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Safety and effectiveness of transcatheter mitral valve replacement in the treatment of mitral regurgitation A protocol for Systematic review and meta-analysis

Liu, HX[1]; Liu, GZ[2]; Chen, Y[3]; Liu, SD[4]; Zhang, YL[5]; Song, B[6].

Corresponding author:
Bing Song

songbinldyy@163.com

Author Affiliation:
The First School of Clinical Medicine,Lanzhou University.

ADMINISTRATIVE INFORMATION

Support - None.

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

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 September 2023 and was last updated on 16 September 2023.

INTRODUCTION

Review question / Objective At present, there is insufficient evidence to prove the safety and efficacy of TMVR in the treatment of MR. The purpose of this study is to seek relevant evidence support for clinical reference.

Condition being studied Mitral Regurgitation (MR) refers to the incomplete closure of the mitral valve leads to the reverse flow of blood into the left atrium during systolic period, which affects the function of the heart. MR Includes primary Mitral Regurgitation (PMR) caused by disease of the mitral valve itself and Secondary Mitral Regurgitation (SMR) caused by left ventricular (LV) dysfunction or left atrial dilation. PMR, also known as organic Mitral Regurgitation (OMR), is usually caused by degenerative mitral valve disease. SMR is also known as functional mitral regurgitation (FMR), and the mitral valve structure is usually normal or only manifested as late secondary fibrosis and/or annular dilation. MR Is the second most common Valvular Heart Disease (VHD) in Europe, after Aortic Stenosis (AS), accounting for 21.3% of VHD. According to the 2010 census data, MR Is also the second most common heart valve disease in China, after aortic regurgitation (AR), with a prevalence of about 1.1% and increasing with age. Due to the poor prognosis of patients with severe MR, if there is no active intervention, severe MR will lead to chronic left ventricular volume overload, accompanied by increased pressure of left atrium and pulmonary artery, and eventually lead to pulmonary edema, right ventricular dysfunction and secondary tricuspid regurgitation, and the 5-year mortality rate is as high as 50%. 90% of survivors will develop heart failure, atrial fibrillation, or indications for mitral

valve formation or replacement, so early intervention is necessary in high-risk MR patients. However, nearly half of elderly patients over 75 years old cannot tolerate thoracotomy due to their underlying diseases and high surgical risks, and the long-term survival and quality of life improvement of thoracotomy for severe SMR remains unclear. This clinical need has driven the development of minimally invasive procedures such as transcatheter edge-to-edge mitral valve repair, TEER) and transcatheter Mitral Valve Replacement (TMVR). On June 12, 2012, Lars Sondergaard completed the world's first human TMVR in Copenhagen, Denmark. After nearly 10 years of development, relevant clinical studies have been published continuously, but the sample size of relevant studies is insufficient and there is a lack of randomized controlled trials to provide effective evidence for clinical work. The objective of this study was to evaluate the safety and efficacy of TMVR in clinical MR patients.

METHODS

Participant or population Patients ≥18 years of age who were diagnosed with MR By echocardiography.

Intervention The approach of TMVR is transapical or transfemoral.

Comparator Compared with TEER, TMVR is also less invasive, and it is technically simpler and more repeatable . So TMVR is more promising than TEER. Therefore, the purpose of this study is to explore the effectiveness and safety of TMVR in the treatment of MR, and to provide clinical reference.

Study designs to be included Single-arm or cohort studies of MR treated by TMVR.

Eligibility criteria 1.Inclusion criteria.(1). Single-arm or cohort studies of MR treated by TMVR. Subjects. (2). Patients ≥18 years of age who were diagnosed with MR By echocardiography.(3). The approach of TMVR is transapical or transfemoral. (4). The main outcome measures was the success rate of valve implantation, while the 30-day postoperative mortality, 30-day postoperative NYHA cardiac function grade ≤II, 30-day postoperative massive bleeding, intraoperative thoracotomy, 30-day postoperative new atrial fibrillation, 30-day postoperative MR≤ mild (1+) were the secondary outcome measures.2.Exclusion criteria.(1). Reviews, case reports, conference abstracts, conference reports, comments and editorials, etc; (2). Literatures that cannot extract relevant data; (3). The subjects of the literatures were patients who underwent TMVR while undergoing aortic valve intervention; (4). The subjects of the studies were patients who had undergone mitral valve surgery or mitral valve intervention; (5). Studies that the interventions were transductal mitral midvalve replacement (ViV), transductal mitral ring midvalve replacement (ViR), and transductal mitral valve replacement with calcified mitral ring (ViMAC); (6). Duplicate publications.

Information sources PubMed, Cochrane Library, Web of Science, Embase, CNKI, VIP, WanFang and CBM databases were searched by computer, and the retrieval time was from the establishment of the database to December 2021. This paper adopts the search method of combining subject words and free words. Key words: Transcatheter mitral valve replacement, Transcatheter mitral valve implantation. At the same time, literature traceability was carried out according to references included in the literature.

Main outcome(s) The main outcome measures was the success rate of valve implantation, while the 30-day postoperative mortality, 30-day postoperative NYHA cardiac function grade ≤II, 30-day postoperative massive bleeding, intraoperative thoracotomy, 30-day postoperative new atrial fibrillation, 30-day postoperative MR≤ mild (1+) were the secondary outcome measures.

Quality assessment / Risk of bias analysis The quality of the literature was evaluated by two researchers using MINORS(Methodological index for non-randomized studies) evaluation tools. There were 12 evaluation indicators in total. The single-arm study used the first 8 indicators for evaluation, with a total score of 16 points, and the cohort study used 12 indicators, with a total score of 24 points.

Strategy of data synthesis Meta analysis was performed using Stata17.0 software. Heterogeneity was determined quantitatively by P-value and I2. If there was no significant heterogeneity between studies (P > 0.10 and I2≤ 50%), the fixed-effect model was used for meta-analysis. Otherwise, the random effects model was used for meta-analysis.

Subgroup analysis Subgroup analysis according to different surgical routes: transapical (TA) and transfemoral (TF) through the atrial septal (TS).

Sensitivity analysis For studies with significant heterogeneity, sensitivity analysis should be performed first.

Country(ies) involved China - The First School of Clinical Medicine,Lanzhou University.

Keywords Transcatheter mitral valve replacement; Mitral valve insufficiency; Meta-analysis.

Contributions of each author

Author 1 - Hongxu Liu.
Email: 15320570241@163.com
Author 2 - Guangzu Liu.
Author 3 - Yang Chen.
Author 4 - Shidong Liu.
Author 5 - Yalan Zhang.
Author 6 - Bing Song.