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A Randomized Single Blind Controlled Trial to Evaluate the Analgesic Effect by Application of *Katuki Lepa* and Lidocaine 2% Gel in Fissure in Ano

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ABSTRACT:

Anal fissure is the common disease having the incidence of 30 to 40% of the population, young adult's i.e.80-90% will have the posterior midline and rarely anterior. *Parikartika* is *'Kartanavat vedana* in *Gudapradesh*' and it is not mentioned as a single disease ailment but explained as *Vyapat*, *Purvarupa*, *Lakshana* of other diseases. The aim and objective of this study was to evaluate to the analgesic effect by application of *Katuki Lepa* and lidocaine 2% gel in fissure in ano. Subjects were selected from attending *Shalyatantra* O.P.D of K.L.E's *Ayurveda* Hospital Belgaum, Karnataka, India. Randomly fissure in ano subjects age between 20 to 60 yrs subjects are selected as per randomization chart. Each trial and control group containing 15 subjects were included in the study. In trail group *Katuki Lepa* applying externally daily once and continued for 7 days. In control group 2% lidocaine gel for external application daily once for 7 days. Subject was assessed daily for 7 days. Subjects showed improvement in aspects of decreasing pain and sphincter spasm. Pain reduction in treated group was 94.65 % in control group and 73.73% trial. Analgesics effect of effective in fissure in ano and helped in preventing fistula in ano as further complication.

Keywords: *Parikartika*, *Katuki Lepa*, Lidocaine 2% gel, Fissure in ano.

INTRODUCTION

Anal fissure is an anoxic wound in Anoderm. It is the second most common condition seen in Anorectal clinic and about 30 – 40% of population suffers from Proctologic pathologies at least one in their lives. In young adults80-90% of people it is present with posterior midline and rarely anterior.[1] *Parikartika* is '*Kartanavat Vedana* in *Gudapradesh'* and it is not mentioned as a single disease ailment but explained as a *Vyapat*, *Purvarupa*, *Lakshana* of other diseases. *Picchabasti* and *Anuvasana Basti* are specified by *Acharya Sushruta* in its management.[2] In conventional practice application of local Anesthetics, Oral Analgesics, Stool softener, anal dilatation, Sphincterotomy

are usually practiced. These procedures are sometimes associated with complications like post operative anal Stenosis, Sphincter incontinence and re-occurrence.[3]*Karmukata* of *Katuki* as *Shulagna, Vrinya* and *Dahashamaka* is explained in *Dravya Sangrahaniya Adhyaya* of *Sushruta Samhita*, among *Mustadi, Patoladi*, *Pippalyadi* and *Nyagrodadi Gana*.[4]Adverse reactions of Lidocaine 2% gel on Cutaneous lesion, Anaphalytic reaction, Urticaria[5] edema etc. Various conventional methods of the practice in the management of the pain in fissure in ano has a limitation as inhibition of wound healing, symptomatic relief of pain where in fissure in ano is not sufficient for longer duration of pain management. In concern with the drawbacks with prolonged administration of NSAIDs it is essential to treat the fissure in ano locally with analgesic and anti inflammatory approach. Surgical intervention for fissure in ano is one of the major approaches, but it has complications like life time anal stenosis, reoccurrence, incontinence of stool and chronic infections[5]

Parikartika is characterized by *Vedana, Shopha and Daha* due to *vata and pitta prakopa.* Hence, *lepa with Sheeta Virya dravya like Katuki* is helpful to reduce *Vrina Shopha*, *Daha* and *Shula*. Researches on *Katuki* have proved its Anti spasmodic; Anti-inflammatory and Analgesic activity[6] *Katiki Lepa* would be the best remedy as non invasive technique for the management of fissure.

AIMS AND OBJECTIVE OF THE STUDY

1. To assess the analgesic effect of *Katuki Lepa.*
2. To evaluate the analgesic effect of *Katuki Lepa* comparatively with Lidocaine 2% Gel in *Parikartika*.

