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Sociedade
Brasileira de
Cirurgia
Cardiovascular

J Am Coll Cardiol 2019;73:2609-35

Consenso da American Heart Association redefine Estratégias para Otimizar Atendimento a Doença Valvular: novos requerimentos para Certificação de Centros Especializados

2019 AATS/ACC/ASE/SCAI/STS Expert Consensus Systems of Care Document: A Proposal to Optimize Care for Patients with Valvular Heart Disease

COMENTÁRIO EDITORIAL

Com a reunião de cinco sociedades cardiovasculares dos Estados Unidos, este documento de consenso estabelece diversas mudanças e propostas para a otimização do tratamento dos pacientes com doença valvar cardíaca (DCV).

A intenção do documento é propor um sistema hierarquizado em dois níveise regionalizado de tratamentode pacientes com DVC, cujo objetivo principal é otimizar os resultados, melhorar o atendimento e racionalizar custos. Esta abordagem visamelhorar o diagnóstico de pacientes com DVC e enfatizar as melhores práticas conforme descritas em Diretrizes. Propõe também promover a utilização eficiente dos recursos, facilitar a comunicação e a continuidade dos cuidados e realçar a necessidade de transparência com divulgação de resultados em bases de dados especificas e nacionais.

Alguns pontos principais do documento:

O modelo de cuidado integrado proposto para pacientes com DVC baseia-se em um conceito de sistema hierarquizado em dois níveis, na complexidade da doença e na resolutividade dos centros de referência, denominados Centro Valvar Primárionível II ou um Centro Valvar Compreensivo nível I.

A diferença principal entre centros reside principalmente no espectro mais amplo de serviços e maior densidade de pessoal especializado disponível em um centro abrangente de nível I.

- Oscentrosdesignadoscomoespecializadosem DVCnãodevemrealizarapenasos procedimentos específicos, mas também possuir equipes multidisciplinares capazes de avaliar e tratar pacientes de acordo com diretrizes baseadas em evidências, ao mesmo tempo que devem dispor de Heart Team para tomada de decisões compartilhadas.

- Os Centros Valvares Primários (nível II) devem ter, no mínimo, a competência e os recursos para realizar a trocavalvar aórtica cirúrgica, com ou sem a cirurgia de revascularização miocárdicaassociada e também TAVR. A competência de

realizar o reparo valvar mitral durável em pacientes com insuficiência mitral primária causada por lesão isolada do folheto posterior é desejável, mas não obrigatória.

• Os Centros Valvares nível I devem ter os recursos e capacidades para avaliar e executar todos os procedimentos intervencionistas e cirúrgicos disponíveis, incluindo TAVR por abordagens não-transfemural e TAVR *valve-in-valve,* tratamento percutâneo transcateter da valva mitral e oclusãopercutânea de vazamentos perivalvares; além de procedimentos cirúrgicos complexos, incluindo operações complexas da raiz da aorta, como a cirurgia de David e a capacidade de tratar pacientes com endocardite infecciosa complicada.

• Todos os centros devem possuir e dispor acesso consistente a ecocardiografia de alta qualidade e ecocardiografistas com experiência em DVC e com competência estendida em intervenção. Além disso, devem ter modalidades avançadas de imagem, incluindo ecocardiografia 3D e ressonância magnética cardíaca.

Todos os centros valvares, tanto I como II, devem possuir:

• Equipe multidisciplinar formal (Heart Team) composta de profissionais com experiência no tratamento de pacientes com DVC.

• Participar e incluir dados nos registros nacionais.

• Servir como centros de referências em investigação para avaliação de novas tecnologias.

• Prover educação continuada aos médicos e profissionais envolvidos nos cuidados de pacientes com DVC.

• Divulgar publicamente os resultados de intervenções cirúrgicas e transcateter.

Walter José Gomes
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BACKGROUND

In the past decade, the evaluation and management of patients with VHD has changed dramatically. Advances in noninvasive imaging have enabled reliable, reproducible, and objective measurements of valve disease severity, along with an appreciation of any associated hemodynamic and structural consequences. There is enhanced understanding of the natural history of VHD based upon longitudinal studies of large numbers of patients that have correlated outcomes with noninvasive measurements as well as with data obtained during exercise testing.

Advances in surgical techniques, especially those associated with valve repair; improved operative results; and perioperative management strategies have contributed substantially to better patient outcomes. Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of patients with symptomatic, severe aortic stenosis (AS) and now provides a lessinvasive treatment option for many eligible patients. Transcatheter repair of mitral regurgitation (MR) with na edge-to-edge clip device occupies a specific treatment niche currently, and more options for this valve lesion are anticipated in the near future. Transcatheter mitral valve replacement (TMVR) is the subject of intense investigation, and tricuspid valve interventions in high-surgical-risk patients are being developed. Collectively, these advances have led to an increasing number of treatment options, lower thresholds for and earlier timing of intervention, and the provision of less-invasive therapies to an older, sicker, and more frail population. As the number and complexity of VHD treatment options have expanded, expert clinical judgment from na experienced multidisciplinary team (MDT) has assumed increasing importance.

The development of an integrated model of care for patients with VHD is based on the concept of a graduated system in which the first tier has the critical function of recognition and consideration of referral. Subsequently, the patient is matched on the basis of disease complexity with the required center expertise, experience, and availability of resources.

The following principles are emphasized:

- The primary goal is to improve the care of all patients with VHD.

- The first step is recognition and subsequent diagnosis of VHD, usually by a primary care physician, advanced practice provider, or general cardiologist.

- The second step often involves referral to a local general cardiologist who can

further refine the diagnosis, initiate medical therapy as indicated, and identify those who can be managed for the time being without further intervention or who may need more specialized care such as surgery or transcatheter valve repair or replacement.

· Access to specialized care requires establishment of well-defined referral lines to centers having graduated levels of expertise and resources (Figure 1). Increasing disease complexity often requires higher-order, comprehensive care at a Level I center, whereas less complex disease can be managed at a Level II center.

