Letters in Response to Previously Published Articles

Is semen analysis necessary prior to initiation of finasteride treatment?

Sir,

We have read with great interest the article on "Safety of important dermatological drugs (retinoids, immune suppressants, antiandrogens and thalidomide) in reproductively active males with respect to pregnancy outcome: A brief review of literature", Indian J Dermatol Venereol Leprol 2018;84:539-46 by Kumar *et al*.

This letter is with respect to finasteride, which is a synthetic 5-alpha-reductase inhibitor that prevents the conversion of testosterone to dihydrotestosterone. It is commonly used in dermatology for the treatment of androgenetic alopecia at a dose of 1 mg per day. The article rightly notes that various studies have reported adverse effects caused by finasteride which includes erectile dysfunction, ejaculatory dysfunction and loss of libido. However, the authors have mentioned that it is *prudent to get a baseline semen analysis before starting any patient on finasteride* to rule out oligospermia and/or subfertility. We express our reservations about this statement, as the authors have not quoted sufficient evidence to back such recommendation. The level of evidence quoted is of low quality and is based on two published reports[1,2] and one clinical study[3] with a small study population. We raise this issue because the recommendation is a far-reaching statement with important consequences for dermatology practice. It is impractical to carry out such investigations routinely before starting the drug for each patient, particularly in a matter that concerns sexual issues. Such a statement can have serious medicolegal implications—a patient can quote this recommendation in a court of law putting a dermatologist in jeopardy.

We studied this matter and found that there is no other published study or guideline which has made such a recommendation earlier. Overstreet *et al*. in a double-bind placebo-controlled study included patients on low-dose finasteride of 1 mg orally for a period of 48 weeks. Baseline semen analysis was assessed and at 24 weekly intervals thereafter. The study concluded that 1 mg finasteride had no significant effects on spermatogenesis, sperm motility and semen production.[4]

A study conducted by Amory *et al*. included 99 patients and semen analysis was done at baseline and subsequently after initiating finasteride 5 mg. The analysis showed decreased total sperm count, semen volume, sperm concentration and sperm motility but no effect on sperm morphology. However, the dose in this study was much higher (5 mg) and not the regularly prescribed dosage (1 mg) in dermatological practice.[3]

US Food and Drug Administration recommended that clear causal links between finasteride (Propecia and Proscar) and sexual adverse events have not been established and that information about these adverse events be provided to patients as part of a discussion of risk and benefits of finasteride when determining the best treatment option.[5] There was no mention of prior semen analysis in the recommendation.

Indian Association of Dermatologists, Venereologists and Leprologists therapeutic guidelines committee recommended that it is better to avoid the drug in patients who have had a history of oligospermia or infertility, particularly if they are newly married and trying to raise a family. A patient who is anxious and expresses reservations about taking the drug also may avoid the drug. There was no recommendation that semen analysis should be carried out before prescribing the drug.[5]

Thus, all these articles recommend caution to be exercised while prescribing the drug, and that, full information is to be provided to the patient while prescribing the drug, but none have recommended that baseline sperm count to be estimated while starting the drug. The mention by authors that such baseline estimation of semen analysis to be done in the article is therefore hasty and based on insufficient evidence.

Such a recommendation is impractical to be implemented in routine practice and will put off patients from taking the drug. It will deny the patients of one of the few evidence-based treatments for androgenetic alopecia. It also can have far-reaching impact in a possible medicolegal situation arising out of finasteride administration.

We, therefore, feel that the recommendation is made either without an evidence-based assessment or evaluation of the practical impact of such a statement.

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Conflicts of interest

There are no conflicts of interest.

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