EDITORIAL

Do 5-ARIs have a role in preventing BPH?

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TREATING ASYMPTOMATIC OLDER MEN WITH 5-ALPHA REDUCTASE INHIBITORS (5-ARIs) MAY REDUCE THEIR risk of developing benign prostatic hyperplasia (BPH). However, the case for prophylactic use of these drugs is still unproven.

A study, published in *European Urology,*[1] used data from the long-running Prostate Cancer Prevention Trial (PCPT), set up to examine the effect of finasteride in reducing the risk of development of prostate cancer.

Patients were excluded if at the outset they had a diagnosis of BPH, had received treatment for the condition or had significant lower urinary tract symptoms (LUTS) defined as an IPSS score > 8. Around half the participants were excluded as a result, leaving data on 9,253 men suitable for analysis.

Patients were followed up for a median of 5.3 years. The development of clinical BPH was defined as initiation of medication, having BPH-related surgery or sustained clinically significant urinary symptoms (IPSS > 14).

It is important to note that this is a post-hoc analysis of the data within the study, and was not a predefined outcome measure, and as such the findings must be interpreted with caution.

The rate of clinical BPH was 19 per 1,000 patient-years in the placebo arm versus 11 per 1,000 patient-years in the finasteride arm ($p < 0.001$).

In a covariate-adjusted model, finasteride reduced the risk of incident clinical BPH by 40%, hazard ratio 0.60 (95% CI: 0.51-0.69; $p < 0.001$).

For men over the age of 65, use of finasteride led to a relative risk reduction of 44%. The number needed to treat (NNT) to prevent one case of clinical BPH over 7 years ranged from 58 (95% CI: 35-177) for men aged 55-59 years, to 31 (95% CI: 19-83) for men ≥ 65.
The authors note that these NNTs compare well with those for established drugs used in primary prevention of cardiovascular disease, such as aspirin, statins, diuretics and beta-blockers.

The authors conclude that finasteride substantially decreases the risk of clinical BPH in healthy older men and state that. 'These results should be considered in formulating recommendations for the use of finasteride to prevent prostate diseases in asymptomatic older men.'

This would of course represent a huge departure from current practice, with substantial implications in terms of cost etc. In an accompanying editorial entitled *5-α reductase inhibitors: Preventing the treatable,*[2] the conclusions of the authors are examined in more detail.

The authors of the editorial argue that prevention involves a trade-off between benefits and risks. The need for prevention must be based on the severity of the outcome concerned. Hence prophylactic mastectomy for patients with BRCA genes and strong family history of breast cancer may be justified, as is prevention of potentially fatal myocardial infarction. However, preventing BPH which, if it occurs, is relatively easily treated makes much less sense and would therefore require a much lower NNT than these other situations to seem worthwhile.

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Furthermore, 5-ARIs, while generally well tolerated, can have significant side effects, particularly with regard to sexual function, tiredness and gynaecomastia.

As we are unable to stratify men with no LUTS into those at highest risk of developing clinical BPH (as opposed to those with established clinical BPH who can be stratified into those at risk of progression) it would seem that we are far from proving a case for the use of 5-ARIs to prevent LUTS/BPH in asymptomatic older men.

REFERENCES
1 Kellogg Parsons J, Schenk JM, Arnold KB et al. Finasteride reduces the risk of incident clinical benign prostatic hyperplasia. *Eur Urol* 2012;62:234-241 Epub ahead of print
2 Hamilton RJ, Andriole GL, Freedland SJ. (Editorial) 5α-reductase inhibitors: Preventing the treatable. *Eur Urol* 2012; 62:242-45 Epub ahead of print

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