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Effectiveness Of Topical Sucralfate Ointment For Healing And Postoperative Pain Reduction After Milligan Morgan Hemorrhoidectomy

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ABSTRACT

Introduction: Hemorrhoids, characterized by symptomatic enlargement and displacement of anal cushions, pose a significant medical and socioeconomic challenge. Hemorrhoidectomy, particularly the Milligan-Morgan technique, remains a common surgical intervention for advanced cases. However, postoperative pain is a notable complication, often leading to prolonged hospital stays. This study aimed to assess the role of topical sucralfate ointment in reducing postoperative pain and enhancing healing following open hemorrhoidectomy.

Methods: The study included 80 patients with third- and fourth-degree hemorrhoids undergoing Milligan-Morgan hemorrhoidectomy. Patients were randomly assigned to receive either topical 10% sucralfate cream (n=40) or a placebo (n=40). Postoperatively, both groups followed a standard care regimen. Demographic profile, postoperative pain, and healing, along with pain during defecation, were analyzed respectively.

Results: The sucralfate group exhibited significantly lower pain scores at postoperative days 1, 7, 14, and 28 compared to the placebo group. Wound healing was notably better in the sucralfate group, with 90% achieving complete healing compared to 60% in the placebo group on day 28. Additionally, pain during defecation was significantly lower in the sucralfate group at 1 and 2 weeks postoperatively.

Conclusion: Topical sucralfate demonstrates effectiveness in reducing acute postoperative pain and promoting wound healing following Milligan-Morgan hemorrhoidectomy. Despite study limitations, these findings highlight the potential of sucralfate as a valuable adjunct in post-hemorrhoidectomy care. Further research is recommended to refine randomization techniques and explore variations in sucralfate cream strength and dosage...

Keywords: Milligan-Morgan hemorrhoidectomy, 10% sucralfate, Wound healing, Postoperative Pain.

1. INTRODUCTION

Hemorrhoids has been well described since ancient time (1750 BC in Babilonia, 1550 BC in Egypt).1 It is a symptomatic enlargement and distal displacement of the normal anal cushions and affects worldwide population and becomes major medical and socioeconomic problem.2 Most of the people (40%)suffering from hemorrhoids are asymptomatic.3 Multiple factors were found in the etiology of hemorrhoidal development.4 The causes of increase intraabdominal pressures, leading to haemorrhoids are Chronic cough, constipation, straining during defecation, repetitive Valsalva maneuver, sitting for a long period on the toilet seat, Pregnancy, obesity.5-8 Hemorrhoids still have unknown etiology because of the tendency of using self medications rather than seeking proper medical advice.People with higher economic status and and of whitws were affected more frequentlly.9 The most common symptoms are painless rectal bleeding, itching, soiling, perianal irritation, or mucus discharge.Failure of conservative management in grade 4 hemorrhoids require surgery.2(8) 38.9% of the peoples suffers from haemorrhoids,in which 8.16% are grades III and 0.53% are grade IV.3 Symptomatic hemorrhoids usually present with painless rectal bleeding at the end of defecation or may drip into the toilet,..

perianal itching and pain due to thrombosis.2(6)58% of the general population aged >40 years suffering from symptomatic haemorrhoid(58% of general population). For grade I and grade II of haemorrhoid diease conservative management is sufficient but for for grades III or IV haemorrhoids which are nonresponding to medical treatment Haemorrhoidectomy is an effective treatment.10 Milligan-Morgan technique is established by Edward Campbell Milligan and Clifford Naughton Morgan, in this technique open excision haemorrhoidectomy done and resected haemorrhoidal tissues left open for healing by a secondary mechanism. It practiced more commonly in developing countries.11,12 Postoperatively patient complaints of bleeding from wound site, pain, , pruritus, and other conditions until the wound gets completely epithelialised.13 These complaints depends on the surgical procedures, use of analgesics after surgery, and the tolerance of individual patient.14 also due to presence of surgical wound in the sensitive anoderm and perianal skin and the edema from tissue inflammation around the wound.15,16 Generally in routine practice post-haemorrhoidectomy pain managed by Lignocain ointment/gel, analgesics, calcium channel blockers, and metronidazole etc.2 Sucralfate is an aluminium hydroxide salt of sucrose octasulfate and has been in use as a therapy for inflammatory gastrointestinal ulcer for over 30 years.17 Topical sucralfate having antibacterial activity and it used in burns only.18-20 Sucralfate ointment forms insoluble adherent complexes by absorbing bile salts that prevent the mechanical damage of operative wound.It has antimicrobial and antioxidant activity.21,22,also stimulates PGE2 release leading to increased vascularity and mucus formation .It increases the production of EGF (epidermal growth factor) causing increased angiogenesis.23The aim of the study was to evaluate the role of topical Sucralfate ointment in reducing postoperative pain and in improving healing after open hemorrhoidectomy

