Using real-world data to extrapolate evidence from randomized controlled trials – experiences from Dubrava University Hospital

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Introduction: Findings from clinical trials cannot be generalized to population at large due to the stringent eligibility criteria. Real-world data (RWD) are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD complement clinical trials by generalizing the findings from clinical trial to general population. Furthermore, RWD can provide information on other areas, such as natural history and course of disease, effectiveness studies, outcome studies, and safety surveillance[1].

Methods: In Dubrava University Hospital, RWD are a part of our every -day practice. Currently there are real world data concerning acute myocardial infarction, transcatheter aortic valve implantation, oral anticoagulation therapy in atrial fibrillation and pulmonary embolism, efficacy, and safety of sodium-glucose co-transporter-2 inhibitors (SLGT2i) in patients with heart failure. We collect RWD from Electronic health records (EHRs). After the enrolment, patients are followed up by accessing data from hospital information system and by telephone visits. Telephone visits are performed for all patients every 6 months to collect information on endpoints.

Conclusion: Real-world data encompass a wide range of research methodologies and data sources and can be broadly categorized as non-interventional studies, patient registries, claims database studies, patient surveys and electronic health record studies. Studies that use RWD include a patient population that is far more representative of unselected patient populations than those of randomized clinical trials (RCT) but they do not provide a robust basis for comparing treatment strategies RWD cannot substitute RCT, they can complement the findings from RCTs by providing valuable information on treatment practices and patient characteristics among unselected patients. RWD from our center have been recognized in Croatian and global scientific community. It takes much effort to conduct such real-world data bases, it can be time consuming in everyday practice, but the results are what motivate us and drive us forward.

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LITERATURE

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