

Angiotensin Receptor Blockers (ARBs): Ongoing Safety Review for Cancer Risk

AUDIENCE: Cardiology, Oncology, Family Practice

ISSUE: A recently published study - a meta-analysis combining cancer-related findings from several clinical trials - suggested use of ARBs may be associated with a small increased risk of cancer.

BACKGROUND: ARBs are used in patients with high blood pressure and other conditions. Brand names include Atacand, Avapro, Benicar, Cozaar, Diovan, Micardis, and Teveten.

The meta-analysis included data from over 60,000 patients in several long-term, randomized, controlled clinical trials evaluating ARBs for which adverse events related to cancer were captured during the study. The mean duration of follow-up ranged from 1.7 to 4.8 years.

The study reported the frequencies of new cancer occurrence to be 7.2% for patients receiving ARBs compared to 6.0% for those not receiving ARBs (risk ratio = 1.08, 95% Confidence Interval: 1.01-1.15). No statistically significant difference in cancer deaths was noted.

RECOMMENDATION: FDA has not concluded that ARBs increase the risk of cancer. The Agency is reviewing information related to this safety concern and will update the public when additional information is available. FDA believes the benefits of ARBs continue to outweigh their potential risks.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Online: www.fda.gov/MedWatch/report.htm