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Original Article

Vaseline zinc oxide and finger anal dilatation for the treatment of anal fissure: a comparison cohort study

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Abstract

Introduction: Anal fissure is one of the most painful diseases of the anus region. Diverse approaches for managing this condition have been examined, however, no unanimous approach has been achieved. The current study aimed to evaluate the efficacy of topical triamcinolone NN plus Vaseline zinc oxide and finger dilation versus triamcinolone NN alone to manage anal fissures.

Method: The current comparative cohort study has been conducted on 90 patients suffering from anal fissure. The group of topical Vaseline zinc oxide plus finger dilation (n=45) was prescribed to administer the blend of triamcinolone NN (1 cc) and Vaseline zinc oxide (2 cc) topically three times a day and to enter their little finger into the anus 18-20 times per day. Since the second week, they used the index finger. Topical triamcinolone NN only was administered by another group (n=45). The patients were weekly followed for three weeks and assessed pain severity using the Visual Analog Scale and bleeding incidence. The obtained data was analyzed by SPSS software (version 23). The Chi-square test, student t-test, and repeated measured ANOVA were used for data analysis. The P-value of less than 0.05 was defined as the level of significance.

Results: Pain intensity (P =0.057) and bleeding (P =0.75) were similar in both groups at baseline, while the cases experienced significantly lower frequencies of bleeding in all follow-up visits (P <0.001). Pain severity was reduced significantly in cases within three weeks after the interventions (P-value<0.001) as well as the controls (P =0.021); however, the presented scores by the controls were significantly higher in all follow-up visits (P <0.001).

Conclusion: According to the findings of this study, the administration of topical Vaseline zinc oxide and daily anal sphincter self-massage can effectively lead to anal fissure symptoms control; however, further studies with a more prolonged period of follow-up are strongly recommended.

Keywords: Anal Canal, Anus Fissure, Zinc Oxide, Dilatation, Triamcinolone

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Introduction

One of the most common pathologies of the anorectal region is the anal fissure (1). Defined as the presence of a rupture in the mucosa of the anus that usually extends to the muscular circular ring and internal anal sphincter. The rupture is mostly located posterior to the midline of the anoderm below the dentate line (2).

According to the course of time, anal fissure is divided into acute (less than six weeks) and chronic (more than six weeks) phases (3).

The etiology of this condition has not been well-elucidated; however, chronic constipation seems to play the most substantial role. The increased pressure of the anal sphincter during defecation or even at rest is assumed as the underlying condition leading to anal fissure advent (3, 4).

Accordingly, a vicious circle would emerge in which the mucosa does not recover appropriately, and due to the pain, the patient postpones defecation by which constipation gets deteriorated, and this process continues to exacerbate.

Anal fissure causes severe painful defecation and anal bleeding that negatively affects the quality of life by distressing the patient following the sensation of defecation (5, 6).

According to the pathological process, numerous approaches to decrease sphincter tone and prevent constipation have been examined (7).

The most popular medical treatments recommended by physicians include a high-fiber diet, hot water baths, use of laxative drugs to prevent constipation, as well as other agents such as nitroglycerin, botulinum toxin, corticosteroids, nifedipine, and diltiazem to break down the exaggerated tone of the sphincter and relax it (8).

In recent years, surgical treatment of anal fissure, open sphincterotomy, has yielded comparable results; however, its potential complications such as hematoma, external sphincter damage, and incontinences have outweighed conservative medical management over the surgical approaches (9-11).

Recent investigations have revealed that anal dilation using a finger can acceptably reduce the pain and heal the fissure (12). Besides, the topical administration of Vaseline zinc oxide has been accompanied by favorable outcomes and pain relief (13).

Accordingly, the current study is one of the limited investigations aimed at assessing the efficacy of anal sphincter dilatation using fingers and topical administration of zinc oxide to manage anal fissures.

Materials and Methods

This study is a comparative cohort study on 90 patients suffering from anal fissure. The studied population referred to Amin and Kashani Hospitals affiliated with Isfahan University of Medical Sciences from January 2018 to October 2019. The study proposal has been approved by the Ethics Committee of Isfahan University of Medical Sciences based on code number IR.MUI.MED.REC.1398.395.

