

THE CLINICAL RESPONSE OF OBSTRUCTIVE BENIGN PROSTATIC ENLARGEMENT (BPE) TO BOTULINUM TOXIN A (BTX-A) INJECTION LOCALLY. A REPORT ON SELECTED CASES WITH 12 MONTHS FOLLOW-UP

Hypothesis / aims of study

Obstructive BPE patients are usually managed successfully medically or surgically. While some fail medical treatment, others refuse surgical intervention due to subsequent ejaculatory dysfunction, and others are poor surgical candidates. In men, studies following BTX-A injection showed significant improvement of IPSS and flow rate, decreased prostate volume and PSA. This is a preliminary report evaluating the safety and efficacy of single injection into prostate with BTX-A toxin on both lower urinary tract symptoms (LUTS) and quality of life (QOL) in selected cases with obstructive BPE together with its correlation to PSA & TRUS volume changes.

Study design, materials and methods

18 patients with obstructive BPE were selected with mean age of 64.2±6 yr failing medical treatment, refusing the risk of retrograde ejaculation post TURP or with high anesthesia risk and/or impaired bleeding profile. All patients included had an international prostate symptom score (IPSS) >18, mean peak flow rate of 9.7±ml/s, mean prostate volume of 46.7± 6.9 ml, mean PSA 3.4±0.4 (<4) ng/dl and obstructed P-Q plot. Each prostate lobe was injected endoscopically with 2ml lidocaine reconstituted BTX-A100u in two sites. A 12 Ch silicone Foley's catheter was kept indwelling for 6 hours then removed. All patients received 2 weeks course of alpha blocker tamsulosin 0.4mg post injection. IPSS and peak flow rate Q max; prostate volume and serum PSA at baseline, 1, 3, 6 and 12 months after treatment were assessed and compared. Our study exclusion were either confirmed or suspected malignancy or previous BPH interventional therapy.

Results

We demonstrated improvement in IPSS by 32 % and 37 % during 6 & 12 months respectively. Free flowmetry demonstrated an improvement in Qmax between 33% and 40 % in 6 & 12 months respectively. There was no statistically significant difference demonstrated at 4 weeks for both IPSS & Qmax improvement (p>0.5) while, the changes were found statistically significant starting from 12 week & maintained significantly improving during the whole study period when compared to baseline (p<0.05). TRUS prostate volume demonstrated an improvement from baseline between mean of 32% & 42% during 6 & 12 months respectively (p<0.05). Serum PSA, demonstrated a significant drop from baseline by 41-50% respectively (p<0.05). Both TRUS volume & serum PSA changes were found to statistically significant when compared to baseline and were found well correlated as well.

Interpretation of results

Our data demonstrated & suggested the possibility of dual mechanism action of BTX-A injection in the prostate for both static (manifested by volume changes) & dynamic components manifested by early symptoms (IPSS & Qmax) improvement at 4 weeks and maintained throughout the study period.

Concluding message

Prostate injection with BTX-A could be an effective, well tolerated, and safe alternative treatment for selected patients with obstructive BPE who were either refusing or unfit for surgery. Further cases and longer follow-up with immuno-histochemical analysis are necessary to confirm this mechanism of action & its durability.

References

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 Novel action of botulinum toxin on the stromal and epithelial components of the prostate gland. *J Urol* 2006; **173**: 1158–63
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Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
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Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes