Trials

STUDY PROTOCOL

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Pericardiectomy with routine cardiopulmonary bypass: a multicenter, randomized controlled trial

Jing-bin Huang[1*], Chang-chao Lu[1] and Zhao-ke Wen[1]

Abstract

Constrictive pericarditis is a result of chronic inflammation characterized by thickening and calcification of pericardial fibers, impaired diastolic filling, reduced cardiac output, and ultimately heart failure. The main objective of this multicenter trial is to evaluate whether conventional extracorporeal circulation pericardial resection has a better prognosis than pericardial resection without extracorporeal circulation. This study is a multicenter, randomized controlled, evaluator blinded, parallel group study with an advantageous framework. A total of 436 participants with constrictive pericarditis will be randomly assigned to either the extracorporeal circulation pericardial resection group or the non-extracorporeal circulation pericardial clearance group in a 1:1 ratio using a computer. Incomplete pericardial detachment is associated with low cardiac output syndrome after pericardial resection. The causes of low cardiac output syndrome are related to incomplete resection of thickened pericardium, unsatisfactory relief of left ventricular compression, excessive ventricular dilation after pericardial dissection, myocardial weakness, and heart failure. The relief of left ventricular compression is crucial for the postoperative recovery of cardiac function.

Introduction

Constrictive pericarditis is a result of chronic inflammation characterized by thickening and calcification of pericardial fibers, impaired diastolic filling, reduced cardiac output, and ultimately heart failure. The surgical mortality risk of pericardiotomy remains high, ranging from 5 to 20% [1–3]

The normal pericardium is composed of an inner layer of serosa and an outer layer of fibers. The pericardial cavity typically contains about 20 to 50 ml of fluid. The pericardium has multiple functions such as mechanical effects (keeping cardiac geometry, restricting dilation, elevating ventricular coupling interactions, completing frictionless motion, and acting as an infection barrier), vasodilation, immunity, paracrine secretion, and fibrinolytic activity. Currently in Western countries, viral or idiopathic pericarditis is the main cause of constrictive pericarditis, followed by post cardiac stimulation and mediastinal irradiation. Tuberculosis is still the main cause of pericarditis in developing countries [4–7]

In 1913, German surgeon Ludwig Rehn successfully completed the first case of pericardiotomy for constrictive pericarditis, which was later considered a treatment method [5]. Pericardial resection can be completed through sternotomy or left anterior lateral thoracotomy. The sternotomy can effectively enter the right ventricle, major blood vessels, and right atrium, clearing the thickened pericardium from the phrenic nerve to the phrenic nerve. Left anterior thoracotomy is mainly used for infectious suppurative pericarditis to avoid postoperative sternum infection.

Different surgical techniques and methods, such as partial pericardiotomy and total pericardiotomy, the

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necessity of extracorporeal circulation, and sternotomy and lateral thoracotomy, are still under debate. The sternotomy can more thoroughly remove the pericardium. In cases of suppurative pericarditis and exudative constrictive pericardial disease, left anterior thoracotomy should be the preferred option due to the risk of empyema and sternum infection. Despite the success of pericardial resection, residual and long-term contraction or myocardial atrophy after myocardial processes may still lead to long-term heart failure. The causes of death include multiple organ failure, heart failure, and respiratory dysfunction [8–12].

Our study also suggests that incomplete pericardial dissection is related to surgical mortality after pericardiotomy without cardiopulmonary bypass (CPB). During the surgical process, the additional time of extracorporeal circulation is very short and has little impact on the risk of the main surgery. Incomplete pericardial resection may be the cause of postoperative residual stenosis and high diastolic blood pressure leading to multiple organ failure. The use of extracorporeal circulation for complete pericardial resection (removal of diaphragm to diaphragm and thickening of posterior lateral and inferior wall pericardium) may be a routine method for completely relieving cardiac contractions [13].

Purpose and assumptions

The main objective of this multicenter trial is to evaluate whether conventional extracorporeal circulation pericardial resection has a better prognosis than pericardial resection without extracorporeal circulation. We assume that pericardial resection combined with conventional extracorporeal circulation can reduce mortality and the incidence of major complications. The results of this trial will lay the foundation for future clinical recommendations on routine extracorporeal circulation pericardial resection and may improve the treatment of patients with constrictive pericarditis.

