RECENT ADVANCES IN INTERVENTIONAL CARDIOLOGY

Dr.YAYHA KIWAN

MBChB |MRCP|FRCP (London) |FRCP (Glasgow) |FRACP|FSCAI|FACC

Consultant Interventional Cardiologist

HOD of Cardiology-BSH

CORONARY INTERVENTIONS

- Single Vessle Disease
- Two Vessle Disease
- Three Vessle Disease
- Left Main Stem Disease
- Primary Angioplasty

INTERVENTION FOR VALVULAR HEART DISEASE

- Balloon Dilatation of Mitral, Aortic and Tricuspid Stenoses
- Percutaneous Aortic Valve Implantation
- Percutaneous Mitral Valve Repair
- Percutaneous Closure of Paravalvular Leak
- Alcohol Septal Ablation for HOCM

INTERVENTIONS IN CONGENITAL HEART DISEASE

- Pulmonary Balloon Valvuloplasty
- ASD and PFO Closure
- VSD Closure
- PDA Closure
- Percutaneous Pulmonary Valve Implantation
- Left Atrial Appendage Occlusion

PERIPHERAL INTERVENTION

- Coarctation of Aorta
- Renal artery Stenosis
- Carotid Stenosis
- Adbdominal Aortic Anyrusem Stenting
- Renal Sympathetic Denervation Therapy

Endovascular Valve Edge-to-Edge REpair Study (EVEREST II) Randomized Clinical Trial: Primary Safety and Efficacy Endpoints

Ted Feldman, Laura Mauri, Elyse Foster, Don Glower on behalf of the EVEREST II Investigators

American College of Cardiology
March 14, 2010
Atlanta, GA

NorthShore University HealthSystem
Evanston Hospital

EVEREST II at 4 Years: Surgery Maintains Early Advantage, But MitraClip Durable

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Key Points:

EVEREST II: MitraClip, surgery show similar mortality, composite efficacy at 4 years
Percutaneous repair far more likely to require surgical intervention, but only within first 6 months
Surgery more effective, so why not choose it upfront? outside expert asks

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By Kim Dalton
Wednesday, May 15, 2013

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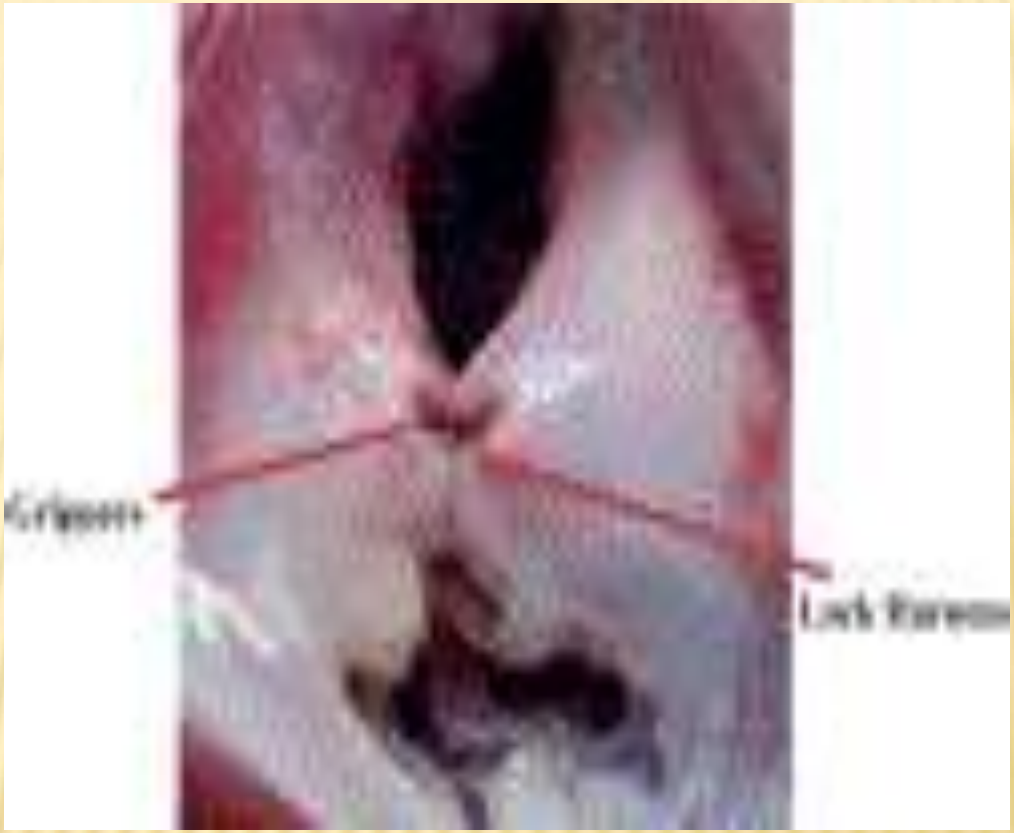
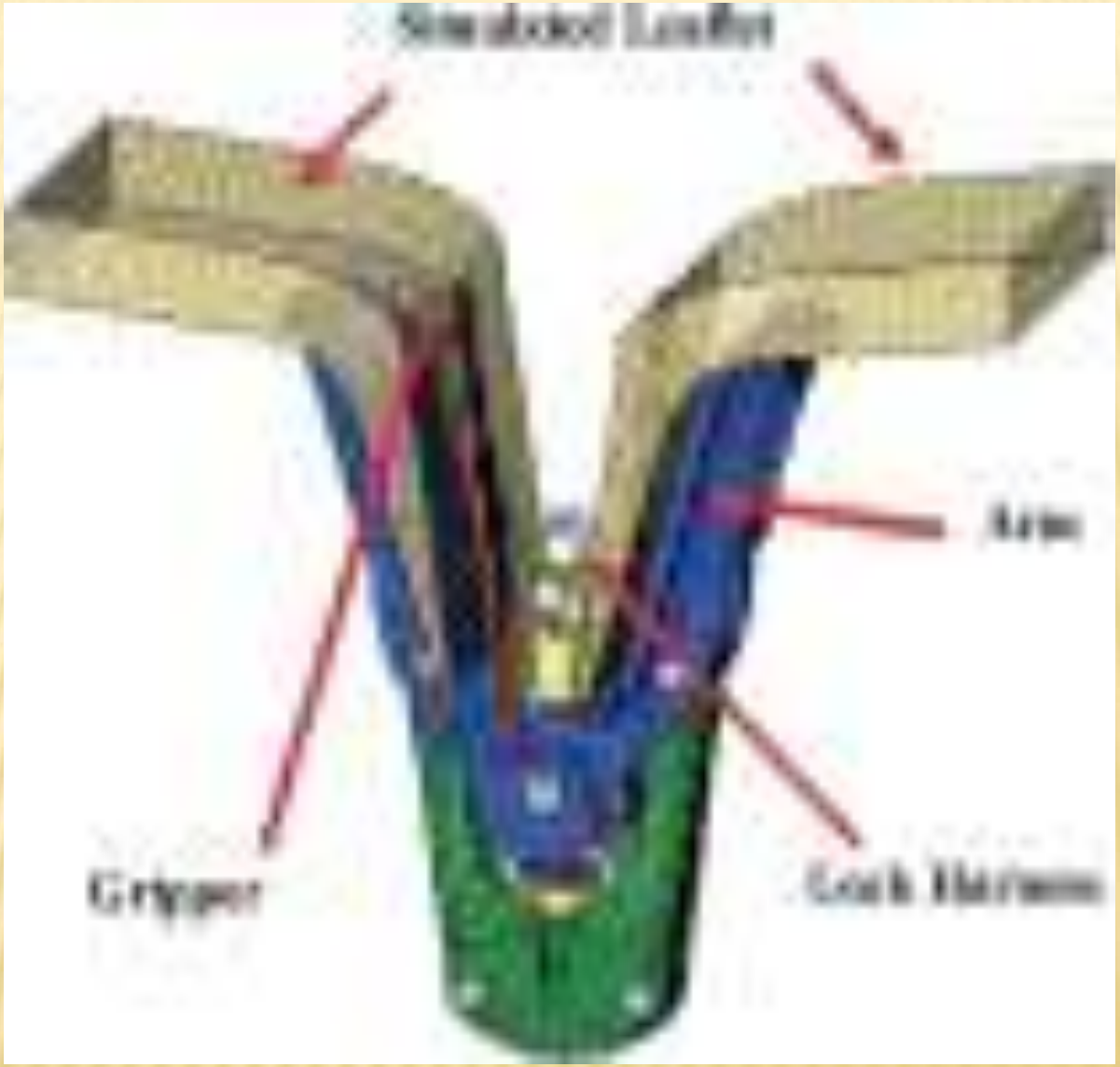
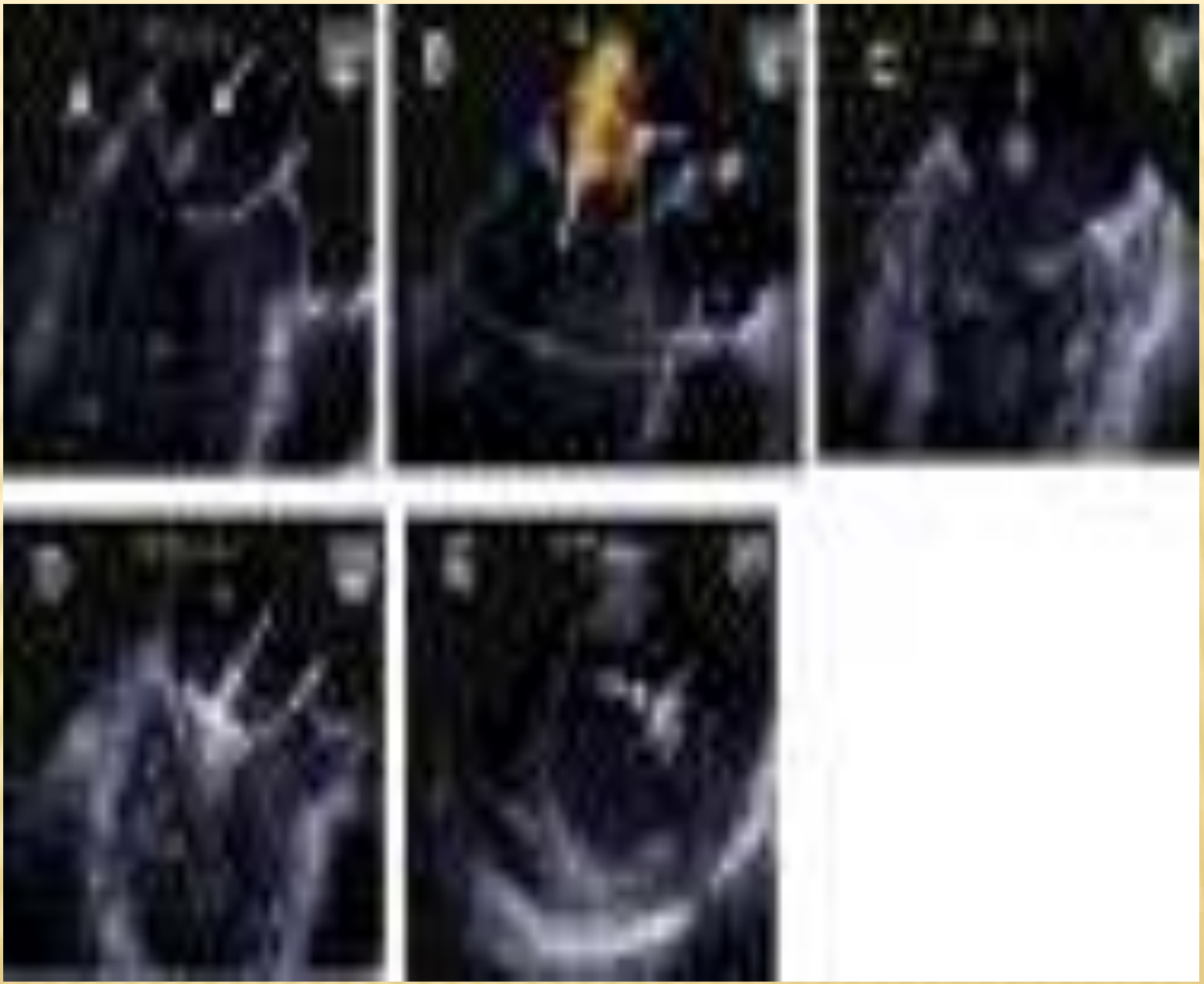
At 4 years, patients with mitral valve regurgitation who undergo repair with a novel percutaneous device experience mortality rates and mitral regurgitation (MR) levels comparable to those that accompany surgery, according to updated data from the EVEREST II trial scheduled to be published online May 7, 2013, ahead of print in the *Journal of the American College of Cardiology*. While surgery continues to hold an early advantage in MR and need for surgical reintervention, few differences between treatment groups were apparent beyond 1 year.

The EVEREST II trial randomized 279 patients with moderately severe or severe (grade 3+ or 4+) MR in a 2:1 ratio to percutaneous treatment with the MitraClip system (Abbott Vascular; Santa Clara, CA; n = 184) or surgical repair or replacement (n = 95).

At 1 year, rates of the primary efficacy endpoint, a composite of freedom from death, surgery for mitral valve dysfunction, and grade 3+ or 4+ MR, favored surgery (73% vs. 55%; $P = 0.007$), with need for surgical intervention for mitral valve dysfunction tenfold lower than in the percutaneous group (2% vs. 20%; $P < 0.01$). However, the percutaneous approach was safer (30-day MACE 15% vs. 48%; $P < 0.001$).







JACC Journals

From: The Evolution From Surgery to Percutaneous Mitral Valve Interventions: The Role of the Edge-to-Edge Technique

J Am Coll Cardiol. 2011;58(21):2174-2182. doi:10.1016/j.jacc.2011.07.046

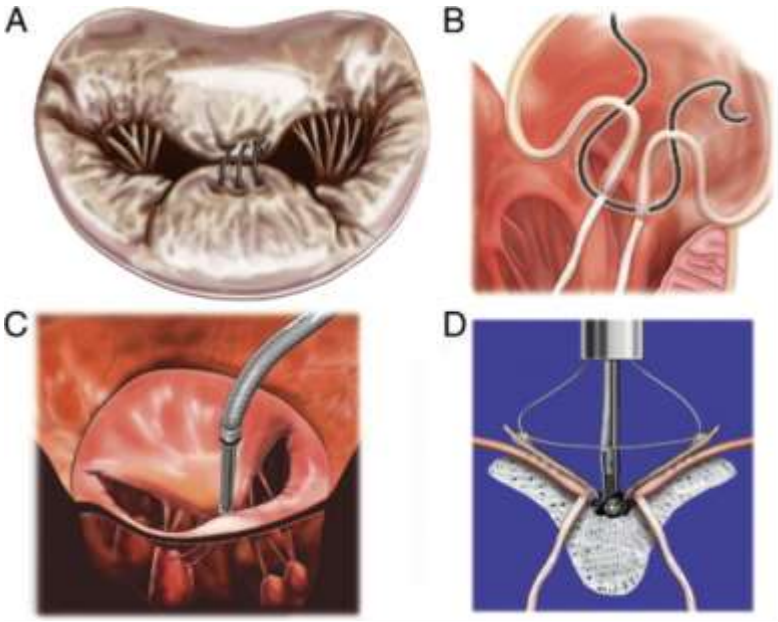


Figure Legend:

Surgical Edge-to-Edge Technique Versus MitraClip

(A) The surgical technique involves a continuous suture of the free edge of the leaflets at the site of the regurgitation. In case the lesion is in the A2-P2 area, a double orifice valve is created. (B) The sutures engage the free edge of the facing leaflets, suture bite depth depends on the amount of redundant tissue (larger in case of degenerative disease, and minimal in case of functional mitral regurgitation). (C) The MitraClip (Abbott Vascular, Menlo Park, California) is implanted in the A2-P2 region, similarly to the surgical technique. The drawing illustrates the clip partially open, to demonstrate tissue penetration into the clip. Once proper leaflet grasping is confirmed, the clip is closed to enhance coaptation. (D) The free edges of the leaflets are engaged between the clip arms and the grippers. The clip is closed with leaflet facing. Compared with surgery where tissue is imbricated into the suture with no

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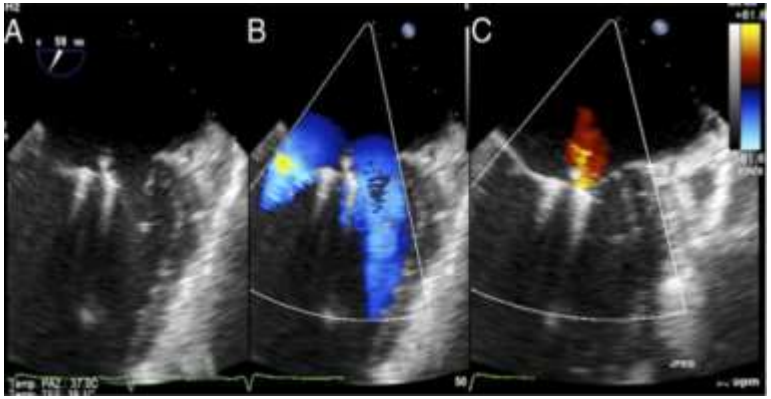

Figure Legend:

Hemodynamic Outcome of a Double MitraClip Implant

(A) Bidimensional echocardiography at 60° to show the intercommissural view. Two clips are implanted in the middle of the valve. (B) The diastolic flow shows no turbulence. (C) A residual minimal jet is found laterally to the second implanted clip.

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Both Approaches Show Durability

For the current study, investigators led by Laura Mauri, MD, of Brigham and Women's Hospital (Boston, MA), analyzed data at 4-year follow-up. The composite efficacy endpoint was numerically higher with surgery, but the difference was no longer significant. Rates of mortality and moderate-to-severe and severe MR were comparable between the groups. However, the need for surgery for mitral valve dysfunction was almost 5 times greater after percutaneous therapy (table 1).

Table 1. Four-Year Cumulative Outcomes

	Percutaneous (n = 161)	**Surgical** (n = 73)	***P* Value**
Composite Efficacy Endpoint	39.8%	53.4%	0.070
Death	17.4%	17.8%	0.914
Surgery or Re-operation for Mitral Valve Dysfunction	24.8%	5.5%	< 0.001
MR 3+ or 4+	21.7%	24.7%	0.745

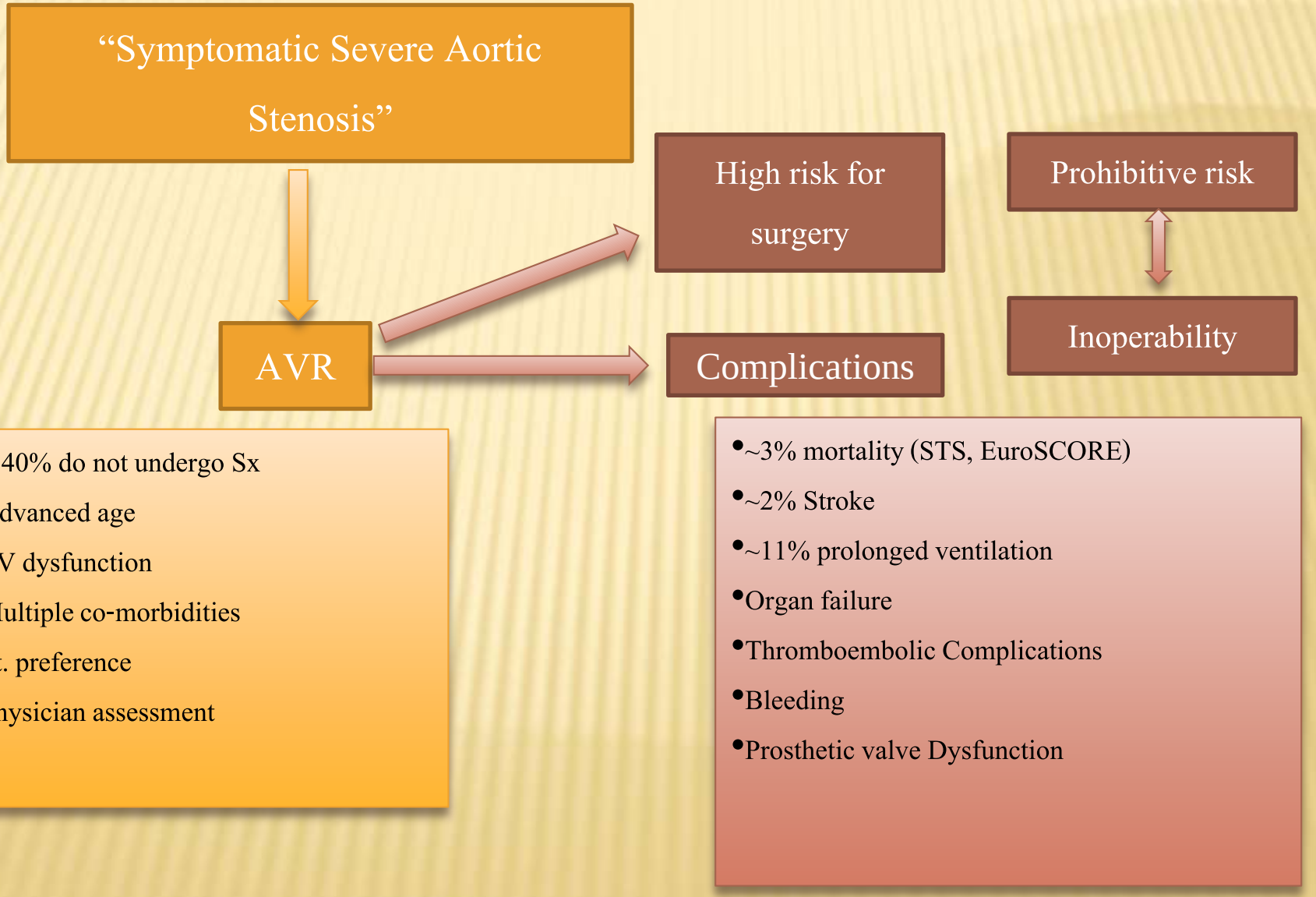
In the percutaneous group, 5 patients underwent reintervention with a second MitraClip within the first year. Implantation failed in 1 case, and a second, successful reintervention was performed between the first and fourth years. The majority of the surgeries required for residual regurgitation occurred within the first year after implantation, with only 3 patients undergoing surgical repair after that time point. In the surgical group, 2 patients underwent reoperation over the first 12 months and 2 between years 1 and 4.

The surgical group experienced a greater reduction in MR at discharge and throughout follow-up compared with the percutaneous group (20.6% vs. 9.1% at 4 years). Also at 4 years, the percutaneous and surgical arms showed similar improvements in left ventricular dimensions, except for a larger left ventricular internal diameter, diastolic, in the device group (5.25 ± 0.65 cm vs. 4.84 ± 0.67 cm; $P < 0.001$). Likewise, both groups experienced substantial declines in the proportion of patients in NYHA class III or IV from baseline to 12 months (45.7% to 2% for the percutaneous group, 44.8% to 13.4% for the surgical group) that were mostly maintained at 4 years (5.7% and 6.3%, respectively).

