Evaluation of Clinical outcomes of Generic versus Reference Ivabradine in Heart Failure Patients

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Abstract

Economic benefits associated with the usage of generic drugs have been suggested to increase patients' adherence to their medications and to improve patients' health outcomes. However, the therapeutic equivalence of certain generic products to their branded counterparts has been questioned. Our study aims to compare the efficacy and safety of generic and branded ivabradine in adult patients with chronic heart failure with reduced ejection fraction (Ò40%) (HFrEF). This was a randomized, open-label, crossover, and two-period comparative study. A total of 32 patients with HFrEF were randomized into two groups. Group A received brand ivabradineÈ for 12 weeks followed by generic ivabradine for the next 12 weeks. Group B received generic ivabradine for 12 weeks followed by brand ivabradine for the next 12 weeks with no washout period. The efficacy outcomes included resting heart rate (HR), New York Heart Association Functional Classification (NYHA FC), Quality of life (QoL) using Minnesota Living with Heart Failure (MLWHF), and ejection fraction (EF). After taking the drugs for the first 12 weeks, no statistically significant difference was detected in all efficacy outcomes between Group A and Group B. After crossover and taking drugs for a further 12 weeks, similar results were obtained. Only minor side effects, mainly phosphenes were observed in both products. No mortality was demonstrated in both groups. This study showed no statistically significant difference between the generic and brand ivabradine in terms of efficacy and safety. The results suggest that generic ivabradine can be a safe substitute for branded ivabradine for economic reasons.
Keywords: Heart Failure; ivabradine, generic; brand; Therapeutic Equivalence.

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