-1 P* | AT-2 P* | AT-3 P* |
|----------------|---------|---------|---------|
|----------------|---------|---------|---------|

| | Gr-A | Gr-B | Gr-C | Gr-A | Gr-B | Gr-C | Gr-A | Gr-B | Gr-C |
|-------------------|----------|------|------|----------|------|------|----------|------|------|
| Pain | 13.3 | 26.6 | 20 | 53 | 60 | 70 | 86.6 | 93.3 | 90 |
| Ulcer | 3.3 | 3.3 | 15 | 36.6 | 36 | 60 | 86 | 86 | 95 |
| Burning sensation | 16.6 | 25 | 30 | 66.6 | 83 | 50 | 88.8 | 83 | 80 |
| Itching | 30 | 33.3 | 30 | 70 | 50 | 70 | 80 | 66.6 | 70 |
| Bleeding P/R | 56 | 35 | 33.3 | 81.2 | 85 | 66.6 | 81.2 | 85 | 66.6 |
| Constipation | 22 | 41.6 | 38.9 | 72.7 | 75 | 38.9 | 72.7 | 95.8 | 50 |
| Sentinel tag | 16.6 | 17 | 12 | 16.6 | 17 | 12 | 17 | 17 | 13 |
| | $n_1=15$ | | | $n_2=15$ | | | $n_3=10$ | | |

Where, N = Total number of patients, n_1 = number of pts. in Gr-A, n_2 = number of pts. in Gr.-B, n_3 = number of pts. in Gr.-C, T₁ = Treatment 1 after 7 days, T₂ = Treatment 2 after 14 days, T₃ = Treatment 3 after 21 days. P* = Average percentage of improvement in Sign & Symptoms.

Table 3 Inter group comparison of the effect of therapies after T₁, T₂ & T₃

Table showing the statistical assessment of the effectiveness of the drugs on pain among the patients of group-A, B & C.

| Sign & Symptom | Treatment Group | Duration of Treatment | Mean ± S.D. | p-value | Remarks |
|-------------------|-----------------|-----------------------|---------------|---------|---------|
| Pain | Gr-A | BT | 1.067 ± 0.258 | | |
| | | AT3 | 0.067 ± 0.258 | <0.001 | **** |
| | Gr-B | BT | 1.067 ± 0.258 | | |
| | | AT3 | 0.067 ± 0.258 | <0.001 | **** |
| | Gr-C | BT | 1.100 ± 0.316 | | |
| | | AT3 | 0.1 ± 0.316 | <0.001 | **** |
| Ulcer | Gr-A | BT | 1.33 ± 0.488 | | |
| | | AT3 | 0.133 ± 0.352 | <0.001 | **** |
| | Gr-B | BT | 1.2 ± 0.414 | | |
| | | AT3 | 0.133 ± 0.352 | <0.001 | **** |
| | Gr-C | BT | 1.4 ± 0.516 | | |
| | | AT3 | 0.1 ± 0.316 | <0.001 | **** |
| Burning Sensation | Gr-A | BT | 1.111 ± 0.333 | | |
| | | AT3 | 0.111 ± 0.333 | <0.001 | **** |
| | Gr-B | BT | 1.167 ± 0.408 | | |
| | | AT3 | 0.167 ± 0.408 | <0.02 | ** |
| | Gr-C | BT | 1.2 ± 0.447 | | |
| | | AT3 | 0.2 ± 0.447 | <0.02 | ** |
| Itching | Gr-A | BT | 1.2 ± 0.447 | | |
| | | AT3 | 0.2 ± 0.447 | <0.02 | ** |
| | Gr-B | BT | 1.333 ± 0.577 | | |
| | | AT3 | 0.333 ± 0.577 | >0.05 | # |
| | Gr-C | BT | 1.2 ± 0.447 | | |
| | | AT3 | 0.4 ± 0.548 | <0.02 | ** |
| Bleeding P/R | Gr-A | BT | 1.125 ± 0.354 | | |
| | | AT3 | 0.25 ± 0.463 | <0.001 | **** |
| | Gr-B | BT | 1.1 ± 0.316 | | |
| | | AT3 | 0.2 ± 0.422 | <0.001 | **** |
| | Gr-C | BT | 0.833 ± 0.408 | | |
| | | AT3 | 0.333 ± 0.516 | <0.01 | *** |
| Gr-A | BT | 1.091 ± 0.302 | | | |

