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To investigate the efficacy of topical application of heparin sodium, benzyle nicotinate and nifedipine paste in external thrombosed prolapsed haemorrhoids

Bhanjan Kumar Meher

Assistant professor, Department of General Surgery, Bhima Bhoi Medical College and Hospital, Balangir

Sasmita Meher

Assistant professor, Department of Pulmonary Medicine, Bhima Bhoi Medical College and Hospital, Balangir

Sahoo Soni

Assistant professor, Department of Ophthalmology, Bhima Bhoi Medical College and Hospital, Balangir

Pravin G. Dhone*

Professor & Head, Department of Pharmacology, RSDKS GMC, Ambikapur
* Corresponding author

Neeta Rai

Assistant professor, Department of Pharmacy, Vishwakarma university, Pune

Abstract---Eighty-six patient (49males, 37 females) with acute thrombosed external prolapsed haemorrhoids from January 2019 to January 2022 were treated topically with heparin sodium plus benzyl nicotinate along with 0.5% nifedipine ointment paste (t.i.d.) for 8 wk. All the patients were advised to take a high-fibre diet and assessed post-treatment at 2, 4 and 8 weeks. The healing of external thrombosed haemorrhoids and any side effects were recorded. The patients were again followed up subsequently in the outpatient department for the period of 2years and contacted by phone every three months thereafter, while they were encouraged to come back if symptoms recurred. Seventy-nine of the 86 patients followed the instruction regularly and completed the 8-wk treatment course, of them 77 patients (85.2%) achieved a complete remission indicated by resolution of pain and swellings symptoms and resolution of the thrombosis of haemorrhoids. Of the remaining nine unhealed patients

(14.8%), 5 opted to undergo haemorrhoidectomy and the other 4 to continue therapy for four additional weeks, resulting in healing and resolution of pain and swellings symptoms and resolution of the thrombosis of haemorrhoids. All the 81 patients with complete remission and resolution of pain and swellings symptoms and resolution of the thrombosis of haemorrhoids had a mean follow-up of 22.9 ± 14 (range 6-52) mo. Recurrence of symptoms occurred in nine of these 81 patients (16%) who were successfully treated with an additional 4-wk course of topically with heparin sodium plus benzyle nicotinate along with 0.5% nifedipine ointment paste . one of the 86(7.4%) patients who completed the 8-wk treatment presented with moderate headache as a side effect of nifedipine. Topical application of heparin sodium plus benzyle nicotinate along with 0.5% nifedipine ointment paste appears to be highly effective and significantly healing rate for acute external thrombosed prolapsed haemorrhoids and might capable of preventing recurrences thrombosis.

Keywords---external thrombosed prolapsed haemorrhoids, nifedipine, heparin, benzyle nicotinate.

Introduction

External haemorrhoids are present outside of the dentate line and covered by anoderm [1,2]. Thrombosed external haemorrhoids are most common form of acute anorectal diseases which are associated with severe pain in perianal region. The etiology of this disease is still unknown. External thrombosed prolapsed piles is a painful condition which affects a good number of people of the population [3,4]. Pain which is caused by external thrombosed prolapsed haemorrhoids is usually presented during standing, sitting or defecating [5,6,7,]. Patients undergo treatment hospital because of unbearable severe pain in the anorectal region which is caused by internal sphincter hypertonicity [8,9,10] . During physical examination of the anal area, a single or multiple external prolapsed venous thrombosed haemorrhoid is visible or a perforating clot of blood on top of the external haemorrhoid may be visible [1,2]. These symptoms are usually accompanied by bleeding per rectum [11,12] . The aim of this study was to investigate the efficacy of local application of a new preparation of nifedipine ointment (0.5%), heparin sodium, benzyl nicotinate as an aggressive therapeutic modality in healing external thrombosed hemorrhoids and preventing its evolution to chronicity.

Materials and Methods

It is a prospective study where the study group consisted of 86 patients with diagnosed thrombosed external haemorrhoids who were treated in the Out Patient department of General Surgery, BHIMA BHOI MEDICAL COLLEGE AND HOSPITAL, BALANGIR, with consent and a correctly filled questionnaire. The survey was conducted from January 2019 to January 2022. Patients had been directed to the proctology outpatient room by general practitioners, medicine and

gynaecologists. The diagnosis was made after proctologic assessment in the knee-chest position.

