

Dutasteride Side Effects - Surprisingly Low

Posted by : admin on Oct 10, 2007 - 11:44 PM

New Research

Recent study shows Dutasteride has fewer side effects than we might have anticipated. According to a new major study for Benign Prostatic Hyperplasia, the incidence of side effects with Dutasteride was surprisingly low. See all the side effects and their prevalence in this article...I got that dutasteride for BPH study last night (the first and so far, the ONLY published study using dutasteride in humans), and it's interesting to see that the reported incidence of side-effects of ALL kinds from using the standard 0.5 mg dose of dutasteride for a full 2 years is quite nominal.

Once again, I'm talking about: "Efficacy and Safety of a Dual Inhibitor of 5-Alpha-Reductase Types 1 and 2 (Dutasteride) In Men With Benign Prostatic Hyperplasia", Roehrborn et al, Urology 60:434-441, 2002.

Here's all their text comments about side effects, followed by a table at the end which shows all the data...

Tolerability

Dutasteride was well tolerated. Overall, 75% of the placebo-treated versus 77% of the dutasteride-treated patients experienced an adverse event (AE) in the course of the 24-month study. The most common AEs were ear-nose-throat infections, musculoskeletal pain, and upper respiratory infections.

Drug-related AEs were seen in 14% and 19% of placebo-treated and dutasteride-treated patients, respectively, with sexually related AEs the most common in both groups. Impotence, reduced libido, ejaculation disorders, and gynecomastia occurred more frequently in dutasteride-treated patients (Table III).

Additionally, the diagnosed prostate cancer incidence was 42 (1.9%) of 2158 for the placebo group and 24 (1.1%) of 2167 for the dutasteride group during the 24 months.

[...]

The majority of AEs reported in the present study were not drug related in the judgement of the investigators. Of those considered to be related to the drug, sexually related AEs were the most common.

More patients exposed to dutasteride than placebo experienced impotence, decreased libido, ejaculation disorders, and gynecomastia in the course of the 24-month study. However, most of these effects were transient, and the incidence of new occurrences of each event decreased in the second year.

Additionally, discontinuation because of AEs was rare. These results compare favorably with the AE profile of the existing type II 5-alpha-reductase inhibitor, demonstrating that the more pronounced reduction in DHT by the dual inhibitor of 5ARI does not lead to an increase in the number or severity of AEs.

TABLE III
Drug-related adverse events

Study Period	Sexual Adverse Event	Placebo	Dutasteride
Entire study	Impotence	86 (4.0)	158 (7.3)
	Decreased libido	46 (2.1)	91 (4.2)
	Gynecomastia	16 (0.7)	50 (2.3)
	Ejaculation disorder	17 (0.8)	48 (2.2)
0-1 yr	Impotence	65 (3.0)	130 (6.0)
	Decreased libido	41 (1.9)	80 (3.7)
	Gynecomastia	11 (0.5)	28 (1.3)
	Ejaculation disorder	15 (0.7)	40 (1.8)
1-2 yr	Impotence	21 (1.2)	29 (1.7)
	Decreased libido	6 (0.3)	11 (0.6)
	Gynecomastia	5 (0.3)	23 (1.3)
	Ejaculation disorder	2 (0.1)	9 (0.5)

(Data presented as the number of patients, with the percentage in parentheses)

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HLT