



# “A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF GANDHAKA DRUTI PICHU AND YASHTIMADHU TAILA PICHU IN THE MANAGEMENT OF PARIKARTIKA WITH SPECIAL REFERENCE TO ACUTE FISSURE-IN-ANO”

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*Abstract* Parikartika is one of the most painful and commonest condition in Gudagata Vikaras affecting majority of the population in the world<sup>1</sup>. Acharya's have explained it as one among the Vamana Virechana Vyapat<sup>2,3</sup> and Bastivyapat<sup>4</sup>. It is caused by Sthana Samshraya of vitiated Vata & Pitta Dosha in Gudapradesha, leading to Kartanavat Vedana and Daha in Gudapradesha. It can be correlated to fissure-in-ano based on signs and symptoms<sup>5</sup>. In the Chikitsa of Parikartika, Acharyas have mentioned Madhura, Kashaya Rasa Sneha Yukta Dravya's in the form of Piccha Basti, Anuvasana Basti<sup>6</sup>, Pichu, Varti & Lepa, which pacifies Vata and Pitta Dosha's. Acharya Sushrutha has mentioned Anuvasana Basti with Grithamanda & Yastimadhu Taila in Parikartika<sup>7</sup>. Acharya Sushrutha has mentioned Pichu Prayoga in the context of Shashti Upakrama<sup>8</sup>, in the management of Vrana. Gandhaka Druti<sup>9</sup> is mentioned in Rasa Ratna Samucchaya in the context of Uparasas, is having Vedanasthapaka and Vranaropaka properties, so it has been selected in the treatment of Parikartika. Hence the present study is under taken to evaluate and compare the efficacy of Gandhaka Druti Pichu and Yastimadhu Taila Pichu in the management of Parikartika w.s.r to Acute Fissure-in-Ano.

*Index Terms* - Parikartika, Fissure in Ano, Gandhaka Druti Pichu, Yastimadhu Taila Pichu, Vrana.

## I. INTRODUCTION

Ayurveda, a science of life aims to cure the disease and to keep persons healthy. Nowadays, life is very fast and stressful. People are unable to follow Swasthavritta and Sadvritta Paricharya<sup>10</sup> which has been explained in our classics. In Ayurvedic treatise it is precisely stated that if one follows Sadvritta and Swasthavritta, they are never affected by diseases. But hectic life of people leads to irregular eating and sleeping habits, Vega-Dharana, Smoking, Alcohol Consumption and mental stress. All these causes several changes in the biological system of human being<sup>11</sup>. Acharya Vagbhata explained that diseases are consequence of Mandagni<sup>12</sup>. This leads to Vibhanda (Constipation). Vibhanda is the major feature of Ano rectal disorders. Constipated persons when passes hard stools with straining which causes longitudinal ulcer in the lower anal canal, this condition is called as Parikartika (Fissure in-Ano). Parikartika is one of the most painful and commonest condition in Gudagata Vikaras affecting majority of the population in modern world. Acharya's have explained it as one among the Vamana Virechana Vyapat and Bastivyapat. It is caused by Sthana Samshraya of vitiated Vata &

Pitta Dosha's in Gudapradesha, leading to Kartanavat Vedana and Daha in Gudapradesha. It can be correlated to fissure-in-ano based on signs and symptoms. Fissure-in-ano is an elongated ulcer in longitudinal axis of lower anal canal associated with constipation, severe pain & burning sensation during defecation and bright red bleeding<sup>13</sup>. In acute type pain is so severe that, patient develops fear for defecation and this further worsens the condition. Fissure-in-ano occurs most commonly in midline posteriorly, in males usually posteriorly 95%, anteriorly 5%, & in females posteriorly 80%, & anteriorly 20%<sup>14</sup>. About 30–40% of the population suffers from proctologic pathologies at least once in their lives, in that anal fissure comprises of 10–15%<sup>15</sup>. It occurs equally in both men & women and is common in all age groups especially adults of 15-40 years<sup>16</sup>. The incident is supposed to be high in one who passes hard & dry stool<sup>17</sup>. In the Chikitsa of Parikartika, Acharyas have mentioned Madhura, Kashaya Rasa Sneha Yukta Dravya's in the form of Piccha Basti, Anuvasana Basti, Pichu, Varti & Lepa, which pacifies Vata and Pitta Dosha's. Acharya Sushruta has mentioned Anuvasana Basti with Grithamanda & Yastimadhu Taila in Parikartika. Acharya Sushruta has mentioned Pichu Prayoga in the context of Shashti Upakrama, in the management of Vrana. Yastimadhu Taila is having Vata-Pittahara Guna, Sheeta Veerya, which acts as Dahaprashamaka and Vranaropaka, hence it is taken as standard drug by previous research works done. Gandhaka Druti is mentioned in Rasa Ratna Samucchaya in the context of Uparasas, it is Taila obtained of Gandhaka, which acts as Vedanasthapaka and Vranaropaka, so it has been selected in the treatment of Parikartika. Hence the present study is under taken to evaluate and compare the efficacy of Gandhaka Druti Pichu and Yastimadhu Taila Pichu in the management of Parikartika w.s.r to Acute Fissure-in-Ano.

## II. AIMS AND OBJECTIVES

- To evaluate the effect of Gandhaka Druti Pichu in the management of Parikartika with special reference to Acute Fissure-in-ano.
- To evaluate the effect of Yastimadhu Taila Pichu in the management of Parikartika with special reference to Acute Fissure-in-ano.
- To compare the effect of Gandhaka Druti Pichu and Yastimadhu Taila Pichu in the management of Parikartika with special reference to Acute Fissure-in-ano.

## III. MATERIALS AND METHODS

### MATERIALS:

Source of Data

Literary source

- 1) Classical text books (Samhitas) & Modern text books
- 2) Articles from periodicals, journals, and other published works
- 3) Related source of the data from internet

Clinical source

A. Patients: The OPD and medical camps conducted by BVVS Ayurved Medical College and Hospital, Bagalkot.

B. Drugs:

1. Gandhaka Druti
2. Yastimadhu Taila

in the management of Parikartika.

## IV. Materials

Materials required for the Study

- Gandhaka Druti (study drug) - was prepared in BVVS Ayurved Pharmacy as per the reference of Rasa Ratna Samucchaya, in the context of Uparasa Adhyaya.
- Yastimadhu Taila (Standard Drug) - was procured from SDM Pharma.

## V. Methodology for drug preparation (Study Drug):

Collection and authentication of raw materials:

Raw drugs for the preparation of Gandhaka Druti were collected from local available sources as well as from BVVS Ayurved Pharmacy and were authenticated by experts of Dravya Guna and Rasashastra & Bhaishajya Kalpana Departments of BVVS Ayurved Medical College and Hospital Bagalkot.

## VI. Preparation of Gandhaka Druti:

According to Rasa Ratna Samucchaya all the ingredients taken in appropriate quantity for the preparation and formula preparation was done in BVVS Ayurved Pharmacy Bagalkot under the guidance of faculties of Dept of Rasasastra & Bhaishajya Kalpana.

Table : Ingredients of Gandhaka Druti<sup>9</sup>

| Sl. No | Ingredients          | Quantity            |
|--------|----------------------|---------------------|
| 1      | Shuddha Gandhaka     | 1 part              |
| 2      | Trikatu Churna       | 1/16th part         |
| 3      | Moorchita Tila Taila | Quantity sufficient |

## Method of Preparation:

1 part of Shudda Gandhaka and 1/16th part of Trikatu Churna are taken.

The mixture is spread on a piece of cloth of 1 Artni size.

The cloth is rolled along with the powder into a wick, tightly fastened with thread and dipped in Moorchita Tila Taila for 3 hours.

Later, it is taken out and burnt; drops of melted Gandhaka are collected.

This is called, "Gandhaka Driti" (Molten sulphur).

## VII. METHODS:

### Diagnostic criteria:

Patients of Parikartika (Acute Fissure-in-ano) are selected on following features:

- Kartanavat Vedana (Cutting type of pain in anal region during & after defecation)
- Daha (Burning sensation in anal region)
- Gudagata Raktasrava (Bleeding per rectum)
- Vibhanda (Constipation) O/E
- Per rectal longitudinal ulcer in the anal verge.

