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Enxertos Multiarteriais Revisitados: Resultados Tardios de Estudo Canadense Apontam Melhores Desfechos, do que o uso Trivial de uma Mamária com Safena(s)

Long-term Outcomes of Multiple Arterial Coronary Artery Bypass Grafting: A Population-Based Study of Patients in British Columbia, Canada

IMPORTANCE
Although the long-term survival advantage of multiple arterial grafting (MAG) vs. the standard use of left internal thoracic artery (LITA) supplemented by saphenous vein grafts (LITA+SVG) has been demonstrated in several observational studies, to our knowledge its safety and other long-term clinical benefits in a large, population-based cohort are unknown.

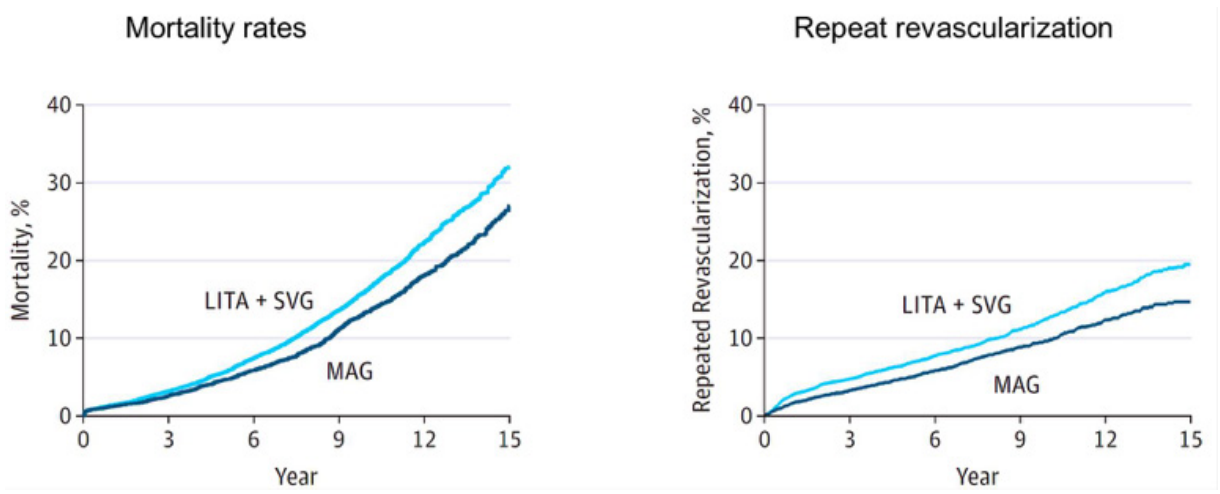
OBJECTIVE
To compare the safety and long-term outcomes of MAG vs. LITA+SVG among overall and selected subgroups of patients.

DESIGN, SETTING, AND PARTICIPANTS
In this population-based observational study, we included 20 076 adult patients with triple-vessel or left-main disease who underwent primary isolated coronary artery bypass grafting (MAG, n=5580; LITA+SVG, n=14 496) in the province of British Columbia, Canada, from January 2000 to December 2014, with follow-up to December 2015. We performed propensity-score analyses by weighting and matching and multivariable Cox regression to minimize treatment selection bias.

EXPOSURES
Multiple arterial grafting or LITA+SVG.

RESULTS
Of 5580 participants who underwent MAG, 586 (11%) were women and the mean (SD) age was 60 (8.7) years. Of 14 496 participants who underwent LITA+SVG, 2803 (19%) were women and the mean (SD) age was 68 (8.9) years. The median (interquartile range) follow-up time was 9.1 (5.1-12.6) years and 8.1 (4.5-11.7) years for the groups receiving MAG and LITA+SVG, respectively. Compared with LITA+SVG, MAG was associated with reduced mortality rates (hazard ratio [HR], 0.79; 95% CI, 0.72-0.87) and repeated revascularization rates (HR, 0.74; 95% CI, 0.66-0.84) in 15-year follow-up and reduced incidences of myocardial infarction (HR, 0.63; 95% CI, 0.47-0.85) and heart failure (HR, 0.79; 95% CI, 0.64-0.98) in 7-year follow-up. The long-term benefits were coherent by all 3 statistical methods and persisted among patient subgroups with diabetes, obesity, moderately impaired ejection fraction, chronic obstructive pulmonary disease, peripheral vascular disease, or renal disease. Multiple arterial grafting was not associated with increased morbidity or mortality rates at 30 days overall or within patient subgroups.

CONCLUSIONS
Compared with LITA+SVG, MAG is associated with reduced mortality, repeated revascularization, myocardial infarction, and heart failure among patients with multivessel disease who are undergoing coronary artery bypass grafting without increased mortality or other adverse events at 30 days. The long-term benefits consistently observed across multiple outcomes and subgroups support the consideration of MAG for a broader spectrum of patients who are undergoing coronary artery bypass grafting in routine practice.



Lancet. 2017 Nov 1. pii: S0140-6736(17)32714-9. doi: 10.1016/S0140-6736(17)32714-9. [Epub ahead of print]

Estudo Órbita: Angioplastia com Stents Farmacológicos não Reduz Mortalidade ou Taxa de IAM, nem Alivia Angina, em Pacientes com Doença Coronariana Estável

Percutaneous Coronary Intervention In Stable Angina (ORBITA): a Double Blind, Randomised Controlled Trial

BACKGROUND

Symptomatic relief is the primary goal of percutaneous coronary intervention (PCI) in stable angina and is commonly observed clinically. However, there is no evidence from blinded, placebo-controlledrandomised trials to show its efficacy.

METHODS

ORBITA is a blinded, multicentre randomised trial of PCI versus a placebo procedure for angina relief that was done at five study sites in the UK. We enrolled patients with severe (≥70%) single-vessel stenoses. After enrolment, patients received 6 weeks of medication optimisation. Patients then had pre-randomisation assessments with cardiopulmonary exercise testing, symptom questionnaires, and dobutamine stress echocardiography. Patients were randomised 1:1 to undergo PCI or a placebo procedure by use of an automated online randomisation tool. After 6 weeks of follow-up, the assessments done before randomisation were repeated at the final assessment. The primary endpoint was difference in exercise time increment between groups. All analyses were based on the intention-to-treat principle and the study population contained all participants who underwent randomisation. This study is registered with ClinicalTrials.gov, number NCT02062593.

RESULTS

ORBITA enrolled 230 patients with ischaemic symptoms. After the medication optimisation phase and between Jan 6, 2014, and Aug 11, 2017, 200 patients underwent randomisation, with 105 patients assigned PCI and 95 assigned the placebo procedure. Lesions had mean area stenosis of 84·4% (SD 10·2), fractional flow reserve of 0·69 (0·16), and instantaneous wave-free ratio of 0·76 (0·22). There was no significant difference in the primary endpoint of exercise time increment between groups (PCI minus placebo 16·6 s, 95% CI -8·9 to 42·0, p=0·200). There were no deaths. Serious adverse events included four pressure-wire related complications in the placebo group, which required PCI, and five major bleeding events, including two in the PCI group and three in the placebo group.

INTERPRETATION

In patients with medically treated angina and severe coronary stenosis, PCI did not increase exercise time by more than the effect of a placebo procedure. The efficacy of invasive procedures can be assessed with a placebo control, as is standard for pharmacotherapy.

FUNDING

NIHR Imperial Biomedical Research Centre, Foundation for Circulatory Health, Imperial College Healthcare Charity, Philips Volcano, NIHR Barts Biomedical Research Centre.

Research in context

Evidence before this study

More than 500 000 percutaneous coronary interventions (PCIs) are done annually worldwide for the relief of angina but no placebo-controlled trials have been done on the subject. Unblinded PCI is reported to increase exercise time by 96 s more than medical therapy. Single antianginal agents typically increase exercise time by more than 45 s compared with placebo so ORBITA was designed conservatively to detect an effect size of 30 s.

