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Kuo H[1], Liu H[1]
1. Buddhist Tzu Chi General Hospital

WILL SUBUROTHELIAL INJECTION OF DIFFERENT DOSE OF BOTULINUM A TOXIN HAVE SIMILAR THERAPEUTIC EFFECTS AND LESS ADVERSE EVENTS FOR REFRACTORY DETRUSOR OVERACTIVITY ?

Hypothesis / aims of study
To investigate if suburothelial injection of a small dose of botulinum A toxin (BoNT-A) can have similar therapeutic effect but less adverse events compared to 200U BoNT-A in patients with refractory detrusor overactivity.

Study design, materials and methods
Seventy-five patients with detrusor overactivity refractory to anticholinergics were enrolled and randomized to receive 100, 150, or 200U of BoNT-A injected into the suburothelial space at 40 sites. The therapeutic effects, adverse events and urodynamic parameters were assessed at 3 months.

Results
An excellent result at 3 months was obtained in 34.8%, 36%, and 40.7% of patients treated with 100U, 150U and 200U of BoNT-A, respectively. Patients who received 100U of BoNT-A had a lower incidence of large postvoid residual (PVR$\geq$150ml) than those who received 150U and 200U (30.4% vs 52% and 72%, respectively, p=0.011) after treatment. Urinary retention developed in 0%, 8% and 22% of patients receiving 100U, 150U and 200U of BoNT-A, respectively (p=0.025). The post-treatment urodynamic parameters were similar between the patients who received 150U and 200U of BoNT-A, but the changes of bladder capacity and PVR were greater than the patients treated with 100U. The duration of therapeutic effectiveness was significantly shorter in patients treated with 100U compared to those treated with 150U and 200U of BoNT-A.

Interpretation of results
This study has demonstrated that suburothelial injection of a smaller dose of BoNT-A (100U or 150U) had a similar overall therapeutic result compared to 200U of BoNT-A in patients with refractory detrusor overactivity. Significantly fewer patients who received 100U of BoNT-A had post-treatment large PVR or episode of urinary retention compared to those who received 150U or 200U. However, patients who received 100U of BoNT-A had a significantly shorter duration of therapeutic effectiveness compared to those treated with 150U or 200U. From the results of this study, it seems rational to use suburothelial injection of 200U of BoNT-A as an initial treatment for NDO to achieve a higher rate of excellent result. However, for patients with IDO, 100U of BoNT-A seems adequate to achieve an excellent result. The adverse events such as urinary retention or large PVR can be prevented in most of the patients treated with 100U of BoNT-A. However, frequently repeat treatment might be necessary due to short duration of the therapeutic effect of 100U of BoNT-A.

Concluding message
Suburothelial injection of 100U of BoNT-A achieved a similar rate of excellent result and had significantly fewer adverse events compared to 150U or 200U. The dose of suburothelial BoNT-A has impacts on the duration of therapeutic effectiveness and the occurrence of post-treatment adverse events.

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the IRB of Tzu Chi General Hospital, Hualien, Taiwan and followed the Declaration of Helsinki Informed consent was obtained from the patients.