Boletim Científico

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Sociedade
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Registro Anual da Society of Thoracic Surgeons Adult Cardiac Surgery: Resultados e Tendências em 233.022 Procedimentos

The Society of Thoracic Surgeons Adult Cardiac Surgery Database: 2019 Update on Outcomes and Quality

The Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) was established in 1989 as the first component of what has ultimately evolved into the STS National Database. At that time, STS leaders recognized the need to directly address the limitations of coronary artery bypass grafting (CABG) mortality data published by the federal government 3 years earlier. Those mortality results, derived solely from administrative claims data, could not properly account for the differences in the inherent risk of patients. Accurate risk assessment would require the development of a detailed and comprehensive clinical data set not then available. From its outset, the primary and ongoing objective of the ACSD is to provide highly accurate and clinically relevant information to ACSD participants to assist in self-assessment and quality-improvement efforts.

Information generated from this extensive data set supports nationally benchmarked performance assessment and feedback, statistically powerful risk-adjustment models, performance measurement, quality improvement efforts, voluntary public reporting, and comparative effectiveness research, and has helped to inform health policy development.

We report current national aggregate cardiac surgical volume trends and procedural outcomes and summarize quality measurement and performance improvement activities resulting from the ACSD.

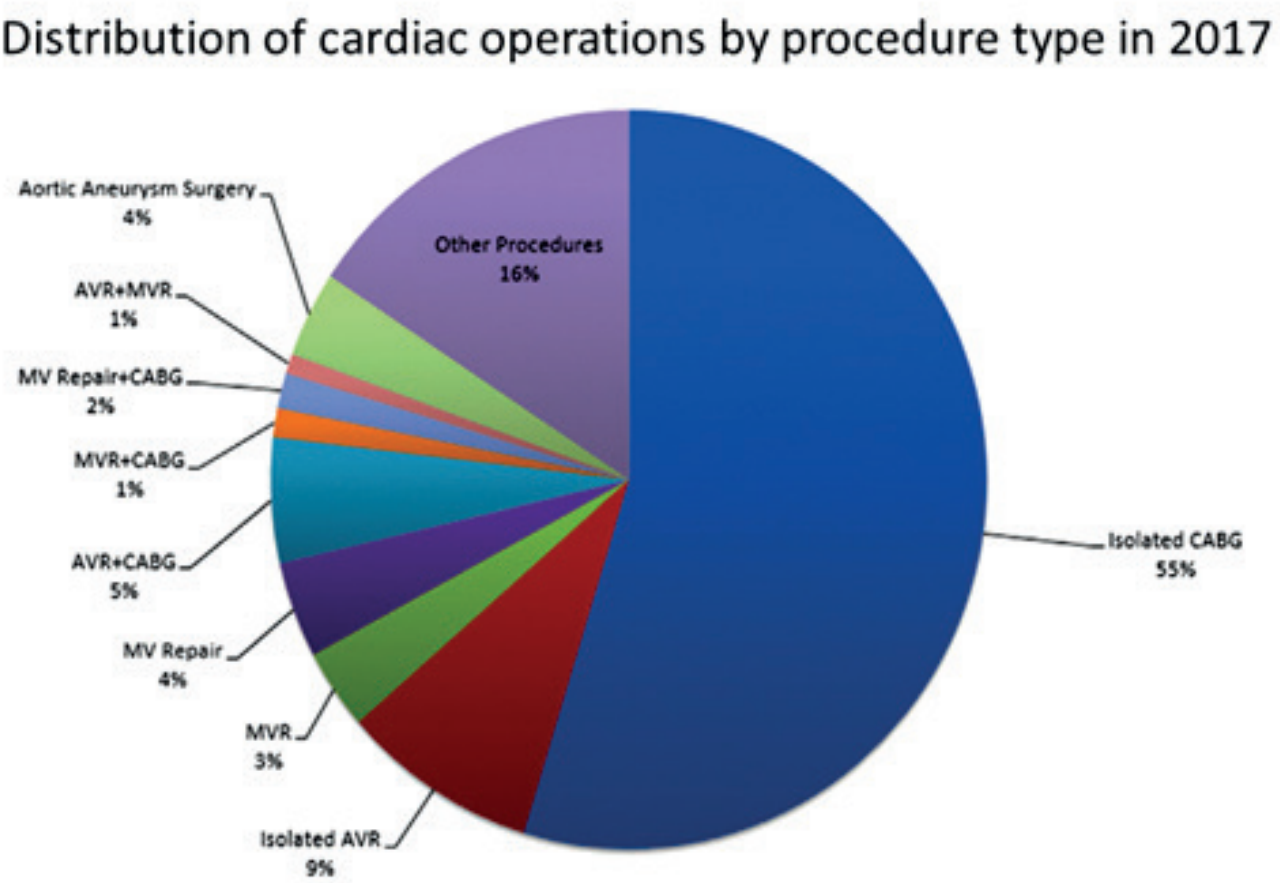
As of September 2018, the ACSD includes 1.111 participant groups comprising 3.137 surgeons from all 50 United States states, 10 sites in Canada, and 22 participants in 9 other countries. There are 67 participants in the anesthesiology module comprising 627 anesthesiologists.

The ACSD is the keystone of the Society's activities in performance measurement, quality improvement, public reporting, and outcomes research in adult cardiac surgery.

Current and future initiatives, including linking the ACSD with other data registries, will provide a foundation for efforts in longitudinal

outcomes assessment, device surveillance, comparative effectiveness research, and health policy development.

The STS ACSD is committed to remaining at the forefront of clinical databases and to helping cardiothoracic surgeons remain leaders in providing the highest quality and value care to their patients.



Change in procedure volume for AVR, AVR-CABG, and TAVR: 2008 to 2017.

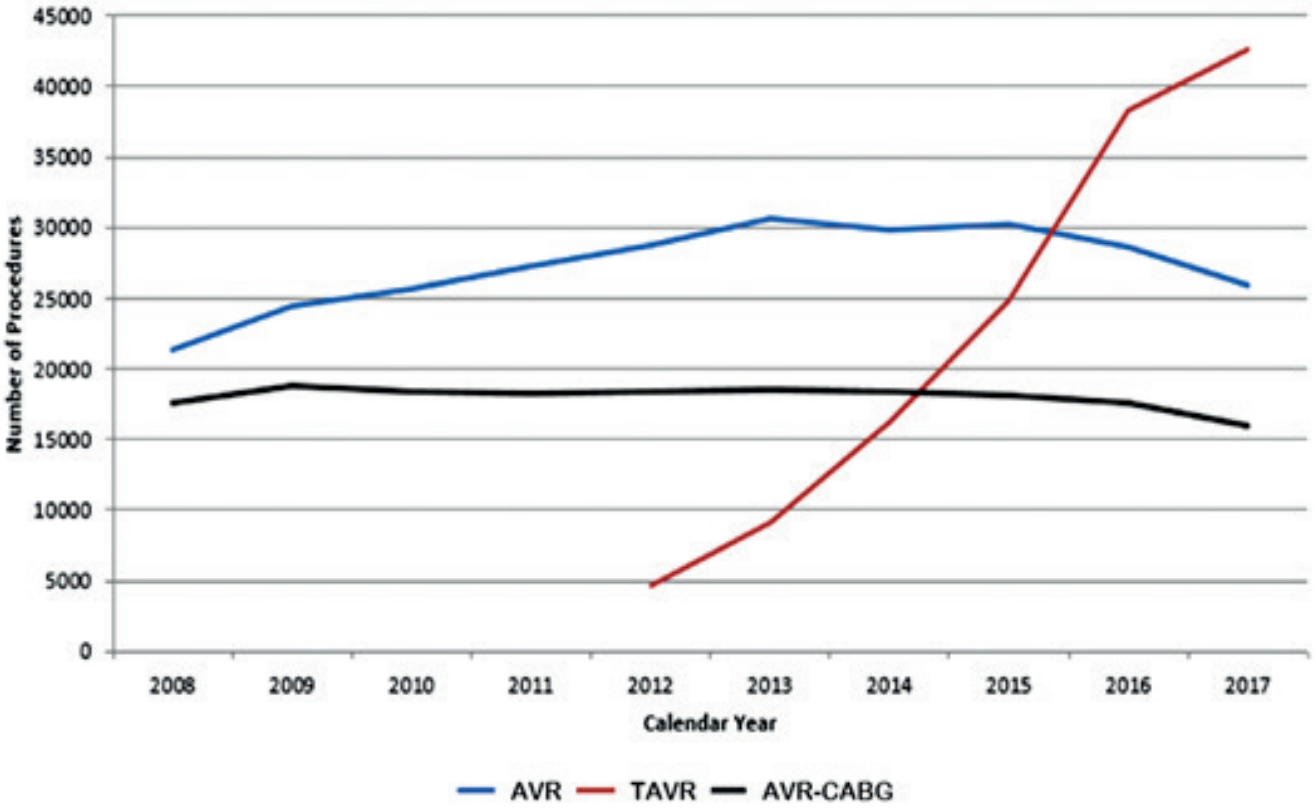


Table 1. Selected outcomes of the Performed Cardiac Surgical Procedures in 2017.

Variable	CABG (n = 160,160)	AVR (n = 25,940)	AVR + CABG (n = 15,971)	MVR (n = 10,332)	MVR + CABG (n = 3,706)	MV Repair (n = 12,388)	MV Repair + CABG (n = 4,525)
Mortality, %							
In-hospital	1.8	1.5	3.1	4.2	8.3	0.9	4.3
Operative[a]	2.3	2	3	5	9.4	1.2	5.3
Major morbidity, %							
Reoperation	2.5[b]	4.6	6.8	8.8	11.7	4.2	7.4
DSWI/mediastinitis	0.3	0.2	0.4	0.2	0.6	0	0.4
Permanent stroke	1.4	1.3	1.9	2.3	3.1	1.1	3
Prolonged ventilation >24 hours	7.6	6.4	11.8	17.7	28.3	5.7	19.8
Renal failure	2.2	1.8	3.8	4.9	10.3	1.7	6
New-onset atrial fibrillation	25.1	29.5	39	33	44.1	29.9	42.5
Readmission ≤30 days of discharge	10	9.6	12.1	15.6	18.5	8.8	13.7
Post-op length of stay, days							
Mean	6.9	6.9	8.4	10.2	12	6.8	10
Median	6	6	7	8	9	5	8

Circulation 2018;138:2943–51. DOI:10.1161/CIRCULATIONAHA.118.035970

Análise Crítica dos Ensaios EXCEL, NOBLE, SYNTAX e FREEDOM Aponta Méritos e Falhas Metodológicas, Questões Ainda Não Respondidas, e Quais Conclusões Podemos Incorporar na Prática Clínica

Myocardial Revascularization Trials. Beyond the Printed Word

ABSTRACT

This article reviews the context and evidence of recent myocardial revascularization trials that compared percutaneous coronary intervention with coronary artery bypass grafting for the treatment of left main and multivessel coronary artery disease.

We develop the rationale that some of the knowledge synthesis resulting from these trials, particularly with regard to the claimed noninferiority of percutaneous coronary intervention beyond nondiabetic patients with low anatomic complexity, may have been affected by trial design, patient selection based on suitability for percutaneous coronary intervention, and end point optimization favoring percutaneous coronary intervention over coronary artery bypass grafting.

We provide recommendations that include holding a circumspect interpretation of the currently available evidence, as well as suggestions for the collaborative design and conduct of future clinical trials in this and other fields.

CONCLUSIONS

From the above considerations pertaining to trials that compare PCI and CABG for the treatment of LM and multivessel CAD, we recommend the following:

- Public funding should be made available and used to design, oversee, and execute myocardial revascularization trials.
- Methods articles of RCTs should be published early, ideally before trials have made significant strides in patient enrollment. Although updates on www.clinicaltrials.gov are practical, they also should highlight the first approved version of each protocol, including original target recruitment numbers and end point definitions.
- Rather than the design and pooling of data from trials with short follow-up duration, only trials with
- Outcomes of an arbitrary nature and prone to considerable variability between trials and within trials such as periprocedural myocardial enzyme release assay thresholds should not be used as components of the primary end point in RCTs that compare PCI and CABG.
- Revascularization guidelines should not be changed on the basis of the EXCEL trial and the recent meta-analysis by Head and colleagues[10] until meaningful follow-ups are completed and analyzed using primary end point components that are not arbitrarily defined or subject to modification during the course of the trial, as well as adequately powered, methodologically justified noninferiority boundaries and subgroup analyses.
- If myocardial revascularization trials have randomized primarily patients likely to do as well with PCI as with CABG, with most of the screened patients not having been randomized and having majoritarily undergone CABG instead, then the conclusions of these trials and the guidelines stemming from them should not be applied to the entire population of patients with severe CAD.
- The development of guidelines should follow the methodology suggested by the Institute of Medicine,[38] with an independent epidemiology/statistician group appraising the evidence and detecting statistical flaws and a separate group made of physicians writing the recommendations on the basis of the synthesized evidence and its independent critical analysis.[39]
- Data from myocardial revascularization RCTs should better focus on the anatomic characteristics of LM lesions to ascertain who the patients with LM CAD are who may fare as well with PCI as with CABG.
- Until more evidence is available, except for ostial or midshaft isolated LM disease or LM disease associated with 1-vessel disease, all decisions for stable multivessel, LM with 2- or 3-vessel disease, or LM with bifurcation CAD should be discussed with the patient after review and recommendation by a heart team, which includes a cardiac surgeon.
- Patients undergoing CABG should be offered the best and latest in terms of adjunctive GDMT, not only within the context of myocardial revascularization trials but also, and more important, because they represent such a large population of patients with severe CAD who crucially can benefit from GMDT.
- Cardiologists and cardiac surgeons must work closely together in true collaborative fashion and with balanced leadership opportunities to advance the optimal clinical care and research aimed at improving the current and future status of patients with severe CAD.

Ann Thorac Surg, jan 2019. doi.org/10.1016/j.athoracsur.2018.07.076

Ensaio Randomizado aponta Maior Mortalidade com a CRM Sem Circulação Extracorpórea, em Pacientes Diabéticos

Off-Pump versus On-Pump Impact: Diabetic Patient 5-Year Coronary Artery Bypass Clinical Outcomes

BACKGROUND

For diabetic patients who require coronary artery bypass graft (CABG) operation, controversy persists whether an off-pump or an on-pump approach may be advantageous. This US-based, multicenter, randomized, controlled trial, Department of Veterans Affairs Randomization On versus Off Bypass Follow-up Study, compared diabetic patients' 5-year clinical outcomes for off-pump versus on-pump procedures.

METHODS

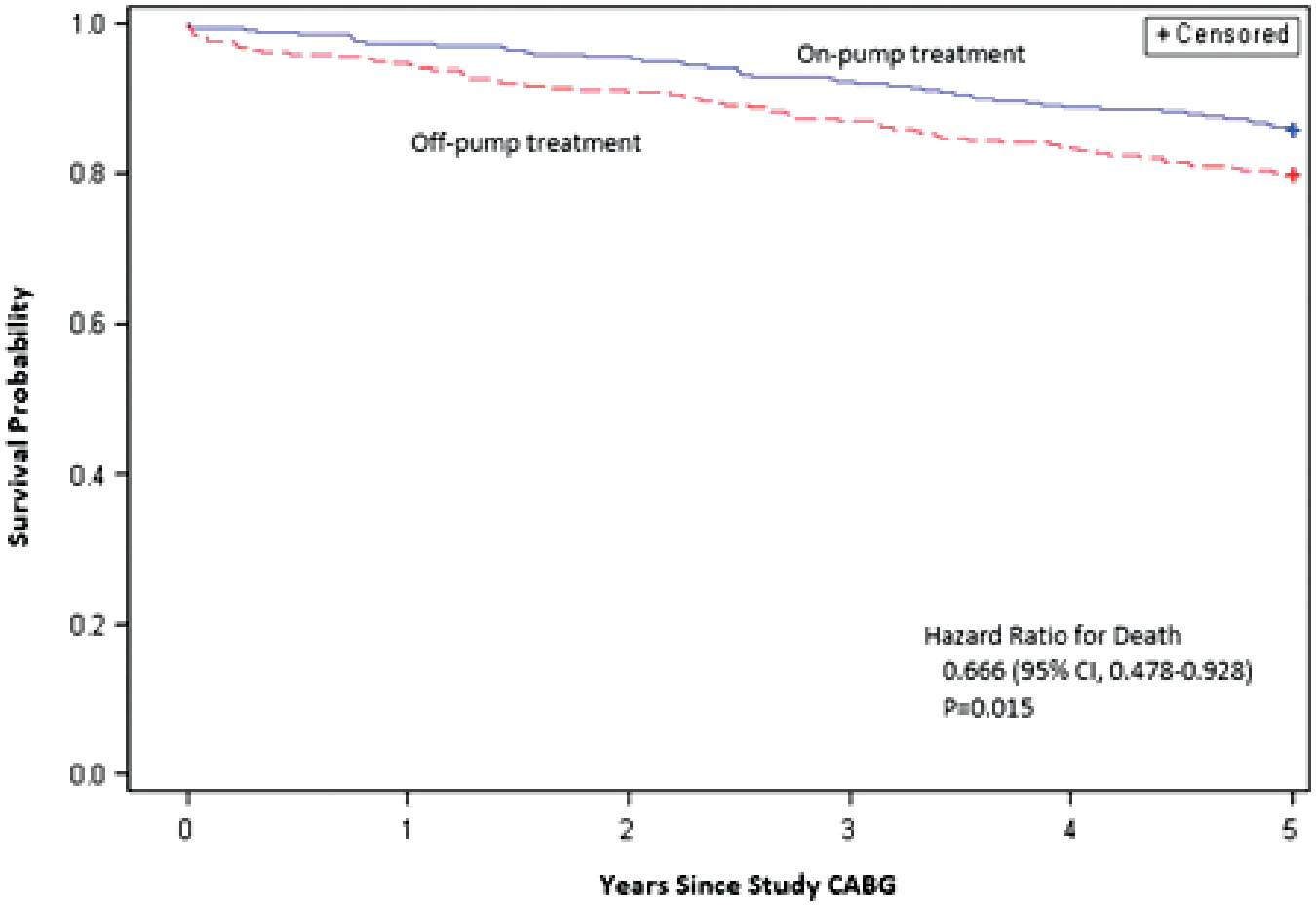
From 2002 to 2008, 835 medically treated (ie, oral hypoglycemic agent or insulin) diabetic patients underwent either off-pump (n = 402) or on-pump (n = 433) CABG. Five-year primary end points included all-cause death and major adverse cardiovascular events (MACE; composite included all-cause death, myocardial infarction, or repeat revascularization). Secondary 5-year end points included cardiac death and MACE-related components. With baseline risk factors balanced, outcomes were evaluated by using a p value less than or equal to 0.01; nonsignificant trends were reported for P values greater than 0.01 and less than or equal to 0.15.

RESULTS

Five-year all-cause death rates were 20.2% off pump versus 14.1% on pump (P=0.0198). No differences were seen in MACE (32.6% off-pump approach versus 28.6% on-pump approach, P=0.216), repeat revascularization (12.4% off-pump approach versus 11.8% on-pump approach, P=0.770), and nonfatal myocardial infarction (12.7% off-pump approach versus 10.4% on-pump approach, P=0.299). Cardiac death trended worse with off-pump CABG (9.0%) than with on-pump CABG (6.25%, P=0.137). Sensitivity analyses that removed conversions confirmed these findings.

CONCLUSIONS

With a 6.1% absolute difference, a strong trend toward improved 5-year survival was observed with on-pump CABG for medically treated diabetic patients. No off-pump advantage was found for any 5-year end points. A future clinical trial now appears warranted to rigorously compare off-pump versus on-pump longer term outcomes for diabetic patients.



JAMA Int Med, dec 2018. doi.org/10.1001/jamainternmed.2018.5967

Aumento no Número de Angioplastias Coronárias "Ambulatoriais", em Angina Instável, Gera Alerta e pode estar Relacionado a Fraudes

Gaming, Upcoding, Fraud, and the Stubborn Persistence of Unstable Angina

Unstable angina (UA) is unique among the Acute Coronary Syndromes (ACS) in that, despite clinical evidence of myocardial ischemia, biomarkers of myocardial necrosis are notelevated.

In the early 1990s, in an era that preceded widespread use of troponin assays, UA was one of the most common reasons for hospital admission. With the introduction of more sensitive troponin biomarkers, an increasing proportion of patients previously diagnosed with UA began being reclassified as NSTEMI based on elevation of biomarkers.

With the introduction of more sensitive troponin assays beginning in around 2010, the number of patients who present with an ACS without a rise in detectable troponin has continued to decline.

In 2014, when sensitive troponin assays were widely available, 40% of PCIs in the United States were coded as being performed for UA. The high percentageof PCI for UA in an era of increasingly sensitive biomarkers has long suggested that at least some patients with stable angina are being upcoded to a diagnosis of UA.

In the article published in current issue of JAMA Internal Medicine, Wadhera et al (see figure below) now provide more evidence of upcoding (euphemistically referred to as "gaming"). Using administrative data, they describe the trends in PCI being performed for UA and NSTEMI in the outpatient setting from 2010 to 2014 in 3 states. In theory, a patient with a true ACS would be admitted to the hospital and not be treated in the outpatient setting. Nevertheless, the authors document both an increase in the proportion and the raw number of PCIs being performed for acute conditions in the outpatient setting, driven by PCI for UA. This rise did not correlate with a decrease in PCIs for acute conditions on inpatients, which might have suggested shifting of the admission classification from inpatient to outpatient (see figure below).

Upcoding may be an unintended consequence of and facilitated by the appropriate use criteria (AUC), which were developed to codify the appropriateness of coronary revascularization for patients with various clinical syndromes. In the AUC for ACS, UA and NSTEMI are considered

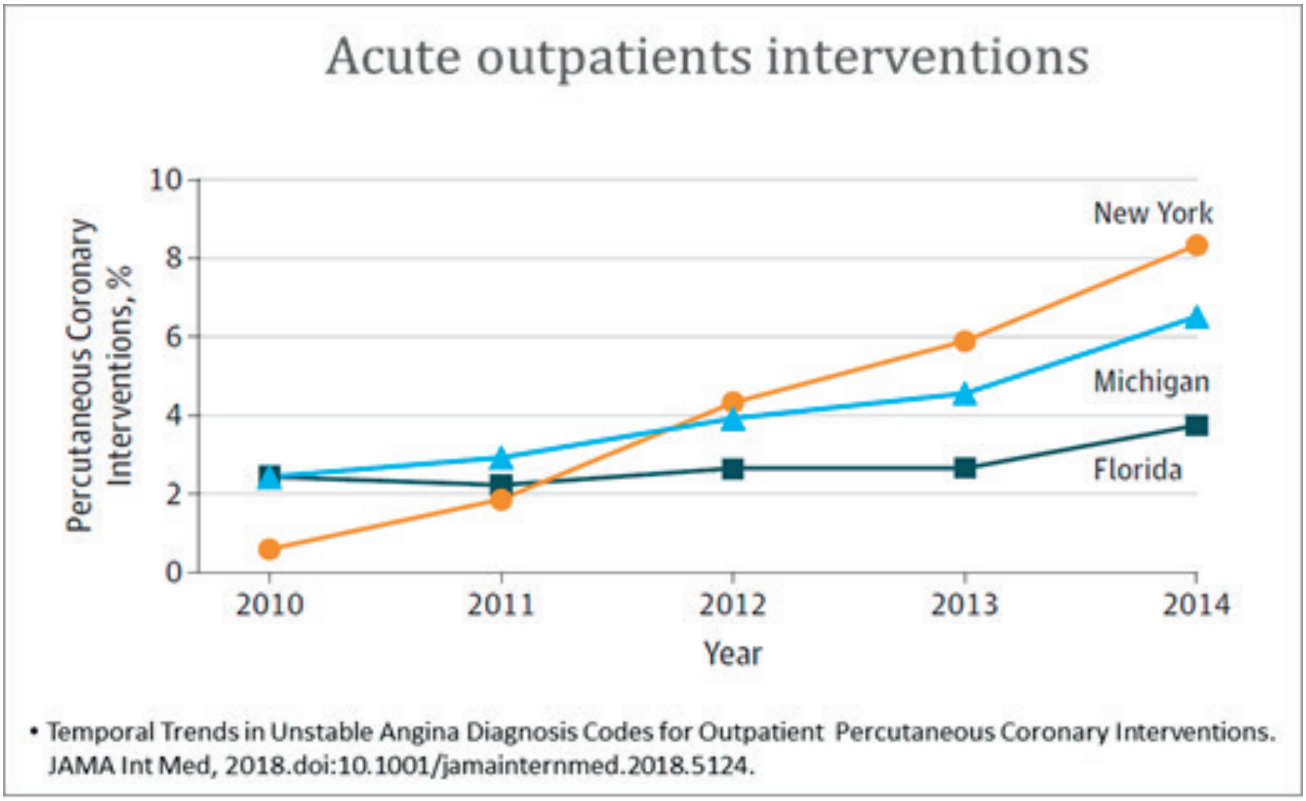
equivalent with no setting specified in which revascularization is “rarely appropriate.”

In contrast, the AUC for stable angina includes thresholds for symptoms,
prior antianginal therapy,andresults of noninvasive stress testing in determining appropriateness of PCI.

The rationale for upcoding of UA remains unclear but very concerning. The AUC were intended for internal quality improvement and bench marking by PCI programs. Thus, without public disclosure of the appropriateness of procedures performed by individual hospitals or cardiologists, there is no motive for upcoding referrals. Furthermore, since the indication For PCI (stable angina vs UA) does not affect reimbursement, differential payment is unlikely to explain upcoding.

A more likely albeit trouble some explanation could be to justify performance of PCI in patients who may not need the procedure. Because many patients with stable angina will become asymptomatic on medical therapy, current guidelines recommend PCI in the setting of stable angina only for patients with anginal symptoms refractory to medication.

Thus, in the absence of a better explanation, it seems that upcoding to unstable angina is being used to circumvent the guideline mandated trial of medical therapy prior to PCI and thereby justify inappropriate PCI in stable angina patients.



• Temporal Trends in Unstable Angina Diagnosis Codes for Outpatient Percutaneous Coronary Interventions. JAMA Int Med, 2018.doi:10.1001/jamainternmed.2018.5124.

ALICE Group: Metanálise Aponta Alta Mortalidade Precoce e Tardia com o Clip Mitral

Transcatheter Mitral Valve Replacement for Mitral Regurgitation. A Meta-Analysis

OBJECTIVE

We performed a meta-analysis to determine the outcomes in patients undergoing transcatheter mitral valve replacement (TMVR) for mitral regurgitation (MR).

METHODS

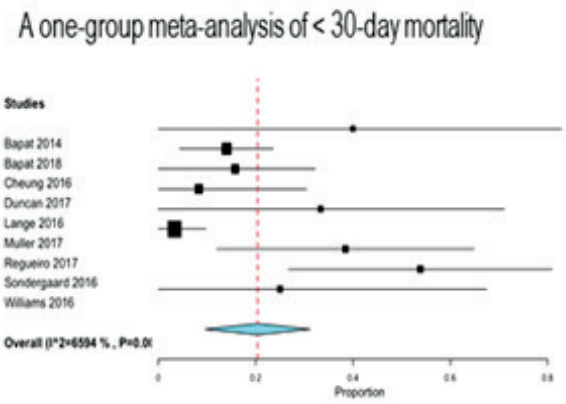
Databases including MEDLINE and EMBASE were searched through April 2018 using Web-based search engines (PubMed and OVID) to identify single-arm observational (case series) studies of TMVR enrolling ≥5 patients with MR. For each study, data regarding observed 30-day mortality and predicted operative mortality (Society of Thoracic Surgeons Predicted Risk of Mortality) were used to generate risk ratios (RRs) and 95% confidence intervals (CIs). Study-specific estimates were combined using the inverse variance-weighted average of logarithmic RRs in the random-effects model. One-group meta-analyses of 30-day and >30-day (including 30-day) mortality were also performed in the random-effects model.

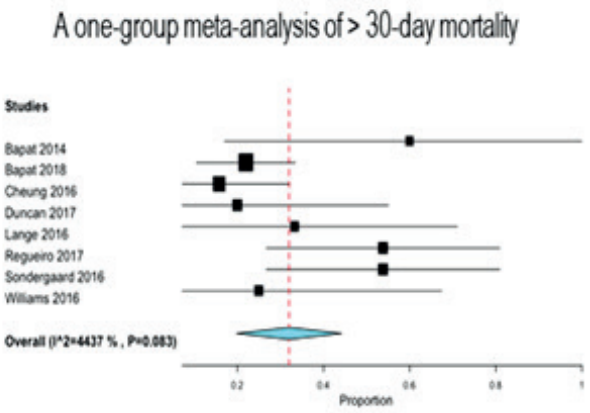
RESULTS

Of 222 potentially relevant articles screened initially, nine eligible studies enrolling a total of 146 patients with MR undergoing TMVR were identified. In all but two studies, STS-PROM was available and varied from 3.3% to 15.4% (arithmetic mean, 7.6%). Pooled analyses demonstrated 30-day mortality of 20.4% (95%CI, 9.6-31.2%), >30-day mortality of 32.0% (95%CI, 19.8-44.2%), and non-significantly higher observed 30-day mortality than predicted operative mortality (RR, 1.70; 95%CI, 0.85-3.42; P = 0.14). There was no evidence of significant publication bias.

CONCLUSION

TMVR for patients with MR results in increased early and late mortality.





Ann Thorac Surg 2019;107:47–53

Desfechos Imediatos do Tratamento Hibrido do Arco Aórtico, utilizando Frozen Elefant Trunk com TORAFLEX™ no Canadá

Early Clinical Outcomes of Hybrid Arch Frozen Elephant Trunk Repair With the Thoraflex Hybrid Graft

BACKGROUND

Hybrid aortic arch surgery has evolved to include several technical variations, with most including an off-label use of a conventional thoracic endograft. We describe the early clinical outcomes of the Thoraflex Hybrid graft (Vascutek, Glasgow, Scotland) specifically designed for the treatment of complex arch and proximal descending aortic disease.

METHODS

Between 2014 and 2017, 40 consecutive patients underwent hybrid aortic archand frozen elephant trunk repair with the multibranched Thoraflex Hybrid graft at 9 Canadian centers. Surgical indications included transverse arch or proximal descending aortic aneurysm in 100%, acute dissection in 10%, chronic dissection in 43%, and acute aortic rupture in 1 patient. Antegrade cerebral perfusion and moderate hypothermia (24.3 ± 1.8°C) were employed in all cases.

RESULTS

All 40 device implants were successful. The 30-day or in-hospital mortality was 5%. Stroke and transient neurological deficits occurred in 5% and 3% of patients, respectively. Two (5%) patients experienced transient spinal cord ischemia-there were no instances of permanent paraplegia. Mean follow-up was 550 ± 328 days and late complications included type A aortic dissection in 1 patient, type B dissection in 2 patients, and further distal endografting in 2 patients. Survival at 30 days, 1 year, and 2 years was 95%, 95%, and 90%, respectively.

CONCLUSIONS

Hybrid aortic arch repair with the Thoraflex Hybrid graft appears to be associated with good clinical outcomes, despite being early in the learning curve with this graft. Further investigation with this device is warranted to establish its role within the variations of hybrid arch repair.

Table 3. In-Hospital/30-Day Complications

Outcome	All Patients (N = 40)
Mortality[a]	2 (5)
Neurological injury	
Stroke[a]	2 (5)
Temporary neurological deficit	1 (3)
Delirium	6 (15)
Spinal cord injury	2 (5)
Transient paraparesis	2 (5)
Permanent paraplegia	0
Reoperation for bleeding	1 (3)

Table 4. Follow-Up Outcomes

Follow-Up	All Patients (N = 40)
Distal seal of the FET	34 (85)
Regression of aneurysm sac around FET	29 (73)
False lumen thrombosis around proximal stent graft[a]	18 (100)
Type 1a endoleak	0
Type 1b endoleak	0
Type 2 endoleak	2 (5)
Type 3 endoleak	0

Artif Organs 2018;42:1043-51

Utilização da Oxigenação Extracorpórea por Membrana (Extracorporeal Membrane Oxygenation - ECMO) em Tgrauma Grave: Experiência Inicial

The Impact of an Advanced ECMO Program on Traumatically Injured Patients

ABSTRACT

In June 2016, an advanced extracorporeal membrane oxygenation (ECMO) program consisting of a multidisciplinary team was initiated at a large level-one trauma center. The program was created to standardize management for patients with a wide variety of pathologies, including trauma. This study evaluated the impact of the advanced ECMO program on the outcomes of traumatically injured patients undergoing ECMO. A retrospective cohort study was performed on all patients sustaining traumatic injury who required ECMO support from January 2014 to September 2017. The primary outcome was to determine survival in trauma ECMO patients in the two timeframes, before and after initiation of the advanced ECMO program. Secondary outcomes included complication rates, length of stay, ventilator usage, and ECMOdays. One hundred and thirty eight patients were treated with ECMO during the study period. Of the 138 patients, 22 sustained traumatic injury. Seven patients were treated in our pre-group and 15 in our post-group. The majority of patients were treated with VV ECMO. Our post group VV ECMO extracorporeal survival rate was 64% and our survival to discharge was 55%. This study demonstrated an improvement in survival after implementation of our advanced ECMO program. The implementation of a multidisciplinary trauma ECMO team dedicated to the rescue of critically ill patients is the key for achieving excellent outcomes in the trauma population.