Added value of this study

ORBITA investigated the efficacy of PCI versus placebo to improve exercise capacity in patients with severe coronary disease who were receiving guideline-directed optimum medical therapy. The coronary stenoses were severe and had large haemodynamic effects . Despite PCI markedly improving haemodynamic and imaging indices, PCI did not improve exercise time compared with placebo.

Implications of all the available evidence

The common clinical perception is that patients with stable angina will receive substantial symptom relief from PCI. The results of ORBITA, the only blinded, randomised placebo-controlled trial of PCI, show that even with severe coronary stenosis, exercise capacity and symptoms are not improved significantly compared with a placebo intervention. Physicians advising patients on interventional treatment choices for symptom relief should favour placebo-controlled data. ORBITA shows this approach to be feasible and informative.

Embora Rara, a Trombose Sintomática após TAVI é Evento Grave, com Altas Taxas de AVC, Choque Cardiogênico e Morte, Revela Registro do FDA Americano

Clinical or Symptomatic Leaflet Thrombosis Following Transcatheter Aortic Valve Replacement: Insights from the U.S. FDA MAUDE Database

BACKGROUND

Data on clinical or symptomatic leaflet thrombosis after transcatheter aortic valve replacement (TAVR) are limited. Whether clinical leaflet thrombosis has significance beyond peri-TAVR stroke or transient ischemic attacks (TIA) is yet to be elucidated.

METHODS

Between January 2012 - October 2015, we searched the MAUDE database for all entries with the identifier code, "NPT," designed by the U.S. FDA to identify TAVR-related adverse events (AEs). Selected entries were searched further for the terms "leaflet," "central aortic regurgitation," and "aortic stenosis" to capture all events related to leaflet thrombosis causing structural valve dysfunction (SVD). Presentation of leaflet thrombosis (aortic stenosis or regurgitation or mixed valve lesion), mode of diagnosis (echocardiography, computed tomography, surgical explantation, or autopsy), and duration of onset after TAVR were recorded. For all AEs of SVD due to leaflet thrombosis, the following outcomes were recorded: stroke or TIA, cardiogenic shock, and death from any cause.

RESULTS

A total of 5,691 TAVR-related AEs were reported in the MAUDE database. SVD due to leaflet thrombosis was reported in 30 cases. Most cases (n=18/30, 60.0%, 95% CI 0.41 - 0.77) occurred in the first year following TAVR. SVD manifested as aortic stenosis (n=16/30, 53.3%, 95% CI 0.34 - 0.72), or regurgitation (n=7/30, 23.3%, 95% CI 0.10 - 0.42), or both (n=4/30, 13.3%, 95% CI 0.04 - 0.31). Interventions to address leaflet thrombosis included either escalation of antiplatelet or anticoagulant therapy (n=9/30, 30.0%, 95% CI 0.15 - 0.49), valve-in-valve TAVR (n=5/30, 16.7%, 95% CI 0.06 - 0.35), or surgery (n=14/30, 46.7%, 95% CI 0.28 - 0.66), or their combination. Outcome following leaflet thrombosis included stroke/TIA (n=3/30, 10.0%, 95% CI 0.02 - 0.27), cardiogenic shock (n=2/30, 6.7%, 95% CI 0.01 - 0.22), and death (n=9/30, 30.0%, 95% CI 0.15 - 0.49).

CONCLUSION

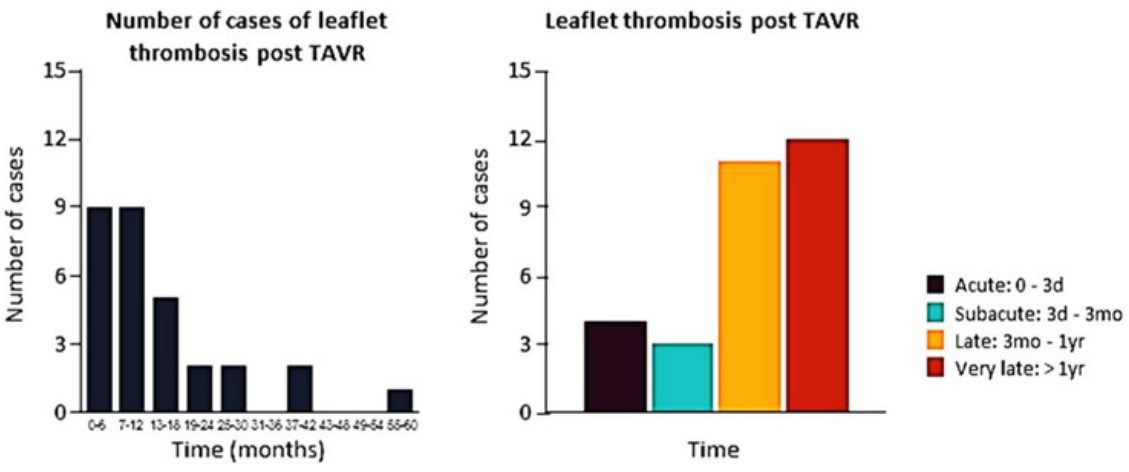
Clinically manifest leaflet thrombosis was associated with serious clinical manifestations that included stroke, cardiogenic shock, and death.

KEY MESSAGES

Leaflet thrombosis of transcatheter heart valves is a recently recognized and important mechanism of transcatheter heart valve failure. Whether clinically manifest leaflet thrombosis has significance beyond peri-TAVR stroke or transient ischemic attacks (TIA) is yet to be elucidated.

In this study, clinically manifest leaflet thrombosis was associated with serious clinical manifestations that included stroke, cardiogenic shock, and death.

Clinical or symptomatic leaflet thrombosis following TAVR should not be regarded casually as a benign event, and needs to be addressed seriously. As indications for TAVR expand, an early diagnosis of leaflet thrombosis may be crucial for planning appropriate management and optimizing clinical outcome.



Fechamento Percutâneo do Forâmen Oval Patente (FOP) de Alto Risco Diminui Recorrência de ACV Criptogênico, Mas Aumenta a Taxa de Fibrilação Atrial, Aponta Resultado Final do Estudo CLOSE

Patent Foramen Ovale Closure or Anticoagulation vs. Antiplatelets After Stroke

BACKGROUND

Trials of patent foramen ovale (PFO) closure to prevent recurrent stroke have been inconclusive. We investigated whether patients with cryptogenic stroke and echocardiographic features representing risk of stroke would benefit from PFO closure or anticoagulation, as compared with antiplatelet therapy.

