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Perioperative assessment and management of cardiovascular risk in patients undergoing noncardiac surgery who under the care of surgical and medical co-management.

Submission date
16/12/2023

Recruitment status
No longer recruiting

Registration date
19/12/2023

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aim
Perioperative myocardial injury/infarction (PMI) following noncardiac surgery has been increasingly recognized as a frequent cardiac complication, which occurs in at least 8% of elective procedures, and 20% of major surgeries. Moreover, PMI is independently associated with an increased risk of cardiovascular (CV) morbidity and mortality at 30 days and up to 1 year after noncardiac surgery. The practice of surgical and medical co-management (SMC) is gaining popularity, as there has been a rapid increase in the percentage of noncardiac surgical patients under SMC, mainly in the United States. However, little is known about the incidence, predictors, or impact of PMI on 30-day mortality in intermediate- or high-risk noncardiac surgery patients under the care of the SMC model in a real-world clinical setting. The study team is a perioperative SMC team with 35 years of clinical experience in perioperative management. This study aims to evaluate the incidence, risk, and impact of PMI in patients at increased CV risk who underwent intermediate- or high-risk noncardiac surgery under the SMC model.

Who can participate?
Patients aged ≥ 65 years old, or ≥ 50 years old with a history of cardiovascular disease (CVD) or CV risk factors (e.g., smoking, obesity, hypertension, diabetes, and dyslipidemia), and treated with intermediate- or high-risk noncardiac surgery and with a postoperative stay of ≥ 2 days during hospitalization in our department between January 2017 and December 2022.

What does the study involve?
Patients can voluntarily participate in this study if they are fully aware of our study. All patients were routinely treated at the discretion of the SMC team during hospitalization, following the updated clinical guidelines without other intervention. The SMC model was initiated when surgical intervention was indicated and throughout the entire perioperative period. The incidence, risk factors, and impact of PMI on 30-day mortality were analyzed. The ability of the Revised Cardiac Risk Index (RCRI), frailty, and their combination to predict PMI was evaluated.

What are the possible benefits and risks of participating?
Patients' perioperative condition will be better monitored and guided if they are participating in this study. This study does not involve specific study drugs, and there are no prescription requirements. Based on the study itself, it will not bring any risk or adverse reactions for patients.

Where is the study run from?
Second Medical Center, Chinese PLA General Hospital (China)

When is the study starting and how long is it expected to run for?
January 2016 to December 2023.

Who is funding the study?
National Clinical Research Center for Geriatric Diseases (China)

Who is the main contact?
Dr. Xi, xishaozhi@163.com

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Perioperative cardiovascular risk assessment and management after intermediate- or high-risk noncardiac surgery in patients under surgical and medical co-management.

Study objectives
This study evaluated the incidence, risk, and impact of perioperative myocardial injury/infarction (PMI) in patients at increased cardiovascular (CV) risk who underwent intermediate- or high-risk noncardiac surgery under the surgical and medical co-management (SMC) model.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/11/2016, Ethics Committee of Chinese PLA General Hospital (No. 28 Fu Xing Road, Beijing, 100853, China; +86 10 6693 7166; jfjzyygw@163.com), ref: S2023-555-01

Study design
Single-center prospective cohort study

Primary study design
Observational

Study type(s)
Prevention, Screening, Treatment

Health condition(s) or problem(s) studied
Perioperative cardiovascular risk after intermediate- or high-risk noncardiac surgery.

Interventions
Patients who are at increased cardiovascular risk when undergoing intermediate- or high-risk noncardiac surgery during hospitalization will be recruited. All patients will be routinely treated with perioperative management by the surgical and medical co-management (SMC) team. The SMC model is initiated when a surgical intervention is indicated and throughout the entire perioperative period. The incidence, risk factors, and impact of perioperative myocardial injury /infarction (PMI) on 30-day mortality will be analyzed.

Intervention Type
Other

Primary outcome(s)
Impact of perioperative myocardial injury/infarction (PMI) on 30-day mortality measured using patient medical records at one time point

Key secondary outcome(s))
Postoperative complications measured using patient medical records at one time point include:
1. Acute coronary syndrome (ACS)
2. The Clavien-Dindo classification of surgical complications
3. 30-day mortality

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. ≥ 65 years old, or ≥ 50 years old with a history of cardiovascular disease (CVD) or CV risk factors (e.g., smoking, obesity, hypertension, diabetes, and dyslipidemia).
2. Treated with intermediate- or high-risk noncardiac surgery according to the criteria of the ESC /ESA surgical risk score and with a postoperative stay of ≥ 2 days.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
50 years

Upper age limit
99 years

Sex
All

Total final enrolment
623

Key exclusion criteria
Patients were excluded if one of the following was met:
1. Cardiac surgery or MI within 14 days before admission
2. Surgery involving a cardiac surgeon
3. Low-risk noncardiac surgery
4. No cTn measurement within 14 days before surgery or 3 days after surgery
5. Elevated preoperative cTn level
6. Lost to follow-up after discharge

Date of first enrolment
01/01/2017

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
China

Study participating centre
Chinese PLA General Hospital
No. 28 Fu Xing Road
Beijing
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Sponsor information

Organisation
Chinese PLA General Hospital

ROR
https://ror.org/04gw3ra78

Funder(s)

Funder type
Research organisation

Funder Name
National Clinical Research Center for Geriatric Diseases

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Dr. Xi, xishaozhi@163.com.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/06/2024	17/01/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes