

INPLASY PROTOCOL

To cite: Mei et al. Physician modified stent grafts during fenestrated thoracic endovascular aortic repair for unfavourable landing: A Systematic Review and Meta-Analysis. Inplasy protocol 202160065. doi: 10.37766/inplasy2021.6.0065

Received: 20 June 2021

Published: 20 June 2021

Corresponding author:
Tong Mei

7703@enzemed.com

Author Affiliation:
Taizhou Hospital of Zhejiang Province affiliated to Wenzhou Medical University.

Support: 20ywb26.

Review Stage at time of this submission: The review has not yet started.

Conflicts of interest:
None declared.

Physician modified stent grafts during fenestrated thoracic endovascular aortic repair for unfavourable landing: A Systematic Review and Meta-Analysis

Mei, T¹; Xu, T²; Zhang, L³; Chen, J⁴; Lu, Y⁵.

Review question / Objective: Fenestrated thoracic endovascular aortic repair using physician modified stent grafts for unfavourable landing has been increasingly reported in treating acute and subacute complex aortic arch lesion. The aim of this study was to evaluate the safety and outcome of this technique by performing a systematic review and meta-analysis.

Condition being studied: Aortic dissection, aneurysm and other aortic lesion often involve single or multiple superior branch vessels of the arch, which result in insufficient anchoring zones for thoracic endovascular aortic repair (TEVAR). Due to the development of chimney technology and fenestrated / branching stent-grafts, TEVAR is now more widely used in thoracic aortic lesions with short landing zones. Fenestrated thoracic endovascular aortic repair (f-TEVAR) can maintain blood perfusion of the superior aortic arch. In recent years, f-TEVAR using physician modified stent grafts for unfavourable landing has been successful for revascularizing the supra-aortic branches.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 June 2021 and was last updated on 20 June 2021 (registration number INPLASY202160065).

INTRODUCTION

Review question / Objective: Fenestrated thoracic endovascular aortic repair using physician modified stent grafts for unfavourable landing has been increasingly reported in treating acute and subacute complex aortic arch lesion. The aim of this

study was to evaluate the safety and outcome of this technique by performing a systematic review and meta-analysis.

Rationale: Some centers have reported their initial experience about f-TEVAR using physician modified stent grafts for unfavourable landing, but most of the

current studies are single-center studies with small sample size. In addition, it is difficult to form a clear conclusion about the technical success rate, the patency rate of stent, complications and 30-day mortality. Therefore, we designed this meta-analysis to evaluate the safety and outcome of Fenestrated thoracic endovascular aortic repair using physician modified stent grafts for unfavourable landing.

Condition being studied: Aortic dissection, aneurysm and other aortic lesion often involve single or multiple superior branch vessels of the arch, which result in insufficient anchoring zones for thoracic endovascular aortic repair (TEVAR). Due to the development of chimney technology and fenestrated / branching stent-grafts, TEVAR is now more widely used in thoracic aortic lesions with short landing zones. Fenestrated thoracic endovascular aortic repair (f-TEVAR) can maintain blood perfusion of the superior aortic arch. In recent years, f-TEVAR using physician modified stent grafts for unfavourable landing has been successful for revascularizing the supra-aortic branches.

METHODS

Search strategy: The search was applied to Embase, PubMed and Cochrane databases and included all published English articles in which the patients were diagnosed with aortic arch lesion and treated through the in situ laser fenestration and thoracic endovascular aortic repair in humans between August 2018 and July 2021. The literature search for relevant articles was performed using the following keywords alone and in combination: “physician-modified endovascular grafts” OR “thoracic endovascular aortic repair” OR “aortic disease” OR “aortic dissection” OR “” OR “fenestrated stent-graft” OR “aortic arch branches,” OR “aortic arch aneurysm,” OR “aortic arch dissection,” OR “aortic arch pathologies,” OR “thoracic aortic dissection”.

Participant or population: Patients were treated by Fenestrated thoracic

endovascular aortic repair using physician modified stent grafts because of unfavourable landing.

