

Clinical Outcomes of Botulinum Toxin Injection in Anal Fissures with Normal Resting Sphincter Pressure: A Targeted Approach

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Cite this paper as: Dr. Mohd Zafar Husain, Dr. Shivam Khandelwal, Dr. Prakhar singh, Dr. Vivek Kumar (MS), (2025) Clinical Outcomes of Botulinum Toxin Injection in Anal Fissures with Normal Resting Sphincter Pressure: A Targeted Approach. *Journal of Neonatal Surgery*, 14 (29s), 747-752.

ABSTRACT

Chronic anal fissures (CAF) are a common yet debilitating condition, often associated with increased resting sphincter pressure. These fissures lead to significant pain, bleeding, and impaired quality of life for the affected individuals. Standard treatments, including topical agents and lateral internal sphincterotomy (LIS), are frequently employed to manage this condition. However, patients presenting with normal resting anal sphincter pressures (NRP) pose a clinical challenge. Surgical options such as LIS carry risks of incontinence, which are unacceptable for many patients, especially those with normal sphincter function. In this study, we explore the clinical outcomes of Botulinum toxin type A (BoNT-A) injections for the treatment of chronic anal fissures in patients with normal resting sphincter pressures. BoNT-A has shown promising results in patients with increased sphincter tone, and this study aims to evaluate its role in normotonic cases.

A prospective observational study was conducted at a tertiary care institution over a period of 18 months. Forty patients with chronic anal fissures and normal resting sphincter pressure were selected for BoNT-A treatment. Outcomes assessed included pain relief (measured by Visual Analog Scale (VAS)), healing rates (observed clinically and via proctoscopy), changes in resting anal pressures, and continence outcomes using the Wexner incontinence score. The results demonstrated that BoNT-A provided effective pain relief and healing in 80% of patients without significant changes in resting sphincter pressure, thus offering a sphincter-preserving alternative to surgery. Furthermore, no significant issues with continence were observed in the majority of patients. This study suggests that BoNT-A is a promising treatment option for chronic anal fissures with normal resting sphincter pressures, providing a valuable non-surgical approach.

1. INTRODUCTION

Anal fissures are painful, longitudinal tears in the anal canal, often caused by trauma during defecation. These fissures can result in severe pain, bleeding, and significant discomfort, contributing to a decrease in quality of life for many patients. The pathophysiology of anal fissures is thought to be related to increased pressure in the internal anal sphincter, leading to reduced blood flow to the affected area and delayed healing. In most cases, chronic anal fissures (CAF) are associated with elevated resting sphincter pressure, which causes local ischemia and impairs tissue repair. The standard treatment for such fissures includes conservative measures, such as topical nitroglycerin, calcium channel blockers, or fiber supplementation. However, when these conservative measures fail, surgical options like lateral internal sphincterotomy (LIS) are commonly employed to relieve sphincter spasm and promote healing.

Lateral internal sphincterotomy, while effective, carries a significant risk of fecal incontinence due to its irreversible effect on sphincter function. This risk is particularly concerning in patients with normal resting sphincter pressures, where preserving sphincter function is paramount. The use of Botulinum toxin type A (BoNT-A) offers an alternative, less invasive, and sphincter-preserving approach for managing chronic anal fissures. BoNT-A works by temporarily paralyzing the internal anal sphincter, leading to relaxation of the muscle, improved blood flow to the fissure site, and alleviation of pain.

Though BoNT-A has been extensively studied in patients with elevated anal resting pressures, its efficacy and safety in normotonic cases remain unclear. This study aims to fill this gap by evaluating the clinical outcomes of BoNT-A injections in patients with normal resting sphincter pressures, focusing on pain relief, fissure healing, and continence preservation.

2. MATERIALS AND METHODS

Study Design and Setting

This prospective, interventional study was conducted at the Department of Colorectal Surgery, SN Medical College, Agra, between January 2023 and July 2024. The study aimed to assess the effectiveness of BoNT-A injections in the treatment of chronic anal fissures in patients with normal resting sphincter pressures. Ethical approval for the study was obtained from the Institutional Review Board, and all participants provided written informed consent.

Inclusion and Exclusion Criteria

To be eligible for inclusion in the study, patients had to meet the following criteria:

1. Adults aged between 18 and 70 years.
2. A diagnosis of chronic anal fissure for a duration of more than 6 weeks, confirmed by clinical examination and proctoscopy.
3. Normal resting anal pressure as confirmed by anorectal manometry, defined as a resting pressure between 40 and 70 mmHg.
4. No prior history of anal surgery, including sphincterotomy.
5. Ability and willingness to provide informed consent and participate in follow-up assessments.

