


BMJ Open Protocol for Guo's aortic Arch reconstruction: a prospective, multicentre and single-arm study to evaluate the safety and efficacy of the WeFlow-Arch modular inner branch stent-graft system for aortic arch lesions (GIANT study)

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ABSTRACT

Introduction Endovascular repair of the entire aortic arch provides treatment opportunities for patients with aortic arch lesions who are intolerant to open surgery. However, the complex anatomical configuration, high-speed blood flow and long access from the femoral artery increase the difficulty of endovascular aortic arch repair. On the basis of our earlier studies, a new modular inner branch stent-graft system was developed specifically for lesions located in the aortic arch and part of the ascending aorta. This study aims to evaluate the safety and efficacy of the novel modular branch stent-graft system in patients with aortic arch lesions who are unsuitable for open aortic arch replacement.

Methods and analysis This prospective, multicentre, single-arm, clinical trial will enrol 80 patients with aortic arch lesions requiring intervention, namely, true aortic arch aneurysms, pseudo-aortic arch aneurysms and penetrating ulcers involving the aortic arch. Clinical information and CT angiography (CTA) images will be collected and analysed to investigate the safety and efficacy of the novel modular branch stent-graft system. Patients will be followed up for 5 years. The primary outcome will be all-cause mortality and severe stroke within 12 months after the procedure. In addition, this trial will evaluate mid-term to long-term clinical and imaging outcomes through the annual clinical and CTA follow-up for 2–5 years postoperatively.

Ethics and dissemination We have registered the study on a registry website (<https://clinicaltrials.gov/ct2/home>). The study findings will be disseminated through peer-reviewed journals, physician newsletters, conferences and the mass media.

Trial registration number NCT04765592.

INTRODUCTION

The supra-aortic branches provide the blood supply to the brain, and the revascularisation of these branches is part and parcel of aortic arch repair. Endovascular repair of the aortic arch, which avoids a long hypothermic

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is a prospective, multicentre, single-arm study with a 60-month follow-up, and the participating centres are from different geographical climate regions of China.
- ⇒ This is the first study focusing on our novel modular branch stent-graft system, which is dedicated for endovascular repair of the entire aortic arch.
- ⇒ This is a single-arm prospective study, and there is no control group for comparison with other treatment modalities.
- ⇒ This is an open-label study, which has the potential to introduce bias.
- ⇒ This study will be performed in an East Asian population, resulting in limitations associated with ethnicities and geographical regions.

cardiopulmonary bypass, circulatory arrest, and antegrade or retrograde cerebral perfusion, provides a curative chance for patients with aortic arch pathology who cannot tolerate open surgical repair.^{1–3} Combined with surgical debranching of the supra-aortic branches, the use of endovascular-based approaches, including parallel stent-grafts, scallop or fenestrated stent-grafts, in situ fenestrations and branched stent-grafts, has recently expanded rapidly.⁴

With technological advancements, endovascular repair of the entire aortic arch (proximal landing located in zone 0, distal landing in zone 3) in accordance with Ishimaru⁵ has become attractive. However, endovascular repair remains very difficult when the ascending aorta or aortic arch is involved. The main technical challenge is to maintain sustained blood flow to the supra-aortic branches to avoid prolonged cerebral and

upper extremity ischaemia during the procedure. In addition, arch curvature and a long access from the femoral artery increase concerns about precise alignment and deployment of a stent-graft. Furthermore, owing to the proximity of the landing zone to the left ventricle, with great pulsatility and large blood flow, a windsock effect of the stent-graft before complete deployment could lead to stent-graft migration or kinking.⁶⁻⁸ The current clinical evidence indicates that procedural complications, namely, cerebral ischaemia, endoleak and retrograde dissection, are associated with endograft design and a complicated procedure.⁹⁻¹²

To address the stated challenges, several innovative dedicated stent-grafts for total endovascular aortic arch repair have been developed, namely, the Inoue outer branched stent-graft,^{9 13} Najuta fenestrated stent-graft,^{14 15} Cook two-inner branch endograft,^{16 17} Bolton inner double-branch endoprosthesis^{18 19} and Endospa NEXUS stent-graft.^{20 21} However, there is no ideal endovascular solution to the ascending aorta/aortic arch challenge that can completely exclude the aortic arch pathology, avoid embolic stroke and preserve perfusion of the supra-aortic multi-branches without surgical debranching of the supra-aortic branches or a complex endovascular procedure.