· A Multidisciplinary Team (MDT) and an emphasis on patient shared decision-making are essential to the operations of both Level I and II valve centers.

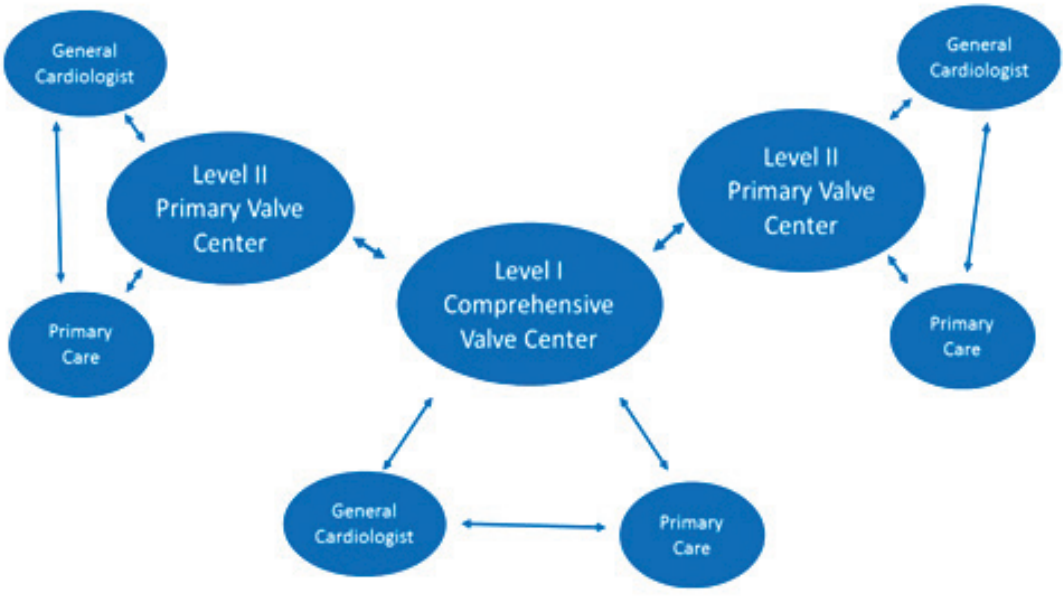
· Full institutional support is required for provision of appropriate imaging and procedural resources, equity among the individual stakeholders of the MDT, care pathways that span the continuum, registry participation, and results reporting.

· Transparency, public reporting, mandatory participation in national registries, ongoing analysis of processes and outcomes, and a commitment to research are essential.

· Bidirectional communication and ongoing education of members of the MDT and the community of referring providers/centers are required to improve the quality of care in all settings.

· Processes of care should emphasize informed consent (information provided in various formats and languages), SDM, patient experiences, and individual choices.

FIGURE 1 **Relationships Among Primary Care Clinicians, General Cardiologists, and Valve Centers**



N Engl J Med 2019;380:1695-1705

PARTNER 3 trial: resultados da Válvula Aórtica Transcateter (TAVI) em Pacientes de Baixo Risco

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

BACKGROUND

Among patients with aortic stenosis who are at intermediate or high risk for death with surgery, major outcomes are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. There is insufficient evidence regarding the comparison of the two procedures in patients who are at low risk.

METHODS

We randomly assigned patients with severe aortic stenosis and low surgical risk to undergo either TAVR with transfemoral placement of a balloon-expandable valve or surgery. The primary end point was a composite of death, stroke, or rehospitalization at 1 year. Both noninferiority testing (with a prespecified margin of 6 percentage points) and superiority testing were performed in the as-treated population.

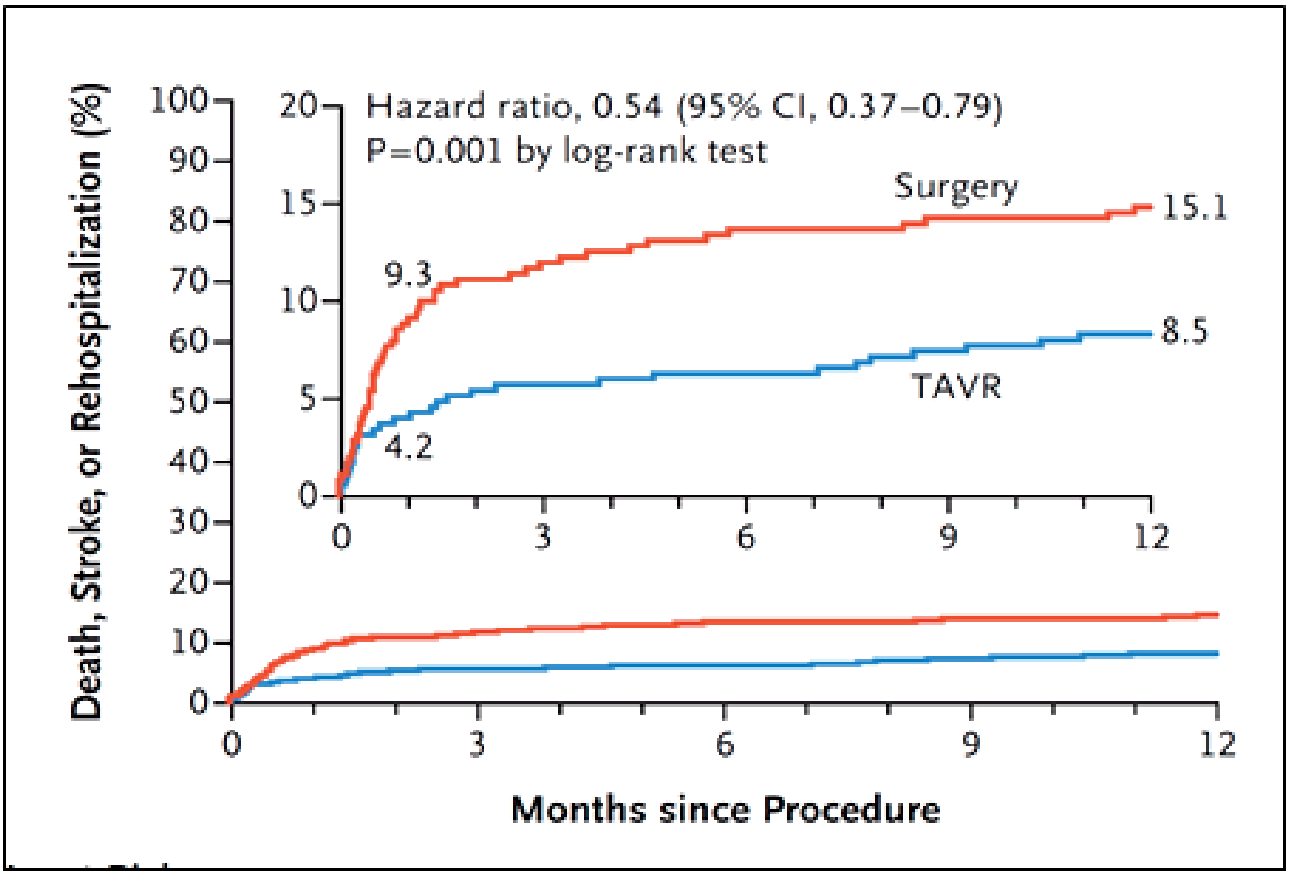
RESULTS

At 71 centers, 1000 patients underwent randomization. The mean age of the patients was 73 years, and the mean Society of Thoracic Surgeons risk score was 1.9% (with scores ranging from 0 to 100% and higher scores indicating a greater risk of death within 30 days after the procedure). The Kaplan-Meier estimate of the rate of the primary composite end point at 1 year was significantly lower in the TAVR group than in the surgery group (8.5% vs. 15.1%; absolute difference, -6.6 percentage points; 95% confidence interval [CI], -10.8 to -2.5; P<0.001 for noninferiority; hazard ratio, 0.54; 95% CI, 0.37 to 0.79; P=0.001 for superiority). At 30 days, TAVR resulted in a lower rate of stroke than surgery (P=0.02) and in lower rates of death or stroke (P=0.01) and new-onset atrial fibrillation (P<0.001). TAVR also resulted in a shorter index hospitalization than surgery (P<0.001) and in a lower risk of a poor treatment outcome (death or a low Kansas City Cardiomyopathy

Questionnaire score) at 30 days (P<0.001). There were no significant between-group differences in major vascular complications, new permanent pacemaker insertions, or moderate or severe paravalvular regurgitation.

CONCLUSIONS

Among patients with severe aortic stenosis who were at low surgical risk, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVR than with surgery. (Funded by Edwards Lifesciences; PARTNER 3 ClinicalTrials.gov number, NCT02675114.).



J Am Coll Cardiol 2019;73:1877-86

Desfechos Tardios após Cirurgia de Revascularização Miocárdica, em Pacientes com Lesão de Tronco de Coronária Esquerda (TCE): comparação dos Ensaios SYNTAX e EXCEL

Contemporary outcomes Following Coronary Artery Bypass Graft Surgery for Left Main Disease

BACKGROUND

Although results of percutaneous coronary intervention (PCI) have been steadily improving, whether surgical outcomes have improved over time is not fully elucidated.

OBJECTIVES

This study sought to compare the current outcomes of patients undergoing coronary artery bypass grafting (CABG) with prior surgical results, in the context of randomized trials including the left main (LM) coronary artery stem.

METHODS

The authors performed a propensity-matched analysis of patients randomized to CABG in the SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) (enrollment period 2005 to 2007) and EXCEL (Evaluation of XIENCE Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) (enrollment period 2010 to 2014) trials. All patients had left main (LM) disease with or without multivessel disease. Adjustment was based on 15 clinical and angiographic variables, including anatomic SYNTAX score, with a 2:1 ratio for the EXCEL and SYNTAX trials, collectively analyzing 909 subjects (n = 580 and n = 329, respectively). The primary endpoint was the composite of all-cause death, myocardial infarction (MI), stroke, or ischemia-driven revascularization at 3 years.

RESULTS

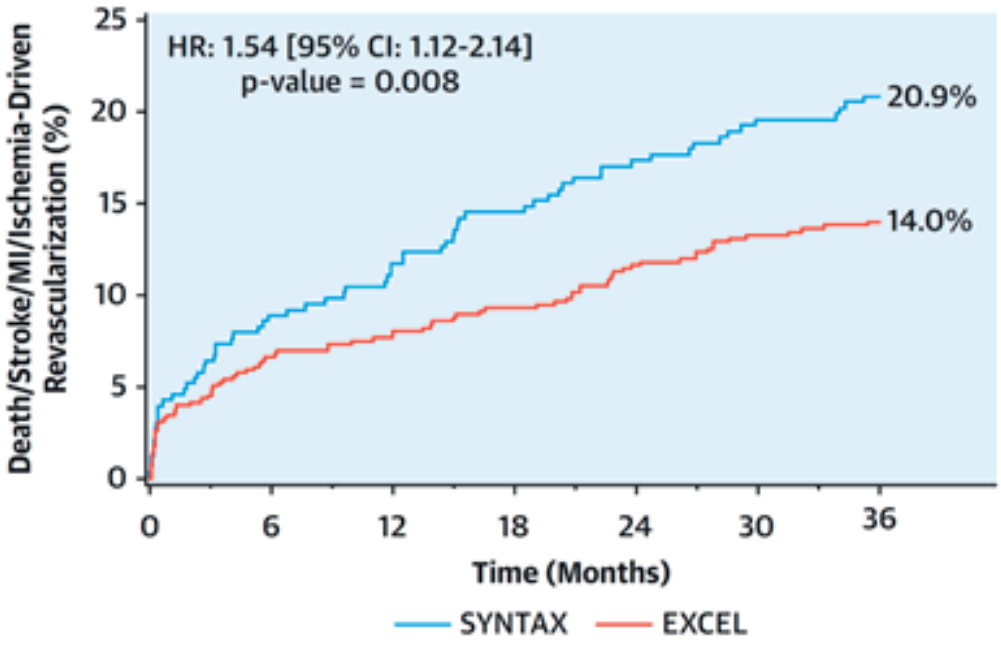
Baseline characteristics, anatomic SYNTAX score, number and types of grafts, and duration of hospitalization for the procedures were similar in both groups. CABG procedures in the EXCEL compared with the SYNTAX trial were more often off-pump (29.6% vs. 15.4%; P<0.001), and guideline-directed medical therapies were used more frequently in the EXCEL surgical cohort. The primary endpoint occurred in 14.0% and 20.9% (P = 0.008) of patients in the EXCEL and SYNTAX trials,