2. MATERIAL & METHODS:

This study was conducted in the Department of General Surgery in Chirayu Medical College & Hospital, Bhopal (MP) over a period of 6 months during February 2023 to July 2023 after taking approval from Institutional Ethical committee. Patient of both the sexes ages from 20 years to 60 years who had third-degree and fourth degree hemorrhoids who had not responded to medical management and had been elected to surgical treatment were included in the study. Disease related to anus and rectum (e.g. fistulae, prolapse, abscess), age younger than 20 years or older than 60 years, patient with inflammatory bowel disease, poorly controlled Diabetes Mellitus, long term use of corticosteroids, patient with a history of radiation exposure, recent history of chemotherapy(<2 weeks),non completion of the study protocol and patients who were drug abusers were excluded in study. It was single centric prospective randomized controlled study.After taking written informed consent all enrolled patients underwent haemorrhoidectomy by Milligan–Morgan technique and the end of surgery patients were randomly (even–odd randomization according to their number of enrollment) assigned into two groups. The sucralfate group (40 patients) received topical 10% sucralfate cream at the end of surgery. The placebo group (40 patients) received topical placebo cream of petroleum jelly. Patients were instructed to apply a fixed amount of the cream (sucralfate or placebo) on the surgery site two times daily. All participants received written instructions on postoperative wound care/Sitz bath and a demonstration on the proper way to apply the topical treatment. Both groups were asked to avoid using any other antiseptics. As standard therapy, all patients received diclofenac sodium 50 mg tablets to be taken two times daily and metronidazole 400 mg tablets to be taken three times daily for 7 consecutive days after the operation. All patients were discharged on the second postoperative day and called after 7,14 & 28 days for follow-up. Postoperative pain was evaluated using the visual analog pain score scale.[24] Patients rated the level of pain from score 0 (no pain) to 10 (the severest pain could be imagined). Wounds that were fully epithelialized with no discharge were judged to be completely healed. Pain on defecation was also recorded on first passage of stool, by the end of first and second weeks. After 4 weeks, the degree of wound healing was recorded as inadequate, adequate, or complete healing. Data were analysed by using SPSS package for Windows (version 16) (USA, Chicago, SPSS Inc.).

3. RESULTS:

The present study was conducted on a total of 80 patients who underwent open hemorrhoidectomy and at the end of surgery patients were randomly divided into two groups i.e. sucralfate and placebo group with 40 patients in each group. The findings of our study are tabulated as under-

Table 1: Demographic Profile & characteristics of patients.

Baseline characters		Sucralfate Group (n=40)	Placebo group (n=40)	P Value
Age	Mean±SD	38.5±8	39.6±6	0.49
Sex	Male	22 (55%)	24 (60%)	0.65
	Female	18 (45%)	16 (40%)	
Piles grade	III	24 (60%)	28 (70%)	0.35
	IV	16 (40%)	12 (30%)	

Diet	Vegetarian	16 (40%)	18 (45%)	0.65
	Non-vegetarian	24 (60%)	22 (55%)	
No. of piles removed (Range)		1-3	1-3	-

As observed from table 1, mean age of patients of sucralfate group was 38.5±8 years whereas that of placebo group was 39.6±6 years. Majority of cases in both the groups were males, had piles grade II and were non vegetarian. We observed no significant difference in baseline characters between the sucralfate group and placebo group (p>0.05).

Table 2.Comparison of severity of pain on the visual analogue pain scale at 1,7,14,28 days post operatively

Post operative Day	Sucralfate Group (n=40)	Placebo group (n=40)	P Value
Day 1	5.14±1.27	7.01±2.33	0.001
Day 7	1.03±0.26	3.14±0.75	0.001
Day 14	0.87±0.04	1.67±0.31	0.001
Day 28	0.13±0.01	0.98±0.44	0.001

In present study, pain scores were significantly lower in cases of sucralfate group at post-operative day1, day 7, day 14 and day 28 as compared to placebo group (p<0.05) (table 2).

