



‘An Open Labelled Randomised Control Trial To Evaluate The Efficacy Of Murivenna Malahara And Diltiazem Ointment In The Management Of Parikartika With Special Reference To Acute Fissure- In – Ano’’

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ABSTRACT

Anal fissure is very painful anorectal disease. It is also having the symptoms like burning sensation, bleeding from anus. Several treatment methods are explained for Parikartika for relieving symptoms. Diltiazem ointment is widely used for pain & healing of wound. In Ayurveda is Murivenna malahara is best vranaropaka. So compare the efficacy of Murivenna malahara and Diltiazem ointment in the management of Parikartika w.s.r. to Acute fissure -in-ano. This study has taken. **Material and Methods :** A total of 40 patients of Acute Fissure-in-Ano of either sex was selected from OPD and IPD of Shalyatantra Dept, Taranath Government Ayurvedic Medical College and Hospital, Ballari. And randomly was allotted in to 2 groups namely Group- A (Murivenna malahara) and Group -B (Diltiazem ointment) with 20 patients each. **Results:** Murivenna malahara was more effective in reducing pain & for wound healing in Parikartika when comparing to Diltiazem ointment. **Conclusion:** Murivenna malahara is more efficacious than Diltiazem ointment in the management of Parikartika.

KEY WORDS- Murivenna Malahara, Diltiazem ointment, Parikartika, Vrana shodhana, Vranaropaka.

INTRODUCTION

Fissure-in-ano is one among the life style disorders. It is mainly occurring due to constipation. The description of *Parikartika* (Fissure-in-ano) is available in all *Brihatrayees* and *Laghutrayees*. The word *Parikartika* is mentioned in *Vamana* and *virechana vyapat & Basti netra vyapat* ¹ In *Brihatrayees* it is not described as independent disease but as a complication of other disease pertaining to anorectal region.

In contemporary science this can be correlated with Fissure-in- ano. It is a painful condition which commonly occurs in ano-rectal region. It is affecting the majority of population (30-40%). Fissure in ano creates more inconvenience to the patients through affecting their routine life².

Fissure-in-ano is medico surgical condition. Medical management of fissure-in-ano are Analgesics, Stool softeners, and soothing ointments. The drawback these treatments are such as gastric irritation, habituation and headache respectively with 50% chances of reoccurrence. Botulinum toxin injection is very costly and leads to weakness of Sphincter with varying degree of incontinence.

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Acharyas have recommended the use of *Madhura, sheeta, snigdha dravyas* internally as well as locally. Different type of *basti karma* has described such as *Piccha basti* and *Anuvāsana basti* with *ghritamanda, yastimadhusiddhataila* (drugs processed with *vata shamaka, vana ropaka* and *pitta shamaka* properties)⁴.

Murivenna is a medicated oil which is prepared with eight medicinal plants - *Karanja, Kumari, Tamboola, Sigru, Paribhadra, Palandu, Vasuka and Satavari*⁵. It is widely used in the conditions like contusions, fresh wounds, ano-rectal diseases and even for fractures. “Due to its *Vata Dosha Shamaka* and *Vranaropaka* properties, *Murivenna* is very effective in the management of *Parikartika*. *Matra basti* and *Pichu* with *Murivenna* are widely practiced by Ayurvedic practitioners in throughout India. Mostly difficulty in administering the *matra basti* by themselves was experienced by the patients.

So alternative form for application of *Murivenna malahara*⁶ should be easily applicable, equally effective and acceptable by the patient to overcome the above said difficulties. “Malahara usage is quite easy than oil for application”. Also being a cost-effective therapy, the present research work aims on the preparation of

Murivenna malahara, find out its efficacy in *Parikartika* and to compare its efficacy with Diltiazem hydrochloride⁷ 2% Gel which is widely used in modern practice.

AIMS AND OBJECTIVES:

1. To evaluate the efficacy of *Murivenna malahara* application in the management of *parikartika* with special reference to Acute fissure - in - Ano.
2. To evaluate the efficacy of Diltiazem ointment application in the management of *parikartika* with special reference to Acute fissure - in - Ano.
3. To evaluate the comparative effect of *Murivenn malahara* and Diltiazem ointment application in the management of *parikartika* with special reference to Acute fissure - in - Ano.

MATERIAL AND METHODS:

A. Study design

A comparative clinical study containing 40 patients diagnosed as Parikartika w.s.r to Acute fissure-in-ano., were included for the study and was randomly selected allotted in to 2 groups namely Group A(*Murivenna malahara*) and Group B (Diltiazem ointment) with 20 patient each.

