

# A Novel Variable Length Needle For Intravesical Botox Injection: Preliminary Results In Sixteen Patients

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## Abstract

Botulinum toxin-A (BTX-A) is a neurotoxin derived from the bacterium *Clostridium botulinum* and has its primary use in urology for treating overactive bladder syndrome (OAB) refractory to anticholinergics. The toxin is injected into the detrusor muscle through an injection needle during cystoscopic examination, which can be of different length and diameter. The needle is inserted into the bladder wall, followed by the injection of the toxin and the retraction of the needle. However, different bladder wall anatomy in different puncture sites may lead to superficial infiltration and bleb formation. Sixteen patients of either sex aged between 18 and 80 years (mean 43,6) with spinal cord injury with overactive bladder (OAB) symptoms and urodynamically proven neuropathic detrusor overactivity (NDO) with or without incontinence were submitted to botox cystoscopic injection. All injections could be performed without any clinically evident adverse events and none of the patients felt discomfort or pain. No systemic side effects were observed in any patient directly after the injection or during follow-up. The injeTAK needle has so far proven to be safe and may help urologist to obtain optimal botox injection regardless of differences in bladder thickness.

## INTRODUCTION

Botulinum toxin-A (BTX-A) is a neurotoxin derived from the bacterium *Clostridium botulinum*. It has been used in different medical fields to treat conditions predominantly associated with muscle overactivity. Urologists have focused primarily on treating overactive bladder syndrome (OAB) refractory to anticholinergics.<sup>1</sup> Evidence from randomized controlled trials have validated its use in neurogenic and idiopathic detrusor overactivity.<sup>2</sup>

The toxin is injected into the detrusor muscle during cystoscopic examination. The injection needle, which can be of different length and diameter, is inserted into the bladder wall, followed by the injection of the toxin and the retraction of the needle. This is usually performed at multiple sites of the bladder wall, depending on the technique and amount of toxin chosen for therapy.<sup>3</sup> Target structure of the toxin is the detrusor muscle, as its main mechanism of action is at the neuromuscular junction.<sup>4</sup> However, detrusor thickness is variable and depends on several factors such as gender, age, bladder filling volume and the presence of neurogenic lesion or obstruction.<sup>5</sup>

Although injection is performed under cystoscopic guidance, injection depth can only be estimated by the surgeon. Therefore, it remains difficult to estimate exactly in which

layer the toxin is injected and where it spreads out. The sole visual control could be a bulging of the bladder wall after injection. If a big transparent bleb forms, the injection was probably superficial in the mucosa, if a slight bulging of bladder wall tissue can be observed the injection was probably in the detrusor layer. But very often, no bulging can be observed at all and it remains a very insecure sign of a correct injection. The particular anatomy of the bladder and its distensibility during bladder filling makes it necessary to use a specific needle for injecting the toxin. The purpose of this article is to present a specific variable length needle for injecting botox in the detrusor bladder muscle.

## MATERIALS AND METHODS

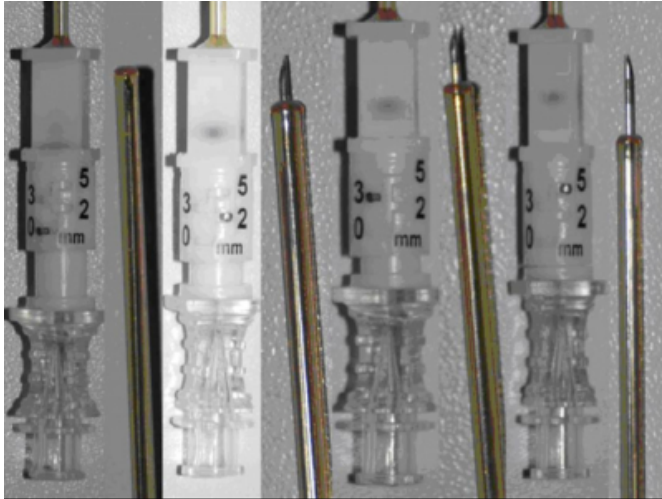
Sixteen patients of either sex aged between 18 and 80 years (mean 43,6) with spinal cord injury with overactive bladder (OAB) symptoms and urodynamically proven neuropathic detrusor overactivity (NDO) with or without incontinence were submitted to botox cystoscopic injection. They had failed a trial of anticholinergics owing to poor efficacy or tolerability. All patients gave written informed consent.

The injeTAK™ Adjustable Tip Needle was applied in all procedures, which consists of a metal needle cannula and an outer movable sheath with an attached adjusting mechanism. The needle sheath diameter is 6Fr with 35-50 cm in length,

The stainless steel needle cannula is 25 gauge. Needle tip length adjusting mechanism is used to adjust and set the relative distance between the distal needle point to the distal end tip of needle sheath in a range of 0-5 millimeter (mm). Numbers (0, 2, 3, 5) printed on handle of the adjusting mechanism are used to indicate the individual needle tip penetration lengths in millimeter unit. (Figure 1)

### Figure 1

Figure 1: Variable length needle from Laborie



The injeTAK needle permits the use of variable lengths during botox injection. The 2mm length is used when injecting the bladder dome, the 3 and 5 mm lengths are employed when injecting the bladder base and trigone due to the angle of injection (less than 30 degrees).

### RESULTS

All injections could be performed without any clinically evident adverse events and none of the patients felt discomfort or pain. No systemic side effects were observed in any patient directly after the injection or during follow-up. Bleeding from the injection sites was minimal and stopped shortly after retracting the needle. Bulking was observed in all injection sites and no transparent bleb formation was seen.

### DISCUSSION

Technologically speaking, the injeTAK Adjustable Tip Needle is a rigid and flexible needle intended to be accessory for common cystoscopes for the use of administering a variety of legally marketed drugs into tissues or structures during cystoscopic procedures.

Detrusor perforation during some of the injections is a described complication and should be suspected when contrast agent is detected outside the detrusor.<sup>2</sup> This is probably not uncommon following cystoscopic injections, as the surgeon can only estimate the relation of needle length to detrusor thickness. These two factors, e.g. needle length and detrusor thickness, are most crucial in regard to injection depth. In this context the variable length needle may be a simple useful approach to solving the problem without needing so much technical skills. The variable length needle can standardize the injection technique so as to make it even more comparable to future clinical studies.

### ACKNOWLEDGEMENTS

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