Clinical effect of Lord’s Anal Dilatation and Ksharasutra Suturing in Parikartika w.s.r. to chronic fissure-in-ano

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Abstract:
Parikartika can be correlated to fissure-in-ano in modern parlance and commonly found among all ano-rectal disorders. This study has been planned to evaluate the role of Ksharasutra suturing along with Lord’s anal dilatation in Parikartika (chronic fissure). Total 50 patients of chronic fissure-in-ano aged between 20-60 years of either sex were randomly selected for the study. Lord’s anal dilatation followed by Ksharasutra suturing was done once under low spinal anesthesia and after slough out of Ksharasutra; wound dressing was done for four weeks. The results were assessed by weekly interval up to 4 weeks and paired ‘t’ test was applied for statistical analysis of observed findings. Finally encouraging results observed by Ksharasutra suturing (KSS) after anal dilatation in Parikartika (chronic fissure-in-ano) without recurrence.

Key Words: Fissure in ano, ksharasutra, Dilatation

INTRODUCTION:
Sushruta has described “Parikartika” as a condition of Guda (anus) with cutting and burning pain which can be correlated to fissure-in-ano. The factors responsible for Parikartika are Arsha (piles), Atisara(diarrhoea), Grahani (duodenitis), Udavarta (hiccup), complication of Basti (therapeutic medicated enema), etc are mentioned in various texts. Parikartika is defined as kartan vat vedana (sharp cutting pain) in Guda, the seat of Sadyapranahara Marma.(vital part) [1,2] The prevalence of fissure-in-ano is approximately 30% to 40% of total ano-rectal sufferings where as the incidence is supposed to be very common in constipated people. The common site of fissure-in-ano is 6 o’clock i.e. midline posterior, lower half of anal canal which is commonly found in males and after delivery in females. The disease has been classified into two varieties viz. acute fissure-in-ano and chronic fissure-in-ano. Acute condition is marked with fresh anal linear ulcer with agonizing pain while chronic condition is fibrosed anal ulcer bed along with moderate pain with skin tag or anal papilla. The present trend of treatment of acute condition is conservative treatment where as chronic anal fissure entails surgical intervention. In general surgery surgeon adopted various treatments like Lord’s anal dilatation, sphincterotomy, fissurectomy. [3] But these methods are being practiced with their certain limitations; in addition to complications like anal stricture, incontinence and recurrences.

After reviewing the Ksharakarma, Kshara (caustics) has been advocated to prepare from different herbal plants like Achyranthus aspera, Sesamum indicum, etc. [4] The Paneeya Kshara is used internally in GIT disorders while Pratisarniya kshara is used for external application. As chronic anal fissure is a chronic wound so Kshara can be used as Sushruta mentioned indication of Kshara in dushta vrana (infected wound). [5] In sequence of treatment of ano-rectal disorders Sushruta has given more emphasis on Ksharakarma and Shalya Chikitsa (surgery). Regarding the treatment of Parikartika reported research works were mostly on the local application and conservative management. Ksharasutra has been proved effective in fistula in ano, piles, and need to be evaluating its effect in Parikartika. Ksharasutra therapy, in day to day practice, is receiving its nationwide popularity with the extension to developed countries like Japan, USA, Australia and they adopt this Ksharasutra therapy as an important therapeutic tool in their system. [6] In Parikartika linear ulcerative fibrous bed is caused due to changes of tissues in the invaded lesion by frequent sphincter spasm. The objective of this study was to evaluate the role of Lord’s anal dilatation and Ksharasutra suturing in Parikartika (Chronic fissure-in-ano).

MATERIAL & METHODS:
Inclusion Criteria:
The patients of Parikartika having age between 20 years to 60 years having symptoms like pain in ano, per rectal
bleeding and history of constipation. Patients of Parikartika (Chronic fissure-in-ano) associated with Arsha (piles) and Bhagandara (fistula-in-ano) were included in study.

Exclusion Criteria:
The patients who were suffering from acute fissure-in-ano, congenital anal stricture and carcinoma of ano-rectum were excluded from this study. The cases that were positive for HIV, VDRL and Hepatitis-B were also excluded. The patients with diabetes mellitus having chronic fissure-in ano were also excluded from the study.

