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Original Research Article

To assess the effectiveness of intravenous metronidazole as an analgesic in post hemorrhoidectomy patients

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ABSTRACT

Background: Haemorrhoids are one of the most common ano-rectal diseases for referral to a surgeon. Haemorrhoidectomy one of the most common ano-rectal procedures performed. Complaints pertaining to haemorrhoids are one of the most common afflictions of western civilizations. Although the condition is rarely life threatening the complications of therapy can be.

Aims and Objectives: Prospective comparative interventional study to assess the effectiveness of intravenous metronidazole as an analgesic in post hemorrhoidectomy patients was conducted from 1st March 2022 to 31st August 2023 in the department of General Surgery birsa munda government Medical College & Hospital, Shahdol (M.P.).

Materials and Methods: This study included adult patients (over 18 years old) who presented to the surgical outpatient department with rectal bleeding and were diagnosed with grade 3 or 4 hemorrhoids. Patients below 18 years of age, pregnancy, Lactation, other ano-rectal disease, previous ano-rectal disease, hypersensitivity to metronidazole, Coagulation disorder, Anaesthetically unfit patients excluded.

Results: The mean VAS score between Group A (Metronidazole group) and Group B (placebo group) was 1.76 and 0.49 immediately after the procedure, 3.52 and 0.59 after 6 hours of surgery, 3.16 and 0.77 after 12 hours of surgery, 3.24 and 0.63 after 1 day of surgery and 2.72 and 0.62 after 3 days of procedure, which were all statistically significant when compared.

Conclusion: Intravenous Metronidazole has a favourable effect in pain control in the post hemorrhoidectomy patients in addition to antimicrobial effect. Patient satisfaction rates and return back to normal activity seems to be better with Intravenous metronidazole. With the above mentioned observations, we inferred that metronidazole showed a better pain control when compare to the placebo group.

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1. Introduction

Haemorrhoids are one of the most common ano-rectal diseases for referral to a surgeon. Haemorrhoidectomy one of the most common ano-rectal procedures performed.

Complaints pertaining to haemorrhoids are one of the most common afflictions of western civilizations. Although the condition is rarely life threatening the complications of

therapy can be.¹

The Indian Susruta Samhita, an ancient Sanskrit text dated between the fourth and fifth century AD, described treatment procedures comparable to those in the Hippocratic treatise, but with advancement in surgical procedures and emphasis on wound cleanliness.²

For haemorrhoids of grade III and IV the effective treatment even today remains to be hemorrhoidectomy. Milligan Morgan described conventional open hemorrhoidectomy in 1937 and Ferguson in 1959 described

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closed hemorrhoidectomy. Owing to low expense and technical ease open hemorrhoidectomy is the procedure of choice, even though newer modalities have come in to play.^{3,4}

Hemorrhoids not responding to non-operative management, recurrent after banding and sclerotherapy and 3rd and 4th degree are treated surgically by hemorrhoidectomy, stapler hemorrhoidopexy. But it is associated with post-operative complications such as pain, bleeding, non-healing wound, incontinence, stenosis and urinary retention. Pain is the major post-operative complaint and is attributed to surgical wound in sensitive anoderm, edema, spasm and infection. Various remedies have been suggested to alleviate the post-operative pain like GTN 0.2%, topical NSAIDS, Ca channel blockers and metronidazole. Studies show that metronidazole significantly reduces the post-operative pain and improves the wound healing compared to placebo.¹

Many different interventions have been described which attempt to reduce post operative pain: these include infiltration of local anaesthetic, pre operative laxatives and administration of nitro-glycerine ointment with varying degrees of success. Perhaps the most widely used pharmacological intervention following haemorrhoidectomy is the use of prophylactic antibiotics, particularly metronidazole, administered either systemically or topically. Metronidazole offers good protection from anaerobic, enteric commensals that could infect the wounds and, in addition, potentially promotes wound healing as a consequence of its antioxidant effects. Whilst metronidazole is used to reduce post-operative pain, there is a lack of consensus as to its effectiveness with studies of variable quality and design demonstrating conflicting results.⁵

The investigators in this study evaluated the effect of intravenous administration of metronidazole versus placebo with intravenous paracetamol as a base analgesic in pain control after hemorrhoidectomy.

