TITLE (SHORT, 200 CHARACTERS MAX.):

PREDICTION OF CULPRIT LESION BASED ON BASELINE AND RESUSCITATION CHARACTERISTICS IN PATIENTS WITHOUT STEMI UNDERGOING CORONARY ANGIOGRAPHY (STEPCARE SUBSTUDY)

MAIN HYPOTHESES TESTED (2 MAX)

Primary Objective

To identify baseline and resuscitation variables independently associated with the presence of a culprit lesion in patients without ST-elevation undergoing coronary angiography (CAG) after out-of-hospital cardiac arrest (OHCA).

Secondary Objective

To develop and internally validate a predictive model for the presence of a culprit lesion using routinely available clinical parameters.

Main Hypotheses Tested

Certain clinical, ECG, and resuscitation characteristics can predict the presence of a culprit lesion in patients without ST-elevation.

A multivariable model using these characteristics can reliably identify patients who may benefit from urgent CAG and PCI.

SINGLE CENTER [ ] , MULTICENTER [X]

All STEPCARE participating centers

PICO

Patient:

Inclusion Criteria:

All OHCA patients included in the STEPCARE trial

Underwent coronary angiography without ST-segment elevation on post-ROSC ECG

Exclusion Criteria

Patients with STEMI on post-ROSC ECG

Patients who did not undergo coronary angiography

Intervention/Exposure/Prognostic factor: CAG performed, culprit lesion yes/no

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Comparison: Culprit versus No-culprit lesion on CAG

Outcome: Identification of key predictive factors and model to predict culprit lesion in this population

DATA NEEDED FOR THE ANALYSIS (SPECIFY VARIABLES AND MOTIVATE ANY PROPOSED ADDITIONS TO THE ECRF)

Baseline characteristics - all

Acute coronary syndrome data – STEMI/NSTEMI, shock on admission

Coronary angiography findings – time to CAG, 1/2/3 vessel disease, culprit lesion yes/no, PCI yes/no

Outcomes – 30d, 180d

Safety outcomes

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

There are no additional data needed, all data are part of the STEPCARE database

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

Continuous variables: Mean ± SD or median (IQR); t-test or Mann–Whitney U test as appropriate.

Categorical variables: Count (%); Chi-square or Fisher's exact test.

Univariable Analysis: Compare characteristics between culprit vs. no-culprit groups using appropriate statistical tests. Variables with $p < 0.1$ will be candidates for multivariable modeling.

Multivariable Logistic Regression: Outcome: Presence of culprit lesion (binary outcome)

Candidate predictors: Variables selected from univariable analysis + clinically important factors regardless of univariable p-value.

Report adjusted odds ratios (ORs), 95% confidence intervals, and p-values.

Predictive Model Development: Use logistic regression for model derivation. Assess model discrimination (AUC / C-statistic). Assess calibration (Hosmer–Lemeshow test, calibration plot). Internal validation.

FUNDING (IF APPLICBABLE)

NA

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