respectively. With the exception of MI (4.1% vs. 3.7%), all nonhierarchical events tended to contribute to the improved outcomes in the more recent trial: all-cause death (5.5% vs. 8.5%), stroke (3.1% vs. 5.1%), and ischemia-driven revascularization (7.1% vs. 9.4%) in the EXCEL and SYNTAX trials, respectively.

CONCLUSIONS

Over a 5- to 7-year period, significant improvement in event-free survival after surgical revascularization for LM disease at 3 years was noted between the SYNTAX and EXCEL trials, consistent with improving results with cardiac surgery over time. (Synergy Between PCI With Taxus and Cardiac Surgery [SYNTAX]; NCT00114972; Evaluation of XIENCE Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization [EXCEL]; NCT01205776).

CENTRAL ILLUSTRATION **Improvement in Outcomes After Coronary Artery Bypass Grafting for Left Main Coronary Artery Disease**



JAMA Cardiol 2019. doi: 10.1001/jamacardio.2019.0014

Características Clínicas e Perfil de Risco dos Pacientes incluídos no ISCHEMIA Trial

Baseline Characteristics and Risk Profiles of Participants in the ISCHEMIA Randomized Clinical Trial

IMPORTANCE

It is unknown whether coronary revascularization, when added to optimal medical therapy, improves prognosis in patients with stable ischemic heart disease (SIHD) at increased risk of cardiovascular events owing to moderate or severe ischemia.

OBJECTIVE

To describe baseline characteristics of participants enrolled and randomized in the International Study of Comparative Health Effectiveness With Medical and Invasive Approaches (ISCHEMIA) trial and to evaluate whether qualification by stress imaging or nonimaging exercise tolerance test (ETT) influenced risk profiles.

DESIGN, SETTING, AND PARTICIPANTS

The ISCHEMIA trial recruited patients with SIHD with moderate or severe ischemia on stress testing. Blinded coronary computed tomography angiography was performed in most participants and reviewed by a core laboratory to exclude left main stenosis of at least 50% or no obstructive coronary artery disease (CAD) (<50% for imaging stress test and <70% for ETT). The study included 341 enrolling sites (320 randomizing) in 38 countries and patients with SIHD and moderate or severe ischemia on stress testing. Data presented were extracted on December 17, 2018.

MAIN OUTCOMES AND MEASURES

Enrolled, excluded, and randomized participants' baseline characteristics. No clinical outcomes are reported.

RESULTS

A total of 8518 patients were enrolled, and 5179 were randomized. Common reasons for exclusion were core laboratory determination of insufficient ischemia, unprotected left main stenosis of at least 50%, or no stenosis that met study obstructive CAD criteria on study coronary computed tomography angiography. Randomized

participants had a median age of 64 years, with 1168 women (22.6%), 1726 nonwhite participants (33.7%), 748 Hispanic participants (15.5%), 2122 with diabetes (41.0%), and 4643 with a history of angina (89.7%). Among the 3909 participants randomized after stress imaging, core laboratory assessment of ischemia severity (in 3901 participants) was severe in 1748 (44.8%), moderate in 1600 (41.0%), mild in 317 (8.1%) and none or uninterpretable in 236 (6.0%), Among the 1270 participants who were randomized after nonimaging ETT, core laboratory determination of ischemia severity (in 1266 participants) was severe (an eligibility criterion) in 1051 (83.0%), moderate in 101 (8.0%), mild in 34 (2.7%) and none or uninterpretable in 80 (6.3%). Among the 3912 of 5179 randomized participants who underwent coronary computed tomography angiography, 79.0% had multivessel CAD (n = 2679 of 3390) and 86.8% had left anterior descending (LAD) stenosis (n = 3190 of 3677) (proximal in 46.8% [n = 1749 of 3739]). Participants undergoing ETT had greater frequency of 3-vessel CAD, LAD, and proximal LAD stenosis than participants undergoing stress imaging.

CONCLUSIONS

The ISCHEMIA trial randomized an SIHD population with moderate or severe ischemia on stress testing, of whom most had multivessel CAD.

