394

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CHEMODENERVATION OF THE RHABDOSPHINCTER (EUS) ALONE VERSUS COMBINED INJECTION OF BOTH EUS & PROSTATE IN PATIENTS WITH PROSTATITIS AND CHRONIC PELVIC PAIN SYNDROME TYPE III. PROSPECTIVE RANDOMIZED CONTROLLED TRIAL.

Hypothesis / aims of study
Pelvic Floor dysfunction has been suggested in many patients with chronic prostatitis & chronic pelvic pain syndrome type III. Our aim is to elucidate whether there will be an additional benefits of intra-prostatic botulinum A Toxin (BTA) over injection of external urethral sphincter (EUS) alone in those patients with urodynamically proven detrusor external sphincter dyssynergia (DESD) & monitored by improvement of chronic prostatitis symptoms index(CPSI).

Study design, materials and methods
Fifty two male patients, with clinically proven chronic prostatitis & chronic pelvic pain syndrome type III after failure of several courses of medical therapy were selected from patients referred to the neurourology unit of the urology department for voiding dysfunction evaluation and management. All patients were selected according to the classification of NIDDK/NIH (type III) & underwent detailed medical history, laboratory, TRUS investigation & full urodynamics including EMG to EUS. All Patients were randomly allocated into two groups. GI included 26 patients (n=26) who received 100 units of reconstituted BTA toxin into EUS endoscopically. GII included another 26 patients who received combined injection of EUS & Prostate with 100 units for each. All Patients were followed up by NIH-CPSI that includes scoring for pain; urinary symptoms & quality of life impact at 12 weeks, 6 month, and 12 month were compared to baseline assessment. Urodynamic and TRUS evaluation were done at 12 week & at 12 month follow up.

Results
All patients included with age range from 25 to 48 years showed different degrees of both subjective & objective improvements in QOL and LUTS, flow rates and PVR. UDS-EMG evidenced regression in DESD in all Patients of both groups. Improvement of flow rate was shown as early as 4 weeks in GII patients. No Adverse effects were encountered in both groups of patients. 55 % of GI patients were scheduled for second session of combined chemodenervation following the same protocol for GII at the end of the study period.

Interpretation of results
GII patients showed statistically significant improvement in NIH-CPSI scores compared to GI patients ($p<0.05$). This could be explained by the ultrasonically proven reduction of prostate volumes at 6 month follow up in the former group of patients GII. None of GII patients needed second session of chemodernervation throughout the follow up period.

Concluding message
The presence of pelvic floor dysfunction & DESD among patients with chronic pelvic pain syndrome is an important factor responsible for the symptmatology of those patients with long standing history of chronic prostatitis type III not responding to all the known treatment regimen. Chemodenervation of the EUS and/or combined injection of EUS & prostate using Botulinum toxin is a safe, cost effective with an additional benefits among GII patients Intraprostatic injection of BTX –A who showed significant improvement in prostate volumes compared to GI confirming its role in controlling the whole scenario of the disease entity while further larger scale trials in different centers is warranted.

Specify source of funding or grant	**Local Health care provider**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ain shams university and saudi German hospital ethical committees**
Was the Declaration of Helsinki followed?	**No**
This study did not follow the Declaration of Helsinki in the sense that	**it is not submitted**
Was informed consent obtained from the patients?	**Yes**