

INPLASY PROTOCOL

To cite: Tao et al. Efficacy of transannular patch versus pulmonary valve function-preserving strategies in tetralogy of Fallot: a systematic review and meta-analysis. Inplasy protocol 202290062. doi: 10.37766/inplasy2022.9.0062

Received: 14 September 2022

Published: 14 September 2022

Corresponding author:

Tao You

youtao2016@126.com

Author Affiliation:

Department of Cardiovascular Surgery, Gansu Provincial Hospital.

Support: 21JR1RA027.

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest:

None declared.

Efficacy of transannular patch versus pulmonary valve function-preserving strategies in tetralogy of Fallot: a systematic review and meta-analysis

Tao, Y¹; Kang, Y².

Review question / Objective: Pulmonary valve function-preserving strategies are favored by many clinicians, TAP remains the most commonly used method to reconstruct the right ventricular outflow tract. The efficacy and extent of use of pulmonary valve function-sparing strategies compared with TAP have not been established. Based on this, we performed a meta-analysis of TAP and pulmonary valve reconstruction and repair. We use TAP to make a control group, and divided pulmonary valve repair and pulmonary valve reconstruction into two groups as experimental groups according to the different methods of different operative methods for pulmonary valve. By comparing the different methods of TOF, it will provide reference for the clinical treatment of TOF.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 September 2022 and was last updated on 14 September 2022 (registration number INPLASY202290062).

INTRODUCTION

Review question / Objective: Pulmonary valve function-preserving strategies are favored by many clinicians, TAP remains the most commonly used method to reconstruct the right ventricular outflow

tract. The efficacy and extent of use of pulmonary valve function-sparing strategies compared with TAP have not been established. Based on this, we performed a meta-analysis of TAP and pulmonary valve reconstruction and repair. We use TAP to make a control group, and

divided pulmonary valve repair and pulmonary valve reconstruction into two groups as experimental groups according to the different methods of different operative methods for pulmonary valve. By comparing the different methods of TOF, it will provide reference for the clinical treatment of TOF.

Rationale: Currently, the technology of preserving pulmonary valve function in tetralogy of Fallot is in full swing. The effectiveness of some strategies to preserve pulmonary valve function has been initially demonstrated, but most of them are observational studies with small number of cases. Therefore, transannular patch (TAP) is still the most used method for radical tetralogy of Fallot. More often than not patients treated with a TAP require surgical or catheter-based intervention to restore competency to the pulmonary valve, unload the RV, and stimulate reverse remodeling, in order to improve quality of life and prolong survival. It is on this basis that in the past several decades the surgical community has been moving towards a more aggressive approach to sparing the pulmonary valve at the time of the initial full repair, with the goal of improving symptoms and preventing the need for future pulmonary valve replacement/catheter-based intervention by means of preserving pulmonary valve competence, without increasing the rate of reintervention for residual RVOT obstruction. Although most studies of valve-sparing repair for appropriately selected patients have demonstrated success in this regard, an STS database study has shown that the vast majority of full repairs for TOF/PS are still performed with a TAP. Based on this, we conducted this meta-analysis to provide an overview of contemporary efficacy comparisons of TAP and pulmonary valve function-preserving strategies. Most studies of valve-sparing repair for appropriately selected patients have demonstrated success in this regard, an STS database study has shown that the vast majority of full repairs for TOF/PS are still performed with a TAP. Although these methods can effectively prevent from PI, the vast

majority of complete repair of TOF is still TAP. Both pulmonary valve repair and pulmonary valve reconstruction have advantages and disadvantages compared to TAP. Based on this, we conducted this meta-analysis to provide an overview of contemporary efficacy comparisons of TAP and pulmonary valve function-preserving strategies.

