

EUROPEAN REGISTRY EVALUATING MANAGEMENT PRACTICES OF GENERAL PRACTITIONERS AND UROLOGISTS AND PHARMACOLOGICAL TREATMENT OUTCOMES IN MEN WITH LOWER URINARY TRACT SYMPTOMS ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA.

Hypothesis / aims of study

Information on pharmacological management practices and outcomes in men with LUTS/BPH treated in real-life is sparse. We collected data from 2175 males treated for their LUTS/BPH and evaluated its effects on symptoms, quality of life and sexual function.

Study design, materials and methods

Between February'10 and April'11 2175 males, aged ≥ 50 years, were enrolled in 5 countries by GP's and urologists. 337 men were not evaluable mainly because of missing questionnaires (8%); no pharmacological treatment (40%) or ineligibility (44%). 575 untreated men (UM) with an IPSS ≥ 8 and 1263 treated men (TM) commenced pharmacological treatment and were allowed to stop or change the type of treatment. Visits took place at 6 (UM only), 12 and 24 months. Men completed self-assessment questionnaires. The primary objective was to evaluate symptom persistence defined as IPSS ≥ 8 at 24 months.

Results

UM and TM started with the following pharmacological treatments: 393(68%) and 791(63%) alpha-blockers; 91(16%) and 66(5%) phytotherapeutics; 21(4%) and 88(7%) 5-ARI inhibitors; 45(8%) and 222(18%) alpha-blockers combined with 5-ARI inhibitors, respectively. (Table).

		France (%)	Germany (%)	Italy (%)	Spain (%)	UK (%)
alpha blockers	TM	91 (43)	348 (82)	136 (65)	100 (54)	116 (50)
	UM	46 (52)	129 (68)	96 (74)	54 (68)	68 (78)
alpha blockers and phytotherapy	TM	24 (11)	6 (1)	4 (2)	9 (5)	0
	UM	1 (1)	1 (1)	5 (4)	0	0
phytotherapy	TM	41 (20)	13 (3)	6 (3)	5 (3)	1 (1)
	UM	30 (34)	39 (21)	15 (12)	7 (9)	0
anticholinergics	TM	0	2 (1)	0	0	4 (2)
	UM	0	2 (1)	0	0	5 (6)
5 ARI	TM	19 (9)	20 (5)	15 (7)	15 (8)	19 (8)
	UM	5 (6)	3 (2)	2 (2)	3 (4)	8 (9)
5ARI and alpha blockers	TM	28 (13)	29 (7)	47 (23)	48 (26)	70 (30)
	UM	5 (6)	14 (7)	12 (9)	10 (13)	4 (5)
other	TM	7 (3)	9 (2)	0	9 (5)	22 (9)
	UM	2 (2)	2 (1)	0	5 (6)	2 (2)

The proportion of men with symptom persistence decreased in both groups during the registry period as follows: BL; M12; and M24: Treated: 0.77(95%CI:0.75–0.80); 0.64(95%CI:0.61–0.67) and 0.62(95%CI:0.58–0.65), respectively. Untreated: 1.0; 0.67(95%CI:0.62–0.71) and 0.59 (95%CI:0.54–0.64), respectively.

The proportions of men with an IPSS reduction ≥ 3 points at M12 and M24 were: Treated at M12: 0.38 (95%CI: 0.35-0.41); Treated at M24: 0.42 (95%CI: 0.38-0.45); Untreated at M12: 0.65 (95%CI: 0.61-0.69); Untreated at M24: 0.70 (95%CI: 0.66-0.75). The 95%CI for the proportions of men with clinical progression at M12 (Treated:0.10 [95%CI:0.09-0.12]; Untreated: 0.13 [95%CI:0.11-0.16] and M24 (Treated:0.17 [95%CI:0.15-0.19]; Untreated: 0.16 [95%CI:0.13-0.19] were clearly overlapping and thus not significantly different between initial treatment categories. In the UK, the proportion of men with clinical progression was higher than in other countries.

Interpretation of results

The quick decrease in proportions of men with symptom persistence is due to a positive treatment effect while at longer term the continuing decrease may be due to continuous improvement of LUTS of men on treatment or (positive) selection bias of non-responders dropping out or undergoing surgery.

Concluding message

The real life data from this registry indicate that pharmacological treatment of men with LUTS leads to an IPSS reduction ≥ 3 points at 24 months in 42% of the pharmacologically treated men and 70% of the pharmacologically untreated men. Nevertheless, symptom persistence, defined as an IPSS ≥ 8 , remains present in 62% of the treated men and in 59% of the untreated men. A total of 17% of the treated men and 16% of the untreated men developed clinical progression at month 24.

Disclosures

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Subjects: HUMAN **Ethics Committee:** Ethics committees of all participating centres have approved this project. Only central committees for each country are stated: UK: Bath Research Ethics Committee Italy: Comitato Etico dell' Azienda Ospedaliera Sant' Andrea, Rome Spain: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Madrid Germany: Ethikkommission der Landesärztekammer Nordrhein, Düsseldorf France: CCTIRS, Paris **Helsinki:** Yes **Informed Consent:** Yes