

XXIX Giornate Cardiologiche Torinesi ADVANCES IN CARDIAC ARRHYTHMIAS AND GREAT INNOVATIONS IN CARDIOLOGY

Turin, October 27-28, 2017 Centro Congressi Unione Industriale

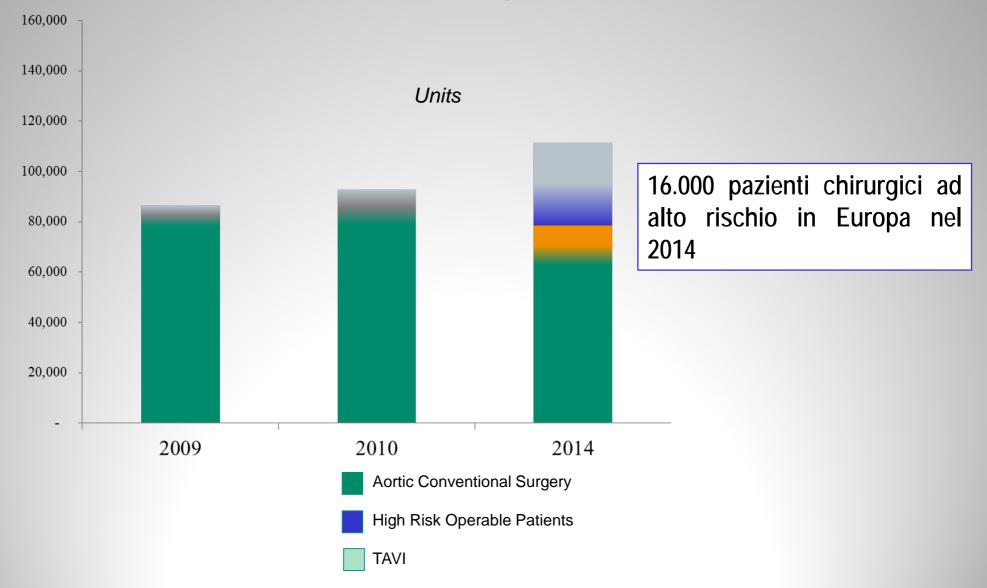
WHAT HAS CHANGED IN CARDIAC SURGERY?

Biological or mechanical valve prosthesis? Dr.ssa Chiara Comoglio Dr Riccardo Casabona

Maria Pia Hospital - Torino GVM Care & Research



Pazienti che ricevono una protesi aortica Europa



Sources: TAVI est. by Morgan Stanley Research Nov 2010, Company Data, Biba Research, National Registries

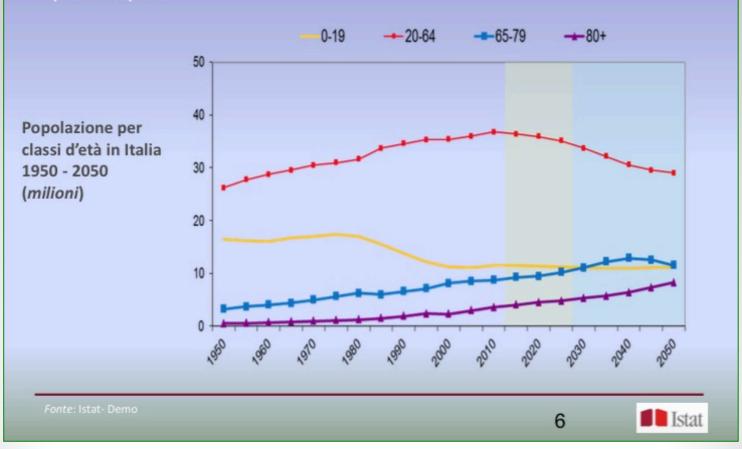


Xv° Censimento Generale Della Popolazioni 2011

L' evoluzione demografica in Italia

Un paese di anziani:

nel 2050 gli ultrasessantacinquenni rappresenteranno un terzo della popolazione, dal 20% attuale, e gli ultraottantenni cresceranno dall'attuale 5,8% al 13,6%.



