

Original Research

Clinical Study of Pile Relief Device with Special Reference to Haemorrhoids and Fissure in Ano during Pregnancy

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ABSTRACT:

Anal fissures and haemorrhoids both are very common during last few months of pregnancy. It is due to increased blood flow to pelvic region. The veins become swollen and filled with blood and gravid uterus exerts pressure over colons and rectum. Nutritional supplements such as calcium, folic acid, vit. B12 etc. are used for the development of foetus which results in constipation in the patients, The patient strains for passing the stool; develops haemorrhoids and anal fissures. Limited scope of oral medication and proctology ointment the patient does not get relief and cure. So a clinical study has been carried out at Rana Piles Hospital, Sirhind (Punjab), to treat the fissures and haemorrhoids by a cryotherapy device called Pile Relief Device. The 30 pregnant patients of anal fissures and haemorrhoids were selected. The patient was screened thoroughly before application of pile relief device. The pile relief device is inserted with lubricant veg. glycerine and placed in anal canal for 5 to 7 min. and prior after sign symptoms noted. The result shown that there is significant regression of haemorrhoidal pile mass, healing of fissure mucosa and no anal stenosis. The results were shown that the Pile Relief Device is effective over todays conventional line of treatment.

Keywords: Haemorrhoids, Fissure in ano, Cryotherapy Device, Pile Relief Device, Veg. Glycerin, Pregnancy.

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INTRODUCTION

In present day there is no safe and proper treatment protocol to treat the anorectal haemorrhoids and fissures during pregnancy. We have limitation to suggest the oral medications and limitation to use a local topical ointments. We can suggest only the dietary changes and advise to drink plenty of water.

But it is not enough to cure or treat the haemorrhoids and the fissure in ano in pregnant women. For that we have been looking forward for another treatment protocol for safe and better results in the haemorrhoids and fissures during pregnancy. We are using cryotherapy device called “pile relief device” in the management of the haemorrhoids and fissure in

ano in pregnant women and the effectiveness and safety of this treatment has to be studied during this research project.

Anal fissures and haemorrhoids both are very common in the pregnant women. Bleeding haemorrhoids and fissures may occur during 3rd trimester of pregnancy. It is due to gravid uterus having pressure over colons and the rectum.

All haemorrhoids and fissures occur in the same way. There are veins which become swollen and filled with blood for the nourishment of foetus, resulting in the high blood circulation in the pelvic region. In the pregnant women's anal cavity as well as in uterus these veins become swollen due to the pressure of the gravid uterus. Haemorrhoids usually appear inside and around the anal cavity opening and it can be painful or itchy. When pregnant women go for defecation they have to strain for passing the stool this over straining may result in to anal mucosal rupture resulting in to the Haemorrhoids associated with the fissure in ano due to constipation.

An anal fissure is basically one or more little tears in the anal cavity which can be bleed when hard stool has been passed. Anal fissures may become larger if pregnant women is constipated. And pregnant women's is more prone to be constipated due to multiple nutritional supplements like calcium, iron, folic acid, B12, etc., lack of fibre rich diet, decreased water intake etc. So that the in the last few months pregnant women has chances to develop the haemorrhoids and the fissure in ano.

AIM:

To study the effectiveness of "pile relief device" in the management of haemorrhoids and fissures during pregnancy.

REVIEW OF LITERATURE:

The effectiveness of certain medication, local ointments, or suppositories for proctological use is relative, the active ingredients of these medicines temporarily improve symptoms as results of their anesthetic, analgesic, and anti-inflammatory effects but their safety is doubtful.

The pile relief cryotherapy device was created to improve upon these principles. This device, based on cold therapy with topical glycerine as lubricant application, can produce vasoconstriction, tissue hypoxia, analgesia, and muscle relaxation. Cold related vasoconstriction causes heat loss from the skin and deep tissues. This vasoconstriction occurs by direct action and spinal reflex action; it decreases blood supply and is considered as the main mechanism for reducing swelling and bleeding. Vasoconstriction also decreases edema under inflammatory response, thereby decreasing the initial severity of haemorrhoids and fissure in ano.

Coldness inhibits the release of chemical mediators such as histamine and reduces oxygen needs because of lower metabolic demand. These two factors, together with vasoconstriction, explain the reduction

of inflammation. Application of cold can either cause pain or relieve pain. Pile relief cryotherapy device plays dual role in regard to its action on pain, and the mechanisms involved in this action have not been explained. Application of cold relieves pain by interrupting the Pain-Spasm-Pain cycle which was triggered by the haemorrhoids or fissure and thereby acts to reduce pain and muscle spasm. Theories that attempt to explain this action are based on the decrease in sensory impulses, reflex mechanisms, and decreased the muscle spasm. Application of pile relief device also work as muscle relaxing effect through cold.

Inclusion criteria

- 1) Prediagnosed pregnant women having haemorrhoids and fissure in ano.
- 2) Age group- 20years to 40years female.

Exclusion criteria

- 1) Pregnant women with another anorectal conditions such as anal fistula, pinoidal sinuses, perianal abscess, rectal prolapsed, etc.
- 2) Patients with other pregnancy related problems such as Diabetes Melitus, Hypertension, Preeclampsia, Eclampsia, etc.

MATERIAL AND METHODS

Material-

Pile relief device-

The pile relief cryotherapy device is anatomically designed for the direct application of cold therapy to the haemorrhoids and fissure in ano of patients. It was designed with the consideration of human anatomy and medical concepts of for treatment of this medical condition. It has been shown that direct application of cold can provide immediate relief of pain, itching, and inflammation due to the vasoconstrictive and analgesic properties of this medical device.



