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Intra vesical injection of botulinum a toxin (btx-a) in the management of painful bladder syndrome /intersticial cystitis (a ranomized control study)

Hypothesis / aims of study
With the wide spread use of BTX-A in lower urinary tract dysfunction including
painful bladder syndrome and with encouraging results from some small pilot studies, we assessed the efficacy of BTX-A intravesical injection in patients with PBS/IC who did not respond to any of the conventional treatment modalities.

Study design, materials and methods
This Study started March 2008 and included 28 patients (23 women and 5
men),who were randomly divided into 2 groups:G1,18 patients(16 women&2men) were injected 200U of BTX-A diluted in 20ml normal saline, while GII,10 patients(7 women & 3men)injected normal saline only.
Submucosal injection was done under GA after cystoscopic examination & hydrodistention in both groups with video recording of the injection sites in a similar mapping in both groups.
Voiding chart, the Visual Analog Scale(VAS) for pain,Cystoscopic and Urodynamic assessment were performed pre&post treatment at 1,3&6 months.

Results
16 patients from G1(88%) reported significant improvement at 1,3&6 months follow up, mean VAS score significantly reduced (p<0.001), decreased frequency (p<0.00l) with increased bladder capacity 28% at three month follow up.
One patient only in GII reported subjective improvement which was non significant. No side effects detected in any patient

Interpretation of results
16 patients from G1(88%) reported significant improvement at 1,3&6 months follow up, mean VAS score significantly reduced (p<0.001), decreased frequency (p<0.00l) with increased bladder capacity 28% at three month follow up.
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Concluding message
Intravesical BTX-A injection is a very effective measure in management of painful bladder syndrome/intersticial cystitis,significantly reducing bladder pain,urinary
frequency and improve bladder capacity but still it is a short term management and reinjection is considered

Specify source of funding or grant	**no fundig for this research,but institutional study**
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	**Ain Shamas University Ethical Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**