Come cambia il mondo. Tendenze demografiche, economiche e geopolitica. Prof. A. Golini

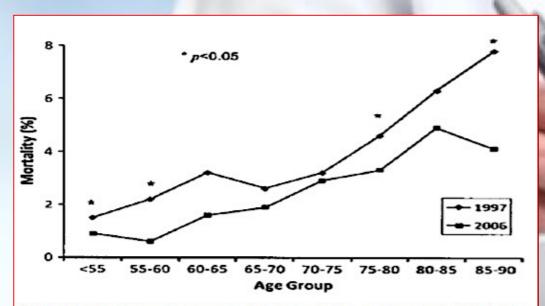
Aortic Valve Replacement in Octogenarians: Risk Factors for Early and Late Mortality

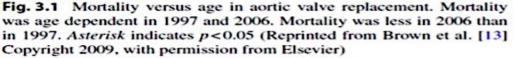
Spencer J. Melby, MD, Andreas Zierer, MD, Scott P. Kaiser, BS, Tracey J. Guthrie, RN, Jason D. Keune, BA, Richard B. Schuessler, PhD, Michael K. Pasque, MD, Jennifer S. Lawton, MD, Nader Moazami, MD, Marc R. Moon, MD, and Ralph J. Damiano, Jr, MD

Division of Cardiothoracic Surgery, Department of Surgery, Washington University School of Medicine and Barnes-Jewish Hospital, St. Louis, Missouri Ann Thorac Surg 2007

Morbidity And Mortality Decrease Applying

Recent Advances Of Cardiosurgical Techniques





Ŀ	luestions	
• •	How severe is VHD?	
• \	What is the aetiology of VHD?	
• [Does the patient have symptoms?	
• /	Are symptoms related to valvular disease?	
	Are any signs present in asymptomatic patients that indicate a worse outcome if the intervention is delayed?	
• \	What are the patient's life expectancy* and expected quality of life?	
	Do the expected benefits of intervention (versus spontaneous outcome) outweigh its risks?	
(What is the optimal treatment modality? Surgical valve replacement mechanical or biological), surgical valve repair, or catheter ntervention?	
	Are local resources (local experience and outcome data for a given ntervention) optimal for the planned intervention?	BFSC 2017
• \	What are the patient's wishes?	ECC

European Society doi:10.1093/eurheartj/ehx391 of Cardiology

ESC/EACTS GUIDELINES





2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

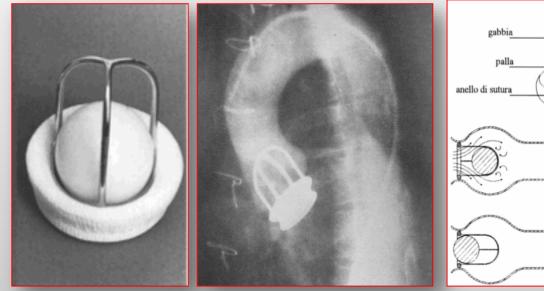
Rick A. Nishimura, Catherine M. Otto, Robert O. Bonow, Blase A. Carabello, John P. Erwin III, Robert A. Guyton, Patrick T. O'Gara, Carlos E. Ruiz, Nikolaos J. Skubas, Paul Sorajja, Thoralf M. Sundt III and James D. Thomas

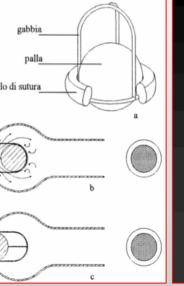
Summary of Recommendations for Prosthetic Valve Choice

Recommendations	COR	LOE
Choice of valve intervention and prosthetic valve type should be a shared decision process	I	C
A bioprosthesis is recommended in patients of any age for whom anticoagulant therapy is contraindicated, cannot be managed appropriately, or is not desired	I	C
A mechanical prosthesis is reasonable for AVR or MVR in patients <60 y of age who do not have a contraindication to anticoagulation	lla	В
A bioprosthesis is reasonable in patients >70 y of age	lla	В
Either a bioprosthetic or mechanical valve is reasonable in patients between 60 y and 70 y of age	lla	В
Replacement of the aortic valve by a pulmonary autograft (the Ross procedure), when performed by an experienced surgeon, may be considered in young patients when VKA anticoagulation is contraindicated or undesirable	llb	C

Types of Artificial Heart Valves: mechanical

1960 HARKEN-SOROFF aortic prosthesis - STARR-EDWARDS mitral valve





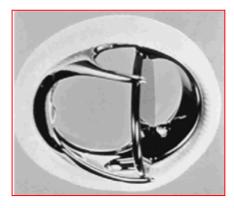
Starr Edwards

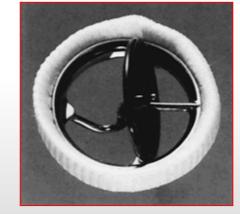
- Philip Admunson, stenosi mitralica;
- 02/09/1960, la prima sostituzione valvolare mitralica nell'uomo coronata da successo;
- Sopravvisse per 15 anni, morì perr caduta accidentale mentre verniciava casa.