Source of data

Subjects were randomly selected from the outpatient department of *Shalya tantra*, KLE'S BMK AMC Hospital and Research centre Belagavi, Karnataka, India.

MATERIALS AND METHODS

Source of data

Subjects were randomly selected from the outpatient department of Shalyatantra, KLE'S BMK AMC Hospital and Reasearch centre Belagavi. Ethical clearance was obtained from Institutional Ethic committee of , KLE'S BMK AMC Hospital and Reasearch centre Belagavi ,Karnataka, India (IEC No. BMK/12/PG/SL/09 dated 21-01-2013).

Methods of Collection of Data

Inclusion Criteria

- ❖ Patients with *Lakshana* of *Parikartika*.

a) Pain in Anal region during and after defecation
b) Burning sensation
c) Presence of sphincter spasm and with a longitudinal ulcer in the anal region will be selected.
d) Either sex between 20-60years of age.

Exclusion Criteria

a) Patients with piles and fistula in ano and any other anorectal diseases.
b) Systemic disorders like Bronchial asthma, Cardiac diseases, Renal Failure, Diabetes Mellitus etc.
c) Infectious and immuno-compromised conditions.

Securing of Drugs

Drug: *Katuki Choorna*

Drug required for the preparation of *Katuki Lepa* was collected from GMP certified K.L.E Ayurveda Pharmacy, Belgaum. Identification; authentication has been done with the help of CRF, K.L.E.s Ayurveda College, Belgaum.

Study Design

30 subjects between the age group of 20-60yrs who were attending the outpatient department of Shalyatantra of KLE's BMK AMC and Hospital, Belagavi, Karnataka, India, living in and around Belagavi city, Karnataka, India and who were to be put to fissure in ano were selected randomly and were taken up for the study after following the criteria laid as above. These 30 subjects were divided randomly in to two groups:

1. Group A – Study group – containing 16 subjects.
2. Group B – Control group – containing 14subjectss.

Out of a total number of 30 subjects for the study, three dropped out in the middle and did not continue treatment, one in trial group and two were in control group. While out of 18 in control

Group, 2 dropped out. Complete history and clinical examination of all these fissure in ano was carried out and recorded in a specially designed pro-forma by the postgraduate department of *Shalya tantra* of KLE's BMK AMC Belagavi, Karnataka, India.

Assessment Criteria

1. Pain and burning sensation during & after defecation.
2. Prolonged pain after defecation for 3-4 hrs.
3. Streak of blood to the stool
4. Hypertonic sphincter
5. Tenderful Ani

Preparation of the trial drug

The *Katuki* fine powder with sieve no 200 taken and triturated with distilled water to prepare paste and will be applied on the fissure.

Mode of Administration of supplementation

- · **Pre-operative Procedures**
  - OT Consent.
  - Part preparation
- **Operative Procedure:**
  1. Patient will be made to lie down in lithotomy position.
  2. Anus and surrounding area will be cleaned with distilled water.
  3. Then *Katuki* / lidocaine 2% will be applied over fissure and left for 24 hrs for observing the effect of pain
  4. Same application procedure will be continued for 7 days.
  5. Everyday assessment of pain - VAS & Sphincter spasm-Proctomanometer
- **Post operative procedure:**
  - Next day onwards patient will be advised for warm water sitz bath after passing motion for 10-15 mins.
  - Diet restriction will be advised to the patient.

Follow up Study

After 30 days to assess if any complications.

OBSERVATION

In the present study, 30 patients suffering from *Parikartika* fulfilling the inclusion criteria were studied. Patients were single blind randomly categorized by computerized randomization into Lidocaine 2% gel and *Lepa* groups. Following pages describes the *Nidanatmaka* aspects of these patients in tabular form with brief description of each finding. Thereafter the effects of both the therapies are described along with their statistical analysis.