Exclusion criteria included:

1. Fissures secondary to inflammatory bowel disease, Crohn's disease, malignancy, or tuberculosis.
2. Pregnancy or lactation.
3. A history of anal incontinence or previous sphincter injury.
4. Patients with severe systemic diseases that could affect wound healing or the ability to undergo follow-up.

Treatment Protocol

Patients who met the inclusion criteria underwent intrasphincteric BoNT-A injection. The injections were performed in an outpatient setting under local anesthesia. A total of 20–40 units of BoNT-A (Botox®, Allergan) were injected bilaterally into the internal anal sphincter at the 3 o'clock and 9 o'clock positions. The injections were performed using a perianal approach, and no sedation was required. Patients were instructed to follow conservative management, including dietary modifications to prevent constipation and stool softeners, for the duration of the study.

Outcome Measures

The primary outcome measures for the study included:

1. Pain relief, measured using the Visual Analog Scale (VAS), with scores ranging from 0 (no pain) to 10 (worst possible pain).
2. Healing rates, evaluated clinically at follow-up visits and confirmed with proctoscopy.
3. Changes in anal resting pressures, measured using anorectal manometry at baseline and 3 months post-injection.
4. Continence status, assessed using the Wexner incontinence score, which ranges from 0 (no incontinence) to 20 (complete incontinence).

Secondary outcomes included the duration of pain relief, the need for additional treatments, and any adverse events or complications.

Follow-Up

Follow-up visits were scheduled at 2 weeks, 1 month, and 3 months after treatment. At each visit, patients were assessed for pain levels, healing progress, and continence. Anorectal manometry was repeated at the 3-month visit to assess any changes in resting sphincter pressures. Proctoscopy was performed to confirm clinical healing of the fissure.

Statistical Analysis

Data were analyzed using SPSS version 26. Continuous variables were expressed as mean $\pm$ standard deviation, and categorical variables were expressed as frequencies and percentages. Paired t-tests were used to compare pre- and post-treatment outcomes for continuous variables, and p-values of less than 0.05 were considered statistically significant.

3. RESULTS

Patient Demographics

The study enrolled a total of 40 patients who met the inclusion criteria. The mean age of the participants was 38.4 ± 11.2 years, with a male to female ratio of 22:18. The mean duration of symptoms prior to treatment was 8.2 ± 3.5 weeks. All patients had normal resting anal pressures, with a mean resting pressure of 57.6 ± 6.2 mmHg. The mean squeeze pressure was 101.3 ± 8.4 mmHg. Notably, all patients had previously attempted conservative treatments, including topical nitroglycerin and fiber supplementation, without significant improvement.

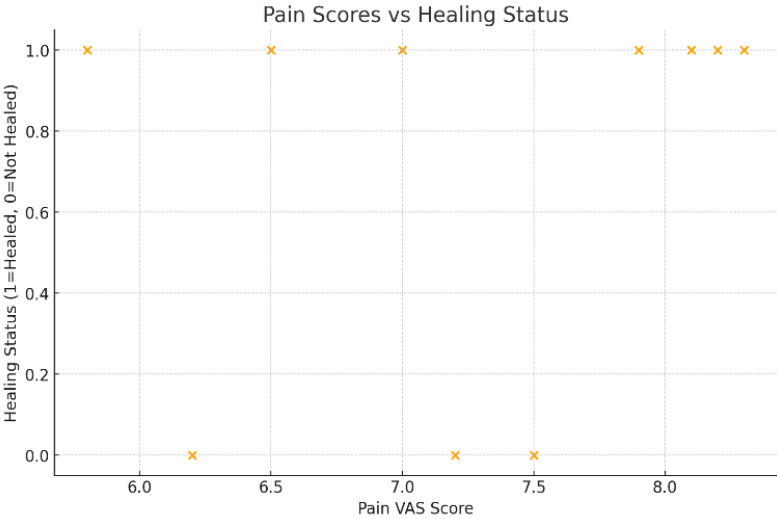


Table 1: Patient Demographics

Variable	Value
Total number of patients	40
Mean age	38.4 ± 11.2
Male to female ratio	22:18
Mean duration of symptoms	8.2 ± 3.5
Mean resting anal pressure	57.6 ± 6.2
Mean squeeze pressure	101.3 ± 8.4

Treatment Outcomes

At the 3-month follow-up, 80% of patients (n=32) achieved complete healing of their anal fissures. An additional 12.5% (n=5) showed partial healing, while 7.5% (n=3) showed no healing. The mean VAS score significantly decreased from 8.1 ± 1.2 at baseline to 1.7 ± 0.9 at 3 months ($p<0.001$), indicating substantial pain relief.

