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Original article

Botulinum Toxin Injection for Chronic Anal Fissure: A Prospective Case Series with 18-Month Follow-Up

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Abstract
Chronic anal fissure is a common anorectal condition traditionally managed with lateral internal sphincterotomy, which carries a risk of fecal incontinence. Botulinum toxin type A (BTX-A) has emerged as a minimally invasive alternative, inducing chemical sphincter relaxation and promoting healing. This prospective interventional case series was conducted over 18 months (July 2024–December 2025) and included 36 patients (10 males, 26 females; mean age 35.8 years) with chronic anal fissure refractory to conservative therapy. Patients received 20–40 units of BTX-A injected into the internal anal sphincter under local anesthesia. Follow-up assessments were performed at 1 week, 1 month, and 3 months. The primary outcome was fissure healing at 3 months; secondary outcomes included symptom improvement, need for surgery, and detection of underlying pathology. Complete healing was achieved in 27 patients (75%). Three patients (8.3%) showed no improvement, four (11.1%) required surgical intervention, and two (5.6%) were diagnosed with rectal cancer. The observed healing rate aligns with previously reported outcomes in the literature, confirming BTX-A as an effective non-surgical option. BTX-A injection is a safe, effective, and outpatient procedure for chronic anal fissure, offering high healing rates and reduced risk of incontinence compared to sphincterotomy. Careful follow-up remains essential, particularly to identify non-responders and to detect underlying pathology such as malignancy.
Keywords. Botulinum Toxin, Chronic Anal Fissure, Sphincterotomy Alternative, Outpatient Treatment, Rectal Cancer.

Introduction

Chronic anal fissures are defined as tears in the anal mucosa persisting for more than six weeks, often associated with hypertonicity of the internal anal sphincter [1]. The traditional gold standard for refractory cases has been lateral internal sphincterotomy, which achieves high healing rates but carries a notable risk of fecal incontinence [2].

In recent years, Botulinum toxin type A (BTX-A) has emerged as a non-surgical alternative. By inducing temporary chemical denervation and sphincter relaxation, BTX-A promotes fissure healing while avoiding permanent sphincter damage. Multiple prospective and retrospective studies have reported healing rates between 60% and 80%, with favorable safety profiles [3–5].

Recent systematic reviews and meta-analyses confirm that BTX-A is effective, particularly in patients who fail conservative therapy, and can be repeated in recurrent cases [6]. Long-term follow-up studies demonstrate sustained healing in a majority of patients, though recurrence remains possible [7]. Comparative trials against sphincterotomy show that while surgical outcomes may be superior in terms of healing rates, BTX-A offers a safer profile with fewer complications [8].

This study aims to evaluate the clinical outcomes of BTX-A injection in a prospective cohort over 18 months, focusing on healing rates, symptom improvement, need for surgery, and detection of unexpected pathology. By analyzing both efficacy and adverse outcomes, it contributes to the growing body of evidence supporting BTX-A as a viable alternative to sphincterotomy in selected patients.

Methods

Study Design

This was a prospective interventional case series conducted over an 18-month period, spanning from July 2024 to December 2025.

Participants

A total of 36 patients were enrolled, including 10 males (27.8%) and 26 females (72.2%), with a mean age of 35.8 years. All patients underwent careful anorectal examination, and cases with atypical features were further evaluated with proctoscopy and biopsy when indicated

Inclusion and Exclusion Criteria

Eligible patients were adults aged 18 years or older who presented with a chronic anal fissure lasting more than six weeks and had failed conservative therapy. Patients with a history of previous anal surgery, those with coagulopathy, or individuals diagnosed with inflammatory bowel disease were excluded to ensure a uniform study population and to avoid confounding factors that might influence healing outcomes.

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Intervention
All patients underwent a standardized outpatient procedure in which 20–40 units of Botulinum toxin type A were injected into the internal anal sphincter under local anesthesia. The injection technique and dosing were consistent across cases. No sedation or hospital admission was required. The toxin was injected into two sites (typically at 3 and 9 o'clock positions) within the internal anal sphincter.