Laboratory Investigations:
- Routine Haemogram- Hb%, TLC, DLC, CT, ESR, FBS, PPBS, RFT- Blood urea, Serum creatinine
- HIV, VDRL, HBsAg (Australia antigen)
- Urine Analysis-Albumin, Sugar & Microscopic examination.
- Stool examination-Microscopic, ova & cyst, RBC, etc.
- LFT- Sr. Bilirubin, SGPT, SGOT.

These investigations were done at base line for fitness of the patients from anesthesia point of view.

MATERIALS:
1) 50 patients of diagnosed cases of Parikartika were registered.
2) Standard Apamarga Ksharasutra was used.
3) Sphatikadi Yoga for sitz bath two times a day
4) Vatagajankush Vati 250 mg three times a day.
5) Panchasakara Churna 5gm at night
6) Jatyadi taila for per anal instillation

Ingredients of Apamarga Ksharasutra:
1. Thread - Linen Barbour No-20
2. Fresh Snuhi Ksheera (latex of Euphorbia nerifolia Linn.)
3. Apamarga Kshara (Caustic of Achyranthus aspera Linn.)
4. Haridra churna (Fine powder of Curcuma longa Linn.)

Ingredients of Sphatikadi Yoga:
1. Sphatika (Potash Alum) - one part
2. Khadira (Acacia catechu Wild) - one part
3. Karanja beeea (Pongamia pinnata (L) Pierre) - one part
4. Dry neem beea (Azadirachta indica A. Juss) - half part

Ingredients of Vatagajankush Vati:
Parada bhasma (Rasasindur)
Lauhabhasma (Iron)
Suvarnamakshik bhasma Copper) Shudha Gandhaka (Sulphur)
Shudha Hartala (Arsenic Trisulphide) Tankan (Borax)
Haritaki (Terminalia chebula Retz.) Karkatakashringingi (Pistacia integerrima L.)
Shunthi (Zingiber officinalis Linn.) Shudha Vatsanabha (Aconitum ferox)
Pippali (Piper longum Linn.) Maricha (Piper nigram L.)
Nirgundi (Vitex negundo L.) Agnimanthra (Premna mucronata L.)

Ingredients of Panchasakara Churna:
1. Senna /Swarnaapatra (Cassia angustifolia Vahl.)
2. Small Haritaki (Terminalia chebula Retz.)
3. Saindhava (Sodium chloride)
4. Sunthi (Zingiber officinalis Linn.)
Shatapushpa /Saunpha (Feniculum vulgare)

Ingredients Jatyadi Taila:
Jati leaf (Jasminum officinalis L.)
Neem leaf (Azadirachta indica A.Juss.)
Patol Leaf (Tricosanthis diocca L.)
METHODOLOGY:

After Lord’s anal dilatation Ksharasutra Suturing (KSS) at fissure bed followed by trans-fixation of sentinel tag was done under spinal anesthesia. The detail of methodology is described in three steps as follows.

OPERATIVE PROCEDURE:

a) Pre-Operative Procedure:

The written informed consent of all patients was taken before intervention. The fitness for anesthesia and surgery was ensured. Patients were kept nil orally for 6 hours before starting surgery. The shaving of perianal area and spinal area was made. Soap water enema at 8 am on the day of operation was given for proper evacuation of stool. Inj. Tetanus Toxoid 0.5 ml, intramuscular and inj. xylocaine 2% sensitivity test was done before surgery. The spinal anesthesia (Saddle block) was given to all the patients.

b) Procedure of Ksharasutra Suturing (KSS):

The patient was laid down in the Lithotomy position after giving anesthesia and perianal area was cleaned and draped with sterilized cut sheet. Lord’s anal stretching (four fingers anal dilatation) was performed with the help of lubricating fingers. The whole fissure bed including all fibrous tissue was sutured by continuous suture with the help of round body curved needle swaged with Ksharasutra. Total 2-4 bites or as per the need / length of fissure bed were taken and sentinel tag was trans-fixed. After proper haemostasis, ‘T’-bandage was applied. The whole procedure was carried out in the Operation Theater. The patient was shifted to the ward in conscious and stable condition.

c) Post-Operative Procedure:

The patient was laid down in head low position for 3 hours. Oral liquids allowed after waving off of the anesthetic effect. The appropriate anti-inflammatory- analgesic and antibiotics were given for initial 3 days. Avagaha Swedan (Warm water sitz bath) with Sphatikadi Yoga was advised two times a day, from 2nd post operative day. Panchasakara churna 5gm at bed time with luke warm water was prescribed from next day of operation. Vatagajankusha vati - 250 mg three times a day with plain water was prescribed from next day of operation. The dressing was done with 10 ml Jatyadi Taila once a day as Matra Basti from next day of operation. Patients were advised to take fiber rich diet and more liquids from next day of operation.