2. Aims and Objectives

Prospective comparative interventional study to assess the effectiveness of intravenous metronidazole as an analgesic in post hemorrhoidectomy patients was conducted from 1st March 2020 to 31st August 2023 in the department of General Surgery Birsa Munda government Medical College & Hospital, Shahdol (M.P).

3. Materials and Methods

3.1. Inclusion criterion

All the patients attending surgery outpatient department with the complaints bleeding per rectum and diagnosed to have hemorrhoidal disease grade 3 and grade 4 hemorrhoid patients above 18 years of age.

3.2. Exclusion criterion

1. Patients below 18 years of age
2. Pregnancy
3. Lactation
4. Other anorectal disease
5. Previous anorectal disease
6. Hypersensitivity to metronidazole.
7. Coagulation disorder
8. Anaesthetically unfit patients.

Prospective comparative controlled interventional study to assess the effectiveness of intravenous metronidazole as an analgesic in post hemorrhoidectomy patients composed of 50 patients of either sex, who underwent elective hemorrhoidectomy for hemorrhoidal disease grade 3 and grade 4 after anaesthetic clearance. We collected demographic and clinical variables. Informed consent was taken from every participant. The surgery performed was Modified Milligan Morgan open hemorrhoidectomy in which Transfixation ligature of vicryl (2-0) is applied to the pedicle, the pile is excised well distal to the ligature and after ensuring hemostasis, the ligature is cut long. They were assigned to receive intravenous metronidazole 500mg thrice a day in a study group and placebo in control group. In study group 25 patients received intravenous metronidazole 3 times for day for 3 days. In control group 25 patients received placebo 3 times for day for 3 days. Both the groups received single dose of intravenous paracetamol 1gm after 6 hours of surgery as a base analgesic. Postoperative pain was assessed by visual analog scale at 6hours, 12hours, 1 and 3 days. Complication rates such as bleeding, abscess, relapse, urinary retention and recurrence were assessed.

Visual analogue scale (VAS) is a measurement instrument that is used to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. It is often used in epidemiologic and clinical research to measure the intensity or frequency of various symptoms. For example, the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective, this spectrum appears continuous ± their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised.

3.3. Purpose

The pain VAS is a unidimensional measure of pain intensity, which has been widely used in diverse adult populations.

3.4. Statistical analysis

Data was entered in Microsoft excel and analysis was done using SPSS version 23.0. Categorical variables were

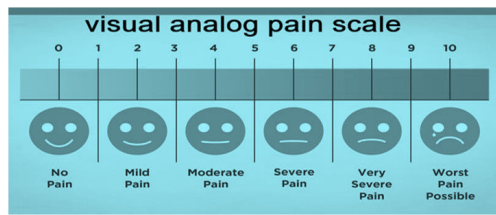


Figure 1:

expressed in frequency and percentage and continuous variables were expressed in mean and standard deviation. To test the significance between groups independent t test were used and chi square test was used to find the association between categorical variables. P value less than 0.05 were considered to be statistically significant.

4. Observations and Results

The present study was done to demonstrate the efficacy of metronidazole in the pain control post hemorrhoidectomy with paracetamol as a base analgesic.

The demographic and perioperative profile of the patients were comparable in both the group of patients were comparable. (Tables 1, 2 and 3)

As evident from the Table 4, Mean VAS score and SD of Group A appears to be statistically significant than Group B with a p value <0.0001.