Table 4. Randomized Participant Stress Test and Coronary Computed Tomographic Angiography Findings Intent-to-Treat Population, Imaging Stress Test vs Exercise Tolerance Test

Characteristic, Stress Test Summary	No./Total No. (%)		
	Total (n = 5179)	Imaging Stress Test (n = 3909)	Exercise Tolerance Test (n = 1270)
Core laboratory summary, baseline ischemia			
Severe	2799/5167 (54.2)	1748/3901 (44.8)	1051/1266 (83.0)
Moderate	1701/5167 (32.9)	1600/3901 (41.0)	101/1266 (8.0)
Mild	351/5167 (6.8)	317/3901 (8.1)	34/1266 (2.7)
None	254/5167 (4.9)	226/3901 (5.8)	28/1266 (2.2)
Uninterpretable	62/5167 (1.2)	10/3901 (0.3)	52/1266 (4.1)
CCTA findings[a]			
Any obstructive disease ≥50% stenosis by CCTA	3832/3836 (99.9)	2785/2786 (>99.9)	1047/1050 (99.7)
Multivessel disease ≥50% stenosis by CCTA	2679/3390 (79.0)	1923/2441 (78.8)	756/949 (79.7)
Vessels ≥50% stenosis by CCTA			
0	4/2986 (0.1)	1/2147 (0.0)	3/839 (0.4)
1	697/2986 (23.3)	508/2147 (23.7)	189/839 (22.5)
2	938/2986 (31.4)	699/2147 (32.6)	239/839 (28.5)
≥3	1347/2986 (45.1)	939/2147 (43.7)	408/839 (48.6)
Specific native vessels with ≥50% stenosis by CCTA			
Left main	40/3845 (1.0)	37/2794 (1.3)	3/1051 (0.3)
Left anterior descending	3190/3677 (86.8)	2286/2659 (86.0)	904/1018 (88.8)
Proximal LAD	1749/3739 (46.8)	1189/2711 (43.9)	560/1028 (54.5)
Left circumflex	2354/3495 (67.4)	1690/2546 (66.4)	664/949 (70.0)
Right coronary artery	2311/3359 (68.8)	1668/2417 (69.0)	643/942 (68.3)

Abbreviations: CCTA, coronary computed tomographic angiography; LAD, left anterior descending.

Korean J Thorac Cardiovasc Surg 2019;52:70-7

Resultados da Cirurgia de Revascularização Miocárdica após Parada Cardiocirculatória e Assistência Ventricular Extra-corpórea

Outcomes of Coronary Artery Bypass Grafting after Extracorporeal Life Support in Patients with Cardiac Arrest or Cardiogenic Shock

BACKGROUND

Extracorporeal life support (ECLS) is used as a bridge to revascularization in high-risk patients with ischemic heart disease. We reviewed our experiences of coronary artery bypass grafting (CABG) after ECLS in patients with cardiac arrest or refractory cardiogenic shock.

METHODS

We retrospectively reviewed 4,616 patients who underwent CABG at our institution between May 2006 and February 2017. We identified patients who underwent CABG following ECLS for cardiogenic shock or cardiac arrest. Twenty-three patients (0.5% of all CABG cases) were enrolled in the analysis. Their median age was 65 years (Q1-Q3, 58-77 years). Nine patients (39.1%) were diagnosed with ST-elevation myocardial infarction. Mechanical complications after acute myocardial infarction, including acute mitral regurgitation, left ventricular rupture, and ventricular septal defect, occurred in 9 patients (39.1%).

RESULTS

The median time from cardiopulmonary resuscitation to ECLS initiation was 25 minutes (Q1-Q3, 18.5-28.5 minutes). Conventional CABG was performed in 10 patients (43.5%) who underwent concomitant intracardiac procedures. Postoperative ECLS was required in 16 patients (69.5%). The rate of successful ECLS weaning was 91.3% (n=21). There were 6 early mortalities (26.1%).

CONCLUSIONS

CABG after ECLS was very rare in real-world circumstances. Although the early mortality rate was high, the risk of mortality may be acceptable under such devastating circumstances.

Table 3. Early postoperative outcomes	
Variable	No. of patients (%)
Early mortality	6 (26.1)
Early morbidity	
Atrial fibrillation	10 (43.5)
Respiratory complication	4 (17.4)
Low cardiac output syndrome	2 (8.7)
Stroke	7 (30.4)
Acute kidney injury requiring dialysis	10 (43.5)
Reoperation for postoperative bleeding	3 (13.0)
Gastrointestinal bleeding	1 (4.3)
Limb ischemia	1 (4.3)

Eur J Cardiothorac Surg 2019;55:714-720

Estudo de Coorte Avalia Momento Seguro para Descontinuação do Ticagrelor, Antes da Cirurgia Cardíaca

The Association between a Three-Day Ticagrelor Discontinuation and Perioperative Bleeding Complications

OBJECTIVES

Dual antiplatelet therapy at the time of cardiac surgery is associated with excessive perioperative bleeding. International guidelines, therefore, recommended discontinuing oral adenosine diphosphate receptor antagonists prior to non-emergency surgery. In this study, we analysed whether a 3-day ticagrelor discontinuation was sufficient to avoid major bleeding complications.

