

# Comparative study between effect of topical sucralfate cream and glyceryl trinitrate cream on post haemorrhoidectomy pain and wound healing

Original  
Article

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## ABSTRACT

**Background:** Haemorrhoidectomy is the treatment of choice for third- and fourth-degree haemorrhoids. Haemorrhoidectomy is avoided by many patients because it is linked to severe pain after surgery.

Topical sucralfate cream hastens the healing of wounds and reduces discomfort following hemorrhoidal surgery. After a haemorrhoidectomy, topical use of glyceryl trinitrate (GTN) can reduce spasm and postoperative pain; also, increase Ano dermal blood flow, and accelerate the healing of the wound.

**Patients and Methods:** This prospective randomized control single-blinded study was conducted over a one-year duration. In General Surgery Department, Mansoura Faculty of Medicine with the inclusion of 60 patients with third- and fourth-degree piles who underwent conventional Milligan–Morgan haemorrhoidectomy.

Three groups of 60 patients were randomly assigned to participate in the current study: group A (the control group): included 20 patients who received a placebo (petrolatum cream). group B (the sucralfate group), group C (GTN cream group).

The visual analogue scale (VAS 0–10) was used to assess postoperative pain on days 1, 7, and 14 following surgery and wound healing was assessed after 28 days.

**Results:** There was no significant difference between the three study groups as regards demographic data, symptoms, and the VAS score on the first postoperative day.

On the seventh and 14<sup>th</sup> day postoperative, respectively, the VAS score was statistically significantly lower in the GTN group followed by the Sucralfate group and finally the control group ( $P < 0.001$ ). The duration for complete wound healing and the duration to return to daily activities were statistically significantly shorter in the sucralfate group followed by the GTN group.

**Key Words:** Haemorrhoidectomy, glyceryl trinitrate, sucralfate.

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## INTRODUCTION

Hemorrhoidal problem is caused by the prolapsing of hemorrhoidal tissue, which can lead to complications and symptoms. Bleeding, discomfort, pruritus, faecal soiling, prolapse, and mucus discharge are the commonest symptoms<sup>[1]</sup>.

The severity of the condition determines the course of treatment. For the majority of patients in the early stages of the disorder, conservative therapies including diet and lifestyle modification to achieve regular bowel movement with oral phlebotonics to reduce symptoms are effective<sup>[2]</sup>.

Treatment of choice for third- and fourth-degree piles is haemorrhoidectomy. Haemorrhoidectomy is avoided

by many patients because it is linked to severe pain after surgery. Because of severe pain and suffering associated with haemorrhoidectomy, many patients prefer to live with their hemorrhoidal symptoms rather than undergoing surgery<sup>[3]</sup>.

Various approaches to reduce pain following haemorrhoidectomy have been studied. Numerous pharmacotherapies, including metronidazole, botulinum toxin, calcium channel blockers, nitrates, and local anaesthetics, have been used to treat posthaemorrhoidectomy pain. Despite the fact that these medications have been demonstrated to be effective in lowering postoperative pain, many factors restrict their use, including their short half-lives, unpleasant side effects and poor potency<sup>[3]</sup>.

Opioids and nonsteroidal anti-inflammatory drugs are used to control pain after haemorrhoidectomy, but these are short acting, have significant side effects, and can be expensive. These reasons justify the need to find new treatment to reduce pain after haemorrhoidectomy<sup>[4]</sup>.

Sucralfate is a mucosal protective agent that attaches itself specifically to injured or inflamed tissue to create a protective layer or coat over mucous membranes. According to Singh and colleagues, ultra-structural analysis showed that topical application of sucralfate might influence neo angiogenesis, enhance wound contraction, encourage reepithelization of the wound, and reduce the inflammatory response<sup>[5]</sup>.

