# Effect of empagliflozin versus placebo on body composition in patients with acute myocardial infarction and type 2 diabetes mellitus: subgroup analysis of the EMBODY trial

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**Funding Acknowledgement:** Type of funding source: Private grant(s) and/or Sponsorship. Main funding source(s): Boehringer Ingelheim

**Background:** Prevention of heart failure is one of the most important challenges after acute myocardial infarction (AMI). The development of heart failure is closely associated with fluid balance which can be evaluated by the measurement of body composition such as total body water (TBW), extracellular water (ECW), and intracellular water (ICW). This subgroup analysis of the EMBODY trial was designed to determine whether the Sodium–glucose cotransporter 2 (SGLT2) inhibitor affect fluid balance and improve heart failure in patients after AMI.

**Methods:** The EMBODY trial was a prospective, multicenter, randomized, double-blind, placebo-controlled trial in patients with AMI and type 2 diabetes in Japan. A total of 105 patients were randomized (1:1) to receive once-daily 10 mg empagliflozin, an SGLT2 inhibitor or placebo 2 weeks after the onset of AMI. In this subanalysis, we investigated the time-course of body composition measured by a bioelectrical impedance analyzer "InBody®". The primary endpoints were changes in every particular parameter of body composition at week 0, 4, 12, and 24. Secondary endpoints were changes in blood pressure (BP), body weight and N-terminal pro b-type natriuretic peptide (NT-proBNP).

**Results:** Overall, 55 patients were included in the full analysis set (67.2±10.0 years, male 78.2%, and n=30 in empagliflozin group and 25 in placebo group). Baseline characteristics were not significantly different between the two groups. The change between at baseline and 24 weeks in TBW was −0.44 L (P=0.19) in the empagliflozin group and +1.14 L (P=0.0002) in the placebo group, adjusted difference −1.58 L, 95% confidence interval (CI) −2.46 to −0.70 L (P=0.0006). The empagliflozin group showed significant decreases in the body weight, ECW, ICW and systolic BP compared with the placebo group (−2.2 kg vs, +0.01 kg, P=0.004, −0.21 L vs, +0.40 L, P=0.001, −0.23 L vs, +0.74 L, P=0.0007, and −11.0 mmHg vs, +5.0 mmHg, P<0.0001, respectively). On the other hand, NT-Pro BNP levels significantly decreased in the empagliflozin group and placebo group (1028.7 pg/mL to 370.3 pg/ml, p=0.0001 and 1270.6 pg/mL to 673.7 pg/ml, p=0.006, respectively). In the multiple regression analysis of the change in TBW and ICW for the empagliflozin group, systolic BP was identified as a significant factor (P=0.001, and 0.003, respectively). In stratified analysis of BMI 25 kg/m$^2$ or more, the empagliflozin group showed significant decreases in body weight, TBW, ECW and ICW compared with the placebo group, but not below BMI 25 kg/m$^2$ group.

**Conclusion:** Empagliflozin reduced not only body weight, but also TBW, ECW and ICW. Interestingly, this tendency was remarkable at BMI 25 or more. This study suggested that early SGLT2 inhibitor administration in obesity patients with AMI and DM might be effective to reduce body weight and TBW.