Tolerability Profile and Discontinuation Causes of Sacubitril/Valsartan Treatment in 'Real-life' Patients with Heart Failure and Reduced Ejection Fraction

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Aims: To describe the clinical characteristics, safety and tolerability profile, and discontinuation causes of sacubitril/valsartan (SV) treatment in patients attending an outpatient heart failure clinic.

Design and methods: We collected data from 119 consecutive patients between May and November 2018. Variables were collected baseline and post-SV titration period.

Results: 64 patients (53.8%) were treated with SV. Mean age was 63 ± 10 years, 76.6% men. Mean left ventricular ejection fraction 28 ± 6%; 39% had ischaemic aetiology; and 67% were New York Heart Association class II. Median NT-proBNP 1,176 pg/ml (IQR 364–3,945). Mean glomerular filtration rate (GFR) was 71.7 ± 20.6 ml/min and potassium 4.4 ± 0.4 mEq/l. The majority (84%) of patients were treated with angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers, 95% with beta-blockers and 86% with mineralocorticoid receptor antagonists. Median titration time was 6.5 weeks (IQR 3–13.2). Target dose was achieved in 23 patients (40%). Dose reduction was needed in 24 patients (37.5%) and 10 (15.6%) discontinued therapy. Causes for therapy discontinuation were hypotension, defined as systolic blood pressure (SBP) <90 mmHg (n=4, 6.2%), potassium >5.5 mEq/l (n=2, 3.1%) and diarrhoea (n=1, 1.6%). Patients who presented with at least one adverse event were older, with lower SBP and GFR (all $p<0.05$). In a multivariate analysis, lower SBP (OR 0.94, 95% CI [0.90–0.99]) was the only variable independently associated with adverse events.

Conclusion: In our cohort, SV has an acceptable tolerability profile. The proportion of patients who achieved target dose was lower than the reported in clinical trials, despite a longer titration time. Hypotension represents the main cause of reduction or discontinuation of SV. ■