Effect of empagliflozin as add-on therapy on decongestion and renal function in diabetic patients hospitalized for acute decompensated heart failure: a prospective randomized controlled study

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Background: The mainstay of treatment of acute decompensated heart failure (ADHF) is decongestion by diuretic therapy. Empagliflozin has been shown to reduce the risk of hospitalization for heart failure in patients (pts) with type 2 diabetes mellitus (T2D) and cardiovascular disease. This may be explained by natriuresis and osmotic diuresis caused by empagliflozin, leading to plasma volume (PV) contraction and decongestion. However, little is known about the therapeutic effect of empagliflozin on decongestion and its association with renal function in T2D pts with ADHF.

Purpose: We sought to elucidate the effect of empagliflozin as add-on therapy on plasma B-type natriuretic peptide (BNP) level, hemoconcentration, PV contraction and renal function in T2D pts with ADHF.

Methods: We enrolled 38 consecutive T2D pts admitted for ADHF. On admission, enrolled pts were randomly assigned in a 1:1 ratio to either empagliflozin add-on therapy (EMPA(+)) or conventional glucose-lowering therapy (EMPA(−)). All pts in EMPA(+) group received empagliflozin (10mg/day) throughout the study period. Left ventricular ejection fraction (LVEF) was measured at baseline using echocardiography. Body weight and vital signs, such as blood pressure and heart rate, were measured, and blood and urine samples were collected at baseline and 1, 2, 3 and 7 days after randomization. Hemoconcentration was defined as a ≥3% absolute increase in hematocrit (Hct). Percent change in PV between admission and subsequent timepoints (%ΔPV) was calculated using the Strauss formula as follows: %ΔPV = ((Hb1/Hb2) × ((100 − Hct2)/(100 − Hct1))) − 1) × 100 (%), where 1 = baseline values and 2 = subsequent values. Worsening renal function (WRF) was defined as an increase in serum creatinine ≥0.3 mg/dL above baseline within 7 days of randomization.

Results: Twenty pts were assigned to the EMPA(+) group, and 18 pts were assigned to the EMPA(−) group. There were no significant baseline differences in LVEF, plasma BNP level, Hct or serum creatinine level between the EMPA(+) and EMPA(−) groups. Seven days after randomization, plasma BNP level was significantly lower in the EMPA(+) group than in the EMPA(−) group (median 213 [IQR 116–360] pg/mL vs 362 [226–776] pg/mL, p=0.0437) and hemoconcentration was more frequently observed in the EMPA(+) group than in the EMPA(−) group (53% vs 12%, p=0.0105). The decrease in %ΔPV was larger in the EMPA(+) group than in the EMPA(−) group 2 days (−8.74±9.92% vs 1.14±14.71%, p=0.0228), 3 days (−11.28±10.65% vs −0.02±14.70%, p=0.0121) and 7 days after randomization (−10.62±14.89% vs 0.97±13.72%, p=0.0211). The incidence of WRF did not significantly differ between the EMPA(+) and EMPA(−) groups (15% vs 22%).

Conclusions: This study demonstrated that empagliflozin as add-on therapy can achieve effective decongestion without an increased risk of WRF in T2D pts with ADHF.