The study protocol was presented to the patients; they were reassured regarding the confidentiality of their personal information and signed written consent for participation in the study. Eighteen-to-sixty-five-year-old patients with anal fissured who had fresh wounds and were able to tolerate pain sensation following finger dilation of the anal were included in the study.

The unmet criteria were defined as being a candidate for surgical treatment, being under other conservative medications or using topical corticosteroids within four previous weeks and the presence of skin pathologies, including blister, inflammation, itching, peeling, irritation, bruising, redness or swelling. The study exclusion criteria were over 20% defects in the medical records, failure to continue the medications or participate in the follow-up visits, altering the therapeutic approach, and having diarrhea. Since medical treatments with anal dilations and routine softeners are used to treat the anal fisher.

Patients referred to the clinic with entry criteria were divided into two groups and were followed up. The patients entered the study using the convenience sampling method until achieving

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the desired numbers of the study population. 45 patients receiving treatment with topical Vaseline zinc oxide plus finger dilation were selected as a group and 45 patients receiving treatment with topical topical triamcinolone NN only were selected versus another group. At the first visit, the mechanism of the anal fissure was briefly explained to the patients.

The first group of patients was advised to sit in the warm bath every 4 hours for 10 to 15 minutes. Afterward, they were recommended to wait to relax the sphincter spasm and relieve the pain.

Then, they were prescribed to blend 1 cc of triamcinolone NN (Irandarou, Iran) and 2 cc Vaseline zinc oxide (Minoo, Iran) and rub it on the site of the wound using their fifth finger.

They should repeat this procedure at least 3 times. Besides, they should enter their fifth finger into the anus 18-20 times per day without ointment application.

This process has been done using the fifth finger for the first week. Since the second week onwards, the index finger was administered for anal dilation.

Another group was recommended to use triamcinolone NN only. Furthermore, the patients were suggested to use lactulose (Alborzdarou, Iran) to prevent constipation.

Treatment time was done for three weeks. The patients were visited weekly for three weeks and examined. The primary outcomes of this study were to assess the presence of bleeding and the severity of pain sensation in patients.

Accordingly, they were asked about the incidence of bleeding within the previous week and the severity of pain based on the Visual Analog Scale (VAS). This is a rating means for assessing pain, scoring from zero to ten ranging from no pain to the most severe pain (14).

Other information, including age, gender, and the duration between disorder onset and referral to the physician, was entered into the study checklist. The obtained data was analyzed by SPSS software (SPSS Inc., Chicago, IL, USA) version 23. Descriptive data were presented in mean, standard deviation, percentages, and absolute numbers. The Chi-square test, student t-test, and repeated measured ANOVA were used for data analysis. The P-value of less than 0.05 was defined as the level of significance.

Results

The current study has been conducted on 90 patients suffering from anal fissure that were equally divided into two groups of cases (12 males and 33 females) and the controls (19 males and 26 females). The studied population had a mean age of 36.96±8.35 years old.

The demographic characteristics of the studied groups, including age (P=0.11), the period between symptoms initiation and interventions (P=0.34), were similar Table 1. Also, in case group 12 (26.7%) patients and in control group 19 (42.2%) patients were male, that was not significantly different in two groups (P=0.10). Table 2 and 3 show the frequency of bleeding and the severity of pain in the two assessed groups. Based on this table, the baseline assessments were similar in the studied groups (P >0.05). Further evaluations revealed a significantly lower rate of bleeding and scores of VAS in the patients treated with anal sphincter dilatation using fingers and topical administration of Vaseline zinc oxide plus triamcinolone NN rather than the controls (P<0.05). Both groups revealed significant pain release in the third week's visit (P<0.05).