Table 3 Comparison between the two groups regarding the degree of wound healing at 28 days postoperatively

Wound Healing	Inadequate	Adequate	Completely healed
Sucralfate Group(n=40)	1 (2.5%)	3 (7.5%)	36 (90%)
Placebo group(n=40)	3 (7.5%)	13 (32.5%)	24 (60%)
P value	0.008		

Wound was completely healed in 90% cases of sucralfate group as compared to 60% cases of placebo group and the wound healing was significantly better in sucralfate group as compared to placebo group (p<0.05).

Table 4: Pain on defecation after 1 & 2 weeks

VAP Scale	Sucralfate Group (n=40)	Placebo group (n=40)	P Value
After 1 week	6.77±2.89	8.61±3.9	0.001
After 2 weeks	3.77±1.17	6.10±3.01	0.001

Mean pain on defecation in sucralfate group was 6.77±2.89 and 3.77±1.17 at 1 week and 2 week postoperatively respectively, which reduced to 8.61±3.9 at 1 week and 6.10±3.01 at 2 week in placebo group. The observed difference in mean VAS score during defecation was significantly lower in sucralfate group as compared to placebo group after 1 week and 2 week postoperatively (p<0.05).

4. DISCUSSION:

Post operative pain and delayed wound healing noted after Morgan haemorrhoidectomy due to the large wound area.[13,25] It is usually multifactorial, which dependents on the surgical technique, anesthesia, postoperative analgesia, and individual tolerance.[14] Surgical wound in the sensitive anoderm and perianal skin and edema from tissue inflammation around the wound causes reflex spasm of internal anal sphincter and all lead to more worsening of post-operative pain.[26] Post-haemorrhoidectomy pain is also a common cause of prolonged hospital stays.[27] Sucralfate is an essential aluminium salt of sucrose octa sulphate and acts as an anti-ulcer drug.[6,7] It increased epidermal growth factor (EGF), basic fibroblast growth factor (bFGF) concentration, angiogenesis and granulation tissue in subcutaneous of rats.[18,28] In this study out of 40, majority of the patients were male 46 (57.5 %) as compared to females 34(42.5%). Average age of patients were 39.05 years. Similar

results showed by Muhammad K et al.[29] and Alkhateep Y et al in which they showed population of male patients was high 55% to 70% as compared to females and average age of patients was 40years.[23] We noticed the difference between the visual analogue pain scale score in both the groups.We also observed that the analgesic effect of sucralfate is more pronounced with the time (Table 2).Also, the average visual analogue pain scale score on day 7, 14 & 28 were significantly lower in cases of sucralfate group as compared to placebo group. Ala et al.[27] in 2013,Mirani et al in 2015[30] and by Ayman A. Albatanony in 2016.[31] Alkhateep Y and Fareed[23] showed the same results that more frequent application gives better effect. In a randomized controlled study by Gupta et al on 116 patients, topical sucralfate reduced pain at days 7 and 14 after hemorrhoidectomy but later on had no effect more than placebo.[32] Gupta et al studied the effect of a 7% topical sucralfate cream on postoperative pain and healing after open haemorrhoidectomy.[32] Against this, study by Mirani et al. showed that topical sucralfate ointment (10%) has a significant analgesic effect and can reduce both acute and chronic pain after hemorrhoidectomy but its analgesic effect is not obvious before 24 hours.[30] In this study sucralfate group showed adequate healing in 90% cases as compare to plcebo group that is 60% on 28 post operative day.(Table no 3)These results were comparable to the results of Gupta et al.[32] which reported that by the end of the sixth week, complete wound healing achieved in all patients in the sucralfate group. Jóhannsson et al.[9] and Arroyo et al.[34] showed healing rates of 80 and 70%, respectively, and the wound healing was between 6 and 8 weeks. Hwang et al.[35]showed a complete wound healing at the sixth week follow-up after open hemorrhoidectomy. But, Malik et al.[36]observed that complete wound healing occurred in all cases by the end of the sixth week using the standard therapy. In present study the difference in mean VAS score during defecation was significantly lower in sucralfate group as compared to placebo group after 1 week and 2 week postoperatively ($p<0.05$).(Table no 4) Similar study is done by Alvandipour M[17] in 2016.It showed that the mean VAS after first defecation was significantly lower in the sucralfate group than in the placebo group (5.92 vs. 8.64).[23]

5. CONCLUSION:

The topical sucralfate is effective in reducing the acute postoperative pain and it can improve the rate of wound healing. This study has some limitations. The used technique of randomization (even/odd) can be improved in future studies by large sample sizes and a more advanced randomization technique to prevent confounding ,violation of allocation concealment and selection bias. Further studies can be done with different strength and doses of sucralfate cream, focusing on the reduction of oral analgesic doses used along with topical sucralfate ointment..

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