Duration of Treatment: Single stage operation for Parikartika with Ksharasutra suturing after Lords anal dilatation was done and patients were assessed on weekly interval up to 4 weeks.

Follow-up: One month.


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ASSESSMENT CRITERIA:

Assessment was made by adopting gradation method on the features of per-rectal pain, oozing of blood from fissure bed and healing of wound.
Gradation for Pain:

0= Patients free from pain
1= Pain at the time of defecation & bearable which
does not require any analgesic drug
2= Pain at the time of defecation & continuous which
relieves after giving oral analgesic drug
3= Unbearable and continuous pain which relieves af-
after giving injectable analgesic

Gradation for Oozing:

1= Observe dry gauze piece after 24 hours of dressing
2= Observe spot of blood on gauze piece after 24
hours of dressing
3= Observe partially wet gauze piece with blood after
24 hours of dressing
4= Observe complete wet gauze piece with blood af-
after 24 hours of dressing

Gradation for Wound Healing:

1= Complete healed wound with healthy scar
2= Partially healed wound with healthy granulation tis-
3= Cleaned wound without slough / discharge
4= Fresh wound with mild discharge

OVERALL ASSESSMENT:

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

cured = Complete relief in pain and bleeding during
/ after defecation within 7 days after cut through of suture / removal of the Ksharasutra

Improvement = Complete relief in pain and bleed-
ing during / after defecation within 8-14 days after cut through
of suture / removal of the Ksharasutra

Moderate improvement = Complete relief in pain and
bleeding during / after defecation within 15-21 days after
cut through of suture / removal of the Ksharasutra

Mild improvement = Complete relief in pain and bleed-
ing during / after defecation within 22-28 days after cut
through of suture / removal of the Ksharasutra

Un-Changed = No relief in pain and bleeding during / after
defecation even after 28 days (04 weeks) after cut through
of suture / removal of the Ksharasutra

OBSERVATIONS & RESULTS:

Pain intensity at anal region decreased day by day and com-
plete pain relief was observed on 14th post operative day in
all 50 patients (table no.2) while oozing was stopped in all
patients on 28 days (table no.3). Hence statistically highly
significant (p<0.001) results have been seen in pain and
oozing by weekly assessment. In case of wound healing,
though statistically significant result were observed in all
patients by weekly assessment but 2 patients had taken more
than 28 days time for wound healing due to associate dis-
ease fistula-in-ano (table no.4).

DISCUSSION:

Discussion on Observations:

The male (64%) patients in age group between 31-
40 years (46%) were observed maximum but fissure-in-
ano can occur irrespective to the gender.[7] The patients
belong to Hindu (82%) religion, urban habitat (72%), socio-
economically poor (64%), having labor occupation (38%)
were maximum due to location of study centre. Sound sleep
was found in 78% of patients because pain in ano is mostly
occurred after defecation.[8] In this study, Vishamashana
(unwholesome consumption food- 40%) followed by
Adhyashaana (excess consumption of food- 34%) type of
dietetic habit, krura koshtha (44%) were observed   in
maximum patients. Due to such types of eating habits pa-
tients were suffering from indigestion- agnimandya-
malabdhata and ultimately Parikartika as Mandagni
(78%), Irregular bowel habit was noted by 76% patients is
said to be the root cause of most of diseases.[9]

In the study, all the patients had chronicity more
than 1 year among them 1 to 2 years of chronicity of dis-
ease was seen in maximum (38%) of patients because selected patients were of chronic fissure-in-ano. The 66% patients were observed with fissure at posterior (6 o’clock) position of anus because due to direct pressure of stool at posterior part of anus during defecation. The sentinel tag was seen in 80% of patients as it is cardinal sign of chronic fissure-in-ano. Per rectal digital examination showed spasmotic anal sphincter in 92% of patients which delayed the healing. (Table no-1) These findings are also supported by previous research work done by Jonas M. et.al. (2012). [10]

Discussion on Results:

The main symptom of Parikartika is Vedana (pain in ano); after treatment highly significant (‘p’ value <0.001) relief was observed. After Ksharasutra pain wear off due to relaxation of anal sphincters as well as removal of unhealthy tissue by KSS. The smeared Kshara on Ksharasutra is alkaline in nature (pH-10.39) so it inhibits the bacterial growth. In maximum patients relief in oozing was seen within 7th post operative day and very few patients had taken 14 days to stop oozing and showed highly significant results. In maximum patients wound healing was observed within 21 days by secondary intension. The relaxed sphincters due to anal dilatation, sitz bath with Sphatikadi yoga and Matra basti (instillation of medicated oil per rectum) of Jatyadi taila also helped for Shodhan (Clean) and Ropan (Healing) of wound.

Malbaddhata (constipation) was relieved in all patients within 14 days by use of Panchasakara powder orally and Matra Basti of Jatyadi tail locally. Panchasakara acted as Anulomaka (laxative) to evacuate the feces easy and smoothly. Jatyadi tail is found helpful in relieving Rukshata (dryness), Malbaddhata and anal sphincter spasm by virtue of its Snigdha (unctuous), Shodhan (cleaning) and soothing properties. Raktastrava (bleeding) was stopped after Ksharasutra suturing in all patients within 7 days; as removal of fissure bed leads to clean and healthy wound. In this study only in one patient developed perianal abscess might be due to irritation of Kshara. That patient was treated accordingly by incision and drainage (I & D).

Probable mode of action of Ksharasutra in Parikartika:

Ksharasutra prepared with standard method described in Ayurvedic Pharmacopia of India. [11] The Apamarga Kshara has properties of Chhedana (Excision), Bhedana (Incision), Ksharana (Debridation), Stambhana (Haemostatic), Shodhana (Cleansing) and Ropana (Healing). Ksharasutra sutured at fissure bed excises the fibrotic tissue by action of Ksharana and removes unhealthy fibrous tissue and debris; make the wound Shuddha (clean) by Shodhana property. [12] Snuhi Ksheer also has antibacterial property which helped to check secondary infection. [13] Haridra has anti-inflammatory as well as anti-bacterial properties and hence promote healing. [14]

Probable mode of action of Adjuvant Drugs:

The Sphatikadi Yoga has Shodhana, Stambhana, Shothahara (anti-inflammatory) and Vedanahara (Analgesic) properties, which helped to relieve pain, local Shotha (edema) as well as to stop oozing and maintained perianal hygiene. [15,16] The ingredients of Panchasakara churna has Deepana, (Appetizer) & Pachana (Digestive), Anulomana (Laxative) properties so helpful to easy evacuation of stool by regulating Vata dosha. [17] The ingredients of Vatagajankusha Vati are Vatahara, Shothahara, Shulahara, and Tridoshaghnaha (Equilibrium of three dosha) so prescribed to pacify the Vata Dosha. The Vatsanabha (Aconitum ferox) plays role as Vedanahara (analgesic) by acting through the nervous system might be due to Vyavayi (Act directly) and Vikasi (Quick absorption) properties. [18] Most of the ingredients used in Jatyadi taila are Shothahara, Vedanasthapana and Ropaka which helped in wound healing. The ingredients of Jatyadi Taila like Neem (Azadirachta indica) and Daruharidra (Beriberi aristate DC) also promote wound healing. [19]

Overall Result:

Total 80% patients were found cured while 18% patients were observed under improvement category and only 2% patients were noted in moderate improvement as per assessment criteria fixed for relief in sign and symptoms.
Limitations:

1. The Ksharasutra can be done in chronic fissure and not in acute condition.

2. The spinal anesthesia is required for the procedure so hospitalization is necessary.

CONCLUSION:

The study was concluded that in Parikartika (chronic fissure-in-ano), Lord’s anal dilatation with Ksharasutra Suturing is effective treatment without any untoward effect.