Surgical Benefit Attenuated for Functional MR

TRANSCATHETER AORTIC VALVE INTERVENTION

INTRODUCTION



REQUISITES

- 'Heart team' approach
  - Specific team leader
  - Close communication
  - 'Preplanning procedure'
- Large cathlabs/ 'hybrid' rooms
  - Fluoroscopic imaging
  - TEE capabilities
  - GA/ CPB
  - Vascular intervention
  - Urgent AVR, CABG, Vascular complications
- Anesthesia
  - Conscious sedation/ GA
  - CPB facility
  - Hemodynamic monitoring and management

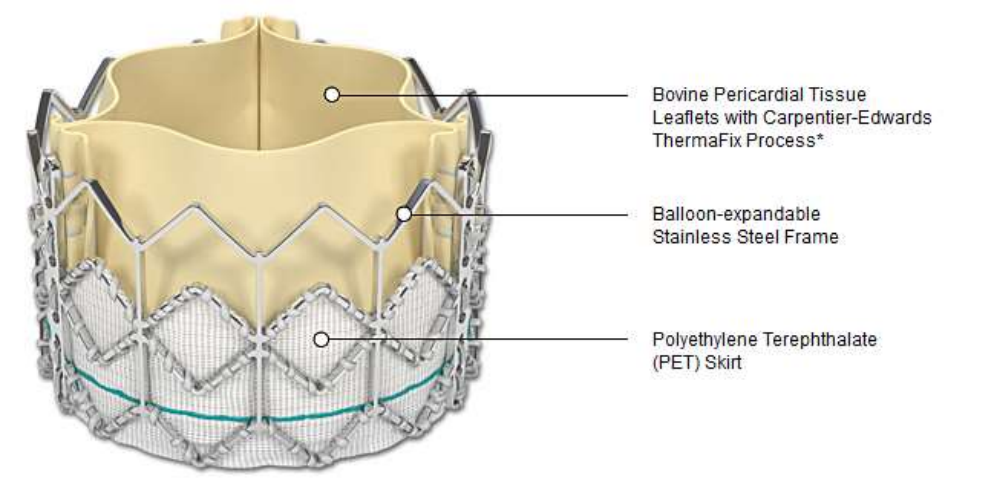
INDICATIONS

- A *Symptomatic severe calcific Aortic Stenosis* [trileaflet] who have aortic and vascular *anatomy suitable* for TAVR and a predicted survival *≥12 months*, and who have a *prohibitive surgical risk* as defined by an estimated 50% or greater risk of mortality or irreversible morbidity at 30 days or *other factors* such as frailty, prior radiation therapy, porcelain aorta, and severe hepatic or pulmonary disease.

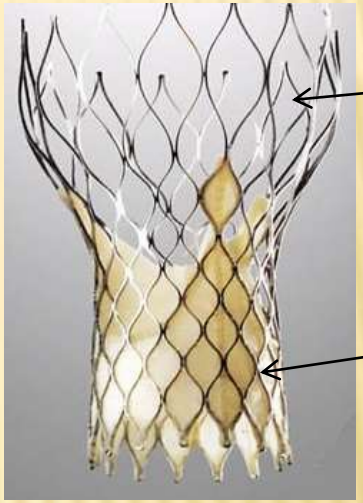
- TAVR is a *reasonable alternative* to surgical AVR in patients at *high surgical risk* (PARTNER Trial Criteria: STS ≥8)

PROCEDURE & HARDWARE

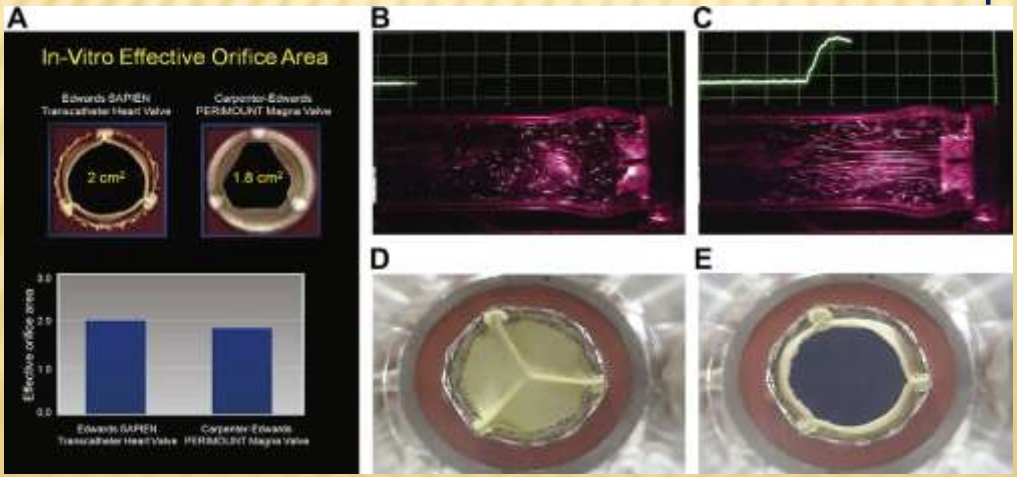
'Sapien XT' device



'CoreValve' device



European Heart Journal (2011) 32, 140–147

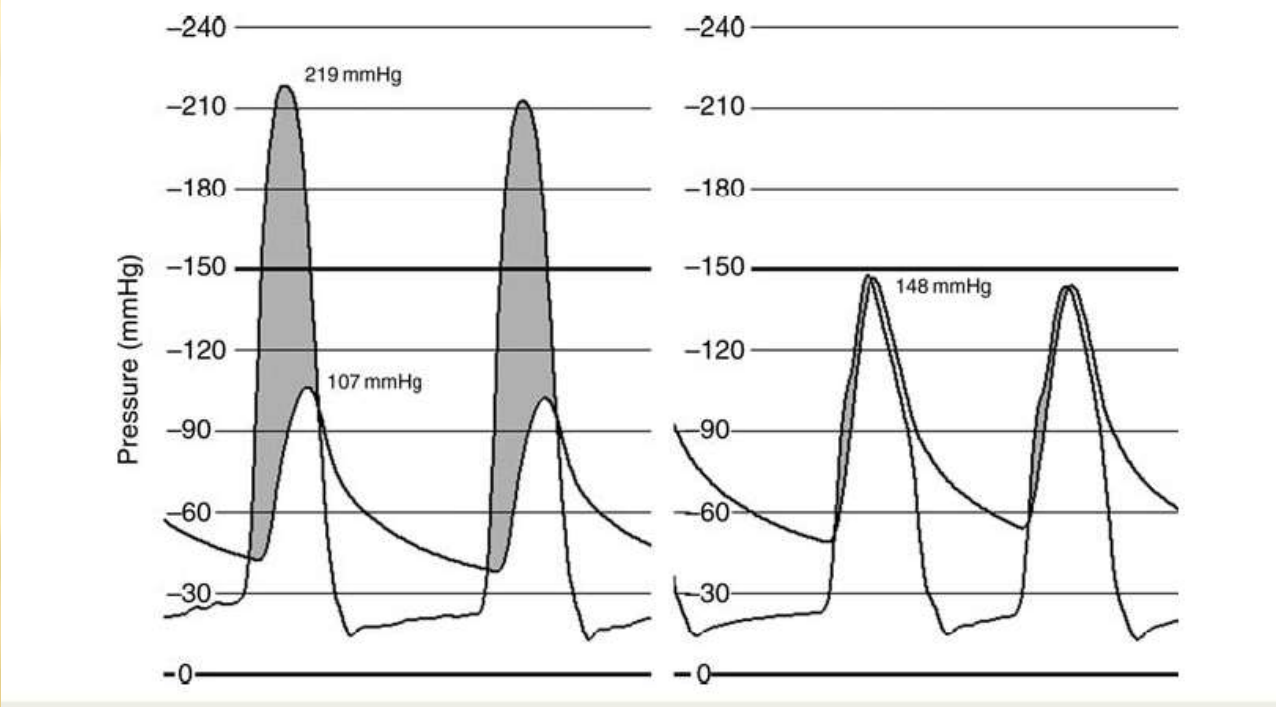


- Superior hemodynamics
- Lower risk for PPM

Cardiol Clin 29 (2011) 211–222

PROCEDURE & HARDWARE

Pressure tracings before and after TAVR



NON-VALVULAR ATRIAL FIBRILLATION STROKE PREVENTION

MEDICAL RX

- Warfarin cornerstone of therapy
- Assuming 51 ischemic strokes/1000 pt-yr
  - Adjusted standard dose warfarin prevented 28 strokes at expense of 11 fatal bleeds
  - Aspirin prevented 16 strokes at expense of 6 fatal bleeds
- Warfarin
  - 60-70% risk reduction vs no treatment
  - 30-40% risk reduction vs aspirin

3000838-10

CHALLENGES IN TREATING AF

- However warfarin is not always well-tolerated
  - Narrow therapeutic range (INR between 2.0 – 3.0)
  - Effectiveness is impacted by interactions with some foods and medications
  - Requires frequent monitoring and dose adjustments
- Published reports indicate that less than 50% of patients eligible are being treated with warfarin due to tolerance or non-compliance issues
- SPORTIF trials suggest only 60% of patients treated are within a therapeutic INR range, while 29% have INR levels below 2.0 and 15% have levels above 3.0

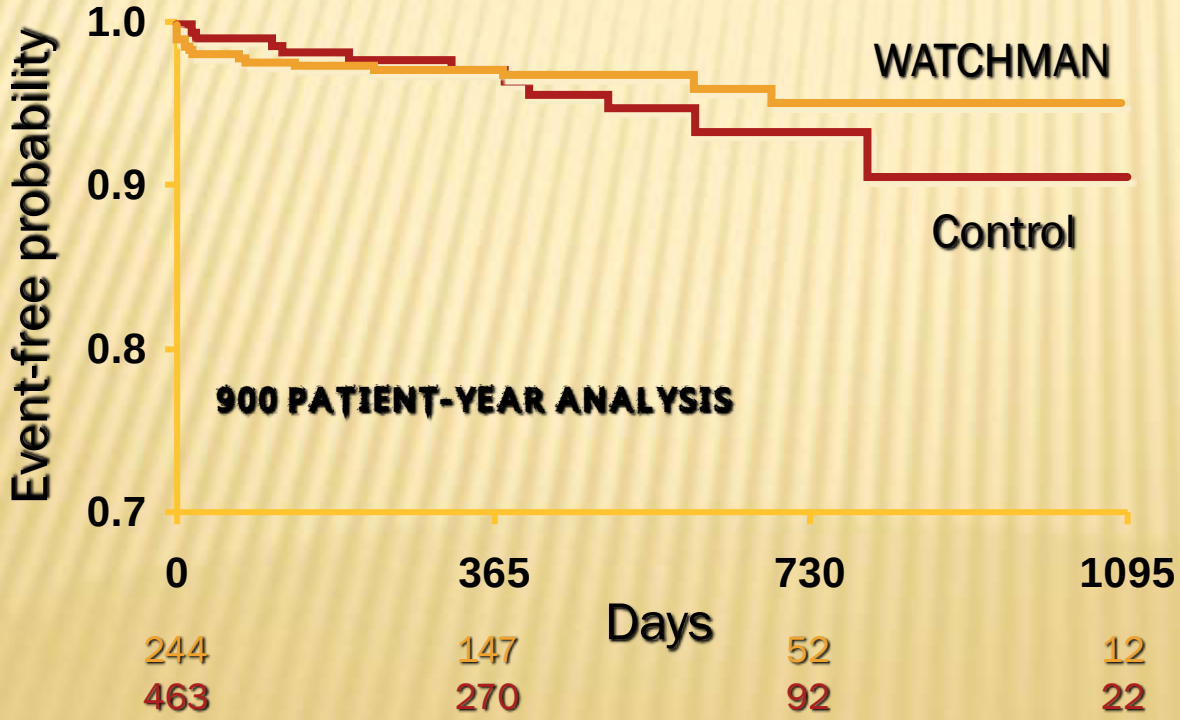
PROTECT AF TRIAL ENDPOINTS

- Primary Efficacy Endpoint
  - All stroke: ischemic or hemorrhagic
    - deficit with symptoms persisting more than 24 hours or
    - symptoms less than 24 hours confirmed by CT or MRI
  - Cardiovascular and unexplained death: includes sudden death, MI, CVA, cardiac arrhythmia and heart failure
  - Systemic embolization
- Primary Safety Endpoint
  - Device embolization requiring retrieval
  - Pericardial effusion requiring intervention
  - Cranial bleeds and gastrointestinal bleeds
  - Any bleed that requires $\geq$ 2uPRBC
- NB: Primary effectiveness endpoint contains safety events

Intent-to-Treat

All Stroke

	Device			Control				Posterior probabilities	
Cohort	Events eve	Total pt-yr	Rate (95% CI)	Events (no.)	Total pt-yr	Rate (95% CI)	RR (95% CI)	Non-inferiority	Superiority
600 pt-yr	14	409.3	3.4 (1.9, 5.5)	8	223.6	3.6 (1.5, 6.3)	0.96 (0.43, 2.57)	0.927	0.488
900 pt-yr	15	582.9	2.6 (1.5, 4.1)	11	318.1	3.5 (1.7, 5.7)	0.74 (0.36, 1.76)	0.998	0.731



RANDOMIZATION ALLOCATION (2 DEVICE:1 CONTROL)

ITT cohort: Non-inferiority criteria met

SUMMARY

- Long-term warfarin treatment of patients with AF has been found effective, but presents difficulties and risk
- PROTECT AF trial was a randomized, controlled, statistically valid study to evaluate the WATCHMAN device compared to warfarin
- In PROTECT AF, hemorrhagic stroke risk is significantly lower with the device.
  - When hemorrhagic stroke occurred, risk of death was markedly increased
- In PROTECT AF, all cause stroke and all cause mortality risk are non-inferior to warfarin
- In PROTECT AF, there are early safety events, specifically pericardial effusion; these events have decreased over time

CONCLUSION

The WATCHMAN LAA Technology offers a safe and effective alternative to warfarin in patients with non-valvular atrial fibrillation at risk for stroke and who are eligible for warfarin therapy

SYMPLICITY HTN–2

Systolic BP >160mmHg

(>150mmHg with type II diabetes)

despite 3 or more anti-hypertensive drugs

Excluded

- eGFR<45mL/min
- type 1 diabetes
- substantial valvular heart disease
- MI/ unstable angina/ stroke < 6 months

Treatment: Renal Denervation

For: Resistant hypertension

Background:

Resistant hypertension is defined as a sustained clinic systolic blood pressure of ≥ 160 mm Hg (≥150 mm Hg in type 2 diabetes) in patients on 3 or more anti- hypertensive medications. This is equivalent to stage 2 hypertension which is an average clinic blood pressure >160 mm Hg and equivalent to a daytime average on ambulatory blood pressure >150 mm Hg as defined by the 2011 National Institute of Health and Clinical Excellence (CG 127) Hypertension Guideline.[2]

Renal denervation for proven resistant hypertension is a new procedure with an emerging evidence base for clinical effectiveness and safety. Hypertension (or chronic high blood pressure) is usually treated with lifestyle changes or medication to reduce the blood pressure and the risk of having events, such as heart attack, stroke, or death. Sometimes these medical treatments have not been enough to reduce an individual's blood pressure (hence the term resistant) and alternative interventions have been sought. The renal nerves (to the kidney) act to communicate information between the kidney and the brain to control the blood pressure; this is likely to be part of a complex control mechanism in the body. The renal denervation procedure inserts a device through the groin to deliver radiofrequency energy to the nerves in the wall of the renal arteries; damaging (or ablating) these nerves has been shown to reduce blood pressure.

The renal denervation system with the greatest amount of clinical data (Symplicity) is produced by Medtronic.[1] The

Systematic Reviews and Health Technology In 2012 NICE IPG418 concluded:

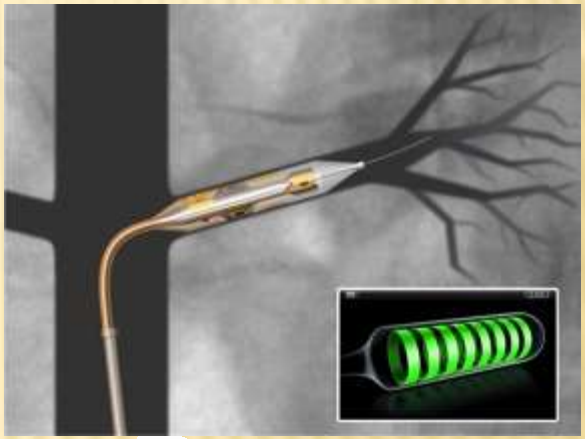
Current evidence on percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension is from limited numbers of patients, but there is evidence of efficacy in the short and medium term. There is inadequate evidence on efficacy in the long term; this is particularly important for a procedure aimed at treating resistant hypertension. The limited evidence suggests a low incidence of serious periprocedural complications, but there is inadequate evidence on long-term safety. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.[6]