In this series of 30 patients of *Parikartika* maximum number of the patients (30%) was from the age group of 51-60 years. It followed by 26.6% patients belonging to 20-30& 31-40 years, and minimum i.e. 16.66 % to 41-50 years age groups.In this series maximum number of the patients i.e. 66.66% was of male sex and remaining 33.33% were females. In this series maximum of 46.66% patients were noted with moderate occupations whereas 36.66 % were with strenuous occupation and 16.66% were labors by occupation

Diet Habit (Table No1): In this series maximum number of patients i.e. 53.33% patients were taking vegetarian diet and remaining 46.66% were taking mixed diet.

Stool consistency (Table No2): In this series maximum number of patients i.e. 63.33% patients were noted with hard consistency of stool, followed with 30% well-formed and 6. 66% with mucoid stool. In this series maximum number of patients i.e. 43.33% patients were having the sound sleep, 40% with mild sleep and 16.66% were noted.

Chronicity (Table No3): In this series, maximum of 63.33% patients had chronic fissure in ano and 36.66% patients had acute fissure in ano.

Position of Fissure (Table No 04): In this series a maximum of 63.33% patients had fissure at posterior, 23.33% had fissure at both anterior & posterior.10% had fissure at anterior and 3.33% had fissure at lateral position

RESULTS AND DISCUSSION

In this series of 30 patients of *Parikartika* were treated in two groups each comprising of 15 patients. The patients of one group were treated with lidacaine 2% application as a standard while the patients of the second group were treated with *Katuki Lepa* application. In both the groups' *Lepa* was applied on *Parikartika* only once in a day and assessed for continuous 7 days. The group wise results in detail are being described under the separate headings.

Results within group

There is a significant result (< 0.0001) seen in 3rd to 7th day in the reduction of pain in control group. There is a significant result (< 0.0001) seen in 2nd to 7th day in the reduction of sphincter spasm in control group. There is a significant result (< 0.0001) seen in 2nd to 7th day in the reduction of pain in trial group. There is a significant result (< 0.0001) seen in 3rd to 7th day in the reduction of sphincter spasm in trial group.(Table 5,6)

Results between groups: Statistical comparison of results between the groups on pain shows the significant differences on 1st, 2nd, 3rd, 4th, 6th and 7th day. i.e. *Katuki Lepa* does the significant decrease in the pain compared to Lidocaine 2% gel.

Statistical comparison of results between the groups on pain shows the significant differences on post-operative day 2nd, 3rd and 7th day i.e. *Katuki Lepa* does the significant decrease in the sphincter spasm compared to Lidocaine 2%.(Table 7,8)

Discussion on Effects of the Therapies:

Effect on pain:

In control group, on 1st day (18.75%), 2nd and 3rd day (35.75), 4th day (46.5%), 5th day (62.5%), 6th day (80.3) and on 7thday – 94.65% reduction of pain was seen. In trial Group, 1st day there is no changes in a pain compared to control group, 2nd day (20%), 3rd day (26.66%), 4th day (38.66%), 5th day (54.66%), 6th day (65.33%) and on 7th day it was 73.73% reduction was seen.

When assessed statistically, the significant results were seen from 3rd day of the procedure till the 7th day in control group where in trial group the significant result seen from the 2nd day of the study i.e 0.0001 in both groups.

Effect on Sphincter spasm:

In control group, on 1st day (15.48%), 2nd day (26.03), 3rd day (13.71%), 4th day (48.61%), 5th day (61.24%), 6th day (80.27) and on 7thday -121.10 reduction of sphincter was seen. In trial Group, 1st day (7. 94%), 2nd day (12.64%), 3rd day (25.33%), 4th day (42.61%), 5th day (61.92%), 6th day (72.58%) and on 7th day it was 81.73% reduction was seen. When statistically assessed, in both the group the significant result (0.0001) was seen in a 3rd day of the treatment (Table 9)

Reoccurrence:

The follow up study showed no reoccurrence of symptoms in both groups.

Comparison of the Effects:

Pain:

Statistical comparison of results between the groups on pain shows the significant differences on 1st, 2nd, 3rd, 4th, 6th and 7th day. i.e. Katuki lepa does the significant decrease in the pain compared to Lidocaine 2% gel. (Table-59). In 3rd and 7th day it shows high significant

In this way Katuki lepa may be considered more efficient in the treatment of reducing pain in Parikartika of when compared to Lidocaine 2%.

