



Original research

High-dose circumferential chemodenervation of the internal anal sphincter: A new treatment modality for uncomplicated chronic anal fissure: A retrospective cohort study (with video)



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HIGHLIGHTS

- Botulinum toxin injection into the anal sphincter is effective for anal fissures.
- High-dose circumferential chemodenervation (HDCC) with 100 IU botulinum toxin.
- HDCC achieved a healing rate of 90.7% at 3 months.
- At 2 weeks and 3 months, there were no major adverse outcomes.

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ABSTRACT

Background: Botulinum toxin injection into the internal anal sphincter is gaining popularity as a second line therapy for chronic anal fissures if medical therapy fails. The dosage of botulinum toxin reported ranged from 20 to 50 IU with no more than 3 injection sites and results in a healing rate of 41%–88% at 3 months. We propose a new injection method of high-dose circumferential chemodenervation of 100 IU in treating chronic anal fissure.

Methods: This was a retrospective review at a single academic center. 75 patients (50 women and 25 men) with uncomplicated chronic anal fissures underwent high-dose circumferential chemodenervation-internal anal sphincter (100 IU). We measured fissure healing, complication, and recurrence rates at 3 and 6 months post injection.

Results: Of the 75 patients, healing rate was 90.7% at 3 months follow up with the first injection and 81.3% with the second injection. The recurrence rates were 20.6% and 12.5% at 6 months after the 1st and 2nd injections respectively. Excluding 5 patients who lost follow up, the total healing rate of the study cohort was 100%. At 2 weeks and 3 months, there were no major complications including hematoma, infection, flatus, fecal, and urinary incontinence.

Conclusions: High-dose circumferential chemodenervation-internal anal sphincter (100 IU) is a safe and effective method for uncomplicated chronic anal fissure.

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1. Background

Anal fissure is a longitudinal split in the distal anoderm many

times extending to the internal anal sphincter. Internal sphincter hypertonia has been implicated as the pathophysiologic cause of anal fissures [1–3]. Anal fissure is quite painful and clearly affects the quality of life. Anal fissures are categorized as acute versus chronic and uncomplicated versus complicated. Acute anal fissures are treated conservatively with dietary modification, proper anal hygiene, and topical nitrates or calcium channel blocker applications. Anal fissure is defined as chronic after 6 weeks of conservative management [1,2]. A complicated fissure involves a concurrent

Acronyms: IAS, Internal anal sphincter; LIS, lateral internal sphincterotomy; HDCC, high-dose circumferential chemodenervation.

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anal condition such as abscess, fistula, sentinel pile, skin tag, hypertrophied anal papilla, and/or hemorrhoids.

For chronic anal fissure, surgery is currently the treatment of choice after conservative management fails [4–6]. The healing rate is reported up to 95% with lateral internal sphincterotomy (LIS). However, LIS has been associated with varying degrees of incontinence (up to 14%) [6–9]. Since it was first reported in 1993 by Jost and Schimrigk, botulinum toxin injection has gained popularity as a second line therapy if medical therapy fails [10–22]. The injection dosage reported in the literature ranges from 20 to 50 IU with injection sites either directly under the fissure or both sides of the fissure. No study exceeded 3 injection sites [22]. Healing rates reported have varied from 41% to 88% without irreversible incontinence [20]. In the literature, some reports suggest increased effectiveness with larger doses and with more injection sites [11–13]. More data is needed to establish the ideal dosage regimen and ideal injection site [22]. One commercial vial of botulinum toxin contains 100 IU so the cost is not an issue if the entire 100 IU is used during each treatment session. In approaching achalasia, it is standard of practice to inject 100 IU of botulinum toxin into the lower esophageal sphincter in divided dosage at four quadrants. As the internal sphincter hypertonia is likely not restricted at the midlines, the treatment should target the entire circumference of the sphincter. Therefore, we hypothesized that maximal reversal of internal sphincter hypertonia may be achieved with circumferential injections with resultant higher dosage of botulinum toxin. This may result in higher clinical healing rates.

2. Objective

In this study, we propose a new injection method of high-dose circumferential chemodenervation (HDCC) of 100 IU in treating chronic anal fissure.