- FLUSSO PERIFERICO E TURBOLENTO
- ALTO GRADIENTE TRANSPROTEICO
- ALTA TROMBOGENICITA'

Mechanical prosthesis: single-disc

1967 - LILLEHEI-KASTER





1982 BJORK-SHILEY C-C

1968 BJORK-SHILEY e

1977 MEDTRONIC



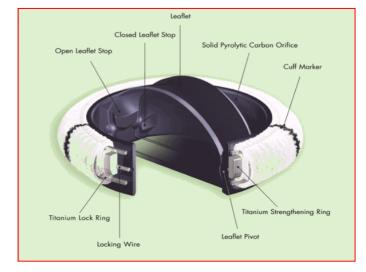


1978 OMNISCIENCE I 1982 OMNISCIENCE II



Mechanical prosthesis BILEAFLET

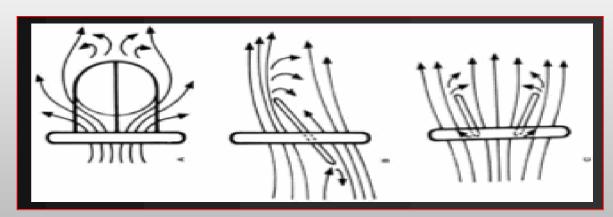








Bicarbon Slimline



Biological prosthesis since 1970

VALVOLE PORCINE









Ideal valve





1. Good hemodynamic Quiet 2. 3. Require no anticoagulation 4. Last for life time 5. Cheap 6. Easy to implant

Two historic randomized clinical trials compared outcomes after valve replacement with a first-generation porcine heterograft and the original Bjork-Shiley tilting-disc mechanical valve: The Edinburgh Heart Valve Trial, conducted between 1975 and 1979 with an average follow-up of 12 years The Veteran Affairs (VA) Cooperative Study on Valvular Heart Disease, conducted between 1979 and 1982 with an average follow-up of 15 years.

The Edinburgh trial

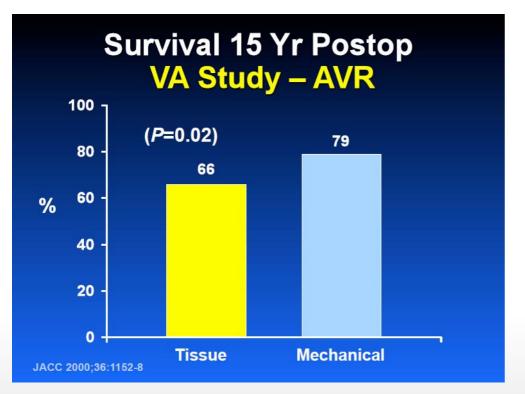
a small survival advantage associated with a mechanical valve in the aortic but not in the mitral position

both trials showed:

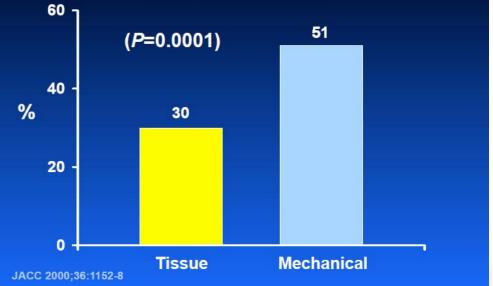
- increased bleeding associated with mechanical valves

- increased reoperation with tissue valves;

- structural failure of tissue valves and overall thromboembolic complications were greater after mitral than after aortic valve replacement.



Bleeding During 16 Yr Follow-up Aortic Valve



The investigators found that patients younger than 65 years who received a bioprosthetic valve had a greater rate of primary valve failure for both aortic valve replacements (AVR) and mitral valve replacements (MVR) 15 years after implantation compared with similarly aged patients with mechanical valve replacements (bioprosthetic vs mechanical 26% vs 0%, P, 0.001 for AVR and 44% vs 4%, P, 0.001 for MVR).

This large randomized control study demonstrates the excellent durability of mechanical heart valves compared with bioprosthetic heart valves.