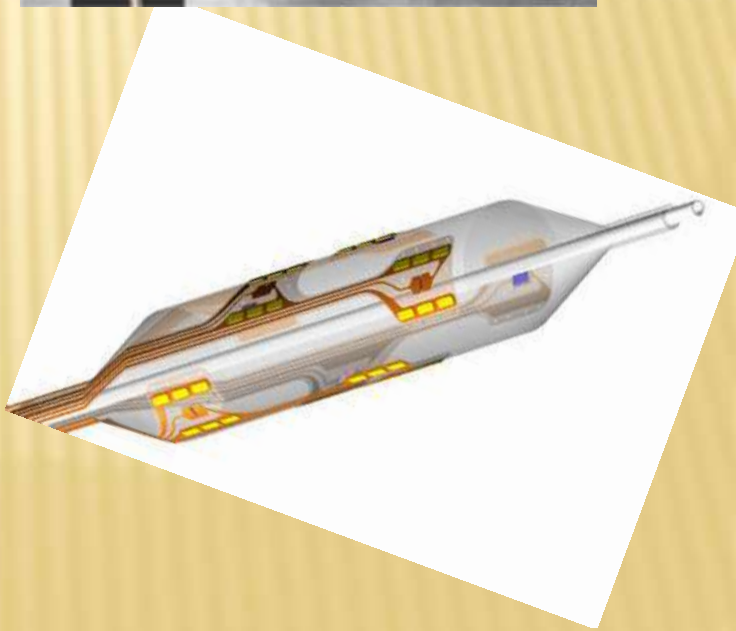
A randomised controlled trial[7] of 100 patients treated by renal artery denervation (n = 49) or unchanged medical therapy (n = 51) reported an average reduction in blood pressure of 32/12 mmHg and an increase of 1/0 mmHg respectively at 6-month -up ($p < 0.0001$ for both systolic blood pressure [SBP] and diastolic blood pressure [DBP] in the treatment group compared with $p = 0.83$ for SBP and $p = 0.77$ for DBP in the control group).

A case series of 153 patients[8] reported a mean reduction in blood pressure of 25/11 mmHg at 6 months (n = 86), 23/11 mmHg at 12 months (n = 64), 26/14 mmHg at 18 months (n = 36) and 32/14 mmHg at 24 months (n = 18) (withinpatient changes in both SBP and DBP from baseline were $p < 0.0001$ at all-time points except at 24 months [$p = 0.002$

VESSIX VASCULAR V2

- RF electrodes and thermistors on balloon
- 4-8 gold electrode pairs
- 30 sec inflation/ treatment per renal artery





ANATOMICAL LOCATION OF RENAL SYMPATHETIC NERVES

- Arise from T10-L1
- Follow the renal artery to the kidney
- Primarily lie within the adventitia

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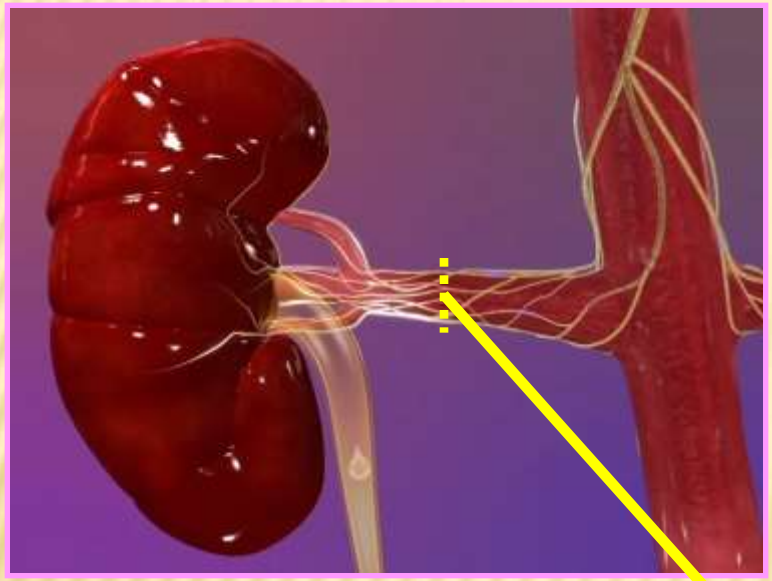