3. Design and settings

Chronic anal fissure was defined as painful defecation with split or ulceration in the posterior or anterior midline location for at least 6 weeks. These were typical anal fissures. Jost categorized anal fissures into complicated and uncomplicated types based on whether the patients had skin tag or sentinel pile, etc [10]. In fact, he excluded these patients with “complicated anal fissure” from his study cohort and they did not receive botulinum toxin injection. The healing rate of his cohort was 79% using standard low dose of botulinum toxin. To compare the healing rates, we divided our study cohort into these two types and report their treatment outcomes using 100 units of botulinum toxin. Uncomplicated anal fissure was defined as anal fissure without concurrent anal conditions including abscess, fistula, sentinel pile, skin tag, hypertrophied anal papilla, and/or hemorrhoids. The healing rates of HDCC-IAS (100 IU) in complicated anal fissures is reported in a separate study. Since 2008, a single colorectal surgeon (CL) has been managing all patients with uncomplicated chronic anal fissures who failed conservative measures with HDCC-IAS (100 IU) without surgical sphincterotomy. Each patient had failed dietary modification, proper anal hygiene, and topical nitrates or calcium channel blocker applications for 6 weeks. Each patient was fully informed about the procedure and possible side effects of HDCC and gave their informed consent. This is a retrospective single center and single arm review that was approved by the Institutional Research Board at University of Mississippi Medical Center.

4. Interventions

HDCC is an anoscopy assisted percutaneous botulinum toxin A

(Botox[®], Allergan, San Francisco, CA, USA) injection involving greater than 8 injection sites in a circumferential technique under conscious sedation provide by anesthesia team (Video 1). The anal area and anal sphincters are circumferentially anesthetized with local injection of 15 ml of 1% lidocaine with epinephrine, 15 ml of 0.5% bupivacaine with epinephrine and 30 ml of normal saline. The IAS was located by palpation using a Pratt bivalve placed inside the anal canal. A total dose of 100 IU was diluted in 20 ml normal saline and injected while the patient was laying on his/her left side. A 20 ml syringe and a 21 gauge needle were used for injection. After injection, the patient was discharge home with conservative management.

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5. Main outcome measures

The patients were followed up after two weeks in clinic and assessed by the performing surgeon and then 3 months until the fissure healed. Post-injection complications were defined as hematoma, infection, flatus, fecal, and urinary incontinence. When the fissure failed to heal after prior injection, repeat botulinum toxin injection was performed at 3 months. After each subsequent injections, the patients were followed up the way as after the 1st injection: two weeks in clinic and then 3 months until the fissure healed. Follow up data were obtained by chart review and office follow up for a time period of 3–6 months following the procedure. Anal fissure healing was based on symptomatic relief and confirmed healing (complete epithelialization) on perianal examination. Recurrence was recorded for any recurrence of pain and reappearance of fissure on examination after healing.

6. Statistical analysis

Descriptive statistics were used to describe patient characteristics and outcomes.

7. Results

Of 75 patients, the 1st injection success rate was 90.7% at 3 months follow-up with an average healing time of 6.2 weeks (Fig. 1 and Table 1). The healing rate was 81.3% at 3 months with the second injection. The recurrence rates were 20.6% and 12.5% at 6 months after the 1st and 2nd injections respectively. Excluding 5 patients who lost follow up, the total healing rate of the study cohort was 100%. Only 3 patients needed more than 2 treatment sessions and they experienced complete fissure healing. A total of 6 patients developed transient flatus or fecal incontinence after the 1st injection, but shortly resolved within 7 days. There were no major complications following HDCC-IAS including hematoma, infection, flatus, fecal, and urinary incontinence after 2 weeks and 3 months.

8. Limitations

Retrospective, single surgeon, and single center experience.

9. Discussions

Anal fissure is a painful condition. Measured by high-resolution anorectal manometry with electromyography, patients with anal fissures had higher resting anal pressure than controls [3]. These patients have higher internal anal sphincter hypertonicity and reduced internal sphincter relaxation. Early data suggest certain waveform on anorectal physiological studies can predict response

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