

Finasteride/tamsulosin: no serious, unexpected adverse events

No serious, unexpected adverse events associated with finasteride or tamsulosin were seen in a review of 2 large, observational cohort studies conducted in the UK, which utilised prescription event monitoring, report S Shakir and colleagues from the Drug Safety Research Unit in the UK.

The 2 studies involved 14 772 finasteride recipients and 12 484 tamsulosin recipients, who were predominantly men (mean age 69 and 62.2 years, respectively), with 2 and 70 woman in each cohort, respectively.* Data were collected approximately 6 months after treatment initiation, between October 1992 and February 1994, for finasteride, and after approximately 12 months' treatment, between June 1996 and January 1998, for tamsulosin.

Both finasteride and tamsulosin were well tolerated, with 69.6 and 62% of patients from each cohort still receiving their respective agent after 6 months' treatment. Reported adverse events were consistent with the known pharmacology of the 2 drugs, and occurred in 95 and 226 of the finasteride and tamsulosin recipients, respectively [see table]. No deaths deemed attributable to either agent were reported, nor were there any serious, unexpected adverse events.

Shakir and colleagues note that, although uncommon, cases of gynaecomastia with finasteride, and hypotension and/or dizziness with tamsulosin, 'are worth an appropriate level of precautionary interest in patients in whom they might have adverse consequences'.

Table. Ten most frequent adverse events associated with finasteride and tamsulosin in 2 large observational cohort studies

Finasteride (n = 14 772)	Tamsulosin (n = 12 484)	Adverse event	Number of patients	Adverse event	Number of patients
10	10	Impotence	10	Dizziness	10
5	5	Headache	5	Nausea	5
10	10	Rash	10	Palpitations	10
3	3	Dizziness	3	Headache	3
8	8	Gynaecomastia	8	Lassitude	8
3	3	Disorders	3	Breast	3
5	5	Hypotension	5	Dry mouth	5
3	3	Decreased libido	3	Rash	3
3	3	Dyspepsia	3	Nausea	3
7	7	Drowsiness	7	Retrograde ejaculation	7
3	3	Intolerance	3		3
3	3	Dry mouth	3		3

* The women received the drugs mainly for miscellaneous urinary conditions.

Shakir S, et al. Finasteride and tamsulosin used in benign prostatic hypertrophy: a review of the prescription-event monitoring data. *BJU International* 87: 789-796, No. 9, Jun 2001 800869919