



Original article

Botulinum toxin improves pain in chronic anal fissure

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ABSTRACT

Introduction: Chronic anal fissure is a common condition associated with intense pain. Local botulinum toxin injection is a valid option in its management. The purpose of this study was to evaluate the efficacy of botulinum toxin on pain relief in chronic anal fissure patients.

Methods: We conducted a retrospective cohort study, involving 81 consecutive patients referred to a chronic pain management unit due to a chronic anal fissure for treatment with botulinum toxin, during a 4 year period. Data were collected from hospital records regarding pre-treatment and post-treatment pain (numeric rating scale), side effects, need for botulinum toxin reinjection and need for surgical treatment. We used standard statistical methods for inter (*t*-test and χ^2) and intra-group (paired sample *t*-test) comparisons, according to variables distribution.

Results: Pain intensity rest score significantly improved after BoNT injection [variation: -4.2 ± 2.9 ($p < 0.001$)], as did pain post-defecation score [variation: -5.1 ± 3.0 ($p < 0.001$)]. 8.6% needed botulinum toxin reinjection and 23.5% were submitted to surgery. Side effects were reported in 8.6%.

Discussion: The efficacy of botulinum toxin use on pain reduction along with its non-permanent and minor side effects support its role in the resolution of chronic anal fissure. However, treatment failure in the long term is still significant.

Conclusion: Botulinum toxin is effective on pain relief in patients with chronic anal fissure, which supports its inclusion in the management algorithm of this condition.

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Introduction

Anal fissure is a tear localized at the distal part of the anal canal.¹ Chronicity of this condition is often defined as a history of pain lasting more than 6 weeks.¹

It usually occurs between the ages of 20 and 40 with an equal distribution between men and women and an estimated lifetime incidence of about 8–11%.^{1,2} Most of the fissures are localized in the posterior midline.^{1,2}

Its pathophysiology includes several pathogenic factors. Constipation, resulting in hard and bulky stools usually triggers the initial event of a tear in the anoderm.³ The persistence of the fissure is justified by a vicious circle involving the hypertonia/spasm of the internal anal sphincter and pain caused by the ulceration and the passage of stools. Local ischemia of the anoderm also contributes to the non-healing of the fissure.³

Thus, most treatments, currently proposed, are aimed at achieving the relaxation of the internal anal sphincter.⁴ Conservative treatment is usually recommended as an initial approach and surgical treatment is usually reserved for refractory cases.^{4,5}

Numerous conservative therapeutic alternatives have been proposed, such as topical nitrates. Their role as inhibitory neurotransmitters in the relaxation of the internal sphincter is still being investigated and their prolonged use provides fissure healing in some patients.^{4,6} However, adverse effects (anal burning, headaches and hypotension) and escape phenomena (tachyphylaxis) often limits their prescription.^{4,6}

Surgery of the internal anal sphincter (irreversible lateral sphincterotomy) results in pain relief and fissure healing in more than 95% of cases.^{4,5} However, it can also induce fecal incontinence in up to 14% of patients and its costs are significantly higher than its conservative counterparts.^{7,8}

In that line of thought, injecting botulinum toxin (BoNT) into the anal internal sphincter eliminates the muscle spasm by blockage of neurotransmission, inducing a reversible chemical sphincterotomy while breaking the pain-spasm-pain cycle.^{9–12} BoNT injection for the treatment of chronic anal fissure has also been proven effective in alleviating anal pain.¹³ It constitutes a viable alternative and

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several studies have been conducted to investigate its real value in the management of this specific condition.⁹⁻¹²

It has also been used in combination with other conservative treatments¹⁴ or with less aggressive surgical treatments in order to try to maximize its effect and diminish the risks associated with classical surgeries.¹⁵

The main purpose of this study was to evaluate the efficacy of BoNT on pain relief in patients with chronic anal fissure. Secondly the measures of treatment failure and morbidity were also investigated.

Methods

We conducted a retrospective cohort study, involving 81 consecutive patients referred to a chronic pain management unit, by their assisting surgeon, due to a chronic anal fissure, for treatment with BoNT injection. Patients were recruited between January 2009 and December 2013.