The pain was assessed using visual analogue scale (VAS) immediately after the surgery, after 6 hours, after 12 hours, at day 1 and at day 3. The mean VAS score between Group A (Metronidazole group) and Group B (placebo group) was 1.76 and 0.49 immediately after the procedure, 3.52 and 0.59 after 6 hours of surgery, 3.16 and 0.77 after 12 hours of surgery, 3.24 and 0.63 after 1 day of surgery and 2.72 and 0.62 after 3 days of procedure, which were all statistically significant when compared. With the above mentioned observations, we inferred that metronidazole showed a better pain control when compare to the placebo group. (Table 4)

In this study our secondary objective was to evaluate the complication rates between the group A and group B. The frequency distribution of bleeding was 8.00% and 12.00%, the frequency distribution was abscess was 0.00% and 8.00%, the frequency distribution of urinary retention was 4.00% and 8.00%, the frequency distribution of recurrence was 0.00% and 4.00% respectively, which were all statistically insignificant except for prolapse when compared. (Table 5)

The mean score of return to normal activity between group A and group B were 8.6 and 2.17 respectively, which were all statistically significant when compared. With the above mentioned observations, we inferred that return to normal activity (in days) were better in the group A compare to group B. (Table 6)

5. Discussion

The pain control mechanism after hemorrhoidectomy seems to be still a mystery even after introduction of several analgesic in this modern era, leading to the sphincter spasm, which eventually leading to the delay in recovery of the patient.

According to the study conducted by Ray-Offor E et al. Over half of the population affected was above the age of 50 years with male sex predominance. A literature search showed paucity of literature on epidemiology of hemorrhoids in Africa, but interventional studies from Nigeria reported a peak incidence in the late and early third and fourth decades respectively with a male predominance. A national study in a Caucasian population recorded hemorrhoids most commonly between the ages of 45–65 years affecting 5% of the population with no sex dominance. In general, it is estimated that 50% of the people older than 50 years have hemorrhoids symptoms at least for a period.⁵ In our study findings showed a peak of incidence in the age group between 30-50yrs of around 54% of the people involved in this study with male predominance as respect to sex distribution In a study done by Erica B Sneider et al. have shown that symptomatic hemorrhoids are more common in Caucasians and those of higher socioeconomic status—speculated to be a result of a low fiber diet—although equally affecting men and women.⁶ As compared to our study even our study was done in a rural population of India and our participants mostly belong to the lower and middle socio economic status.

To explore factors associated with hemorrhoids, we analyzed data from colonoscopy reports that were collected as part of a chemoprevention study of colorectal adenomas. To learn more about potential risk factors for hemorrhoids, we considered multiple possible risk factors including bowel habits, diet, tobacco use, NSAID use, aspirin use, physical activity or lack thereof, body mass index, and obstetrical history. We hypothesized that a low fiber diet, constipation, straining with defecation, diarrhea, sedentary behavior, obesity, multigravida and live births would be associated with an increased risk of hemorrhoids on colonoscopy.^{7,8} This finding is in accordance with our study that patient's history revealed consumption of low fibre diet, constipation and straining and the affected patients were in the age group of 30-50yrs of age.

The results of the present study is in accordance with those of Syed Tatheer Abbas et al., who compared the topical metronidazole with the oral metronidazole for seven days. Patient's post hemorrhoidectomy was measured using VAS scale. The results showed that topical metronidazole significantly reduces pain in post hemorrhoidectomy as compared to oral metronidazole. It should, however be noted that our study used intravenous metronidazole as compared to the placebo group with paracetamol as a base analgesic. Another striking inference was that the

Table 1: Age distribution

Age Group	Drug Given				Chi square	P value
	IV paracetamol+ IV metronidazole		IV paracetamol+ placebo			
	Frequency	%	Frequency	%		
22-30 yrs	4	16.00%	6	24.00%	3.84	0.427
31-40 yrs	8	32.00%	8	32.00%		
41-50 yrs	5	20.00%	7	28.00%		
51-60 yrs	5	20.00%	4	16.00%		
61-70 yrs	3	12.00%	0	0.00%		

Table 2: Sex distribution

Sex	Drug Given				Chi square	P value
	IV paracetamol + IV metronidazole		IV paracetamol + placebo			
	Frequency	%	Frequency	%		
F	6	24.00%	11	44.00%	2.23	0.136
M	19	76.00%	14	56.00%		

Table 3: Associated comorbidities and surgery done

		Drug Given				Chi square	P value
		IV paracetamol + IV metronidazole		IV paracetamol + placebo			
		Frequency	%	Frequency	%		
Co-morbidities	No	21	84.00%	22	88.00%	0.17	0.684
	Yes	4	16.00%	3	12.00%		
Surgery Done	Open haemorrhoidectomy	25	100.00%	25	100.00%	0	0.010