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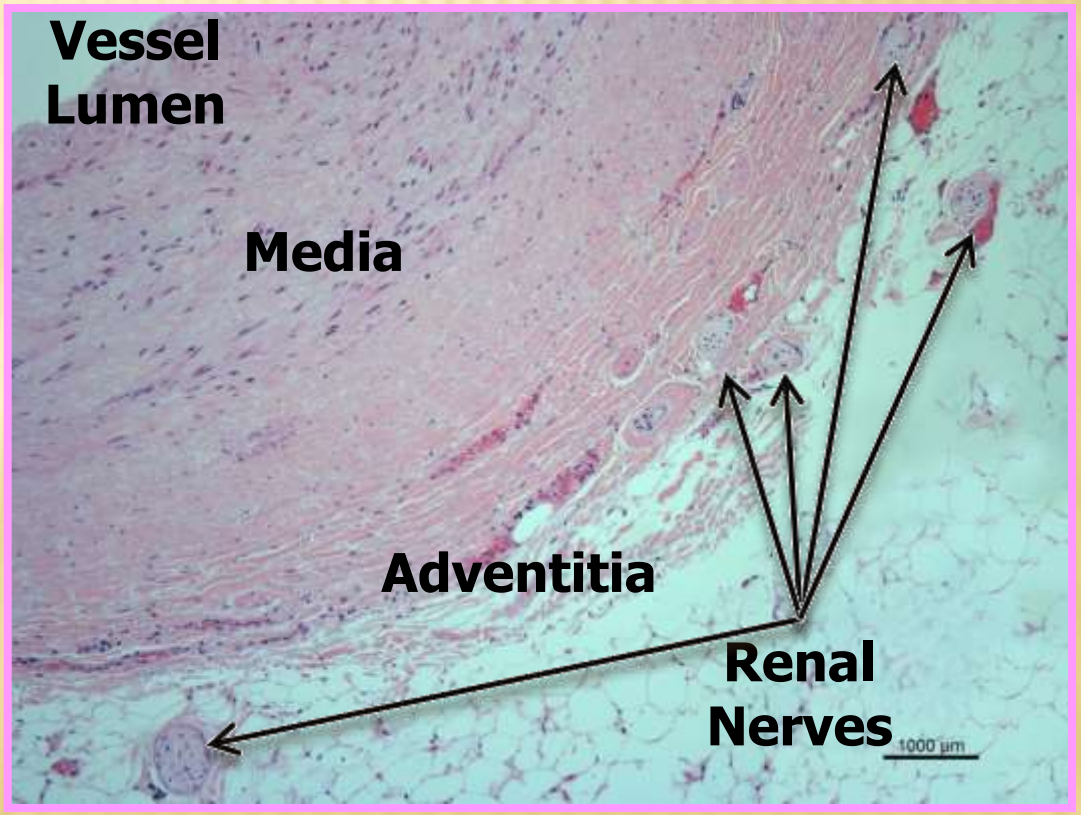
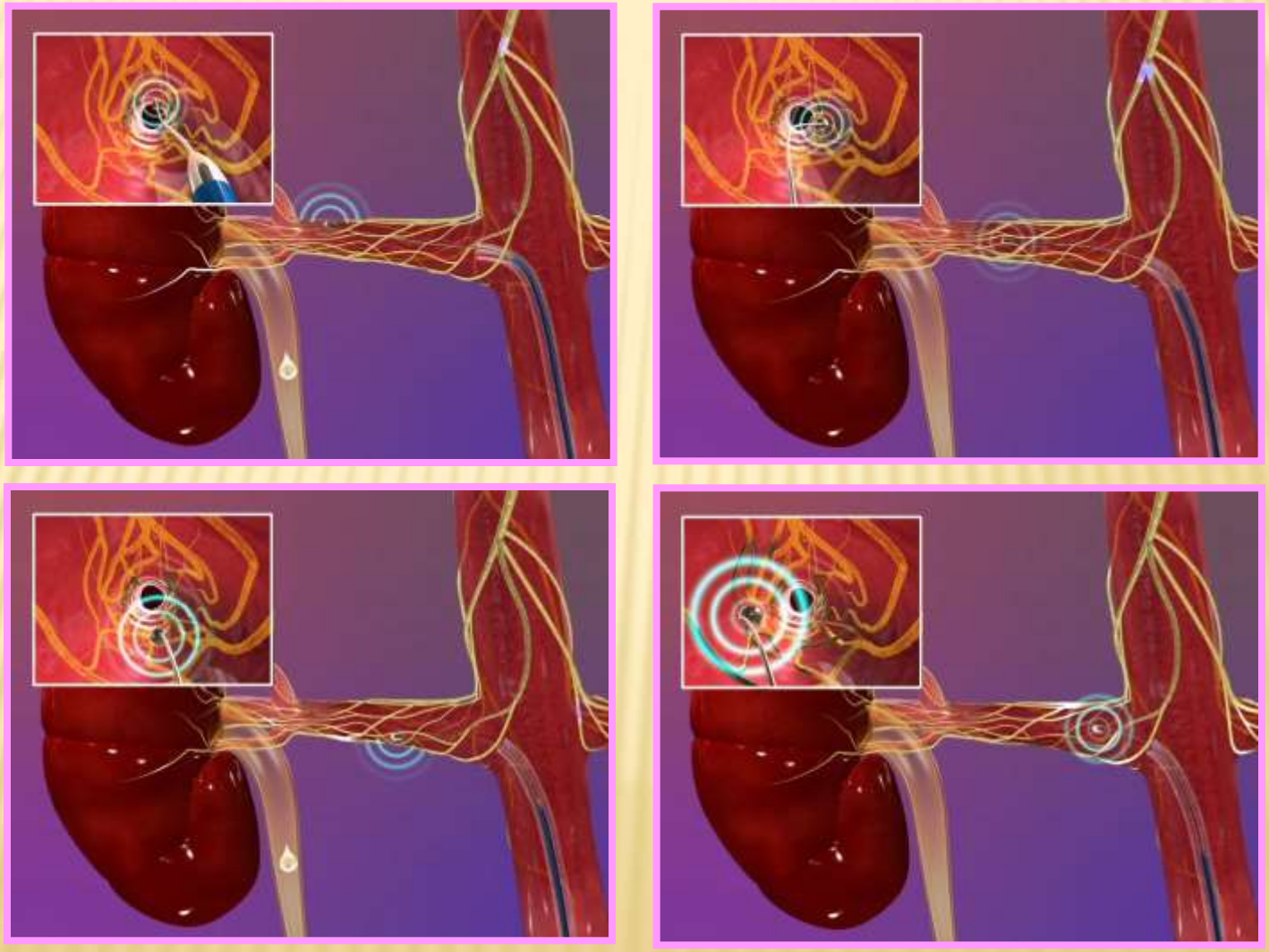
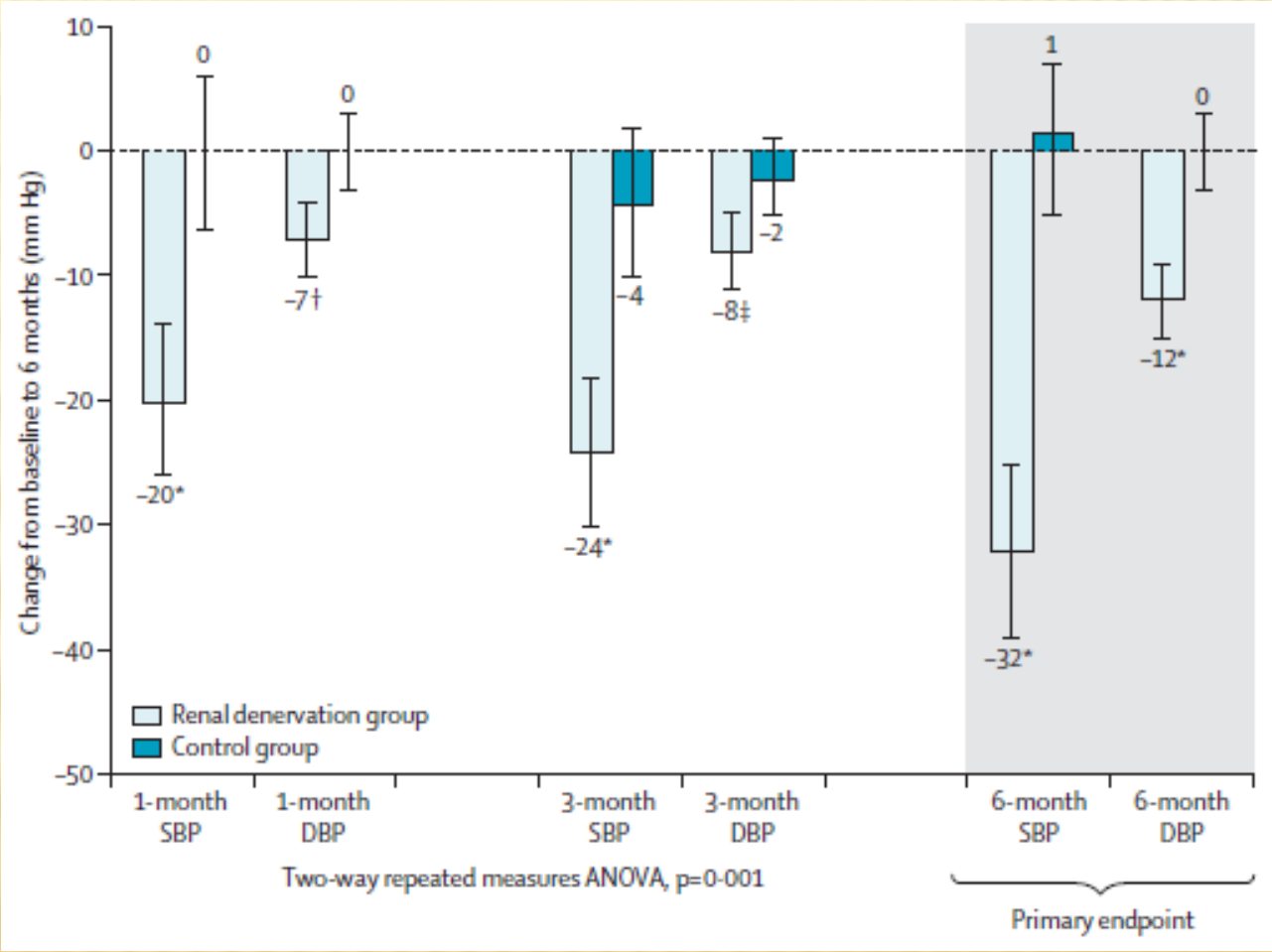


