

CRITICAL REVIEW FORM: THERAPY

Citation: Zinman B, Wanner C, Lachin JM, et al ; EMPA-REG OUTCOME Investigators. Empagliflozin, cardiovascular outcomes, and mortality in type 2 diabetes. *N Engl J Med* 2015 ; 373 :2117-28.

Guide	Comments
I	How serious was the risk of bias?
1	Did intervention and control groups start with the same prognosis?
1a	Were patients randomized?
1b	Was randomization concealed?
1c	Were patients in the study groups similar at baseline with respect to prognostic factors?
2	Was prognostic balance maintained as the study progressed?
2a	To what extent was the study blinded?
3	Were groups prognostically balanced at the study's conclusion?
3a	Was follow-up complete?
3b	Were patients analyzed in the groups to which they were randomized?
3c	Was the trial stopped early?

II	What are the Results?	
1	How large was the treatment effect for the primary outcome (composite of death from cardiovascular causes and nonfatal MI or stroke)?	
2	How precise was the estimate of the treatment effect for the primary outcome (composite of death from cardiovascular causes and nonfatal MI or stroke)?	
III	How can I apply the results to my patient care?	
1	Were the study patients similar to my patient?	
2	Were all patient- important outcomes considered?	
3	Are the likely benefits worth the potential harms and costs?	