

■ Research Article

Enhanced healing and pain relief in anal fissure treatment: evaluating the role of triticum vulgare in conjunction with diltiazem cream

Anal fissür tedavisinde artırılmış iyileşme ve ağrı giderme: diltiazem krem ile birlikte triticum vulgarenin rolünün değerlendirilmesi

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Abstract

Aim: Chronic anal fissure (CAF), a painful condition linked to increased sphincter tone, is often treated with calcium channel blockers. This study explored whether adding the wound-healing agent Triticum vulgare improves outcomes for these patients.

Material and Methods: This study compared two groups of anal fissure patients: those treated with topical diltiazem alone versus diltiazem plus Triticum vulgare. We excluded patients under 18, pregnant women, and those with prior treatments. Data on demographics, comorbidities, and 1-month follow-up (bleeding, pain, and wound healing) were collected from hospital records and compared between the groups.

Results: In the study including 91 patients, the median age was determined as 42. 58.2% (n = 53) of the patients were male. 21 patients (23.1%) received a combination therapy of Triticum vulgare plus topical diltiazem, while 70 patients (76.9%) were treated with topical diltiazem alone. At the end of one month, all patients in the case group had complete wound healing, while this rate was 82.9% in the control group (p = 0.042).

Conclusion: When Triticum vulgare treatment was added to topical diltiazem treatment in the treatment of anal fissure, there was a decrease in the patients' bleeding and pain symptoms, but this was not statistically significant. However, wound healing was complete after 1 month in the Triticum vulgare added group and this change was found to be statistically significant. This suggests that anal fissure physiopathology is more than just a crack or wound in the anal region.

Keywords: anal fissure, triticum vulgare, diltiazem

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Öz

Amaç: Kronik anal fissür (KAF), artan sfinkter tonusuyla ilişkili ağrılı bir durum olup genellikle kalsiyum kanal blokerleri ile tedavi edilir. Bu çalışma, yara iyileştirici ajan Triticum vulgare'nin eklenmesinin bu hastalarda sonuçları iyileştirip iyileştirmedini araştırmıştır.

Gereç ve Yöntemler: Bu çalışma, anal fissür hastalarının iki grubunu karşılaştırdı: sadece topikal diltiazem ile tedavi edilenler ve diltiazem artı Triticum vulgare ile tedavi edilenler. 18 yaş altı hastalar, hamile kadınlar ve daha önce başka tedaviler almış hastalar çalışma dışı bırakıldı. Demografik veriler, komorbiditeler ve 1 aylık takip sonuçları (kanama, ağrı ve yara iyileşmesi) hastane kayıtlarından toplanarak gruplar arasında karşılaştırıldı.

Bulgular: Çalışmaya dahil edilen 91 hastada medyan yaş 42 olarak belirlendi. Hastaların %58,2'si (n = 53) erkekti. 21 hasta (%23,1) Triticum vulgare artı topikal diltiazem kombinasyon tedavisi alırken, 70 hasta (%76,9) sadece topikal diltiazem ile tedavi edildi. 1 ayın sonunda, olgu grubundaki tüm hastalarda tam yara iyileşmesi gözlenirken, bu oran kontrol grubunda %82,9 idi (p = 0,042).

Sonuç: Anal fissür tedavisinde topikal diltiazem tedavisine Triticum vulgare tedavisinin eklenmesiyle hastaların kanama ve ağrı semptomlarında azalma oldu ancak bu istatistiksel olarak anlamlı değildi. Ancak, Triticum vulgare eklenen grupta 1 ay sonra yara iyileşmesi tamdı ve bu değişiklik istatistiksel olarak anlamlı bulundu. Bu durum, anal fissür fizyopatolojisinin sadece anal bölgedeki bir çatlaktan veya yaradan daha fazlası olduğunu düşündürmektedir.