METHODS

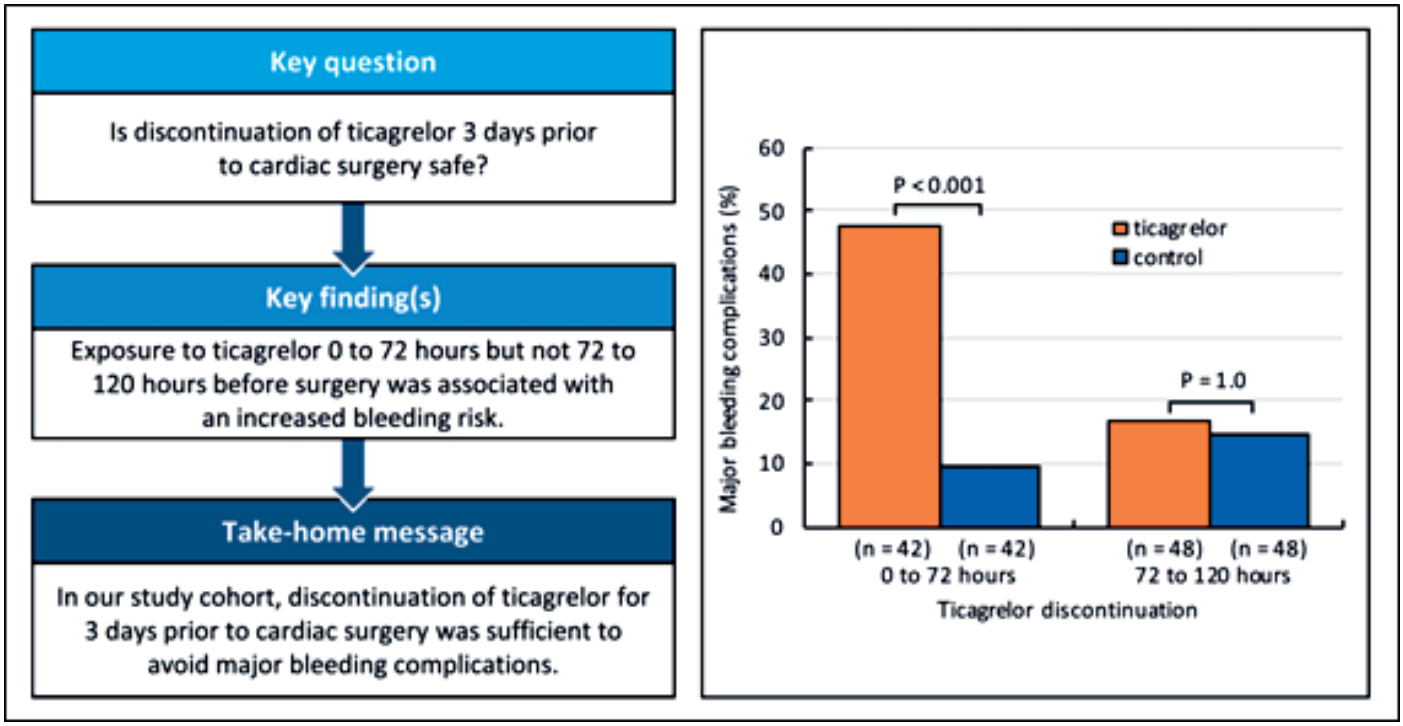
This study is a retrospective cohort analysis of 3377 patients undergoing coronary artery bypass or single-valve surgery from January 2013 to September 2017. Patients exposed to ticagrelor prior to surgery were compared with control patients exposed to aspirin only. Outcome measures included transfusion requirements, bleeding volumes, the need for re-exploration and the composite outcome major bleeding complication. Data were retrieved from the the Western Denmark Heart Registry.

RESULTS

During the study period, 101 patients were preoperatively exposed to ticagrelor, whereas 3276 patients were exposed to aspirin only. Propensity-score matching resulted in 90 pairs of patients. Overall, ticagrelor exposure was associated with a greater risk of major bleeding complications compared with control patients [31 vs 12%, relative risk 2.6, 95% confidence interval (CI) 1.4-4.8]. While ticagrelorexposure within 0-72 h before surgery (n = 42) was associated with a substantially increased risk of major bleeding complications (48 vs 10%, relative risk 5.0, 95% CI 1.9-13.4), ticagrelor exposure 72-120 h before surgery (n = 48) showed no statistically significant association (17 vs 15%, relative risk 1.1, 95% CI 0.4-2.9).

CONCLUSIONS

In our historical cohort, ticagrelor exposure 0-72 h prior to cardiac surgery was associated with an increased risk of major bleeding complications. On the other hand, ticagrelor exposure 72-120 h prior to surgery was not associated with a clinically relevant increase in major bleeding complications.



Catheter Cardiovasc Interv 2019;93:859-74

Consenso da Academia Americana de Neurologia estabelece requerimentos para Fechamento de Forâmen Oval Patente

SCAI expert consensus statement on operator and institutional requirements for PFO closure for secondary prevention of paradoxical embolic stroke: The American Academy of Neurology affirms the value of this statement as an educational tool for neurologists

ABSTRACT

Until recently, evidence to support Patent Foramen Ovale (PFO) closure for secondary prevention of recurrent stroke has been controversial. Publication of high-quality evidence from randomized clinical trials and the subsequent FDA approval of two devices for percutaneous PFOclosure is expected to increase the volume of PFO closure procedures not only in the United States but worldwide. As this technology is disseminated broadly to the public, ensuring the safe and efficacious performance of PFO closure is essential to mitigate risk and avoid unnecessary procedures. This document, prepared by a multi-disciplinary writing group convened by the Society for Cardiovascular Angiography and Interventions and including representatives from the American Academy of Neurology, makes recommendations for institutional infrastructure and individual skills necessary to initiate and maintain an active PFO/stroke program, with emphasis on shared decision making and patient-centered care.

TABLE 3 PFO closure requirements—Procedural specialist and medical facility

Procedural specialist[a]	*Initial qualification* • Clinical knowledge-base that includes a comprehensive understanding of stroke-related PFO closure and appropriate treatment strategies for this unique patient population. • Suitable training on the PFO closure device(s) approved by the FDA. • Understanding of atrial anatomy and imaging • >50 life-time structural/congenital[b] catheter interventions with either a minimum of 25 involving septal interventions[c] or 12 specific to PFO device placement. • Experience with catheter-based management of potential complications, including pericardiocentesis, recognition of device malposition, and embolized device retrieval. *Novice operators* • Mandatory peer-to-peer training course. • Physician proctor or mentor during interventional training--10 cases total. • Physician proctor present for 3–5 cases for each new device system. *Ongoing* • Over a 2-year period, >30 procedures that involve septal interventions[c] or >15 specific to PFO device placement. • Process for identifying whether additional training is required on the basis of technological or clinical changes.

TABLE 4 Proposed quality assessment measures

Metric	Target performance
Operator and institutional requirements met	100%
Percentage of patients who were seen by both a cardiologist and neurologist prior to PFO closure	100%
Procedure-related major adverse outcomes: • Mortality • Intraprocedure stroke • Air embolism • Device embolization • Major vascular complications	<1% or below the 10th percentile if registry benchmarking data becomes available
• Major bleeding complications • Atrial fibrillation, transient or sustained, if treatment required, and if oral anticoagulation initiated • Myocardial infarction • Pericardial effusion with and without tamponade • Emergency surgery	<5%

JAMA 2019;321:1176-8

Ensaio Clínico Demonstra que a Injeção de Células Mesenquimais Intramiocárdicas não adiciona Benefício ao Suporte Circulatório Mecânico, em Pacientes com Insuficiência Cardíaca Refratária

Intramyocardial Injection of Mesenchymal Precursor Cells and Successful Temporary Weaning From Left Ventricular Assist Device Support in Patients with Advanced Heart Failure: a Randomized Clinical Trial

IMPORTANCE

Left ventricular assist device (LVAD) therapy improves myocardial function, but few patients recover sufficiently for explant, which has focused attention on stem cells to augment cardiac recovery.

OBJECTIVE

To assess efficacy and adverse effects of intramyocardial injections of mesenchymal precursor cells (MPCS) during LVAD implant.

DESIGN, SETTING, AND PARTICIPANTS

A randomized phase 2 clinical trial involving patients with advanced heart failure, undergoing LVAD implant, at 19 North American centers (July 2015-August 2017).
The 1-year follow-up ended August 2018.

INTERVENTIONS

Intramyocardial injections of 150 million allogeneic MPCs or cryoprotective medium as a sham treatment in a 2:1 ratio (n = 106 vs n = 53).

MAIN OUTCOMES AND MEASURES

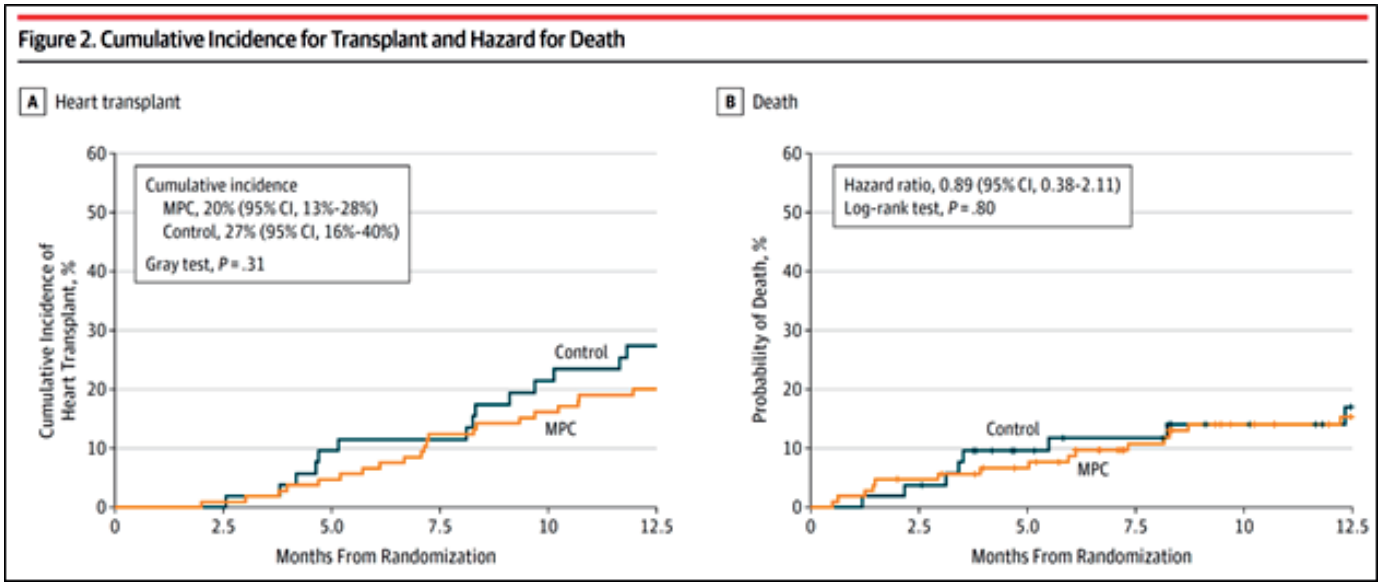
The primary efficacy end point was the proportion of successful temporary weans (of 3 planned assessments) from LVAD support within 6 months of randomization. This end point was assessed using a Bayesian analysis with a predefined threshold of a posterior probability of 80% to indicate success. The 1-year primary safety end point was the incidence of intervention-related adverse events (myocarditis, myocardial rupture, neoplasm, hypersensitivity reactions, and immune sensitization). Secondary end points included readmissions and adverse events at 6 months and 1-year survival.

RESULTS

Of 159 patients (mean age, 56 years; 11.3% women), 155 (97.5%) completed 1-year of follow-up. The posterior probability that MPCs increased the likelihood of successful weaning was 69%; below the predefined threshold for success. The mean proportion of successful temporary weaning from LVAD support over 6 months was 61% in the MPC group and 58% in the control group (rate ratio [RR], 1.08; 95% CI, 0.83-1.41; P=.55). No patient experienced a primary safety end point. Of 10 prespecified secondary end points reported, 9 did not reach statistical significance. One-year mortality was not significantly different between the MPC group and the control group (14.2% vs 15.1%; hazard ratio [HR], 0.89; 95%, CI, 0.38-2.11; P=.80). The rate of serious adverse events was not significantly different between groups (70.9 vs 78.7 per 100 patient-months; difference, -7.89; 95% CI, -39.95 to 24.17; P=.63) nor was the rate of readmissions (0.68 vs 0.75 per 100 patient-months; difference, -0.07; 95% CI, -0.41 to 0.27; P=.68).

CONCLUSIONS AND RELEVANCE

Among patients with advanced heart failure, intramyocardial injections of mesenchymal precursor cells, compared with injections of a cryoprotective medium as sham treatment, did not improve successful temporary weaning from left ventricular assist device support at 6 months. The findings do not support the use of intramyocardial mesenchymal stem cells to promote cardiac recovery as measured by temporary weaning from device support.



