Botulinum Toxin Type A Promising for Poststroke Spasticity

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By Myra Partridge [1]

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A 50% improvement in function was seen in patients treated with botulinum toxin type A (BTX-A, Botox) for the reduction of spasticity in the wrist, finger, or arm after stroke. The need for caregiver assistance also decreased. These were the results of a multicenter open-label study presented at a joint conference of the American College of Rehabilitation Medicine and the American Society for Neurorehabilitation on September 30 in Boston.¹

"Our study shows the real-life functional improvements that patients experience after BTX-A injection and the effect it can have on their families," said Elie Elovic, MD, lead author of the study and director of the Traumatic Brain Injury Laboratory at Kessler Medical Rehabilitation Research and Education Corporation in West Orange, New Jersey, and associate professor in the Department of Physical Medicine and Rehabilitation at the University of Medicine and Dentistry of New Jersey in Newark.

The study included 279 stroke patients who presented with spasticity of the wrist, hand, or elbow at 6 months or more following stroke. The effects of treatment were measured using scales and questionnaires completed by patients, physicians, and caregivers. After 6 weeks of treatment with at least 200 to 400 U of BTX-A, muscle tone in the wrist, fingers, thumb, and elbow was markedly decreased compared with muscle tone at baseline. This improvement was sustained throughout the 1-year study.

Elovic said that both the physical administration of BTX-A and patient selection could determine the effectiveness of the therapy. "It's important to technically perform the task [of BTX-A administration], and it's important to choose patients with realistic goals for the intervention," he said. "We took patients with spasticity caused by brain injury, such as stroke, who had at least a moderate amount of spasticity, defined by a score of 2 on the Ashworth Scale. My patients had to have a disability that I thought could be effectively treated with this therapy. Together, the doctor and patient chose what the primary outcome variable would be."

Spasticity occurs in an estimated 19% to 38% of patients as a consequence of stroke. Upper limb spasticity can often result in skin deterioration, malodor, and difficulty in washing hands and dressing. For this reason, Elovic measured his patients' functional disability in 4 areas: hygiene, dressing, limb posture, and pain using the Disability Assessment Scale. Before the first treatment, patients selected 1 principal therapeutic intervention target. At least 50% achieved a 1-point or greater improvement in the area selected.²

"I don't treat tone just to treat tone. The issues individual patients have could be related to hygiene or the ability to dress himself or herself, for example," Elovic said. Posture could be an issue. Also, some patients' hands hurt when they are cramped up--so pain might be the issue."

Before treatment with BTX-A, 57% of patients reported being either moderately, very, or extremely limited in their mobility and walking ability because of impaired arm function. After treatment, 46% to 49% of these patients reported improvements in their ability to walk and in overall mobility. Tone in one part of your body, such as an arm that is tight and spastic, will throw you off balance," said Elovic.

Patients also reported improvements in their work activities. Before treatment, 79% of patients experienced significant impairment in performing their work because of impaired arm function. After treatment, 44% to 51% of these patients reported improvements in their work activities. Patients also required less assistance from family members. Before treatment, patients required an average of 26.2 hours per week of assistance by a caregiver, who took an average of 2.5 days per month off from work to provide care. After treatment, the average number of hours per week of assistance was reduced and the average caregiver's work time lost was reduced by an average of 1.5 days.
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Treatment-related adverse events, including transient mild to moderate muscle weakness or pain in the extremities, were reported in 6.5% of patients. No serious adverse effects were reported. "It's a very safe treatment, except for bruising or soreness in the muscles," said Elovic. "There are not a lot of possible systemic adverse effects, unlike with oral medications."

Elovic said that he expected to see these results from the study. "The assessment is a very important issue, and the 1-point assessment scale increase by 50% of patients who had limitations in daily activities did not surprise me," he said. "This is one of the classic mantras I talk about. The bottom line is that [treatment with BTX-A] can make the patient looser--but would you come to me to stick 40 needles in your arm to make your hand a little looser? Probably not. So, it's not just the tightness, it's often the suffering that is caused by the limitation of function. If a patient has a really tight hand and he lives in Maine and can't get a glove on that hand, it means something. If a patient can't wash his hands or can't get a shirt on, that's a major limitation in a daily activity."

However, Elovic pointed out that the study was limited because it was an open-label trial. "I think it was important to validate this information, but this study doesn't prove much right now. The next step would be a double-blind study," he said. "We are doing some of the work on this right now. But if you can't see the effects before and after in something like this, you'll never be able to distinguish the effects in a randomized controlled trial."

The results of this study clearly emphasize the need for careful patient selection, he said. "The key is function. We know we're [improving spasticity by making tone] looser; what we're searching for is functional improvement. You should have concrete objective goals before injecting someone with a medication--even if it has a low adverse effect profile."

REFERENCES


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