Amiodarone-induced thyroid dysfunction: brand-name versus generic formulations. CMAJ. 2011 Sep 6;183(12):E817-23. Epub 2011 Jul 11. (Original) PMID: 21746822

Abstract

BACKGROUND: Amiodarone is associated with dysfunction of the thyroid. Concerns have arisen regarding the potential for adverse effects with generic formulations of amiodarone. We evaluated and compared the risk of thyroid dysfunction between patients using brand-name versus generic formulations of amiodarone and identified risk factors for thyroid dysfunction.

METHODS: We conducted a retrospective cohort study of patients with atrial fibrillation aged 66 years and older. We used administrative databases that linked information on demographics and clinical characteristics, claims for prescription drugs and discharges from hospital. We estimated thyroid dysfunction using person-year incidence.

RESULTS: Of the 60,220 patients in the cohort, 2804 (4.7%) used the brand-name formulation of amiodarone and 6278 (10.4%) used the generic formulation. Baseline characteristics between these two groups were comparable. The median maintenance dose of amiodarone was 200 mg/d for both groups. The total incidence rate for thyroid dysfunction was 14.1 per 100 person-years for both formulations. The mean time to clinical dysfunction of the thyroid was 4.32 years for the brand-name formulation and 4.09 years for the generic formulation. In a multivariate analysis, there was no significant difference in the incidence rates of thyroid dysfunction between the generic and brand formulations (hazard ratio 0.97, 95% confidence interval 0.87-1.08). Factors associated with an increased risk of thyroid dysfunction were being a woman, increasing age and having chronic obstructive pulmonary disease.

INTERPRETATION: In this population-based study, we saw no difference between brand-name and generic formulations of amiodarone in terms of incidence of thyroid dysfunction.

Comments from Clinical Raters

Cardiology

In this retrospective cohort study, the authors found no difference in the incidence of thyroid dysfunction between generic and brand-name amiodarone. I was impressed by the rather high incidence of hypothyroidism at 13 per 100 patient-years. Female gender, older age, and chronic obstructive lung disease were risk factors for thyroid dysfunction. The authors recommend that clinicians should monitor TSH before treatment and every 3 to 6 months afterwards in high-risk
patients. Because of this study, I will keep a closer watch on thyroid function in my patients on long-term amiodarone, particularly in high-risk patients.