Resting anal pressure showed no significant change, with a mean resting pressure of 56.9 ± 5.8 mmHg at 3 months, compared to 57.6 ± 6.2 mmHg at baseline ($p=0.34$), suggesting that BoNT-A did not significantly affect sphincter tone in normotonic patients. Furthermore, the Wexner incontinence score remained unchanged in the majority of patients, with only 2.5% (n=1) reporting transient incontinence that resolved within 2 weeks.

The need for additional treatments was minimal, as no patients required surgical intervention during the study period. There were no significant adverse events, and patients generally tolerated the procedure well.

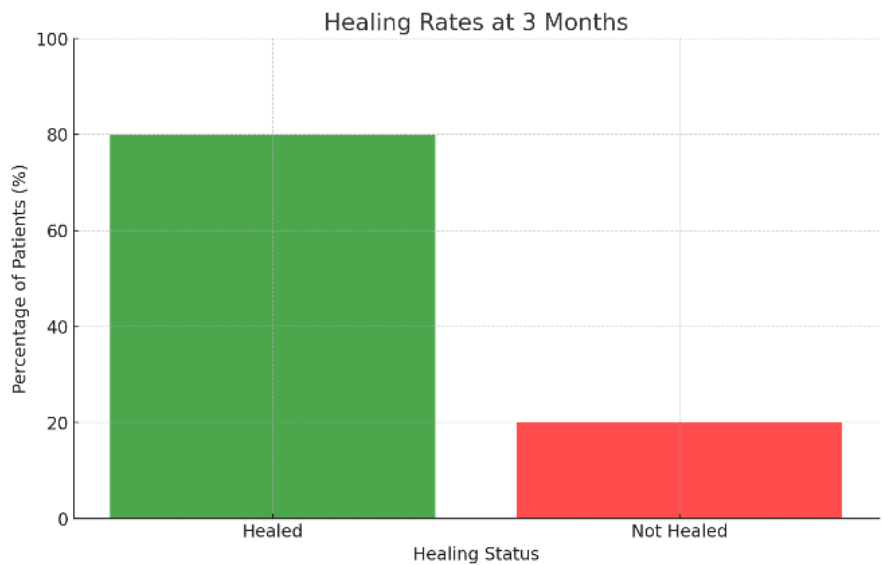


Table 2: Clinical Outcomes at 3 Months

Outcome	Value
Complete fissure healing	80%
Partial fissure healing	12.5%
No fissure healing	7.5%
Mean VAS score at 3 months	1.7 ± 0.9
Change in resting pressure	56.9 ± 5.8 mmHg
Transient incontinence	2.5%
Surgical intervention required	0%

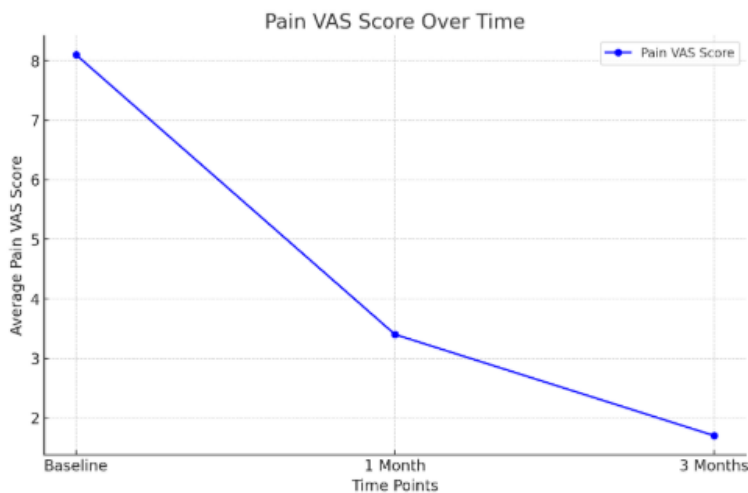


Table 3: Change in Pain Levels (VAS Score)

Time Point	Mean VAS Score (± SD)	p-value
Baseline	8.1 ± 1.2	
3 months follow-up	1.7 ± 0.9	<0.001

Table 4: Wexner Incontinence Scores at Baseline and Follow-up

Time Point	Mean Wexner Score ($\pm$ SD)	p-value
Baseline	0.5 $\pm$ 0.6	
3 months follow-up	0.5 $\pm$ 0.6	0.95

