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CLINICAL AND QUALITY OF LIFE OUTCOMES IN MALE NON-NEUROGENIC OVERACTIVE BLADDER MANAGED WITH INTRA-DETRUSOR BOTULINUM TOXIN TYPE A: AN 8 YEAR EXPERIENCE

Hypothesis / aim of study

There is a paucity of data on the clinical outcomes of men with drug-refractory non-neurogenic overactive bladder (NNOAB) managed with intradetrusor botulinum toxin type A (BTXA) injections. The aim of this study was to assess the efficacy of cystoscopically administered BTXA injections in men with NNOAB.

Study design, materials and methods

Data was collected prospectively from all men in a single institution who received intra-detrusor BTXA injections for drug-refractory NNOAB from 2004 to 2012. All patients underwent urodynamics prior to BTXA injection and had previously trialled at least one anti-cholinergic medication. A total of 68 injections were given amongst a group of 43 men. Health-related quality of life (HRQOL) was measured using the Patient Global Impression of Improvement (PGI-I) score. For men with wet NNOAB, change in number of pads per day was also assessed. Only response to the first injection was included in this study. PGI-I score as well as pad usage was assessed at 1-4 months post-injection. Apart from being analysed as a whole group, men were subdivided into groups based on whether they had had prior prostatic surgery (transurethral resection of the prostate (TURP) or radical prostatectomy (RP)) or not. Average PGI-I score and pad usage were obtained for each group and results compared using students t-test.

Results

43 men with a mean age of 69 (range 36-85) received at least one injection. Of the 43 men, 20 (47%) had had prior prostate surgery – 11 men had had RP and 9 had had TURP. PGI-I scores were available for 41 (95%) patients. Data regarding continence status and pre- and post-injection pad use was available for 34 (79%) patients. On urodynamics, 36 men (84%) had detrusor overactivity, 4 men (9%) had both detrusor overactivity and reduced compliance and 3 men (7%) had reduced compliance alone. Of those with reduced compliance, 2 were in the no surgery group, 3 in the RP group and 2 in the TURP group. No men had a normal filling phase. 4 men (9%) had had previous radiotherapy – 3 in the no surgery group and 1 in the RP group. 5 men (12%) had had previous incontinence surgery (all following RP) - 4 AUS and 1 AdVance sling. In terms of incontinence, all men in the RP group, 80% in the TURP group and 30% in the no surgery group were suffering from some degree of incontinence preinjection. Post-injection, for all men, mean PGI-I score was 2.7±0.4 (mean ± 95%CI). When comparing men who had had prior prostate surgery with men who had not had prior prostate surgery, there was no statistically significant difference in PGI-I score, 2.6 ± 0.5 and 2.8 ± 0.5 respectively (p > 0.05). When comparing men who had had previous TURP with men who had had previous RP, there was a statistically significant difference (p < 0.05) in PGI-I score: 3.3±0.8 and 2.0±0.5 respectively. Men who had undergone surgery experienced a statistically significant reduction in pad use $(2.8\pm1.2 \text{ to } 1.6\pm0.7 \text{ pads/day}, p < 0.05)$ whereas men who had not undergone surgery did not $(0.8\pm0.7 \text{ to } 0.3\pm0.4 \text{ pads/day}, p > 0.05)$. Men who had RP experienced a statistically significant reduction in pad use (3.5±1.7 to 1.6±0.9 pads/day, p < 0.05) while this was not the case amongst men who had TURP $(1.7\pm1.5 \text{ to } 1.4\pm1.5 \text{ pads/day}, p > 0.05).$

Interpretation of results

When considering the overall effect of BTXA in men, a benefit is offered, with a PGI-I score of 2.7±0.4 – "a little better" to "much better".

When men who had prior prostate surgery were compared to those who had not had prior prostate surgery, there was no significant difference in improvement in symptoms between the two groups. When considering those men who had had previous RP, it was interesting to note that they of all others did show the greatest symptomatic improvement with a PGI-I score of 2.0 ± 0.5 – "much better". When considering men who had had previous TURP, it was also interesting to note that compared to all others, they did show the least symptomatic improvement with a PGI-I score of 3.3 ± 0.8 – "no difference" to "a little better". While this study does not give a reason for this difference, we would suggest that this difference lies in the fact that men who have undergone TURP were previously suffering from chronic bladder outlet obstruction: long standing raised intra-vesical pressure with subsequent detrusor hypertrophy and fibrosis. This adds to the complexity of their pathology and so it is not surprising to see a difference in response to BTXA injection.

Furthermore, whilst there was a statistically significant improvement in pad usage in the surgery group but no difference in the no-surgery group, there was no statistically significant difference in PGI-I score between the two groups. The lack of a statistically significant improvement in pad usage in the no-surgery group is possibly due to the fact that there were fewer patients suffering from incontinence in this group compared to the surgery group. Amongst the patients who did have surgery, it was only those who had RP that demonstrated a statistically significant reduction in pad usage. This is possibly due to the fact that men who have had RP have a relative degree of sphincter deficiency and would be more likely to suffer from incontinence from a lesser degree of detrusor overactivity than men whose sphincteric function was more fully preserved.

This study shows that even the male cohort is in itself a heterogeneous one, let alone combining both men and women in the same study group. A man who has had RP for prostate cancer is different from a man who has had TURP for BPH and suffered from bladder outlet obstruction for many years.

<u>Concluding message</u>
Overall, BTXA injections in men with drug refractory NNOAB do provide a symptomatic benefit both in men who have had prior prostate surgery and in men who have not. Amongst men who have had prior prostate surgery, men who have had RP experience a greater benefit than men who have had TURP, both in regards to PGI-I score and pad use. This data would be useful when counselling male patients about the outcome of BTXA injection and adds to clinical outcome data on BTXA use in men, which is currently lacking.

Disclosures

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