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Table 1: GENERAL OBSERVATIONS:

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Observations</th>
<th>No. of Patients (Maximum)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Age (31-40 years)</td>
<td>23</td>
<td>46%</td>
</tr>
<tr>
<td>2.</td>
<td>Sex (Male)</td>
<td>32</td>
<td>64%</td>
</tr>
<tr>
<td>3.</td>
<td>Occupation (Laborer)</td>
<td>19</td>
<td>38%</td>
</tr>
<tr>
<td>4.</td>
<td>Religion (Hindu)</td>
<td>41</td>
<td>82%</td>
</tr>
<tr>
<td>5.</td>
<td>Dwelling Status (Urban)</td>
<td>36</td>
<td>72%</td>
</tr>
<tr>
<td>6.</td>
<td>Socio economic status (Poor)</td>
<td>32</td>
<td>64%</td>
</tr>
<tr>
<td>7.</td>
<td>Sleep pattern (Sound sleep)</td>
<td>39</td>
<td>78%</td>
</tr>
<tr>
<td>8.</td>
<td>Diet habit (Vishamashana)</td>
<td>20</td>
<td>40%</td>
</tr>
<tr>
<td>9.</td>
<td>Koshta (Krura)</td>
<td>22</td>
<td>44%</td>
</tr>
<tr>
<td>10.</td>
<td>Agni (Mandagni)</td>
<td>39</td>
<td>78%</td>
</tr>
<tr>
<td>11.</td>
<td>Bowel habits (Irregular)</td>
<td>38</td>
<td>76%</td>
</tr>
<tr>
<td>12.</td>
<td>Chronicity (1 year - 2 years)</td>
<td>19</td>
<td>38%</td>
</tr>
<tr>
<td>13.</td>
<td>Position of fissure (at 6 o’clock position)</td>
<td>33</td>
<td>66%</td>
</tr>
<tr>
<td>14.</td>
<td>Sentinel tag (observed)</td>
<td>40</td>
<td>80%</td>
</tr>
<tr>
<td>15.</td>
<td>Anal sphincter (Spasmodic)</td>
<td>46</td>
<td>92%</td>
</tr>
</tbody>
</table>
Table 2: Pain Relief: \( n=50 \)

<table>
<thead>
<tr>
<th>Days</th>
<th>Mean</th>
<th>SEM</th>
<th>Std dev</th>
<th>M Diff</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Day</td>
<td>2.300</td>
<td>±0.104</td>
<td>0.735</td>
<td>-</td>
<td>7.361</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>7th Day</td>
<td>1.020</td>
<td>±0.177</td>
<td>1.253</td>
<td>↓1.280</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14th Day</td>
<td>0.000</td>
<td>±0.000</td>
<td>0.000</td>
<td>↓2.300</td>
<td>22.115</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>21st day</td>
<td>0.000</td>
<td>±0.000</td>
<td>0.000</td>
<td>↓2.300</td>
<td>22.115</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>28th day</td>
<td>0.000</td>
<td>±0.000</td>
<td>0.000</td>
<td>↓2.300</td>
<td>22.115</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

Table 3: Relief in Oozing: \( n=50 \)

<table>
<thead>
<tr>
<th>Days</th>
<th>Mean</th>
<th>SEM</th>
<th>Std dev</th>
<th>M Diff</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Day</td>
<td>2.440</td>
<td>±0.0765</td>
<td>0.541</td>
<td>-</td>
<td>17.444</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>7th Day</td>
<td>0.520</td>
<td>±0.135</td>
<td>0.953</td>
<td>↓1.920</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14th Day</td>
<td>0.140</td>
<td>±0.0640</td>
<td>0.452</td>
<td>↓2.300</td>
<td>28.027</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>21st day</td>
<td>0.0600</td>
<td>±0.0444</td>
<td>0.314</td>
<td>↓2.380</td>
<td>29.656</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>28th day</td>
<td>0.000</td>
<td>±0.000</td>
<td>0.000</td>
<td>↓2.440</td>
<td>31.915</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

Table 4: Status of Wound Healing: \( n=50 \)

<table>
<thead>
<tr>
<th>Days</th>
<th>Mean</th>
<th>SEM</th>
<th>Std dev</th>
<th>M Diff</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Day</td>
<td>4.000</td>
<td>±0.000</td>
<td>0.000</td>
<td>-</td>
<td>8.056</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>7th Day</td>
<td>3.300</td>
<td>±0.0869</td>
<td>0.614</td>
<td>↓0.700</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14th Day</td>
<td>2.040</td>
<td>±0.143</td>
<td>1.009</td>
<td>↓1.960</td>
<td>13.731</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>21st day</td>
<td>0.580</td>
<td>±0.134</td>
<td>0.950</td>
<td>↓3.420</td>
<td>25.468</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>28th day</td>
<td>0.0800</td>
<td>±0.0560</td>
<td>0.396</td>
<td>↓3.920</td>
<td>70.015</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

* Highly significant results.

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Conflict of Interest: None