Sphincter spasm:

Statistical comparison of results between the groups on pain shows the significant differences on post-operative day 2nd, 3rd and 7th day i.e. Katuki lepa does the significant decrease in the sphincter spasm compared to Lidocaine 2%. (Table-59). 7th day it shows highly significant result it may be due to prolonged action of *Katuki Lepa*. In this way *Katuki Lepa* may be considered more efficient in the treatment of decrease in the sphincter spasm in the *Parikartika* of when compared to Lidocaine 2%.

CONCLUSION

1) Physicochemical analysis revealed sample is within standard limits.
2) Phytochemicals analysis showed presence of reducing sugar, steroids, coumarin glycosides, Alkoloids, tannins and flavonoids which helps in conducting analgesic effects.
3) The drug has not produced any dermal toxicity so it is safe for application in Fissure in ano.
4) *Katuki Lepa* has shown significant analgesic activity in *Parikartika*.

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Conflict of Interest – None

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Table No. 01 – *Ahara* wise Distribution of 30 Patients of *Parikartika*

Ahara	**Standard**		**Trial**		**Total**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Shakahari	6	42.86	10	62.5	16	53.33
Ubhaya	8	57.14	6	37.5	14	46.66

Table No. 02 – Mala wise Distribution of 30 Patients of *Parikartika*

Mala	**Standard**		**Trial**		**Total**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Well formed	7	50	2	12.5	9	30
Hard	7	50	12	12.5	19	63.33
Watery	0	0	0	0	0	0
Mucoid	0	0	2	12.5	2	6.66

Table No. 03 -Stagewise Classification of fissure in ano

Stage	**Standard**		**Trial**		**Total**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Acute	8	57.14	3	18.75	11	36.66
Chronic	6	42.86	13	81.25	19	63.33

Table No. 04 - Position wise Distribution of 30 Patients of *Parikartika*

Position	**Standard**		**Trial**		**Total**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Anterior	3	21.42	0	0	3	10
Posterior	9	64.28	10	62.50	19	63.33
Both	2	12.5	5	31.25	7	23.33
Lateral	0	0	1	6.25	1	3.33

RESULT

Table No. 05-Pain assessment in Control group

Statistical parameters	BT	D1	D2	D3	D4	D5	D6	D7
Mean	8.000	7.857	6.571	5.143	4.286	3.000	1.571	0.4286
Std. Deviation	1.754	1.834	1.453	1.512	1.541	1.519	1.399	1.158
Std. Error	0.4688	0.4901	0.3882	0.4041	0.4118	0.4060	0.3738	0.3095

S.No	**Treatment duration**	**Mean Difference**	**Confidence Interval**	**Significant?**	**Results**	P value	P value summary
1.	BT vs d1	0.1429	-1.654 to 1.940	No	Ns	< 0.0001	****
2.	BT vs d2	1.429	-0.3681 to 3.225	No	Ns		
3.	BT vs d3	2.857	1.060 to 4.654	Yes	***		
4.	BT vs d4	3.714	1.918 to 5.511	Yes	***		
5.	BT vs d5	5.000	3.203 to 6.797	Yes	***		
6.	BT vs d6	6.429	4.632 to 8.225	Yes	***		
7.	BT vs d7	7.571	5.775 to 9.368	Yes	***		

Table No.06-Proctomanometer assessment in Control group

Statistical parameters	BT	D1	D2	D3	D4	D5	D6	D7
Mean	10.14	11.71	12.79	14.00	15.07	16.36	18.07	22.43
Std. Deviation	1.916	2.335	2.665	2.320	2.129	1.082	1.900	3.797
Std. Error	0.5120	0.6240	0.7124	0.6202	0.5690	0.2891	0.5078	1.015