On the basis of our earlier studies,²²⁻²⁴ we developed a new modular inner branch stent-graft system (WeFlow-Arch; Hangzhou Endonom Medtech Co., Ltd., Hangzhou, China) specifically for lesions located in the aortic arch and part of the ascending aorta. The stent-graft system is under review by the National Medical Products Administration. In our centre, the preliminary results of eight cases from June 2019 to October 2021 showed a technical success rate of 100%, and no patients suffered symptomatic cerebral ischaemia. The Guo's aortic Arch reconstruction (GIANT) study is a prospective, multicentre, single-arm study. The aim is to investigate the clinical results after endovascular aortic arch repair using this stent-graft system in patients with aortic arch lesions who are unsuitable for open aortic arch replacement.

OBJECTIVE

The objective of the study is to evaluate the safety and efficacy of the modular branch stent-graft system (WeFlow-Arch) in endovascular repair of the aortic arch.

The primary outcome will be all-cause mortality and severe stroke within 12 months after the procedure. All-cause mortality will comprise cardiac mortality, non-cardiac mortality and mortality from unknown causes. Severe stroke is defined as a modified Rankin scale score ≥ 2 at 90 days following stroke onset.²⁵

The secondary outcomes are as follows:

1. Technical success, defined by the composite of successful stent-graft deployment, all branching stents patency, and the absence of type I/III endoleaks, migration and rupture at the final angiography;

2. Twelve-month clinical success, defined as aortic aneurysm diameter growth ≤ 5 mm compared with the preoperative aortic aneurysm size;
3. The maximum diameter of aortic aneurysm at 1 month, 6 months, 12 months and 2–5 years after the surgery;
4. Incidence of endoleak (type I/II/III/IV) immediately after the surgery, and 1 month, 6 months, 12 months and 2–5 years after the surgery;
5. Incidence of stent-graft migration 1 month, 6 months, 12 months and 2–5 years after the surgery, with migration defined as aortic or branching stent-graft migration of >10 mm;
6. Supra-aortic branch patency rate 1 month, 6 months, 12 months and 2–5 years after the surgery;
7. Incidence of stent-graft-induced aortic dissection leading to conversion to open surgery or secondary intervention 1 month, 6 months, 12 months and 2–5 years after the surgery;
8. Incidence of 30-day major adverse events, namely, all-cause mortality, myocardial infarction, ischaemic stroke, or respiratory failure;
9. Twelve-month aortic aneurysm-related mortality;
10. Incidence of severe adverse events 1 month, 6 months, 12 months and 2–5 years after the surgery, including death, serious deterioration in patient health and any adverse event requiring interventional therapy or open surgery;
11. Incidence of device-related adverse events (as determined by the clinical investigators) 1 month, 6 months, 12 months and 2–5 years after the surgery.

METHODS

Study design

This is a prospective, multicentre, single-arm study. All enrolled patients will undergo CT angiography (CTA) and clinical evaluation 30 days, 3 months, 6 months and 12 months in the first year postoperatively, and annuals in 2–5 years after the surgery. Clinical information will be acquired through the patients' electronic medical records and the CTA Digital Imaging and Communication in Medicine files from the radiology department databases.

The clinical study was conceived, designed and initiated, and will be performed by the Department of Vascular Surgery, Chinese PLA General Hospital. Twenty-three additional medical centres with high annual surgery volume (thoracic endovascular aortic repair >30 cases per year) in different geographical climate regions of China were invited to participate in this study. The geographical distribution of all participating centres at the start of the trial comprises the following: Northeast China ($n=2$), North China ($n=6$), East China ($n=11$), Central China ($n=2$), South China ($n=1$) and Southwest China ($n=3$) (table 1). All participants received specific training and passed a training test prior to performing the formal procedure.

Table 1 Participating trial centres

Clinical trial institution	Geographical region
Chinese PLA General Hospital	North China
Peking University People's Hospital	North China
Beijing Anzhen Hospital, Capital Medical University	North China
Tianjin Medical University General Hospital	North China
Peking Union Medical College Hospital, Chinese Academy of Medical Sciences	North China
The First Affiliated Hospital of PLA Air Force Military Medical University	North China
The Second Affiliated Hospital of Harbin Medical University	Northeast China
The First Affiliated Hospital of China Medical University	Northeast China
Zhongshan Hospital, Fudan University	East China
Nanjing First Hospital	East China
Nanjing Drum Tower Hospital	East China
The Affiliated Hospital of Qingdao University	East China
The Ninth People's Hospital, Shanghai Jiaotong University School of Medicine	East China
Renji Hospital, Shanghai Jiaotong University School of Medicine	East China
Shandong Provincial Hospital	East China
The First Affiliated Hospital of Soochow University	East China
First Affiliated Hospital of Zhejiang University School of Medicine	East China
Second Affiliated Hospital of Zhejiang University School of Medicine	East China
The Second Affiliated Hospital of Nanchang University	East China
Xiangya Hospital of Central South University	Central China
First Affiliated Hospital of Zhengzhou University	Central China
The First Affiliated Hospital, Sun Yat-sen University	South China
West China Hospital of Sichuan University	Southwest China
The First People's Hospital of Yunnan Province	Southwest China

The centres listed in the table are the originally participating hospitals at the start of the trial.

PLA, People's Liberation Army.

Participants

This study uses competitive enrolment. We plan to recruit 80 patients who meet the inclusion criteria to participate in this study from June 2021 to December 2022. All patients will be followed up until death or the end of follow-up (5 years after surgery). The endpoint of the study is defined as the date of the last follow-up visit of the last participant. The estimated end date is December 2027.

Criteria

Inclusion criteria:

1. Patients aged 18–80 years;
2. Patients who are diagnosed with aortic arch lesions requiring intervention, namely, true aortic arch aneurysms, pseudo-aortic arch aneurysms and penetrating ulcers involving the aortic arch;
3. Patients with surgical contraindications or high surgical risk;
4. Patients with a suitable vascular condition, namely, ascending aorta length ≥ 50 mm (from the sinotubular

junction to the proximal margin of the innominate artery (IA))

- a. Ascending aorta diameter ≥ 24 mm and ≤ 48 mm;
 - b. Proximal anchoring zone length ≥ 30 mm;
 - c. IA diameter ≤ 24 mm and ≥ 7 mm, length ≥ 20 mm;
 - d. Left common carotid artery (LCCA) or left subclavian artery (LSA) diameter ≤ 24 mm and ≥ 7 mm, length ≥ 20 mm;
 - e. Suitable arterial access for endovascular treatment (such as diameter, tortuosity and calcification);
5. Patients who understand the purpose of the trial, have good compliance and are able to complete the follow-up.

Exclusion criteria:

1. Patients who experienced systemic infection within the previous 3 months;
2. Patients who underwent surgeries in the neck within 3 months of the endovascular procedure;
3. Patients who underwent endovascular interventional treatment involving the aortic arch;

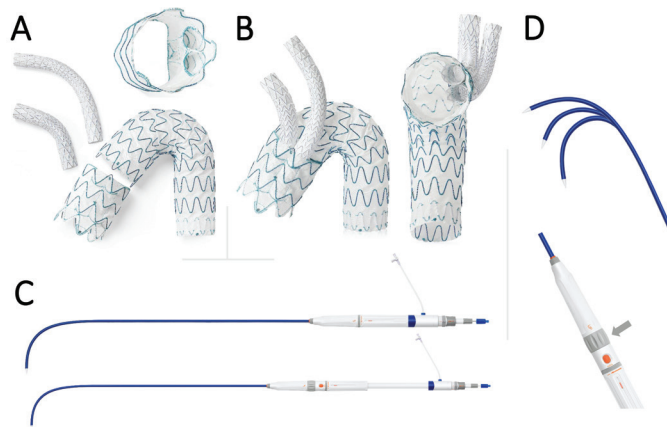


Figure 1 Design of the new modular inner branch stent-graft and delivery system. The modular stent-graft before (A) and after (B) assembly. The dedicated delivery systems are shown for ascending aorta stent-grafting (upper image in panel C; pre-curved design) and aortic arch stent-grafting (lower image in panel C; pre-curved plus steerable design). Schematic diagram of the steering operation of the pre-curved plus steerable delivery system (D). First, ascending aorta stent-graft; second, bridging cover-stents; third, aortic arch stent-graft. The arrow indicates the control dial that is used to steer the direction of the tip.