METHODS

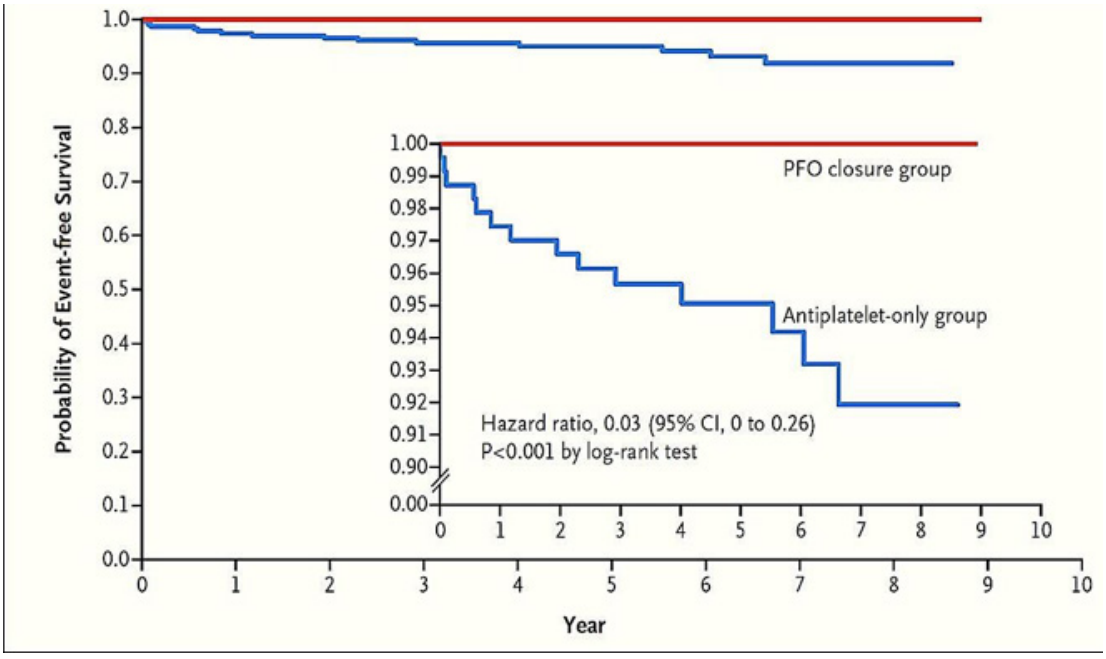
In a multicenter, randomized, open-label trial, we assigned, in a 1:1:1 ratio, patients 16 to 60 years of age who had had a recent stroke attributed to PFO, with an associated atrial septal aneurysm or large interatrial shunt, to transcatheter PFO closure plus long-term antiplatelet therapy (PFO closure group), antiplatelet therapy alone (antiplatelet-only group), or oral anticoagulation (anticoagulation group) (randomization group 1). Patients with contraindications to anticoagulants or to PFO closure were randomly assigned to the alternative noncontraindicated treatment or to antiplatelet therapy (randomization groups 2 and 3). The primary outcome was occurrence of stroke. The comparison of PFO closure plus antiplatelet therapy with antiplatelet therapy alone was performed with combined data from randomization groups 1 and 2, and the comparison of oral anticoagulation with antiplatelet therapy alone was performed with combined data of randomization groups 1 and 3.

RESULTS

A total of 663 patients underwent randomization and were followed for a mean (±SD) of 5.3±2.0 years. In the analysis of randomization groups 1 and 2, no stroke occurred among the 238 patients in the PFO closure group, whereas stroke occurred in 14 of the 235 patients in the antiplatelet- only group (hazard ratio, 0.03; 95% confidence interval, 0 to 0.26; P<0.001). Procedural complications from PFO closure occurred in 14 patients (5.9%). The rate of atrial fibrillation was higher in the PFO closure group than in the antiplatelet-only group (4.6% vs. 0.9%, P=0.02). The number of serious adverse events did not differ significantly between the treatment groups (P=0.56). In the analysis of randomization groups 1 and 3, stroke occurred in 3 of 187 patients assigned to oral anticoagulants and in 7 of 174 patients assigned to antiplatelet therapy alone.

CONCLUSIONS

Among patients who had had a recent cryptogenic stroke attributed to PFO with an associated atrial septal aneurysm or large interatrial shunt, the rate of stroke recurrence was lower among those assigned to PFO closure combined with antiplatelet therapy than among those assigned to antiplatelet therapy alone. PFO closure was associated with an increased risk of atrial fibrillation. (Funded by the French Ministry of Health; CLOSE ClinicalTrials.gov number, NCT00562289.)



J Am Coll Cardiol. 2017 Oct 16. pii: S0735-1097(17)39676-6. doi: 10.1016/j.jacc.2017.09.018. [Epub ahead of print]

A Exemplo do Publicado em Relação a Doença Coronariana Estável, American Heart Association Lança Consenso para o uso de Critérios Apropriados Para Manejo da Estenose Aórtica – Mais de 90 Cenários Clínicos São Avaliados por 17 Experts

ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/STS 2017 Appropriate Use Criteria for the Treatment of Patients With Severe AorticStenosis: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Valve Society, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons

ABSTRACT

The American College of Cardiology collaborated with the American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Valve Society, Society of Cardiovascular Anesthesiologists,Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons to develop and evaluate Appropriate Use Criteria (AUC) for the treatment of patients with severe aortic stenosis (AS).