S.No	**Treatment duration**	**Mean Difference**	**Confidence Interval**	**Significant?**	**Results**	P value	P value summary
1.	BT vs d1	-1.571	-4.361 to 1.218	No	Ns	< 0.0001	****
2.	BT vs d2	-2.643	-5.432 to0.1464	No	Ns		
3.	BT vs d3	-3.857	-6.646 to -1.068	Yes	**		
4.	BT vs d4	-4.929	-7.718 to -2.139	Yes	***		
5.	BT vs d5	-6.214	-9.004 to -3.425	Yes	***		
6.	BT vs d6	-7.929	-10.72 to -5.139	Yes	***		
7	BT vs d7	-12.29	-15.07 to -9.496	Yes	***		

Table No.07 -Pain assessment in Trial group

Statistical parameters	**BT**	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**
Mean	9.375	9.375	8.125	6.875	5.750	4.250	3.250	2.500
Std. Deviation	1.204	1.204	1.544	1.258	1.438	1.612	1.238	1.366
Std. Error	0.3010	0.3010	0.3860	0.3146	0.3594	0.4031	0.3096	0.3416

S.No	**Treatment duration**	**Mean Difference**	**Confidence Interval**	**Significant?**	**Results**	**P value**	**P value summary**
1.	BT vs d1	0.0	-1.000 to 1.000	No	Ns	< 0.0001	****
2.	BT vs d2	1.250	0.2498 to 2.250	No	**		
3.	BT vs d3	2.500	1.500 to 3.500	Yes	***		
4.	BT vs d4	3.625	2.625 to 4.625	Yes	***		
5.	BT vs d5	5.125	4.125 to 6.125	Yes	***		
6.	BT vs d6	6.125	5.125 to 7.125	Yes	***		
7.	BT vs d7	6.875	5.875 to 7.875	Yes	***		

Table No.08-Proctomanometer assessment in Trial group

Statistical parameters	**BT**	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**
Mean	9.375	10.13	10.56	11.75	13.25	15.19	16.19	17.06
Std. Deviation	1.204	1.147	1.548	2.049	2.324	1.424	0.9811	1.436
Std. Error	0.3010	0.2869	0.3870	0.5123	0.5809	0.3561	0.2453	0.3590

S.No	**Treatment duration**	**Mean Difference**	**Confidence Interval**	**Significant?**	**Results**	**P value**	**P value summary**
1.	BT vs d1	-0.7500	-2.467 to 0.9667	No	Ns	< 0.0001	****
2.	BT vs d2	-1.188	-2.904 to 0.5292	No	Ns		
3.	BT vs d3	-2.375	-4.092 to -0.6583	Yes	**		
4.	BT vs d4	-3.875	-5.592 to -2.158	Yes	***		
5.	BT vs d5	-5.813	-7.529 to -4.096	Yes	***		
6.	BT vs d6	-6.813	-8.529 to -5.096	Yes	***		
7.	BT vs d7	-7.688	-9.404 to -5.971	Yes	***		

Table no 09: Comparison between Control and Trial in the Pain assessment

S.No	**Duration**	**Mean**		**Mean Difference**	**95% CI of diff.**	**t value**	**Significant?**	**Results**
		Control	**Trial**					
1.	Day 0	8	9.375	1.375	-0.08 to 2.8	2.598	P > 0.05	Ns
2.	Day 1	7.857	9.375	1.518	0.05 to 2.9	2.868	P < 0.05	*
3.	Day 2	6.571	8.125	1.554	0.09 to 3.0	2.935	P < 0.05	*
4.	Day 3	5.143	6.875	1.732	0.27 to 3.1	3.273	P<0.01	**
5.	Day 4	4.286	5.75	1.464	0.003to 2.9	2.766	P < 0.05	*
6.	Day 5	3	4.25	1.25	-0.21 to 2.7	2.362	P > 0.05	Ns
7.	Day 6	1.571	3.25	1.679	0.21to 3.14	3.171	P < 0.05	*
8.	Day 7	0.4286	2.5	2.071	0.61 to 3.5	3.914	P<0.001	***