Table 4: VAS score at various time interval

VAS Score	IV paracetamol+ IV metronidazole (Group A)					IV paracetamol+ Placebo (Group B)					t test	P value
	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max		
Immediate after procedure	25	1.76	0.97	1	5	8.08	0.49	7	9	25	29.05	<0.0001
After 6hrs	25	3.52	0.59	3	5	8.52	0.59	8	10	25	30.17	<0.0001
After 12hrs	25	3.16	0.75	2	5	8.48	0.77	7	10	25	24.80	<0.0001
After day 1	25	3.24	0.66	2	5	8.32	0.63	7	9	25	27.82	<0.0001
After day 3	25	2.72	0.68	2	4	8.16	0.62	7	9	25	29.50	<0.0001

Table 5: Complications

	Complications	Drug Given				Chi square	P value
		IV paracetamol+ IV metronidazole		IV paracetamol+ placebo			
		Frequency	%	Frequency	%		
Bleeding	No	23	92.00%	22	88.00%	0.22	0.637
	Yes	2	8.00%	3	12.00%		
Abscess	No	25	100.00%	23	92.00%	2.08	0.149
	Yes	0	0.00%	2	8.00%		
Prolapse	No	24	96.00%	24	96.00%	0	0.010
	Yes	1	4.00%	1	4.00%		
Urinary retention	No	24	96.00%	23	92.00%	0.35	0.552
	Yes	1	4.00%	2	8.00%		
Recurrence	No	25	100.00%	24	96.00%	1.02	0.312
	Yes	0	0.00%	1	4.00%		

Table 6: Return to normal activity and patients satisfaction score

Variable	IV paracetamol + IV metronidazole					IV paracetamol + placebo					t test	P value
	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max		
Return to normal activity (Days)	25	8.6	0.65	8	10	12.76	2.17	8	16	25	9.20	<0.0001
Patient's satisfaction Score	25	4.6	0.50	4	5	1.44	0.51	1	2	25	22.20	<0.0001

complication rates, return to normal activity in days and patient's satisfaction was seemed to be better in metronidazole group as compared with the placebo group.⁹

In a study by B. D. Wilkie et al. conducted a double controlled trial. The main aim was to examine the efficacy of oral metronidazole in reducing posthaemorrhoidectomy pain versus placebo over 21 days, measured on a 10-point Likert scale. The study concluded that there were no significant differences between groups with regards to age, gender, smoking status, self-reported general health or quality of life, haemorrhoid-related pain, haemorrhoid-related impact on quality of life, reported satisfaction with surgery, experience of surgery, median overall pain score or likelihood of recommending surgery to others. The data do not support the hypothesis that postoperative metronidazole has a clinically meaningful effect on posthaemorrhoidectomy pain. Our study differs from this study from the aspect of route of administration and use of paracetamol as a base analgesic and our study has a positive correlation towards metronidazole having an analgesic effect.¹⁰

Moreover, in a another study by Weisi Xia et al. (2018) conducted a systematic review of the literature was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Randomized controlled trials (RCTs) published in PubMed/Medline, EMBASE, CENTRAL and CINAHL, from inception to December 2016 were retrieved. The primary outcome investigated was post-operative pain reported as visual analogue score (VAS). Secondary outcomes were analgesia use, complications and time to return to normal activity. Meta-analysis was performed using Review Manager version 5.3 software. Nine randomized controlled trials including 523 patients were included in the final analysis. Five studies used oral administration and four used topical. Meta-analysis showed that post-operative VAS of patients receiving metronidazole by either route was significantly less than those in comparison groups. VAS means decreased at all the time points for both oral and topical metronidazole. Topical and oral routes of administration were not compared in any study. Both topical and oral metronidazole reduce post-operative pain without an increase in complication rates and result in an earlier return to normal activity. This study results were also in accordance with our study results the only difference was in route of administration.¹¹

