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COMPARATIVE STUDY OF EFFICIENCY AND SAFETY OF INTRAPROSTATIC INJECTIONS OF BOTULINUM TOXIN AND POLIDOCANOL IN MEN WITH BPH AND LUTS

Introduction & Objectives

The botulinum toxin (BoNT-A) has been used in urology for therapy of patients with pelvic floor disorders, voiding dysfunctions such as overactive bladder, bladder outlet obstruction, neurogenic bladder and chronic pelvic pain. Recently few studies showed efficiency of intraprostatic injections of botulinum toxin in men with BPH and LUTS. The injection of BoNT-A into the prostatic tissue induces selective denervation and following atrophy. This results in improvement of IPSS, Qmax and reduction of prostate volume. Some other agents have been used for intraprostatic injections, such as ethanol. In 2007 we conducted a pilot experimental study of efficacy of aetoxysklerol (polidocanol) injection into the rat prostatic tissue. Aetoxysklerol (polidocanol) is regularly used for varicosity. The injection of polidocanol into the rat prostate induced prostate atrophy and resulted in reduction of prostate volume.

Material & Methods

According to the result of this study, we decided to implement this method to clinical practice and perform comparative randomize trial to assess efficacy and safety of aetoxysklerol (polidocanol) injections in men with BPH and LUTS and compare with results of BoNT-A intraprostatic injections. 60 patients participated in this study after written informed consent. Evaluation of patients was a performed (DRE, TRUS, urofloumetry, PSA). The mean age of patients was 61±8 years, mean IPSS was 26±3, mean prostate volume was 44.7±5.5cm3, and mean Qmax was 4.8±3.8ml/s. The patients were equally (randomized) divided into two groups. There were 30 patients in each group. Ultrasound-guided injections of 150 units BoNT-A into the each lobe of prostate through the N-DO endoinjector were performed in the patients of 1st group. Injections of 8 ml of 1.5% solution of polidocanol into the each prostate lobe were conducted in the patients of 2nd group.

Results

	BoNT-A	1st	group		Polidocanol	2nd	group	
	Baseline	1 mo	3 mo	6 month	Baseline	1 month	3 month	6 month
IPSS	25	15	12	12	26	14	12	11
Qmax(ml/sec)	5.1	11.2	12.7	11.3	4.6	12.3	14.6	16.2
Prostate volume(sm3)	43.9	37.4	35.3	33.9	45.5	35.1	32.8	31.7

The patients were evaluated within 6 month follow-up.

No early complications have been observed in both groups.

Conclusions

In our opinion, both methods showed the comparable effectiveness and safety. The intraprostatic injections of BoNT-A and polidocanol can be alternatives to surgical methods in patients with cardiovascular risk.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of Kuban State Medical University**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**