Although the precise mechanism of sucralfate activity is uncertain, it is known that it increase growth factor bioavailability and reduce oxygen free radical generation. Sucralfate binds to Fibroblast growth factors (FGF) and Epidermal growth factor (EGF) to promote angiogenesis, reduce the amount of bacterial translocation, produce granulation tissue, and re-epithelialize, Sucralfate also increases the synthesis of Prostaglandin E (PGE2). All of these contribute to maintenance of mucosal vascular integrity and enhanced blood flow<sup>[6]</sup>. Topical sucralfate cream hastens the healing of ulcer and reduce pain following hemorrhoidal surgery<sup>[7]</sup>.

Topical use of glyceryl trinitrate after haemorrhoidectomy, can reduce spasm and postoperative

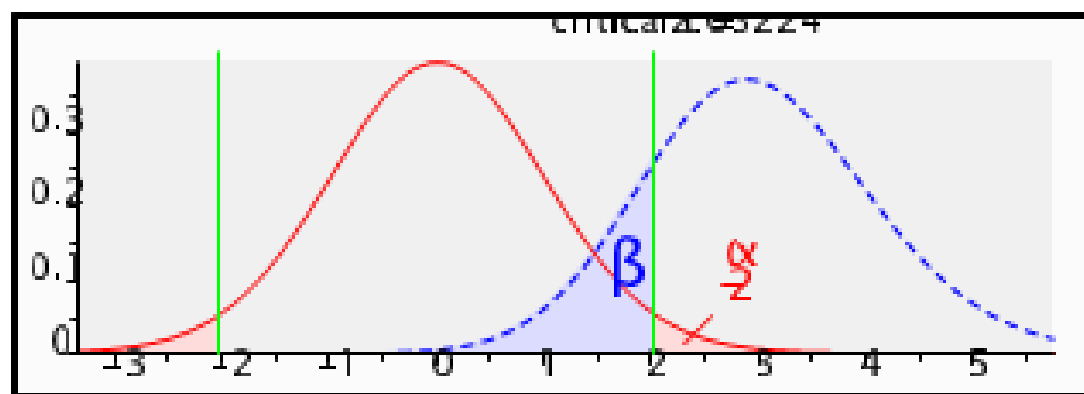
discomfort; also, increase Ano dermal blood flow and accelerate wound healing. Headaches and subsequent requirement for analgesic drugs may reduce the advantages of nitroglycerine<sup>[8]</sup>.

#### PATIENTS AND METHODS:

This prospective randomized control study was conducted over a 1-year duration, from September 2022 to September 2023. In General Surgery Department, Mansoura Faculty of Medicine, Mansoura University, Egypt. Including 60 patients of both sex with grade three and grade four piles who underwent conventional Milligan–Morgan haemorrhoidectomy with excision of 3, 7, 11 haemorrhoids at the three cushions in all patients by the same surgeon team leaving nearly equal wound sizes.

#### Sample size calculation

Sample size calculation was based on difference in mean vas score post haemorrhoidectomy between topical sucralfate cream and glyceryl nitrate cream retrieved from previous researches [Albatanony (2016) and Arash Karimi (2019)]. Using G power program version 3.1.9.4 to calculate sample size based on effect size of 0.98, using two-tailed test,  $\alpha$  error=0.05 and power=80.0%, the total calculated sample size will be 20 in each group (total 60).



#### Statistical analysis

Data will be analysed using SPSS (statistical package for social sciences) version 22. Qualitative data will be presented as number and percent, Quantitative data will be tested for normality by Kolmogorov–Smirnov test then described as mean and standard deviation for normally distributed data and median and range for nonnormally distributed. The appropriate statistical test will be applied according to data type with the following suggested tests:  $\chi^2$  for categorical variable, Spearman or Pearson correlation will be used to correlate continuous variables.

All patient were subjected to preoperative history taking, clinical assessment and anal and per rectal examination, routine preoperative investigation.

All patients signed an informed written consent after explaining the aim of the research, advantages and disadvantages of each intervention. Patient confidentiality was preserved, and the collected data was used only for scientific purposes.

**Informed Consent Form**

Please take a moment to read our informed consent before completing the form. We thank you for your support in helping us conduct this clinical research study.

