

## BOTOX FOR ANAL PAIN: IS IT EFFECTIVE?

### Hypothesis / aims of study

Botox blocks acetylcholine release and causes reversible denervation of muscles, leading to relief of the anal spasm and pain associated with anal fissures (AF) and Levator Ani Syndrome (LS). The surgical options for treatment of AF is a lateral internal sphincterotomy. Chemical sphincterotomy offers a solution without surgery. Most LS patients do not have many options for symptomatic relief.

The aim of this study was to evaluate symptom relief after treatment with Botox in AF and LS.

### Study design, materials and methods

Patients who were treated with botox injections for anal pain due to a medically refractory AF or LS from 2005-2012 were included. Demographics and relevant clinical data was collected from the electronic medical record (EMR). Phone interviews were conducted with patients who had no follow up in the EMR. Patient satisfaction after treatment was assessed with visual analog pain scores for anal pain(0:no pain;10:worst pain).

### Results

66 patients (54 female) with AF and 37 patients (28 female) with LS with mean ages of 44 years and 54 years respectively were included. Duration of symptoms for AF was 1 month to 36 months and for LS 1 to 72 months. 64% AF patients had a posteriorly located anal fissure. The minimum/maximum dose of botox for AF was 20/100 units and for LS was 50/200 units with a majority of AF patients receiving 100 units and LS patients receiving 200 units.18(27%) patients with AF and 28(76%) patients with LS received >1 Botox treatment. Time interval between injections varied between 1-12 months. General or monitored anesthesia was used in 103 patients. Mean follow-up was 6 months for AF and 9 months for LS. Symptom resolution was noted in 59%AF and 43% LS patients. Mean pre/post treatment pain scores for both groups were 5.46 and 2 (P <0.001) for AF and 6 and 4 (P= 0.02) for LS. Overall <30 days complications were recorded as pain and bleeding in 15.3% and 2.8%. 9/12(75%) patients were relieved after a failed sphincterotomy.11 AF patients (17%) had a sphincterotomy after a failed botox treatment. Temporary fecal incontinence was reported in 3/66 (4.5%) AF and 3/37(8%) LS patients. 13/19(8 LS/5 AF) patients recommended botox treatment, 14 /19(9 LS/5 AF) patients were happy with the treatment.

### Interpretation of results

The dose of Botox is not standardized in anal conditions. Anal fissures were symptomatically better after Botox. Fecal incontinence as a result of the injection is temporary.LS patients received a much larger dose. Some LS patients received steroid injections concurrently.Relief of symptoms was seen in less than half the LS patients.

### Concluding message

Botox injections are a non-invasive option before a surgical option . Botox injections have an over all low complication rate.

Botox has more effect in symptom relief in AF than LS especially after failed sphincterotomy.

Botox is an option in medically refractory cases of LS. Higher doses of Botox are safe to use in LS however their efficacy needs to be evaluated.

<b>Results</b>	<b>Overall n = 103</b>	<b>Anal fissure n = 66</b>	<b>Levator Syndrome n = 37</b>
<b>Previous Treatment - Surgical</b>	12(11.6%)	12 (18%)	0
<b>Patients receiving &gt;1 injection</b>	46(45%)	18(27%)	28(76%)
<b>Concurrent steroid injection</b>	27(26%)	5 (7.5%)	22(59.4%)
<b>Symptom resolution</b>	55 (53.3 %)	39(59%)	16 (43% )
<b>Botox recommended : Phone Interview</b>	13/19 (68%)	5/7 (71.4%)	8/12 (66.7%)
<b>Symptom Improvement: Phone interview N=19</b>			
Improved/Much improved	11 (58%)	5/7 (71%)	6/12(50%)
Same	7 (36.8%)	2/7 (28.5%)	5/12 (41%)

### Disclosures

**Funding:** Internal : Department of Colorectal Surgery **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Institutional Review board of Cleveland Clinic **Helsinki:** Yes **Informed Consent:** No