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# WHEN DO WOMEN WITH IDIOPATHIC OVERACTIVE BLADDER STOP THE BOTULINUM TOXIN INJECTIONS?

Hypothesis / aims of study
Intra-detrusor Botulinum Toxin A (BTX-A) has been considered the 21st Century “Penicillin for the Bladder”. Repeat injections are safe and effective. The aim of this study was to evaluate the drop out and loss to follow-up rates, and anticholinergic therapy requirement in poor responders in relation to the number of required injections.

Study design, materials and methods
Prospective observational study of women undergoing intravesical Botulinum Toxin A injections with 500-1000u of Dysport® for refractory OAB. Inclusion criteria include symptoms of more than 6 months duration and failure to respond to, severe side-effects on taking or contra-indication to anticholinergic therapy. All women underwent baseline urodynamic testing and were reviewed pre and post therapy with patient based questionnaires assessing symptoms and QoL. Outcome was based on urinary diary and symptom questionnaires.

Results
Eighty three women with idiopathic OAB underwent one or more intradetrusor botulinum toxin injections (Dysport) (table 1). The intervals between injections are shown in table 2. In 4/83 women the OAB symptoms were cured after the first injection and did not required further treatment. Eight women required anticholinergic therapy during the course of botulinum toxin or after refusing further injections. Twenty one women were lost to follow up (n=11) or refused further injections (n=10) as they did not experience significant improvement of their symptoms (table 3). The remaining women are still under surveillance and have further injections as indicated by their symptoms.

Interpretation of results
The majority of the women undergoing botulinum toxin injections who are lost to follow up or refuse further treatment, do so after the first (n=9) or the second (n=10) injection. This observation may be helpful in the counselling of those women requiring multiple injections of botulinum toxin and the decision making on further treatments.

Concluding message
The majority of patients with refractory OAB require more than one botulinum toxin injections and a significant number of them require concomitant oral anticholinergic therapy to control their symptoms. Loss to follow-up or drop out is common and is usually observed after the first or second injection, probably representing dissatisfaction with treatment. Treatment for this difficult syndrome should be individualised and include detailed counselling about the possible outcomes, success and drop out rates.

Table 1. Number of women requiring multiple injections.

| Number of Dysport injections | Number of women | % |
|---|---|---|
| 1 | 29 | 35 |
| 2 | 30 | 36 |
| 3 | 10 | 12 |
| 4 | 4 | 5 |
| 5 | 9 | 11 |
| 6 | 1 | 1 |
| Total | 83 | |

Table 2. Intervals between injections.

| | Mean values (median, SD) | | | |
|---|---|---|---|---|
| | 1st-2nd | 2nd-3rd | 3rd-4th | 4th-5th |
| Intervals between injections (months) | 10.8 (10, 3.6) | 11.6 (9, 5.7) | 12.2 (12, 4,7) | 11.9 (12, 5.9) |

Table 3. Drop out, lost to follow up and cure rates in relation to number of injections.

| **Number of injections** | Lost to Follow up | Refused more injections | Cured |
|---|---|---|---|
| **1** | 5 | 4 | 4 |
| **2** | 5 | 5 | |
| **3** | 1 | 1 | |
| **Total** | **11** | **10** | **4** |


| | |
|---|---|
| ***Specify source of funding or grant*** | **No funding or grant.** |
| ***Is this a clinical trial?*** | **No** |
| ***What were the subjects in the study?*** | **HUMAN** |
| ***Was this study approved by an ethics committee?*** | **Yes** |
| ***Specify Name of Ethics Committee*** | **London, Surrey and Borders Research Ethics Committee.** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |