Boletim Científico 02/2023

Dr. Luciano Cabral Albuquerque
Dr. Walter José Gomes
Dr. Fernando Ribeiro de Moraes Neto
Dr. Orlando Petrucci Junior

SOCIEDADE BRASILEIRA DE CIRURGIA CARDIOVASCULAR

Eur Heart J. 2023 Jun 8:ehad369.
doi: 10.1093/eurheartj/ehad369.

Registro Europeu Comprova Menor Mortalidade e Melhores Desfechos com a Revascularização Cirúrgica do Miocárdio, em Pacientes com Lesão de Tronco (TCE)

PCI or CABG for left main coronary artery disease: the SWEDEHEART registry

BACKGROUND

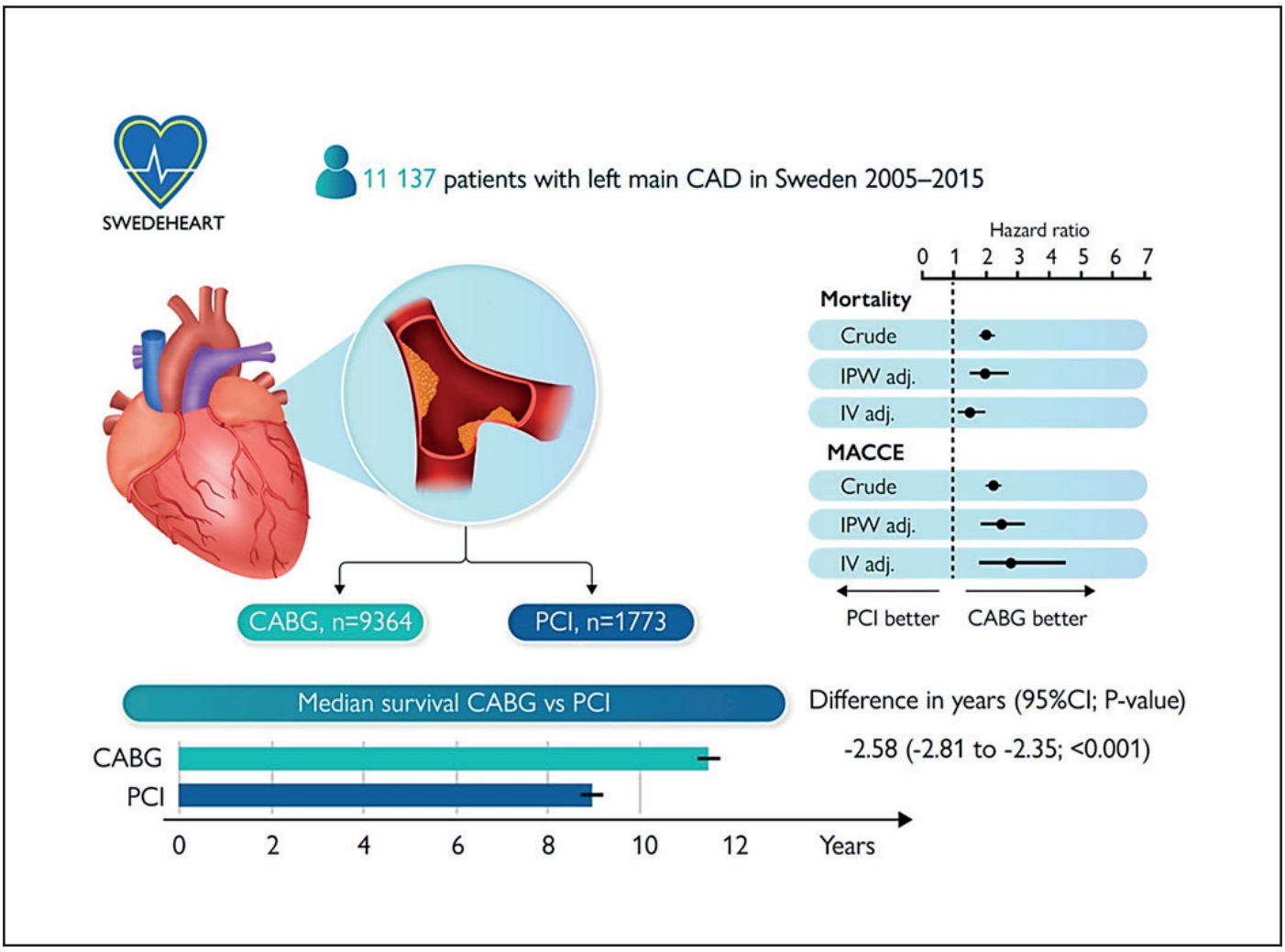
An observational nationwide all-comers prospective register study to analyse outcomes after coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) in unprotected left main coronary artery (LMCA) disease.

METHODS AND RESULTS

All patients undergoing coronary angiography in Sweden are registered in the Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies registry. Between 01/01/2005 and 12/31/2015, 11 137 patients with LMCA disease underwent CABG (n = 9364) or PCI (n = 1773). Patients with previous CABG, ST-elevation myocardial infarction (MI) or cardiac shock were excluded. Death, MI, stroke, and new revascularization during follow-up until 12/31/2015 were identified using national registries. Cox regression with inverse probability weighting (IPW) and an instrumental variable (IV), administrative region, were used. Patients undergoing PCI were older, had higher prevalence of comorbidity but lower prevalence of three-vessel disease. PCI patients had higher mortality than CABG patients after adjustments for known cofounders with IPW analysis (hazard ratio [HR] 2.0 [95% confidence interval (CI) 1.5-2.7]) and known/unknown confounders with IV analysis (HR 1.5 [95% CI 1.1-2.0]). PCI was associated with higher incidence of major adverse cardiovascular and cerebrovascular events (MACCE; death, MI, stroke, or new revascularization) than CABG, with IV analysis (HR 2.8 [95% CI 1.8-4.5]). There was a quantitative interaction for diabetic status regarding mortality (P = 0.014) translating into 3.6 years (95% CI 3.3-4.0) longer median survival time favouring CABG in patients with diabetes.

