

Il percorso clinico del paziente con protesi valvolari e valvole artificiali
percutanee
Milano, 28-29 Ottobre 2010

Indicazioni alla terapia chirurgica del
distacco protesico. Quando il distacco
non va operato?

L.A.Menicanti
IRCCS Policlinico San Donato

QUANDO E'
LIEVE – MODERATO
SENZA IMPEGNO
EMODINAMICO
E SENZA EMOLISI

Clinical Significance of Turbulence

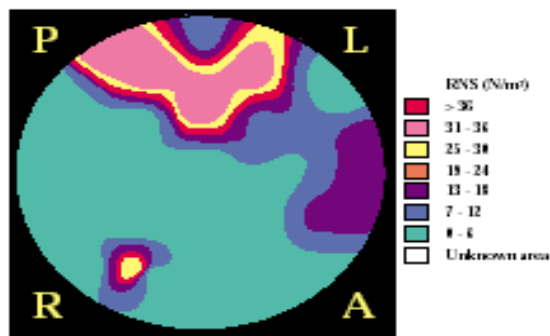
Turbulent blood flow downstream of prosthetic valves has been shown to:

- Cause severe damage to blood cells
- Contribute to thrombus formation
- Create stress on the heart leading to hypertrophy of the left ventricle¹



Normal Aortic Valve

For normal valves, the maximum RNS value was below 4 N/m^2 , whereas the averaged mean systolic RNS value was below 2 N/m^2 .¹³



Stenotic Native Valve

For stenotic valves, the maximum RNS value was up to 30 N/m^2 and the averaged mean RNS value was up to 7 N/m^2 .¹³

Figure 3a. Turbulent stress distributions in the normal aortic and stenotic native valve.¹³

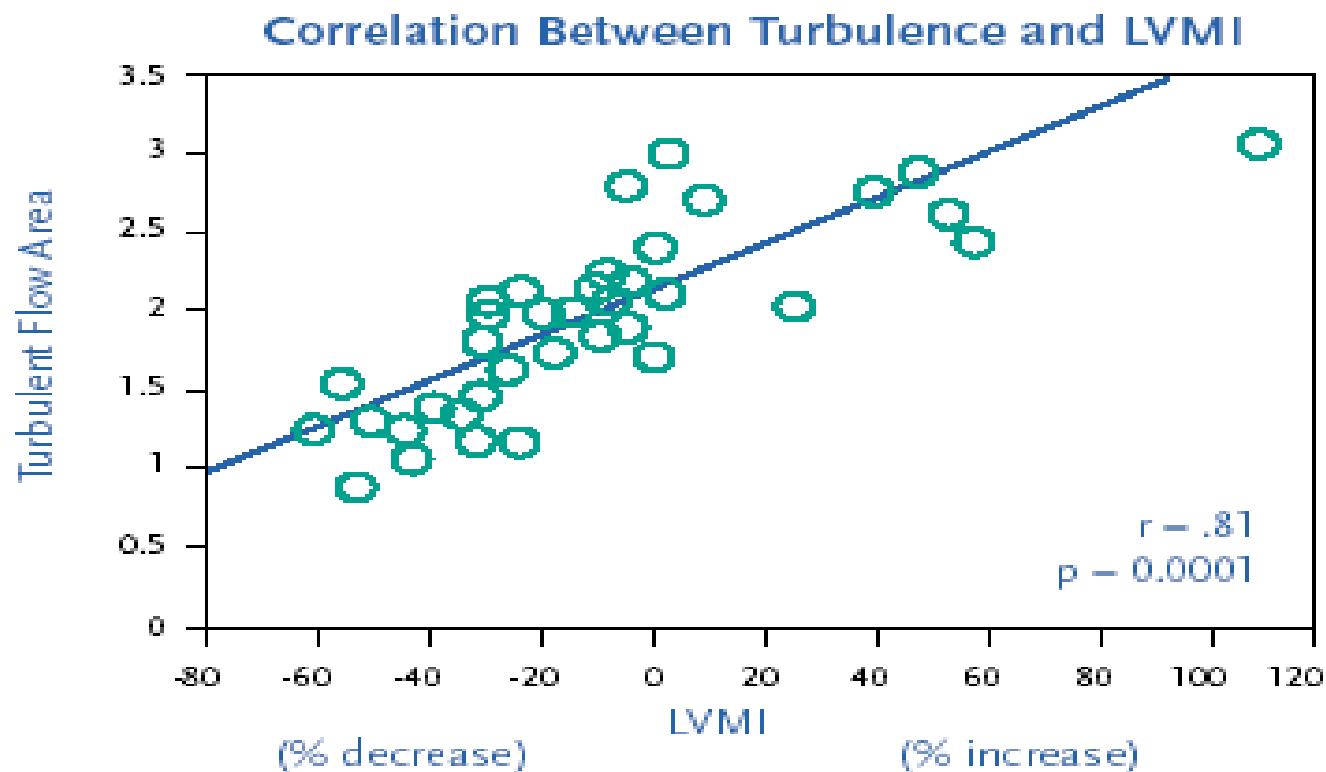
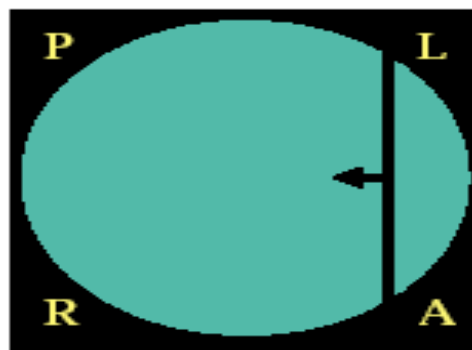


Figure 5. A strong correlation ($r = 0.81$, $p < 0.0001$) was found to exist between turbulence and LVMI.



90° Mean 6.0 Max 24
St. Jude Medical Valve

For the SJM valve, the maximum RNS value was 24 N/m^2 whereas the averaged mean systolic RNS value was 6 N/m^2 .¹



135° Mean 2.8 Max 6
Medtronic Hall™ Valve



For the Medtronic Hall valve, the maximum RNS value was 6 N/m^2 and the averaged mean RNS value was 2.8 N/m^2 .¹

Figure 3b. Turbulent stress distributions in the St. Jude Medical and Medtronic Hall valve.

Orientamento del flusso

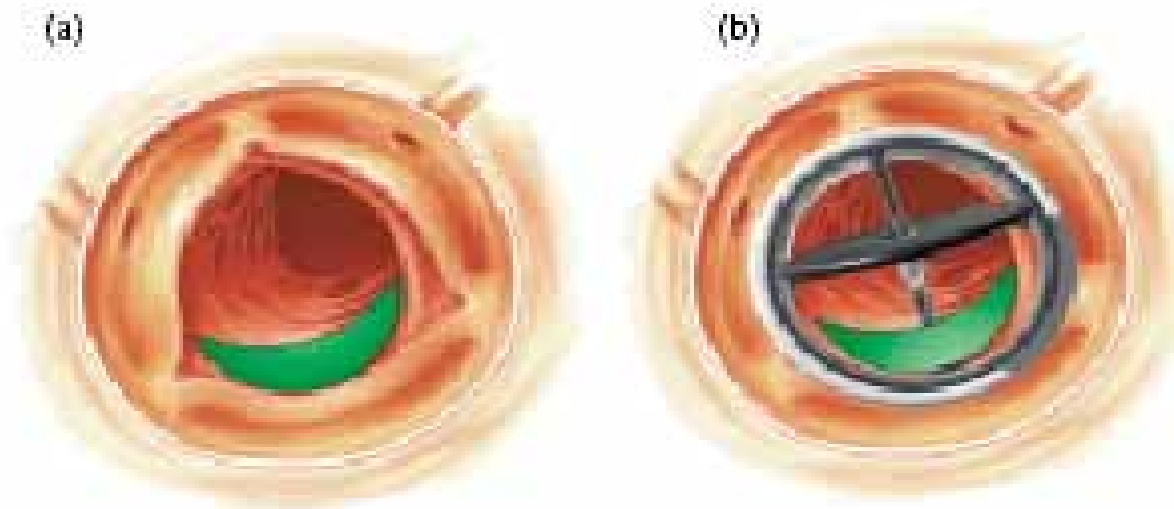


Figure 7. (a) Cross-sectional representation of region of highest blood flow velocities through the native aortic valve and (b) proper orientation of the Medtronic Hall[®] and the Hall-Easy Fit[™] valves.

Energy Loss Due to Paravalvular Leak With Transcatheter Aortic Valve Implantation

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Department of Surgery, University of California at San Francisco Medical Center, and San Francisco Veterans Affairs Medical Center, San Francisco, California

Background. Mild to moderate paravalvular leaks commonly occur after transcatheter aortic valve (TAV) implantation. Current TAVs match and may exceed hemodynamic performance of surgically implanted bioprostheses based on pressure gradient and effective orifice area. However, these hemodynamic criteria do not account for paravalvular leaks. We recently demonstrated that TAV implantation within 23 mm Perimount bioprostheses (Edwards Lifesciences, Irvine, CA) yields similar hemodynamics to the 23 mm Perimount valve. However, mild paravalvular leakage was seen after TAV implantation. The present study quantifies energy loss during the entire cardiac cycle to assess the impact of TAV paravalvular leaks on the ventricle.

Methods. Four TAVs designed to mimic the 23 mm SAPIEN valve (Edwards Lifesciences) were created. Transvalvular energy loss of 19, 21, and 23 mm Carpentier-Edwards bioprostheses were obtained in vitro within a pulse duplicator as a hemodynamic baseline ($n = 4$). The 23 mm TAVs were subsequently implanted within

the 23 mm bioprostheses to assess energy loss due to paravalvular leak.

Results. The 23 mm bioprosthesis demonstrated the least energy loss (213.25 ± 31.35 mJ) compared with the 19 mm (330.00 ± 36.97 mJ, $p = 0.003$) and 21 mm bioprostheses (298.00 ± 37.25 mJ, $p = 0.008$). The TAV controls had similar energy loss (241.00 ± 30.55 mJ, $p = 0.17$) as the 23 mm bioprostheses. However, after TAV implantation, total energy loss increased to 365.33 ± 8.02 mJ significantly exceeding the energy loss of the 23 mm bioprosthesis ($p < 0.001$). Due to mild TAV paravalvular leakage, 39% of energy loss occurred during diastole.

Conclusions. Substantial energy loss during diastole occurs due to TAV paravalvular leakage. In the presence of mild paravalvular leakage, TAV implantation imposes a significantly higher workload on the left ventricle than an equivalently sized surgically implanted bioprosthesis.