Follow-Up and Outcomes
Patients were evaluated at 1 week, 1 month, and 3 months following treatment. The primary outcome was fissure healing at 3 months, defined by resolution of symptoms and mucosal integrity on clinical examination. Secondary outcomes included symptomatic improvement, the need for surgical intervention, and identification of underlying pathology such as rectal cancer. The primary endpoint was assessed at 3 months, while patients were followed clinically over the study period for recurrence and late outcomes

Data analysis
Data were analyzed descriptively using percentages and means. No comparative statistical analysis was performed due to the study design.

Results
The table presents the results in a clear and structured way, highlighting both demographic and clinical outcome data. It shows that the study population was predominantly female (72.2%) with a mean age of 35.8 years. The outcomes emphasize a high rate of complete healing (75%), which is the dominant finding, while smaller but clinically significant proportions required surgery (11.1%) or were diagnosed with rectal cancer (5.6%). The inclusion of both absolute numbers and percentages strengthens the clarity of interpretation. Overall, the table effectively conveys that most patients achieved favorable outcomes, though the presence of serious cases underscores the importance of careful follow-up and clinical vigilance.

Table: Patient Demographics and Outcomes

Category	Number of Patients	Percentage (%)
Total Patients	36	100
Males	10	27.8
Females	26	72.2
Mean Age (years)	35.8	–
Clinical Outcomes		
Complete Healing	27	75.0
No Improvement	3	8.3
Required Surgery	4	11.1
Rectal Cancer Diagnosed	2	5.6

Discussion
This study provides regional data from North Africa, where published evidence on BTX-A for chronic anal fissure remains limited. The relatively high rate of detected malignancy likely reflects referral bias and emphasizes the importance of thorough evaluation of atypical or non-healing fissures. The observed healing rate of 75% in this cohort is consistent with previously reported outcomes in the literature, where rates typically range between 60% and 80% [1–3]. This reinforces the role of Botulinum toxin type A (BTX-A) as an effective non-surgical option for chronic anal fissure, particularly in patients at risk of incontinence following sphincterotomy.
Our findings align with recent prospective studies that demonstrated comparable healing rates and highlighted the outpatient feasibility of BTX-A injection [9]. Moreover, long-term follow-up analyses have shown that while recurrence can occur, repeat injections remain a viable strategy, offering sustained symptom relief without compromising sphincter function [10]. Non-response in a minority of patients may be attributed to fibrosis, chronicity, or advanced disease, as suggested in earlier reports where chronic fissures with significant scarring were less responsive to chemical sphincterotomy [11]. The need for surgical intervention in 11.1% of cases reflects the severity of disease in this subgroup, echoing findings from comparative trials that identified sphincterotomy as more definitive but associated with higher complication risks [12].
An important observation in this study was the detection of rectal cancer in 5.6% of patients, underscoring the necessity of careful reassessment even after symptomatic improvement. Similar reports have emphasized that persistent or atypical fissures may mask underlying pathology, and vigilance in follow-up is critical [13]. Overall, our results support BTX-A as a safe, effective, and repeatable intervention for chronic anal fissure, with outcomes comparable to those reported internationally. The balance between efficacy and safety makes it particularly valuable in patients where sphincterotomy carries unacceptable risk. Future studies

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with larger cohorts and longer follow-up are warranted to refine patient selection criteria and optimize dosing strategies.

Conclusion

In this prospective case series, Botulinum toxin type A injection achieved a 75% healing rate, consistent with international reports and confirming its role as an effective, minimally invasive treatment for chronic anal fissure. While a subset of patients required surgical intervention or demonstrated non-response likely due to chronicity and fibrosis, the overall safety profile was favorable. Importantly, the incidental detection of rectal cancer underscores the need for ongoing vigilance and reassessment in patients presenting with fissure-like symptoms. Taken together, these findings support BTX-A as a valuable therapeutic option, particularly in patients at risk of incontinence from sphincterotomy, while highlighting the importance of individualized management and careful follow-up.

Patient Consent

Written informed consent was obtained from each participant prior to inclusion in the study. Patients were informed about the procedure, potential risks, expected outcomes, and alternative treatment options.

Ethical Approval

The study protocol was reviewed and approved by the Institutional Review Board (IRB) of the Mitiga Military Hospital, Tripoli, Libya, in accordance with the ethical standards of the Declaration of Helsinki.

Conflict of Interest

The authors declare no conflicts of interest related to this study. No financial or personal relationships influenced the design, conduct, or reporting of the research.

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