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Medscape Medical News

Efficacy of Botulinum Toxin Does Not Sag Over Time

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February 5, 2008 (San Antonio) — A number of studies presented here at the American Association of Dermatology 66th Annual Meeting demonstrated the long-term efficacy of botulinum toxin type A.

The effectiveness of a single treatment lasts approximately 3 to 4 months, and treatment can be repeated indefinitely without a loss in intended action, investigators said.

"Botulinum toxin has been used for more than 30 years. There is no muscle atrophy over time, except for some temporal muscle atrophy, but this is compensated for with extra muscle activity in the surrounding areas," said Amy Derick, MD, FAAD, formerly of the University of Chicago and now director of Derick Dermatology in Barrington, Illinois, in an interview with *Medscape Dermatology*.

In one study, Japanese investigators presented data showing long-term efficacy and safety of botulinum toxin type A for glabellar lines, with response rates persisting through 64 weeks of treatment.

Makoto Kawashima, MD, from the Department of Dermatology, Tokyo Women's Medical University, Japan, was the principal investigator of a study of 363 women presenting for treatment for severe glabellar lines.

Women were randomly assigned to received either 10 or 20 U botulinum toxin type A (*Botox*, Allergan Inc) or placebo. Injections were given at 5 glabellar sites at each treatment. This was repeated as necessary when moderate to severe frown lines (a score of 2 or 3 on a 3-point scale) were present and at least 12 weeks had passed since the previous treatment.

"Efficacy duration did not decline after multiple treatments," Dr. Kawashima and colleagues reported. "Improvement rates were greater than 90% at week 4 at each treatment cycle."

In addition, "[r]esponse rates declined more slowly [in the 20-U group] than in the 10U group and were higher at 12 weeks in each treatment cycle."

The mean efficacy duration was longer ($P < .001$) in the 20-U group (17.1 ± 6.58 weeks) than in the 10-U group (14.8 ± 5.38 weeks). There was no difference in depth of line at rest compared with depth at maximum frown.

Subjects rated the success of treatment at 4 weeks at 94.5% for 20-U injections compared with 84.3% for injections of 10 U. Overall satisfaction was 76.0% for 20-U injections and 61.8% for injections of 10 U ($P = .002$ at week 4 of each cycle).

The incidence of blepharoptosis was 3.3% for 10-U injections and 4.4% for 20-U injections, a difference that was not statistically significant.

Neutralizing antibodies did not develop in any of the patients.

Repeated dosing "did not affect long-term efficacy and safety," with efficacy more pronounced and patient satisfaction level higher with the larger dose, Dr. Kawashima's team reported. The investigators note that there actually are a number of anecdotal reports indicating that efficacy appears to, in fact, get stronger with success treatments.

"Botulinum toxin is completely safe, and it can be repeated whenever it is needed," Dr. Derick told *Medscape Dermatology*. "The muscles don't atrophy, with the exception of some temporary atrophy in the temporal area. It really is completely safe, and it has been used long enough to establish its safety. It is one of the safest treatments we use."

The Japanese study was funded by Allergan, Inc. Dr. Derick has disclosed no relevant financial relationships.

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