

Botulinum Toxin Type A: Once Feared, Now Revered

Rod J. Rohrich, M.D., and Jeffrey E. Janis, M.D.

Dallas, Texas

Nothing befuddles judgment as much as success, and nothing clears the mind more than failure.
—Paul Craig Roberts

Botulinum toxin, once known as a substance to be feared, is now perceived as a “wonder drug.” Although botulinum toxin has been used medically for more than two decades, recent magazine articles, television news reports, and advertisements supporting its safety and efficacy for cosmetic wrinkle improvement have resulted in a dramatic surge in demand. This demand has been further stimulated by recent Food and Drug Administration approval to use Botox (Allergan, Inc., Irvine, Calif.), a purified neurotoxin complex of botulinum toxin type A, for glabellar rhytides. More than 855,000 people were treated with botulinum toxin in 2001, according to American Society of Plastic Surgeons’ statistics, making it the number 1 nonsurgical procedure performed by board-certified plastic surgeons. There are no signs that this trend is slowing, and the number of patients treated this year is expected to skyrocket. Just as in the business world, supply of medical products must meet patient demand. More and more physicians have started to offer botulinum toxin injections to patients for both on-label and off-label purposes. Soaring patient demand has resulted in questionable practices by some physicians, both challenging our ethical standards and raising legal issues that have potential for disaster.

Botulinum toxin type A is a drug. The administration of this drug is classified as a medical procedure and should be performed by

qualified physicians who are familiar with the properties of the drug and the specific anatomy of the face. As with any drug, there is a potential for complications and adverse reactions if administered improperly.

Physician assistants or professional nurses who are properly trained and licensed may perform injections of botulinum toxin type A under direct supervision of a physician, under certain circumstances. These circumstances present a quandary that each physician must answer. Are you using botulinum toxin to cure wrinkles or for cosmetic facial shaping? If you are using it for wrinkle ablation, is it appropriate to use properly trained ancillary paramedical personnel who are properly supervised? If you are performing a cosmetic procedure, such as reshaping a patient’s eyes or brow, or correcting subtle asymmetries, then a physician should perform the procedure to ensure that secondary facial distortions are prevented. No matter who performs the procedure, the properly trained, licensed physician is ultimately responsible. Unsupervised injections or injections performed by medical professionals who do not possess proper qualifications and training can lead to undesirable consequences. The potential for abuse is great.

To meet demand and cater to patients, physicians have become involved in what have been called “Botox parties.” Typically, a number of prospective patients attend at a host’s private residence to receive botulinum toxin injections. Parties have also been reported in shopping malls, offices, and club meetings. Alcohol is frequently served, fostering a cocktail

The American Society of Plastic Surgeons has issued a policy statement entitled “PSN Resource Guides, Policy Statement: Administration of Botulinum Toxin,” which was approved by the Executive Committee in June of 2002. It is an excellent overview of the guidelines for the proper clinical and ethical use of botulinum toxin and can be accessed on the Society’s Web site at www.plasticsurgery.org.

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party atmosphere. For the unwary physician, this may seem to be an attractive venue where multiple procedures can be quickly performed. The shelf life of a reconstituted vial of botulinum toxin is limited; therefore, it is in a physician's best interests to use the entire vial without waste. These parties allow several injections to be performed at one time, thus lowering the cost to the physician and each patient. However, a recent American Society of Plastic Surgeons Web survey reports that although 57 percent of respondents plan to have botulinum toxin injections in the next 6 to 12 months, only 3 percent would feel comfortable receiving their treatment at a "Botox party." The vast majority of respondents (93 percent) felt most comfortable receiving treatment in a doctor's office.

The injection of botulinum toxin is a medical procedure, not entertainment for a party. Because it is a medical procedure, each patient must be carefully screened and properly selected. The procedure and the drug must be explained to each patient, along with the inherent risks and complications. After the patient fully understands the procedure, proper informed consent must be obtained. The alcohol frequently served at Botox parties can confound the informed consent process and may also lead to peer pressure from fellow partygoers to undergo botulinum toxin injections. Alcohol can have adverse effects with the concomitant administration of botulinum toxin type A. It may also adversely affect the physician's ability to administer proper dosages and influence ability to judge post-procedure reactions. Furthermore, the injection procedure should be performed at a medical facility with proper lighting, equipment, and staff. Although rare, possible complications such as accidental overdose and severe allergic reactions to the toxin can occur.

There have also been reports of marketing promotions by physicians in which botulinum toxin injections are awarded as prizes. Not only

is this practice considered unethical, but it has also been addressed in the recently released (June of 2002) American Society of Plastic Surgeons Policy Statement on the Administration of Botulinum Toxin. In fact, according to the Code of Ethics of the American Society of Plastic Surgeons and the American Society of Aesthetic Plastic Surgeons, this behavior may even serve as grounds for expulsion from our societies.

Botulinum toxin type A is a very useful product with excellent, yet temporary, benefits. Its addition to the tools of plastic surgery has had a substantial impact. As a board-certified plastic surgeon, I have used Botox for more than 4 years and continue to welcome its newly approved uses for our patients. Nevertheless, it must be used with respect for the drug and the patient. Proper patient selection is paramount, and sound clinical judgment during administration is imperative. Botulinum toxin injections should be performed by physicians or properly trained and licensed ancillary paramedical personnel under the direct supervision of a physician in a proper medical facility.

No matter how great the demand, we must avoid the temptation to cut corners or compromise our ethical standards to capitalize on the latest fad. A healthy respect for both the drug and the patient will help avoid potential injury and complications. In the end, the use of botulinum toxin is to be both feared *and* revered.

Examine each question in terms of what is ethically and aesthetically right, as well as what is economically expedient.

—Aldo Leopold

Rod J. Rohrich, M.D.

Co-editor, Plastic and Reconstructive Surgery
 Department of Plastic Surgery
 UT Southwestern Medical Center
 5323 Harry Hines Boulevard
 Suite E7.210
 Dallas, Texas 75390-9132
 rod.rohrich@utsouthwestern.edu