4. Patients with infectious aortic disease, Takayasu arteritis, or Marfan syndrome (or other connective tissue diseases);
5. Severe stenosis, calcification, thrombosis, or tortuosity of the carotid or subclavian artery;
6. Patients who underwent heart transplantation;
7. Patients who suffered myocardial infarction or stroke within 3 months of the endovascular procedure;
8. Patients with New York Heart Association class IV heart function;
9. Patients with an active peptic ulcer or upper gastrointestinal bleeding within 3 months of the endovascular procedure;
10. Patients with haematological abnormalities, namely, leucopenia (white blood cell count $<3 \times 10^9/L$), acute anaemia (haemoglobin $<90 \text{ g/L}$), thrombocytopenia (platelet count $<50 \times 10^9/L$), or a history of bleeding diathesis or coagulopathy;
11. Patients with renal insufficiency (creatinine $>265 \mu\text{mol/L}$) or end-stage renal disease;
12. Patients who are pregnant or breast feeding;
13. Patients with allergies to contrast agents;
14. Patients with a life expectancy of less than 12 months;
15. Patients participating in another drug or device study;
16. Any other disease or abnormality that the investigators believe may hinder endovascular treatment.

Design of the device

The concept of Guo's aortic arch reconstruction is to use different dedicated stent-graft modules to achieve the goals of covering aortic arch lesions and reconstructing supra-aortic arteries, respectively. Segmental deployment simplifies procedures associated with complicated

anatomical matching and avoids extended interruption of the supra-aortic blood supply. The endografts of the modular inner branch stent-graft system consist of three modules: one ascending aorta stent-graft with two inner branches, bridging cover-stents and one tubular aortic arch stent-graft (figure 1A and B).

Module 1, the ascending aorta stent-graft (proximal non-bare stent), ranges in size from 28 mm to 52 mm in proximal diameter and from 30 mm to 70 mm in length. The distinguishing feature of this module is the two inner branches of equal diameter in the anterior aspect of the endograft, which are designed to connect to the IA by the anterior inner branch and to the LCCA or LSA by the posterior inner branch. In addition, integral suturing of the connection sites seals the gutter around the inner branches to avoid potential endoleaks. The module's delivery system has a self-aligning design. The module is mounted in the pre-curved delivery system (size range from 22 Fr to 24 Fr) (figure 1C, upper image), and the two inner branches align with the anterior aspect of the ascending aorta. Radiopaque marker rings are attached at both ends of the inner branches for imaging identification during reconstruction of the supra-aortic arteries.

Module 2 is a self-expandable tapered cover-stent that is mounted in a delivery system with a diameter of 12 Fr and which is used to bridge the inner branches of module 1 to the supra-aortic arteries via the right brachial or LCCA access. The tapered design allows the distal and proximal segments of module 2 to match the diameters of the inner branch and the supra-aortic arteries, respectively. Module 3, which is a tubular aortic arch stent-graft, is mounted in a pre-curved delivery system (size range from 20 Fr to 22 Fr) with the steerable device (figure 1C (lower image) and D), which is designed to avoid iatrogenic displacement of module 1 during introducing manipulations.

Endovascular aortic procedures

The procedures are performed under general anaesthesia in a hybrid operating room.

Operation step one: approach preparation

Bypass between the LCCA and LSA is performed before the endovascular procedure. After the LCCA and LSA are exposed surgically through a neck incision, intravenous heparin is administered to achieve an activated clotting time of at least 250s. After the bypass is performed, the LCCA is directly punctured, and a 6 Fr sheath is inserted to establish vascular access. The approach to the right brachial artery or axillary artery is surgically exposed according to the diameter of the IA to meet the delivery system size, and the artery is directly punctured. Left radial artery catheterisation is performed with a 5/6 Fr sheath. One of the femoral arteries is cannulated percutaneously with a 6 Fr sheath, and two Perclose ProGlide (Abbott Vascular, Redwood City, CA, USA) sutures are prepositioned. Intraoperative use of a temporary pacemaker to reduce cardiac output is at the discretion of