The pile relief device is filled with internally with a jelly having composition of Mono ethylene glycol 62%, Carbopol 8%, Triethanolamine 30%.

The device is made up of two plastic pieces. The top, which is inserted into the rectum, has a curved tip to facilitate insertion. The base is wide. The two pieces (top and base) meet at the base and are joined there. The top is having length 49.37mm, width from bottom and tip are 23.83mm and 12.06mm respectively. Base having the length of 64.18mm and width 37.58mm. The device as supplied with packaged in a plastic case and it includes 3 bottles of veg.glycerine as lubricant to facilitate insertion.

Proctoscope-

Proctoscope is used for the before and after application of pile relief device in the examination of the patients.

METHODOLOGY

Procedure:

- 1) Prediagnosed pregnant patients having haemorrhoids and fissure were selected.
- 2) All the pregnant patients having complaints of piles and fissures were screened thoroughly before application of the pile relief device.
- 3) Written informed consent was taken and counselling of the patient about the procedure of application of pile relief device was done.
- 4) The sign and symptoms and local manual examination were noted.
- 5) Patient was advised to lie on lithotomy position, The pile relief cryotherapy device was taking out from freezer make it to device, It is stored in the freeze for minimum 3hrs, then the pile relief device having 3 bottles of veg.glycerine, the veg. glycerin applied over the top to facilitate

lubrication for the easy insertion of device top in to the rectum.

- 6) Keep it in the rectum for 5 to 7 min. and gently remove after that.
- 7) Same procedure has been done twice a day for next five days, and the clinical sign symptoms and the proctological examination were noted.

Assessment criteria:

Subjective criteria-

The following clinical sign symptoms in the patients were assessed including pain, inflammation, bleeding, itching, burning sensation, and constipation on grading basis of mild, moderate, severe and none.

Objective criteria-

Patients assessed on the basis of local and proctological examination by expert physician. In that we recorded the size of pile mass, healing of mucosa in anal fissure, anal stenosis.

Criteria for assessment of overall symptoms:

1. Patients have been assessed for the clinical sign and symptoms individually in the pre and post procedure of application of device.
2. Also each sign symptoms graded with following manner-
Severe- 3 (+++)
Moderate- 2 (++)
Mild- 1 (+)
None- 0 (-)
3. At the end of five day treatment each sign symptoms improvement were noted individually with relief in the symptom and statistically presented with the percentage wise in following tables.

RESULTS

Pile relief device is effective over today's conventional line of treatment and during pregnancy it is safe to use

OBSERVATIONS

Table no.1 Clinical sign symptoms and its findings

Sign/symptoms	No. of patients presented with complaints	Total Relief/ Total Cured in complaints	Relief %
1)Pain	25	24	96 %
2)Bleeding P/R	15	15	100 %
3)Inflammation	28	28	100 %
4)Itching	21	15	71.42 %
5)Burning sensation	27	25	92.59%
6)Constipation	29	29	100%

Table no.2 Proctological examinations findings.

Sign/Symptoms	No. of patients	Completely cured	Relief %
1)Healing of fissure mucosa	20	20	100 %
2)Regression of pile mass	15	12	80 %
3)Anal stenosis and spasm	28	28	100 %

DISCUSSION

This device, based on cold therapy with topical glycerine as lubricant application, can produce vasoconstriction, tissue hypoxia, analgesia, and muscle relaxation. Cold related vasoconstriction causes heat loss from the skin and deep tissues. This vasoconstriction occurs by direct action and spinal reflex action ; it decreases blood supply and is considered the main mechanism for reducing swelling and bleeding. Vasoconstriction also decreases edema under inflammatory response, thereby decreasing the initial severity of haemorrhoids and fissure in ano.

Cold inhibits the release of chemical mediators such as histamine and reduces oxygen needs because of lower metabolic demand. These two factors, together with vasoconstriction, explain the reduction of inflammation. Application of cold can either cause pain or relieve pain. Pile relief cryotherapy device plays dual role in regard to its action on pain, and the mechanisms involved in this relationship have not been explained. Application of cold relieves pain by interrupting the Pain-Spasm-Pain cycle that was triggered by the haemorrhoids or fissure and thereby acts to reduce pain and muscle spasm. Theories that attempt to explain this action are based on the decrease in sensory impulses, reflex mechanisms, and decreased the muscle spasm. Application of pile relief device also work as muscle relaxing effect through cold. In this project work the minimum temperature of pile relief device -4 to -5 degree celcius is noted.

The effectiveness of pile relief device against the clinical sign symptoms of haemorrhoids and anal fissure were pain, bleeding P/R, inflammation, itching, burning sensation, and constipation were studied, also the proctological findings of pile mass regression , healing of fissured mucosa, anal stenosis were examined and they were noted in that the 96% patients shows no pain, no bleeding and inflammation in 100% patients , burning sensation decreased upto 92.59% patient and constipation relieved upto 100 % patients.

Also proctological examination showed marked improved results the healing of fissured mucosa and anal stenosis or anal spasm has been relieved 100% where as the pile mass regression in 80% patients.

In all participated patients did not shows any adversed

effect over foetus or on the carrying the pregnancy.

CONCLUSION

Based on our study , we have been conclude that the pile relief device is effective over the todays conventional line of treatment, relatively easy, and having no any side effects over the medicinal treatment and during pregnancy.

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