Anahtar kelimeler: anal fissür, triticum vulgare, diltiazem

Introduction

Chronic anal fissure (CAF) is a pathology with an unclear etiology that causes pain in the anal region [1]. Although in general medical practice it is thought that it develops as a result of trauma due to constipation, many patients do not have constipation [2]. Manometry and Doppler flowmetry studies show that ischemia occurs secondary to high sphincter pressure and that ischemic ulcer develops accordingly. However, there is not enough data on why the internal anal sphincter tone increases [3, 4]. Although the etiology is not fully elucidated, all treatment options for CAF are aimed at reducing sphincter hypertonia [1]. The gold standard method in treatment remains lateral internal sphincterotomy. However, due to the risk of incontinence, surgical methods are avoided today. Fecal incontinence rates up to 16% are reported [5].

Due to complications, pharmacological methods are preferred today to relax the hypertonia in the sphincter. Nitric oxide donors, calcium channel blockers, and botulinum toxin injection provide reversible relaxations and are used in treatment [6]. Calcium channel blockers are preferred as first-line treatment due to their less side effect profile and more effective treatment [7]. These pharmacological agents are not directly effective in wound healing, but provide treatment by sphincter relaxation and subsequent regression of ischemia, resulting in spontaneous healing of the ulcer tissue [8]. It has been shown that through this physiology, it may be beneficial in the treatment of patients with levator ani syndrome [9].

Triticum vulgare is a product used in wound treatment, known to accelerate wound repair by triggering the proliferation of fibroblast and endothelial cells. This product has been shown to reduce inflammation and may prevent damage secondary to inflammation [10].

This study aimed to retrospectively examine the differences in wound healing and symptom regression between patients using calcium channel blockers in the treatment of anal fissure and patients using Triticum vulgare additionally.

Material and Methods

Patients who were diagnosed with anal fissure for the first time between January 1, 2024 and December 31, 2024 and were treated with topical calcium channel blocker (diltiazem) alone and with Triticum vulgare added were included in this retrospective study. Patients who had previously received other treatments, patients under the age of 18, and pregnant women were excluded from the study. Then, in the same period, patients who were diagnosed with anal fissure for the first time and received only topical calcium channel blocker (diltiazem) treatment were included in the study as a control group. Demographic data, comorbidities, and 1-month follow-up results of all patients were obtained from the hospital data system. A comparison was made between the 2 groups at the 1-month follow-up, based on symptoms such as bleeding, pain, and macroscopic wound healing findings. The study was conducted in accordance with the Declaration of Helsinki with ethical approval (No: 2025/28) from Amasya University Non-Interventional Clinical Research Ethics Committee.

Statistical Analysis

The sample size for this study was determined through power analysis using G-Power 3.1 software, targeting a power ($1-\beta$) of 0.80 and a confidence level of 95%. This calculation indicated that 18 participants per group were required, resulting in a total minimum sample size of 36 participants across both groups. The normality of the data was tested using the Shapiro-Wilk test. Nonparametric tests, specifically the Mann-Whitney U test, were used where appropriate. Descriptive statistics, including medians and interquartile ranges (IQR), were reported. Categorical variables were analyzed with chi-square tests, with results presented as frequencies and percentages. Statistical significance was defined as $p < 0.05$.

Results

A total of 91 patients were enrolled in the study, comprising 53 males (58.2%). The median age was 42 years (interquartile range [IQR], 29–51 years). Two treatment protocols were administered: 21 patients (23.1%) received a combination therapy of *Triticum vulgare* plus topical diltiazem, while 70 patients (76.9%) were treated with topical diltiazem alone (Table 1).

Post-treatment evaluation revealed that bleeding symptoms persisted in only 3 patients (3.3%). Pain levels, assessed using the Visual Analog Scale (VAS), showed a significant reduction, with a median VAS score decreasing from 5 (IQR, 4–7) at baseline (VAS1) to 0 (IQR, 0–2) after treatment (VAS2) (Figures 1,2). Complete healing of anal fissures was observed in 78 patients (86.8%), while 12 patients (13.2%) demonstrated partial healing (Table 2, Figure 3).