Methods

Research design

This study is a multicenter, randomized controlled, evaluator blinded, parallel group study with an advantageous framework. Eight hospitals in China will participate: The People's Hospital of Guangxi Zhuang Autonomous Region, Ruikang Hospital affiliated with Guangxi University of Traditional Chinese Medicine, Wuzhou People's Hospital, Qinzhou People's Hospital, Chongzuo People's Hospital, and Laibin People's Hospital.

The design of this protocol complies with the standard protocol project for interventional trials: Intervention Trial Recommendations (SPIRIT) guidelines [14]. The SPIRIT diagram is shown in Fig. 1 [15–17]. The participating center will be required to sign a cooperation contract that specifies responsibilities, intellectual property ownership, and publishing processes. The funds for this experiment will only be used for organizing expenses and meetings; This experiment is not supported by third-party funding. Before proceeding, any changes to the agreement will be submitted to our ethics committee and detailed explanations of the changes will be provided. All ongoing serious adverse events will be followed up and recorded until the final outcome is determined.

Diagnosis of constrictive pericarditis

The diagnosis of constrictive pericarditis is based on clinical manifestations, echocardiography, chest computed tomography (CT), cardiac catheterization, surgical and pathological criteria. The most important diagnostic tool is to suspect that patients with signs and symptoms of right-sided heart failure have constrictive pericarditis, which are not commensurate with the lungs of left-sided heart disease. Typical symptoms and signs include significant changes in jugular vein pulse x and y, difficulty breathing forcefully, palpitations, bloating, and swelling of the ankle or leg. Echocardiography and chest computed tomography showed severe thickening or calcification of the pericardium, while cardiac catheterization revealed elevated end diastolic pressure and the "square root sign" of right ventricular pressure tracking. Thickening of the pericardium beyond 4 mm on cardiac CT is helpful for diagnosis and is the best way to evaluate pericardial calcification. A review of surgical and pathological results was conducted to confirm preoperative diagnosis.

Qualification criteria

The inclusion criteria include patients with constrictive pericarditis aged more than 18 years who are scheduled to undergo pericardiotomy alone. Exclusion criteria include patients with constrictive pericarditis who are not scheduled to undergo pericardiotomy, or aged $\leq$18 years, or redo pericardiotomy, or pericardiotomy with left anterior thoracotomy, or pericardiotomy with valvular surgery or coronary artery bypass grafting. Pericardiotomy in emergency is also excluded.

Ethics and registration

The protocol of this study follows the guidelines set forth in the Helsinki Declaration and complies with the Medical Research Act on Human Subjects and the Good Clinical Practice Guidelines. The Biomedical Ethics Committee of Guangxi Zhuang Autonomous Region People's Hospital has confirmed the central ethical approval (number PHGX 0886), and we will not begin recruitment at other centers of the trial until we obtain local ethical approval [15–18]. All results will be presented in

	Study period				
	Enrollment	Allocation	Post-Allocation		
Time points	Day-1-0	Surgery Day0	Inpatient	Follow up: Clinic visit/telephone/micro-message	postoperative day 30
Enrollment:					
Eligibility screen	√				
Informed consent	√				
Allocation		√			
Intervention: Pericardiectomy on CPB		√			
Pericardiectomy without CPB		√			
Demographic data	√				
Medical history	√				
Blood sample	√				
CPB data			√		
Mortality			√	√	√
Acute kidney injury			√		
Low cardiac output syndrome			√		
Multiorgan failure			√		
Mechanical ventilation time			√		
ICU stay			√		
Length of hospital stay postoperative			√		
Packed red cell			√		
Frozen plasma			√		

Fig. 1 Schedule of enrollment, intervention, and assessment according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Statement

accordance with the Consolidated Trial Reporting Standard (CONSORT) declaration (Fig. 1).

Recruitment of research population

After obtaining surgical consent, the surgical researcher will explain the trial to the patient or their relatively sufficient information, including the benefits and drawbacks of participation. Simple language will be used to promote understanding of medical terminology. Agreed participants will provide demographic and general medical data, as described in the "Baseline study visit" section below.

The target study population is all patients ≥18 years who have been diagnosed with constrictive pericarditis and are planning to undergo pericardiotomy alone. If the patient is over 18 years old and diagnosed with constrictive pericarditis, they are eligible to participate in this study. If patients are unable to understand or provide informed consent, if they are pregnant, or if they have participated in another clinical trial that may interfere with the primary or secondary outcomes of this trial, they will be excluded from the study. If patients are willing, they can leave the study at any time for any reason without any consequences. Patients who withdraw from

the study will not be replaced. Exit will be recorded in the electronic case report form. Researchers may decide to withdraw from the study due to urgent medical reasons.

Data collection and management

All data will be recorded on a paper case report form. After recording hospitalization data, trained assessors will input clinical data from paper case report forms into a web-based database. All participating centers and primary researchers have 24-h access to electronic case report forms. If the data input is incomplete or incorrect, the primary researcher can contact the participating center for further clarification. All outcome parameters will be recorded by the trial team members of each center at the time of enrollment and throughout the entire follow-up period. All experimental data will be stored on a secure server in the data coordination center, which will remain confidential and retained for 15 years after the completion of the study (defined as 365 days after the last patient follow-up), and will be anonymized if requested by authorities. The parameters that are crucial to the main objectives of this experiment will be remotely monitored. There will be a formal interim analysis.

Baseline study visit

As part of the baseline examination, we will collect patient information including gender (female/male), age, pre diuretic weight, post diuretic weight, time between symptoms and surgery, pericardial thickness, NYHA grading, cachexia, tuberculosis, rheumatic heart disease, infective endocarditis, valvular heart disease, coronary heart disease, pleural effusion, left ventricular end diastolic size, left ventricular ejection fraction, aortic valve regurgitation, mitral regurgitation, tricuspid regurgitation, pericardial thickening, pericardial effusion, pericardial calcification, and serum creatinine. Enhanced chest and abdominal computed tomography scans will be performed to confirm preoperative diagnosis. Additional clinical and research data will also be collected at baseline and other study time points.

Randomization and blinding methods

Patients will be randomly assigned to either the pericardial resection plus conventional extracorporeal circulation group or the non-extracorporeal circulation group using a computer-generated randomization list by independent statisticians who did not participate in the trial. Random grouping will be conducted upon entering the operating room. An independent statistician who did not participate in the trial is responsible for generating the allocation sequence and put it in a sealed envelope, and the give it to an independent doctor who did not participate in the trial. An independent doctor who did not participate in the trial is responsible for obtaining informed consent. The design of this study resulted in both the outcome assessors and patients being blinded. The chief researcher of each center will disclose the randomization status to the perfusionist, but will not perform perfusion or collect or analyze data. The perfusionist will perform extracorporeal circulation, record the extracorporeal circulation data, and input the data into the electronic case report form. The outcome evaluator will obtain informed consent and collect preoperative and postoperative follow-up data. These data will be entered into the electronic case report form by the data administrator, who will log in with their own account information and will not be able to access the data entered by the infusion therapist.

Statisticians will only consider these two groups as Group 1 and Group 2. Surgeons, perfusionists, and anesthesiologists will not turn a blind eye to patient allocation due to the need to perform the corresponding surgery correctly. If the patient meets the exclusion criteria after randomization, they will withdraw from the trial, but their identification code (randomization number) will be retained. Due to the involvement of surgical procedures in treatment allocation, surgeons, perfusionists, anesthesiologists, and other operating room personnel will not turn a blind eye to patient allocation. The perfusionist will record intraoperative data. The evaluator will be responsible for collecting preoperative data and obtaining informed consent, as well as conducting postoperative follow-up. Doctors who interact with patients outside the operating room will have no knowledge of treatment allocation. The details of randomization will be kept confidential until the data analysis is completed (Fig. 2).

Experimental intervention plan

Surgical techniques

Extracorporeal circulation pericardial resection (complete pericardial resection)

Perform extracorporeal circulation pericardiotomy on the beating heart through sternotomy at a mild temperature (32–34 °C). Cardiopulmonary bypass is performed through catheterization of the aorta, superior vena cava, and inferior vena cava. During the entire extracorporeal circulation process, the aorta is released without cardiac arrest fluid, and the heart remains beating. In extracorporeal circulation, the pericardium is completely removed (resection from diaphragm to diaphragm and resection of thickening of the posterior lateral and inferior pericardium) to completely alleviate cardiac contraction. After sternotomy, palpate the pericardium to determine the relatively soft and non-calcified area, and

