Valve replacement: Choice of prosthesis

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Mechanical prostheses

- **Ball valves**

The original Starr-Edwards prosthesis comprised a silastic ball which seated in the sewing ring when closed and moved forward into the cage when open. More than 200 000 have been implanted.



- **Disc valves**

The Bjork-Shiley prosthesis is comprised of a single graphite disc coated with pyrolite carbon which tilts between two struts of the housing which is made of stainless steel or titanium. The Bjork-Shiley valve is no longer manufactured. More than 360 000 Bileaflet valves have two semicircular Bjork-Shiley prostheses have been implanted. Other manufacturers continue to produce single disc prostheses—for example, the Medtronic-Hall and the Aortech Ultracor.



- **Bileaflet valves**

They have two semicircular leaflets which open and close creating one central and two peripheral orifices. The St Jude medical valve was introduced in 1977, and more than 600 000 have been implanted. It and similar valves produced by other manufacturers are now the most



Biological prostheses

- **Autologous valves**

In the 1970s valves were fashioned freehand from the patient's own fascia lata in the operating theatre.

- **Autograft valves**

Described by Donald Ross in 1967 the Ross procedure involves replacing the patient's diseased aortic valve with their own pulmonary valve which is in turn replaced by a homograft.

- **Homograft valves (Allografts)**

Homografts from human cadavers have been used in some centres for aortic valve replacement for over 30 years.

- **Porcine heterograft (or xenograft) valves**

Porcine valves are treated with glutaraldehyde which both sterilises the valve tissue and renders it biologically acceptable to the recipent.

- **Bovine pericardial valves**

These valves are fashioned from bovine pericardium mounted on a stented frame. The Ionescue-Shiley pericardial valve proved less durable than porcine valves and has been withdrawn.





STUDIES EVALUATING DIFFERENT TYPES OF MECHANICAL PROSTHESES

- Most are observational studies of the results of valve replacement with one type of prosthesis.
- Most have shown excellent long term results for prosthesis survival, with no difference in durability between types of prosthesis.
- There have been few randomised controlled trials comparing outcomes after mechanical valve replacement.
- Bileaflet prostheses such as the St Jude valve appear to have the lowest risk of thromboembolism.
- Rates of thromboembolism are higher following mitral valve replacement than following aortic valve replacement.

STUDIES EVALUATING DIFFERENT TYPES OF BIOLOGICAL PROSTHESES

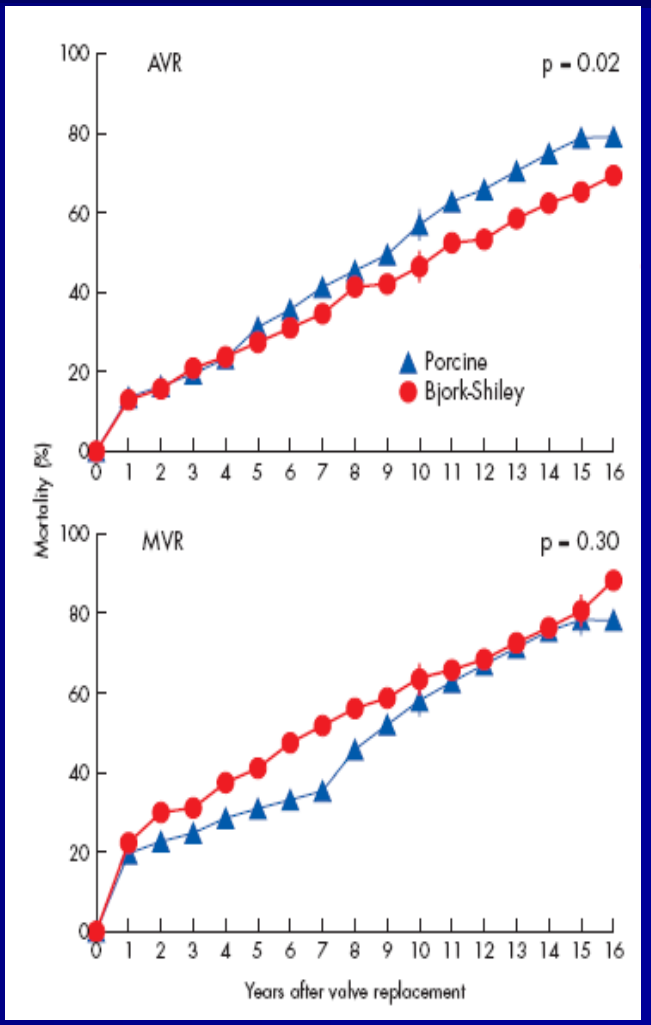
- Most studies have been observational, reporting results with one type of prosthesis.
- Several studies have identified porcine valve failure seven or more years after implantation, particularly in younger patients.1 2 7
- One study compared results with stentless porcine prostheses with stented prostheses in the aortic position in a non-randomised case–controlled study of patients undergoing aortic valve replacement, and showed apparently enhanced durability of the stentless prosthesis.8
- Advocates of the stentless prosthesis point to its superior haemodynamics with an effective valve area some 10% larger than a stented prosthesis of equivalent size.
- To answer properly the question of whether stentless prostheses give superior long term results, a randomised controlled trial is needed.