In a clinical trial conducted by Sergio Solorio-López in 2015 in adult patients who underwent elective hemorrhoidectomy for grade III/IV hemorrhoids. Patients were assigned to receive metronidazole (500 mg q8 h orally; study group, SG) or placebo (control group, CG) for 7 days after surgery. Pain was assessed using a visual analog scale after surgery. Analgesic administration (time and use of analgesics) and resumption of daily life activities were also assessed. Forty-four patients were included, 22 in each group. Postoperative pain differed significantly between the SG and CG. The study concluded that oral administration of metronidazole is effective in pain management after hemorrhoidectomy. This study differs from our study in the route of administration of metronidazole and the results are in accordance with our results.¹²

In a another study conducted by N J R Lyons et al. a meta-analysis of all randomized controlled trials (RCTs) that investigated the use of metronidazole for pain relief after haemorrhoidectomy. A systematic review was undertaken in accordance with the PRISMA protocol using the MESH headings 'haemorrhoidectomy', 'hemorrhoidectomy', 'hemorrhoidectomy', 'haemorrhoid', 'metronidazole', 'Flagyl®', 'antibiotic' and 'pain'. The search returned 421 articles of which eight were RCTs suitable for inclusion in the review with a total population of 437 patients. The outcomes of interest were postoperative pain intensity on days 1, 2 and 7 and on first defaecation as measured using a visual analogue scale. Limitations of this study include variation in the grade of haemorrhoids treated and variability in the quality of included studies. The study concluded that metronidazole is a cheap, safe and effective intervention for reducing postoperative pain following conventional haemorrhoidectomy. This study has got similar results with our study except the route of administration has not been mentioned in this review.¹³

Congruent with our study, Shahram Ala et al. (2008) conducted a double-blind, randomized trial was conducted to compare posthemorrhoidectomy pain with use of topical metronidazole (10 percent) vs. placebo carrier, applied to surgical site. Forty-seven patients were randomly allocated to receive metronidazole (n=25) or placebo (n=22). Pain was assessed using a visual analog scale preoperatively and on postoperative hours 6 and 12 and at days 1, 2, 7, and 14. The use of narcotic, additional analgesics, and complications were recorded. (Pain scores were calculated and compared with baseline values and control group (t

test, SPSS ver. 10). Patients in the topical metronidazole group had significantly less postoperative pain than those in the placebo group up to day 14 ($P \leq 0.04$). There was no significant difference in narcotic analgesic requirements between groups, except on hour 12 ($P < 0.05$). In the metronidazole group, after-defecation pain was ranked significantly lower at day 2 ($P = 0.016$) and patients required fewer additional analgesics postoperatively on days 2 and 7 ($P \leq 0.04$). These findings indicate that topical 10 percent metronidazole significantly reduce posthemorrhoidectomy discomfort, and postoperative defecation pain is reduced compared with that of the placebo control group. These findings proved metronidazole has an analgesic effect as compared to placebo.¹⁴

Topical metronidazole has comparative results as compared to Intravenous metronidazole, it can also be considered as an alternative option owing to its ease of use.¹⁵ But still intravenous metronidazole can be preferred in patients who are uncomfortable with the topical application of metronidazole. It also reduces the use of additional antibiotic in post hemorrhoidectomy patients as metronidazole serves both the purpose of analgesia and antibiotic.

From these findings, it can be stated that intravenous metronidazole was better in pain control in post hemorrhoidectomy patients when compared with placebo. The complication rates, return to normal activity and patient satisfaction rates were better in the metronidazole group. Owing to its analgesic action patient's overall morbidity were low.

6. Conclusion

The conclusion of this study is as follows:

1. Intravenous Metronidazole has a favourable effect in pain control in the post hemorrhoidectomy patients in addition to antimicrobial effect.
2. Patient satisfaction rates and return back to normal activity seems to be better with Intravenous metronidazole.

7. Limitations of our Study

1. This study only included patients undergoing open hemorrhoidectomy. It did not include patients undergoing other hemorrhoidal surgeries.
2. A sample size of 50 cannot be projected over a populations of millions.
3. Further, studies with larger sample size and more clinical trails can aid in its mainstream clinical implementation.

8. Sources of Funding

None.

9. Conflict of Interest

None.

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