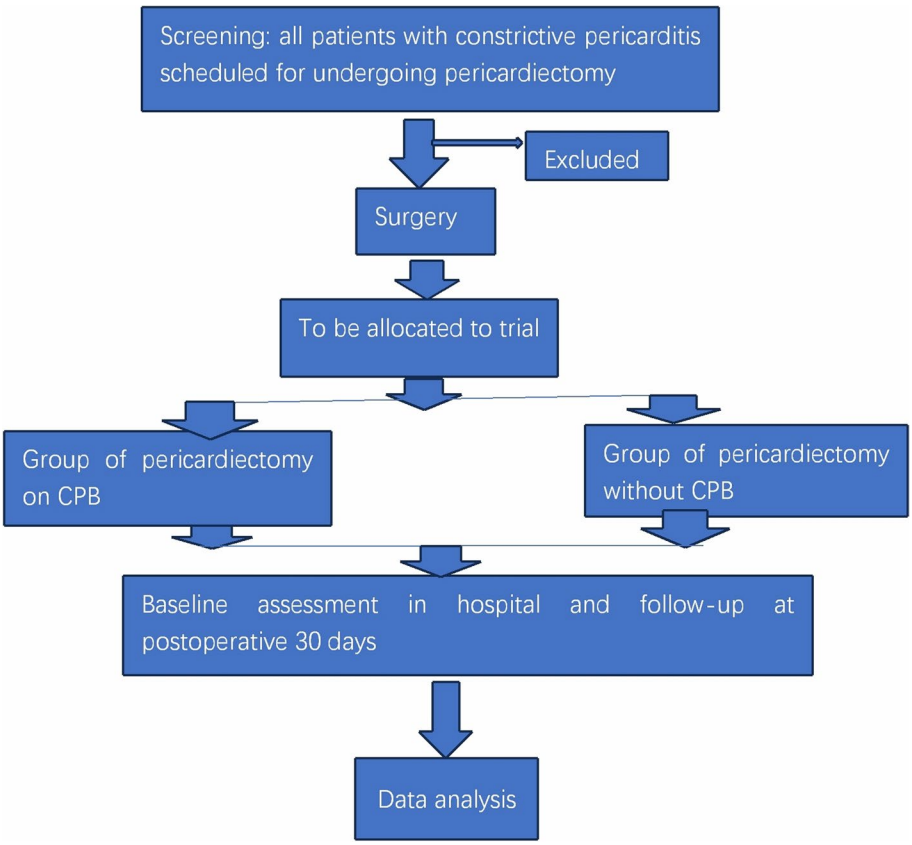

Fig. 2 Flow chart of clinical trial. Patients will be randomly assigned to either the group of pericardiectomy with routine CPB or without CPB by an independent statistician uninvolved in the trial using a computer-generated randomization list

remove the thymus from the side. Make a number sign-shaped incision on the pericardium.

Anatomy starts from the bottom of the aorta and extends downwards to the lateral and posterior walls of the left ventricle, followed by the diaphragm and pericardium. Finally, remove the pericardium above the right atrium and vena cava. Then expose the myocardium and move the heart downwards to the phrenic nerve. If there are calcified plaques that penetrate the epicardium, we will leave small "islands" of calcified pericardial tissue. Complete pericardial resection and then perform extracorporeal circulation.

Pericardial resection without extracorporeal circulation (incomplete pericardial resection)

Pericardial resection is performed through a median sternotomy without the need for extracorporeal circulation. The pericardium is removed from between the two phrenic nerves and from the large blood vessels to the basal side of the heart. After sternotomy, palpate the pericardium to determine the relatively soft and non-calcified area, and remove the thymus from the side. Make a number sign-shaped incision on the pericardium. The aortic root begins to dissect and extends downwards to the left ventricular sidewall. Finally, remove the pericardium above the right atrium and vena cava. Then expose the myocardium and move the heart downwards to the phrenic nerve.

A total of 436 participants with constrictive pericarditis will be randomly assigned to either the extracorporeal circulation pericardial resection group or the non-extracorporeal circulation pericardial clearance group in a 1:1 ratio using a computer. All patients will be admitted to the cardiovascular intensive care unit (ICU) after surgery, where they will remain until they are deemed stable enough to be transferred back to the general ward.