(Ann Thorac Surg 2009;88:1857–63)

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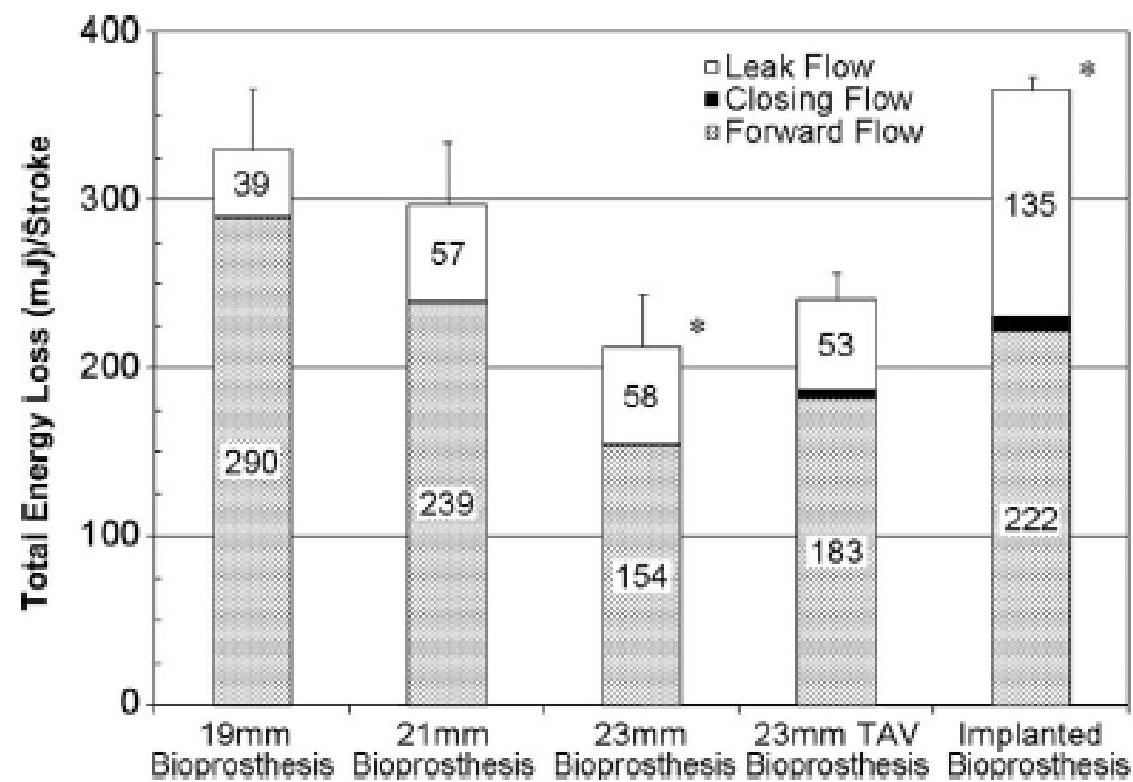


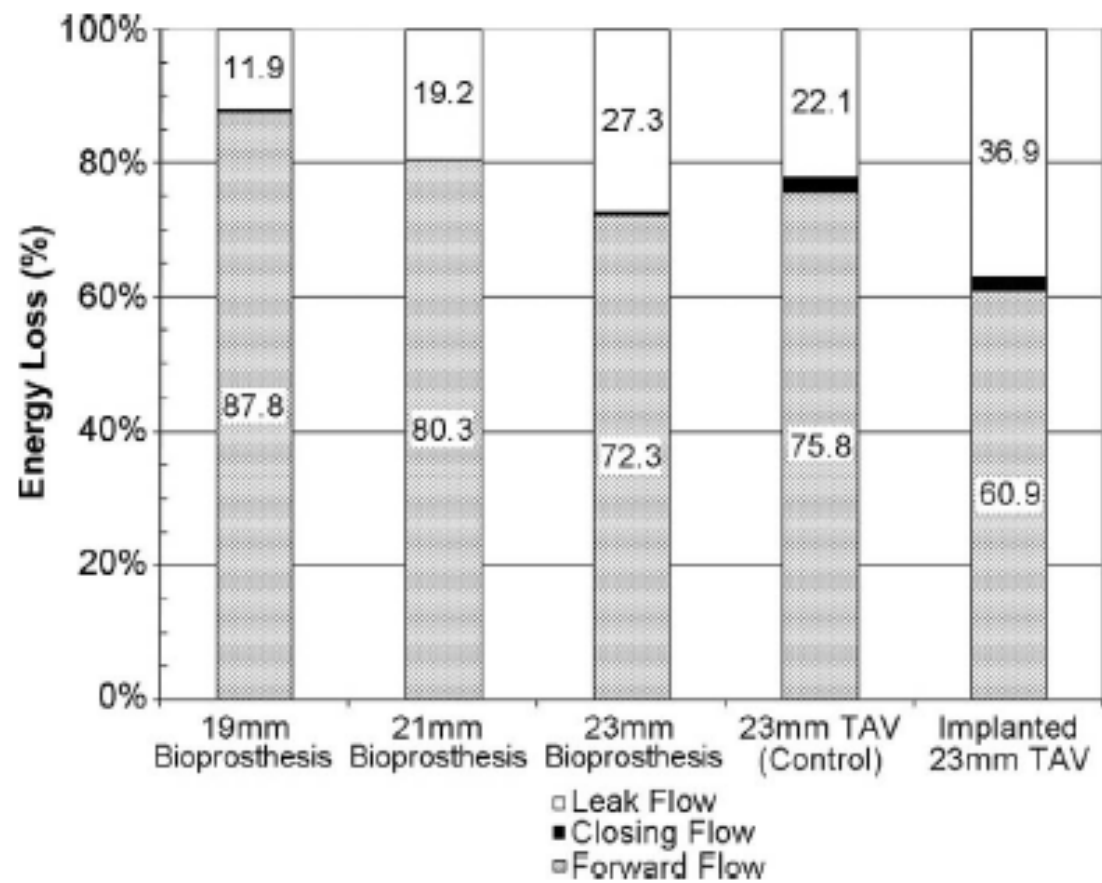
Fig 3. Total energy loss of three Carpentier-Edwards Perimount bioprostheses, and the TAV before and after implantation within the 23mm bioprosthesis. (□ = leak flow; ■ = closing flow; ▨ = forward flow; * is $p < 0.001$.)

Table 1. Hemodynamics of Carpentier-Edwards Perimount Bioprostheses and the 23 mm TAV Before and After Implantation Within the 23 mm Bioprosthesis [16]

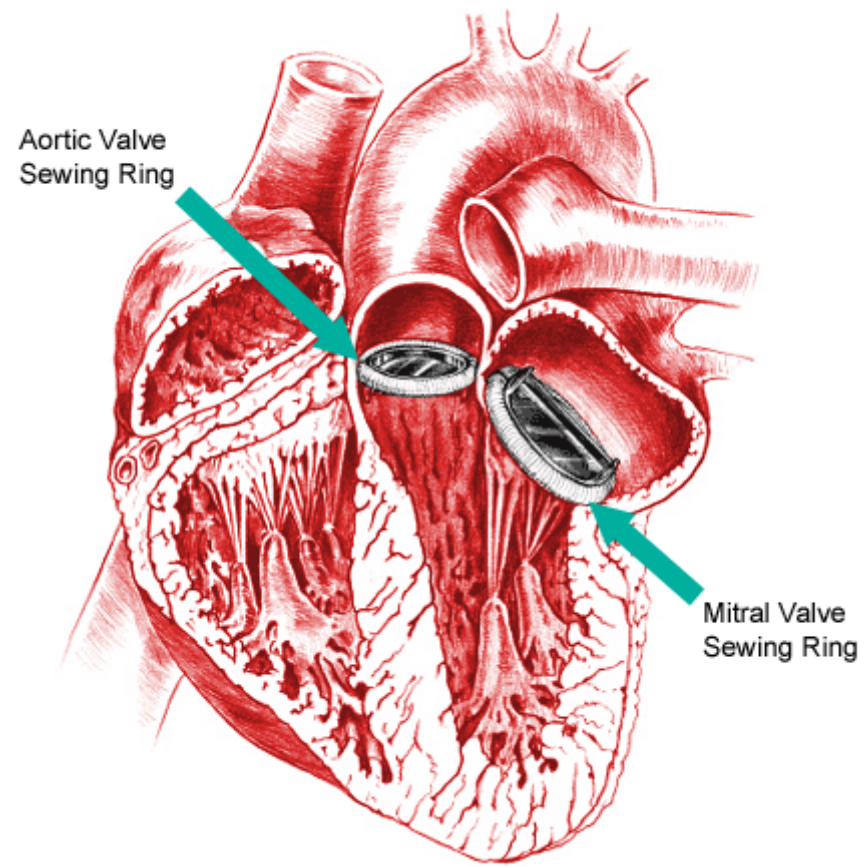
	Mean Pressure Gradient (mm Hg)	Effective Orifice Area (cm ²)	Regurgitation Fraction (%)
19 mm bioprosthesis	16.2 ± 2.2	1.3 ± 0.1	6.1 ± 1.0
21 mm bioprosthesis	11.8 ± 1.9	1.5 ± 0.2	8.2 ± 2.0
23 mm bioprosthesis	5.9 ± 0.9	2.1 ± 0.2	8.4 ± 1.8
23 mm TAV (control)	6.8 ± 1.0	2.0 ± 0.1	10.6 ± 1.4
Implanted TAV	8.3 ± 1.2	1.8 ± 0.2	19.1 ± 0.9

TAV = transcatheter aortic valve.

Fig 4. Percentage of energy loss during forward, closing, and leak flow. (□ = leak flow; ■ = closing flow; ▨ = forward flow.)



However, mild to moderate paravalvular leak frequently occurs after TAV implantation. In this study, we demonstrated that a substantial portion of TAV energy loss is due to the paravalvular leak and in the presence of mild prosthetic regurgitation, energy loss during diastole is comparable to energy loss during systole. The TAV implantation with mild regurgitation imposes a significantly higher workload on the left ventricle than surgical aortic valve replacement of equivalent bioprosthetic size. Paravalvular leak is expected to remain the major issue to be addressed in the next generation of TAVs, if TAV indications are expanded to younger and healthier patients



Aortic Valve
Sewing Ring

Mitral Valve
Sewing Ring

Perché una valvola protesica può staccarsi?

