

Generic versus brand name: the other drug war

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Clinical question

Is there any benefit to prescribing brand-name medications rather than generic brands?

Bottom line

According to the best available evidence, generic medications are bioequivalent and produce similar clinical outcomes to brand-name medications.

Evidence

Bioequivalence¹

- Regulators require 90% CIs for the maximum peak concentration and total drug exposure over time, or area under the curve (AUC), to be within the limits of 0.80 to 1.25.
—This means the absolute differences in bioequivalence must be no more than about 5% to 7%.
- Between 1996 and 2007, 2070 single-dose bioequivalence studies showed the average differences in maximum peak concentration and AUC were 4.35% and 3.56%, respectively.
- Overall, 98% of studies showed the AUCs of generic and innovator products differed by less than 10%.
- Generic and brand-name levothyroxine have been shown to be bioequivalent.²

Clinical outcomes (brand-name vs generic medications)

- A systematic review (38 trials) of cardiovascular medications³ found the following:
—Clinical equivalence was shown in 35 of 38 trials including all β -blocker, antiplatelet, statin, angiotensin-converting enzyme inhibitor, α -blocker, class 1 antiarrhythmic agent, and warfarin trials; and most diuretic (10 of 11) and calcium channel blocker (5 of 7) trials.
—Differences in single outcomes were found in 3 trials.
—Brand-name furosemide produced more diuresis in a 1985 trial.
—For calcium channel blockers, 2 trials found differences in the PR interval on electrocardiography but no associated changes in heart rate or other clinical outcomes.
- A systematic review of warfarin⁴ found the following:
—Five trials (higher level evidence) found no statistically significant difference in international normalized ratio or dosage changes required.
—Six observational studies (lower level evidence) showed inconsistent results at higher risk of bias.

Context

- Of 43 editorials on generic medication issues, 23 (53%) expressed negative views about generic substitution,⁵

while only 8% of trials found any difference in any outcome.³

- If there were important clinical differences between generic and brand-name medications, companies would do studies to prove brand-name superiority and prevent losing millions of dollars from generic substitution.
—In fact, one company tried to suppress data demonstrating equivalence of its product to related generics.⁵

Implementation

Generic and brand-name medications produce similar clinical outcomes. Nonetheless, differences in shape, colour, taste, and name can lead to patient, and sometimes clinician, confusion. These differences have been associated with nonpersistent use of medications.⁶ Also, generic medications can contain different fillers, and rarely some patients might not tolerate the medication for that reason. To prevent confusion, it is essential that we let patients know they might, over time, receive medications that look or sound different but contain the exact same medication. If they have any concerns they should always check with their pharmacist, physician, or health care provider. 🌿

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