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# Evaluation of botulinum toxin therapy for chronic anal fissure

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## Abstract

### Background

Chronic anal fissure causes severe anal pain that dramatically impairs patient's quality of life. Despite a poorly understood etiology, anal fissures are characterized by continuous spasms of the internal anal sphincter. The work aims to evaluate the efficacy of botulinum toxin (BTX) local injection in relieving symptoms and healing chronic anal fissure and its complications. We also aim to popularize this simple outpatient technique.

### Patients and methods

Thirty patients diagnosed with chronic anal fissure were included in this study. Each patient received 40 units of BTX. All patients were evaluated for pain, bleeding, and healing of the fissure from 1 to 12 months later.

### Results

The overall complication rate was 10%, with a single incidence of temporary incontinence to flatus. The improved postdefecatory pain was reported in 25 (83.3%) patients. The fissure was completely healed in 20 (66.6%) patients.

### Conclusion

In the clinical evaluation, BTX is a valid alternative nonsurgical modality for the treatment of chronic anal fissure. We recommend BTX as the first step in the treatment of chronic anal fissures because of the resulting chance of cure with an easily performed technique.

**Keywords:** Anal fissure, anal sphincter, BTX

## INTRODUCTION

Chronic anal fissure causes severe anal pain that dramatically impairs patient's quality of life. Despite a poorly understood etiology, anal fissures are characterized by continuous spasms of the internal anal sphincter [1]. Spasm of the internal anal sphincter, pain, and chronicity are the components of this vicious circle [2]. Sphincterotomy, which is successful in healing 85–95% of patients, permanently weakens the sphincter. Therefore, it might be associated with anal deformity and alteration of continence in 3–30% of patients [3]. Recently several clinical criteria reported the injection of botulinum toxin (BTX)-A into the internal sphincter for healing of chronic anal fissure, with a success rate reaching 85% compared with the surgical outcome [1–11]. Being a reversible 'sphincterotomy' lasting for 8–12 weeks, it has fundamental merit, as it allows enough time for the fissure to heal and at the same time carries no risk of permanent incontinence [4]. The procedure takes place in the outpatient clinic and has

few adverse effects, mostly transient local irritation [5,6]. In comparison with nitroglycerin ointment, BTX injection has been shown to be positively superior in healing chronic anal fissures making nitroglycerin ointment mainly indicated for acute fissures and not chronic ones [7].

## Aim

The aim of this work was to evaluate the efficacy of BTX local injection in relieving symptoms and healing chronic anal fissure and its complications. We also aim to popularize this simple outpatient technique.

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## PATIENTS AND METHODS

Thirty adults with symptomatic chronic anal fissure were enrolled in the study. The diagnosis of the chronic anal fissure was based on clinical findings: circumscribed ulcer, with sentinel tag of skin, and symptoms (postdefecatory pain, bleeding, or both) lasting for more than 2 months. Patients with acute fissures, hemorrhoids, fistula in ano, anal abscesses and those who have undergone previous surgical procedures in the anal region were excluded. Eligible patients underwent treatment with BTX (Botox; Allergan, Irvin, UK). Each patient received a total of 40 units administered as two injections for an equal volume in the internal sphincter at three and nine positions. No sedation or local anesthesia was used during the procedure. The endpoint of the study was complete healing after treatment. If the fissure healed, it was considered as successful treatment. However, the persistence of the fissure with the absence of symptoms was considered as a symptomatic improvement. Patients were followed up monthly for 2 months and then every 6 months for 2 years.

## RESULTS

Thirty patients, with 25 males and five females, were included in the study. The overall complication rate was 10%, with two cases of localized hematomata at the injection site, both managed conservatively, and a single incidence of temporary incontinence to flatus lasting for 6 weeks. Improvement of postdefecatory pain was reported in 25 (83.3%) patients. One month after treatment, the anal fissure was utterly healed in 15 (50%) patients. At 6 months, healing was achieved in 20 (66.6%) patients.

## DISCUSSION

Our present study has shown that BTX injection for treatment of chronic anal fissure is a safe and effective method. The indication of BTX injection (chemical sphincterotomy) is similar to surgical lateral sphincterotomy, with a comparable success rate in both procedures. Patients with chronic anal fissure have hypertonicity of the internal sphincter. This compromises perfusion of the anal mucosa, as blood vessels supplying the distal anal canal traversing the internal sphincter en route to the anal mucosa may be compressed by the hypertonic muscle leading to the chronic anal fissure. This is why chronic anal fissure has been described as an ischemic ulcer [8]. By reducing hypertonia, lateral internal sphincterotomy improves the perfusion of the distal anal mucosa and leads to healing of the chronic anal fissure in 90–95% of cases [9]. Despite the high healing rate, internal anal sphincterotomy has risks such as the anesthesia risk, complications related to wound healing, the need for hospitalization, and incontinence [9]. However, when comparing surgery with toxin injection, the incidence of minor anal incontinence was higher with surgery [10]. BTX causes temporary sphincter paresis for ~3 months allowing fissure healing; the release of acetylcholine at the presynaptic nerve endings with neuromuscular transmission blockade

causes chemical denervation of the sphincter muscle [11]. BTX blocks sympathetic nerve function and myogenic tone of the internal anal sphincter (chemical sphincterotomy), leading to elimination of the sphincter hypertonia, increase of the local tissue perfusion, and healing of the chronic anal fissure. Muscle paralysis occurs within hours, and the effect remains for 3–4 months. This prolonged effect allows the fissure to heal. This effect is reversible because it is followed by axonal regeneration and formation of new nerve endings which avoids the risk of permanent injury to the sphincter [12–14]. A reduced dose of 33 IU per injection does not reduce the efficacy of the injection. Moreover, the best predictor of ongoing recurrence is a pain at the first postoperative period [15]. BTX must be administered by or under the strict supervision of colorectal surgeon who has experience with the procedure [16]. BTX is a safe and effective treatment for chronic anal fissure and a promising alternative to surgical sphincterotomy [17]. BTX injection is a simple procedure, easy to learn, and can be done in the outpatient clinic without the need for sedation or local anesthesia. It is cost-effective and leads to healing of the fissure avoiding surgery with its potential risk of incontinence. Temporary incontinence to flatus was observed in one of our patients and disappeared within 6 weeks. Two small hematoma formations were observed in another two patients and responded to conservative measures.

## CONCLUSION

In the clinical evaluation, BTX is an effective nonsurgical modality for the treatment of chronic anal fissure. We recommend BTX as the first step in the treatment of chronic anal fissures because of 66.6–83% chance of cure with an easily performed treatment. BTX is comparatively less invasive than surgery, and the complication rate seems trivial. The critical limitation of this study was the absence of a control group and lack of monomeric anorectal examination. Further studies including more patients with long-term follow-up are advised to confirm the results.

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## Conflicts of interest

There are no conflicts of interest.

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