1) QUALITÀ DEI TESSUTI SU CUI È SUTURATA:

TESSUTI FRAGILI (PAZIENTI IN TRATTAMENTO CORTISONICO)

TESSUTI CALCIFICI

2) TECNICA DI SUTURA , continua , punti semplici, punti a U, punti a U con pledget

3) DISPROPORZIONE tra l'anello nativo e l'anello protesico

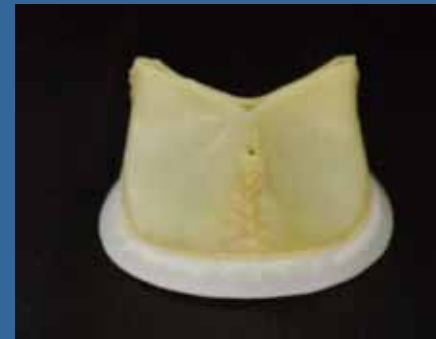
4) INFEZIONI



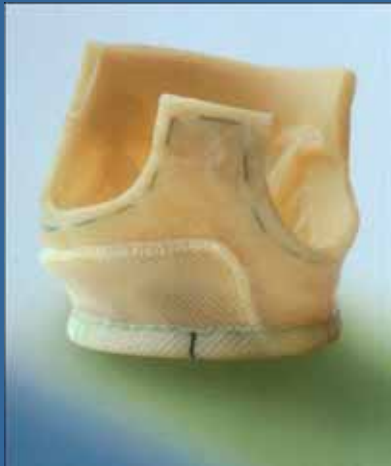
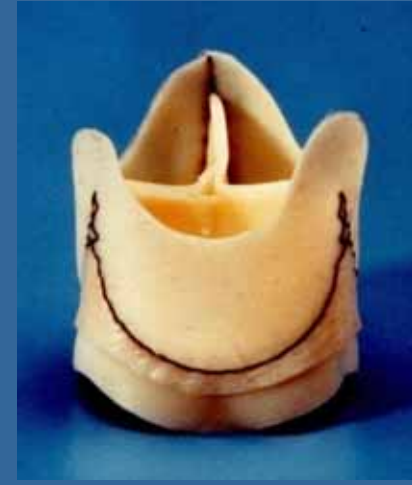
Stented Porcine Bioprostheses

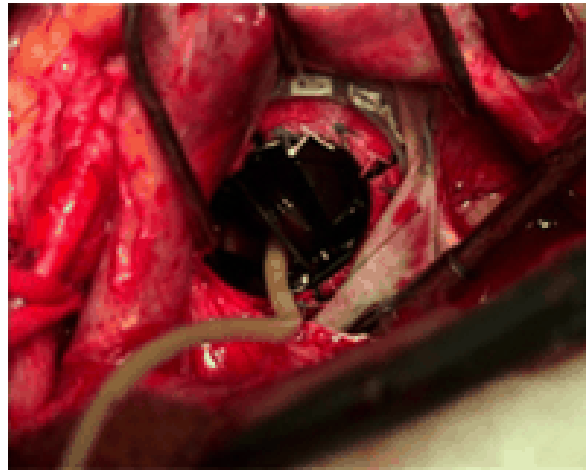
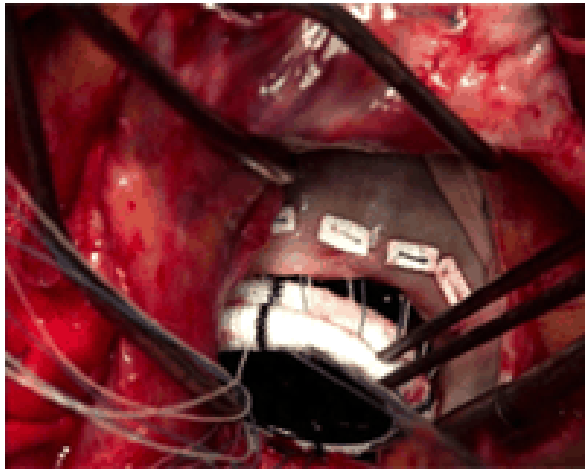
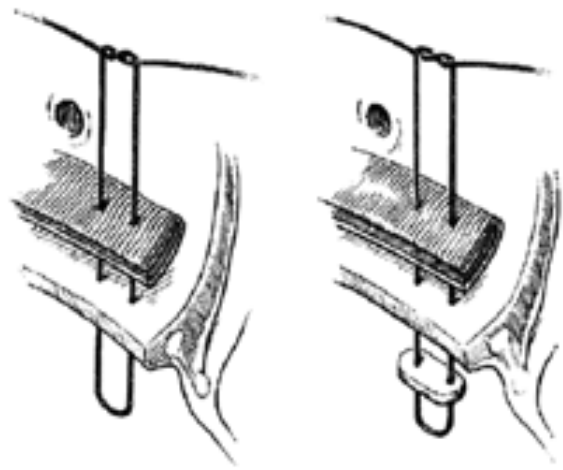
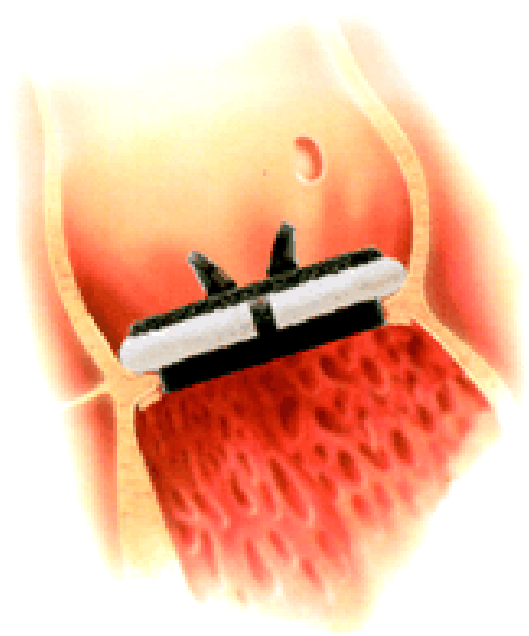
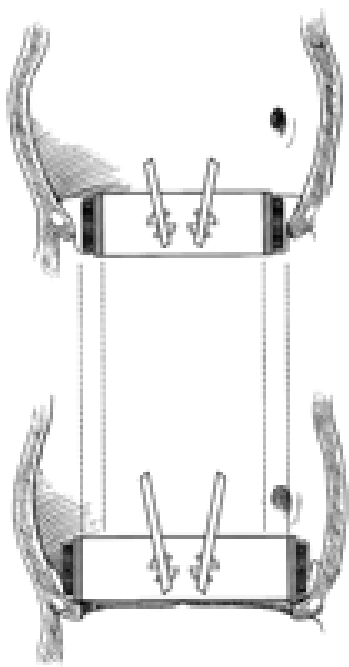


Pericardial Stented & Stentless Bioprostheses



Stentless Alternatives





Importance of implant technique on risk of major paravalvular leak (PVL) after St. Jude mechanical heart valve replacement: a report from the Artificial Valve Endocarditis Reduction Trial (AVERT)[☆]

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Table 7
Multivariable model and predictors for major PVL

Attribute	Hazard ratio	95% CI	p value*
Silzone valve versus conventional	2.5	(0.98, 6.52)	0.055
Use of pledget	0.3	(0.12, 0.69)	0.005
	Number of PVL events	Number of patients	Percentage
Conventional valve	6	404	1.5
Silzone valve	15	403	3.7
No pledget use	9	172	5.8
Pledget use	9	635	1.7

* Results of the multivariable model.

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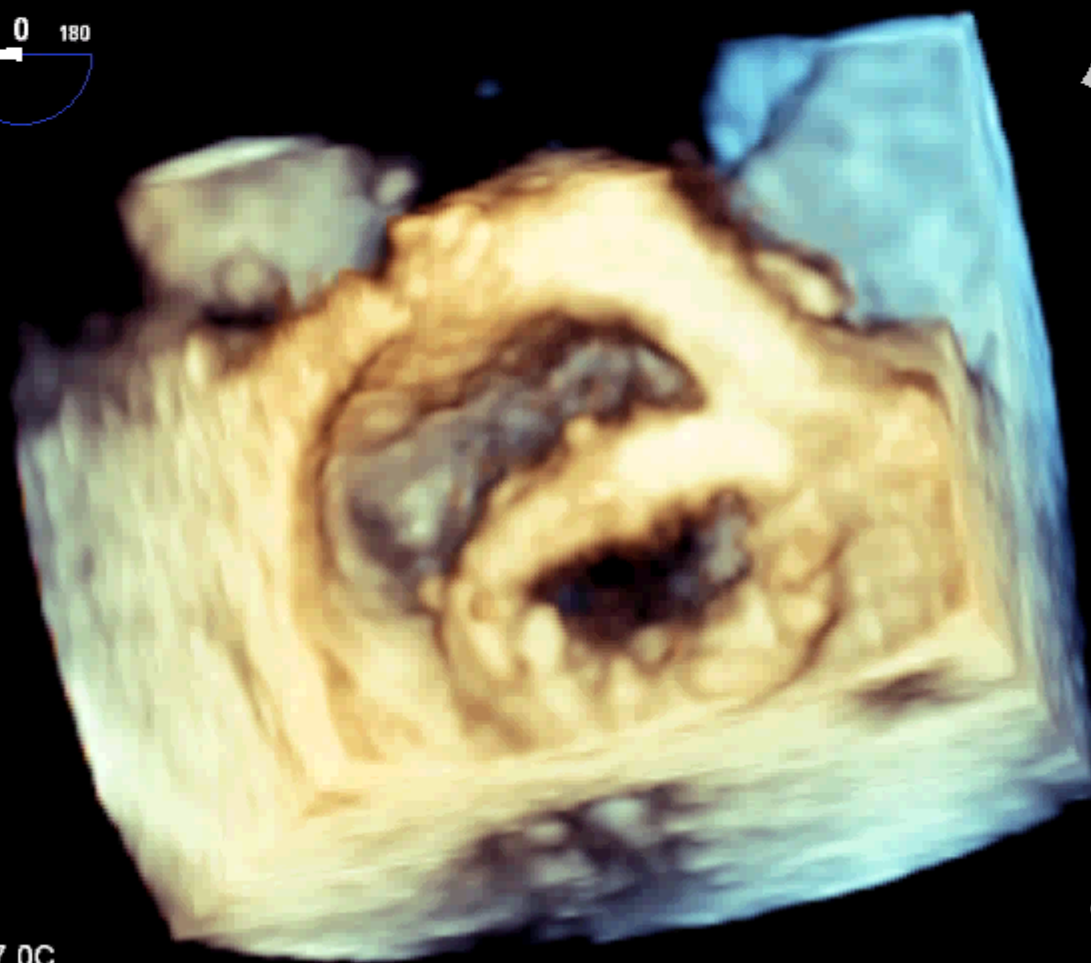
ITm0.2 IM 0.5

X7-2t/Adulte

CI 12Hz
11cm

C4

3D Live
3D 21%
3D 40dB
Gén



JPEG

T PAT: 37.0C
T ETO: 38.9C

75 bpm

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ITm0.2 IM 0.5

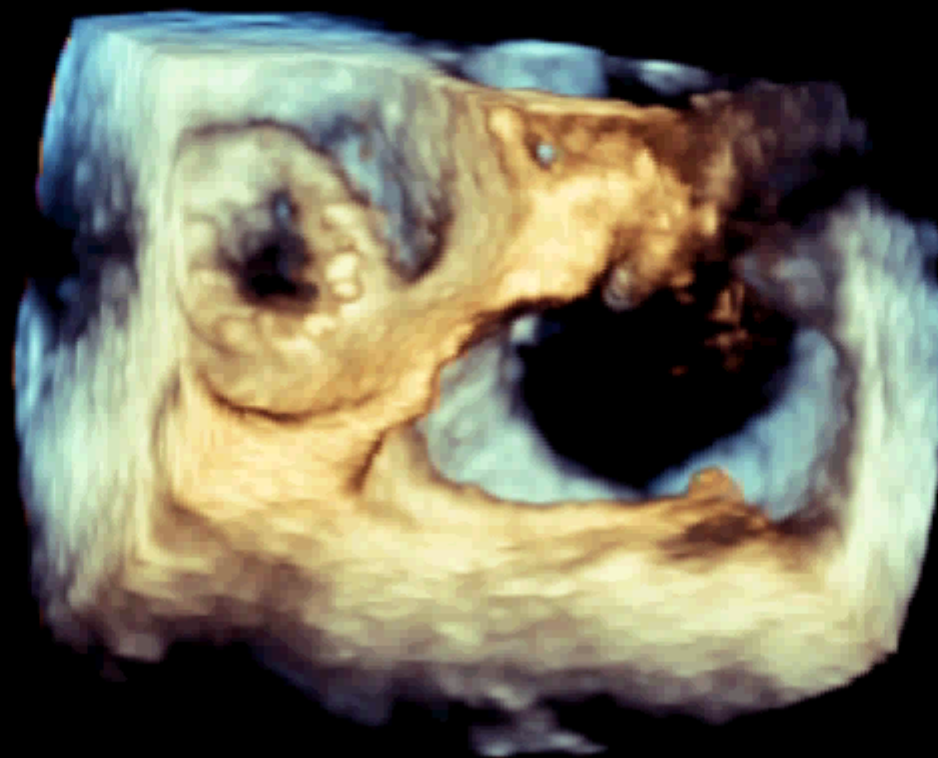
X7-2t/Adulte

CI 8Hz
12cm

3D Live
3D 20%
3D 40dB
Gén



C4



JPEG

T PAT: 37.0C
T ETO: 39.4C

75 bpm

PHILIPS

11/03/2009 20:52:10

ITm0.3 IM 0.5

X7-2t/ETO

CI 8Hz
7.5cm

3D Live
3D 27%
3D 40dB
Gén



C4



JPEG

117 bpm

T PAT: 37.0C
T ETO: 39.6C

- Reoperation to replace a prosthetic heart valve is a **serious clinical event**. It is usually required for moderate to severe prosthetic dysfunction (structural and nonstructural), **dehiscence**, and prosthetic endocarditis. Reoperation may also be needed for **recurrent thromboembolism**, severe intravascular hemolysis, severe recurrent **bleeding** from anticoagulant therapy, and thrombosed prosthetic valves

ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): Developed in Collaboration With the Society of Cardiovascular Anesthesiologists : Endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons

Circulation 2006;114:450-527



- For the patient with **catastrophic** prosthetic valvular dysfunction, **surgery is clearly indicated and urgent.**
- The patient without endocarditis or severe prosthetic valve dysfunction requires careful hemodynamic evaluation, and the decision about reoperation should then be based on ***hemodynamic abnormalities, symptoms, ventricular function, and current knowledge of the natural history of the particular prosthesis.***



GUIDELINES AND STANDARDS

Recommendations for Evaluation of Prosthetic Valves With Echocardiography and Doppler Ultrasound

A Report From the American Society of Echocardiography's Guidelines and Standards Committee and the Task Force on Prosthetic Valves, Developed in Conjunction With the American College of Cardiology Cardiovascular Imaging Committee, Cardiac Imaging Committee of the American Heart Association, the European Association of Echocardiography, a registered branch of the European Society of Cardiology, the Japanese Society of Echocardiography and the Canadian Society of Echocardiography, Endorsed by the American College of Cardiology Foundation, American Heart Association, European Association of Echocardiography, a registered branch of the European Society of Cardiology, the Japanese Society of Echocardiography, and Canadian Society of Echocardiography

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- Tutte le protesi comportano un certo livello di **ostruzione**, *la cui entità dipende dal modello, dalla taglia e dall'orientamento (meccaniche)*
- La maggior parte delle protesi meccaniche presenta un **rigurgito**, con **morfologia e severità peculiari a ogni singolo modello.**

- **Si deve quindi analizzare in una situazione antifisiologica, il grado di anomalia al di sopra del quale si parla di disfunzionamento**

- Lo stato clinico del paziente e' **FONDAMENTALE** per definire il grado di disfunzione, noi trattiamo persone non numeri che definiscono gradienti o volumi di rigurgito
- Se esistono incongruenze tra stato clinico e parametri fluidodinamici uno stretto follow-up puo' essere la soluzione piu' saggia

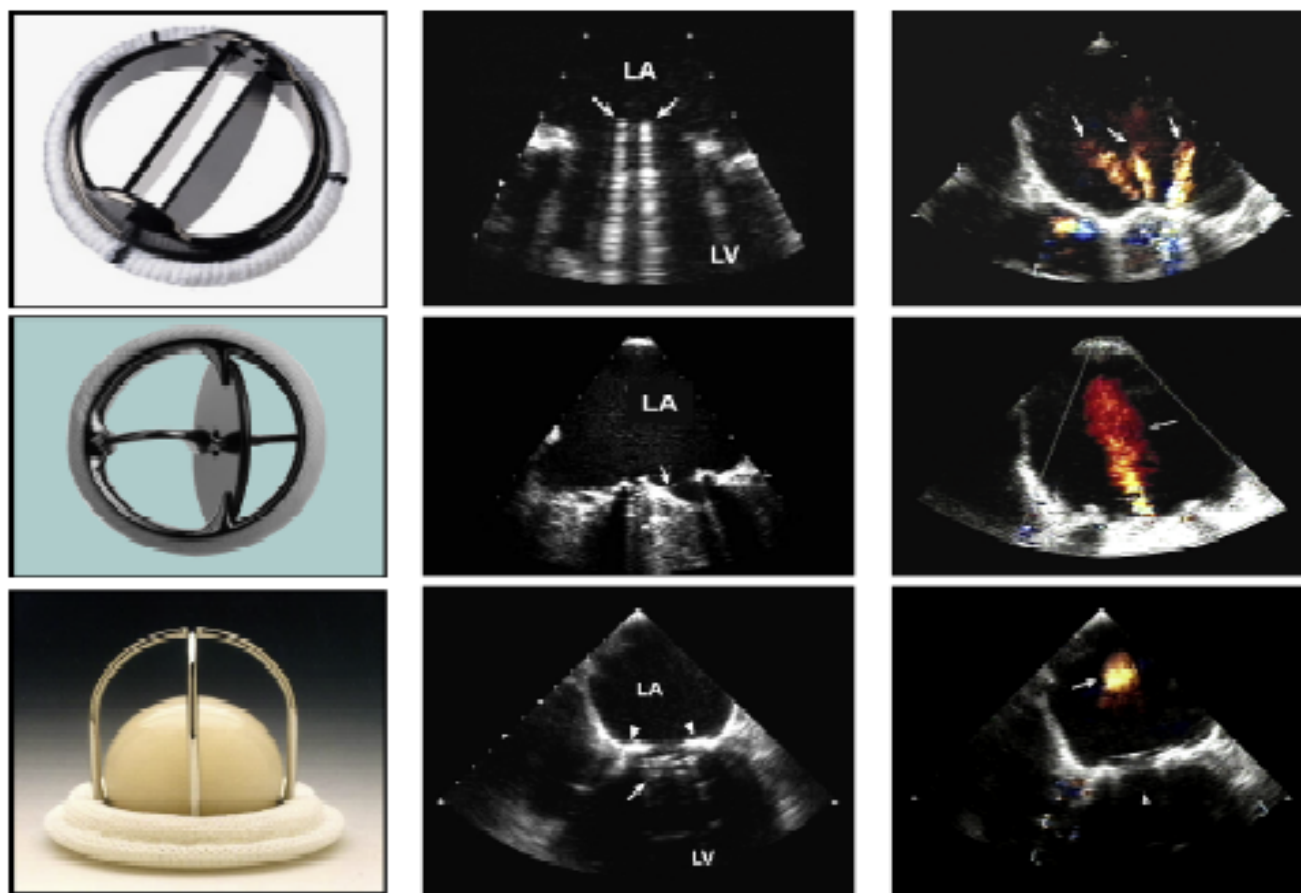


Figure 1 Examples of bileaflet, single-leaflet, and caged-ball mechanical valves and their transesophageal echocardiographic characteristics taken in the mitral position in diastole (*middle*) and in systole (*right*). The arrows in diastole point to the occluder mechanism of the valve and in systole to the characteristic physiologic regurgitation observed with each valve. Videos 1 to 6 show the motion and color flow patterns seen with these valves. [View video clips online.](#)