**Title of Study**

**Purpose of Study**

**Principal Investigator**                      **Email**

**Name**   

**First**    **Last**

**Date**

I have read all the information and am willing to participate in the clinical research study.

**Signature**

Method of randomisation: sealed envelope method (single blinded the investigators were aware which topical cream used)

### **Exclusion criteria**

(a) Presence of associated anal or rectal pathologies (e.g. Fistula, prolapse, abscess, fissure).

(b) Immunocompromised patients, diabetic or drug abusers.

(c) Recurrent piles.

(d) Missed patients during follow-up.

(I) The 60 patients were randomly divided into three groups, to participate in the current study:

(a) Group A (the control group): included 20 patients who received placebo (petrolatum cream).

(b) Group b (the sucralfate group): included 20 patients who used sucralfate 10% cream in an inert carrier (petrolatum cream) post haemorrhoidectomy for 30 days.

(c) Group C (glyceryl trinitrate) cream: included 20 patients who received glyceryl trinitrate 0.5% cream post haemorrhoidectomy for 30days.

The visual analogue scale (VAS 0–10) was used to assess postoperative pain on days 1, 7, and 14 after surgery.

Patients were discharged usually on the first postoperative day unless complications were encountered. Follow-up visits were scheduled every week for the first month, then monthly for the remaining 5 months, making the follow-up duration 6 months.

### **Outcome measures**

Evaluation and comparison of the effect of sucralfate 10% cream and GTN 0.5% as regard:

(a) Postoperative pain at day 1, 7, and 14 after surgery.

(b) Duration and rate of wound healing (complete epithelisation) on postoperative day 28.

(c) Time needed to restore normal daily activity

The study gained approval from the institutional research board (IRB) of the Faculty of Medicine, Mansoura University.

The Statistical Package for Social Science was used, on a PC. (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp). Data were shown, and appropriate analysis was carried out based on the kind of data found for each parameter.

Normality of data: as a test of normality, the Kolmogorov–Smirnov test was employed; if the significance level is higher than 0.05.

Descriptive statistics: for parametric quantitative data, the mean  $\pm$ SD was utilized, for nonparametric quantitative data, the median and range were employed.

### **Analytical statistics**

(a) One way analysis of variance (ANOVA): the difference in three study group means' statistical significance was evaluated.

(b) Kruskal–Wallis test was employed to evaluate the nonparametric variable's difference between the three research groups' statistical significance.

(c)  $\chi^2$  test was employed to look into the connection between two or more qualitative factors.

(d) Monte–Carlo test was employed as an alternative to the  $\chi^2$  test when the frequency is less than five in one or more cell ( $>2 \times 2$  tables) to investigate the association between two or more qualitative variables. *P value*: the significance level. This level was set at 0.05, *P values* less than 0.05 are significant, and *P values* less than 0.01 are highly significant.

**RESULTS:**

Tables 1, 2

**Table 1:** Analysis of the demographic data and history in the three study groups

Variables	Control group (N=20) [n (%)]	Sucralfate group (N=20) [n (%)]	Glyceryl trinitrate group (N=20) [n (%)]	Test of significance
Age (years)	36.55±9.81	37.25±8.90	35.90±10.03	F=0.099 P=0.906
Sex				
Males	14 (70)	15 (75)	14 (70)	$\chi^2=0.164 P=0.921$
Females	6 (30)	5 (25)	6 (30)	
BMI (Kg/ m <sup>2</sup> )	29.16±2.76	28.16±2.55	28.09±3.24	F=0.878 P=0.421

P: probability all the time data are expressed as mean ± SD. Categorical data expressed as Number (%)  $\chi^2$ =Chi-square test. F: One-Way analysis of variance test.

Table 3 shows that there was no statistically significant difference between the three groups regarding the age, gender, and BMI. The mean age was 36.55±9.81 years, 37.25±8.90 years and 35.90±10.03 years in the control,

sucralfate, and GTN group, respectively. There were 70, 75, and 70% males in the control, sucralfate, and GTN group, respectively.

