

Impact of poor nutrition on survival rates in patients with aortic dissection undergoing heart surgery

Submission date 22/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/10/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Aortic dissection is a serious and potentially deadly condition where the inner layer of the aorta tears. This study looks at how a person's nutritional status, measured by the prognostic nutritional index (PNI), affects their chances of survival after surgery for type B aortic dissection (TBAD).

Who can participate?

The study included patients from the Aortic Dilatation Database of the First Affiliated Hospital of Naval Medical University. Patients with connective tissue diseases, traumatic dissection, secondary interventions, tumors, or incomplete data were not included.

What does the study involve?

Participants' medical records were reviewed to gather data. The study used various statistical models to analyze the relationship between PNI and patient outcomes after surgery.

What are the possible benefits and risks of participating?

The study aims to identify if PNI can predict survival rates, which could help doctors better assess and manage patients with TBAD. Since this is a retrospective study, there are no direct risks or benefits to the participants.

Where is the study run from?

The study is conducted at the First Affiliated Hospital of Naval Medical University in China.

When is the study starting and how long is it expected to run for?

The study reviewed data from January 2009 to July 2023.

Who is funding the study?

The study is funded by the National Natural Science Foundation of China, the Shanghai Emerging Cross Disciplinary Research Project, and the Research Project of Shanghai Municipal Health Commission.

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Low prognostic nutritional index predicts case fatality of type B aortic dissection undergoing thoracic endovascular aortic repair

Study objectives

PNI could serve as a valuable marker for predicting 1-year all-cause mortality in patients with Type B aortic dissections.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 24/08/2020, Shanghai Changhai Hospital Ethics Committee (168 Changhai Road, Yangpu District, Shanghai, 200433, China; +86-21-31162338; changhaiec@126.com), ref: CHEC-Y2020-042

Study design

Single-center observational retrospective cohort study

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Type B aortic dissection (TBAD)

Interventions

This retrospective study, conducted from January 2009 to July 2023, included 1,524 patients with aortic dissection who were treated with Thoracic endovascular aortic repair in the aortic dilation database of the First Affiliated Hospital of Naval Medical University. Among them, 563 patients were subsequently excluded from the study. Therefore, only 912 patients were included in the final analysis.

Demographic variables, laboratory tests, intra-operative details and anatomical characteristics were extracted from medical records. BMI calculated as weight in kilograms divided by height in

meters squared. Aortic dissection was classified into acute (1–14 days), sub-acute (15–90 days), or chronic (>90 days) stages according to “2014 ESC guidelines on the diagnosis and treatment of aortic diseases”. Blood samples were taken from all patients upon admission and tested by the laboratory. The Prognostic Nutritional Index (PNI) was subsequently calculated using the formula: $PNI = \text{albumin (g/L)} + 5 \times \text{lymphocyte (10}^9\text{/L)}$. Based on the derived PNI, patients were stratified into two groups: those with a low PNI ($PNI < 46.83$) and those with a high PNI ($PNI \geq 46.83$), utilizing the specified cut-off point.

Qualified investigators meticulously monitored all patients at two distinct intervals: 30 days and one-year post-surgery, utilizing either telephonic surveys or medical records for data collection. Furthermore, an exhaustive review was conducted on the comprehensive clinical files of patients who were readmitted or treated as outpatients to identify any adverse events.

Intervention Type

Other

Primary outcome(s)

All-cause mortality at (30 days and one year post-surgery) using telephonic surveys or medical records for data collection

Key secondary outcome(s)

Aortic-related adverse events (ARAEs) and major adverse cardiac and cerebrovascular events (MACCEs) at (30 days and one year post-surgery) using telephonic surveys or medical records for data collection

Completion date

01/07/2023

Eligibility

Key inclusion criteria

1. Age range: 18-80 years old
2. Patients with TBAD undergoing TEVAR surgery
3. Complete preoperative albumin, lymphocyte, and other blood test data available
4. No history of aortic surgery
5. No malignant tumor or connective tissue disease

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Total final enrolment

912

Key exclusion criteria

1. Traumatic or iatrogenic aortic dissection
2. Connective tissue diseases such as:
 - 2.1. Marfan syndrome
 - 2.2. Turner's syndrome
 - 2.3. Bicuspid aortic valve
 - 2.4. Bechet's disease
 - 2.5. Ehlers-Danlos syndrome
 - 2.6. Giant cell arteritis
 - 2.7. Ankylosing spondylitis
 - 2.8. Takayasu arteritis
3. Previous aortic surgery
4. History of malignancy
5. Patients with incomplete clinical data

Date of first enrolment

01/01/2009

Date of final enrolment

01/07/2023

Locations**Countries of recruitment**

China

Study participating centre

Department of Vascular Surgery, the First Affiliated Hospital of the Navy Medical University
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Sponsor information**Organisation**

National Natural Science Foundation of China

ROR

<https://ror.org/01h0zpd94>

Funder(s)

Funder type

Government

Funder Name

The National Natural Science Foundation of China [82270513]

Funder Name

Shanghai Emerging Cross Disciplinary Research Project [2022JC011]

Funder Name

Research project of Shanghai Municipal Health Commission [20224Y0351]

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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IPD sharing plan summary

Available on request