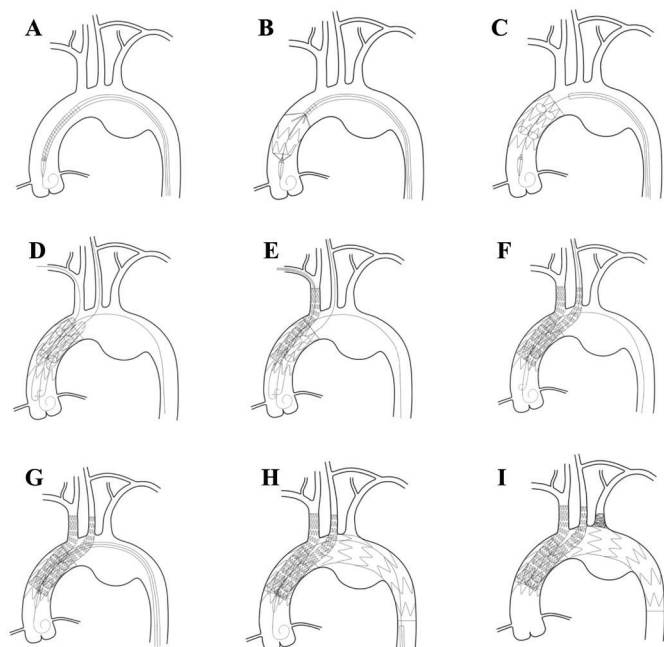


Figure 2 Schematic diagram of the endovascular procedure. A–C, Module 1 is deployed in the ascending aorta, and the two inner branches of the endograft self-align with the anterior aspect of the ascending aorta. D–F, Module 2 is deployed to bridge the inner branches of module 1 to the supra-aortic arteries via the right brachial and left common carotid artery accesses, respectively. G–I, Module 1 is deployed to overlap the lumen of module 1 via a steerable pre-curved delivery system, and the proximal portion of the left subclavian artery is embolised using coils.

the operator. The contralateral femoral vein is used to implant a temporary pacemaker.

Operation step two: ascending aorta stent-grafting

A Lunderquist wire (Cook Medical, Bloomington, IN, USA) is repositioned in the aortic sinus or left ventricle, and module 1 is advanced beyond the IA ostium and deployed in zone 0 (under rapid pacing if necessary). Device rotation is automatically controlled by the pre-curved delivery system (figure 2A–C).

Operation step three: bridging cover-stents and aortic arch stent-grafting

Two expanded balloons that are used to verify the wires from the right brachial artery and the LCCA are positioned in the anterior and posterior inner branches, respectively. Module 2 is then introduced over the guide-wire and bridges the IA or LCCA with the inner branches, respectively (figure 2D–F). The module 3 aortic arch stent-graft is introduced over the Lunderquist wire to overlap the lumen of module 1 via a steerable pre-curved delivery system.

Operation step four: balloon dilation and LSA occlusion

After the modules are dilated to the arterial wall by balloon inflation to ensure an adequate seal, embolisation of the proximal portion of the LSA from the LSA orifice to the

vertebral artery origin is performed using coils through the left radial or brachial artery access (figure 2G–I).

The preventive management of spinal cord ischaemia:

1. One-stage left subclavian artery revascularisation using LSA–LCCA bypass
2. Stable blood pressures and haemoglobin levels in perioperative period (mean arterial pressure ≥ 80 mmHg; central venous pressure ≤ 12 mmHg; haemoglobin level ≥ 10 g/dL).
3. Antiplatelet and anticoagulant therapy
4. Postoperative neurological assessments on a one to two hourly before awakening from anaesthesia.
5. Prompt cerebrospinal drainage catheter insertion and maintenance when spinal cord ischaemia is confirmed.

Data collection

Table 2 summarises the schedule for the study visits and data collection. We developed a standardised case report form for use in data collection, which will comprise medical record data, CTA imaging data and follow-up data. Demographics, comorbidities, surgical details and perioperative data will be collected during hospitalisation. Preoperative and follow-up CTA images 1, 6 and 12 months in the first year postoperatively, and annuals in 2–5 years after the surgery will be submitted to an imaging core laboratory in the Digital Images and Communication in Medicine format and will be assessed by experienced vascular surgeons who are blinded to the clinical results. Double data entry and cross-validation methods will be used to ensure the quality of the data. A monitoring team comprising clinical research associates who are independent from the investigators and sponsors will constantly review all clinical study data in accordance with regulatory requirements.