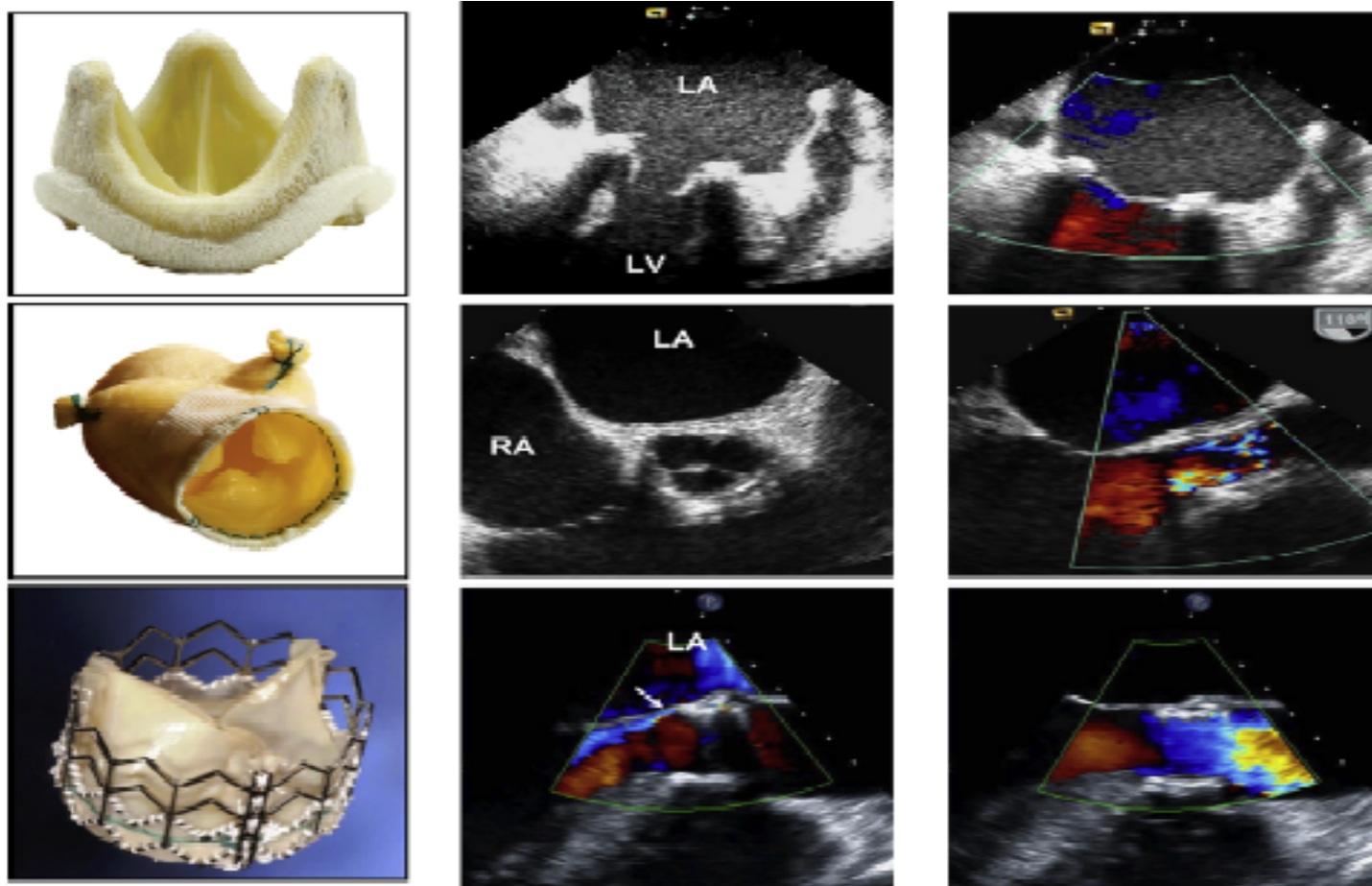


Figure 2 Examples of stented, stentless, and percutaneous biologic valves and their echocardiographic features in diastole (*mid/dle*) and in systole (*right*) as seen by TEE. The stentless valve is inserted by the root inclusion technique. Mild perivalvular AR in the percutaneous valve is shown by arrow. The percutaneous biologic valve is currently for investigational use only. Videos 7 to 10 show the valve motion and color Doppler flow pattern of these valves. [View video clips online.](#)

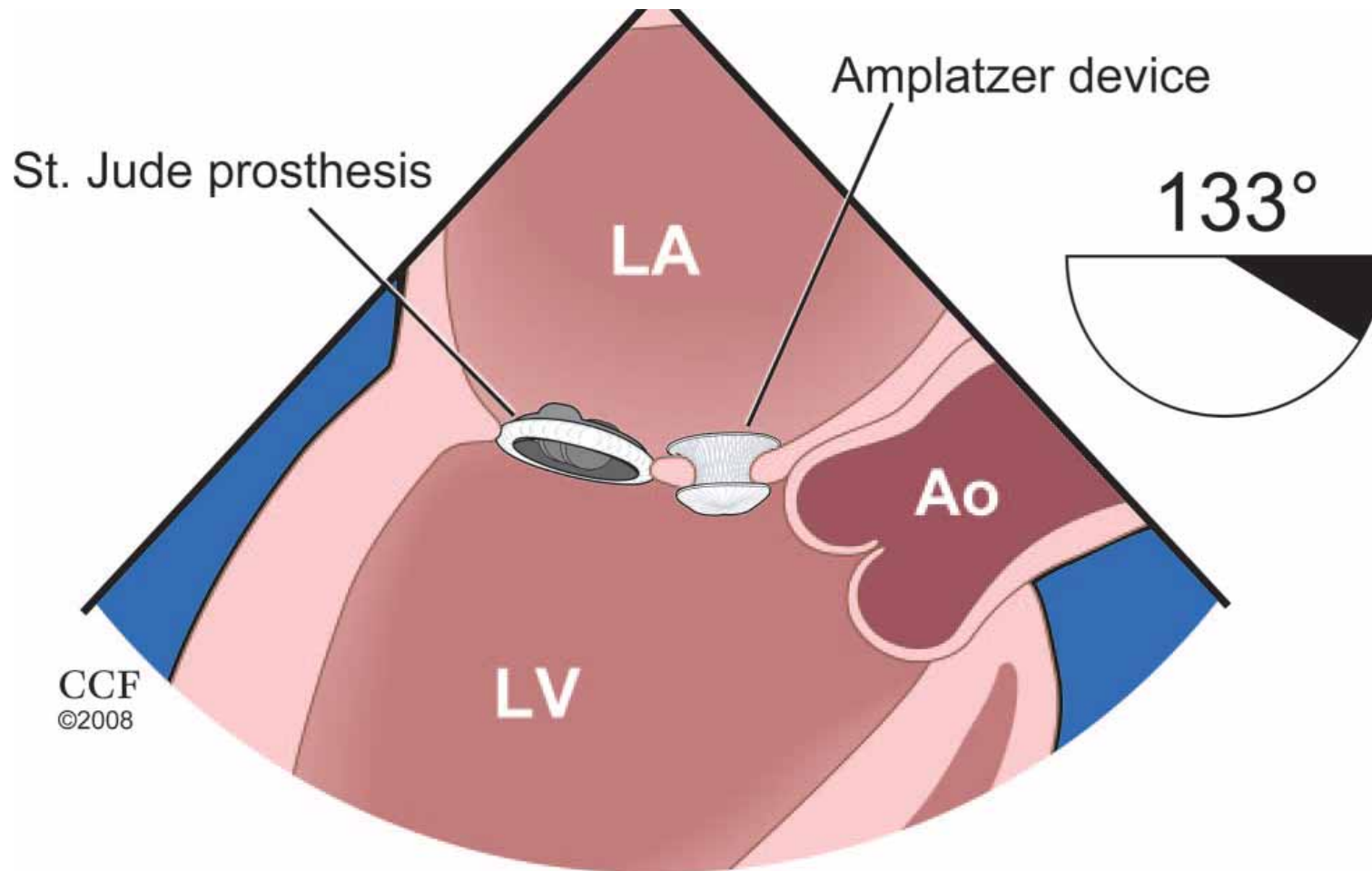
Mortalita' Reinterventi

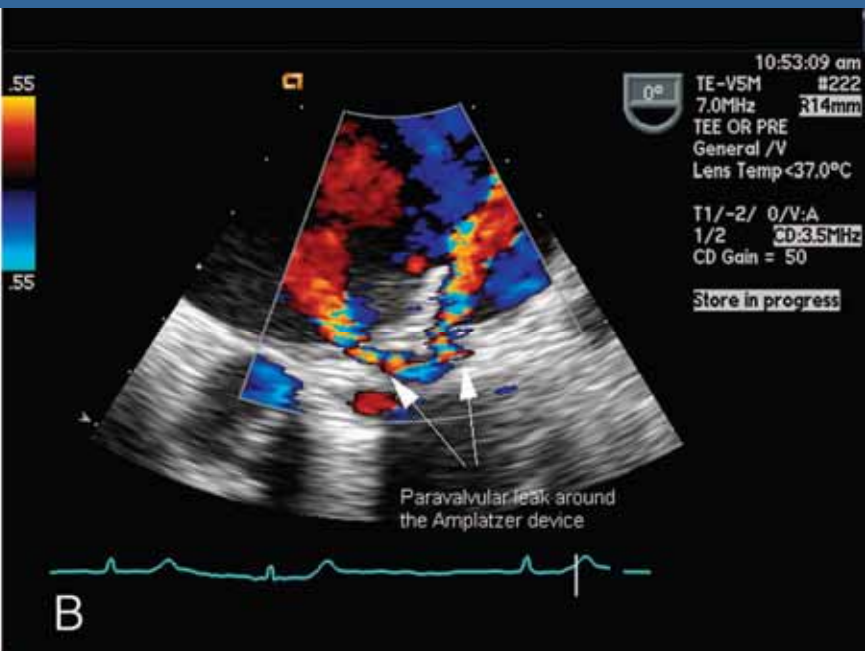
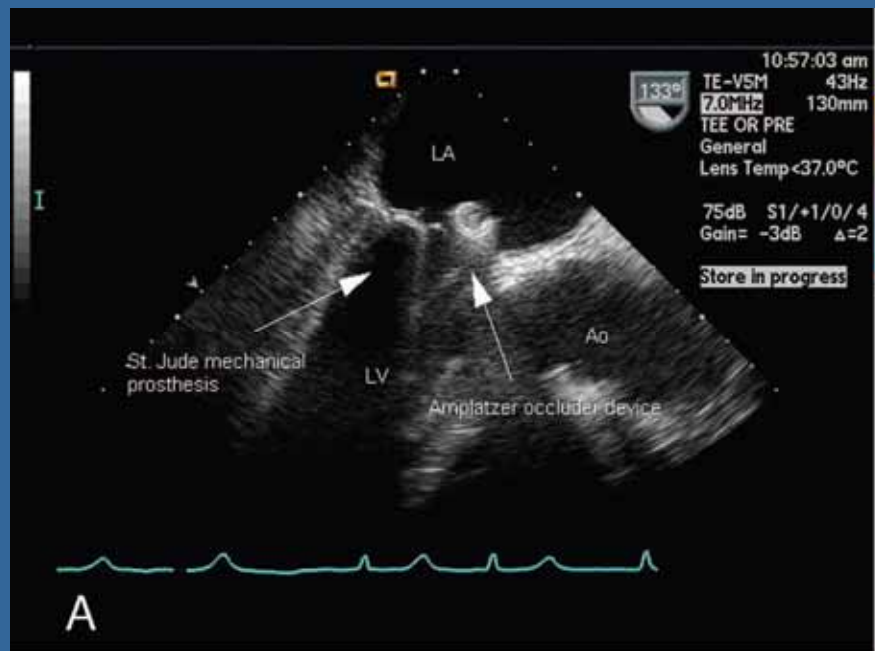
- Vancouver data set (2009)
7.3%
- Hanania (2003)
6 – 11%



Fig. 1

Effect of cardio-pericardial adhesions : after adhesiotomy, identification of the cardiac structures in redo surgery (right picture) is difficult compared with first cardiac operation (left picture).







ELSEVIER

European Journal of Cardio-thoracic Surgery 17 (2000) 14–19

EUROPEAN JOURNAL OF
CARDIO-THORACIC
SURGERY

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Paravalvular leakage after mitral valve replacement: improved long-term survival with aggressive surgery?[☆]

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Received 7 September 1999; received in revised form 23 November 1999; accepted 29 November 1999

Abstract

Background: Following mitral valve replacement, surgical closure of paravalvular leaks is usually advised in severely symptomatic patients and in those requiring blood transfusions for persisting haemolysis. However, the long-term prognosis of less symptomatic patients or those not needing blood transfusions is unknown. **Methods:** Between 1987 and 1997, we observed 96 patients with mitral paravalvular leakage. A paraprosthesis leak was diagnosed after a median time of 119 days (range: 1 day–23 years) after primary mitral valve replacement. During an average follow-up of 5 years (range: 1–23 years), 50/96 patients were referred for surgical closure. **Results:** Compared with patients who received conservative treatment, those referred for surgery had a significantly lower mean preoperative haematocrit ($P = 0.002$) with a higher proportion of patients being in the NYHA class III/IV ($P = 0.03$). Age, gender, left ventricular function and number and size of leaks did not differ between the groups. The 30-day postoperative mortality for valve reoperation was 6% (3/50); during follow-up three further patients died, resulting in an overall mortality rate of 12%. In the group treated conservatively there was a mortality rate of 26% (12/46). Thus, the actuarial survival for patients referred for surgery was 98, 90 and 88% after 1, 5 and 10 years, compared with 90, 75 and 68% for patients treated conservatively (long-rank $P = 0.03$). In addition, there was a significant increase in mean haematocrit levels ($P = 0.0001$) and an improvement in NYHA class III/IV symptoms ($P = 0.002$), vertigo ($P = 0.001$) and fatigue ($P = 0.001$) after surgery. **Conclusions:** Following mitral valve replacement, a more aggressive surgical treatment is recommended for patients with paraprosthesis leaks. Surgery should be offered to less symptomatic patients, as well as those not requiring blood transfusion. © 2000 Elsevier Science B.V.