| | | | | | |
|--------------|------|-----|---------------|--------|---------------|
| Constipation | Gr-B | AT3 | 0.273 ± 0.467 | <0.001 | **** |
| | | BT | 1.167 ± 0.389 | | |
| | Gr-C | AT3 | 0.083 ± 0.289 | <0.001 | **** |
| | | BT | 1.111 ± 0.333 | | |
| | Gr-A | AT3 | 0.556 ± 0.527 | <0.02 | ** |
| | | BT | 1.667 ± 0.557 | | |
| Sentinel Tag | Gr-B | AT3 | 1.333 ± 0.577 | >0.05 | Insignificant |
| | | BT | 1.500 ± 0.577 | | |
| | Gr-C | AT3 | 1.250 ± 0.500 | >0.05 | -do- |
| | | BT | 1.667 ± 0.577 | | |
| | Gr-A | AT3 | 1.333 ± 0.577 | >0.05 | -do- |
| | | BT | 1.500 ± 0.577 | | |

WHERE

****= <0.001- Highly significant at 0.1% level

***= <0.01- Significant at 1% level.

B.T.=Before treatment

d.f.= Degree of freedom

* = Significant at 5% level.

**= <0.02- Significant at 2% level

**= <0.02- Significant at 2% level,

****= <0.001- Highly significant at 0.1% level

= >0.05 Insignificant at 5% level

S.D. =Standard deviation

A.T.=After treatment

t= test of significance(paired)

= Insignificant at 5% level,

***= <0.01- Significant at 1% level.

#= >0.05- Insignificant at 5% level.

p= probability

As per the aims & objective of this study, the hypothesis was found truly scientific which suggests that the topical application of *Sindooradyo Malahara* represents a new, standard, easily handled, and cost effective alternative in the management of anal fissure.

Since the application was local therefore no systemic hazards countered during the study. Hence drug is found safe for use, easy to prepare, economical and acts good in *parikartika* cases.

Probable mode of action of the trial formulation-

❖ Reduces pain by virtue of the lubrication of the anal passage and gradual day-to-day anal dilatation, thus facilitating

for smooth defecation. *Tila taila* having *Vata samak* nature it helps in decreasing pain with the synergetic action with *Rala*, which also carries *vedana sthapaka* activities.

❖ As a potent wound healer *tila taila* & *Sindoor* acts its best. It helps for *vranasodhan* & *vranaropana*.

❖ Mixture of til oil and beeswax lubricates the area and makes easy passage of stool bolus. As a coating agent *Madhucchistha* stabilizes the endothelial lining, and prevents bleeding.

❖ Due to the astringent property of *Rala*, the ointment adheres with the wound surface and thus prevents further injury to mucosal lining while passing stool.

❖ Anti-microbial properties of almost all the ingredients of the medicine, prevents the infection in that area and facilitates for early wound healing.

Similarly the control drug i.e., the mixture of Lignocaine & Sucralfate is also very potent in reducing the sign & symptoms and found efficacious in curing fissure-in-ano, due to their proven analgesic, anaesthetic, wound healing, ulcer protective properties of the ingredients.

CONCLUSION

After thorough discussion on various observations in this comparative clinical study, following conclusions have been drawn:-

☞ There is less detailed description of *Parikartika* as an independent disease in any of the *Ayurvedic* texts. The disease *Parikartika* has similarity with the disease fissure-in-Ano of modern medical science.

☞ Both *Sindooradyo Malahara* and *Sucralfate-Lignocaine* ointment have proved effective in the management of *Parikartika* (Fissure in ano).

☞ Group-B shown maximum effectiveness in comparison to other groups

with the adjuvant therapies like sitz bath, dietary regimen etc.

☞ Respond to itching may be much better with the *Sindooradyo malahara-1* (R.T.21/156-158), due to presence of *Tankana* in it in place of *Rala*. More study needed on it.

☞ All three groups at its best responded to the treatment and no adverse effects of the therapies were encountered during the course of study.

☞ Finally it can be stated that, fissure-in-ano along with some ano-rectal diseases can be prevented by maintaining a healthy life style, healthy food & bowel habit.

RECOMMENDATIONS FOR FURTHER STUDY

☞ The efficacy of *Sindooradyo Malahara* is completely depends on the potency of ingredients, hence detail analysis and standardization of *Sindooradyo Malahara* has to be done.

☞ By appropriate scientific parameters, an effort has to be made to Study the local changes brought by the application of *Sindooradyo Malahara* and also effect on anal sphincters in reducing the pressure in the anal canal.

☞ A longer duration trial on larger sample is required.

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