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Follow-up to REDUCE study shows low rate of prostate cancer diagnosis

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The four-year REDUCE (REduction by DUtasteride of prostate Cancer Events) clinical study evaluated prostate cancer risk reduction in men taking dutasteride, a 5-alpha-reductase inhibitor (5ARI) typically used to treat enlarged prostate. REDUCE results showed that dutasteride decreased the risk of biopsy detectable prostate cancer by 22.8 percent compared to a placebo group, but concerns remained about the drug's effectiveness. Results from a follow-up study are now published in *The Journal of Urology*.

"The REDUCE Follow-up Study was a two-year observational follow-up of men who participated in the four-year REDUCE trial," says lead investigator Robert L. Grubb III, Associate Professor of Surgery (Urology), Washington University of Medicine in St. Louis, Missouri. "The primary objective was to collect data on the occurrence of new cases of prostate cancer for two years beyond REDUCE."

Nearly 2,800 men from the REDUCE study participated, representing extension safety and at-risk populations. In the original study, about half were treated with dutasteride and the remainder received a placebo.

Shortly after the REDUCE study's conclusion, Dr. Grubb and co-investigators followed participants with a clinic visit. They also conducted up to two annual telephone calls, collecting patient data on prostate cancer events, chronic medication use, prostate specific antigen levels, and serious adverse events. No drugs were administered and no additional biopsies were performed except those "for-cause" when

clinically indicated.

Results showed that few new prostate cancers were detected during the two-year follow-up in either treatment group and no deaths were reported. However, the former dutasteride group produced double the number of cancers than the former placebo group (14 vs. 7). Investigators hypothesize that any prostate cancer that may have been suppressed by dutasteride during REDUCE was no longer being suppressed for those subjects who did not continue on 5ARI therapy. To some extent, observations during the follow-up study support this concept.

Using Gleason scores, the system used to evaluate the prognosis of prostate cancer, no high grade prostate cancers (Gleason Score 8-10) were detected. No new safety issues surfaced.

More men from the placebo group underwent biopsy (11.6 percent) than men from the dutasteride group (7.9 percent). A higher incidence of prostate cancer (1.3 percent) was observed in men in the dutasteride group who did not continue 5ARI treatment. Overall, men in either group who took a 5ARI during the follow-up study tended to have fewer cancers.

"Although this study provides real-world observational data for subjects who had been randomized to four years of dutasteride therapy, it has limitations," cautions Dr. Grubb. "Men in the at-risk population had a low risk of prostate cancer diagnosis due to several prior negative biopsies and corresponding conclusions are specific to the population studied. In addition, some men who dropped out of REDUCE early may have been off dutasteride treatment for longer than the two-year observational period."

The two years of additional study have been useful in demonstrating a

low rate of new prostate cancer diagnoses among men from the REDUCE study.

More information: Grubb, R. et al. The REDUCE Follow-up Study: Low Rate of New Prostate Cancer Diagnoses Observed During a 2-year, Observational, Follow-up Study of Men Who Participated in the REDUCE Trial, *The Journal of Urology*, Volume 189, Issue 3 (March 2013). DOI: dx.doi.org/10.1016/j.juro.2012.09.099

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