Figure 1. ECMO management and weaning protocol

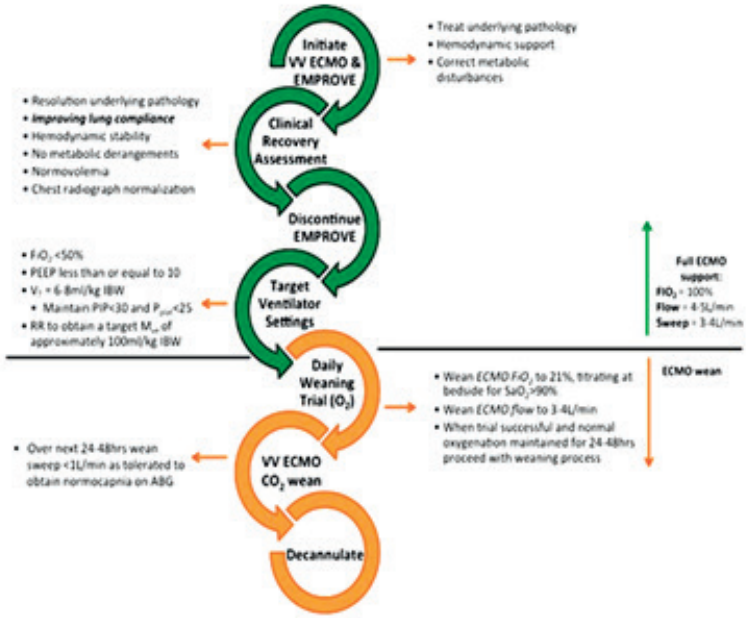
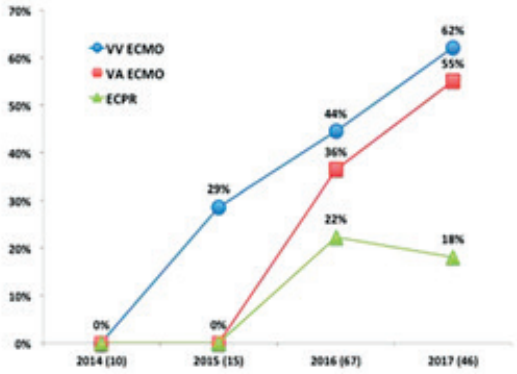


Figure 2. ECMO survival to discharge



JAMA Cardiol, dec 2018. doi:10.1001/jamacardio.2018.4255

Seguimento Estendido de Paciente Operados por Tetralogia de Fallot: Insights do Pediatric Cardiac Care Consortium

Long-term Outcomes of Tetralogy of Fallot. A Study From the Pediatric Cardiac Care Consortium.

IMPORTANCE

Tetralogy of Fallot (TOF) is a surgically repairable form of cyanotic congenital heart disease. Multicenter data for long-termsurvival following repair are sparse.

OBJECTIVE

To evaluate the long-term transplant-free survival of TOF by surgical strategy adjusted for era and patient characteristics.

DESIGN, SETTING, AND PARTICIPANTS

Retrospective cohort study enriched with data from the National Death Index and the Organ Procurement and Transplantation Network through 2014.Multicenter cohort from the Pediatric Cardiac Care Consortium (PCCC), a large, US-based clinical registry for interventions for congenital heart disease. The cohort included patients with adequate identifiers for linkage with the National Death Index and the Organ Procurement and Transplantation Network who were enrolled in the PCCC registry between 1982 and 2003 and survived surgical repair of simple TOF. Data were analyzed between September 2015 and April 2018.

EXPOSURES

We examined patient-associated and surgery-associated risk factors affecting survival.

MAIN OUTCOMES AND MEASURES

We analyzed the transplant-free survival during early (<6 years) and late (≥6 years) phase after TOF surgical repair.

RESULTS

Of the 3283 patients who survived repair for simple TOF and met the study's inclusion criteria, 56.4% were male and 43.6% were female. Twenty-five-year survival following TOF repair was 94.5%. Multivariable analysis demonstrated increased risk of early mortality with staged repair (HR, 2.68; 95% CI, 1.59-4.49) and non-valve-sparing operation (HR, 3.76; 95% CI, 1.53-9.19). Presence of a genetic abnormality was associated with increased risk of death both in the early (HR, 3.64; 95% CI, 2.05-6.47) and late postoperative phase (HR, 4.41; 95% CI, 2.62-7.44).

CONCLUSIONS AND RELEVANCE

Long-term survival after simple TOF repair is excellent. Staged repair and non-valve-sparing operations were negatively associated with survival in the early postrepair phase but not the late postrepair phase. These data are important for patients with repaired TOF and their caretakers and may guide surgical strategies for optimizing the long-term outcomes of this population.