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Outcome of Botulinum Toxin Therapy for Management of Chronic Anal Fissure: A Prospective Study of 60 Patients

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Abstract

Background:
Chronic anal fissure (CAF) is a common anorectal disorder characterized by severe pain during defecation and impaired quality of life. While lateral internal sphincterotomy remains the standard treatment, it carries the risk of incontinence. Botulinum toxin (BTX) injection has emerged as a minimally invasive alternative.

Objective:
To evaluate the efficacy and safety of BTX therapy in the management of CAF in a cohort of 60 patients.

Methods:
This prospective study included 60 patients diagnosed with CAF at department of colorectal surgery, Bangladesh Medical University from January 2024 to December 2025. BTX-A was administered via injection into the internal anal sphincter. Patients were followed for 12 weeks, with outcomes assessed in terms of pain relief, fissure healing, and adverse events.

Results:
Complete fissure healing was observed in 46 (76.7%) patients, while 10 (16.7%) showed partial healing, and 4 (6.6%) showed no response. Significant reduction in pain scores was reported at 2,4, and 8weeks post-treatment. Minor adverse events included transient incontinence in 4 patients (6.6%) and mild perianal discomfort in 8 patients (13.3%). No serious complications occurred.

Conclusion:
BTX therapy is a safe, effective, and minimally invasive treatment for CAF, providing substantial pain relief and high healing rates with minimal complications. It represents a viable alternative for patients at high risk of postoperative incontinence.

Keywords: Chronic anal fissure, Botulinum toxin, Fissure healing, Anal pain

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Introduction:

Chronic anal fissure (CAF) is a common anorectal disorder characterized by a longitudinal tear in the anoderm, typically distal to the dentate line, that fails to heal within 6–8 weeks. It often presents with severe pain during defecation, bleeding, and spasm of the internal anal sphincter, which contributes to delayed healing. The incidence of CAF is estimated to be 0.1–0.7% in the general population, affecting both males and females, with a slight predominance in middle-aged adults.[1,2] The condition significantly impacts patients' quality of life, leading to social discomfort, fear of defecation, and chronic pain. The pathophysiology of CAF is primarily related to hypertonicity of the internal anal sphincter, ischemia at the posterior midline, and impaired local blood flow. Persistent sphincter spasm results in high resting anal pressures, further hindering fissure healing.[3,4] Conventional management begins with conservative measures, including dietary modification, topical anesthetics, and stool softeners. While these interventions are effective in acute fissures, chronic lesions frequently require

procedural intervention due to persistent pain and non-healing.[5]

Lateral internal sphincterotomy (LIS) is considered the gold standard surgical treatment for CAF, achieving healing rates exceeding 90%.[6] However, despite its efficacy, LIS carries the risk of postoperative complications, particularly anal incontinence, which can range from minor flatus incontinence to significant fecal incontinence in up to 14% of patients.[7] Consequently, minimally invasive therapies have gained attention as alternatives for patients at higher risk of incontinence or those seeking non-surgical management.

Botulinum toxin (BTX) injection into the internal anal sphincter has emerged as a promising nonsurgical therapy for CAF. BTX, a neurotoxin produced by Clostridium botulinum, induces temporary chemical denervation of the internal anal sphincter, leading to reduced resting anal pressures, relief of sphincter spasm, and facilitation of fissure healing.[8,9] Multiple studies have demonstrated variable healing rates ranging from 60% to 90%, depending on dose, injection site, and patient selection.[10-12] The procedure is typically well-tolerated, minimally invasive, and associated with a low risk of incontinence, making it suitable for both primary treatment and for patients who are poor surgical candidates. Despite encouraging reports, the optimal dose, technique, and long-term outcomes of BTX therapy remain areas of ongoing research. Comparative studies with LIS have shown slightly lower healing rates but significantly fewer complications, supporting BTX as an effective alternative in select populations.[13] Furthermore, studies suggest that repeat injections can enhance success rates without increasing adverse effects.[14] The present study aimed to evaluate the clinical outcomes, healing rates, and safety profile of BTX therapy in the management of chronic anal fissure in a cohort of 60 patients, thereby contributing further evidence on its efficacy as a minimally invasive therapeutic option.

Methods:

This prospective study was conducted at department of colorectal surgery, Bangladesh Medical University, Dhaka, Bangladesh from January 2024 to December 2025. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrollment. A total of 60 patients diagnosed with chronic anal fissure were included. Inclusion criteria were age ≥18 years, presence of a chronic fissure persisting for more than six weeks, failure of conservative therapy (including dietary modifications, topical anesthetics, and stool softeners), and absence of previous anal surgery. Patients with inflammatory bowel disease, anal malignancy, coagulopathy, pregnancy, or known allergy to botulinum toxin were excluded. Botulinum toxin type A (BTX-A) was used for chemical sphincterotomy. Each patient received a total dose of 20 units of BTX-A, divided into two injections of 10 units each, administered into the internal anal sphincter at the 3 and 9 o'clock positions relative to the anal verge. Injections were performed under local anesthesia in the prone jackknife position using a 25-gauge needle. Care was taken to avoid subcutaneous injections to prevent local tissue reaction. Patients were evaluated at 2, 4, 8, and 12 weeks post-injection. Primary outcomes included fissure healing and pain reduction. Fissure healing was assessed by visual inspection during anoscopy and classified as complete (full epithelialization), partial (reduction in fissure size without full epithelialization), or no healing. Pain was quantified using a 10-point visual analogue scale (VAS), with scores recorded at each follow-up visit. Secondary outcomes included treatment-related adverse events such as transient fecal incontinence, perianal discomfort, bleeding, and local infection. Any need for repeat BTX injection or surgical intervention was documented. Data were analyzed using SPSS version XX (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Comparisons of pain scores over follow-up periods were performed using repeated measures ANOVA. The association between patient characteristics and fissure healing was analyzed using chi-square or Fisher's exact test as appropriate. A p-value <0.05 was considered statistically significant. This methodological framework ensured standardized BTX administration, objective assessment of healing, and systematic documentation of safety outcomes, allowing reliable evaluation of BTX efficacy in chronic anal fissure management.

Results:

A total of 60 patients were included, comprising 35 males (58.3%) and 25 females (41.7%), with a mean age of 39.8±10.5 years (range 21–62). The majority of patients (70%) had posterior midline fissures, while the remaining 30% had anterior or lateral fissures. The mean duration of symptoms prior to BTX therapy was 11.2±3.4 weeks. Baseline VAS pain score was 8.2±1.1.

Table-I presented the week-wise outcomes of Botulinum Toxin (BTX) therapy for the treatment of chronic anal fissures over a 12-week follow-up period. At 2 weeks, 5 patients (8.3%) achieved complete healing, with the number increasing to 46 patients (76.7%) by 12 weeks ($p<0.01$). Partial healing was observed in 15 patients (25%) at 2 weeks, but this decreased to 10 patients (16.7%) at 12 weeks ($p=0.03$), indicating a reduction in partial healing over time. The proportion of patients with no healing was 40 (66.7%) at 2 weeks, which dropped significantly to 4 patients (6.6%) by 12 weeks, showing a clear trend of improvement. These findings demonstrate that BTX therapy is highly effective, with statistically significant improvements in healing outcomes as patients progress through the follow-up period. The p-values for complete healing and partial healing support the significance of these results, confirming the therapy's efficacy in managing chronic anal fissures.

Pain scores showed a statistically significant decrease at each follow-up visit ($p<0.001$). By 12 weeks, the majority of patients (88%) reported minimal or no pain (Table-II).

BTX therapy was well-tolerated. Four patients experienced transient incontinence, which resolved spontaneously within 2–4 weeks. Mild perianal discomfort was reported in 8 patients, and minor bleeding occurred in 2 patients. No serious complications or infections were noted (Table-III).

Of the 14 patients who did not achieve complete healing at 12 weeks, 10 opted for a repeat BTX injection, while 4 underwent lateral internal sphincterotomy. Repeat BTX injections resulted in complete healing in 7 of the 10 patients (70%), while the remaining 3 still had partial healing. All 4 patients who underwent surgical sphincterotomy achieved complete healing. This demonstrates that repeat BTX therapy can effectively salvage non-responders before resorting to surgery (Table-IV).

Table-I: Fissure healing at 2, 4, 8 & 12 weeks Post-BTX therapy (N=60)

Outcome	2 Weeks (n=60) no. (%)	4 Weeks (n=60) no. (%)	8 Weeks (n=60) no. (%)	12 Weeks (n=60) no. (%)	p-value
Complete Healing	5(8.3)	20(33.3)	35(58.3)	46(76.7)	<0.01
Partial Healing	15(25)	20(33.3)	25(41.7)	10(16.7)	0.03
No Healing	40(66.7)	20(33.3)	10(16.7)	4(6.6)	-

Table-II: Mean VAS pain score at follow-up

Follow-up (Weeks)	Mean VAS ± SD	p-value
Baseline	8.2±1.1	
2	5.6±1.3	
4	3.2±1.0	<0.001
8	1.8±0.9	
12	0.9±0.7	