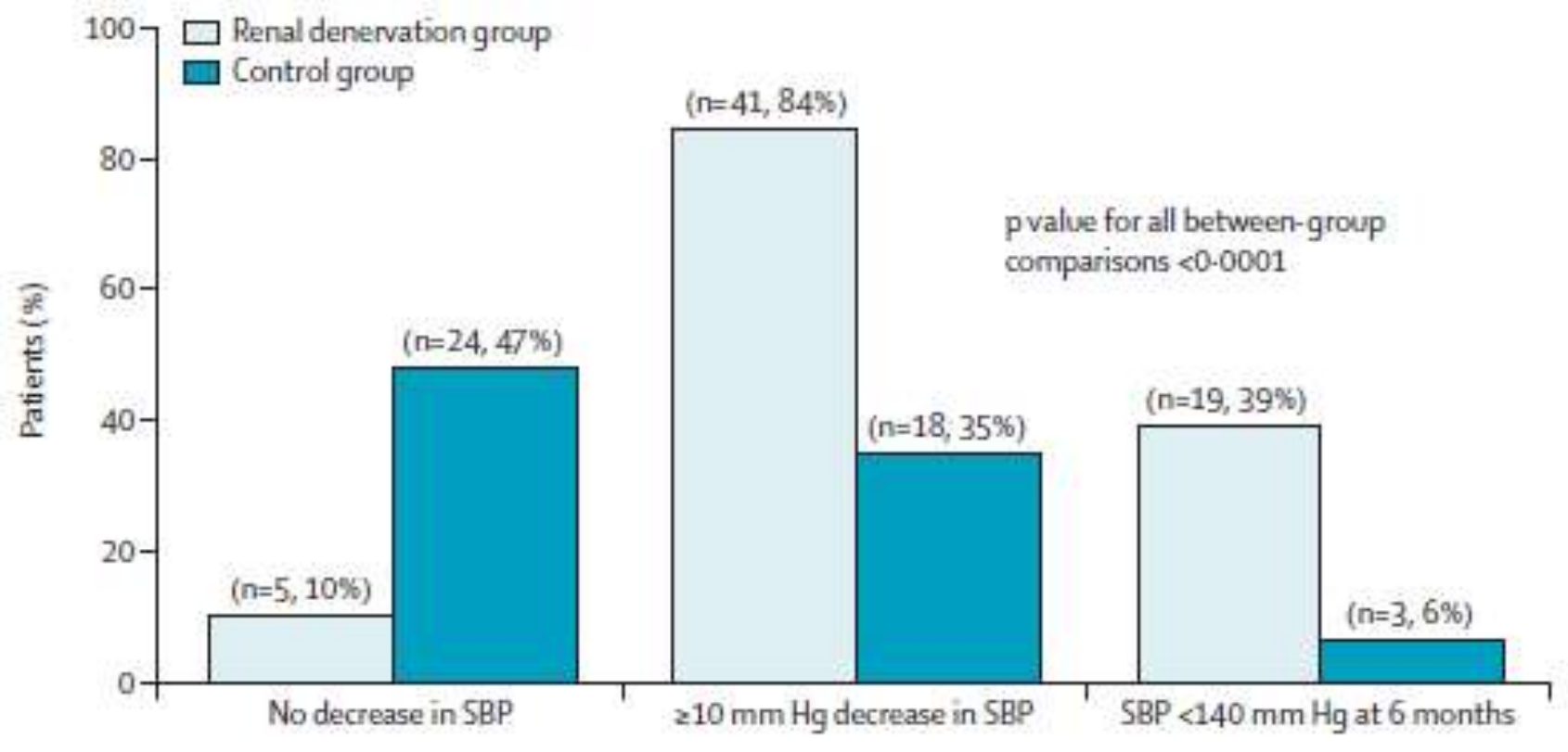
Treatment by Renal RF Catheter



OFFICE BP AT 1, 3 & 6 MONTHS



CATEGORIES OF RESPONSE, BY TREATMENT



SUMMARY

- Renal denervation lowers BP in refractory HT
- Effect is maintained 2-4 years+
- Few procedure-related adverse effects

- Optimal denervation uncertain
- Unable to pre-select responders
- Long-term benefits and risks unknown
- Uncertain whether effective in milder hypertension

FUTURE POTENTIAL INDICATIONS

- Hypertension
  - less severe
  - medication-intolerant patients
  - non-compliant patients
- Heart failure
- Renal failure
- Obstructive sleep apnoea

Percutaneous Pulmonary Valve Implantation in the Young2-Year Follow-Up FREE

Marko Vezmar, MSc, MD; Rajiv Chaturvedi, MD, PhD; Kyong-Jin Lee, MD; Claudia Almeida, MD; Cedric Manlhiot, BSc; Brian W. McCrindle, MD; Eric M. Horlick, MD; Lee N. Benson, MD

[+] Author Information

J Am Coll Cardiol Intv. 2010;3(4):439-448. doi:10.1016/j.jcin.2010.02.003

Abstract

Objectives The aim of this study was to investigate physiological and clinical consequences of percutaneous pulmonary valve implantation (PPVI) in patients with chronic right ventricular outflow tract (RVOT) obstruction and volume overload.

Background The PPVI is a nonsurgical technique to address RVOT conduit dysfunction.

Methods Twenty-eight adolescents (median age 14.9 years; age range 10.9 to 19 years) underwent PPVI due to RVOT stenosis and/or pulmonary regurgitation (PR). Before and after PPVI echocardiographic and magnetic resonance imaging, cardiopulmonary exercise tests were obtained.

Results The RVOT gradient ($p < 0.001$) and right ventricular (RV) systolic pressure decreased ($p < 0.001$), acutely. Magnetic resonance imaging (median 6 months) documented reduction in RV end-diastolic (149 ± 49 ml/m^2 vs. 114 ± 35 ml/m^2, $p < 0.005$) volume, increases in left ventricular (LV) end-diastolic ($p < 0.007$) volume and cardiac output (RV: $p < 0.04$ and LV: $p < 0.02$), and reduced PR fraction ($24 \pm 10\%$ to $7 \pm 7\%$, $p < 0.0001$). Symptoms, aerobic exercise performance (maximal oxygen consumption: $p < 0.0001$) and ventilatory response to carbon dioxide production ($p < 0.003$) improved. After 24 months, echocardiography demonstrated the RV/systemic-pressure ratio, and RVOT peak pressure gradient reductions persisted, and PR was absent in 93% ($n = 12$ of 13) of the cohort. Freedom from surgery was 91%, 83%, and 83%, and freedom from transcatheter reintervention was 91%, 80%, and 80%, at 12, 24, and 36 months, respectively. There were no acute device-related complications, with stent fractures noted in 10.8%.

Conclusions Percutaneous pulmonary valve implantation is feasible and safe in the young with dysfunctional RVOT conduits. An improvement in symptoms, hemodynamic status, and objective findings of exercise performance occurs. Early follow-up demonstrates persistent improvement in ventricular parameters, PR, and objective exercise capacity.

Systematic Reviews and Health Technology In 2012 NICE IPG418 concluded:

Current evidence on percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension is from limited numbers of patients, but there is evidence of efficacy in the short and medium term. There is inadequate evidence on efficacy in the long term; this is particularly important for a procedure aimed at treating resistant hypertension. The limited evidence suggests a low incidence of serious periprocedural complications, but there is inadequate evidence on long-term safety. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.[6]

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Clinical Outcomes in Patients Undergoing Percutaneous Closure of Periprosthetic Paravalvular Leaks FREE

Carlos E. Ruiz, MD, PhD; Vladimir Jelnin, MD; Itzhak Kronzon, MD; Yuriy Dudiy, MD; Raquel Del Valle-Fernandez, MD; Bryce N. Einhorn; Paul T.L. Chiam, MD; Claudia Martinez, MD; Rocio Eiros, MS; Gary Roubin, MD, PhD; Howard A. Cohen, MD

[+] Author Information

J Am Coll Cardiol. 2011;58(21):2210-2217. doi:10.1016/j.jacc.2011.03.074

Abstract

Objectives The purpose of this study was to evaluate the feasibility and efficacy of the percutaneous device closure of a consecutive series of patients with periprosthetic paravalvular leaks referred to our structural heart disease center with congestive heart failure and hemolytic anemia.

Background Clinically significant periprosthetic paravalvular leak is an uncommon but serious complication after surgical valve replacement. Percutaneous closure has been utilized as an alternative to surgical repair of this defect in high-risk surgical patients.

Methods This is a retrospective review of 57 percutaneous paravalvular leak closures that were performed in 43 patients (67% male, mean age 69.4 ± 11.7 years) between April 2006 and September 2010. Integrated imaging modalities were used for the evaluation, planning, and guidance of the interventions.

Results Closure was successful in 86% of leaks and in 86% of patients. Twenty-eight of 35 patients improved by at least 1 New York Heart Association functional class. The percentage of patients requiring blood transfusions and/or erythropoietin injections post-procedure decreased from 56% to 5%. Clinical success was achieved in 89% of the patients in whom procedure was successful. The survival rates for patients at 6, 12, and 18 months after paravalvular leak closures were 91.9%, 89.2%, and 86.5%, respectively. Freedom from cardiac-related death at 42 months post-procedure was 91.9%.

Conclusions Percutaneous closure of symptomatic paravalvular leaks, facilitated by integrated imaging modalities has a high rate of acute and long-term success and appears to be effective in managing symptoms of heart failure and hemolytic anemia.

Abstract

Abstract | Abbreviations and Acronyms | Methods | Results | Discussion | Conclusions | References

Objectives The purpose of this study was to evaluate the feasibility and efficacy of the percutaneous device closure of a consecutive series of patients with periprosthetic paravalvular leaks referred to our structural heart disease center with congestive heart failure and hemolytic anemia.

Background Clinically significant periprosthetic paravalvular leak is an uncommon but serious complication after surgical valve replacement. Percutaneous closure has been utilized as an alternative to surgical repair of this defect in high-risk surgical patients.

Methods This is a retrospective review of 57 percutaneous paravalvular leak closures that were performed in 43 patients (67% male, mean age 69.4 ± 11.7 years) between April 2006 and September 2010. Integrated imaging modalities were used for the evaluation, planning, and guidance of the interventions.

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