## VIII. Research Design:

The present study is comparative clinical study to find out the effect of Gandhaka Druti Pichu and Yastimadhu Taila Pichu in the management of Parikartika with special reference to Acute Fissure-in-Ano. Where study and standard groups are selected and dependent variables are measured before, during and after treatment.

## IX. Study design:

Randomized comparative clinical study.

Sample size: Total number of patients taken for the study was 40, excluding dropouts.

Sampling Method: Patients were divided into 2 groups with 20 patients in each group by computerized randomization technique ([www.randomnumber.com](http://www.randomnumber.com)).

## X. Inclusion criteria:

- Patient diagnosed with Parikartika (Acute fissure-in-ano) are selected.
- Patients of either sex, aged between 18 – 60 years.
- Patients with diabetes & hypertension which are under control.

## XI. Exclusion criteria:

- Patients diagnosed with other co-existing Ano rectal diseases.
- Fissure in ano due to systemic disorders.
- Patients suffering from infectious diseases.
- Patients of chronic fissure in ano with sentinel pile.
- Pregnant women & lactating women.

## Grouping:

Group A: Study group – Gandhaka Druti Pichu

Group B: Standard group –Yastimadhu Taila Pichu

### 1. Group A:

- Study group – Gandhaka Druti Pichu
- Route of administration – Local application
- Dosage- Quantity sufficient (1-2ml)

- Timing- Twice a day Duration –7 days

## 2. Group B:

Standard group – Yastimadhu Taila Pichu

Route of administration –Local application

Dosage – Quantity sufficient (1-2ml)

Timing - Twice a day

Duration –7 days

### XII. Procedure–

- Patients were educated about the procedure.
- Patient was advised to clean the perianal region.
- Then after taking the comfortable position, advised to insert the medicated Pichu in the anal region.
- Advised to remove it after 6 hours.

### XIII. Advice –

- Suitable Pathya and Apathya was advised for both the groups.
- For both the groups Triphala Choorna 1 Tsp was given daily at night during procedure period with warm water.

### XIV. Duration of Treatment: 7 days

### XV. Follow- Up: After 8 days (on 15th Day)

### XVI. Total Study Duration: 15 Days

### XVII. Observations Period:

The parameters were recorded according to the case proforma before (Day 0), during treatment (Day 3rd), after treatment (Day 7th) and Follow-up (Day 15th).

### XVIII. Assessment Criteria:

The result of the treatment was assessed on the basis of subjective & objective criteria by a suitable score / grading to each parameter.

### XIX. Subjective Parameters:

1. Kartanavat Vedana in Guda Pradesh (Cutting type of pain in anal region)
2. Daha (Burning Sensation)
3. Bleeding per rectum (Drop wise bleeding, streaks of blood on stool)
4. Constipation

### Objective Parameters:

1. Size of the ulcer

### Subjective Parameters:

1. Vedana (Pain)<sup>18</sup> – Assessed by Visual Analogue Scale

| Pain          | Score | Grade |
|---------------|-------|-------|
| No Pain       | 0     | P0    |
| Mild Pain     | 1     | P1    |
| Moderate Pain | 2     | P2    |
| Severe Pain   | 3     | P3    |

## 2. Daha<sup>19</sup> (Burning Sensation)

| Burning Sensation          | Score | Grade |
|----------------------------|-------|-------|
| No Burning Sensation       | 0     | B0    |
| Mild Burning Sensation     | 1     | B1    |
| Moderate Burning Sensation | 2     | B2    |
| Severe Burning Sensation   | 3     | B3    |

3. Bleeding per Rectum<sup>18</sup>

| Bleeding per Rectum | Score | Grade |
|---------------------|-------|-------|
| No Bleeding         | 0     | B10   |
| Mild Bleeding       | 1     | B11   |
| Moderate Bleeding   | 2     | B12   |
| Severe Bleeding     | 3     | B13   |

4. Constipation / Bowel habit<sup>20</sup>

| Constipation  | Score | Grade |
|---|-------|-------|
| Passes stools regularly without difficulty              | 0     | C0    |
| Passes stools regularly with difficulty                 | 1     | C1    |
| Passes hard stools irregularly with difficulty          | 2     | C2    |
| Passes pellet like stool once in a week with difficulty | 3     | C3    |

Objective parameters:

[1] Size of ulcer<sup>21</sup> – After calculation of length & width. Two-dimensional size.

| Size of the ulcer | Score | Grade |
|-------------------|-------|-------|
| No ulcer          | 0     | S0    |
| 0.1 – 5 mm        | 1     | S1    |
| 5.1 – 10 mm       | 2     | S2    |
| >10mm             | 3     | S3    |

## XX. Investigations:

The following laboratory investigations were carried out if necessary.

1. Hb%, CT-BT, TC-DC
2. RBS
3. RVD
4. HbsAg

## XXI. Statistical Analysis:

Data collected and statistically analyzed by applying Friedman test within the group and Mann Whitney U test for comparing results between the group.

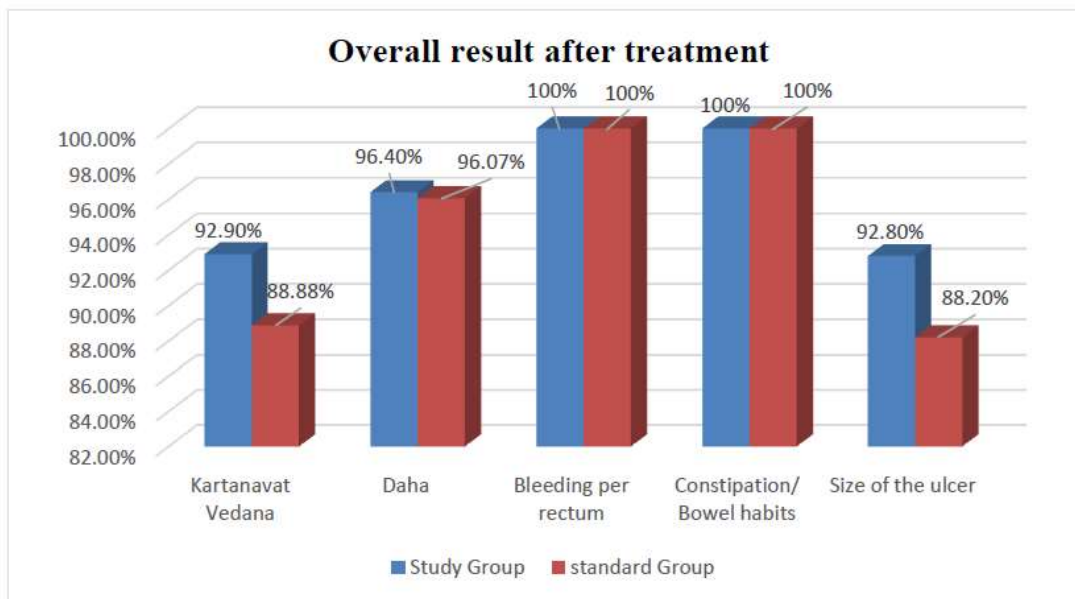
Overall clinical Assessment of the Trail

| Improvement          | Percentage |
|----------------------|------------|
| Cured                | 100%       |
| Maximum improvement  | 75-99%     |
| Moderate improvement | 50-75%     |
| Mild improvement     | 25-50%     |
| No improvement       | 0-25%      |

Overall clinical assessment is based on the percentage of reduction of individual symptoms of each patient. The improvement was reported as cured (100%), maximum improvement (75-99%), moderate improvement (50-75%), mild improvement (25-50%), no improvement (0-25%).

RESULTS

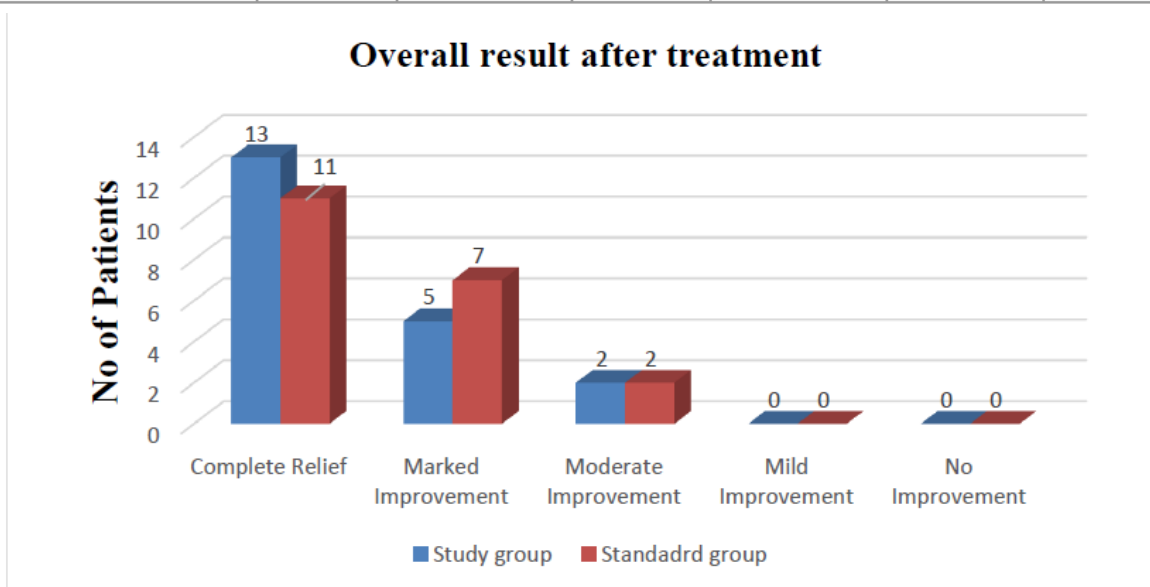
| Parameters                 | Study Group |            | Standard Group |            |
|----------------------------|-------------|------------|----------------|------------|
|                            | Mean        | Percentage | Mean           | Percentage |
| Kartanavat Vedana          | 0.20        | 92.9%      | 0.30           | 88.88%     |
| Daha                       | 0.01        | 96.4%      | 0.10           | 96.07%     |
| Bleeding per rectum        | 0           | 100%       | 0              | 100%       |
| Constipation/ Bowel habits | 0           | 100%       | 0              | 100%       |
| Size of the ulcer          | 0.15        | 92.8%      | 0.20           | 88.2%      |



In the present study the overall result after treatment showed that, 92.9% and 88.88% improvement in Kartanavat Vedana, 96.4% and 96.07% of improvement in Daha and 92.8% and 88.2% of healing in ulcer size in study group and standard group respectively. And 100% of improvement in bleeding per rectum & constipation in both the groups with P value

| Overall result After treatment (7 <sup>th</sup> day) | Study Group     |            | Standard Group  |            | Chi square test | P value |
|--|-----------------|------------|-----------------|------------|-----------------|---------|
|  | No. of Patients | percentage | No. of Patients | percentage |                 |         |
| Cured  | 13              | 65.0       | 11              | 55.0       | 0.500           | <0.001  |
| Maximum Improvement                                  | 5               | 25.0       | 7               | 35.0       |                 |         |
| Moderate Improvement                                 | 2               | 10.0       | 2               | 10.0       |                 |         |
| Mild Improvement                                     | 0               | 0          | 0               | 0          |                 |         |
| No improvement                                       | 0               | 0          | 0               | 0          |                 |         |
| Total  | 20              | 100.0      | 20              | 100.0      |                 |         |

| Overall result<br>After treatment<br>(7 <sup>th</sup> day) | Study Group        |              | Standard Group     |              | Chi<br>square<br>test | P value |
|--|--------------------|--------------|--------------------|--------------|-----------------------|---------|
|  | No. of<br>Patients | percentage   | No. of<br>Patients | percentage   |                       |         |
| Cured  | 13                 | 65.0         | 11                 | 55.0         | 0.500                 | <0.001  |
| Maximum<br>Improvement                                     | 5                  | 25.0         | 7                  | 35.0         |                       |         |
| Moderate<br>Improvement                                    | 2                  | 10.0         | 2                  | 10.0         |                       |         |
| Mild<br>Improvement  | 0                  | 0            | 0                  | 0            |                       |         |
| No improvement   | 0                  | 0            | 0                  | 0            |                       |         |
| <b>Total</b>   | <b>20</b>          | <b>100.0</b> | <b>20</b>          | <b>100.0</b> |                       |         |



The overall result after treatment between the groups showed complete relief in 13(65%) and 11(55%) patients, marked improvement in 5(25%) and 7(35%) patients in both study and standard group respectively, moderate relief in 2(10%) patients in both the group with P value <0.001. i.e., statistically significant.