Postoperative follow-up will be conducted during hospitalization (regardless of the length of hospital stay), and if the patient is discharged, the postoperative follow-up time will be to the end of the investigation which will be sufficient to demonstrate the prognosis of surgical treatment. The following members of the study will have no knowledge of patient group allocation: the patient themselves, outcome assessors, and statisticians. The infusion doctors and surgeons in the experiment will have experience in performing necessary surgeries. The intervention

measures will be carried out during the surgery. We will review the patient's medical records to understand hospitalization complications and medication use.

The pericardial tissue removed during surgery should be immediately stored in formalin in the operating room and sent to the pathology department for histological examination and diagnosis as soon as possible.

Primary or secondary outcomes

The primary outcome will be the in-hospital mortality. In-hospital mortality rate is defined as any death that occurs in the same hospital where the surgery is performed.

Secondary outcomes will include the proportion of patients with prolonged postoperative intubation (> 48 h), acute kidney injury postoperative, multi-organ failure, severe liver dysfunction, gastrointestinal complications, surgical re-exploration of bleeding, and deep sternal wound infection, ICU length of stay, hospital length of stay, perioperative blood transfusion volume, and total hospitalization costs. Long term intubation will be defined as the requirement for intubation duration exceeding 48 h. Other complications will be defined according to the Society of Thoracic Surgery (https://www.sts.org/).

Monitoring of adverse events and clinical events

Intraoperative data will include variables related to extracorporeal circulation time, surgical time, packaged red blood cell units, fresh frozen plasma, perioperative platelet aggregation, and highest lactate levels during extracorporeal circulation. Monitor the patient daily for 7 days after surgery, collecting data such as body temperature, partial pressure of oxygen (PaO2) and carbon dioxide (PaCO2), inhaled oxygen (FiO2), ventilation mode, hemoglobin and white blood cell counts, and thoracic drainage volume. In routine diagnostic tests, symptomatic cardiopulmonary complications and other secondary outcome measures will also be recorded.

These parameters and the time of significant events will be tracked until discharge. Patients will be instructed to follow up during hospitalization or after discharge to collect postoperative data. If face-to-face appointment cannot be made, follow-up will be completed by phone. During each visit, patient characteristics will be recorded, including mortality rate, cardiovascular and cerebrovascular events, postoperative kidney and liver function, and gastrointestinal complications. In addition, radiological and electrocardiogram examinations are performed after each discharge, uploaded to the database, and evaluated by outcome assessors who are unaware of the patient's assignment. Preoperative and postoperative data will be recorded by members of the research team at each participating center, who will be unaware of the randomization status and will not be a member of the surgical team implementing the intervention measures. Intraoperative data will be collected by the research perfusionist and anesthesiologist.

Security and monitoring

An independent data and safety monitoring committee composed of cardiovascular surgeons, anesthesiologists and statisticians will monitor the progress and safety of the study, including adverse events and incidence rate. Assess the severity of all adverse events. Any serious adverse events will be recorded on the case report form and reported to the board of directors and the Biomedical Ethics Committee of Guangxi Zhuang Autonomous Region People's Hospital within 24 h.

All unexpected major cardiovascular, cerebrovascular, and other serious adverse events not listed in the plan will be reported to the coordination center within 24 h. The chief researcher will be responsible for reporting all adverse events. We will closely monitor all adverse events until they are resolved or stabilized. Local researchers will review all adverse event reports.

Plan of handling relevant problem during the research process

This study may bring better clinical efficacy. As this study is a prospective randomized controlled clinical trial, the cost will be borne by this project, but the project team will not bear the cost of routine diagnosis and treatment. This study will not bring additional costs for the subjects, and all examinations in this study are routine clinical tests without adding any additional examination items or frequency. The subjects can choose to withdraw from the study at any time without losing any benefits he/she should have received. This study will be conducted according to the conventional clinical pathway without adding any additional burden or risk. If the subjects encounter any related problems due to participating in the study, the doctor will provide necessary medical treatment timely. If injuries related to research occur, the subjects will be evaluated by medical authorities in accordance with relevant laws and regulations.

