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Brief Report

A Randomized Clinical Trial on the Effect of Oral Metronidazole on Wound Healing and Pain after Anal Sphincterotomy and Fissurectomy

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Chronic anal fissure is one of the most common causes of anal pain and surgical therapy is the treatment of choice. There is scarce information regarding the prophylactic effects of oral metronidazole on postoperative complications of anal fissure. The objective of this study was to determine the effects of metronidazole as a prophylactic measure for postoperative anal fissure complications. In a numerical randomized clinical trial, 311 patients with anal fissure were randomized into two groups. The group which received prophylactic oral metronidazole was compared to the control group regarding wound dehiscence, bleeding, discharge, and pain after one and two weeks of operation. One hundred fifty-six patients with mean±SD age of 36±7.3 years were in metronidazole group and 155 patients with mean±SD age of 38±7.1 years were in the control group. Regarding the studied outcome variables, the patients in both groups did not have any significant differences after one and two weeks. Our results did not support the prophylactic use of metronidazole in reducing postsurgical complications after internal sphincterotomy of anal fissure.

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Introduction

Anal fissure is one of the most common causes of anal pain and sphincterotomy is the treatments of choice for patients with chronic anal fissure.[1,2] Conservative therapy may be applied for chronic anal fissure but is less effective than surgery [30 – 60% vs. 90 – 97%].[3–5] In a recent study, chemical sphincterotomy with botulinum toxin and glycerol trinitrate was reported to have advantages over surgical treatment[6] but in nonresponders, surgical therapy is still the treatment of choice.[7] Postsurgical secondary infection may complicate wound healing and cause more pain.[8,9] Prophylactic metronidazole administration for pain relief and improvement of wound healing in postsurgical hemorrhoidectomy has been reported[8–10] but prophylactic effects of metronidazole on postsurgical complications of anal fissure have not been reported in literature.

This study was conducted to determine the effects of metronidazole on postoperative complications of sphincterotomy and fissurectomy for anal fissure.

Patients and Methods

In a numerical randomized controlled clinical trial, 325 patients with chronic anal pain lasted for six to nine months, and confirmed anal fissure, after taking history and physical examination, were studied between April 2003 and March 2005. Fourteen patients were excluded from the study due to concomitant presence of abscess, malignant lesions, or hemorrhoidal disease with anal fissure. The remaining 311 patients were randomized into two groups of metronidazole (n=156) who received

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prophylactic metronidazole, (4 – 8 mg/kg/dose 500 mg TID for one week) after open lateral sphincterotomy and fissurectomy; and control group (n=155) who did not receive any antibiotics after the same operation. Based on patients desire, operations were performed under general or local anesthesia. In patients who received local anesthesia, after preparation of the perianal area in a prone position, 10 mL of 2% lidocaine and epinephrine (1/100,000 concentration) plus 2% Marcaine were injected around the anus and in internal sphincter area. Those who underwent general anesthesia received isoflurane, penthothal and morphine in a standard manner.

All patients were observed in the recovery room for six to eight hours and vital signs, any bleeding from the site of operation were checked. They were discharged in a good condition from hospital with mefenamic acid (one cap q6h for five days), stool softener and advise to use sitz bath (three times a day for five days) and a contact telephone number for advice or assistance for any problem. During the study, there was no need for any extra-antibiotics in the metronidazole group and similarly we did not need to start antibiotic in the control group due to any emerging infection. All patients were operated in a same way by one surgeon during the study and a questioner for recording the amount of bleeding; severity of pain, bowel habits, any pussy discharge and duration of symptoms were completed by a resident of surgery who was blind to the groups the patients belong to. Physical findings like presence of tag, ulcer and fissure were also recorded in the sheet. No prophylactic antibiotic was used by the patients before the start of the study.

All patients were visited after one and two weeks post-operation and were examined for any signs of bleeding, pussy discharge, and severity of pain. The severity of pain was classified into four level: grade 1, without any significant pain; grade 2, with tolerable pain receiving no medication; grade 3, with severe pain subsiding with medication; and grade 4 with intolerable pain. All patients gave their written consent for participating in the study. This survey was approved by the Ethics Committee of Shiraz University of Medical Sciences. The data were analyzed using Kruskal-Wallis (for comparing pain in the two groups before and after operation), and Fisher Exact tests (for comparing pre- and post-operation complication in the two groups). *P* values <0.05 were considered statistically significant.

Results

Ninety patients in the treatment group and 84 in the control group were females; their mean±SD age was 36±7.3 and 38±7.1 years, respectively. Type of anesthesia in both group were similar also. Our results showed that the frequency of postoperative bleeding, discharge and suture rupture were identical in both groups. Wound infection and pain score in follow-up visits did also not significantly different between the two groups (Table 1). Eighty-nine percent of patients had grade 1 (no significant pain),

Table 1. Comparing the postsurgical complication rates between the two groups one and two weeks after the operation.

Parameters		Treatment group *n*=156	Control group *n*=155	*P* value*
Bleeding				
	1 week	7 (4.5)	7 (4.5)	0.6
	2 weeks	2 (1.3)	2 (1.3)	0.6
Wound discharge				
	1 week	24 (15.4)	27 (17.4)	0.3
	2 weeks	3 (1.9)	7 (4.5)	0.2
Suture				
	1 week	7 (4.5)	10 (6.5)	0.3
	2 weeks	2 (1.3)	1 (0.6)	0.5
Wound dehiscence				
	1 week	2 (1.3)	7 (4.5)	0.08
	2 weeks	2 (1.3)	1 (0.6)	0.5
Pain				
	1 week	25 (16)	27 (17.4)	0.4
	2 weeks	6 (3.8)	6 (3.9)	0.6

*Fisher exact test

6.5% had grade 2 (tolerate pain without medication), 4.5% grade 3 (severe pain, subsiding with medication) and no one had grade 4 (intolerable pain) pain; the respective frequencies for the control group were 87.7%, 7.8%, 4.5%, and 0.0%.

Discussion

Anal fissure is a common condition causing severe pain during defecation.[6] Internal sphincterotomy still remains the treatment of choice in complicated chronic anal fissures. In a recent study, pain relief after open hemorrhoidectomy was reported by administration of both oral and topical metronidazole.[8] This can be justified by prevention of secondary infection few days after hemorrhoidectomy. Our study showed that the postoperative infection rate in the control group was similar to the metronidazole group and thus did not support any superior effects for metronidazole after fissurectomy. In contrary to previous reports of metronidazole effects on wound healing after hemorrhoidectomy,[9] in this study, wound healing in metronidazole group was similar to the control group; the postoperative complication rates were not different between the two groups too.

This study does not support the prophylactic use of metronidazole in reducing postoperative complications after internal sphincterotomy and fissurectomy.

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