CONCLUSION

In this non-randomized study, CABG in patients with LMCA disease was associated with lower mortality and fewer MACCE compared to PCI after multivariable adjustment for known and unknown confounders.


SWEDEHEART
11 137 patients with left main CAD in Sweden 2005–2015
CABG, n=9364
PCI, n=1773
Hazard ratio
0 1 2 3 4 5 6 7
Mortality
Crude
IPW adj.
IV adj.
MACCE
Crude
IPW adj.
IV adj.
PCI better
CABG better
Median survival CABG vs PCI
CABG
PCI
0 2 4 6 8 10 12
Years
Difference in years (95%CI; P-value)
-2.58 (-2.81 to -2.35; <0.001)

J Thorac Cardiovasc Surg. 2023 Jul;166(1):74-83.e2.
doi: 10.1016/j.jtcvs.2021.08.081

As Estratégias de Reconstrução Valvar Mitral Interferem no Remodelamento Reverso do Ventrículo Esquerdo?

Mitral repair with leaflet preservation versus leaflet resection and ventricular reverse remodeling from a randomized trial

OBJECTIVE

In the Canadian Mitral Research Alliance (CAMRA) Trial CardioLink-2 leaflet resection versus preservation techniques for posterior leaflet prolapse was investigated and no difference was shown in their effect on mean mitral gradient at peak exercise at 12 months postoperatively. The purpose of this subanalysis was to evaluate the effect of the 2 strategies on left ventricular (LV) reverse remodeling after repair.

METHODS

A total of 104 patients were randomized to either a leaflet resection or leaflet preservation strategy. Echocardiograms, performed at baseline (preoperative), predischarge, and 12 months postoperatively, were analyzed in a blinded fashion at a core laboratory.

RESULTS

All patients underwent successful mitral repair. At discharge, 3 patients showed moderate mitral regurgitation, whereas the remainder showed mild or less regurgitation. Compared with the baseline echocardiogram, the indexed end diastolic volume was reduced at the discharge echocardiogram ($P < 0.0001$) and was further reduced at the 12-month echocardiogram ($P = 0.01$). In contrast, the indexed end systolic volume did not significantly change from baseline assessed at the predischarge echocardiogram ($P = .32$) but improved at 12 months postoperatively ($P < 0.0001$), resulting in a corresponding improvement in ejection fraction at 12 months ($P < 0.0001$). The type of mitral repair strategy had no significant effect on LV reverse remodeling trends.

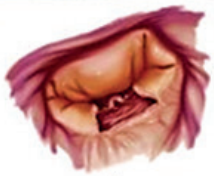
CONCLUSIONS

The mitral repair strategies used did not influence postoperative LV reverse remodeling, which occurred in stages. Although LV end diastolic dimensions recovered before discharge, improvements in LV end systolic dimension were evident 12 months after repair.

Left Ventricular Reverse Remodeling after Resection and Preservation Mitral Repair

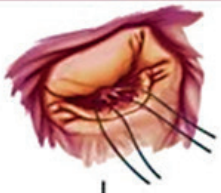
104 Participants with **Posterior Leaflet Prolapse**
7 Cardiac Surgical Centers