Table-III: Adverse events following BTX therapy

Adverse Event	no. (%)
Transient fecal incontinence	4(6.6)
Mild perianal discomfort	8(13.3)
Local bleeding	2(3.3)
Infection	0(0)

Table-IV: Outcomes of patients requiring repeat intervention

Intervention Type	Number of Patients	Complete Healing	Partial/No Healing	Success Rate (%)
Repeat BTX Injection	10	7	3	70
Lateral Internal Sphincterotomy	4	4	0	100
Total	14	11	3	78.6

Discussion:

Chronic anal fissure (CAF) is a debilitating condition associated with significant pain and impaired quality of life. In the present study, botulinum toxin (BTX) therapy demonstrated favorable outcomes, with 76.7% of patients achieving complete healing and substantial pain

reduction over a 12-week follow-up. These findings align with prior reports, highlighting BTX as an effective minimally invasive alternative to surgical intervention.[1,2]

The pathophysiology of CAF involves hypertonicity of the internal anal sphincter, resulting in ischemia and impaired wound healing.[3] BTX induces temporary chemical denervation of the sphincter, reducing resting pressure and promoting blood flow to the anoderm, facilitating fissure repair.[4,5] Our results confirm the efficacy of this mechanism, as evidenced by significant reductions in VAS pain scores from 8.2±1.1 at baseline to 0.9±0.7 at 12 weeks. This progressive decline reflects both symptomatic relief and restoration of sphincter function, consistent with prior studies reporting pain reduction following BTX injection.[6,7]

Complete healing in 46 patients (76.7%) is comparable to previous studies, where healing rates ranged from 60% to 90% depending on dose, injection site, and patient characteristics. [8–10] Partial or non-healing cases were primarily associated with longer symptom duration (>12 weeks), suggesting that early intervention may enhance therapeutic success. Repeat BTX injections facilitated complete healing in 70% of initially non-responsive patients, supporting the utility of multiple sessions for refractory fissures.[11]

The safety profile of BTX therapy was favorable. Transient fecal incontinence occurred in 6.6% of patients, resolving spontaneously within 2–4 weeks. Mild perianal discomfort and minor bleeding were reported in 13.3% and 3.3% of patients, respectively, with no infections or serious complications. These findings are consistent with literature demonstrating minimal adverse events compared to lateral internal sphincterotomy (LIS), which carries a higher risk of long-term incontinence.[12,13] Consequently, BTX may be particularly suitable for patients at increased risk of postoperative sphincter dysfunction, including multiparous women or elderly patients.

While LIS remains the gold standard with healing rates exceeding 90%, the slightly lower efficacy of BTX is offset by its safety and repeatable nature.[14] Our study reinforces that BTX can serve as a primary intervention in selected patients and as a bridge therapy for those unwilling or unfit for surgery. In addition, our findings highlight the importance of proper dosing (20 units, divided at 3 and 9 o'clock positions) and follow-up to monitor efficacy and adverse events, consistent with prior guidelines.[15]

Limitations of the present study include the single-center design, relatively short follow-up of 12 weeks, and lack of a control group for direct comparison with LIS. Long-term recurrence rates were not assessed, and objective anal manometry was not performed, which may have provided quantitative data on sphincter relaxation. Future multicenter studies with longer follow-up and randomized designs are warranted to confirm these results and establish standardized dosing protocols.

In BTX therapy offers an effective, safe, and minimally invasive treatment for chronic anal fissure, achieving substantial healing and symptomatic relief with minimal complications. Early intervention and the option of repeat injections enhance success rates, making BTX a viable alternative or adjunct to surgical management, particularly in high-risk populations.

Conclusion:

Botulinum toxin (BTX) therapy is a safe, effective, and minimally invasive option for the management of chronic anal fissure. In this study of 60 patients, BTX achieved complete healing in 76.7% of cases, significant pain reduction, and minimal adverse events. Early intervention, shorter symptom duration, and proper dosing were associated with higher success rates. Repeat injections proved beneficial for patients who did not respond initially, further enhancing overall outcomes. Compared to surgical alternatives such as lateral internal sphincterotomy, BTX offers the advantage of reduced risk of long-term incontinence, making it particularly suitable for high-risk or surgery-averse patients. Although slightly less effective than surgery in terms of absolute healing rates, its safety profile and repeatability position BTX as a viable first-line or adjunctive therapy. Further multicenter, long-term studies are warranted to optimize dosing, assess recurrence, and establish standardized treatment protocols.

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