

## DULOXETINE IN THE TREATMENT OF POST-SURGERY MALE STRESS URINARY INCONTINENCE: PRELIMINARY DATA

### Hypothesis / aims of study

Duloxetine is a new molecule, recently introduced on the market for the treatment of female moderate to severe stress urinary incontinence. This drug works selectively inhibiting serotonin and norepinephrine reuptake; the increased availability of these mediators, at sacral spinal cord level, causes an amplified excitation of the neurons controlling the striated urethral sphincter (Onuf's nucleus), with consequent increase of sphincter tone (1). No data are yet available on the results of Duloxetine in male stress urinary incontinence. This latter type of incontinence is usually due to previous prostatic surgery, causing a sphincteric injury and/or denervation; thus, post-surgery incontinent male patients could benefit of Duloxetine, in consideration of its mechanism of action. Aim of this study was to evaluate the efficacy and tolerability of Duloxetine in male patients with post-surgical stress incontinence.

### Study design, materials and methods

18 male patients were included in this prospective study. Mean age was 67 (59-73) years. Inclusion criteria were: presence of stress incontinence episodes after surgery; presence of incontinence since at least 3 months. Exclusion criteria were: previous history of incontinence; urinary tract infections; any obvious pathology of the bladder. All patients had undergone surgery for the presence of a prostate cancer: 16 radical open (14) or laparoscopic (2) prostatectomy; 2 High Intensity Focused Ultrasounds (HIFU). All patients signed an informed consent to be treated with Duloxetine and their data to be anonymously collected for research reasons. All patients were treated with Duloxetine 40 mg b.i.d.. Evaluation was performed before (time 0) and after one month (time 1) of Duloxetine treatment by means of bladder diaries, quality of life questionnaires (I-QoL) and urodynamic investigation. Patients showing a decrease of incontinence episodes >50% were considered responders.

### Results

3 patients discontinued the treatment due to presence of non serious adverse events (nausea, vomiting or drowsiness). The results of the remaining 15 patients are reported in table. 9/18 patients were considered responders, according to the above mentioned criteria.

	Time 0	Time 1	p
Detrusor overactivity (n. of patients)	4/15	3/15	ns
	Median		
N. of leakage episodes/day	5	2	0.003
Severity of leakage episodes/day	2	1	0.03
I-QoL	45	75	0.02
	Mean		
VLPP (cmH <sub>2</sub> O)	64,2	65,5	ns
VLPP (cmH <sub>2</sub> O) (responders)	79,2	88,2	0.07
Maximum cystometric capacity (ml)	392	436	0.05

Legend: Severity of leakage episodes: based on a 1-3 scale (1: drops; 2: small amount; 3: clothes change needed due to incontinence). VLPP: Valsalva leak point pressure (obtained in 10/15 patients before and in 8/15 patients after treatment; for the 2 patients in whom VLPP was not obtained after treatment, the maximum abdominal pressure was considered); VLPP in responders is reported separately.

### Interpretation of results

According to our preliminary data, Duloxetine seems to be effective in the treatment of male post-surgery stress urinary incontinence. 50% of patients showed a >50% reduction of incontinence episodes and were thus defined "responders". The median decrease of

incontinence episodes was 60%. These data are comparable to those reported for Duloxetine in female stress urinary incontinence (2). VLPP did not show any increase after treatment, considering all patient population, but an increase (even if not significant) could be observed in responders. A slight but significant increase in maximum cystometric capacity was also seen; this finding, to be confirmed by means of larger controlled series, is not completely unexpected, being already observed in animal models (3). 3 out of 18 patients (16,7%) dropped out the study because of non serious adverse events: this drop-out percentage is similar to that reported in female (2).

#### Concluding message

Duloxetine seems to be effective in the treatment of male post-surgery stress urinary incontinence; further investigations by means of large controlled studies are needed to confirm our preliminary data.

#### References

- 1) Clin Auton Res. 2004 Aug;14(4):220-7
- 2) Int J Gynaecol Obstet. 2004 Jul;86 Suppl 1:S53-62
- 3) J Pharmacol Exp Ther. 1995 Aug;274(2):1014-24.