In vitro and in vivo postmarketing surveillance of Valsartan, alone or in combination with amlodipine or hydrochlorthiazide, among Palestinian hypertensive patients

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Abstract

Objectives:
to evaluate the general quality of the most prescribed products of valsartan (VL) (alone or in combination) and to evaluate their efficacy and safety among Palestinian population through in vivo post-marketing surveillance.

Methods:
The first part was pharmacopeial quality control (QC) assay including dissolution, disintegration, friability and weight uniformity for VL. The second part was 3-months, cardiology clinics, observational, post marketing surveillance pilot study that included 103 hypertensive patients who were prescribed valsartan 80 or 160mg as monotherapy or combination therapy. The endpoint was the reduction of blood pressure (BP) and the rate of incidence of adverse effects (AEs) at weeks 4 and 8.

Results:
according to our QC tests all VL products showed high quality standards according to the international guidelines. A reduction of BP was observed at week 4 and 8 and no significant difference was observed between 80 and 160 strengths, higher BP reduction was observed after the use of combination therapy. Moreover, VL was well tolerated; most of AEs were of mild to moderate intensity. In general, the most frequently reported AEs included headache (17.5%), dizziness (11.75%) and weakness (11.7%). No serious AEs or Death cases were reported during the study period.

Conclusion:
High quality of the used VL tablet products, so the observed efficacy and safety results should be related to patient's factors and not due to any product defects or substandard quality. Moreover, VL is an effective treatment for essential hypertension.