Ann Thorac Surg 2019 . Mar 1. doi: 10.1016/j.athoracsur.2019.01.046

Revisão Avalia Mudanças de Estratégias no Tratamento Cirúrgico da Atresia Pulmonar com Comunicação Interventricular e Colaterais Aorto-Pulmonares, ao longo de 20 anos

A Review of the Management of Pulmonary Atresia, Ventricular Septal Defect and Major Aortopulmonary Collateral Arteries

BACKGROUND

The management of pulmonary atresia with ventricular septal defect and major aorto-pulmonary collateral arteries (PA/VSD/MAPCAs) has significantly changed over the past 20 years. Unifocalization and rehabilitation have been described as diametrically opposed strategies. An updated review focused on the management of this complex and rare condition is needed.

METHODS

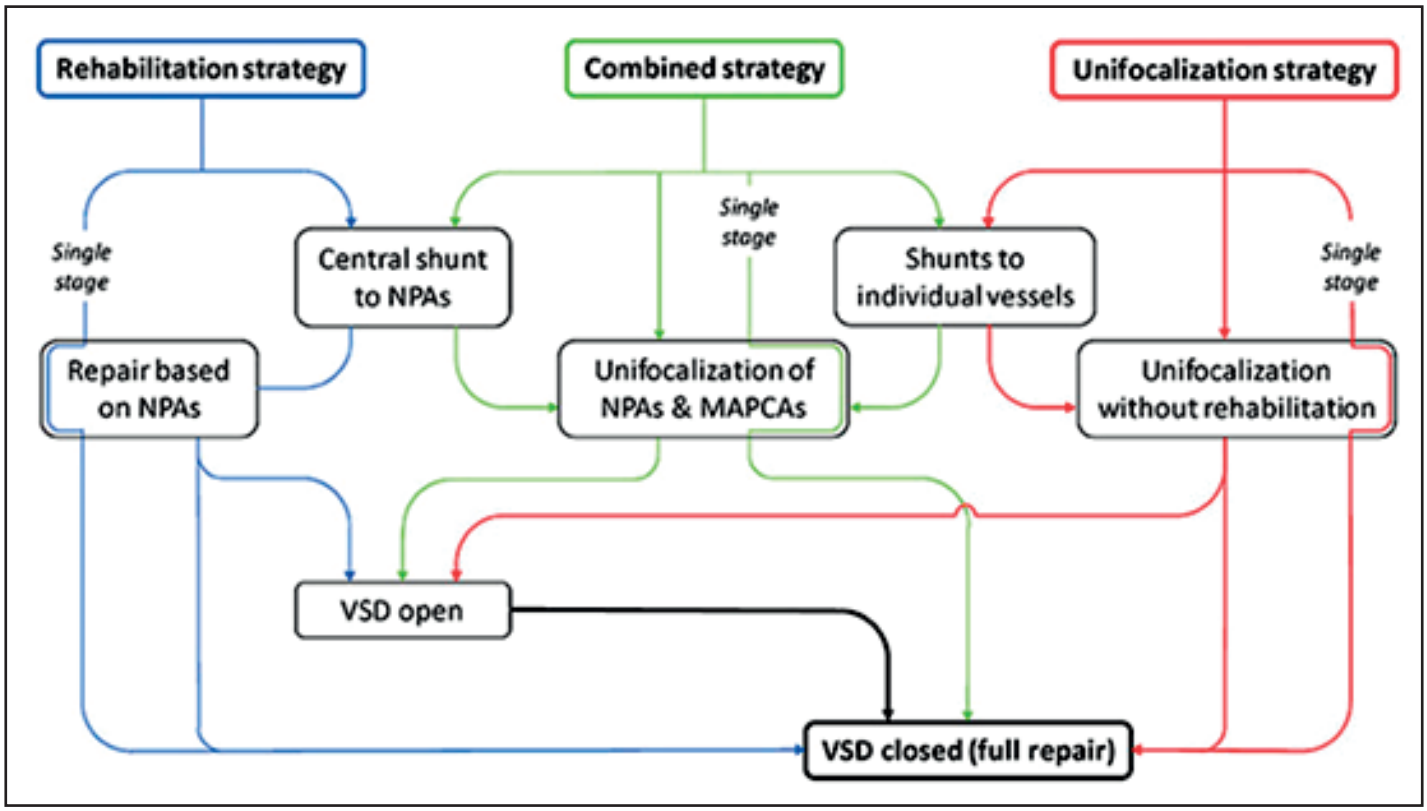
Articles related to PA/VSD/MAPCAs issued until December 2017 were screened. Twelve main studies published in the modern era (since 2000) were selected and analyzed.

RESULTS

Unifocalization and rehabilitation respectively focus on the mobilization of collateral arteries and the growth of native pulmonary vessels. A third strategy, called “combined strategy”, was distinguished from the review of the literature. Surgical cohorts and methods of data reporting were found to be heterogenous. Outcomes, regardless of the strategy, have transformed the natural history of the condition, with a complete repair rate of around 80% and low rates of early and late mortality. Patients with the most unfavorable anatomy (absent central pulmonary arteries and hypoplastic MAPCAs) remain a challenge and are still left palliated.

CONCLUSIONS

Variable surgical strategies are used in management of PA/VSD/MAPCAs. Most teams report a repair rate of 70-80% and a mortality rate lower than 10%. Standardization in data reporting is necessary to better compare the existing strategies.


Rehabilitation strategy
Combined strategy
Unifocalization strategy
Single stage
Central shunt to NPAs
Single stage
Shunts to individual vessels
Single stage
Repair based on NPAs
Unifocalization of NPAs & MAPCAs
Unifocalization without rehabilitation
VSD open
VSD closed (full repair)