B. Source of Patients

A total of 40 patients of Acute Fissure-in-Ano of either sex was selected from OPD and IPD of Shalyatantra Dept, Taranath Government Ayurvedic Medical College and Hospital, Ballari.

DIAGNOSTIC CRITERIA:

INCLUSION CRITERIA:

- Patients irrespective of sex, religion, occupation and economic status was selected for the study.
- Patients suffering from acute & solitary anal fissure with symptoms - Painful defecation, burning sensation, bleeding per anum, constipation.
- Patients between the age of 20-50 years.

EXCLUSION CRITERIA:

- Patients with systemic disorders like Tuberculosis, anemia, Uncontrolled diabetes mellitus, Uncontrolled hypertension, cardiac & renal disorders, ulcerative colitis, chronic and multiple anal fissures with inflamed sentinel tag, crohn's disease, hypotension, HIV and HBSAg. Patients with associated Anorectal diseases like Fistula-in-ano, Haemorrhoids, polyp and growth.

INVESTIGATIONS:

CBC , ESR, RBS, CT, BT, HIV 1&2 HBSAG

MATERIALS REQUIRED FOR STUDY:



Fig. No. 43: Materials used in this study

Table No.14: Showing Materials used in this study.

Lithotomy table	01
OT Lamp	01
Normal saline	01
Sterile surgical gloves	Sufficient number
Sterile gauze piece	Sufficient number
Sterile surgical pad	Sufficient number
Murivenna malahara	Sufficient quantity
Diltiazem ointment	Sufficient quantity
Minor OT of this institution was used for conducting the procedure in group A & group B	

PROCEDURE:

GROUP A

Poorva Karma: The procedure was explained to the patient in his/her own language and informed written consent taken. Required materials were kept ready and Each day of procedure was conducted in the morning.

Pradhana Karma: Patient made to lie down on the OT table and positioned in lithotomy, impart the anal verge with left hand and index finger. The surrounding area of anal region was cleansed with wet mopped gauze piece. Sufficient amount of *Murivenna Malahara* was taken and gently applied to the affected area in anal verge with index finger. Sterile Surgical pad was kept at that place.

Paschat karma: Patient was advised to remain in the same position for 2 minutes. Patient was advised to remove that surgical pad when patient feels urge of defecation.

The procedure was carried out once daily for 7 days. The changes were observed before treatment and on 0th 2nd, 3rd, 4th, 5th, 6th, 7th AT. These observations were recorded in the proforma of case sheet prepared for the study.

GROUP B

Patient made to lie down on the OT table and positioned in lithotomy, impart the anal verge with left hand and index finger. The surrounding area of anal region was cleansed with wet mopped gauze piece. Sufficient amount of Diltiazem ointment was taken and gently applied to the affected area in anal verge with index finger. Sterile Surgical pad was kept at that place. The procedure was carried out once daily for 7 days.

The patients were advised to apply ointment at night for 7 days.

Advised Fiber rich diet, increased intake of fluids, 12 grams of *Haruaki choorna* at bed time with luke warm water and Hot water sitz bath twice a day.

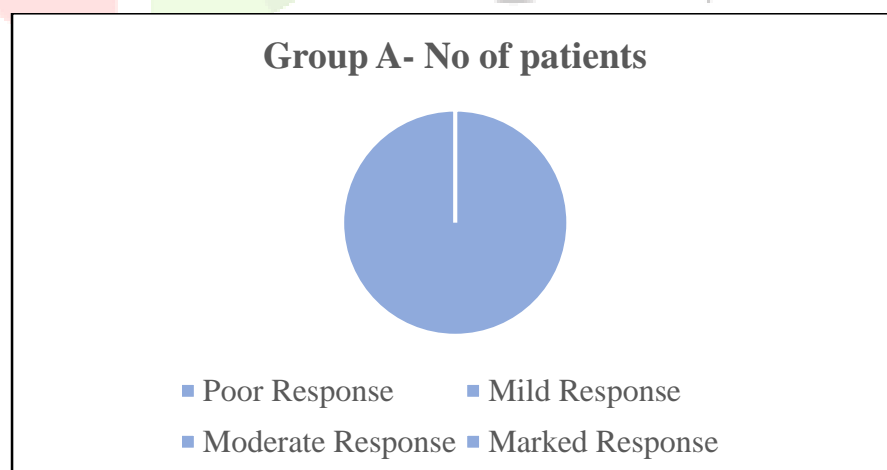
ASSESSMENT CRITERIA:

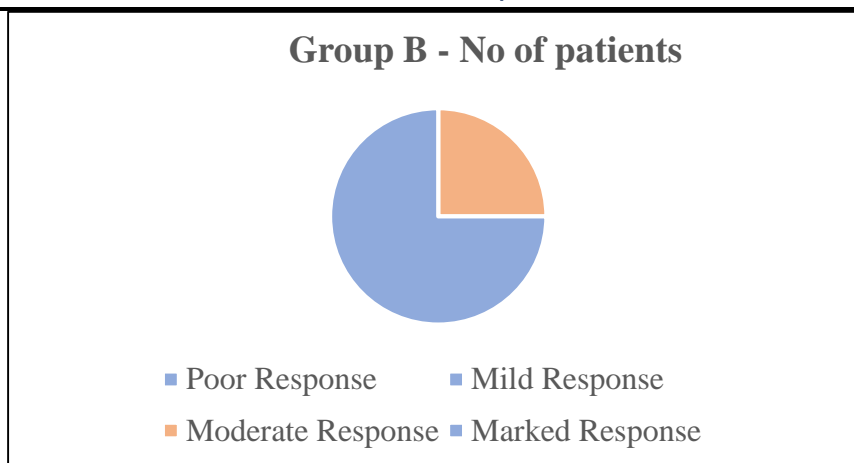
Assesment is based on subjective and objective parameters, assessed before and after treatment.

Subjective parameter	Pain	G0- No pain 0 G1- Mild pain 1-3 G2- Moderate pain 4-6 G3- Severe pain 7-10
	Burning sensation	G0- No burning sensation 0 G1- 1-15mins 1 G2- 16-30mins 2 G3-31-60mins 3 G4->60mins 4
	Bleeding	G0- Absent 0 G1- Present 1
	Constipation	G0- Passes stools regularly without difficulty 0 G1- Passes stools regularly with difficulty 1 G2- Passes hard stool irregularly with difficulty 2 G3- Passes pellet like stool once in a week with difficulty 3
Objective parameter	Length of ulcer	G0- Healed ulcer 0 G1-1 to 5mm 1 G2- 6 to 10mm 2 G3- More than 10mm 3

RESULTS:**Table No.53: Overall effect of treatment on Group A and Group B.**

EFFECT OF TREATMENT					
CLASS					OVERALL ASSESSMENT
	NO OF PTS IN GROUP A	PERCENTAGE % GROUP A	NO OF PTS IN GROUP B	PERCENTAGE % GROUP B	
POOR RESPONSE (0-25%)	00	00	0	00	0
MILD RESPONSE (26%-50%)	0	00	0	00	0
MODERATE RESPONSE (51%-75%)	0	00	5	25%	12.5%
MARKED RESPONSE (76%-100%)	20	100%	15	75%	87.5%
OVERALL RESULTS		94.5%		80.20%	100%

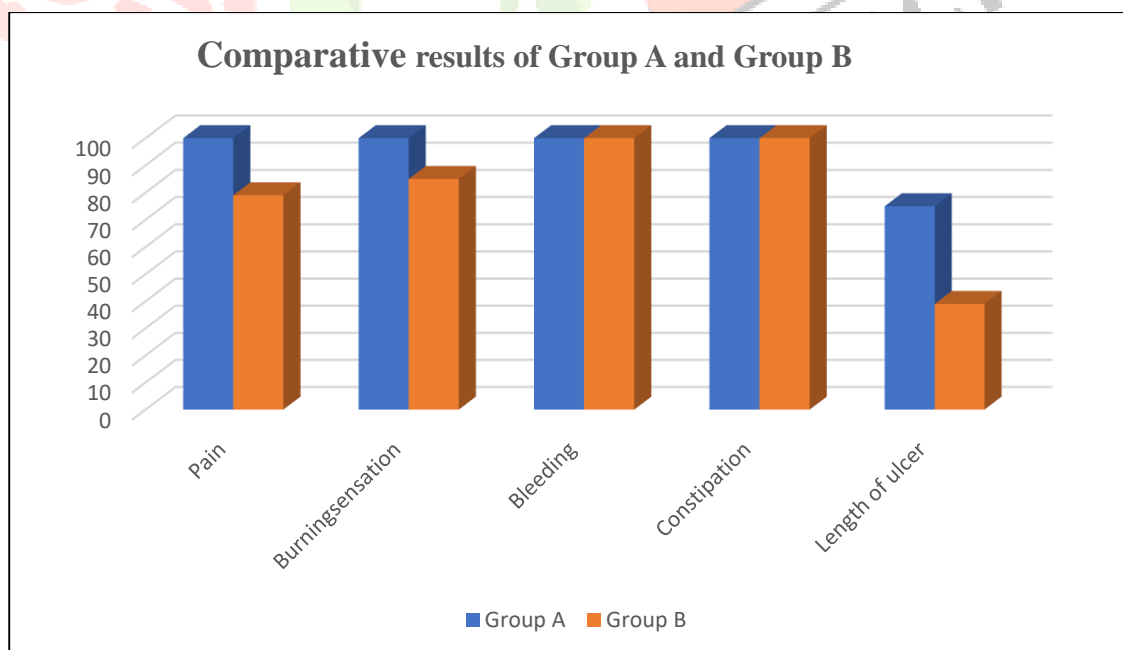
**Graph No. 23: showing over all effect of treatment in Group A.**



