

Comparison of Registered and Published Primary Outcomes in Cardiovascular Randomized Controlled Trials

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Karim Abdur Rehman¹, Haris Riaz¹, Muhammad Khan², Mohamed Gad¹, Safi Khan³, Richard Krasuski⁴, Haitham Ahmed¹

¹Cleveland Clinic Foundation. ²Cook County Hospital. ³Guthrie Hospital. ⁴Duke University

Type of submitter

Fellow in Training

Abstract

Background: Selective reporting can confound the interpretation and validity of randomized controlled trials (RCT). Therefore in 2005, the International Committee of Medical Journal Editors mandated protocol registration for RCT's.

Objective: To investigate the consistency between trials registered with an international clinical trials registry and published primary outcomes among cardiovascular RCT's.

Methods: We searched the MEDLINE database for Phase II and III RCTs published beyond July 2005 through May 2018. For every registered RCT, we determined the time of registration, the measured outcome, the number of outcomes in the published article and corresponding registry. The findings obtained from registry and published article were evaluated for consistency.

Results: Of the 154 RCTs identified, 134 (87.1%) were registered appropriately per ICMJE guidelines with 126 registered with clinicaltrials.gov. Of these, 73 (54.4%) registered a sample size which remained unchanged from the time of registration to publication. 100 (74.6%) RCTs were registered before enrolment, 27 (20.1%) during the study and 7 (5.2%) after completion. These single and multi-center trials were conducted in North America (42.5%), Far East (18%), Europe (18%), and internationally (18%), most of which studied drugs (88%). Primary outcomes involved hard endpoints in 34 (26.1%) RCTs while 99 (73.8%) reported surrogate outcomes. Most trials were funded by the industry (80.5%) and research foundations/academic institutions (17.9%).

Conclusion: Despite mandatory registration, compliance with trial registration continues to lag. In conclusion, the data suggest that only half the phase 2 and 3 trials had a sample size and primary outcome appropriately registered prior to enrollment with outcomes and a sample size unchanged on completion of the study.

Categories

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Program/Institution Name

Cleveland Clinic Foundation

Acute Kidney Injury following Index versus Staged Percutaneous Coronary Intervention in Acute Coronary Syndrome with Multivessel Involvement: A Meta-Analysis

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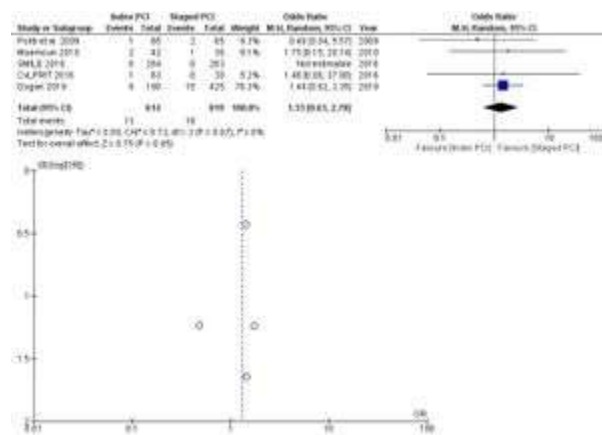
Sindh Avula, Jay Shah, Ma'en Al-Dabbas, Syed Sohail Ali

Mercy Saint Vincent Medical Center

Type of submitter

Fellow in Training

Abstract



Background:

While dealing with a case of acute coronary syndrome (ACS) with multivessel involvement, it remains debatable whether to perform immediate complete revascularization of both the infarct and non-infarct related arteries, index percutaneous coronary intervention (PCI), or immediate revascularization of only infarct-related artery and leaving other narrowed arteries to be treated during another elective procedure (staged PCI). With increasing dose of contrast material used during PCI, the rate of AKI increases. Whether staged delivery of contrast material during PCI plays a role in preventing AKI is controversial. Also, AKI is a major complication of PCI associated with extended hospital stay and poor outcome.

Hypothesis:

Treatment of multivessel PCI during index hospitalization is associated with higher AKI.

Methods:

A systematic search of PubMed/Medline and EMBASE data was performed for all the studies comparing the outcome AKI after index vs staged PCI for multivessel ACS. We calculated comprehensive odds ratio (ORs) and 95% confidence intervals (CIs) using a random-effects model.

Results:

We found 3 RCTs, one post hoc analysis (CvLPRIT) and one registry (Dogan) comprising a total of 1433 PCI procedures (614 index and 819 staged PCI). The primary outcome was development of AKI. Our study demonstrated that there was no significant difference in the occurrence of AKI between the two groups (OR= 1.33; 95% CI: 0.63-2.78, $I^2 = 0\%$, $P=0.45$). There was no heterogeneity among the included trials . Funnel plot looks asymmetrical which suggests higher than minimal publication bias.

Conclusion:

This study provides further information about the differences in the outcomes between the index and staged PCI in multivessel ACS. We couldn't find a significant association between the type of PCI and the risk of developing AKI. Hence, renal complications shouldn't be considered as an important factor while deciding the type of PCI in such patients.

Categories

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Mercy St Vincent Medical Center

High Sensitivity Troponin and the Risk of Atrial Fibrillation in Chronic Kidney Disease: Results from the Chronic Renal Insufficiency Cohort (CRIC) Study

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Scott Janus, Jamal Hajjari, Sadeer Al-Kindi

Case Western

Type of submitter

Fellow in Training

Abstract

Background: Patients with chronic kidney disease (CKD) are at increased risk for atrial fibrillation (AF). There is a need for novel biomarkers to reliably and accurately predict new onset AF in high risk patients. High sensitivity troponin (HsTP) is a relatively new assay that allows detection of very low troponin concentrations with high precision. The utility of HsTP for evaluating the risk of AF in CKD has not been established. We sought to explore the association between HsTP and the risk of incident AF in chronic kidney disease.

Methods: The Chronic Renal Insufficiency Cohort (CRIC) is a prospective cohort of 3939 individuals (21-74 years) with mild to moderate CKD using age related criteria for GFR using the simplified MDRD formula. High sensitivity troponin T was measured at study enrollment. Patients with prior history of AF were excluded. Patients were followed for new onset adjudicated AF, and the association between HsTP and incident AF was examined using Cox regression model.

Results: A total of 3,217 participants free of AF at enrollment were included in this analysis. Over a median follow up of 7.1 year [IQR 5.0-8.4] years, 252 patients developed new-onset AF (12 events per 1000 person-year of follow-up). The incidence of new onset AF was 2.46% (75 events) at three years, 7.06% (192 events) at six years, and 11.5% (250 events) at nine years. (Q4 vs Q1; HR 2.19, 95% CI: 1.31-3.66). Compared with lowest quartile of HsTP (Q1), patients in third quartile of HsTP (HR 2.40, 95% CI: 1.58-3.65, P<0.001), and fourth quartile of HsTP (HR 4.43, 95% CI: 2.98-6.59, P<0.001) had higher incidence of AF. HsTP had modest discrimination of AF risk, with 3-year AUC of 0.66, 6-year AUC of 0.70, and 9-year AUC of 0.67.

Conclusion: High sensitivity troponin levels are associated with increased risk of atrial fibrillation in patients with mild to moderate chronic kidney disease. This association remains significant despite adjustment for traditional AF risk factors and chronic renal disease.

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