

Introduction

Pain and discomfort is a primary concern of patients when undergoing clinical interventions. In an effort to improve a patient's experience during the course of elective botulinum toxin injections for cosmetic purposes, the physician should be well aware of all available analgesic methods. Each patient's experience of discomfort during botulinum toxin injection varies and appropriate analgesia in pain-sensitive patients may improve their overall experience, and avoid attrition due to pain avoidance.

Commonly used methods to decrease pain with botulinum toxin injection include toxin reconstitution in saline instead of sterile water, a slow injection rate, minimizing injection volume, and superficial injection with avoidance of deeper structures such as periosteum and sensory nerve fibers. Other methods commonly used include the application of ice prior to (and sometimes after) injection, the use of topical anesthetics and the use of neural distractors based on the gate control theory. Each of these interventions has their associated downfalls though, including additional time and cost.

In previous literature, the use of ice or a neural distractor has been shown to decrease injection pain but no studies have compared the two interventions. We sought to fill this gap in the literature.

Materials and Methods

A prospective, randomized, single blind clinical study was performed. All patients who presented to our outpatient clinic for the treatment of facial rhytids with botulinum toxin (BT) injection from September 2015 to February 2016 were candidates for the study. All patients were asked if they would participate in the study prior to seeing the physician. Once consent was obtained, the patients were randomly stratified into one of following three treatment cohorts: BT alone, BT with the synchronous use of a neural distractor, or BT after the application of ice to the injection sites for a total of 5 minutes.

Patients who were receiving BT injections for non-cosmetic purposes or had a documented neuromuscular disorders/neuropathy were excluded from the study. Botulinum toxin type A, Botox (Allergan, Irvine, CA), was used in this study. BT was diluted with normal saline to achieve a dilution of 3 U per .1 ml. For all cohorts, BT was injected into the forehead and the glabellar area. All injections were administered with a 1 mL syringe and a 30 G x 1/2 inch needle. For patients in the BT + neural distractor cohort, a vibrating hand piece was used. The distractor was placed within 2 cm of the injection site just prior to injection and was removed at the conclusion of the injection. For patients in the BT + ice cohort, an ice pack was applied to the patient's skin at the injections sites for at least 5 minutes prior to the injection. (Figure 1)

Immediately after injection, patients were asked to fill out a survey which included a visual analog pain scale (VAS) as well as subjective questions regarding overall comfort and site of greatest pain. The VAS scale ranged from "10" being the most unbearable pain to "0" in which there was no pain at all. Results were analyzed for statistical significance using one-way ANOVA and paired t-tests.

Figure 1



Results

The average pain scores for the control, neural distractor and ice cohorts were 2.37, 1.94 and 1.72 respectively. (Table 1) When analyzing the three cohorts together using one way ANOVA testing, there was no statistical significance amongst the three groups. The p value was 0.296 and the F value was 1.233. (Table 2)

When comparing each subgroup to one another with individual paired t-tests, there was also no statistically significant difference between groups. (Table 2) The ice vs control group had a p value of 0.1636 while the neural distractor vs control had a p value 0.2695. When ice and distractor were analyzed together, the highest p-value was obtained at 0.6122.

Table 1

	Ice	Neural Distractor	Control
Average Pain Score (0 - 10)	1.72	1.94	2.37

Table 2

	p value	F value
one way ANOVA	0.296	1.233
Ice vs Control	0.1636	
Ice vs Neural distractor	0.6122	
Control vs Neural distractor	0.2695	

Discussion

Overall, both the ice and neural distractor cohorts showed a trend toward decreased pain when compared to control. However, there was no statistically significant difference amongst the three groups regarding pain scores when using one way ANOVA or individual paired t-tests.

Looking at the individual paired t-tests, both the ice and neural distractor had lower p values when compared to the control, indicating that they tend to have better pain scores compared the control, but this failed to reach significance. Also, when the ice and neural distractor cohorts were analyzed together, the highest p-value was obtained, indicating less variance in pain scores between these two groups.

Unfortunately with failure to reach significance, no conclusions can be drawn to warrant one intervention over the other when attempting to minimize pain associated with botulinum toxin injections. Larger scale studies must be done to further evaluate these interventions. However, these interventions may be useful in patients who have a low pain tolerance, "needle phobia" or whom prefer the additional measures. It is equally imperative that the surgeon or practitioner communicate clearly with the patient to set expectations and assist in minimizing anxiety prior to injection.

Conclusion

Not all patients may desire or benefit from analgesic efforts during botulinum toxin injection. In patients whom qualify, the application of ice for a brief period prior to injection may aid in alleviating patient discomfort. The use of a neural distractor may also play a role in injection analgesia and does not increase visit duration. While no statistical significance was reached, several patients reported significant improvement in pain and overall injection experience when the distractor was used, even specifically requesting its use during future visits. Pain management during BT injections, as with all procedures should be based on setting accurate expectations and open communication between physician and patient prior to intervention.

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