This is the first AUC to address the topic of AS and its treatment options, including surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR). A number of common patient scenarios experienced in daily practice were developed along with assumptions and definitions for those scenarios, which were all created using guidelines, clinical trial data, and expert opinion in the field of AS. The 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and its 2017 focused update paper were used as the primary guiding references in developing these indications. The writing group identified 95 clinical scenarios based on patient symptoms and clinical presentation, and up to 6 potential treatment options for those patients. A separate, independent rating panel was asked to score each indication from 1 to 9, with 1–3 categorized as “Rarely Appropriate,” 4–6 as “May Be Appropriate,” and 7–9 as “Appropriate.”

After considering factors such as symptom status, left ventricular (LV) function, surgical risk, and the presence of concomitant coronary or other valve disease, the rating panel determined that either SAVR or TAVR is Appropriate in most patients with symptomatic AS at intermediate or high surgical risk; however, situations commonly arise in clinical practice in which the indications for SAVR or TAVR are less clear, including situations in which 1 form of valve replacement would appear reasonable when the other is less so, as do other circumstances in which neither intervention is the suitable treatment option. The purpose of this AUC is to provide guidance to clinicians in the care of patients with severe AS by identifying the reasonable treatment and intervention options available based on the myriad clinical scenarios with which patients present. This AUC document also serves as an educational and quality improvement tool to identify patterns of care and reduce the number of rarely appropriate interventions in clinical practice.

The rating panel scored on a scale as follows:

Score 7 to 9: **A**ppropriate care

Score 4 to 6: **M**ay be appropriate care

Score 1 to 3: **R**arely appropriate care

American College of Cardiology Publicam Consenso para Decisão Clínica em Insuficiência Mitral

2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation. A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways

ABSTRACT

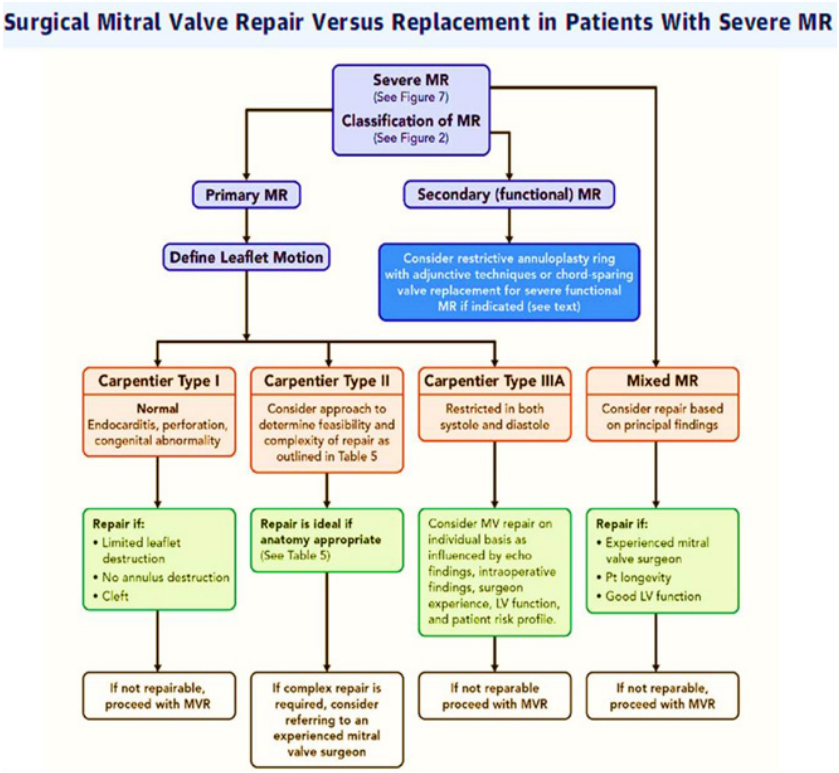
Recent emphasis has been placed on the heart valve team approach to patients with calcific aortic stenosis, in large measure due to improvements in transcatheter and surgical therapies. The evaluation and management of patients with mitral regurgitation (MR), a highly prevalente valve lesion among aging U.S. adults, are more complex, in part related to its various causes, dynamics nature, and insidious progression. MR derives from functional impairment or anatomic derangement of any 1 or more of the components of the mitral apparatus necessary for the valve's normal function, including the left ventricle, papillary muscles, chordae tendineae, leaflets and annulus.