**Table 2:** Analysis of the degree of piles in the three groups

Variables	Control group (N=20) [n (%)]	Sucralfate group (N=20) [n (%)]	Glyceryl trinitrate group (N=20) [n (%)]	Test of significance
Degree of piles				
Third degree	6 (30)	8 (40)	9 (45)	$\chi^2=0.987 P=0.610$
Fourth degree	14 (70)	12 (60)	11 (55)	

P, probability. Categorical data expressed as Number (%)  $\chi^2$ =Chi-square test.

Regarding the degree of piles, (Table 5) shows that in the control group, there were 6 (30%) cases and 14 (70%) cases with third- and fourth-degree piles, respectively. In the sucralfate group, there were 8 (40%) cases and 12 (60%) cases with third- and fourth-degree piles,

respectively, while Sucralfate group in the GTN group, there were 9 (45%) cases and 11 (55%) cases with the third- and fourth-degree piles, respectively. There was no statistically significant difference between the three study groups ( $P=0.610$ ).

**Table 3:** Analysis of the complaints in the three study groups

Variables	Control group (N=20) [n (%)]	Sucralfate group (N=20) [n (%)]	Glyceryl trinitrate group (N=20) [n (%)]	Test of significance
Complaints				
Bleeding	18 (90)	19 (95)	17 (85)	$\chi^2=1.111 P=0.574$
Prolapse	17 (85)	13 (65)	16 (80)	
Itching	7 (35)	6 (30)	7 (35)	$\chi^2=0.150 P=0.928$
Pain	5 (25)	8 (40)	6 (30)	

P, probability. Categorical data expressed as Number (%)  $\chi^2$ =Chi-square test.

Table 3 demonstrates that, with regard to the presenting complaints, there was no statistically significant difference between the three research groups. Bleeding was the most

frequent complaint, followed by prolapse, discomfort, and itching.

**Table 4:** Analysis of visual analogue scale of pain (VAS score) in the three study groups along the follow-up

VAS	Control group (N=20)	Sucralfate group (N=20)	Glyceryl trinitrate group (N=20)	Test of significance
Day 1	6 (4–7)	5 (4–7)	5 (4–7)	KW=1.372 P=0.504
Day 7	4 (2–5)	3 (2–5)	2 (1–4)	KW=16.536 P<0.001*
Day 14	3 (2–4)	2 (2–3)	2 (1–2)	KW=25.205 P<0.001*

KW, Kruskal–Wallis test; P, probability.  
Continuous data are expressed as median (Range).  
\*: statistically significant ( $P \leq 0.05$ ).

Table 4 shows that there was no statistically valuable difference between the three study groups including the VAS score at the first day postoperative ( $P=0.504$ ).

At seventh day postoperative, the VAS score was statistically significantly lower in the Glyceryl trinitrate

group compared with the control group and Sucralfate group ( $P<0.001$ ).

At 14<sup>th</sup> day postoperative, the VAS score was statistically significantly lower in the Glyceryl trinitrate group compared with the control group and Sucralfate group ( $P<0.001$ ).

**Table 5:** Analysis of the late postoperative follow up in the three groups

Variables	Control group (N=20) [n (%)]	Sucralfate group (N=20) [n (%)]	Glyceryl trinitrate group (N=20) [n (%)]	Test of significance
Duration of wound healing (Days)	30 (22–40)	26 (22–31)	26 (22–37)	KW=6.493 P=0.015*
Return daily activity (Days)	22 (19–27)	13 (12–15)	17 (14–19)	KW=51.879 P<0.001*
Number of patients with complete wound healing at 28 days postoperative	10 (50)	17 (85)	13 (65)	$\chi^2=5.550$ P=0.045*

KW, Kruskal–Wallis test; P, probability.  
Continuous data are expressed as median (Range).  
Categorical data expressed as Number (%)  $\chi^2$ =Chi-square test.  
\*: statistically significant ( $P \leq 0.05$ ).

Table 5 shows that the duration for complete wound healing and the duration to return to daily activities were statistically significantly shorter in the sucralfate group as compared with the control and GTN group. Also, the duration for complete wound healing and the duration to return to daily activities were statistically significantly shorter in the GTN group as compared with the control group.

The number of cases with complete wound healing was 10 (50%) in the control group, 17 (85%) in the sucralfate group and 13 (65%) in the GTN group. There was a statistically significant difference between the three groups with the highest incidence of complete wound healing in the sucralfate group.

**Table 6:** Analysis of patient satisfaction in the three study groups according to the patient's satisfaction score

Variables	Control group (N=20) [n (%)]	Sucralfate group (N=20) [n (%)]	Glyceryl trinitrate group (N=20) [n (%)]	Test of significance
Very satisfied	1 (5)	6 (30)	9 (45)	MC=17.749 P=0.023*
Satisfied	4 (20)	6 (30)	7 (35)	
Neutral	6 (30)	5 (25)	3 (15)	
Dissatisfied	6 (30)	3 (15)	1 (5)	
Very dissatisfied	3 (15)	0	0	

MC, Monte–Carlo test; P, probability.  
Categorical data expressed as number (%).  
\*: statistically significant ( $P \leq 0.05$ ).

Table 6 shows that the degree of patients' satisfaction was statistically significantly better in better in the

sucralfate group and glyceryl trinitrate group compared with the control group.



## DISCUSSION

Posthaemorrhoidectomy pain is still a difficult issue, haemorrhoidectomy is still considered the standard procedure for severe and/or advanced haemorrhoids; according to published research, up to 65% of patients may have moderate to severe pain after traditional haemorrhoidectomy<sup>[9]</sup>.

In order to alleviate pain following haemorrhoidectomy, GTN has been developed as a topical medication that may be applied to the perianal skin or the anal canal<sup>[10]</sup>. Sucralfate acting as a mucosal healing promoter and protective barrier<sup>[11]</sup>.

No research comparing the two medications for post-haemorrhoidectomy pain control has been done. This is why the present study comparing the effects of topical glyceryl nitrate cream and sucralfate cream on wound healing and pain control following haemorrhoidectomy.

The present results were likewise in agreement with Khan *et al.*<sup>[12]</sup>, who randomly assign patients having Milligan–Morgan haemorrhoidectomy into three groups. Group B received 2% lignocaine only, group C received 0.2% Glyceryl Trinitrate ointment, and group A received a mixture of 0.2% Glyceryl Trinitrate and 2% lignocaine. The study's findings demonstrated that, in group A, there were statistically significant decreases in pain levels and the amount of analgesics consumed between the first and fourth post-operative days.

This was compatible with a meta-analysis and comprehensive review of 12 RCTs including 1095 patients, which discovered that topical GTN treatment was linked to faster rate of wound healing (by 4–10 days) and marked decrease in pain up to 2 weeks following haemorrhoidectomy when compared with placebo. However, 10% of patients receiving GTN suffered from headache, which may prevent GTN from being used extensively<sup>[13]</sup>.

Because GTN relaxes the IAS, it has been seen to considerably reduce posthaemorrhoidectomy pain. Improvement in healing were also made possible by the reduction in spasm, also increase blood flow and decrease perianal ischemia<sup>[14]</sup>.

According to Mirani *et al.*<sup>[15]</sup>, 48 patients treated with topical sucralfate ointment (10%) reported a considerable improvement in both acute and chronic pain following haemorrhoidectomy.

Additionally, Alvandipour *et al.*<sup>[16]</sup> investigated the impact of topical sucralfate cream 7% on healing and postoperative pain following haemorrhoidectomy.

Compared with the placebo group, the sucralfate group reported decrease pain on postoperative days 7 and 14, matching our study.

Another important element influencing the overall outcome of haemorrhoidectomy is wound healing. After surgery, wound healing is crucial, and large wound could delay healing and exacerbate pain<sup>[17]</sup>.

