International Journal of Population Data Science

Journal Website: www.ijpds.org

A Feasibility Study for CODE-MI: High-Sensitivity Cardiac Troponin - Optimizing the Diagnosis of Acute Myocardial Infarction/Injury in Women.

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Objectives

This feasibility study was conducted to inform the design and power evaluation of CODE-MI, a pan-Canadian trial evaluating the impact of using the female-specific 99th-percentile threshold for high-sensitivity cardiac troponin (hs-cTn) on the diagnosis, treatment and outcomes of women presenting to the emergency department with symptoms suggestive for myocardial ischemia.

Approach

CODE-MI is a multi-center, stepped-wedge cluster randomized trial. The cohort and outcomes will be obtained from routinely collected administrative data. Using linked administrative data from 11 hospitals in Ontario from 2014/10 to 2017/09, this feasibility study obtained the following estimates: number of eligible patients, i.e., women presenting to the emergency department with symptoms suggestive of myocardial ischemia and a 24-hour peak hs-cTn value within the female-specific and overall thresholds (i.e. primary cohort); the rate of the 1-year composite outcome of all-cause mortality, re-admission for non-fatal myocardial infarction, incident heart failure, or emergent/urgent coronary revascularization. Study power was evaluated via simulations.

Results

Overall, 2,073,849 emergency department visits were assessed. Among women, chest pain (with or without cardiac features) and shortness of breath were the most common complaints associated with a diagnosis of acute coronary syndrome. An estimated 7.7% of women with these complaints are eligible for inclusion in the primary cohort. The rate of the 1-year outcome in the primary cohort varied significantly across hospitals with a median rate of 12.2% (95%CI: 7.9%-17.7%). With 30 hospitals, randomized at 5-month intervals in 5 steps, approximately 19,600 women are expected to be included in CODE-MI, resulting in >82% power to detect a 20% decrease in the odds of the primary outcome at a 0.05 significance level.

Conclusion

Routinely collected administrative health data serve as a rich and essential resource for conducting pragmatic trials assessing process change, such as CODE-MI. We demonstrated the strength of using linked administrative health data to guide the design of pragmatic clinical trials and accurately evaluate the study power.

https://doi.org/10.23889/ijpds.v7i3.1815