Data management and quality control

After receiving all case report forms, they will be immediately entered into the secure network system hosted by the data coordination center. Designated research team members will have access to the allocation system and electronic case report form by entering the patient's unique participant identification number, initials, and date of birth in an online form. If the data input is incomplete or incorrect, the primary researcher will contact

the participating center for clarification. In order to control the quality of this study, all perfusionists will receive centralized training before the start of the experiment. All stored records will be kept secure and confidential according to standard guidelines. Whenever data is changed, the reason must be specified and all changes will be saved. During clinical trials, regular quality control and auditing are conducted, including supervision and inspection of data collection and processing, verification and calibration of experimental results, and investigation and handling of adverse events. The data of clinical trials should be strictly confidential and managed, and a comprehensive and secure guarantee mechanism should be established, including data encryption, backup, access control, etc., to ensure the security and integrity of the data.

Except for minor management adjustments, any modifications to the trial protocol need to be resubmitted to the ethics committee for review and can only be implemented after obtaining formal approval. This is to ensure that all changes comply with ethical standards and protect the rights of participants from infringement. All supplementary content or modification suggestions must be unanimously approved by the researchers and the sponsor, and jointly signed and filed by both parties to ensure the understanding and acceptance of the trial protocol by all relevant parties, which helps to maintain cooperation and coordination during the trial process. The revised content approved by the ethics committee should be recorded in detail and clearly marked with its implementation date. All relevant personnel must understand and strictly implement the new regulations to ensure the standardization and consistency of experimental operations.

Information confidential

The data of clinical trials should be strictly confidential and managed, and a comprehensive and secure guarantee mechanism should be established, including data encryption, backup, access control, etc., to ensure the security and integrity of the data. Our country's relevant laws provide protection for privacy, data, and authorized access security. When collecting and processing research information related to the subjects, we will strictly comply with legal requirements to keep information confidential. Unless required by relevant laws, their name, ID card number, address, telephone number, or any information that can directly identify them in the research record will not be disclosed outside the hospital. If the research information about him/her that is transmitted to necessary departments, we will use a number instead to hide their personal information, and the encoded information will be properly stored in the hospital. If the research data obtained from this study are published in scientific conferences or journals, their identity will not be disclosed. But to ensure that the research complies with relevant laws and regulations, their records may be reviewed. Reviewers include relevant national management departments and the Clinical Research Ethics Committee of The People's Hospital of Guangxi Zhuang Autonomous Region. The results of the study will be published in peer-reviewed journals.

Sample size calculation

The sample size was calculated based on the main results of our unpublished pilot study conducted at the People's Hospital of Guangxi Zhuang Autonomous Region (manuscript in preparation). It has been suggested that there is 80% survival at 5 years [19]. In this study, we included 436 patients (218 in each group) and defined the primary outcome as the comprehensive outcome of the 30-day surgical mortality rate and major complications mentioned above. In order to achieve statistical significance, according to the following statistical formula, this experiment requires 436 patients (218 participants per group) (Fig. 3).

Follow-up

All patients discharged from hospital are followed up until the date of the termination of the research or death, undergoing chest X-ray, electrocardiogram, and echocardiography examinations every 6 months. Patients are interviewed at outpatient department or contacted by phone or WeChat.

Unblinding in an emergency

Unblinding is an indispensable part of clinical trials, ensuring the objectivity and credibility of the trial results. Emergency unblinding procedure is following: 1. Notify the applying unit before breaking the blindness. 2. Perform unblinding based on the medication information provided in the emergency letter. 3. The researcher fills in the unblinding record form and makes corresponding notes on the Case Report Form. 4. If the applicant cannot be contacted before unblinding, they should be notified promptly after unblinding.

$$\mathrm{n} = \frac{\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 \left[p_1(1-p_1) + p_2(1-p_2)\right]}{\delta^2}$$

Fig. 3 Statistical formula for sample size calculation. For statistical significance, 436 patients (218 participants in each arm) will be required for this trial according to the following statistical formula

Statistical analysis

All analyses will be conducted based on the intention to treat principle. The data analysis will be conducted by statisticians using SPSS 24.0 (IBM, Chicago, IL, USA). A ($p < 0.05$) has statistical significance. Missing data will be handled statistically by multiple imputation. Continuous variables are reported as mean ± standard deviation or median (interquartile range), and the differences in these variables will be analyzed using independent *t*-test or Wilcoxon signed rank test depending on whether the data follows a normal distribution. The classification parameters will be presented in numerical (percentage) form, and the differences in these variables will be analyzed using chi square test and Fisher's exact test. Kaplan Meier curves and time series analysis will be used to compare between group differences in primary and secondary outcomes. Univariate and multivariate logistic regression will be conducted to determine the relative risk of primary and secondary outcomes in the conventional cardiopulmonary bypass pericardiotomy group compared to the control group.