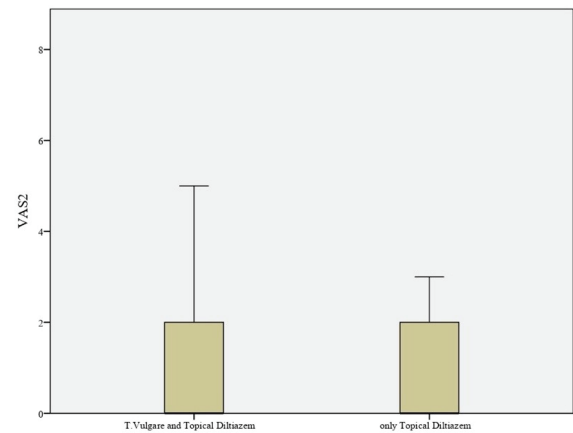


Figure 2: Visual Analogue Scales (VAS) after treatment.

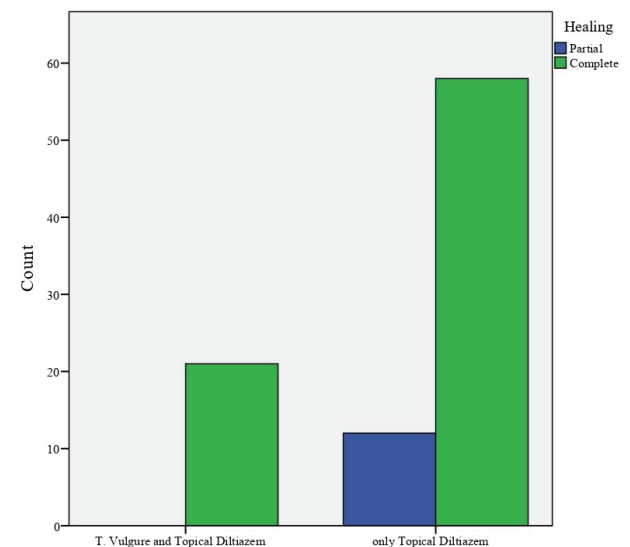


Figure 3: Wound healing status after treatment.

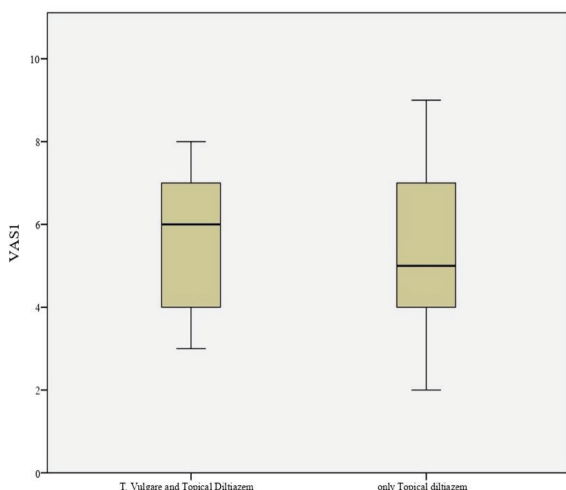


Figure 1. Visual Analogue Scales (VAS) before treatment.

Table 1. Analysis of demographic data.

Variables		n(%)	Median(IQR)
Gender	Male	38(41.8%)	
	Female	53(58.2%)	
Age, years			42(29-51)
Treatment	T. Vulgare plus topical diltiazem	21(23.1%)	
	Only topical diltiazem	70(76.9%)	
Bleeding	Absence	88(96.7%)	
	Presence	3(3.3%)	
VAS1			5(4-7)
VAS2			0(0-2)
Healing	Partial	12(13.2%)	
	Complete	79(86.8%)	

Abbrev.: IQR: Interquartile range, VAS: Visual Analogue Scale

Table 2. Comparative analysis of treatment protocols.