Statistical methods

Sample size calculation

A sample size calculation was performed on the basis of the objective performance of the primary endpoint of the study. Combined with our preliminary single-centre data pertaining to endovascular repair of the aortic arch (unpublished, 2022) and previous studies,^{26–28} we estimated that the incidence rate of the composite primary endpoint of all-cause mortality and severe stroke within 12 months was 35% (objective performance), and the expected incidence rate of the modular branch stent-graft system was 20%. The level of statistical significance was set at 2.5% for one-sided tests, and the overall power was set at 80%. The calculated sample size was 72 subjects. Considering a dropout rate of 10%, the required sample size was increased to 80 subjects. Therefore, the aim is to enrol at least 80 patients in the clinical trial.

Statistical analysis

An interim analysis is performed on the primary endpoint when all patients have completed the 12-month follow-up. The interim analysis is performed by an independent statistician. Three analysis subject sets will be distinguished:

Table 2 Schedule for the study visits and data collection

	Baseline (-15 days-1 day)	Operation day	Discharge day	Post-30 days (±7 days)	Post-6 months (±30 days)	Post-12 months (±30 days)	Post-24 months (±30 days)	Post-36 months (±30 days)	Post-48 months (±30 days)	Post-60 months (±30 days)
Informed consent	x									
Eligibility screen	x									
Medical history/ demographics	x									
Pregnancy test	x									
Physical examination	x	x	x							
Blood routine	x		x							
Urine routine	x		x							
Coagulation function	x		x							
Liver/renal function	x		x							
Modified Rankin score	x		x							
Electrocardiography	x		x							
Echocardiography	x									
Thoracic X-ray	x									
CTA	x				x	x	x	x	x	x
DSA		x								
Operation record		x								
Medication record	x		x	x	x	x	x	x	x	x
Adverse events record	x		x	x	x	x	x	x	x	x

CTA, CT angiography; DSA, digital subtraction angiography; Post, post-procedure.

a full analysis set, a per-protocol set and a safety set. The primary and secondary endpoints will be evaluated using both the full analysis set (using the intention-to-treat principle; all enrolled patients) and the per-protocol set (patients who complete the trial in accordance with the protocol without major violations). All safety analyses will be performed using the safety set (all enrolled patients treated by the device).

Continuous variables will be expressed as mean±SD, or median (IQR) if distributions were skewed. Categorical and ranked variables will be expressed as number and percentage. The Kaplan-Meier method will be used to estimate the cumulative rate of each endpoint, and Kaplan-Meier curves will be created. Statistical calculations will be performed using SAS software (V.9.4 or above; SAS Institute Inc., Cary, NC, USA).

Ethics and dissemination

The study will be conducted in accordance with the tenets of the Declaration of Helsinki. Any significant protocol modifications will be forwarded to the ethics committee for approval.

The patient and his/her family members will be given information about the study, namely, the potential advantages and risks of the modular inner branch stent-graft system, and any alternative treatments that are available. Written informed consent will be provided by the patients or their immediate family members during standard clinical visits required for the endovascular procedure. The example of informed consent form is provided in online supplemental material.

The patients' information will be maintained in accordance with international good clinical practice standards. Data for all enrolled patients will be anonymised and allocated a unique code as a study identification. Only direct members of the study team will have access to the data linked to a participant's identity. Paper-based materials (eg, the case report form) will be stored in locked file cabinets, while electronic data files that are identifiable will be stored in a password-secured separate server behind a firewall to guard against inappropriate use or malicious or accidental loss or destruction. We anticipate that the study results may provide a novel solution for endovascular repair of the entire aortic arch and a novel therapeutic option for aortic arch lesions.

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Contributors FL and HZ contributed equally to this manuscript. WG initiated the conception and design of the study, while FL, YG, DR, XJ, JX, XM, LW and TF helped with the implementation of the study. FL, HZ and WG prepared the first draft of the manuscript. All authors contributed to the study protocol and approved the submitted version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study protocol involves human participants and has been reviewed and approved by the ethics committee of the Chinese PLA General Hospital (2020-034) and each participating centre. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

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