Discussion

Reasons for trial

Incomplete pericardial detachment is associated with low cardiac output syndrome after pericardial resection. The causes of low cardiac output syndrome are related to incomplete resection of thickened pericardium, unsatisfactory relief of left ventricular compression, excessive ventricular dilation after pericardial dissection, myocardial weakness, and heart failure. The relief of left ventricular compression is crucial for the postoperative recovery of cardiac function [20–23].

Apical adhesions should be sufficiently free to restore normal ventricular contraction and rotational function. We hypothesize that incomplete resection of thickened pericardium and unsatisfactory relief of left ventricular compression are associated with low cardiac output syndrome and surgical mortality after pericardiotomy. Without extracorporeal circulation, removing the pericardium from the phrenic nerve to the phrenic nerve often results in insufficient pericardial resection to alleviate contractions, especially when the heart is completely surrounded. The most common is a severely thickened calcified ring around the base. In these cases, thickening of the posterior lateral and inferior pericardium can sometimes be associated with severe cardiac compression. Therefore, in severe constrictive pericarditis, traditional diaphragmatic nerve resection is often insufficient to alleviate the constriction [24–27]. Perhaps it is for this reason that the proportion of patients with low cardiac output syndrome and surgical mortality after pericardiotomy is so high [28–30]. Without extracorporeal circulation, severe pericardial stenosis often cannot be effectively removed. Without extracorporeal circulation, severe calcified myocardial infiltration cannot be safely and effectively cleared, regardless of left ventricular ventilation. Therefore, if the main objective is to completely alleviate contractions, extracorporeal circulation is actually a crucial strategy. In our report, only patients who required simultaneous cardiac surgery received extracorporeal circulation. However, extracorporeal circulation for pericardial resection should be routine rather than exceptional. The brief additional extracorporeal circulation time during pericardial resection has little impact on the risk of the main surgery [5, 31].

The sternotomy can more thoroughly remove the pericardium above the right atrium and vena cava, and allow for extensive pericardial resection through cardiopulmonary bypass. Cardiopulmonary bypass clarifies the appropriate anatomical plane by clearing the ventricular cavity, which facilitates surgical dissection and promotes the management of unexpected cardiac injuries. Therefore, complete pericardial resection with extracorporeal circulation (diaphragmatic to diaphragmatic resection and posterior lateral wall and inferior wall pericardial thickening resection) to completely relieve cardiac contractions should become routine [32–34].

In short, extracorporeal circulation is actually an important means to achieve complete relief of contractions. The brief additional extracorporeal circulation time during the surgical process has little impact on the incidence risk of the main surgery. Incomplete pericardial resection may be the cause of residual stenosis and elevated diastolic blood pressure after surgery, ultimately leading to multiple organ failure. Therefore, complete pericardial resection with extracorporeal circulation (diaphragmatic to diaphragmatic resection and posterior lateral and inferior wall pericardial thickening resection) should be performed as a routine procedure to completely relieve cardiac contractions [35–37].

Trial status

We have completed the electronic case report form system. The study opened to patient recruitment in January 2026. Completion of this trial is expected on 31 December 2029.

Timeline

2026–2027: Development of research strategy and study protocol. 2027–2028: Recruitment and treatment of patients in trial. 2028–2029: Completion of follow-up and data analysis.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08843-5.

Supplementary Material 1.

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Data access statement
Data of the study is available at The People's Hospital of Guangxi Zhuang Autonomous Region. Medical records were reviewed.

Authors' contributions
Jing-bin Huang designed wrote the paper; Zhao-ke Wen, and Chang-chao Lu will assist with the organization of study visits and monitoring. All authors read and approved the final version of this manuscript.

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Declarations

Ethics approval and consent to participate
The clinical trial is being conducted in line with the Declaration of Helsinki. The study protocol has been approved by the Biomedical Ethics Committee of The People's Hospital of Guangxi Zhuang Autonomous Region (No. PHGX 0886). All patients must be informed about the trial and give written informed consent in order to be enrolled. Consent for publication Not applicable.

Competing interests
The authors declare no competing interests.

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