		T. Vulgare plus topical diltiazem		Only topical diltiazem		
Variables		n(%)	Median(IQR)	n(%)	Median(IQR)	P
Gender	Male	12(57.1%)		26(37.1%)		0.103
	Female	9(42.9%)		44(62.9%)		
Age, years			43(30-46)	41(29-52)	0.940*	
Bleeding	Absence	21(100%)		67(95.7%)		0.335
	Presence	0(0%)		3(4.3%)		
VAS1			6(4-7)		5(4-7)	0.240*
VAS2			0(0-2)		0(0-2)	0.947*
Healing	Partial	0(0%)		12(17.1%)		0.042
	Complete	21(100%)		58(82.9%)		

Abbrev.: IQR: Interquartile range, VAS: Visual Analogue Scale, *Mann-Whitney U test

Discussion

This study revealed that the use of *Triticum vulgare* in addition to standard topical diltiazem in the treatment of anal fissure positively affects wound healing, but despite this advantage, it does not have any effect on pain and bleeding. In this context, it can be considered that the pain and bleeding in patients are related to processes other than wound healing.

Anal fissure is a pathology that is seen equally in men and women, frequently in the 3rd and 4th decades, and is characterized by cracks extending from the dentate line to the anal verge, accompanied by bleeding and pain [11]. The gold standard in treatment is lateral internal sphincterotomy. However, today, due to its complications, methods such as topical nitric oxide donors, calcium channel blockers, and botulinum toxin injection are used instead of surgical treatment, which have similar effects [6,12].

The two most important clinical findings of anal fissure are bleeding and pain in the anus [13]. In a study in the literature including 60 patients, an 83.33% improvement in bleeding findings was observed in the 1-month follow-up of the group using topical diltiazem [14]. In this study, the bleeding improvement rate was 95.7% in the control group and 100% in the case group. Although the improvement rate was higher in the case group, this increase was not statistically significant.

VAS is a frequently used parameter for pain measurement. In a study comparing diltiazem, nitric oxide donors, and their combinations, it was determined that the VAS score decreased with treatment, but no difference was observed between treatments [15]. In a prospective double-blind randomized controlled study, topical glycerylnitrate and topical diltiazem treatment methods were compared, but it was observed that pain findings did not show significant differences between

treatments [16]. In this study, it was determined that there was a decrease in pain symptoms in both the control group and the case group, but this decrease was not statistically significant.

In a study comparing the results of 1-month use of nifedipine and diltiazem, the recovery rate in the diltiazem group was found to be 86.67% [17]. In another study, the 2-month recovery rate with nifedipine was 85.71%, while this rate was 86.36% with diltiazem [18]. In a study comparing lateral internal sphincterotomy and diltiazem, the recovery rate after 1 month was found to be 83.33% in the diltiazem group and 90% in the surgery group [14]. In this study, the wound healing rate in the control group using only diltiazem was 82.9% at the end of 1 month, which is consistent with the literature, while this rate was 100% in the control group. It was determined that the difference between the two groups in terms of wound healing was statistically significant.

In conclusion, this study found that adding *Triticum vulgare* to topical diltiazem significantly improved wound healing in anal fissure patients. Despite this, no statistically significant effect was observed on pain or bleeding. This suggests that these symptoms may be influenced by factors beyond the physical healing of the fissure. These results highlight *Triticum vulgare*'s potential to promote fissure closure, though its broader impact on symptom management requires further investigation.

This study's findings are limited by its single-center and retrospective design, which may affect the generalizability and introduce potential biases.

Ethical Approval

This study was approved by Amasya University Non-Interventional Clinical Research Ethics Committee (No: 2025/28).

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Conflicts of Interest

Authors declare that they have no conflicts of interest.

Authors Contribution

S.O. and F.C. contributed to conception, resource provision, writing, and critical review; S.N.Ö. and İ.D. were involved in design, literature review, and critical review; C.C. provided supervision, analysis/interpretation, writing, and critical review; while F.C. and S.N.Ö. executed data collection/processing and provided materials; and S.O. is designated as the Corresponding Author.

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