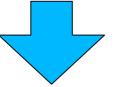
Mechanical valve advantages

2()()()

The most important of which is their greater durability (20–30 years), their greater durability translates into lower reoperation rates among these patients

Mechanical valve disadvantages

Blood flow around the mechanical valve results in high sheer stresses, which can result in platelet activation and a higher risk for thrombosis on the valve surface and a subsequent risk for embolism.



COUMADIN --WARFARIN

The Journal of Thoracic and Cardiovascular Surgery

Patient outcome after aortic valve replacement with a mechanical or biological prosthesis: Weighing lifetime anticoagulant-related event risk against reoperation risk Martijn W. A. van Geldorp,

Although warfarin use is efficacious in reducing thrombosis risk, it heightens hemorrhagic risk

... 60-year-old male with a mechanical valve replacement has a lifetime risk of bleeding of 41% compared with a 12% risk in a similar patient with a bioprosthetic valve replacement

Anticoagulation and bleeding

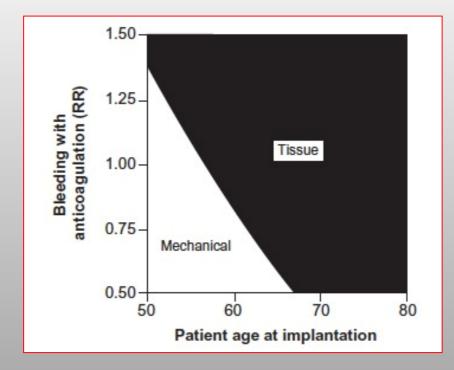
Thrombosis and Haemostasis

1996

Assessment of a bleeding risk index in two cohorts of patients treated with oral anticoagulants.

the risk of bleeding from anticoagulant therapy increases as patients age.

Patients with mechanical values on anticoagulation therapy who are older than 60 years are nearly 7 times more likely to bleed than patients younger than 60. The increased risk of bleeding with a mechanical value replacement in older patients further supports avoiding mechanical values in this population.





Choice of Prosthetic Heart Valve in Adults An Update

Shahbudin H. Rahimtoola, MB, FRCP, DSC (HON)

2010

Therapeutic levels of warfarin are difficult to achieve and maintain, due to both barriers toadherence and the variety of interactions that warfarin has with other medications and diet. A recent study underscored this difficulty by demonstrating that only 62% of those patients with a mechanical valve on anticoagulation medication are found within the appropriate international normalized ratio(INR) range, even in the setting of adequate medication adherence. Journal of the American College of Cardiology





Thromboembolic and Bleeding Complications in Patients With Mechanical Heart Valve Prostheses

S.C. Cannegieter, MD; F.R. Rosendaal, MD; E. Briët, MD

Circulation 1994

Incidence of major embolism after mechanical valve replacement

Absence of antithrombotic therapy

4% per year - plus 1.8% per year risk of valve thrombosis Antiplatelet therapy

2.2% per year - plus 1.6% per year risk of valve thrombosis Wafarin therapy

1% per year

0.8% per year with an aortic valve

1.3% per year with a mitral valve

plus 0.2% per year risk of valve thrombosis

Incidence of major bleeding in patients treated with warfarin

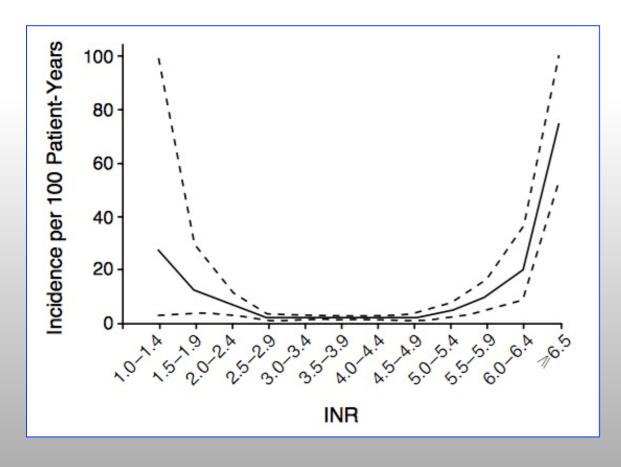
1.4 per 100 patient-years.

OPTIMAL ORAL ANTICOAGULANT THERAPY IN PATIENTS WITH MECHANICAL HEART VALVES

S.C. CANNEGIETER, M.D., F.R. ROSENDAAL, M.D., A.R. WINTZEN, M.D., F.J.M. VAN DER MEER, M.D., J.P. VANDENBROUCKE, M.D., AND E. BRIËT, M.D.

Adverse Events Are Common with Mechanical Valves

INR-Specific Incidence Of All Adverse Events





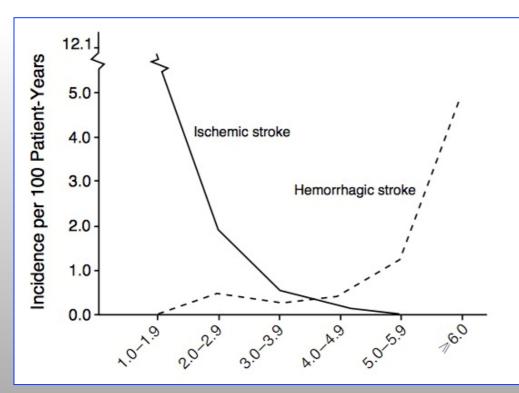
OPTIMAL ORAL ANTICOAGULANT THERAPY IN PATIENTS WITH MECHANICAL HEART VALVES

S.C. CANNEGIETER, M.D., F.R. ROSENDAAL, M.D., A.R. WINTZEN, M.D., F.J.M. VAN DER MEER, M.D., J.P. VANDENBROUCKE, M.D., AND E. BRIËT, M.D.

Adverse Events Are Common with Mechanical Valves

INR-Specific Incidence Of All Adverse Events

Incidence of Ischemic and Hemorrhagic Stroke According to INR Category.





You'll Never Need Another Operation

You can Live without Restrictions

Risks of TE are Minimal

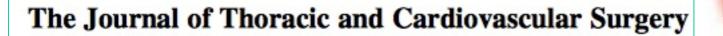
Coumadin is Not a Problem

Myths about Mechanical Valves

WHAT HAS CHANGED IN CARDIAC SURGERY?

Biological or mechanical valve prosthesis?

The main advantage with bioprosthetic



Patient outcome after aortic valve replacement with a mechanical or biological prosthesis: Weighing lifetime anticoagulant-related event risk against reoperation risk

Martijn W. A. van Geldorp,

Conclusion: Even for patients aged 60 years, event-free life expectancy is better with a bioprosthesis. Although the chance of reoperation is higher, the lifetime risk of bleeding is lower compared with a mechanical prosthesis. Comparing lifetime event risks between different types of valve prostheses provides more insight into patient outcome after aortic valve replacement and aids patient selection and counseling.

Prognosis After Aortic Valve Replacement With a Bioprosthesis

Predictions Based on Meta-Analysis and Microsimulation

J. P. A. Puvimanasinghe, 2010

Circulation

Accordingly, patients with bioprosthetic valves have a significantly decreased risk of bleeding.

The bioprosthetic valve also has disadvantages

The process of structural valve deterioration is poorly understood but is thought to result from the accumulation of calcium and lipids on the valve surface.

Improvements in second-generation bioprosthetic valves have reduced the rapidity of deterioration compared with first-generationvalves, but structural valve deterioration remains a major disadvantage for bioprosthetic valves.10

For most patients with a bioprosthetic valve, structural valve deterioration begins around 5 years post-implantation and rapidly increases.

Which biologic valve should we select for the 45- to 65-year-old age group requiring aortic valve replacement?

F. Dagenais, MD, P. Cartier, MD,[†] P. Voisine, MD, D. Desaulniers, MD, J. Perron, MD, R. Baillot, MD, G. Raymond, MD, J. Métras, MD, D. Doyle, MD, and P. Mathieu, MD THE JOURNAL OF THORACIC AND

RDIOVASCULAR SURGERY

2005

There are trends in the United States and Europe toward the increasing use of tissue rather than mechanical valves and toward the use of bioprostheses in progressively younger patients

Age and Valve Size Effect on the Long-Term Durability of the Carpentier-Edwards Aortic Pericardial Bioprosthesis Ann Thorac Surg 2001

Michael K. Banbury, MD, Delos M. Cosgrove III, MD, Jennifer A. White, MS, Eugene H. Blackstone, MD, Robert W. M. Frater, MD, and J. Edward Okies, MD

Freedom from structural valve deterioration

Carpentier-Edwards pericardial aortic valve (age 65)

- 94% at 10 years
- 77% at 15 years
 - 10% chance that a 65-year-old patient would require reoperation before 80 years
- Third-generation bioprostheses may be even more durable, with

92.8% at 12 years (mean age of 54 years)

In addition, advances in myocardial protection and cardiac surgical techniques have led to lower risks at reoperation, making the prospect of redo valve surgery less dangerous.

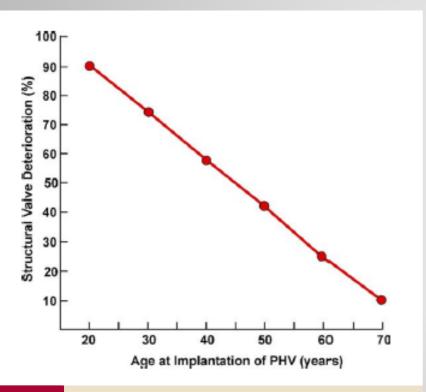
Why bioprosthesis ?

- Expected life expectancy < 10-12 yrs
- Anticoagulation contraindicated.
- Patient cannot or will not take anticoagulant.
- Patient at increased risk for bleeding with anticoagulation.
- INR difficult to control
- Poor compliance

Late incidence and determinants of reoperation in patients with prosthetic heart valves^{$\hat{\pi}$}

Marc Ruel^{a,b,*}, Alexander Kulik^a, Fraser D. Rubens^a, Pierre Bédard^a, Roy G. Masters^a, Andrew L. Pipe^a, Thierry G. Mesana^a

Età



SVD of Biological Valves at 15 to 20 Years Based on Patient Age at Time of PHV Implantation

- Insufficienza renale
- Iperparatiroidismo
- Ipertensione sistemica
- Ipertrofia Vsx
- Funzione Vsx depressa
- Size della protesi

Predittori di degenerazione strutturale delle bioprotesi

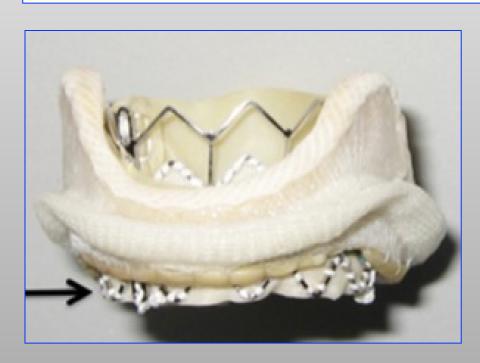
Reasons for increasing use of Bioprosthesis

- Newer generation bioprosthesis are more durable and better.
- Reoperation rates for patients over 65 years of age are particularly low with modern stented bioprostheses,
- Patients undergoing AVR today are older population than those studied in the randomized trials.
- Young patients undergoing aortic valve surgery are often reluctant to accept warfarin therapy and the activity constraints associated with anticoagulants.
- There are some non randomized but relatively large comparative trials that have shown apparent survival benefit for patients receiving bioprostheses, particularly for those over the age of 65 years
- The risks of reoperation have continued to decrease, redo less dangerous, TAVI valve-in-valve

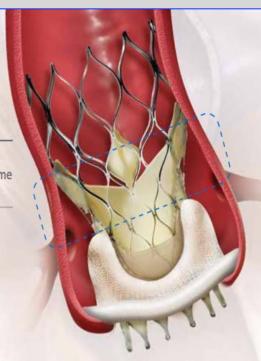
Journal of the American College of Cardiology © 2011 by the American College of Cardiology Foundation Published by Elsevier Inc.

Transcatheter Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

Ronen Gurvitch, MBBS,*† Anson Cheung, MD,* Jian Ye, MD,* David A. Wood, MD,* Alexander B. Willson, MBBS,* Stefan Toggweiler, MD,* Ronald Binder, MD,* John G. Webb, MD* Vancouver, British Columbia, Canada; and Melbourne, Victoria, Australia



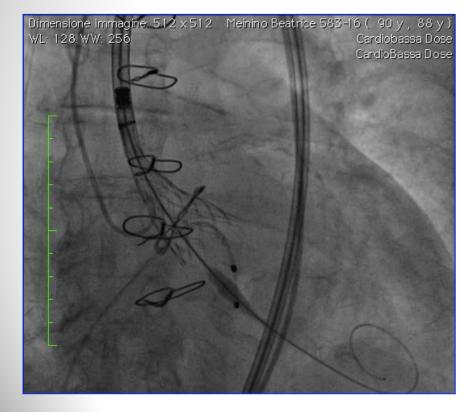




Cardiologia Maria Pia Hospital - Torino GVM Care & Research



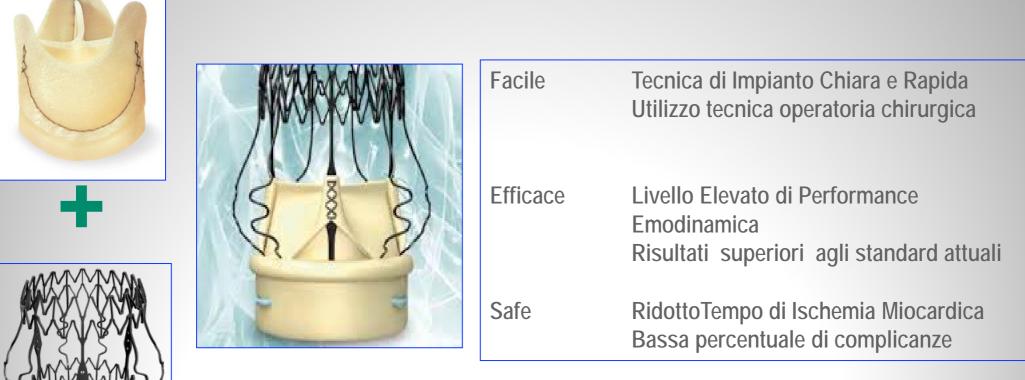






Sutureless





PERCEVAL S A NEW INNOVATIVE SELF-ANCHORING BIOPROSTHESIS: THE RESULTS OF THE FIRST 180 PATIENTS, AT 2 YEARS FOLLOW-UP

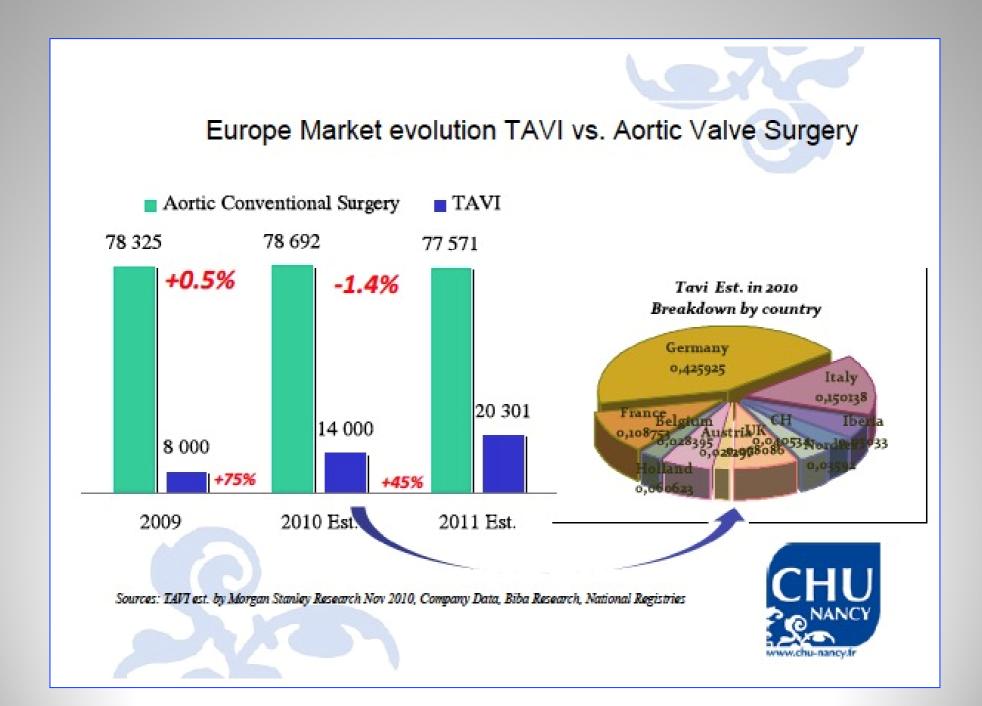
Prof. F. Laborde Institution: L'Institut Mutualiste Montsouris, Paris - France. Presentation: EACTS 2010, Geneva - Switzerland.





CELEBRATING 10 YEARS OF PERCEVAL CLINICAL USE Perceval is designed for Long Term Durability





2017 ESC/EACTS Guidelines for the

management of valvular heart disease

	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE <10%)*		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)*	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty ^b	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+

Favours Favours TAVI SAVR

Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient-prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+

	Favours TAVI	Favours SAVR
Cardiac conditions in addition to aor require consideration for concomita		
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy	8 8	+



2017 ESC/EACTS Guidelines for the management of valvular heart disease

Recommendations	Class*	Level ^t
Anticoagulation		
NOACs should be considered as an alterna- tive to VKAs in patients with aortic stenosis, aortic regurgitation and mitral regurgitation presenting with atrial fibrillation. ^{38–41}	lla	
NOACs should be considered as an alterna- tive to VKAs after the third month of mplantation in patients who have atrial ibrillation associated with a surgical or transcatheter aortic valve bioprosthesis.	lla	с
The use of NOACs is not recommended in patients with atrial fibrillation and moderate to severe mitral stenosis.		с
NOACS are contraindicated in patients with a mechanical valve. ⁴⁵	111	B

Surgical interventions		
Surgical ablation of atrial fibrillation should be considered in patients with symptomatic atrial fibrillation who undergo valve surgery. ³⁷	lla	A
Surgical ablation of atrial fibrillation may be considered in patients with asymptomatic atrial fibrillation who undergo valve surgery, if feasible, with minimal risk.	ШЬ	c
Surgical excision or external clipping of the LA appendage may be considered in patients undergoing valve surgery. ⁴⁶	ШЬ	8

Choice of prosthetic valve

The choice between a mechanical and a biological valve in adults is determined mainly by estimating the risk of anticoagulationrelated bleeding and thromboembolism with a mechanical valve versus the risk of structural valve deterioration with a bioprosthesis and by considering the patient's lifestyle and preferences. Rather than setting arbitrary age limits, prosthesis choice should be discussed in detail with the informed patient, cardiologists and surgeons, taking intoaccount the factors detailed below.



2017 ESC/EACTS Guidelines for the management of valvular heart disease

Choice of the aortic/mitral prosthesis in favour of a mechanical prosthesis; the decision is based on the integration of several of the following factors

Recommendations	Gass	Level®
A mechanical prosthesis is recommended according to the desire of the informed patient and if there are no contraindi- cations to long-term anticoagulation. ^c	1	c
A mechanical prosthesis is recommended in patients at risk of accelerated structural valve deterioration. ^d	1	С
A mechanical prosthesis should be considered in patients already on anticoagulation because of a mechanical prosthesis in another valve position.	lla	с
A mechanical prosthesis should be considered in patients <60 years of age for prostheses in the aortic position and <65 years of age for prostheses in the mitral position. ⁴	lla	с
A mechanical prosthesis should be considered in patients with a reasonable life expectancy ⁴ for whom future redo valve surgery would be at high risk.	lla	с
A mechanical prosthesis may be considered in patients already on long-term anticoagulation due to the high risk for thromboembolism ⁸	нь	с



2017 ESC/EACTS Guidelines for the management of valvular heart disease

Choice of the aortic/mitral prosthesis in favour of a bioprosthesis; the decision is based on the integration of several of the following factors

Recommendations	Class*	Level
A bioprosthesis is recommended according to the desire of the informed patient.	U.	C
A bioprosthesis is recommended when good-quality anticoagulation is unlikely (compliance problems, not readily available) or contrain- dicated because of high bleeding risk (previous major bleed, comorbidities, unwillingness, compliance problems, lifestyle, occupation).	1	c
A bioprosthesis is recommended for reoperation for mechanical valve thrombosis despite good long-term anticoagulant control.	- 4 (C
A bioprosthesis should be considered in patients for whom there is a low likelihood and/or a low operative risk of future redo valve surgery.	la .	с
A bioprosthesis should be considered in young women contemplating pregnancy.	lla	C
A bioprosthesis should be considered in patients >65 years of age for a prosthesis in the aartic position or > 70 years of age in a mitral position or those with a life expectancy ⁴ lower than the presumed durability of the bioprosthesis. ⁴	la .	C



Conclusion



Improvements in tissue valves and implantation technique may reduce structural valve deterioration, thus improving valve durability and reducing reoperation rates.

Any or all of these innovations would substantially affect the current considerations in prosthetic valve selection.

Optimal valve selection results when the patient and provider carefully consider the advantages and disadvantages of each valve type in the context of the individual patient's age, clinical conditions, values, and lifestyle desires.



Grazie, Dr.ssa Chiara Comoglio Dr. Riccardo Casabona

> Cardiovascular Department Maria Pia Hospital - Torino

> > GVM Care & Research