Eighty-six patient (49males, 37females) with acute thrombosed external prolapsed haemorrhoids from January 2019 to January 2022 were treated topically with heparin sodium plus benzyle nicotinate along with 0.5% nifedipine ointment paste (t.i.d.) for 8 wk. All the patients were advised to take a high-fibre diet and assessed post-treatment at 2, 4 and 8 week. The healing of external thrombosed haemorrhoids and any side effects were recorded. The patients were again followed up subsequently in the outpatient department for the period of 2years and contacted by phone every three months thereafter, while they were encouraged to come back if symptoms recurred.

Topical ointment regimen for local application was prepared by diluting 100 mg of nifedipine in 20 g of yellow soft paraffin to produce a preparation of 0.5% and 20mg benzyle nicotinate and 5gm heparin sodium. Each Patients were advised to apply the ointment regimen circumferentially 1 cm inside the anus, near the anal sphincter and over the swelling, every 8 h for 8 wk. The preparation was kept in a opaque glass container and kept in a cool place avoiding direct sunlight with a screw top lid, and discarded 3 week after formulation.

Inclusion criteria included patients with acute external prolapsed thrombosed hemorrhoids and aged 18 years or older. Exclusion criteria were presumed or confirmed surgery, allergy to heparin sodium or benzyle nicotinate or 0.5% nifedipine, associated complications warranting surgery (abscess, fistula and cancer), Crohn's disease, tuberculosis ulcer, leukemic ulcer, HIV-related anal ulcer, cancer, and patient those are unwillingness for consent to participate in the study design.

Observation and Results

We considered the patients who have Presence of acute anal fissure if associated with thrombosed hemorrhoids and the patient presented with a history of anal pain at defecation failed to resolve with conservative therapy consisting of stool softeners, high fiber diet and topical anesthetic creams prescribed by the general practitioner.

Table-3.1 Characteristics of Patients

Characteristic		Percent(%)
Patients(n)	86	100
Mean age+ SD (yr) (Range)	44.4 +11.2(20-72)	
Gender ratio(M/F)	49/37	56.9/43.1
LOCATION		
3'O clock	31	36.04
7'O clock	26	30.23
11'O Clock	29	33.72
Pain	86	100
Bleeding	62	72.09

Mean follow up SD(Month)	22.9 ± 14 (6-52)	
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Discussion

The high healing (85.2%) rate in our study in our study after 8 week of treatment is possibly related to the longer duration of treatment, considering that the usual treatment for acute thrombosed haemorrhoids ranges between 3 and 4 wk. This high healing rate may be attributed not only to the reduction of the anal canal pressure through the inhibition of the flow of calcium into the sarcoplasm of the internal anal sphincter, but also to the anti-inflammatory action of nifedipine and antithrombotic action of heparin and benzyl nicotinate. Experimental studies indicate that nifedipine has a modulating effect on the microcirculation [13] and a local anti-inflammatory effect [14], in addition to relaxation of the internal anal sphincter. However, further studies are needed to elucidate these potential therapeutic properties of this drug in healing acute thrombosed prolapsed piles. A high fibre diet by itself or in addition to topical ointments consists of a part of acute thrombosed haemorrhoids treatment. As we included patients with acute thrombosed haemorrhoids which did not respond to conservative therapy like stool softeners, high fibre diet and topical anesthetic cream, it is impossible to attribute the success of treatment to high fibre diet which we encouraged the patients to continue.

Results

Seventy-nine of the 86 patients followed the instruction regularly and completed the 8-wk treatment course, of them 77patients (85.2%) achieved a complete remission indicated by resolution of pain and swellings symptoms and resolution of the thrombosis of haemorrhoids. Of the remaining nine unhealed patients (14.8%), 5 opted to undergo haemorrhoidectomy and the other 4 to continue therapy for four additional weeks, resulting in healing and resolution of pain and swellings symptoms and resolution of the thrombosis of haemorrhoids. All the 81 patients with complete remission and resolution of pain and swellings symptoms and resolution of the thrombosis of haemorrhoids had a mean follow-up of 22.9 ± 14 (range 6-52) mo. Recurrence of symptoms occurred in nine of these 81 patients (16%) who were successfully treated with an additional 4-wk course of topically with heparin sodium plus benzyle nicotinate along with 0.5% nifedipine ointment paste . one of the 86(7.4%) patients who completed the 8-wk treatment presented with moderate headache as a side effect of nifedipine .

Conclusions

Topical application of heparin sodium plus benzyle nicotinate along with 0.5% nifedipine ointment paste appears to be highly effective and significantly healing rate for acute external thrombosed prolapsed haemorrhoids and might capable of preventing recurrences thrombosis.

Conflict of Interest: None

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