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HOW DURABLE IS THE EFFECT OF MIRABEGRON IN SUCCESSFULLY-TREATED OAB PATIENTS? SECONDARY ANALYSIS OF A MULTICENTRE STUDY.

Hypothesis / aims of study
Many clinical studies indicate that pharmacologic treatment of overactive bladder (OAB) is considered effective and safe, but in real clinical practice a substantial proportion of patients discontinues the treatment. The reason for discontinuing the treatment most frequently reported is lack of efficacy and/or side effects. A further significant proportion of patients reports that they stopped the treatment because the symptoms disappeared or were resolved. This Beta-3 agonist seems to be crucial in providing comparable efficacy in the OAB treatment and better tolerance in comparison with anticholinergics.
Our aim was to investigate the durability of the Mirabegron effect in successfully treated OAB patients and to understand more fully what prompts patients to return to the medication. Is this merely a subjective decision, or is it based on objective worsening of the symptoms?

Study design, materials and methods
This is a secondary analysis of longitudinal multicentre study of OAB Mirabegron treatment persistence. After continuing Mirabegron treatment for 29 months patients were assessed by bladder diary and specific questionnaires. Patients with a UB – VAS score (urgency bother visual analogue scale) of 50 or less were asked to stop the Mirabegron treatment and restart the treatment any time later if they felt the need. Patients recorded the date of return to medication; they kept a daily bladder diary and filled in the same questionnaires as at the time of medication discontinuation. We provide a comparison of symptoms at the time of Mirabegron discontinuation (V1) and at the time of Mirabegron medication restart (V2).

Results
206 patients entered the study. 176 females (85%) and 30 males (15%) with mean age 62.9±12.43, BMI ranging from 16.6 to 48.0 (mean 27.2±4.96).
After 18 months 126 patients were persisting with Mirabegron treatment. 89 patients had UB-VAS score <=50 (89 of 126 patients, i.e. 71%). Those patients were asked to stop the treatment.
From the eligible group of 89 patients, 19 patients (21%) were unwilling to stop the treatment and were therefore excluded. There were no significant differences in bladder diary and QoL characteristics between patients who were unwilling to discontinue the treatment and patients who did stop taking the medication.
The group who stopping treatment comprised 70 patients. At the time of last follow-up 22 patients (31%) had not restarted the medication, with mean follow-up of 122.6 days.
Therapy was restarted by 48 patients (i.e. 69% of 70). The mean time without treatment was 48 days (±32.0 days), median 53 days. Table 1 presents a comparison of subjective and objective parameters when treatment was stopped and when it was restarted.

Table 1: Characteristics of patients who stopped and restarted treatment

N=48	V1		V2		
	Mean	SD	Mean	SD	p-value
TS-VAS (treatment satisfaction)	80.4	(3.48)	n.a.	n.a.	n.a.
UB-VAS (urgency bother)	24.8	(3.19)	63.9	(3.96)	<0.001***
PPBC	2.3	(2.11)	4.1	(2.94)	<0.001***
OAB total score	83.8	(4.01)	64.3	(0.76)	<0.001***
OAB HRQL	85.9	(1.94)	67.3	(3.18)	<0.001***
OAB Symptom bother	20.8	(21.75)	42.2	(1.08)	<0.001***
Frequency/day	9.1	(26.46)	11.7	(23.22)	<0.001***
Urgency gr 3	1.8	(1.26)	3.4	(1.12)	<0.001***
Urgency gr 4	0.3	(16.34)	0.8	(17.93)	0.005**
Urgency (3+4)	2.1	(15.96)	4.2	(19.21)	<0.001***
Nycturia	1.1	(18.67)	1.7	(19.33)	0.001**

Interpretation of results
69% of patients with OAB symptoms successfully treated with Mirabegron (UB-VAS <=50) are unable to discontinue taking the medication for more than 2 months. Subjective bother based on increase number of frequency, urgency, and nycturia causes patients with positive experience to return to Mirabegron treatment.

Concluding message:
The majority of patients with successfully-treated symptoms of OAB who discontinue treatment can only do so temporarily. A worsening of the symptoms occurs rather rapidly.

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