Condition being studied: Tetralogy of Fallot (TOF) is the one of the most common cyanosis congenital heart disease (CHD) in untreated children after the neonatal age. The surgical correction approaches of TOF mainly include complete repair and palliative shut. Transannular patch (TAP) is the most commonly using method of complete repair, which is recognized as a proven way possessing the advantages of high success rate and certain effect. It is mainly suitable for severe dysplasia of the pulmonary valve. However, it mainly causes postoperative PR, and there was a right ventricular incision. TAP will inevitably lead to PR, doctors had been turning to more active methods, such as trying to preserve the function of pulmonary valve instead of TAP. At present, there are two methods to preserve the pulmonary function-Reconstruction and Repair. Although these methods can effectively prevent from PI, the vast majority of complete repair of TOF is still TAP. Both pulmonary valve repair and pulmonary valve reconstruction have advantages and disadvantages compared to TAP.

METHODS

Search strategy: A systematic literature search was performed in the Cochrane Library, PubMed, Web of Science and embase. Databases from the starting date of each database to December, 2021. All outcomes should be written in English. Combinations of the main search terms include: "tetralogy of Fallot", "pulmonary valve".

Participant or population: Patients with Tetralogy of Fallot.

Intervention: Transannular Patch (TAP) Angioplasty.

Comparator: Pulmonary Valve Reconstruction based on TAP, Pulmonary Cusp Augmentation (PCA), Pulmonary Valve-sparing repair, Pulmonary Annular-preserving repair, Pulmonary Valvotomy, Intraoperative Balloon Pulmonary Valvuloplasty (IBPV), Commissurotomy and Hegar dilation.

Study designs to be included: Cohort studies, non randomized controlled trial.

Eligibility criteria: Two investigators independently extracted data based on study design, title of the paper, name of the first author, publication year, follow-up time, patient characteristics, outcomes and common adverse events including PR, mortality, tricuspid regurgitation, arrhythmia, low cardiac output syndrome, thrombus and others. Conflicts about data extraction were discussed and resolved with a third investigator.

Information sources: We conducted a systematic literature search on four databases, including PubMed, the Cochrane Library, Web of Science and EMBASE to retrieve all related articles before January 1, 2022. We searched the references of the included literature through the snowball method.

Main outcome(s): Primary outcomes: reintervention, early mortality (defined as hospital mortality or 30-day death rate), late mortality (defined as the total mortality rate during follow-up). Secondary outcomes: PVR in follow up, moderate/severe PI on discharge, late PI (moderate to severe), postoperative complications, complications in follow up, aortic cross-clamp (ACC) time, cardiopulmonary bypass (CPB) time, postoperative RV/LV pressure ratio, residual RVOT systolic gradient.

Quality assessment / Risk of bias analysis: Two review authors will independently assess risk of bias for each study. For RCT studies, we will assess them according to the criteria outlined in the Cochrane

Handbook for Systematic Reviews of Interventions. We will assess the following domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other relevant biases. We will classify the risk of bias for each domain of the included studies as low, high, or unclear and provided information from the study reports, while justifying our judgment in the 'Risk of bias' table. For retrospective cohort studies, we will use the Newcastle–Ottawa Scale (NOS). The score of the scale is 0–9, and when the score is ≥ 7 , it is considered to be a study with a low risk of bias. Any disagreements will be resolved by discussion or by involving another review author.

Strategy of data synthesis: All data analyses will be performed using RevMan5.3 and Stata16. Binary variables will be represented by odds ratios (ORs), continuous variables are represented by mean differences (MDs) for consistent measurement units, and standardized mean differences (SMDs) will be used for inconsistent measurement units. When necessary, the mean and SD will be estimated from the median, range, and sample size using an online tool. All variables will be calculated with 95% CIs. All reported values of p are two-sided, and $p < 0.10$ and $I^2 \leq 50\%$. Otherwise, the heterogeneity of the study will be considered significant, and the random effects model (D-L method) will be used for analysis.

Subgroup analysis: We planned a subgroup analysis of the primary outcome according to intervention in the control group.

Sensitivity analysis: A sensitivity analysis will be performed to investigate the influence of a single study on the overall effect estimate. Visual funnel plots and Egger's test were used to assess publication bias among the included studies if the outcomes included five or more studies.

Language restriction: Articles written in English.

Country(ies) involved: China.

Keywords: tetralogy of Fallot; transannular patch; pulmonary valve function-preserving strategies; systematic review; meta-analysis.

Contributions of each author:

Author 1 - Tao You.

Email: youtao2016@126.com

Author 2 - Kang Yi.