ISRCTN77727306 https://doi.org/10.1186/ISRCTN77727306

# 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

**Registration date**
25/10/2024

**Overall study status**
Completed

**Last Edited**
24/10/2024

**Condition category**
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Prof. Jian Zhou: zhoujian1_3@163.com
Dr. Shuangshuang Li: lishuangshuangfy@163.com
Ms. Wen Li: daiyaliwen@hotmail.com

# Contact information

### Type(s)
Scientific

### Contact name
Dr Shuangshuang Li

### ORCID ID
https://orcid.org/0000-0001-5887-2280

### Contact details
168 Changhai Road, Yangpu District
Shanghai
China
200433
+86 21-31161670/13611826460
lishuangshuangfy@163.com

### Type(s)
Principal investigator

### Contact name
Prof Jian Zhou

### Contact details
168 Changhai Road, Yangpu District
Shanghai
China
200433
+86 13818896067
zhoujian1_3@163.com

### Type(s)
Public

### Contact name
Ms Wen Li

### Contact details
225 Changhai Road, Yangpu District
Shanghai
China

200433
+86 17821451628
daiyaliwen@hotmail.com

# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
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 = albumin (g/L) + 5 × lymphocyte (109/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 ≥ 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**
Changhai Hospital, 168 Changhai Road, Yangpu District
Shanghai
China
200433

## 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.
zhoujian1_3@163.com

**IPD sharing plan summary**
Available on request