

ARE ANTIMUSCARINICS REALLY EFFECTIVE IN SPINAL CORD INJURY (SCI) PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY (NDO)?

Hypothesis / aims of study

Spinal cord injury (SCI) patients with supra-sacral lesions often present with neurogenic detrusor overactivity (NDO) causing NDO incontinence episodes. These patients are at high risk for upper urinary tract (UUT) deterioration caused by vesico-ureteral reflux. Antimuscarinics (AMs) are recommended by the major international guidelines on Neurourology as the first line treatment for NDO, despite the fact that some AMs have been extensively tested only in idiopathic patients. Furthermore, data on the “real life” efficacy of these drugs are lacking.

Aims of this observational study was to evaluate clinical and urodynamic results of AMs in SCI patients, to understand how many subjects may benefit of this treatment in a “real life” setting.

Study design, materials and methods

Patients with NDO secondary to supra-sacral SCI were included in this observational study. All patients were evaluated at baseline by means of history, 3-day bladder diary and urodynamic (UD) examination. After the initial evaluation patients were prescribed AMs therapy; all patients were then re-assessed after 4 week of AM therapy (T1) by means of UD examination and 3-day bladder diary data. Patients were considered clinical responders to AM therapy if they showed a reduction >50% of n° of incontinence episodes per day; patients were considered urodynamic responders on the basis of a general urodynamic improvement sufficient, in the opinion of the operator, to ensure safety to the UUT. The observational study was stopped when 100 patients had been included. All data were collected in a specific database. For statistical purposes, we decided to include in the study the first 100 consecutive patients studied. Statistical analysis was performed by means of t-test. Data were considered statistically significant with $p < 0.05$.

Results

One hundred patients were included in the study (21 females & 79 males). Patients mean age was 38,3 (± 12 years). Lesion level was cervical in 30 cases, dorsal above D6 in 32, dorsal below or at D6 in 38. All patients had been treated for 4 weeks with oxybutynin (65 pts), solifenacin (20 pts), propiverine (8 pts) and tolterodine (7 pts). At 4 weeks visit, 62% of patients were considered clinical responders; 83.9% of them were considered urodynamic responders; 57% of patients were considered urodynamic responders and 89.5% of them were considered clinical responder.

Urodynamic parameters showed a general improvement even if only bladder filling at first detrusor contraction was significantly changed during treatment (baseline: 167.57 \pm 73,621 mL; T1: 229,26 \pm 121.92 mL. $p=0.000267$). DO was still present in 85% of patients and 60% of patients who showed NDO incontinence during the UD examination.

Interpretation of results

Despite several limitations, this observational study provides interesting informations on AMs efficacy in SCI patients with NDO. Our data confirm that AMs are effective, obtaining clinical and urodynamic improvements in this population. On the other hand, around 40% of patients does not respond to AMs in an observational study setting. Furthermore, many patients do not show safe urodynamic parameters at the UD evaluation. This finding seems to indicate that around 2 out of 5 patients need further (second line) treatments to improve their symptoms possibly preserving their UUT. Furthermore, there is an incomplete correlation between clinical and urodynamic efficacy of AMs.

Limits of this study are: subjective definition of “safe” urodynamic parameters (this choice was due to the absence of strong evidence in literature on this point); non randomized design; different AMs used. Strengths are: “real life” data, not coming from a rigid study protocol.

Concluding message

AMs are effective in around 60% of suprasacral SCI patients with NDO, with clinical and urodynamic improvement demonstrated. On the other hand, around 40% of patients does not respond to AMs. Furthermore, there is an incomplete correlation between clinical and urodynamic efficacy of AMs and urodynamics seem the only method to evaluate the risks of UUT risk of deterioration.

References

1. Eur. Urol. Volume 69, Issue 2, Pages 324–333

Disclosures

Funding: None **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Tor Vergata University Hospital Ethics Committee **Helsinki:** Yes **Informed Consent:** No