Demographic and clinical data were collected from hospital records. Pre-treatment (T1) and 4 weeks post-treatment (T2) pain was accessed using a numeric rating scale (NRS) score (rest and post-defecation). Information on side effects, need for BoNT reinjection and/or surgical lateral sphincterotomy, was also retrospectively obtained.

The treatment consisted of 40 U of lyophilized BoNT (OnabotulinumtoxinA) diluted in 1 ml of isotonic saline solution. The internal anal sphincter was manually identified and injection was done using a 25-G needle, by three spots, two, lateral to the fissure (10U+10U) and another 20U anteriorly. All patients were reevaluated within 4 weeks of BoNT treatment. Patients were then followed by a general surgeon who verified the resolution of the symptoms or the need for additional treatment.

We defined non-responders as those needing subsequent treatment (BoNT reinjection and/or surgical lateral sphincterotomy) during the 12 months that followed the initial BoNT injection.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS® version 21). We used mean and standard deviation to describe continuous variables and proportions for categorical variables. For pain score variation evaluation, we used the paired sample *t*-test for intra-group comparison. For comparison between the responder and non-responder groups we utilized *t*-test for continuous variables and χ^2 testing for categorical variables.

Results

Of the 81 patients studied, the majority were male 44 (54.3%) with a mean age of 49.6 ± 15.3 years.

Only 66 (81.5%) had complete data for NRS (before and after BoNT). Those excluded were younger (mean age: 43.7 ± 15.7 years) and more frequently female (66.7%). NRS rest score significantly improved after BoNT injection [T1: 5.2 ± 2.9 ; variation: -4.2 ± 2.9 ($p < 0.001$)], as did NRS post-defecation score [T1: 7.4 ± 2.5 ; variation: -5.1 ± 3.0 ($p < 0.001$)] (Table 1).

Most patients had previously undergone other conservative treatment strategies including bulk aperients (bran or other forms of fiber), sitz baths and topical agents such as nitrates, calcium channel inhibitors or anesthetics. None of these treatments were successful in healing the fissure before the use of BoNT. There was no concomitant treatment with other medications during or after treatment with botulinum toxin.

A total of 23 (28.3%) non-responders were identified, 7 (8.6%) needed a BoNT reinjection of which 4 needed subsequent surgical treatment. In the end 19 (23.5%) patients were submitted to surgery.

There were no differences between groups (responders vs non-responders) regarding demographic characteristics and post-defecation NRS variation. However, there was significant difference in the improvement of rest NRS score favoring the responder group (Table 2).

Table 1
Pain scores variation after BoNT treatment.

NRS [*] score	Rest NRS T1	Rest NRS T2	Rest NRS T1-T2	<i>p</i> value	Def. NRS T1	Def. NRS T2	Def. NRS T1-T2	<i>p</i> value
Mean	5.2	1.0	4.2	<0.001**	7.4	2.3	5.1	<0.001**
Std. Dev.	2.9	1.8	2.9		2.5	2.4	3.0	

Bold values represent pain scores variation.

NRS: numeric rating scale; Std. Dev.: standard deviation; Def.: defecation; T1: before treatment; T2: 4 weeks after treatment.

* NRS – available results for $n = 66$; responders = 45; non-responders = 21.

** Significant for intragroup NRS variation ($p < 0.05$).

Table 2
Comparison between responder and non-responder groups.

	Conservative treatment response	Mean or proportion	Standard deviation	<i>p</i> value
Male sex	Responders	53.6%		0.811
	Non-responders	56.5%		
Age	Responders	48.5	15.2	0.266
	Non-responders	52.8	15.8	
Variation of rest NRS [*]	Responders	4.7	2.8	0.014**
	Non-responders	2.9	2.6	
Variation of defecation NRS [*]	Responders	5.0	3.1	0.855
	Non-responders	5.2	2.7	

NRS: numeric rating scale.

* NRS – available results for $n = 66$; responders = 45; non-responders = 21.

** Significant for intergroup comparison ($p < 0.05$).

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