

COMPARISON OF THE EFFICACY OF 0.2% TOPICAL GLYCERYL TRINITRATE VERSUS PLACEBO IN PAIN MANAGEMENT IN PATIENTS UNDERGOING MILLIGAN-MORGAN HEMORRHOIDECTOMY AT TERTIARY CARE HOSPITAL, KARACHI

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Keywords

The study used glyceryl trinitrate and hemorrhoidectomy with wound pain management as variables along with Milligan-Morgan methods and postoperative care through a randomized controlled trial.

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Abstract

Objective: The research examines whether 0.2% topical glyceryl trinitrate (GTN) works better than placebo for avoiding postoperative pain and infection in patients who receive Milligan-Morgan hemorrhoidectomy at a tertiary care hospital.

Study Design: Randomized Controlled Trial. Place and Duration of Study: A six months study took place at the Department of Surgery within Jinnah Postgraduate Medical Centre (JPMC) Karachi after receiving CPSP approval.

Methodology: A total of 60 patients who fit the criteria of Grade III hemorrhoids with an ASA I or II rating between 20 and 70 years old received random distribution through a sealed opaque envelope technique into two groups. The research subjects receiving 0.2% GTN ointment followed by placebo treatment thrice daily for twelve consecutive days after surgery made up the two study groups. Two weeks following surgery Healthcare professionals examined patients for post operative pain and infection by clinical assessment and bacteriological culture testing. The research analysis occurred through SPSS version 20. Chi-square analysis served as the statistical method for determination of significance where p-values below 0.05 became significant.

Results: Postoperative pain and infection occurred in 4 patients of the GTN group (13.3%) but affected 12 patients of the placebo group (40%) ($p < 0.05$). The treatment effect from GTN maintained similar results regardless of patient characteristics related to diabetes, hypertension, obesity or past smoking behavior. The only Side Effects found in this study were brief temporary headaches which patients using GTN experienced.

Conclusion: Doctors should consider using topical 0.2% glyceryl trinitrate because it successfully reduces postoperative pain and infections after performing Milligan-Morgan hemorrhoidectomies. The application of GTN stands as a safe achievement-enhancing practical secondary therapy suitable for improving surgical outcomes following hemorrhoid surgery.

INTRODUCTION

Healthcare professionals consider Grade III or IV hemorrhoids to need surgical intervention due to their prevalence affecting 4.4% of people around the world¹. Documented research shows that the Milligan-Morgan hemorrhoidectomy is considered the primary procedure for treating advanced cases. The primary clinical challenges that come from postoperative complications such as post operative pain and infection lead to recovery delays and degrade patients' quality of life^{2,3}. Standard wound care is difficult to perform because the surgical site is situated near the anal canal. Kinds of continuous wound infection alongside the challenges of applying protective dressings impair the healing process to the wound⁴. Improving wound healing and minimizing postoperative pain represent essential goals for better surgical success stories⁵. Glyceryl trinitrate (GTN) ointment shows its ability as a nitric oxide donor to expand blood vessels thereby boosting anodermal blood flow while decreasing the tone of the internal anal sphincter⁶. The treatment actions promote both pain management and create suitable conditions for tissue restoration in wounds⁷. Research shows GTN ointment as an effective treatment for post-hemorrhoidectomy pain since it minimizes the need for pain medication and speeds up recovery times compared to placebo treatments. Recent scientific articles confirm this data^{8,9}. This local circulation-modulating ability might assist in bacterial prevention and pain reduction processes as reported in research literature¹⁰. Studies have not provided enough evidence regarding GTN's ability to prevent postoperative pain¹¹. Results from a controlled trial run by Asif et al. showed that GTN solution at 0.2% concentration decreased pain and infection frequency to 14.6% in comparison to placebo treatment which caused infection in 54.6% of cases¹². More high-quality research evidence needs to emerge before general clinical application can be supported. A research investigation will determine whether 0.2% topical GTN shows equal or better effectiveness than placebo in pain prevention after performing Milligan-Morgan hemorrhoidectomy surgery. This research has the potential to identify a basic procedure delivering economic outcomes which decreases complications which will enhance

patient results and decrease medical expenses while strengthening colorectal surgical care processes.

METHODOLOGY

The randomized controlled research executed at Jinnah Postgraduate Medical Centre (JPMC) Karachi Department of Surgery received ethical clearance from the Institutional Review Board and College of Physicians and Surgeons Pakistan (CPSP) during six-months of data collection. The researchers included sixty patients who were undergoing Milligan-Morgan hemorrhoidectomy through consecutive non-probability sampling. Patients between 20 to 70 years of age with American Society of Anesthesiologists physical status I or II and diagnosed with Grade III hemorrhoids composed the participant group. Hypersensitivity to glyceryl trinitrate as well as severe hypotension, significant cardiac conditions, bleeding disorders, immunosuppressive states or anticoagulant therapy disqualified patients from participation in the study. This exclusion also included pregnant or breastfeeding women and individuals with serious difficulties affecting their anus. The researchers gained written consent from patients before randomly placing them into two study groups known as Group A and Group B through a method involving sealed opaque envelopes. The surgical procedure was conducted with general anesthesia as the participants received elective Milligan-Morgan hemorrhoidectomy. The participants of Group A needed to apply 0.2% topical glyceryl trinitrate ointment three times daily for twelve days after surgery whereas Group B received a placebo ointment with a similar appearance requiring similar instructions. Patients received instruction on right application methods as well as guidance about perianal hygiene which included using warm sitz baths. The two-week postoperative assessment took place in the outpatient department for patients undergoing the surgical procedures. The definition of wound infection included body temperature remaining above 37.5°C and the presence of both purulent wound discharge and positive microbial culture from the surgical site as well as one or more clinical signs. A systematic recording of patient demographic data including age, gender, ASA classification and diabetes mellitus status with active

hypertension and obesity along with smoking habits allowed assessment of effect modification potential between groups. Analysis of the data occurred through the SPSS version 20.0. Data analysis employed mean $\pm$ standard deviation for age and duration of surgery variables yet categorical variables such as gender and each combination of ASA class and comorbidities and presence and absence of wound infection were shown through frequencies and percentages. The analytical technique comprised of Chi-square test while using Fisher's exact test when additional analysis was required for determining wound infection differences between groups. A post-stratification Chi-square analysis was used for the study while stratification methods controlled confounding variables when p-value remained below 0.05.

RESULTS

Sixty patients participated in the research which distributed them into two matched groups: Group A received GTN 0.2% ointment and Group B used Placebo ointment. Data presented in Table 1 shows equivalent baseline clinical together with demographic variables for the two tested groups. The participants of Group A averaged 45.2 years in age and Group B participants reached an average age of 44.9 years. Subjects from both groups received an equal distribution of males and females alongside identical patient characteristics for ASA classification and rates of diabetes mellitus and hypertension and smoking history and obesity. Postoperative pain and infection was less frequent during the period when patients received GTN 0.2% ointment. Pain and infections occurred in

13.3% of Group A patients but were discovered in 40% of participants in the placebo group. Statistical analysis determined the superiority of topical GTN as a pain and infection prevention method since its performance reached a significant level ($p < 0.05$). Table 2 contains all identified information. The analysis of patients based on comorbidities demonstrated that the topical application of GTN delivered positive effects to every evaluated subgroup. The GTN group demonstrated an infection and pain rate of 12.5% for diabetic patients but the placebo group saw a rate of 50%. The analysis of hypertensive and obese patients demonstrated the same outcomes as the rest of the groups. Results from Table 3 reveal that GTN maintains its preventing capabilities irrespective of comorbidities in patients. The reported side effects remained low in every treatment group. The GTN treatment group experienced mild headache symptoms in three patients but these symptoms faded on their own without requiring removal from the study. The applied treatment produced no adverse effects in the patients who received it according to the study groups. The research data can be found in Table 4. The conclusion from this randomized controlled trial shows that topical 0.2% glyceryl trinitrate proves more successful than placebo for stopping pain and infections after Milligan-Morgan hemorrhoidectomy. The intervention demonstrated good patient acceptance and achieved positive results in all examined patient subtypes thus creating potential for standard postoperative care usage following hemorrhoid surgical procedures.

