The valsartan intensified primary care reduction of blood pressure (VIPER-BP) study: a multicentre, randomized trial

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Purpose: Elevated blood pressure (BP) remains poorly controlled in primary care despite effective antihypertensive drugs.

Design: The **V**alsartan **I**ntensified **P**rimary car**E** **R**eduction of **B**lood **P**ressure (VIPER-BP) Study, was a national multicentre randomized trial involving 259 General Practitioners from 114 clinics Australia-wide. The study compared usual primary care (enhanced by automated absolute risk profiling) with an intervention of structured BP reduction and risk management (also comprising automated risk profiling plus standardized pharmacological treatment and computer assisted, intensified follow-up and treatment titration). Following a 14-28 day run-in period (valsartan 80mg/day), hypertensive patients who remained above their individualized BP target were randomized to usual care or the VIPER-BP intervention arm (comprising initial valsartan mono-therapy or 2 forms of valsartan combination therapy - ratio of 1:2). The primary end-point was individualized BP control (NHFA expert guidelines) at 6 month follow-up. Secondary endpoints included change in BP, absolute risk of cardiovascular disease (CVD) and safety profile. The trial design provided > 80% power to detect a minimum 7% absolute difference between groups in BP control at 6 months at a two-sided significance of 0.05.

Study cohort: A total of 2337 hypertensive patients were enrolled and 2183 (59 ± 12 years, 59% men and 60% prior hypertension) with a mean BP of 154 ± 17 / 91 ± 11 mmHg entered the run-in phase. Subsequently, 462 (21%) achieved their individual BP target (126 ± 8 / 76 ± 8 mmHg) and 159 (7%) withdrew. Overall, 1562 patients (59 ± 12 years, 62% men and BP of 149 ± 17 / 88 ± 11 mmHg) with a CVD-free target of 140/90 mmHg (29%), pre-existing CVD (53.5%, target 130/80mmHg) or renal impairment (17.5%, target 125/75 mmHg) remained above their BP target. Patients were randomized to usual care (524, 34%) or the VIPER-BP intervention (1038; 360 and 678 patients assigned initial mono- or combination valsartan therapy, respectively). The groups were well matched according to their demographic and clinical profile (including individual BP targets).