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## URODYNAMIC ASSESSMENT IN SPINAL CORD INJURED MALE AFTER VARDENAFIL ADMINISTRATION

### Hypothesis / aims of study

Recent clinical trials reported that phosphodiesterase type-5 (PDE5) inhibitor (PDE5i) could reduce lower urinary tract symptoms in ED and LUTS-patients<sup>1</sup>. Aim of study is to assess urodynamic changes after PDE5i vardenafil 20 mg administration in spinal cord injured (SCI) male under oxybutynin treatment with persistent neurogenic detrusor overactivity (NDO).

### Study design, materials and methods

We performed a single centre, randomized, double-blind, placebo controlled trial on 25 SCI male with both micturition disorders and erectile dysfunction. Baseline urodynamic assessment, and a subsequent test 1 to 3 hours after vardenafil 20 mg (15 cases) or placebo (10 controls) administration were recorded. In all patients, standard oral oxybutynin administration was not discontinued. Urodynamic studies were carried out according to Good Urodynamic Practice Guidelines<sup>2</sup>. Statistical assessment considered 3 urodynamic parameters: maximum cystometric capacity, maximum detrusor pressure, and neurogenic detrusor overactivity (NDO) with reflex volume.

### Results

The baseline characteristics (age, ASIA scale, SCI location, time from spinal lesion, baseline urodynamics characteristics) for all SCI male and for vardenafil and placebo group are reported in **table 1**.

		All (n=25)	Placebo (n=10)	Vardenafil (n=15)
Age (range)		34,9 (24-60)	35,6 (24-53)	34,5 (24-60)
ASIA severity	Category A	18	7	11
	Category B-C	7	3	4
SCI location	Above D6	13	5	8
	D6 or Below	12	5	7
Maximum Cystometric Capacity pre		241 (109-379)	254 (180-350)	233 (109-379)
Maximum Detrusor pressure pre		61 (30-82)	63 (45-82)	59 (30-80)
Reflex Volume pre		190 (80-300)	213 (140-300)	174 (80-300)

Placebo administration did not affect urodynamic parameters. After vardenafil administration, maximum cystometric capacity considerably improved (233.5 vs. 272 ml,  $p < 0.001$ ), and maximum detrusor pressure was significantly reduced (59.3 vs. 52.1 cmH<sub>2</sub>O,  $p < 0.001$ ). Moreover, the most significant variations were observed for reflex volume (174 vs. 218 ml,  $p < 0.0001$ ). In 7 patients with both ASIA-A and SCI above D6 we observed the most considerable improvement in the evaluated urodynamic items (Maximum Cystometric capacity: 253 vs. 296 ml,  $p = 0.004$ ; Maximum detrusor pressure: 57 vs. 52 cmH<sub>2</sub>O,  $p = 0.039$ ; NDO reflex volume: 177 vs. 229 ml,  $p = 0.003$ ).

### Interpretation of results

Our study is the first randomized, placebo-controlled, trial reporting that a single 20 mg vardenafil administration allows an improvement in urodynamic parameters, including maximum cystometric capacity, maximum detrusor pressure and reflex volume. Even if this trial was performed in a small sample population, the results are highly relevant because the study was conducted in SCI patients, with negligible placebo effect. Furthermore, the presented results are in agreement with previous observations in both animal models and human tissue<sup>3</sup>.

### Concluding message

In conclusion, the present trial in SCI male proved that a single 20 mg vardenafil administration achieved an improvement of maximum cystometric capacity, a reduction of maximum detrusor pressure, with an increase of reflex volume. Therefore, present study confirms that bladder may be considered a direct target for vardenafil and suggests that this PDE5i could have a role in the treatment of neurogenic overactive bladder.

### References

1. *J Urol* 2007; 177: 1071-1077.
2. *Neurourol Urodyn* 21: 261-74, 2002.
3. *Endocrinology* 2006 nov, 148 (3): 1019-1029

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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 university hospital of careggi florence italy and followed the Declaration of Helsinki Informed consent was obtained from the patients.