Graph No. 24: showing over all effect of treatment in Group B

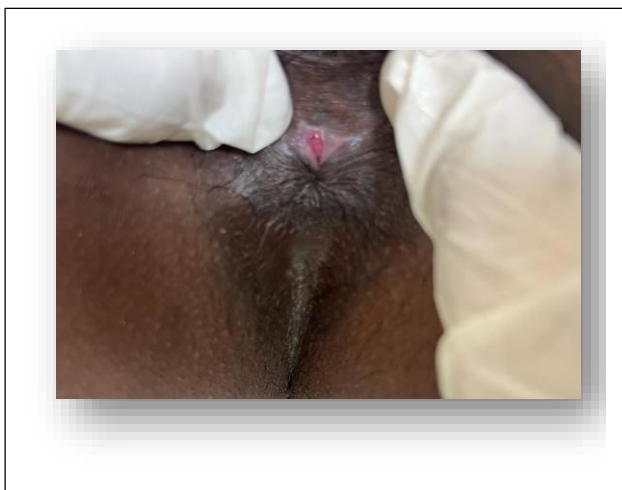
Table No. 52: Comparative Results of Group A and Group B on each parameter.

Parameters	Group A			Group B		
	Mean score		Percentage of Relief	Mean score		Percentage of Relief
	BT	AT		BT	AT	
Pain	2.20	0.00	100 %	1.95	0.40	79%
Burning sensation	2.65	0.00	100%	2.70	0.40	85%
Bleeding	0.50	0.00	100%	0.63	0.00	100%
Constipation	1.25	0.00	100%	0.95	0.00	100%
Length of ulcer	2.00	0.50	75%	1.65	1.00	39%

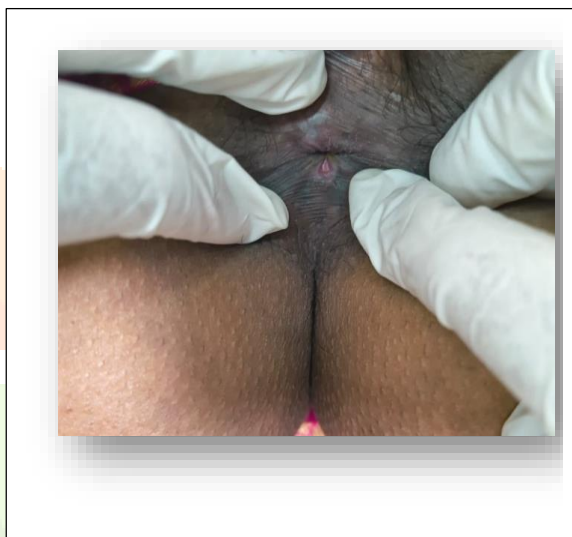
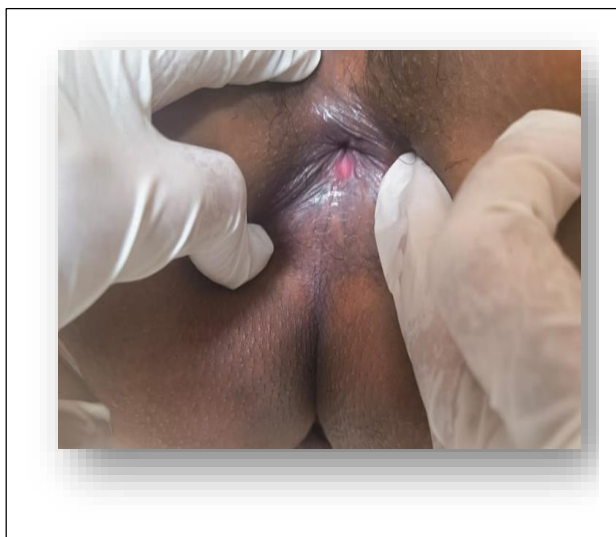


Graph No. 21: Showing Comparative Results of Group A and Group B on each Parameter.

Results of treatment in Group A



Results of treatment in Group B



DISCUSSION:

Probable mode of action on *Murivenna malahara*

In *Parikartika* there is predominance of mainly two doshas namely *vata* and *pitta*. Due to predominance these two doshas the peculiar symptoms are pain and burning sensation. For relief of these symptoms *Murivenna malahara* is selected because it is *vata pitta shamaka* and best *Vranaropaka*. Almost all drugs of *Murivenna* possess *Katu* and *Tikta rasa* and *Kashaya rasa* and *Shatavari* and *Palandu* possess *Madhura rasa* and *Laghu*, *Tikshna*, *Snigdha*, *Ruksha guna* because of these properties. *Murivenna malahara* possesses *Vrana shodhana*, *Vranaropana*, *Vedanasthapana* and *Sothahara* properties.

Katu rasa is having properties like *Kaphasamsamana*, *Lekhana* (remove the debris from wound), *Krmighna* (remove microbes from wound), *Margan vivronoti* (improves the circulation at wound site) thus helps in wound healing (*Vrana ropana*). *Tikta rasa* is having *pitta shamaka*, *krimihara*, *Daha prashamana* and *kanduhara* properties. Hence due to *krimihara* action helps to remove microbes and cleanses the wound, *Dahaprashamana* property helps to reduce burning sensation. *Kapha* and *kleda shoshana* properties helps to remove slough and debris at wound site and dries up the wound. *Madhura rasa* is having action of

dahaprashamana, *sandhanakara* (help healing of wound) and regenerate new tissue at wound site. The above said properties of *rasas* helps in stop the discharge and reduce the inflammation at wound site. *Vranaropana* property in these drugs helps in quick healing of wound in *parikartika*. All these drugs were processed in medium of coconut oil which is having properties like *Daha shamaka*, *pittashamaka*, *Shoola prashamana*, *Vrana ropana*. The properties of *Murivenna* such as *Snigdha*, *Guru*, *Ushna* are totally opposite to the properties of *Vata* act against *vata* and help in subsiding the *Shoola*. *Madhucchista* is to stop discharge, promote healing of wound tissue regeneration, because of *vatahara* reduces pain.

Laghu guna possesses *lekhana* and *ropana* properties, *Ruksha guna* possesses *sthambhanam* and *shoshana* properties. The above said properties of *guna* help in removal of debris and slough, stop the bleeding, discharge at wound site. Thus, helps in wound healing.

Ushna veerya is having *pachana* properties and *Sheeta and anushna sheeta veerya* having properties like *daha shamaka* and *pittashamaka*. The above said properties of *veerya* help in remove *saam avastha* (improper metabolites at wound site), promotes circulation, helps in reducing localise swelling and reduce burning sensation at wound.

Probable mode of action on Diltiazem ointment -

Diltiazem ointment contain diltiazem hydrochloride 2% calcium channel blockers which is used for healing of anal fissures. The ointment relaxes the smooth muscle around the anus and promotes blood flow which helps healing the fissure (tear). Symptoms like pain in anal region is diminished through the reduction in anal canal pressure. Diltiazem are calcium channel blockers which act by blocking the slow L-type calcium channels and preventing the influx of calcium into the smooth muscle cell. Due to this there is reduction in intracellular calcium concentration and causes hinderance of smooth muscle contraction. This causing relaxation of the internal sphincter muscles of anal canal.

CONCLUSION:

- ✓ Overall effect of treatment in Group A (*Murivenna malahara*) is 94.5% and where as in Group B(Diltiazem ointment) is 80.2%.
- ✓ The study showed marked response in the management of Parikartika w.s.r to Acute fissure-in-ano Based on the observations and results following hypothesis is accepted.
- ✓ *Murivenna malahara* application is more efficacious than Diltiazem ointment application in the management of *parikartika* with special reference to Acute fissure-in ano.

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