Resection Repair
54 participants

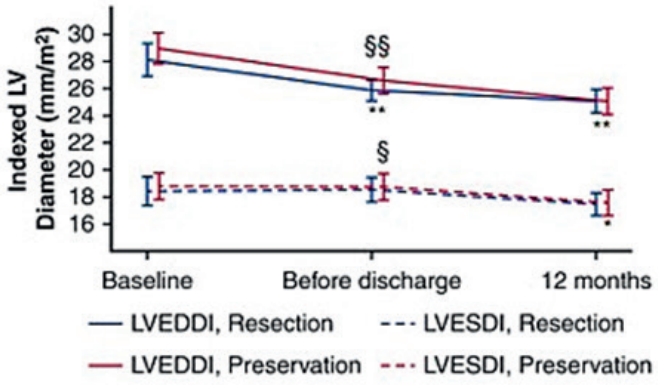


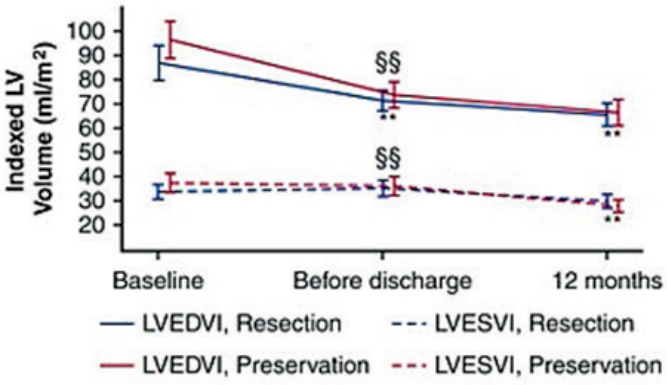
Randomized Allocation

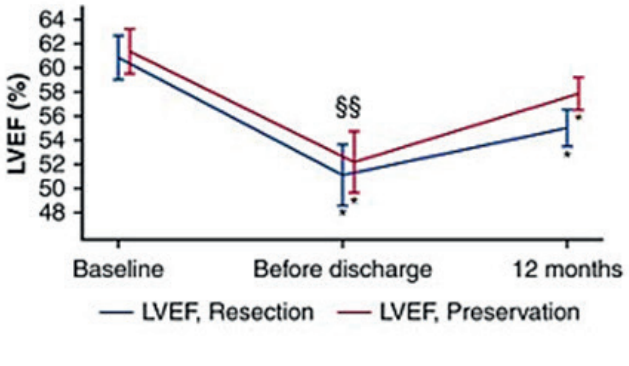
Preservation Repair
50 participants

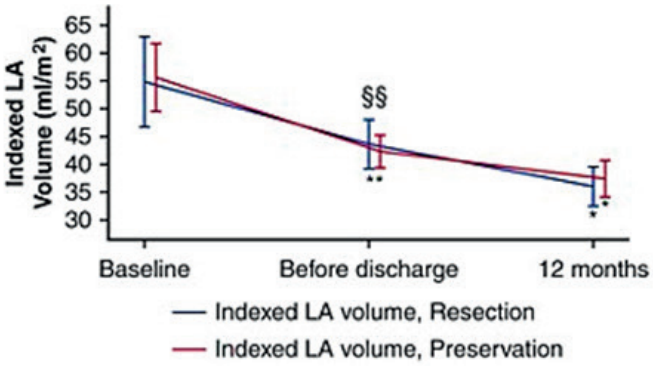


Postoperative Echocardiographic Assessments Blinded to Allocation and Timing









§ represents $P < .05$ for ANOVA and * represents $P < .05$ when compared with the previous time point.

Technique of Mitral Repair does not appear to Significantly Influence Subsequent Reverse Remodeling, which Occurs in Distinct Stages.

JAMA. 2023 Jun 13;329(22):1957-1966.
doi: 10.1001/jama.2023.7800

Ensaio Clínico Compara Desfechos da Minitoracotomia Versus Esternotomia Convencional, em Reparo da Valva Mitral

Minithoracotomy vs Conventional Sternotomy for Mitral Valve Repair: A Randomized Clinical Trial

IMPORTANCE

The safety and effectiveness of mitral valve repair via thoracoscopically-guided minithoracotomy (minithoracotomy) compared with median sternotomy (sternotomy) in patients with degenerative mitral valve regurgitation is uncertain.

OBJECTIVE

To compare the safety and effectiveness of minithoracotomy vs sternotomy mitral valve repair in a randomized trial.

DESIGN, SETTING, AND PARTICIPANTS

A pragmatic, multicenter, superiority, randomized clinical trial in 10 tertiary care institutions in the UK. Participants were adults with degenerative mitral regurgitation undergoing mitral valve repair surgery.

INTERVENTIONS

Participants were randomized 1:1 with concealed allocation to receive either minithoracotomy or sternotomy mitral valve repair performed by an expert surgeon.

MAIN OUTCOMES AND MEASURES

The primary outcome was physical functioning and associated return to usual activities measured by change from baseline in the 36-Item Short Form Health Survey (SF-36) version 2 physical functioning scale 12 weeks after the index surgery, assessed by an independent researcher masked to the intervention. Secondary outcomes included recurrent mitral regurgitation grade, physical activity, and quality of life. The prespecified safety outcomes included death, repeat mitral valve surgery, or heart failure hospitalization up to 1 year.