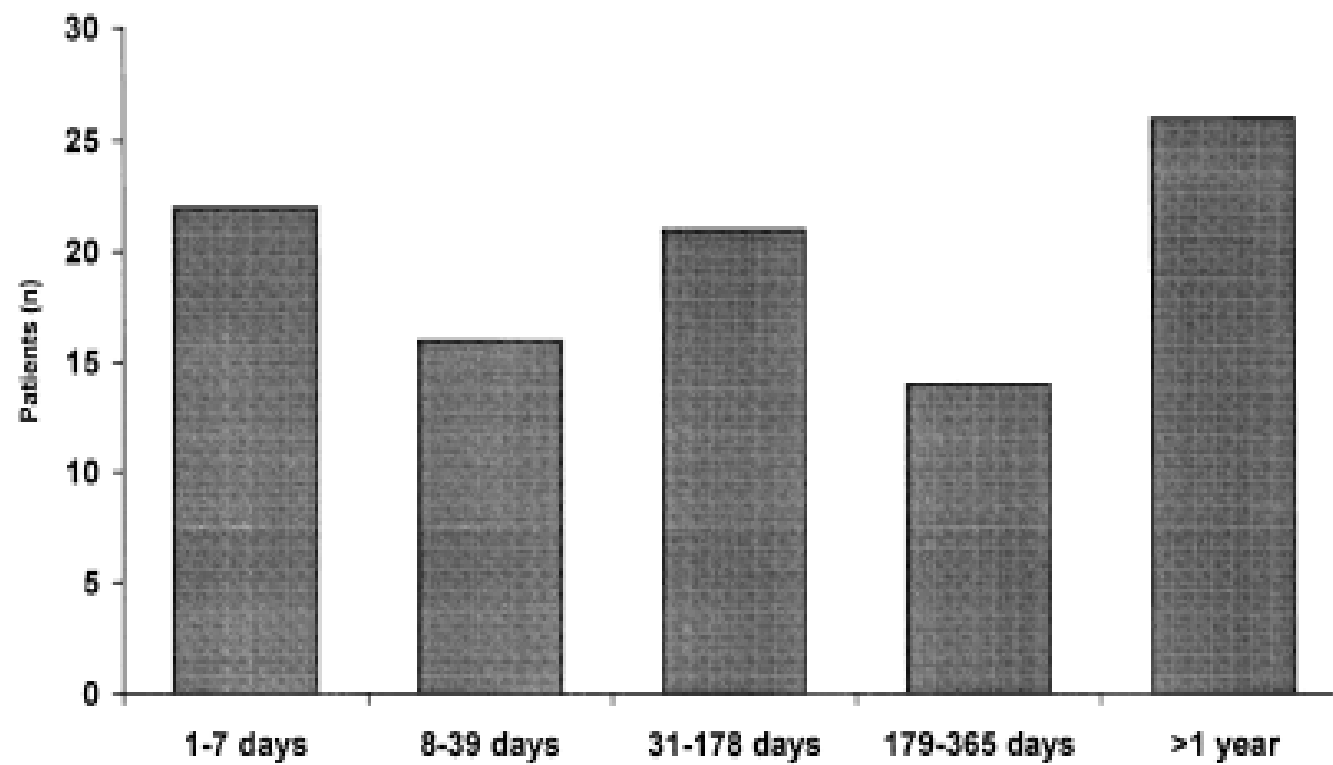


Fig. 2. Interval between mitral valve replacement and diagnosis of paravalvular leak.

Comparison of baseline data between surgically and conservatively treated patients

	<i>P</i> -value
Age	ns
Gender	ns
Size of leak	ns
Localization of leak	ns
Number of leaks	ns
Atrial size	ns
Fatigue	ns
Vertigo	ns
Interval between mitral valve replacement and diagnosis	ns
Underlying disease	ns
Coronary artery disease	ns
Diabetes mellitus	ns
Renal insufficiency	ns
Calcification of the mitral valve annulus	ns
NYHA class III/IV symptoms	0.029
Haematocrit	0.0016
LDH	0.0017

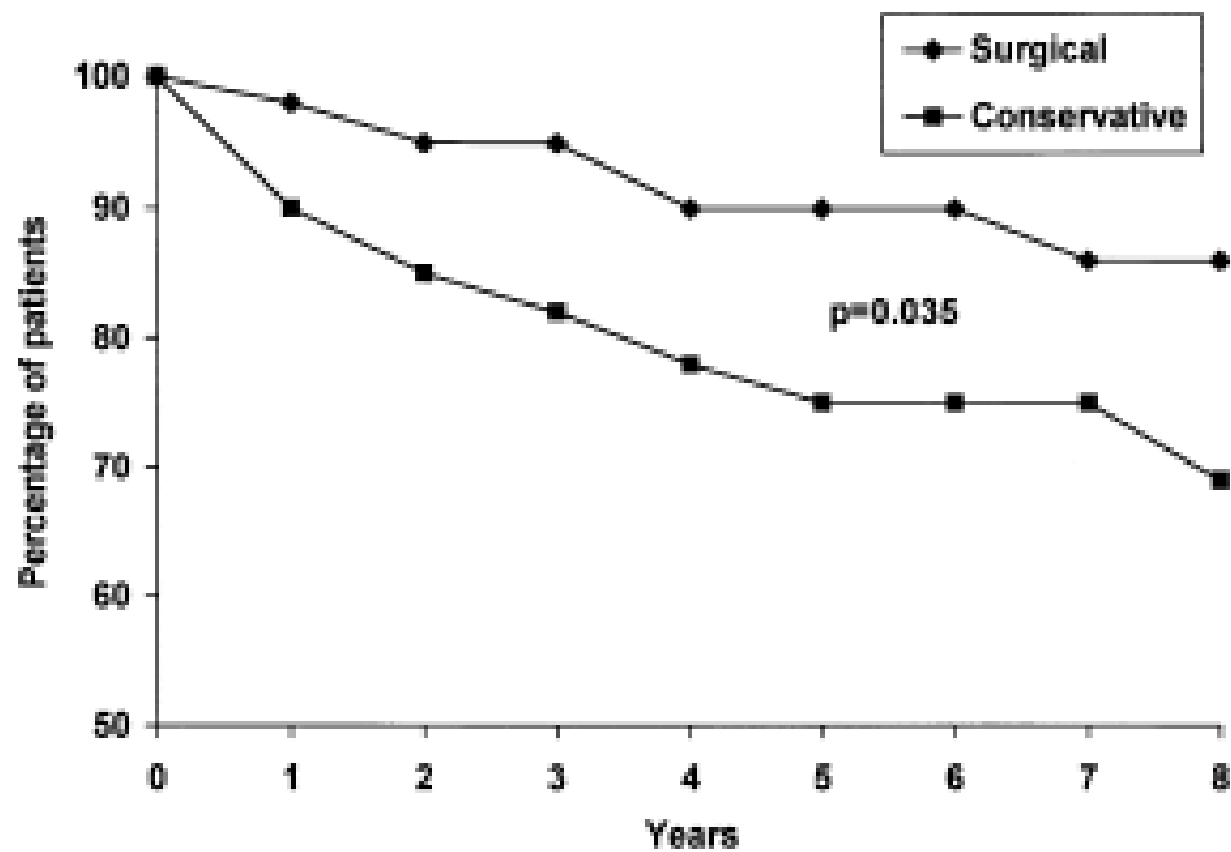


Fig 4. Influence of therapeutic strategy on survival.

Techniche Chirurgiche

- Sostituzione valvolare
- Asportazione trombi
- Pannectomia
- Riorientamento della protesì
- Risutura della protesì

Techniche Chirurgiche

- Techniche di sutura
- Scelta della seconda valvola
- Valve in valve percutanea ?
trans-apicale?

I Quesiti del Chirurgo

Situazione clinica e funzione cardiaca

Entita' della disfunzione

Causa della disfunzione

trombosi

panno

deiscenza

movimento meccanico

Endocardite

attiva

spenta

I Quesiti del Chirurgo

- ECO TRANS TORACICO
- ECOTRANSESOFAGEO
- FLUOROSCOPIA

QUANDO E'
LIEVE – MODERATO
SENZA IMPEGNO
EMODINAMICO
E SENZA EMOLISI

PHILIPS

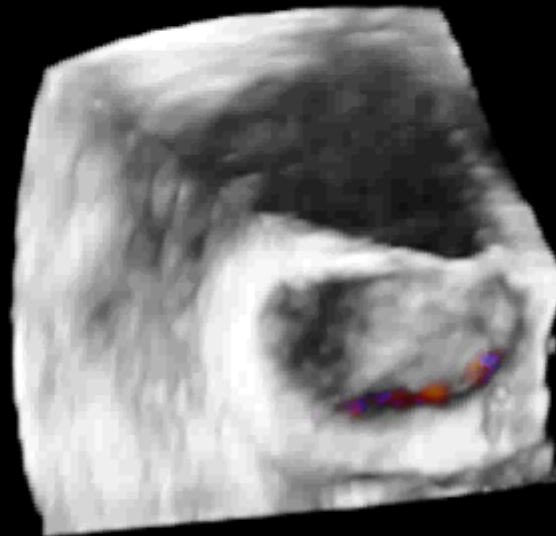
27/02/2009 13:51:28

ITm0.6 IM 0.8

X7-2t/ETO

CI 19Hz
7.0cm

Volume total 0 0 180
3D 47%
3D 40dB
Coul
50%
4.4MHz



T PAT: 37.0C
T ETO: 38.6C

JPEG

82 bpm

PHILIPS

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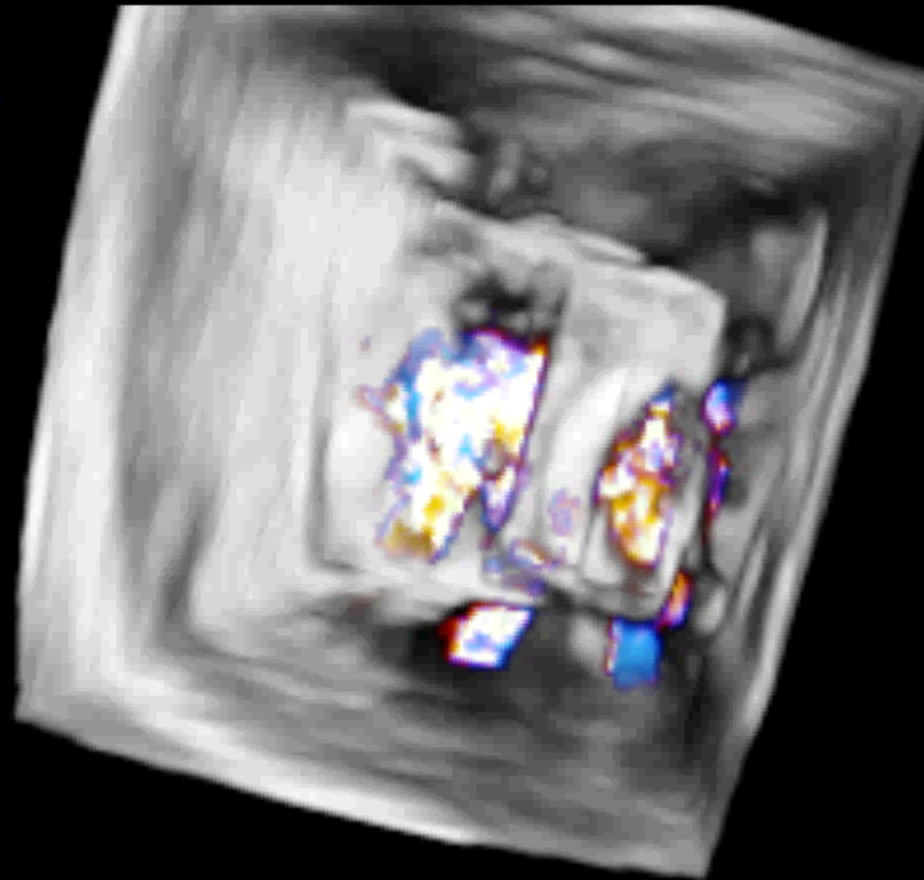
X7-2t/ETO

CI 18Hz
12cm

Volume total 0 5 180

3D 43%
3D 29dB

Coul
50%
4.4MHz



T PAT: 37.0C
T ETO: 38.9C

JPEG

105 bpm

PHILIPS

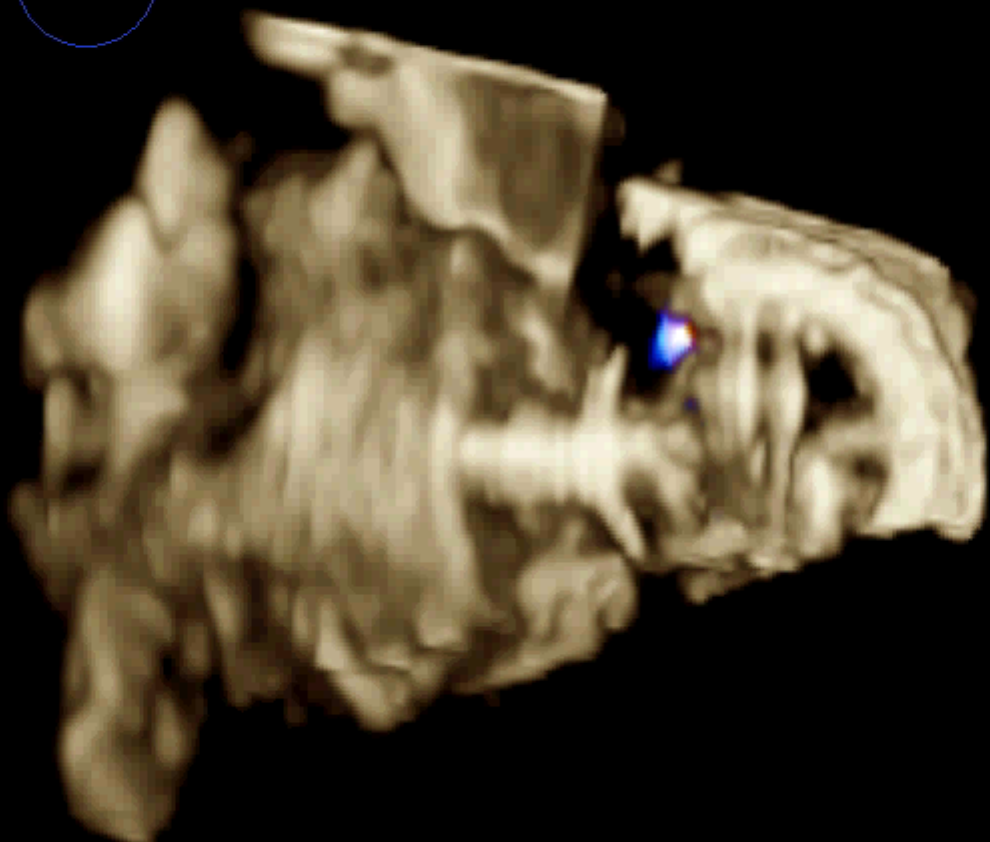
06/04/2009 12:06:37

ITm0.6 IM 0.8

X7-2t/ETO

CI 18Hz
12cm

Volume total 0 0 180
3D 2%
3D 21dB
Coul
50%
4.4MHz



T PAT: 37.0C
T ETO: 38.8C

JPEG

58 bpm

PHILIPS

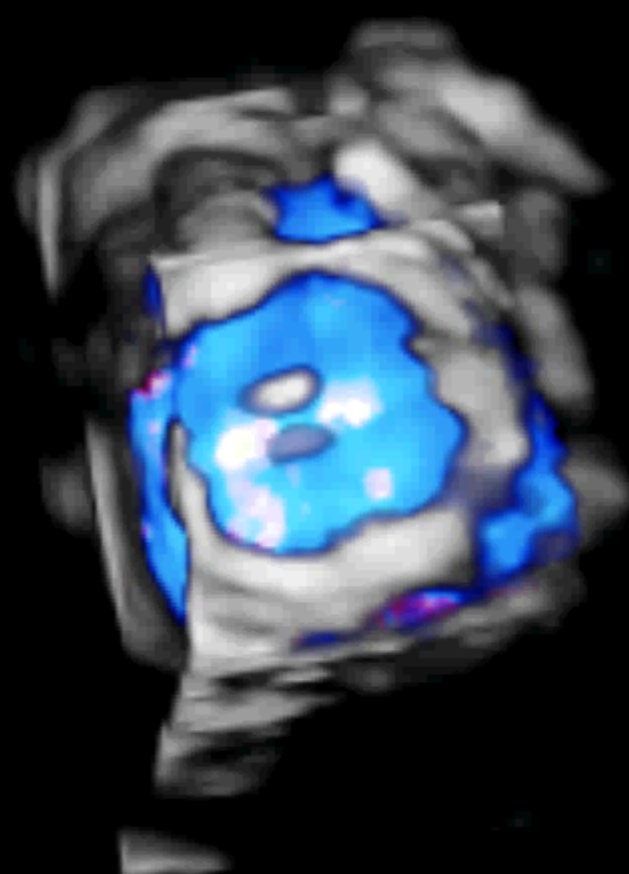
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ITm1.1 IM 0.4

X7-2t/ETO

CI 18Hz
12cm

Volume total 0 60 180
3D 0%
3D 13dB
Coul
50%
4.4MHz



T PAT: 37.0C
T ETO: 40.3C

JPEG

109 bpm

	Mean Valve Size (mm)	Mean Pressure Gradient (mm Hg)
Medtronic Hall™ n=12	24.6	10
St. Jude Medical™ n=12	24.6	20
Notes <ul style="list-style-type: none"> • Randomized, prospective • Same surgical team • Same echocardiographer • Lower turbulence (p<0.05 and better) LVMR (p<0.05) with Medtronic Hall 	50% lower gradient (p<0.019)	

Table 1. Comparison of transvalvular pressure gradients

High Thromboresistance - Design features -

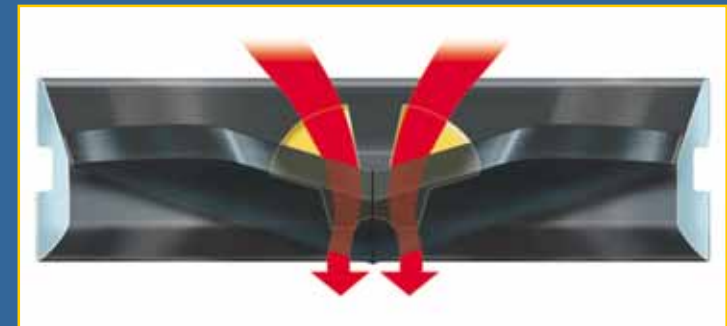
- Opening Angle and Curved Leaflets



- Aerofoil Profile

- Carbofilm Coating

- Passive Blood Washing



Effective Orifice Area Index (EOAI)^{2,3}

Valve Size (mm)	19	21	23	25	27	29
Avg. EOA (cm ²)	1.7	2.0	2.5	2.6	3.5	3.5
BSA (m ²)						
0.6	2.83	3.33	4.17	4.33	5.83	5.83
0.7	2.43	2.86	3.57	3.71	5.00	5.00
0.8	2.13	2.50	3.13	3.25	4.38	4.38
0.9	1.89	2.22	2.78	2.89	3.89	3.89
1.0	1.70	2.00	2.50	2.60	3.50	3.50
1.1	1.55	1.82	2.27	2.36	3.18	3.18
1.2	1.42	1.67	2.08	2.17	2.92	2.92
1.3	1.31	1.54	1.92	2.00	2.69	2.69
1.4	1.21	1.43	1.79	1.86	2.50	2.50
1.5	1.13	1.33	1.67	1.73	2.33	2.33
1.6	1.06	1.25	1.56	1.63	2.19	2.19
1.7	1.00	1.18	1.47	1.53	2.06	2.06
1.8	0.94	1.11	1.39	1.44	1.94	1.94
1.9	0.89	1.05	1.32	1.37	1.84	1.84
2.0	0.85	1.00	1.25	1.30	1.75	1.75
2.1	0.81	0.95	1.19	1.24	1.67	1.67
2.2	0.77	0.91	1.14	1.18	1.59	1.59
2.3	0.74	0.87	1.09	1.13	1.52	1.52
2.4	0.71	0.83	1.04	1.08	1.46	1.46
2.5	0.68	0.80	1.00	1.04	1.40	1.40

EOAI = EOA/BSA

 EOAI ≥ .85 cm²/m²

 .80 cm²/m² < EOAI ≤ .84 cm²/m²

 EOAI < .80 cm²/m²

Endocardite

Terapia Chirurgica → Risultati Precoci

*Mortalità operatoria**

- Endocardite su valvola nativa → 12%
- Endocardite su protesi valvolare → 25%

** Metanalisi di 30 serie chirurgiche*

Endocardite

Terapia Chirurgica → Risultati a Distanza

- su valvola nativa

Sopravvivenza a 5 aa → 75%

Sopravvivenza + libertà da ReDo a 5 aa → 70%

- su protesi valvolari

Sopravvivenza a 5 aa → 55%

Sopravvivenza + libertà ReDo a 5 aa → 40%

Reoperation is not an independent predictor of mortality during aortic valve surgery

Piroze M. Davierwala, MD, Michael A. Borger, MD, PhD, Tirone E. David, MD, Vivek Rao, MD, PhD, Manjula Maganti, MSc, and Terrence M. Yau, MD, MSc

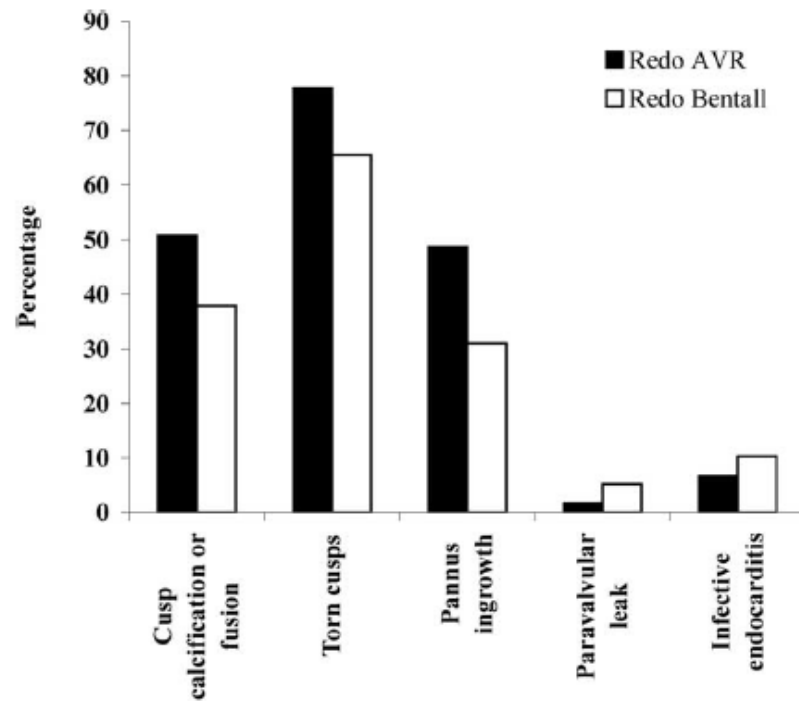


Figure 1. Pathology of explanted bioprosthetic valves. *AVR*, Aortic valve replacement.

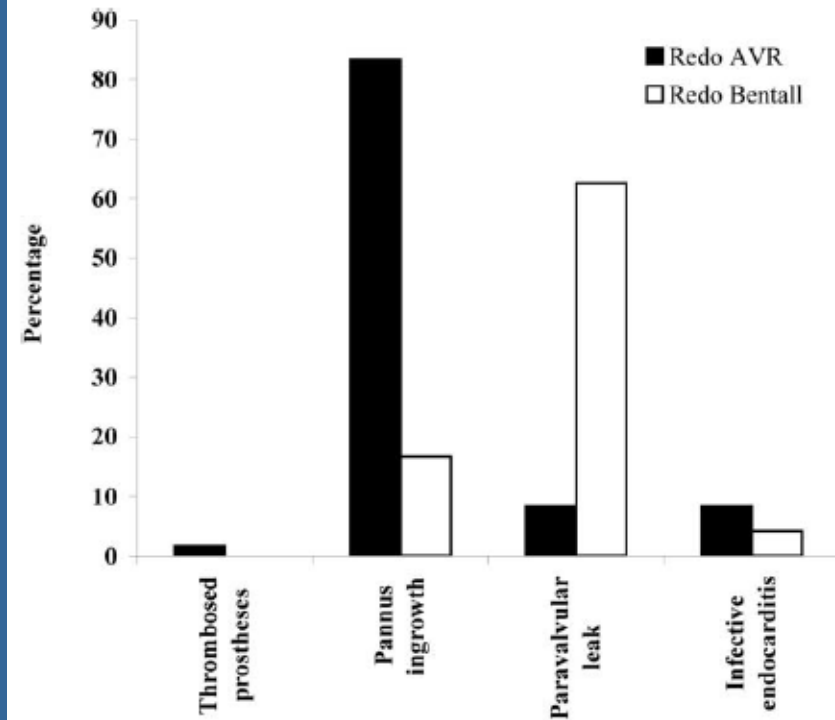


Figure 2. Pathology of explanted mechanical valves. *AVR*, Aortic valve replacement.

216 pazienti redux di sost valv
aortica

83% biologica al primo intervento

82 pazienti redux di Bentall

73% biologica al primo intervento

TABLE 1. Mortality associated with decade of reoperation

Decade	Age (y; mean and range)*	Mean age at deaths* (y)	Mortality†	Percentage†
1969-1978	46 (17-73)	50	21/130	16.2
1979-1988	53 (16-77)	56	22/226	9.7
1989-1998	60 (18-83)	64	15/315	4.8

*Age and time are positively correlated but there is no statistically significant interaction between them.

† χ^2 for linear trend $P < .0005$ with decreased mortality in recent decades.

TABLE 3. Distribution of postoperative outcomes

Variable	Primary AVR	Redo AVR	Bentall-after-AVR	P value
Mortality (%)	2.3	4.6	2.4	.1
Low output syndrome (%)	5.7	4.6	7.3	.7
Postoperative MI (%)	1.6	0.9	0	.4
Postoperative stroke (%)	2.4	4.6	2.4	.1
Postoperative renal failure (%)	2.1	4.2	4.9	.04
Pacemaker insertion (%)	5.6	14	26	<.0001
Reopening for bleeding (%)	4.3	6.9	9.8	.02
Duration of ventilation (h)	19 ± 41	25 ± 52	26 ± 77	.1
Duration of ICU stay (h)	54 ± 71	61 ± 63	74 ± 106	.02
Postoperative hospital stay (d)	10 ± 7.4	11 ± 8.1	12 ± 9.4	.02

AVR, Aortic valve replacement; MI, myocardial infarction; ICU, intensive care unit.

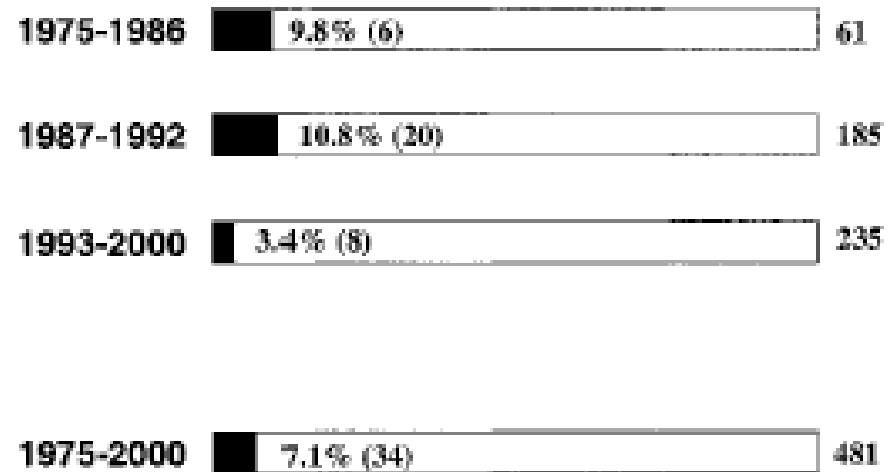


Figure 1. Mitral valve replacement reoperative mortality overall (1975–2000) and by year periods (1975–1986, 1987–1992, and 1993–2000).

(*Circulation*. 2003;108[suppl II]:II-98-II-102.)

TABLE 1. Age Distribution for Mitral Valve Replacement from 1975–1999

Age Groups	Bioprostheses # (%)
≤40	159 (7.4)
41–50	213 (9.9)
51–60	398 (18.5)
(61–65)*	310 (14.4)
(66–70)*	405 (18.8)
61–70	715 (33.2)
>70	667 (31.0)
Total	2,152 (100)

*(61–65) and (66–70) are subsets of 61–70 years.

(*Circulation*. 2003;108[suppl II]:II-98-II-102.)

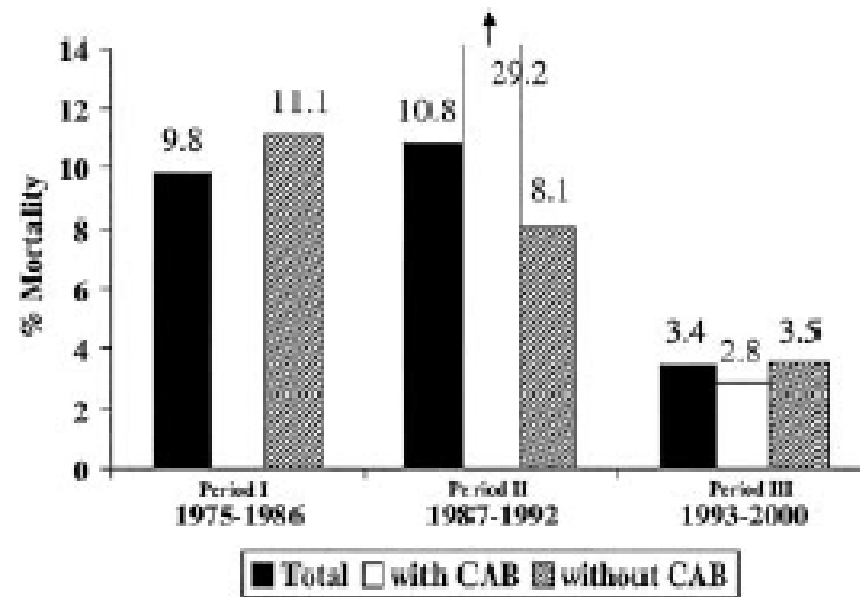


Figure 2. Mitral valve replacement reoperative mortality by year periods overall, and with and without concomitant coronary artery bypass.

(*Circulation*. 2003;108[suppl II]:II-98-II-102.)

TABLE 3. Predictive Risk Factors of Reoperative Mortality (Multivariate Analysis)

	Odds	Ratio (95% CL)	<i>P</i> -Value
Gender	1.9	(0.9–4.2)	<i>P</i> =NS
Age at implant	0.84	(0.73–0.96)	<i>P</i> =0.0113
Age at implant (<60, 60–70, >70)	1.6	(0.5–5.7)	<i>P</i> =NS
Age at explant	1.2	(1.05–1.37)	<i>P</i> =0.0089
Age at explant (60–70)	1.04	(0.4–2.7)	<i>P</i> =NS
(>70)	2.16	(0.5–8.7)	<i>P</i> =NS
CAB Pre-Re-op	1.5	(0.5–4.4)	<i>P</i> =NS
CAB Re-op	1.2	(0.5–3.2)	<i>P</i> =NS
Urgency	2.8	(1.1–7.0)	<i>P</i> =0.0264
NYHA	2.5	(1.2–5.3)	<i>P</i> =0.015
Re-op period			
1975–86 vs 1993–00	5.8	(1.6–20.6)	<i>P</i> =0.0062
1987–92 vs 1993–00	4.0	(1.6–9.8)	<i>P</i> =0.0023