Table 1. The comparison of the demographic and medical characteristics between the studied groups

Variable	Case group (N=45)	Control group (N=45)	P-value
Age (years), mean±SD	36.12±8.96	37.8±8.82	0.11*
Gender, N(%) Male female	 12 (26.7) 33(73.3)	 19 (42.2) 26(57.8)	0.10**
The period between the symptoms initiation and the interventions (week), mean±SD	4.74±0.68	4.86±1.14	0.34*

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Table 2: The comparison of the Bleeding on the studied population

Variable		Case group (N=45)	Control group (N=45)	P-value*
Bleeding, N (%)	On admission	26(57.8)	33(73.3)	0.75
	Within a week	18(40)	36(80)	<0.001
	Within two weeks	9(20)	35(77.8)	<0.001
	Within three weeks	1(2.2)	38(84.4)	<0.001

* Chi-square test

Table 3: The comparison of the Pain severity on the studied population

Variable		Case group (N=45)	Control group (N=45)	P-value*
Pain severity (VAS), mean±SD	On admission	8.50±0.91	8.96±0.76	0.057
	Within a week	4.88±2.25	8.51±1.23	<0.001
	Within two weeks	2.02±1.91	8.37±1.31	<0.001
	Within three weeks	0.48±0.92	8.26±1.23	<0.001
P-value**		<0.001	0.021	

* independent t test

** repeated measured ANOVA

Discussion

The current study is among the rare ones that tried to explain the efficacy of anal sphincter dilatation using fingers and topical administration of vaseline zinc oxide to control major anal fissure symptoms, bleeding, and pain. As the two groups were similar in terms of demographics, duration of suffering from hemorrhoids, and the baseline severity of the related symptoms, we can attribute the findings to the interventions merely. Our investigation revealed promising outcomes regarding this therapeutic strategy as the patients presented significant improvements compared to the controls.

To the best of our knowledge, the concurrent administration of finger dilation plus vaseline zinc oxide ointment has not been evaluated previously; nevertheless, there are studies assessing each of the strategies separately.

Alsumbouly et al. conducted a study in which they found that the enrichment of topical diltiazem 2% with zinc sulfate 2% and followed their patients for eight weeks and presented significant up to 50% reduction in the probability of surgical intervention among the patients treated with zinc sulfate added to diltiazem compared to diltiazem alone or Vaseline as the placebo (15). Similarly, Soltany and colleagues presented favorable outcomes in response to the medical treatment of anal fissures using zinc oxide compared to the other available conservative approaches (13). The other investigations in this regard presented consistent results; however, some have presented that zinc oxide was as efficacious as the other conservative managements, but lateral sphincterotomy was superior to the medical approaches (16). The hypothesis regarding the administration of topical products containing zinc refers to its antioxidant characteristic that promotes the process of wound healing. Besides, since a long

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time ago, zinc oxide has been used to minimize dermatitis (15).

Gaj et al. were the first group of scientists who developed a non-invasive treatment for anal fissure by dilating the anal sphincter via passive and progressive dilatation of the anal canal. Surprisingly, they achieved up to 90% successful reduction in pain and bleeding. The positive effects of this approach remained in 80% of the patients for the next 12 weeks and had superior outcomes to the regular use of topical nitroglycerine (17). Long-term application of the dilators was the most significant limitation of this approach that led to the advent of another strategy in which anal dilation was done by the index finger. By self-massage of the anal sphincter, a success rate of 80% and the recurrence rate of 5% within six months were achieved. These outcomes were considerably less than the recurrence rate of 56% using dilators (12). The theory about self-dilation of the anal sphincter presents that the passive dilation obtained by the finger not only relaxes the hypertrophied sphincter through the local effects but also produces central negative feedback and leads to the relaxation of the hypercontracted anal sphincter (12).

Anal dilatation by standard-sized dilators and injection therapy with botulinum toxin are reliable, consistent, less traumatic, reproducible, non-operator depended, and cheap intervention for the treatment of anal fissure and has the comparable beneficial effects of sphincterotomy on anal fissure without the need for any incision, thereby minimizing the risk of complications (18, 19).

However, we think that our recommended approach for anal sphincter self-massage is superior to Gaj and colleagues, as by using the small finger in the initial steps and upgrading the size of the finder to dilate the sphincter, the probable negative effect in response to the induced pain may minimize (17).

The small sample size and the short period of following the patients are the most significant limitations of this study. Further investigations with larger sample populations and comparing more various types of topical medications are strongly recommended.

Conclusion

According to the findings of this study, the administration of topical Vaseline zinc oxide and daily anal sphincter self-massage can effectively lead to anal fissure symptoms control; however, further studies with a more extended period of follow-up are strongly recommended.

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Conflict of interest

The authors report no conflict of interest.

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