Results of a New Botox Injection Paradigm for Treatment of Migraines: Anatomical, Regional, and Targeted (ART)

Michael Chung BS, Kyle Sanniec MD, Xingchen Li BA, Ali Totonchi MD, Bardia Amirlak MD FACS
Department of Plastic Surgery, UT Southwestern Medical Center, Dallas, TX

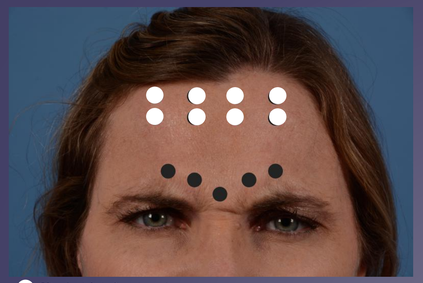
Introduction

Migraine headaches, a serious debilitating disease with no complete cure, affect 37 million people in the US. OnabotulinumtoxinA (Botox) is an effective prophylactic treatment for chronic migraines, with efficacy established by the Phase III Research Evaluating Migraine Prophylaxis Therapy (PREEMPT) landmark trials done by neurologists. The PREEMPT injection protocol is a shotgun approach targeting broad muscle groups, and no alternative injection technique has been studied for improvements in safety, efficacy, and efficiency. However, based on recent neurology studies and plastic surgery experience with nerve decompression surgery, we now know that Botox has direct effects on nerves and specific nociceptors such as TRPA1 and TRPV1. The Anatomical, Regional, and Targeted (ART) injection paradigm was designed by the senior author based on knowledge of topographical nerve locations, anatomical depth, regional location of the pain, and targeted physical examination. Results from this new injection protocol are reported here.

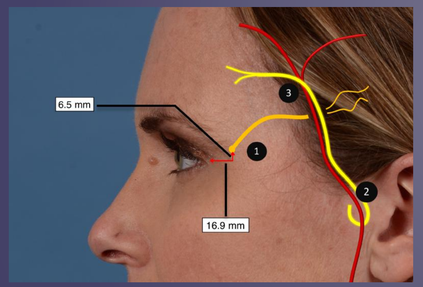
Methods

This study retrospectively reviewed 89 patients who underwent ART injection at University of Texas Southwestern Medical Center, each with previous failure of traditional medications. Of this group, 14 were excluded due to lack of follow-up, confounding treatments, or lack of migraine diagnosis. Based on rigorous patient interview, headache characteristics were reported in frequency, duration, and severity.

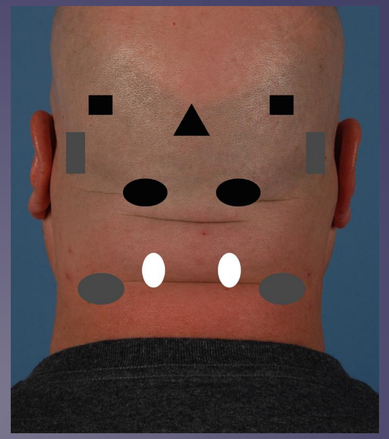
PATIENT CHARACTERISTICS	
Number of Patients	75
Average Age	44.9 years (SD=15.9)
Female	60 (80%)
Male	15 (20%)



- Site I : *high forehead*
- Site I : *Supraorbital nerve (SON), supratrochlear nerve (STN)*

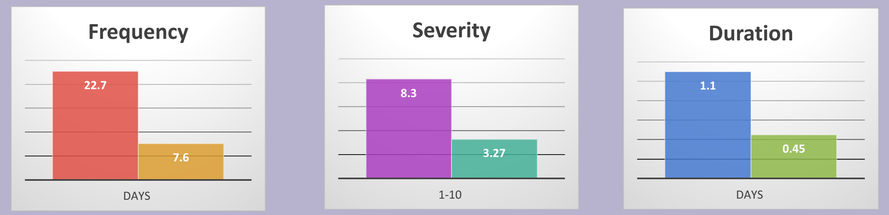


1. Site II : *Zygomaticotemporal branch of the trigeminal nerve (ZTBTN)*
2. Site Vb : *Proximal auriculotemporal nerve (AT)*
3. Site Va : *Distal auriculotemporal nerve (AT)*



- Occipital Protuberance
- 3rd occipital nerve (TON)
- Site IV : *Greater occipital nerve (GON)*
- Site IV+ : *Tail of GON*
- Site IV : *Lesser occipital nerve (LON)*
- Site IV+ : *Tail of LON*

Pre-ART and Post-ART Migraine Symptoms



Results

ART Botox injection resulted in significant reduction of all 3 measures (P<0.001), including mean reductions of 15.0 headache days per month, 5.0 points on a 1-10 severity scale, and 0.65 days in duration of headache episodes. 27% of patients experienced non-serious treatment-related complications, which is comparable with the PREEMPT rate of 29%. On average, 118 units were injected; 45% experienced complete elimination of symptoms, and 80% had at least a 50% reduction in frequency of headache days.

Measure	Pre-ART	Post-ART	Reduction
Frequency (days/month)	22.71 days	7.64 days	**15.07 days** (SD=9.59, P<0.001)
Severity (1-10)	8.30	3.27	**5.03** (SD=3.13, P<0.001)
Duration (days)	1.11 days	0.46 days	**0.65 days** (SD=0.74 (P<0.001)

INJECTIONS	MEAN	(SD)
Total Units Injected	118.0 units	39.9
Units in Site I (SON, STN and high forehead)	45.0 units	6.8
Units in Site II (ZTBTN)	26.1 units	6.4
Units in Site IV (GON and LON)	59.2 units	10.5
Units in Site IV+ (Tail of GON and LON)	18.2 units	9.6
Units in Site Va (Distal AT)	13.1 units	8.7
Units in Site Vb (Proximal AT)	8.8 units	5.5
Months Between Injections (Interval)	3.2 months	1.1

Adverse Effects	Count	%
Neck stiffness and nerve irritation	6	8.0%
Neck weakness	3	4.0%
Eyebrow ptosis	5	6.7%
Eyebrow asymmetry	3	4.0%
Double vision	1	1.3%
Difficulty swallowing	3	4.0%
Bothersome hourglass temple	1	1.3%
TMJ weakness (only with TMJ injections)	2	2.7%

Conclusion

ART is effective in reducing frequency, duration, and severity of migraine headaches. Headache days per month was reduced by 15.1 days, with an average of 118 units injected. In comparison, the PREEMPT studies demonstrated a mean reduction of just 8.4 headache days, using a minimum of 155 and up to 195 units. Although ART injections had a comparable rate of complications, the majority of these were not patient compliance limiting. While it is not a side-by-side comparison, this study suggests that the more dynamic ART injection technique may be more effective and efficient.

References

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