

Researchers find evidence support relationship between finasteride and suicidality

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In the last decade, concerns have emerged around finasteride, a drug used for treating male-pattern baldness and prostate gland enlargement. Organizations such as the Post-Finasteride Syndrome Foundation have warned about suicidality and psychological adverse events in people taking the drug. But studies on the association between finasteride and suicidality have been limited. A team of researchers from Brigham and Women's Hospital has leveraged the World Health Organization's international database of individual case safety reports to add new evidence to the discussion. In *JAMA Dermatology*, the team reports a signal for suicidality and psychological adverse events among people taking finasteride, namely suicidal ideation among younger men taking the medication for hair loss. The team also found that reports of adverse events rose significantly after 2012.

"In this study, we find a signal, but we need further investigations to understand if there is a biological explanation," said corresponding author Quoc-Dien Trinh, MD, a urologist in the Division of Urologic Surgery at the Brigham. "Sometimes, adverse events can act like a self-fulfilling prophecy—the more that people are aware of concerns, the more likely they may be to report them. But this isn't just a fluke. There's a clear signal here, and it challenges us to ask why that is."

David-Dan Nguyen, MPH, a research fellow at the Brigham's Center for Surgery and Public Health and current McGill University medical student, wanted to go beyond simply reporting these signals and additionally further explore this association between finasteride and suicidality and psychological adverse events.



"In 2012, initial studies on adverse events associated with finasteride were published, captured the media's attention, and led to increased interest in the post-finasteride syndrome as shown by Google search trends. It made sense to compare reporting before and after 2012 to explore how increased awareness of the drug impacted adverse-event reporting," said Nguyen. "Additionally, our database allowed us to easily examine other drugs used in the treatment of male-pattern baldness and benign prostatic hyperplasia to explore pharmacologic mechanisms and mitigate confounding by indication."

The team used data from VigiBase, which collects information from 153 countries on all drug-adverse reactions and contains more than 20 million safety reports. VigiBase had 356 reports of suicidality and 2,926 reports of psychological adverse events among people taking finasteride. The researchers found a disproportionate signal for suicidal ideation, depression and anxiety among people taking finasteride for hair loss who were 45 and younger. Such signals were not detected in older patients taking the drug for enlarged prostate glands. The researchers also examined other drugs for hair loss and enlarged prostate gland treatment and found no signal.

The researchers found disproportional reporting of suicidality after 2012, coinciding with highly publicized reports in the media about concerns about the drug. They did not find a signal for all other drugs used for comparison. The team hypothesized that "stimulated reporting" may be at play—increased awareness of concerns may have led to increased attention to and reporting of adverse events. An alternative hypothesis which may explain their findings was that finasteride's well-established side-effects may have a greater toll on younger patients with alopecia (hair loss), resulting in these patients being at higher risk of anxiety, depression and suicidal ideation.

The authors note that adverse events are likely underreported to national



authorities for inclusion in VigiBase. Other limitations to the study include being unable to account for confounding variables, such as social support and higher socioeconomic status, which are associated with decreased risk of suicidality and depression. While the researchers could use the database to look for instances where individuals took finasteride and a psychiatric drug, they could not determine which drug came first. And, like all observational studies, this work could not directly address the question of causation.

"Our findings suggest that risk of suicidality and psychological adverse events should be taken into account when prescribing finasteride to younger patients with male-pattern baldness who may be more vulnerable to these effects," said Trinh. "It also suggests that further study is needed to address key gaps in our understanding of why suicidality and adverse events are associated with this <u>drug</u>."

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