

## LOWER URINARY TRACT SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA IN DEVELOPING COUNTRIES: IS BOTULINUM TOXIN-A COMPLEMENTARY OR COMPETITIVE TO ETHANOL INJECTION?

### Hypothesis / aims of study

The goal of therapy for patients complaining of lower urinary tract symptoms (LUTS) of benign prostatic hyperplasia (BPH) is to reduce or alleviate lower urinary tract symptoms, to prevent complications, and to minimize adverse effects of treatment. Although trans-urethral resection of the prostate (TURP) is the gold standard of treatment of symptomatic prostate, there is increasing interest in alternative lines of management especially secondary to the patient's desire of avoiding surgery (1).

Intra-prostatic absolute alcohol prostatic chemo-ablation has satisfactory results since 1999 (2). Recently, Botulinum toxin type A (BTX-A) injection into the prostate gland induces selective denervation and subsequent atrophy of the prostate with diffuse apoptosis of the gland (3). Hence, it could be used for the treatment of common pathologies of the human prostate.

The aim of the present study is to compare the effect of intra-prostatic injection of ethanol and BTX-A, in patients with LUTS of BPH, with special attention to the financial costs at developing countries.

### Study design, materials and methods

Fifty patients, over the age of 55 years, complaining of LUTS of BPH were included in the present study according to their written desire and consent. All cases, had International Prostate Symptom Score (IPSS) of more than 6, maximum flow rate (Q<sub>max</sub>) between 5 and 15 ml/s of a voided volume of at least 150 ml, a residual urine volume more than 100 ml, and normal prostatic specific antigen level (PSA) (less than 2.4 ng/ml). The first group (25 cases) received intra-prostatic ethanol injection (not more than 15 ml). The second group (25 cases) received intra-prostatic BTX-A (200 IU). The patients were followed and evaluated at 3, 6 and 12 months.

### Results

The IPSS was significantly decreased in both groups during the follow up visits. It decreased from 21.3±5.2, to 9.5±3.4, to 8.3±3, to 5.5±2.9 following ethanol injection. Furthermore, it decreased from 22.1±4.7, to 9.9±4.1, to 8.1±3.3, to 5.2±3 following BTX-A injection. The Q<sub>max</sub> improved significantly in the ethanol group from 8.5±2.4, to 15.8±1.5, to 16.1±1.3, to 15.8±1.1. Also the Q<sub>max</sub> improved significantly among cases of the second group (BTX-A) from 9.2±2.9, to 14.6±2.1, to 15.9±1.7, to 16±1.2. The residual urine decreased significantly from 129±28.5 and 134±26.5 to 34±15.5 and 31.3±14.6 after one year, in both groups respectively. There was no significant difference in the prostate volume before ethanol injection and after 3, 6 and 12 months of follow up, from 53.3±11.9 to 51±8.9 gm. On the contrary, we reported significant decrease of the prostate volume following BTX-A injection after one year, from and 53.9±9.8 to 48.2±9.7. The cost of ethanol dose for one patient equals 0.2\$, while the BTX-A dose used for one patient was 450\$.

### Interpretation of results

Although the intra-prostatic injection of either absolute alcohol or BTX-A, are out of Food and Drug Administration approval, yet their clinical value and safety profile encourages their use in some patients with LUTS of BPH. The results of both drugs were comparable for decreasing IPSS, improving Q<sub>max</sub>, lowering the residual urine, hence improving the quality of life. On the other hand, BTX-A injection showed significant objective decrease of the volume of the prostate, possibly due to its selective denervation, apoptosis and gland atrophy (3).

### Concluding message

Intra-prostatic injection of either absolute alcohol or BTX-A is beneficial for patients complaining of LUTS of BPH, by improving IPSS, Q<sub>max</sub> and quality of life. Since, the cheaper ethanol dose compared to the BTX-A, it is preferable in the developing countries.

### References

1. J. Eururo., 06:001, 2004.
- 2 J. Urology 162:383,1999
3. J.Urology.10:077, 2005

**FUNDING:** Tanta University, Faculty of Medicine

**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study did not need ethical approval because The drugs used are safely applied to man with multi-centre approval, as well as, the written consent of all cases after illustrating the way of application, the clinical values and morbidity of the medicine. but followed the Declaration of Helsinki Informed consent was obtained from the patients.