In the current analysis, the sucralfate group exhibited greatly shorter times for both complete wound healing and returning to daily activities when compared with the control and glyceryl trinitrate groups. Sucralfate showed statistically significant shorter time for both complete wound healing and returning to daily activities.

Our findings also demonstrated sucralfate superiority in reducing pain when compared with the placebo group in agree with Vejdani and colleagues who compared two groups of randomly selected patients (n=40), who had Milligan–Morgan haemorrhoidectomy. Patients in the control group utilized Vaseline as a placebo, whereas the wounds of the other group were treated with a 10% sucralfate ointment. The mean VAS during the postoperative period was (3.7) for the sucralfate group and (6.9) for the control group in agree with this study. Also, the sucralfate group completed epithelialization on day 13, whereas the control group completed it on day 20<sup>[18]</sup>.

Because of its angiogenic properties and its inhibitory impact on fibroblast breakdown, sucralfate relieves pain during haemorrhoidectomy and encourages wound healing<sup>[19]</sup>. According to Gupta *et al.*<sup>[7]</sup>, topical sucralfate facilitates faster wound healing when compared with a placebo and significantly decrease pain following haemorrhoidectomy up to two weeks postoperatively.

Another double-blind randomized trial confirmed the current study findings, showing that sucralfate ointment significantly decreased initial postoperative pain following haemorrhoidectomy compared with the placebo group<sup>[20]</sup>.

Our study found that 10 (50%) of the control group, 17 (85%) of the sucralfate group, and 13 (65%) of the GTN group had complete healing of their wounds after 28 days postoperative. Between the three groups, there was a statistically significant difference, with the sucralfate group showing the greatest incidence of full wound healing and epithelialization.

This was compatible with the findings of a prospective cohort research by Al Khateeb *et al.*<sup>[21]</sup> which involved 50 patients with third- or fourth-degree piles who underwent haemorrhoidectomy.

Following the procedure, the patients were divided into two groups at random. Topical 8% sucralfate cream was administered to the sucralfate group (n=25), the sucralfate group had a considerably greater degree of wound healing after 4 weeks ( $P=0.0001$ ).

## CONCLUSION

The use of sucralfate or GTN as adjuvant treatment following haemorrhoidectomy operation

was associated with better outcome regarding the postoperative pain, time of wound healing and the duration to resume normal daily activities.

GTN usage was linked to better pain control, while sucralfate was associated with better wound healing and return to normal daily activity (Fig. 1).

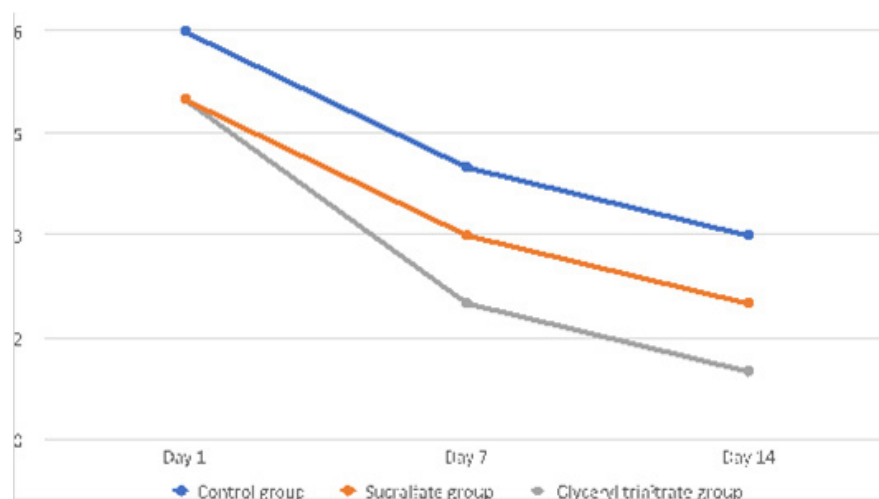


Fig. 1: Visual analogue scale of pain (VAS score) in the three study groups along the follow-up.

## CONFLICT OF INTEREST

There are no conflicts of interest.

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