

CASE REPORTS: POTENTIAL FOREIGN BODY EMBOLI ASSOCIATED WITH BOTULINUM TOXIN A INJECTIONS

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Abstract

Although the injection of Botox Cosmetic for the treatment of dynamic rhytids is safe and effective, there is a potential risk for foreign body embolization. This case report documents the presence of a rubber particle in the reconstituted Botox product. Although the risk of embolization is thought to be very small because it is unlikely that the particle could be injected through most needle orifices, this risk can be eliminated through the use of No Kor needles. Alternatively, alteration of the manufacturing process for the bottle cap may reduce the risk of coring a piece of the cap during reconstitution. Injectors should be aware of this risk and visually inspect Botox prior to injection.

Introduction

Aesthetic treatments with Botox are now the most popular nonsurgical treatments in the US. Approximately 3.3 million people were injected with Botox in 2005 and this represented a 16% increase from 2004.¹ Reasons for the rapid increase in usage of Botox include the cost effectiveness, safety, and efficacy of the procedure. The procedure is associated with high patient satisfaction in validated testing and is also noted to improve patient self esteem.^{2,3} Most patients treated see results within 2 to 5 days following injection and many of these patients will become recurring patients. Reported complications from treatment with botulinum toxins include headaches, blepharoptosis (3%), flu-like symptoms, and bruising.⁴ Many of these symptoms are similar to those experienced by patients injected with placebo. One potential complication with any injectable product is an embolism of either product (if it is a solid or gel material) or of the packaging material. Since Botox is injected as a saline based liquid with no particulate matter present, the risk of product embolization is low. However, the risk from package embolization is not presently known. To date, there have been no reported emboli resulting from packaging material, yet this remains a possibility when certain reconstitution methods are employed.

Case Report

A 43-year-old woman presented for treatment of her glabellar complex as well as her periorbital rhytids. She had been treated with Botox several times in the past with good results and no complications. Dilutions used for her treatment were consistent with the standard dilution used by the physician injector (2 cc normal preserved saline per 100 units botulinum type A toxin).

Reconstitution technique was as follows: the cap was removed from the top of the bottle and the vacuum was broken using a 20-gauge B-D needle (Becton Dickinson, Franklin Lakes, NJ). Once the vacuum was neutralized, normal preserved saline was introduced into the Botox bottle using the same syringe used to break the vacuum. Two

mL of saline were utilized for reconstitution. The metal security ring was removed from the bottle using a scissors so that the material could be withdrawn without blunting the needle used for patient injections. There was no damage to the stopper during its removal.

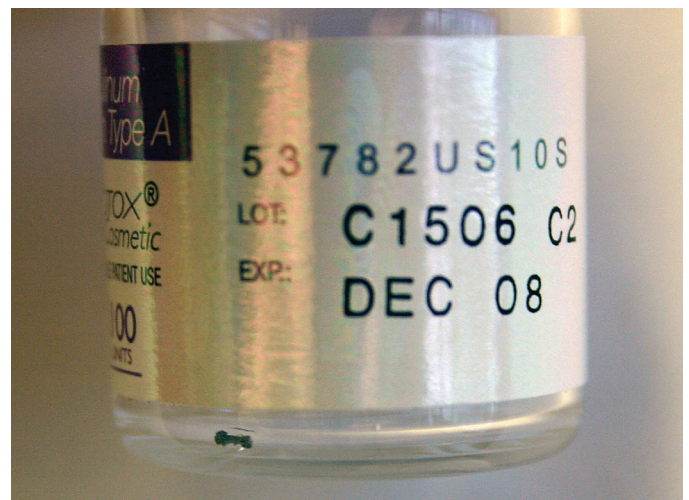
As standard practice, each syringe was visually inspected for air bubbles prior to injection. Upon placing the Botox bottle onto the equipment stand, a small object was noted in the bottom of the bottle. Inspection of this material was consistent with a rubber core from the stopper of the bottle. The size and shape of the core closely approximated that of the bore from the B-D 20-gauge needle (Figure 1).

At no point during the patient treatment was the core present in any material being injected. There was no risk of foreign body embolization in any patient injections.

Discussion

Treatment with botulinum toxins is one of the safest aesthetic procedures performed. Complications observed with

Figure 1.



treatment are typically mild and transient. However, the potential for long-term complications exist if an unintended, nonbiodegradable material is concomitantly injected with the botulinum toxin. To date, there have been no reports of this type of injection and the potential risk that this poses is not known.

It is worth discussing unexpected foreign body injections during injections with Botox for several reasons. The first and most important is that they are easy to avoid. Awareness of this potential and simple visual inspection of the bottle and syringe will preclude most instances of foreign bodies being present within injected botulinum toxins. This type of visual inspection is already recommended by the manufacturer and specified in the package insert but a public education campaign for physicians might help to promote this practice.

While at the present time, there is only one type A toxin commercially available in the US, this situation is about to change and it is not clear what material will be used for the newer type of toxin, nor what the attendant risk of foreign body hitchhiking will be.

A second reason that this potential problem is worth considering is that it may explain some seemingly irrational and unusual complications. For instance, the injection of small amounts of nonbiodegradable materials may result in a foreign body reaction at the site of Botox injections. Certainly, this type of reaction would be unexpected with a solution containing nanogram amounts of protein but would be consistent with a particulate that was injected unintentionally. There may be patients presenting to physicians following injections with Botox that have seemingly impossible reactions that may be explained by this phenomenon.

Finally, this potential issue should be considered during future manufacturing plans. Materials less likely to break off from the stopper could be used in subsequent products.

Conclusion

It is important to note that this article pertains only to the use of a needle size different from that specified in the package insert (a 21-gauge needle). It is not known whether the use of the 21-gauge needle will result in a similar coring of the stopper but the use of needles other than 21-gauge reflect common practice in cosmetic dermatology. There is also no information about the impact of other sized needles used to break the vacuum and it is possible that larger needles such as 18-gauge needles may deposit larger cores into the material to be injected. Finally, there is no information about the relevance of this type of coring (ie, whether or not the rubber cores can fit into the orifices of syringes commonly used for Botox injections). It would be worthwhile to determine whether cores from various sized needles are able to be aspirated into syringes used for Botox injections. For instance, one common syringe utilizes an integrated needle, making it impossible for a rubber core to be withdrawn into this system. Other systems, such as the “no

dead space” syringes used by many injectors, have relatively large apertures and could aspirate cores of rubber.

While Botox injections remain one of the safest and most effective aesthetic treatments available, one potential risk exists in the form of nonbiodegradable particles injected alongside botulinum toxin solutions. As illustrated in this article, simple precautions such as visual inspection of the material prior to injection can completely mitigate this risk. Consideration of this potential risk may lead to newer material utilized for packaging of cosmetic products that require reconstitution and newer recommendations for reconstitution procedures.

References

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