Intervention: Fenestrated thoracic endovascular aortic repair via physician modified stent grafts.

Comparator: No.

Study designs to be included: Randomised control trials (RCTs), case series, case control series, cross sectional studies, cohort studies, prospective studies, retrospective studies.

Eligibility criteria: Original articles reporting more than 5 patients treated using physician modified stent grafts for unfavourable landing during fenestrated thoracic endovascular aortic repair. Exclusion criteria: 1) fewer than 5 patients included; 2) case reports, comments, editorials, review articles and letters; and 3) study in vitro testing studies; and 4) duplicates were excluded. If the same institution had multiple published studies with an overlapping case series, we chose the article with largest sample size to avoid duplicated reporting. Only human clinical studies published in English language were considered for inclusion.

Information sources: We searched the available literature in Medline, Embase, PubMed and Cochrane databases.

Main outcome(s): Primary outcome: pooled technical success rate of in situ laser fenestration and the rate of stent patency; second outcome: the rate of 30-day mortality, the rate of perioperative endoleak, the rate of stroke, the rate of other adverse events.

Data management: (1) NoteExpress and Excel software is used to extract data, and the content will be in electronic chart. (2) Different research will separately screen the titles potential eligibility which comes from the electronic databases. Full texts screening and data extraction will be conducted afterwards independently. Any

disagreement will be resolved by discussion until consensus is reached or by consulting a third author. In this step, we will use NoteExpress. (3)The following data will be extracted: author, year of publication, country, age of patients, number of people included in the study, patients' basic information, etc. Different reserchers will separately extract data.Any diasgreement regarding data extraction will be resolved by discussion until consensus is reached or consulting a third author. In this step, we will use Excel.

Quality assessment / Risk of bias analysis:

The quality of the included studies was independently assessed by two authors using the checklist for quality appraisal of case series studies produced by the Institute of Health Economics, Alberta, Canada.This checklist consists of 20 items, of which 15 were considered applicable to the present study. Each study received one point for each item that was fulfilled on this checklist. The maximum and minimum numbers of points for each study were 15 and 0, respectively. Studies were classified as high quality if they received 13 or more points, moderate quality if they received 11-12 points and low quality if they received 10 points or less.

Strategy of data synthesis: The meta-analyses will be performed using both random effects models and fixed effects models. The presence of heterogeneity between studies will be determined using the chi-square based Q test and quantified using I² statistics. If I² statistics were >50%, heterogeneity was considered to be significant. The potential publication bias was appraised primarily by a funnel plot. An asymmetric plot suggests a likely publication bias. The funnel plot asymmetry was further evaluated using Egger's Test. NoteExpress and Excel software will be stored in electronic chart. All of the analyses will be performed using the statistical software packages R (<http://www.R-project.org>, The R Foundation).

Subgroup analysis: According to the position of stent implantation, they were

divided into Zone0-1 and Zone2 groups.Primary outcome:Pooled technical success rate and the rate of stent patency. Second outcome: The rate of 30-day mortality, the rate of perioperative endoleak, the rate of stroke, the rate of other adverse events may be analysed.

Sensitivity analysis: We conduct the sensinty analysis by excluding literature successively.When the system review contains > 10 articles, the Egger test will be conducted to evaluate publication.

Language: English.

Country(ies) involved: China.

Keywords: physician modified stent grafts, fenestrated thoracic endovascular aortic repair, thoracic aortic dissection, meta-analysis.

Contributions of each author:

Author 1 - Tong Mei - designed extraction table, screened abstracts and extracted data from selected papers, analyzed the data and drafted the manuscript.

Email: 7703@enzemed.com

Author 2 - Tingting Xu - She extracted data from selected papers, helped with the manuscript.

Email: xutt@enzemed.com

Author 3 - Lan Zhang.

Email: 8850@enzemed.com

Author 4 - Jinhui Chen - designed this study, helped with the manuscript.

Email: chenjh6069@enzemed.com

Author 5 - Yongming Lu - designed this study, quality control and modified this paper, corresponding author.

Email: luym@enzemed.com