INTRODUCTION

- Botulinum Toxin-A (BTX-A OnabotulinumtoxinA, Allergan, Ltd) has been shown to be effective at treating refractory idiopathic OAB.
- Success rates vary between 60-80%.
- However, there are associated adverse events which include: Voiding dysfunction necessitating catheterisation (CISC) affecting 6-45% of patients and Urinary Tract Infections affecting 0-45%.
- Currently, there is limited data in the literature in predicting both response to BTX-A as well as adverse events.

AIMS

- To identify patient factors that can be used to predict poor response after first time BTX-A injections in a cohort of patients with refractory idiopathic OAB.
- To identify patient factors which can be used to predict adverse events (UTIs and voiding dysfunction).
- Predicting response and adverse events will allow for better patient selection and counselling.

METHODS

- Single centre, retrospective analysis of a dedicated database of patients who received their first BTX-A injections (100-200 U) to treat symptoms of refractory overactive bladder and idiopathic detrusor overactivity.
- 74 OAB patients (50 female and 24 male) had completed the UD-II questionnaire, filled in at baseline and at 4-6 weeks post-injection.
- < 16.7 reduction in score on UD-II indicates a poor response based on validation studies (MID).
- Occurrence of adverse events (UTIs and voiding dysfunction requiring CISC) were recorded from the database/ electronic patient records.
- Data on baseline patient demographics, urodynamic parameters as well as past medical and surgical history of each patient was collected.
- Preliminary independent samples T-tests or Pearson’s Chi-Square tests comparing various patient factors and outcomes were performed. Subsequent univariate and multivariate logistic regression (forward stepwise method) analysis was performed to identify risk factors.
- Results were considered significant if P <0.05 for a variable with a two-tailed test on multivariate analysis.
- Variables assessed were age, gender, diastolic status, prostate surgery history, incontinence surgery, hysterectomy status, menopause status, prostate surgery Hx and BTX-A dosage.
- The baseline urodynamic parameters assessed were post-void residual volume (PVR), maximum cystometric capacity (MCC), maximum detrusor pressure (MDP), reflex detrusor volume (RDV), maximum urinary flow rate (Qmax), detrusor pressure at Qmax, bladder compliance (BC), projected isovolumetric pressure in females (PIP1) and bladder contractility index in males (BCI).

RESULTS

Only Significant Results Displayed

### Frequency of Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Overall Frequency (%)</th>
<th>Frequency by Gender</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor Response</td>
<td>23 (31.9)</td>
<td>Male: 13 (54.2)</td>
<td>72</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female: 10 (20.8)</td>
<td></td>
</tr>
<tr>
<td>CISC</td>
<td>32 (43.8)</td>
<td>Male: 15 (62.5)</td>
<td>73</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female 17 (34.7)</td>
<td></td>
</tr>
<tr>
<td>UTI</td>
<td>25 (34.2)</td>
<td>Male: 7 (29.2)</td>
<td>73</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female: 18 (36.7)</td>
<td></td>
</tr>
</tbody>
</table>

### Predictors of Poor Response

- Gender (male)
  - OR for Poor Response (95% CI): 5.45 (1.83-16.47)
  - p-value: 0.002
  - n: 70

### Predictors of UTIs

- Pip1 (females only)
  - OR for UTI (95% CI): 0.93 (0.87-1.00)
  - p-value: 0.050
  - n: 33

### Predictors of Voiding Dysfunction necessitating CISC

- Qmax (95% CI): 0.91 (0.83-0.99)
  - p-value: 0.023
  - n: 54
- Gender (Male): 5.14 (1.41-18.72)
  - p-value: 0.013
  - n: 54
- Hystrectomy: 4.55 (1.09-18.87)
  - p-value: 0.038
  - n: 47

### Relationship between CISC and UTI

- UTI Rate (95% CI): 8.6
  - p-value: 0.023
  - n: 64

### Predictors of Voiding Dysfunction necessitating CISC

- Multivariate Logistic Regression
  - Variable | Odds ratio for CISC (95% CI) | p-value | n  |
  - Qmax     | 0.91 (0.83-0.99)             | 0.023   | 54 |
  - Gender   | 5.14 (1.41-18.72)            | 0.013   | 54 |
  - Hysterectomy | 4.55 (1.09-18.87)          | 0.038   | 47 |

### Predictors of UTIs

- Multivariate Logistic Regression
  - Variable | Odds ratio for UTI (95% CI) | p-value | n  |
  - Pip1 (females only) | 0.93 (0.87-1.00) | 0.050 | 33 |

### Multivariate Logistic Regression

- CISC
  - OR for UTI (95% CI): 5.26 (1.38-20.00)
  - p-value: 0.015
  - n: 50

CONCLUSIONS

- Men were at 5.45 times increased odds of having poor response compared to females in this cohort.
- In terms of predicting adverse events, male sex and a lower baseline maximum urinary flow rate (Qmax) was associated with needing CISC.
- In addition, women post hysterectomy were at 4.6 increased odds of needing CISC post BTX-A compared to women without.
- A lower Pip1 (a detrusor contractility variable measured in women) put women at higher risk of contacting a UTI post-BTX-A.
- Patients requiring CISC were at 5 times increased odds of contracting a UTI.
- No relationship was found between adverse events and poor response meaning efficacy of BTX-A was independent of adverse events.

REFERENCES