Sexual dysfunction inadequately reported in hair loss drug trials

April 1 2015

Published reports of clinical trials provide insufficient information to adequately establish the safety of finasteride for treatment of hair loss in men, according to a new Northwestern Medicine study to be published April 1 in *JAMA Dermatology*.

This study is the first meta-analysis of the quality of safety reporting in clinical trials of finasteride for treatment of male hair loss.

Finasteride blocks 5α-reductase in the scalp and male reproductive organs, inhibiting the conversion of the male hormone testosterone to its more potent form, 5α-dihydrotestosterone (5α- DHT). Men who take finasteride experience a 70 percent reduction in the amount of 5α-DHT in their blood.

Not one of the 34 published clinical trial reports provided adequate information about the severity, frequency or reversibility of sexual adverse effects. (Adequate quality of adverse event reporting requires using an explicit toxicity scale to grade adverse event severity and reported numbers and/or rates of occurrence for each specific type of adverse event per study arm.)

The published clinical trial reports did not answer the key questions doctors and patients want to know:

1) How safe is finasteride? Specifically, what is the risk that a man taking finasteride will develop sexual dysfunction?

2) How severe is finasteride-associated sexual dysfunction when it happens to a man?

3) If a man gets sexual dysfunction while taking finasteride, will sexual function return to normal when the drug is stopped? What is the risk of persistent sexual dysfunction associated with taking finasteride?

Finasteride was originally developed to treat enlarged prostate (prostatic hyperplasia) in older men. Men who take the drug for male pattern hair loss are typically younger and take a dose of finasteride that is about one-fifth the dose used for prostatic hyperplasia.

"People who take or prescribe the drug assume it's safe, but there is insufficient information to make that judgment," said lead study author Dr. Steven Belknap, research assistant professor of dermatology and general internal medicine at Northwestern University Feinberg School of Medicine.

"Our findings raise several questions," Belknap said. "Why do the published reports of these 34 clinical trials not provide adequate information about the severity and frequency of sexual toxicity? Was this information obtained but then not included in published articles? Or, were these clinical trials performed in a way that simply didn't capture this essential information? And most importantly, is the risk to benefit ratio of finasteride acceptable?"

The study is a report from the RADAR (Research on Adverse Drug Events and Reports) project at Northwestern's Feinberg School. The RADAR study points to a larger problem in the way clinical trials are performed and analyzed in meta-analyses.

"Typically, there is more focus on the desirable effects of the drug being studied compared to the toxic effects," Belknap said.

Among other key findings of the paper:

Of 5,704 men in the Northwestern Medicine clinical data repository who were treated for male pattern baldness with finasteride, only 31 percent would meet inclusion criteria for the pivotal trials referenced in the manufacturer's "Full Prescribing Information."

Thus, the available information from clinical trials does not apply to most of these men in Northwestern's study population who took finasteride for male pattern baldness. For example, some men with hair loss who are taking finasteride have diabetes mellitus, high blood pressure or are taking other drugs such as diuretics or antidepressants that also increase the risk of sexual dysfunction.

Duration of drug safety evaluation was limited to one year or less for 26 of 34 trials (76 percent.) But 33 percent of men in the Northwestern clinical data repository took finasteride for more than one year.

Provided by Northwestern University