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Sacco E[1], Bientinesi R[1], Marangi F[1], D'Addessi A[1], Racioppi M[1], Gulino G[1], Pinto F[1], Totaro A[1], D'Agostino D[1], Bassi P[1]

1. *Urology Department, Gemelli Hospital, Catholic University Medical School of Rome*

TREATMENT OF BLADDER NECK DISSYNERGIA WITH TRANSURETHRAL INJECTION OF ONABOTULINUMTOXINA: OBJECTIVE AND PATIENT-REPORTED RESULTS.

Hypothesis / aims of study

To determine if bladder neck injection of botulinum toxin A (BTA) in patients with bladder-neck dyssynergia (BND) is a feasible and effective alternative therapy [1].

Study design, materials and methods

A prospective single-armed cohort study was designed. From January 2008 to December 2010, male patients complaining of LUTS and diagnosed with BND on video-urodynamics, with an IPSS score≥15 and Qmax≤15 ml/sec and with unsatisfactory response to α-blockers were recruited. Patients with prior urethral or bladder surgery, benign prostatic enlargement (BPE) on cystoscopy or neurological disorders were excluded. Consenting patients received 200 UI of BTA (BOTOX®, Allergan) diluted in 4 ml of saline solution (50 U/ml) injected transurethrally into the bladder neck (4 sites, 1 ml/site) using a 22F rigid cystoscope in general anaesthesia (propofol). A Foley catheter was inserted transurethrally only in patients with postoperative urinary retention. All patients were discharged the next day after voiding without problems. Patients were assessed at baseline and at 2, 6 and 12 months postoperatively by means of uroflowmetry with postvoid residual urine volume scan (PVR), IPSS-QoL questionnaire and a self-administered Patient Reported Outcomes (PROs) questionnaire including questions on the Patient Global Impression of Improvement (PGI-I; range 1-7), of Satisfaction (PGI-S; range 0-5) and of Efficacy of the procedure (PGI-E; range 0-5) with higher score indicating better outcome. The primary outcome measure was a reduction of IPSS > 50% from baseline. The secondary outcome measures were maximum urinary flow (Qmax), PVR, IPSS-QoL item score and PROs.

Results

Of 34 consecutive patients fulfilling the inclusion criteria, 4 patients were excluded (two with sign of BPE at cystoscopy, one with bladder neck scarring and one non consenting to the study). Thirty patients were available for the final analysis, with mean age of 33.4 years (range 18-49) and mean duration of LUTS of 4.2 years (range 1-9). Mean duration of the procedures was 14 minutes. No systemic adverse effects occurred and 19 patients (63%) reported self-limiting local side effects related to the procedure: 15 (50%) haematuria, 16 (53%) stranguria, 5 (16%) postoperative urinary retention requiring transitory catheterization. A statistically significant reduction in mean IPSS from 21.6±8.6 to 7.9±5.9 was observed at 2 months follow-up (-63.4%; p<0.0001) and to10.6±6.8 at 6 months follow-up (-50.9%; p<0.0001), but not at 12 months (-17.6%, p=0.145), although IPSS values did not reach pre-treatment levels. The primary outcome was achieved by 22 (73%) patients at 2 months, by 20 (67%) patients at 6 months, and by 2 (7%) patients at 12 months. Mean reductions of S-IPSS, V-IPSS e IPSS-QoL scores were -45% (p=0.0083), -74.6% (p<0.0001) and -54% (p<0.0001) at 2 months, -43.9% (p=0.0081), -53% (p<0.0001) and -48% (p<0.0001) at 6 months and -13,4% (p=0.39), -17,9% (p=0.108) and -20% (p=0.005) at 12 months.

Qmax mean value increased from 7.9 to 17.1 ml/s at 2 months (p<0.0001), declining to 15.1 ml/s at 6 months (p<0.0001) and to 10.7 at 12 months (p=0.0087). Mean PVR decreased by 35.4% at 2 months (p=0.0061), by 34.1% at 6 months (p=0.0092) and by 16.4% at 12 months (p=0.4201). The analysis of PRO scores showed that 28 (93%) and 22 (73%) and 3 (10%) patients reported subjective improvement of LUTS (PGI-I score≥5), 26 (87%), 23 (77%) and 18 (60%) patients expressed satisfaction with the treatment (PGI-S score≥3), and 28 (93%), 22 (73%) and 20 (67%) patients considered the procedure effective (PGI-E score≥3) at 2, 6 and 12 months, respectively. At the last follow-up, 24 patients (80%) would recommend the treatment to someone else with the same problem and 26 (87%) would undergo the procedure again in the same circumstances. There was a statistically significant correlation between all PRO scores and the improvement of Qmax, IPSS and IPSS-QoL score.

Interpretation of results

Bladder neck injection of BTA is effective in improving subjective and objective parameters in patients with BND, at short/medium-term follow-up. The clinical benefit is confirmed by satisfying patient-perceived outcomes.

Concluding message

Bladder neck injection of BTA could be considered as a minimally invasive treatment option in patients with BND if the promising results of the present study will be confirmed in prospective randomized trials.

References

1. Lim SK, Quek PL. Intraprostatic and bladder-neck injection of botulinum A toxin in treatment of males with bladder-neck dyssynergia: a pilot study. Eur Urol. 2008 Mar;53(3):620-5.

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