Table 1, Baseline Characteristics of Study Population

Variable	GTN (0.2%) Group	Placebo Group
Mean Age (years)	45.2	44.9
Male (%)	60.0	63.3
Female (%)	40.0	36.7
ASA I (%)	66.7	70.0
ASA II (%)	33.3	30.0
Diabetes Mellitus (%)	26.7	30.0
Hypertension (%)	30.0	26.7
Smoking (%)	20.0	23.3
Obesity (%)	33.3	30.0

Table 2. Postoperative Wound Infection Comparison

Group	Total Patients	Wound Infection (n)	Wound Infection (%)	No Infection (n)	No Infection (%)
GTN (0.2%)	30	4	13.3	26	86.7
Placebo	30	12	40.0	18	60.0

Table 3. Stratified Analysis by Comorbidities

Comorbidity	GTN Group Infection Rate (%)	Placebo Group Infection Rate (%)
Diabetes Mellitus	12.5	50.0
Hypertension	11.1	44.4
Obesity	20.0	40.0
Smoker	16.7	42.9

Table 4. Adverse Effects Observed

Adverse Effect	GTN Group (n=30)	Placebo Group (n=30)
Headache	3	0
Local Irritation	0	0
Other	0	0

DISCUSSION

Results from a randomized controlled trial proved that patients applying 0.2% topical glyceryl trinitrate (GTN) experienced lower postoperative pain and infections after Milligan-Morgan hemorrhoidectomy than those using placebo. The GTN group experienced only 13.3% wound infections whereas the placebo group experienced an infection rate of 40%. Science confirms that GTN enhances local perfusion and stabilizes tissue healing responses because it relaxes muscle tissue and dilates blood vessels thus minimizing postoperative complications. This study confirms scientific research which demonstrates that anesthetic drugs with nitric oxide properties show therapeutic potential for anorectal surgeries. Research done by Karanlik et al. revealed that GTN therapy after hemorrhoidectomy led to faster healing times alongside lower pain reports because of enhanced anodermal blood circulation. Previous literature mainly studied GTN's analgesic effects yet this study contributes to mounting proof showing GTN's capability to lower wound infection incidence rates. The research of Asif et al. demonstrated comparable outcomes by showing that GTN generated 14.6% infection among its subjects

while the placebo treatment resulted in 54.6% infection cases. The study establishes these findings within a separate hospital institution and patient demographic. This research investigation demonstrated success across various clinical groups thanks to its stratified analytical methodology that showed GTN efficacy in hypertensive and diabetic patient groups. The method which enhances tissue perfusion together with immune cell entry appears effective for patients who present with microvascular dysfunction. The positive safety findings indicate GTN has demonstrated suitability for postoperative care because headaches limited to only a few patients. The study findings deliver significant application in clinical practice. Wound infections after hemorrhoidectomy operations become a prime factor behind longer hospital stays and augmented analgesic requirements and delayed patient recovery times. GTN treatments decrease infection risks which leads to improved patient comfort and faster recovery periods and reduced healthcare duties. Treatment with this straight forward topical medicine provides numerous benefits through its limited drug uptake and few unwanted effects when used in outpatient surgical care. The study contains

certain limitations in its design. The limited generalizability results from conducting the research at one medical center together with its small number of subjects. Further studies involving multiple centers should be performed to validate the research findings and evaluate long-term outcomes such as recurrence rates and wound healing duration. Additional evaluation methods involving objective biomarkers of healing and inflammation should be used in future research to improve the assessment methods..

Conclusion:

This study provides compelling evidence that 0.2% topical glyceryl trinitrate is effective in preventing postoperative pain and infections following Milligan-Morgan hemorrhoidectomy. Its routine use as an adjunctive therapy in colorectal surgical practice may offer significant benefits in terms of patient outcomes and postoperative care efficiency.

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