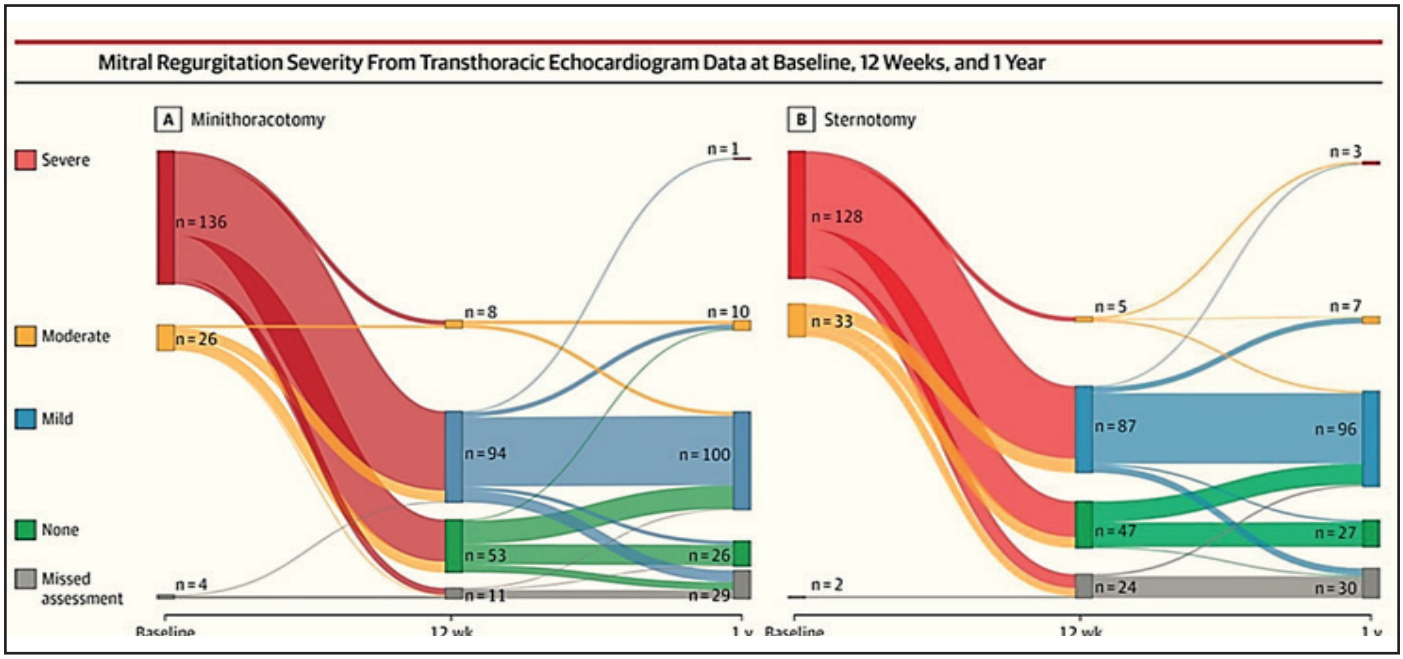
RESULTS

Between November 2016 and January 2021, 330 participants were randomized (mean age, 67 years, 100 female [30%]); 166 were allocated to minithoracotomy and 164 allocated to sternotomy, of whom 309 underwent surgery and 294 reported the primary outcome. At 12 weeks, the mean between-group difference in the change in the SF-36 physical function T score was 0.68

(95% CI, -1.89 to 3.26). Valve repair rates (≈ 96%) were similar in both groups. Echocardiography demonstrated mitral regurgitation severity as none or mild for 92% of participants at 1 year with no difference between groups. The composite safety outcome occurred in 5.4% (9 of 166) of patients undergoing minithoracotomy and 6.1% (10 of 163) undergoing sternotomy at 1 year.

CONCLUSIONS AND RELEVANCE

Minithoracotomy is not superior to sternotomy in recovery of physical function at 12 weeks. Minithoracotomy achieves high rates and quality of valve repair and has similar safety outcomes at 1 year to sternotomy. The results provide evidence to inform shared decision-making and treatment guidelines.
Trial registration: isrctn.org Identifier: ISRCTN13930454.



Implante Transcateter de Valva Aórtica Realizado por Enfermeira, e suas Repercussões no Reino Unido

A photo posted by the cardiology Twitter account at Glenfield Hospital in the United Kingdom, congratulating an advanced nurse practitioner (ANP) for performing a TAVI procedure as first operator, touched off a firestorm on Twitter and Reddit this week and appeared to have caught professional societies off guard.

"Momentous day for Glenfield, UHL and the whole world," reads the now-deleted tweet from @GHCardiology. "John is the first nurse-ANP who has performed the whole TAVI procedure as the first operator [thumbs up emoji] true transformation addressing NHS needs. Congratulations John we are so proud of you [clapping hands emoji]."

A screencap of the tweet has been circulating on Twitter all week. Some cardiologists responding to the photo seemed shocked to learn that a nonphysician had the skills—and permission—to do a complex, transcatheter, structural heart procedure; others defended the rights of an ANP to take the lead, so long as their training was sufficient.

"This took everybody by surprise," said Rohin Francis, MBBS (East Suffolk and North Essex NHS Foundation Trust, England), who tweeted a thread summarizing the concerns of many.

"I thought I'd speak up because I do a lot of teaching of junior doctors," he told TCTMD, "but also I'm the clinical director of my department, so I felt like I can bridge both—the concerns from a hospital management/trust point of view in thinking about waiting lists and service provision through my management role, but also as a clinician and as a trainer."

Learning to do structural heart interventions is typically something a trainee would do only after receiving their certificate of completion of training, which comes after 6 years of medical school and 9 years of training, he said. Moreover, most, if not all, structural heart operators in the UK likely also have a PhD, he added.

Cardiovascular Societies Respond

Cardiovascular organizations in the UK and beyond appear to have been caught flat-footed by the announcement, taking several days to craft their reactions.

The British Cardiovascular Society (BCS) responded to a request for comment from TCTMD by neither praising nor condemning the announcement.

"The BCS supports all cardiovascular healthcare workers to deliver the best care to their patients, whether this be physicians, allied health professionals, or clinical scientists," the statement reads. "Cardiology has always been at the frontier of new models of healthcare delivery and new device therapies to ultimately improve patient symptoms and quality of life. The overriding priority for any aspect of patient care is that the healthcare professional undertaking any procedure is fully trained to deliver that procedure safely. The performance of a specific procedure is only

one part of the patient journey, with consultant cardiologists leading the process of diagnosis, treatment choices, management, and follow-up care in direct consultation with the patient."

Coincidentally, the president-elect of the BCS, electrophysiologist André Ng, MBChB, PhD, is also the head of the department of cardiovascular sciences at the University of Leicester. Ng did not respond to an interview request from TCTMD.

The British Cardiovascular Intervention Society (BCIS) took a similarly careful position but singled out operator volumes as important.

"BCIS welcomes the involvement of highly skilled practitioners in structural hearth disease programs," the group's president, David Hildick-Smith, MD (Brighton and Sussex University Hospitals NHS Trust, Brighton, England), told TCTMD in an email. "An advanced nurse practitioner who has been involved in 2,000 TAVI procedures and whose job is dedicated to the TAVI program has developed a wealth of experience, which is greatly to the benefit of patients."

