PURPOSE: We assessed in real-life practice the impact of age, cardiovascular comorbidity and co-medication on the tolerability and efficacy of 10 mg alfuzosin OD in men with lower urinary tract symptoms suggestive of benign prostatic obstruction. MATERIALS AND METHODS: A total of 6,523 men with a mean age of 64.7 years were enrolled in a 6-month open label study of 10 mg alfuzosin OD. They were stratified by age quartile (younger than 60, 60 to 64, 65 to 70 and older than 70 years), comorbidity (hypertension, ischemic heart disease and diabetes) and antihypertensive co-medication (diuretics, beta-blockers, angiotensin converting enzyme inhibitors, angiotensin II inhibitors and calcium channel antagonists). RESULTS: Alfuzosin was effective and well tolerated. Despite an increased prevalence of cardiovascular comorbidity and antihypertensive co-medication with age changes in blood pressure did not significantly differ among age groups. In controls, ie those with no cardiovascular comorbidity or co-medication, alfuzosin produced minimal decreases in sitting systolic (mean -2.6 to -2.8 mm Hg) and diastolic (mean -1.7 to -1.8 mm Hg) blood pressure. In men with cardiovascular comorbidity mean decreases in systolic (-3.5 to 5.8 mm Hg) and diastolic (-2.0 to -3.3 mm Hg) blood pressure remained marginal. Of
the 6,523 exposed patients 19.3% withdrew from the study, mainly for adverse events (6.4%) or a lack of efficacy (5.3%), while 229 (3.5%) experienced serious adverse events and 1,558 (23.9%) reported at least 1 treatment emergent adverse event. The most commonly reported adverse event was dizziness/postural dizziness (4.8%). Hypotension/postural hypotension was uncommon (0.7%). Age, cardiovascular comorbidity and antihypertensive co-medication had no impact on the safety profile of 10 mg alfuzosin OD. CONCLUSIONS: Alfuzosin (10 mg) OD is effective and well tolerated, and it has marginal effects on blood pressure, including in elderly patients and those with hypertension, ischemic heart disease or diabetes and those receiving antihypertensive agents.

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