This document contains clinical expert consensus recommendations to guide the approach to patients identified with MR. The document emphasizes clinical and echocardiographic assessment, establishment of etiology and mechanism, consideration of associated hemodynamic consequences, recognition of the triggers for surgical referral, appreciation of the graded complexity of mitral valve repair as a function of pathoanatomy, and understanding the currently limited role for transcatheter mitral valve edge-to-edge repair in the United States.

Recommendations are based on the 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease and its 2017 focused update , and augmented with additional clinical context and practical advice for medical and surgical decision making in complex patient scenarios.

Evaluation and management algorithms in this document flow from an echocardiographically validated diagnosis of MR. Primary MR is defined by principal involvement of the leaflets and/or chordae tendineae in the pathological process (e.g., myxomatous disease, endocarditis). Secondary (functional) MR is characterized by incompetence due to adverse changes in left ventricular size, shape, or function with or without annular dilatation (e.g., ischemic cardiomyopathy). Mixed MR is due to both primary and secondary causes (e.g., mitral valve prolapse/flail with ischemic cardiomyopathy). It is now recognized that primary and secondary MR are different diseases with different outcomes and indications for treatment.

The writing committee used the American Society of Echocardiography's 2017 Recommendations for Noninvasive Evaluation of Native Valvular Regurgitation to grade MR severity and emphasized the need for additional testing when severity could not be established with certainty.



Em Formas Graves de Tetralogia De Fallot, as Estratégias de Correção Cirúrgica Precoce ou de Paliação Inicial por Cateter Apresentam Resultados Semelhantes

Young Infants with Severe Tetralogy of Fallot: Early Primary Surgery versus Transcatheter Palliation

BACKGROUND

Infants with severe tetralogy of Fallot may undergo (1) early primary surgical repair (EARLY) or (2) early transcatheter palliation (CATH) before delayed surgical repair. We compared these strategies with (3) elective single-stage tetralogy of Fallot repair (IDEAL).

METHODS

From 2000 to 2012, 453 children underwent tetralogy of Fallot repair (excluding systemic-pulmonary shunts), including 383 in the IDEAL (75%), 42 in the EARLY (9%), and 28 in the CATH (6%) groups. IDEAL repair at The Hospital for Sick Children occurs after 3 months. Risk-adjusted hazard analysis compared freedom from surgical or catheter reintervention. Somatic size, branch pulmonary artery size, and right ventricle systolic pressure were modeled using 2780 echocardiogram reports via mixed-model regression.

RESULTS

CATH involved right ventricular outflow tract stent in 18 patients, right ventricular outflow tract balloon in 9 patients, and ductal-stent in 1 patient. Three patients died (1 per group). Risk-adjusted freedom from surgical reoperation was 89% ` 4%, 88% ` 5%, and 85% ` 6% for the IDEAL, EARLY, and CATH groups, respectively, at 10 years. Patients in the EARLY and CATH groups had similar reoperation rates, except for neonates (<1 month), for whom EARLY repair conferred an increased risk of reoperation. Risk-adjusted freedom from catheter reintervention was lower in the EARLY group (76%) and especially for the CATH group (53%) at 10 years versus the IDEAL group (83%). Somatic growth and progression of right ventricle systolic pressure were similar among groups at 8 years. Although those undergoing EARLY (P 1⁄4 .02) and CATH (P 1⁄4 .09) tend to have smaller branch pulmonary arteries initially, late pulmonary artery size was not significantly different among groups.

CONCLUSIONS

Early primary repair for neonates may increase surgical reoperation, whereas transcatheter palliation comes at a cost of increased catheter reintervention. However, overall outcomes between groups, in terms of survival, growth, and hemodynamic parameters, were comparable, suggesting that both strategies are a reasonable option for children with severe tetralogy of Fallot.