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A Crossover Study of Therapeutic Equivalence of Generic Product Versus Reference Product of Ivabradine in Patients with Chronic Heart Failure

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Abstract : Background: Generic substitution of brand ivabradine prescriptions can reduce drug expenditures and improve adherence. However, the distrust of generic medicines by practitioners and patients due to doubts regarding their quality and fear of counterfeiting compromise the acceptance of this practice. Aim: The goal of this study is to compare the therapeutic equivalence of brand product versus the generic product of ivabradine in adult patients with chronic heart failure with reduced ejection fraction (≤ 40%) (HFrEF). Methodology: Thirty-two Egyptian patients with chronic heart failure with reduced ejection fraction (HFrEF) were treated with branded ivabradine (Procrolan ©) and generic (Bradipect ©) during 24 (2x12) weeks. Primary outcomes were resting heart rate (HR), NYHA FC, Quality of life (QoL) using Minnesota Living with Heart Failure (MLWHF) and EF. Secondary outcomes were the number of hospitalizations for worsening HFrEF and adverse effects. The washout period was not allowed. Findings: At the 12th week, the reduction in HR was comparable in the two groups (90.13±7.11 to 69±11.41 vs 96.13±17.58 to 67.31±8.68 bpm in brand and generic groups, respectively). Also, the increase in EF was comparable in the two groups (27.44 ±4.59 to 33.38±5.62 vs 32±5.96 to 39.31±8.95 in brand and generic groups, respectively). The improvement in NYHA FC was comparable in both groups (87.5% in brand group vs 93.8% in the generic group). The mean value of the QOL improved from 31.63±15.8 to 19.6±14.7 vs 35.68±17.63 to 22.9±15.1 for the brand and generic groups, respectively. Similarly, at end of 24 weeks, no significant changes were observed from data observed at 12th week regarding HR, EF, QoL and NYHA FC. Only minor side effects, mainly phosphenes, and a comparable number of hospitalizations were observed in both groups. Conclusion: The study revealed no statistically significant differences in the therapeutic effect and safety between generic and branded ivabradine. We assume that practitioners can safely interchange between them for economic reasons.

Keywords : bradipect©, heart failure, ivabradine, Procrolan ©, therapeutic equivalence
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