## DISCUSSION

### PROBABLE MODE OF ACTION:

#### GANDHAKA DRUTI:

- 1 The ingredients of Gandhaka Druti are Gandhaka, Trikatu & Moorchita Tila Taila.
- 1 The drug Gandhaka Druti is having Deepana, Pachana, Veadana Shamaka, Vranashodhana, Vranaropana, Tridoshaghna properties.
- 1 Shulahara property of Shunti, Madhura Rasa and Vipaka, Ushna Veerya, and Snigda, Mrudu Guna of drugs which are present in Gandhaka Druti reduces Ruksha, Khara Guna of Prakupita Vata and decreases the Vedana.
- 1 Madhura, Kashaya Rasa and Madhura Vipaka, Sheeta Veerya, Pittahara action of Moorchita Tila Taila reduces Ushna, Teekshna Guna of Prakupita Pitta, thus helps in reducing Daha.
- 1 Kashaya & Madhura Rasa, Madhura Vipaka, Sheeta Veerya, Tridoshaghna Karma of the ingredients (Gandhaka, Moorchita Tila Taila) of the Gandhaka Druti helps in reducing the Bleeding and healing of the ulcer.
- 1 Vranashodhana, Vranaropana action and Snigda, Mrudu Guna helps in healing of the wound.

- 1 Snehana Guna of the Taila brings Mardavata in the anal mucosa and helps in easy evacuation of the stool without injuring the anal mucosa. And decreases the Ruksha & Khara Guna of Vata and helps in relaxation of anal sphincters.

#### YASTIMADHU TAILA:

- The ingredients of Yastimadhu Taila are Yastimadhu and Tila Taila
- The drug Yastimadhu taila is having Madhura Rasa, Snigdha Guna, Sheeta Verya and Madhura Vipaka, acts as Vata-Pittahara and Daha Prashamaka.
- Yashtimadhu is having the Madhura rasa, Pittahara Guna, Vrana Ropaka & Daha Prashamana Karma.
- Madhura, Kashaya Rasa, Sheeta Veerya, Madhura Vipaka and Vata-pittahara action helps in reducing Kartanavat Vedana and Daha and also helps in reducing Bleeding.
- Madhura, Kashaya Rasa and Vata-pittahara Guna of ingredients of Yastimadhu Taila helps in reducing pain and healing of ulcer.
- Madhura and Kashaya Rasa, Madhura Vipaka & Sheeta veerya of drugs does vasoconstriction and reduces the bleeding and Vranaropana property of Yastimadhu Taila helps in healing of wound.

#### PROBABLE MODE OF ACTION OF PICHU:

- Pichu has been explained as Sthanika Chikitsa in Vrana.
  - It helps the medicine to remain at the site for longer time for better action.
  - Pichu brings Mardavata in the anal mucosa (moist environment) and normalizes the function of Apana Vata, by reducing Ruksha and Khara Guna of Prakupita Vata.
  - It facilitates the healing process of the wound by maintaining hydration and decreasing the chance of infection at the wound site.
  - It enhances angiogenesis and collagen synthesis and also increases break down of dead tissue and fibrin at wound site. Thus enhances the wound healing process.

#### DISCUSSION ON OVERALL EFFECT:

The overall result after treatment between the groups showed 92.9% and 88.88% relief in Kartanavat Vedana, 96.4% and 96.07% improvement in Daha and 92.8% and 88.2% of healing in ulcer size were noticed in study group and standard group respectively. And 100% reduction in bleeding per rectum & constipation in both the groups with P value.

#### CONCLUSION

- Gandhaka Druti Pichu is effective in the management of Parikatika.
- Yastimadhu Taila Pichu is effective in the management of Parikatika.
- The present study showed that Gandhaka Druti Pichu is statistically more effective as compared to Yastimadhu Taila Pichu at the level of p value.

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