All TAVI programs in the country, he continued, "benefit greatly from the specialist nurses who run those programs, often load the valves, and sometimes assist in procedures as a second operator. ANP involvement in TAVI should be seen as complementary rather than competitive with trainees. As medicine has changed so there has increasingly been a role for advanced nurse practitioners to take on responsibilities that were previously considered to be the domain of doctors. In turn, that has freed doctors to focus more on the specifics of an intervention that requires their attention. The responsibility for undertaking a successful procedure will always lie with a physician who has had the breadth of training to manage the possible complications that may occur during a procedure. This requires years of training, and there is no shortcut, or substitute."

The British Junior Cardiologists Association declined to comment for this story, pointing TCTMD towards their tweeted response which reads: "All members of the [heart] team are valuable. However, we are concerned about the impact that this decision will have on local trainees."

J Thorac Cardiovasc Surg. 2023 Jul;166(1):38-48.e4.
doi: 10.1016/j.jtcvs.2021.09.009.

O Uso de Anticoagulante Oral Impacta no Estado da Falsa Luz, Após Correção de Dissecção Aórtica Tipo A?

Do oral anticoagulants impact outcomes and false lumen patency after repair of acute type A aortic dissection?

OBJECTIVE

The study objective was to analyze the effects of chronic oral anticoagulation on long-term outcomes after repair of type A acute aortic dissection and its influence on false lumen fate.

METHODS

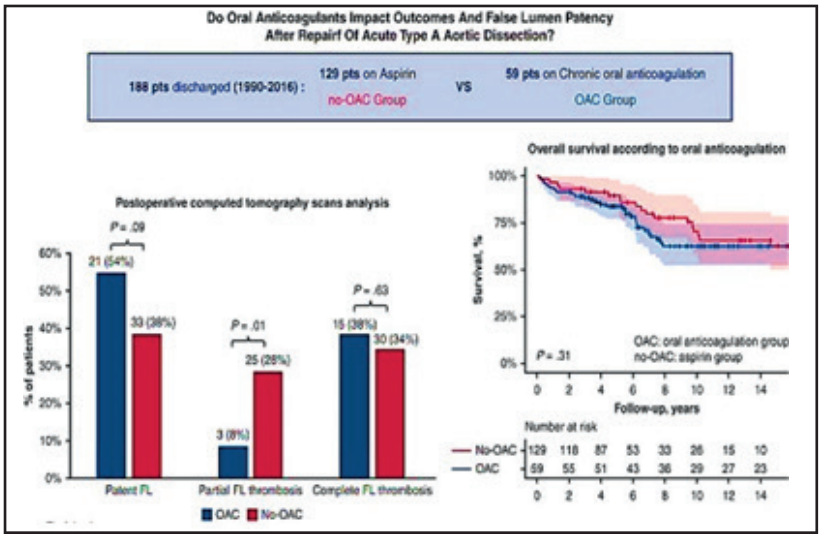
We studied 188 patients (median age, 62 years; 74% were male) who underwent repair of type A aortic dissection; patients receiving postoperative chronic oral anticoagulation (n = 59) were compared with those receiving antiplatelet therapy alone (n = 129).

RESULTS

Median age was similar: 60 years (18-79 years; OAC group) versus 64 years (22-86; no-OAC group) (P = .11); patients taking anticoagulants were more frequently male (88% vs 67%, P = .003). After a median follow-up of 8.4 years (2 months to 30 years), 58 patients died, 18 of aortic-related causes, and 37 patients underwent aortic reintervention. After multivariable adjustment, anticoagulation showed no significant effect on long-term survival (hazard ratio, 0.85; 95% confidence interval, 0.41-1.76; P = .66) or risk of reintervention (hazard ratio, 0.55; 95% confidence interval, 0.27-1.15; P = .11). Analysis of 127 postoperative computed tomography scans showed a patent false lumen in 53% of anticoagulated patients versus 38% of nonanticoagulated patients (P = .09): partially thrombosed in 8% versus 28% (P = .01) and thrombosed in 39% versus 34% (P = .63), respectively. In patients with a control computed tomography, there were 6 late aortic-related deaths, 1 among anticoagulated patients and 5 in those who were not.

CONCLUSIONS

Chronic anticoagulation after repair of type A acute aortic dissection favors persistent late false lumen patency, which is not a risk factor for late mortality or reoperation. Chronic anticoagulation can be administered safely to patients with repaired type A acute aortic dissection regardless of its specific indication.


Do Oral Anticoagulants Impact Outcomes And False Lumen Patency After Repairf Of Acute Type A Aortic Dissection?
188 pts discharged (1990-2016) :
129 pts on Aspirin
no-OAC Group
VS
59 pts on Chronic oral anticoagulation
OAC Group
Posloperative computed tomography scans analysis
% of patients
P = .09
21 (54%)
33 (38%)
P = .01
3 (8%)
25 (28%)
P = .63
15 (38%)
30 (34%)
Patent FL
Partial FL thrombosis
Complete FL thrombosis
OAC
No-OAC
Overall survival according to oral anticoagulation
Survival, %
P = .31
OAC: oral anticoagulation group
no-OAC: aspirin group
Follow-up, years
Number at risk
No-OAC 129 118 87 53 33 26 15 10
OAC 59 55 51 43 36 29 27 23

NEJM Evid 2023;2(7). DOI:10.1056/EVIDoa2300067.

PROACT-Xa Trial: Apixaban Apresenta Piores Desfechos em Relação à Warfarina, em Pacientes com Prótese Aórtica Metálica

Apixaban or Warfarin in Patients with an On-X Mechanical Aortic Valve

BACKGROUND

Vitamin K antagonists are the only oral anticoagulants approved to prevent valve thrombosis and valve-related thromboembolism in patients with mechanical heart valves. Whether patients with an On-X mechanical aortic valve can be safely anticoagulated with apixaban is unknown.

METHODS

Patients with an On-X aortic valve implanted at least 3 months before enrollment were randomly assigned to receive apixaban 5mg twice daily or warfarin (target international normalized ratio 2.0 to 3.0). The primary efficacy end point was the composite of valve thrombosis or valve-related thromboembolism with coprimary analyses comparing apixaban with warfarin for noninferiority and comparing the apixaban event rate with an objective performance criterion (OPC).

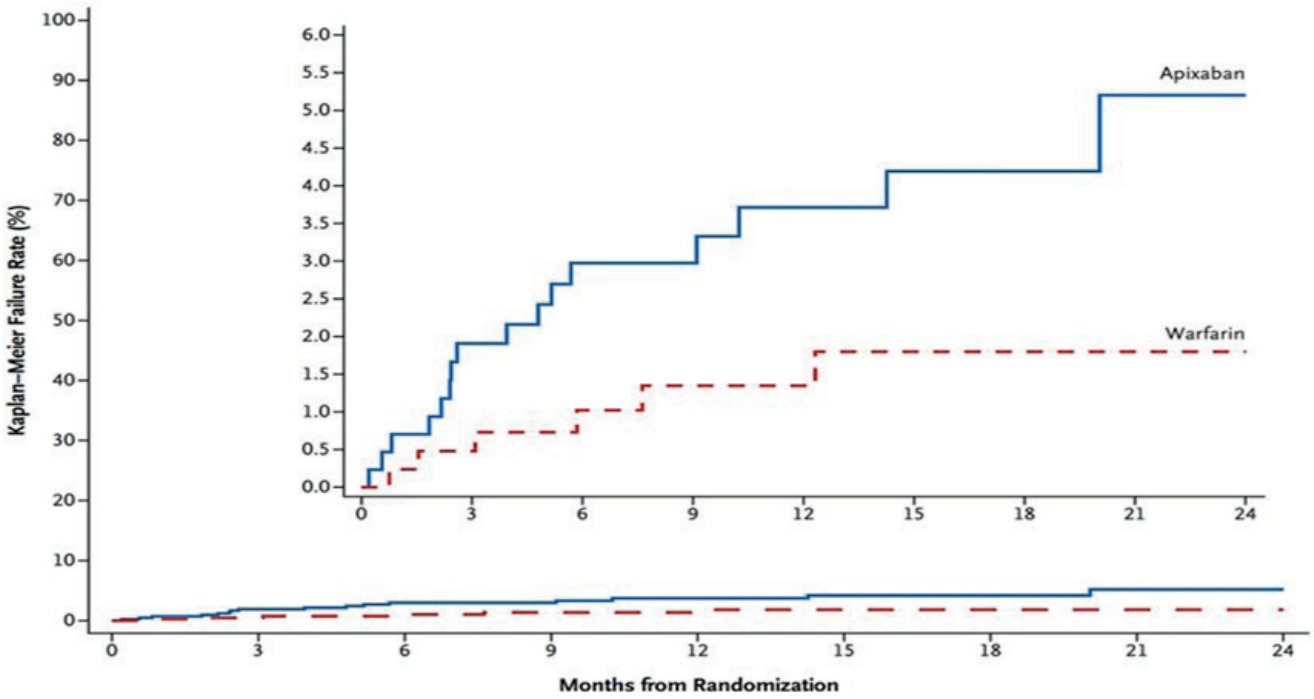
RESULTS

The trial was stopped after 863 participants were enrolled owing to an excesso of thromboembolic events in the apixaban group. Most (94%) participants took aspirin. A total of 26 primary end--point events occurred, 20 (in 16 participants) in the apixaban group (4.2%/patient-year; 95% confidence interval [CI], 2.3 to 6.0) and 6 (in 6 participants) in the warfarin group (1.3%/patient--year; 95% CI, 0.3 to 2.3). The difference in primary end-point rates between the apixaban and warfarin groups was 2.9 (95% CI, 0.8 to 5.0); noninferiority and OPC success criteria were not met. Major bleeding rates were 3.6%/patient-year with apixaban and 4.5%/patient-year with warfarin.

CONCLUSIONS

Apixaban did not demonstrate noninferiority to warfarin and is less effective than warfarin for the prevention of valve thrombosis or thromboembolism in patients with an On-X mechanical aortic valve. (Funded by Artivion; ClinicalTrials.gov number, NCT04142658.)

Cumulative Incidence of Valve Thrombosis or Valve-Related Thromboembolism.



N Engl J Med. 2022 Sep 15;387(11):978-988.
doi: 10.1056/NEJMoa2209051.

INVICTUS Trial: Rivarovaban Associado a Piores Desfechos que Warfarina, em Pacientes com Fibrilação Atrial e Doença Reumática

Rivaroxaban in Rheumatic Heart Disease-Associated Atrial Fibrillation

BACKGROUND

Testing of factor Xa inhibitors for the prevention of cardiovascular events in patients with rheumatic heart disease-associated atrial fibrillation has been limited.

METHODS

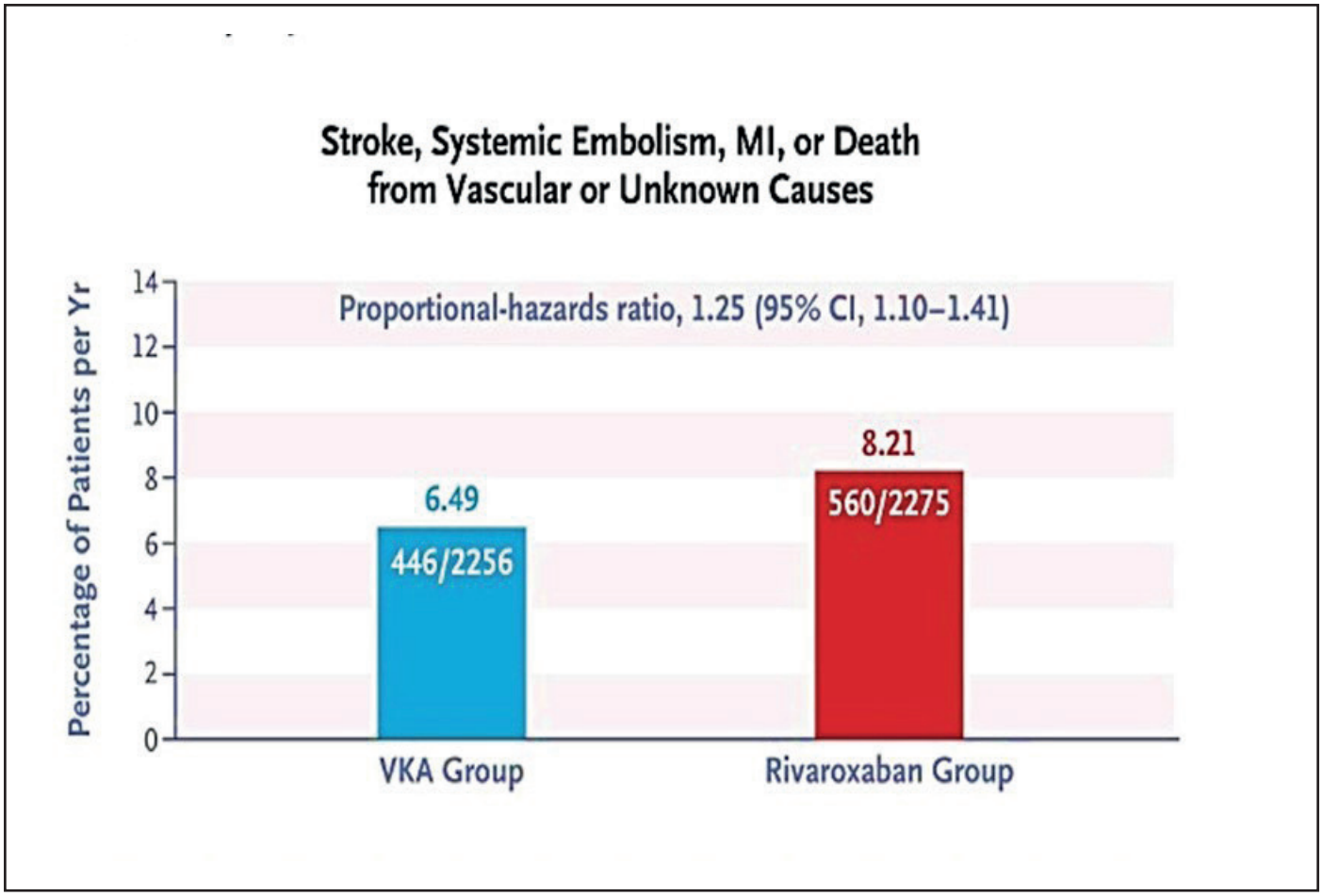
We enrolled patients with atrial fibrillation and echocardiographically documented rheumatic heart disease who had any of the following: a CHA2DS2VASc score of at least 2 (on a scale from 0 to 9, with higher scores indicating a higher risk of stroke), a mitral-valve area of no more than 2 cm2, left atrial spontaneous echo contrast, or left atrial thrombus. Patients were randomly assigned to receive standard doses of rivaroxaban or dose-adjusted vitamin K antagonist. The primary efficacy outcome was a composite of stroke, systemic embolism, myocardial infarction, or death from vascular (cardiac or noncardiac) or unknown causes. We hypothesized that rivaroxaban therapy would be noninferior to vitamin K antagonist therapy. The primary safety outcome was major bleeding according to the International Society of Thrombosis and Hemostasis.

RESULTS

Of 4565 enrolled patients, 4531 were included in the final analysis. The mean age of the patients was 50.5 years, and 72.3% were women. Permanent discontinuation of trial medication was more common with rivaroxaban than with vitamin K antagonist therapy at all visits. In the intention-to-treat analysis, 560 patients in the rivaroxaban group and 446 in the vitamin K antagonist group had a primary-outcome event. Survival curves were nonproportional. The restricted mean survival time was 1599 days in the rivaroxaban group and 1675 days in the vitamin K antagonist group (difference, -76 days; 95% confidence interval [CI], -121 to -31; P<0.001). A higher incidence of death occurred in the rivaroxaban group than in the vitamin K antagonist group (restricted mean survival time, 1608 days vs. 1680 days; difference, -72 days; 95% CI, -117 to -28). No significant between-group difference in the rate of major bleeding was noted.

CONCLUSIONS

Among patients with rheumatic heart disease-associated atrial fibrillation, vitamin K antagonist therapy led to a lower rate of a composite of cardiovascular events or death than rivaroxaban therapy, without a higher rate of bleeding. (Funded by Bayer; INVICTUS ClinicalTrials.gov number, NCT02832544.).


Stroke, Systemic Embolism, MI, or Death
from Vascular or Unknown Causes
Percentage of Patients per Yr
14
12
10
8
6
4
2
0
Proportional-hazards ratio, 1.25 (95% CI, 1.10–1.41)
6.49
446/2256
8.21
560/2275
VKA Group
Rivaroxaban Group

J Thorac Cardiovasc Surg. 2023 Jul;166(1):183-190.
doi: 10.1016/j.jtcvs.2022.11.014.

Switch Arterial de Urgência como Resgate, em Casos de Transposição das Grandes Artérias com Septo Íntegro, e Hipoxemia Refratária

Emergency arterial switch: Rescue therapy for life-threatening hypoxemia in infants with transposition of great arteries with intact intraventricular septum

OBJECTIVE

A small percentage of infants with d-loop transposition of the great arteries with intact intraventricular septum have life-threatening refractory hypoxemia often due to coexistent persistent pulmonary hypertension of the newborn. In this case series we describe the outcomes of a "rescue" emergency arterial switch operation (ASO).

METHODS

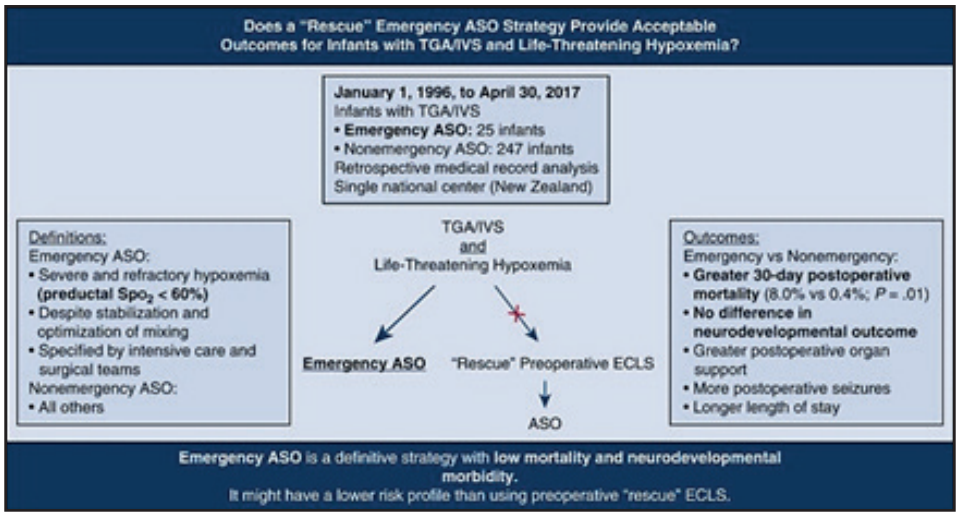
We undertook a retrospective medical record analysis of infants with d-loop transposition of the great arteries with intact intraventricular septum who underwent an ASO in New Zealand from January 1, 1996, to April 30, 2017. Data were compared for those who received an emergency ASO and those with a nonemergency ASO for descriptive purposes. An emergency ASO was defined as one that was undertaken for life-threatening refractory hypoxemia when the only alternative stabilization strategy was preoperative extracorporeal life support. Primary outcome measures were 30-day postoperative mortality and abnormal neurodevelopmental outcome in the survivors. Secondary outcomes were low cardiac output, arrhythmia, renal dysfunction, postoperative seizures, and length of stay. Other known risk factors for morbidity and mortality were also assessed.

RESULTS

Two hundred seventy-two infants underwent an ASO with 25 (9%) who received an emergency ASO. No infants received preoperative extracorporeal life support. The emergency group had greater 30-day postoperative mortality (8.0% vs 0.4%; P = .01) with no difference in abnormal neurodevelopmental outcome among the survivors (17.4% vs 13.8%; P = .35). The emergency group had more therapies for low cardiac output syndrome, more postoperative seizures, and a longer length of stay.

CONCLUSIONS

An emergency ASO is a definitive rescue therapy that can be undertaken with acceptable mortality and neurodevelopmental outcome with consideration of the preoperative clinical state.


Does a "Rescue" Emergency ASO Strategy Provide Acceptable Outcomes for Infants with TGA/IVS and Life-Threatening Hypoxemia?
January 1, 1996, to April 30, 2017
Infants with TGA/IVS
• Emergency ASO: 25 infants
• Nonemergency ASO: 247 infants
Retrospective medical record analysis
Single national center (New Zealand)
Definitions:
Emergency ASO:
• Severe and refractory hypoxemia (preductal Spo2 < 60%)
• Despite stabilization and optimization of mixing
• Specified by intensive care and surgical teams
Nonemergency ASO:
• All others
TGA/IVS
and
Life-Threatening Hypoxemia
Emergency ASO
"Rescue" Preoperative ECLS
ASO
Outcomes:
Emergency vs Nonemergency:
• Greater 30-day postoperative mortality (8.0% vs 0.4%; P = .01)
• No difference in neurodevelopmental outcome
• Greater postoperative organ support
• More postoperative seizures
• Longer length of stay
Emergency ASO is a definitive strategy with low mortality and neurodevelopmental morbidity.
It might have a lower risk profile than using preoperative "rescue" ECLS.