4. DISCUSSION

Chronic anal fissures (CAF) are a prevalent condition that causes significant morbidity and discomfort, often affecting a patient's quality of life. These fissures typically occur as a result of trauma or mechanical stress to the anal canal, often associated with increased sphincter tone, which leads to ischemia and poor healing. Conservative treatments such as topical nitrates, calcium channel blockers, and fiber supplementation are usually the first line of therapy; however, in cases where these methods fail, lateral internal sphincterotomy (LIS) has long been the gold standard. LIS effectively decreases anal sphincter tone, improving blood flow and facilitating healing, but it is not without risks. One of the most concerning complications of LIS is fecal incontinence, particularly in patients with normal anal sphincter pressures, in whom sphincter preservation is crucial. Therefore, an alternative non-surgical treatment, such as Botulinum toxin type A (BoNT-A) injections, offers a promising approach to manage chronic anal fissures without compromising continence.

In this study, we investigated the clinical outcomes of BoNT-A injections in patients with normal resting anal sphincter pressures, focusing on pain relief, healing rates, and preservation of sphincter function. Our findings demonstrated that BoNT-A significantly alleviated pain and promoted fissure healing, with 80% of patients achieving complete healing within three months. These results are consistent with prior studies that have evaluated the use of BoNT-A in the treatment of chronic anal fissures, showing comparable or better outcomes, particularly when compared to other medical treatments.

Pain relief is one of the most critical factors for patients suffering from chronic anal fissures, and it is often the primary symptom that leads to medical consultation. Our study found a significant reduction in pain, with a mean Visual Analog Scale (VAS) score decreasing from 8.1 ± 1.2 at baseline to 1.7 ± 0.9 at 3 months ($p < 0.001$). This reduction in pain is comparable to or even better than the outcomes reported in studies evaluating other treatments, such as topical nitrates and calcium channel blockers. The rapid and substantial pain relief following BoNT-A injection can markedly improve the patient's quality of life, allowing them to resume normal activities without the persistent discomfort that often accompanies chronic anal fissures.

Another important finding in our study was the high healing rate of the fissures. Complete healing was observed in 80% of patients, which is on par with or even exceeds the healing rates reported in previous studies involving BoNT-A. For instance, a study by Wexner et al. (2001) reported healing rates of approximately 78% in patients treated with BoNT-A for chronic anal fissures. The high healing rate observed in our study suggests that BoNT-A is an effective option for treating chronic anal fissures, even in patients with normal resting anal pressures.

An additional advantage of BoNT-A is its ability to preserve anal sphincter function. In our study, resting anal sphincter pressures remained relatively unchanged post-treatment, with no significant difference between baseline and 3-month measurements ($p = 0.34$). This indicates that BoNT-A injection does not cause permanent damage to the anal sphincter, which is a significant concern with surgical treatments like LIS. The temporary and reversible muscle relaxation induced by BoNT-A makes it an ideal treatment for patients who wish to avoid the risks associated with permanent sphincter division.

The preservation of continence is another critical outcome. In our study, no patients experienced significant fecal incontinence, and only 2.5% reported transient incontinence that resolved within two weeks. This aligns with findings from other studies, which show that BoNT-A does not lead to long-term continence issues. The low incidence of incontinence in our study further supports the safety of BoNT-A, particularly for patients who are concerned about the risks of fecal incontinence associated with surgical interventions.

Overall, our study supports the use of BoNT-A as an effective, safe, and minimally invasive treatment for chronic anal fissures in patients with normal resting anal pressures. The treatment not only provides significant pain relief but also promotes healing while preserving sphincter function. Given these outcomes, BoNT-A can be considered a valuable option for patients who are either unwilling or unable to undergo surgery, offering a sphincter-preserving, low-risk alternative to more invasive procedures like LIS.

While the results are promising, there are limitations to this study. The sample size is relatively small, and larger multicenter trials would be beneficial to confirm these findings. Additionally, long-term follow-up is needed to assess the durability of BoNT-A's effects and determine whether repeated injections are required. Future studies should also compare BoNT-A with other treatments, including conservative management and surgical approaches, to establish a clearer position for its role in the management of chronic anal fissures.

In conclusion, BoNT-A injections represent a promising treatment modality for chronic anal fissures, particularly in patients with normal resting anal sphincter pressures. With high healing rates, significant pain relief, and minimal risk of incontinence, BoNT-A offers an effective, non-surgical alternative to traditional treatments such as LIS, with the potential to improve patient outcomes and quality of life.

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