Mechanical vs Biological

- The Department of Veterans Affairs (VA) trial randomised 575 male patients undergoing single valve replacement in 13 centres between 1977 and 1982 to receive either a Bjork-Shiley tilting disc prosthesis or a Hancock porcine prosthesis.
- The Edinburgh heart valve trial randomised male and female patients undergoing valve replacement between 1975 and 1979 to receive a Bjork-Shiley or porcine (Hancock or Carpentier-Edwards) prosthesis.

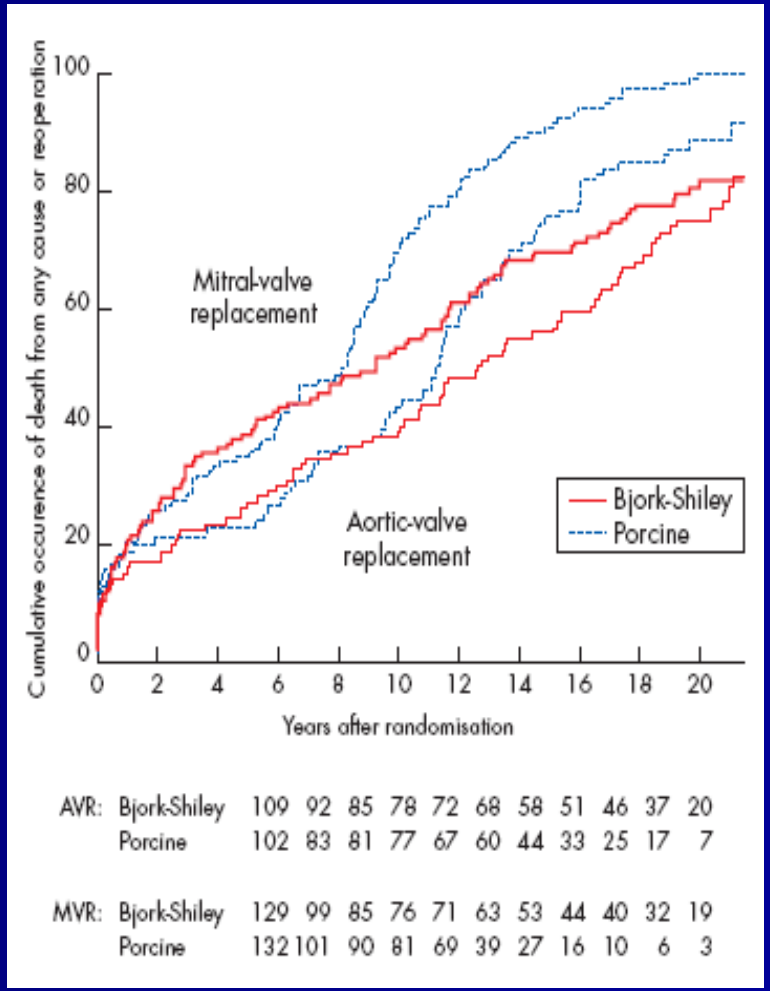
Conclusions from DVA trial

1. After AVR, use of mechanical valve resulted in a lower mortality (66.3% vs. 79.3%) and a lower reoperation rate (10.3% vs. 29.5%). The difference became apparent after 10 years, indicating the need for follow-up of 15 years.
2. The mortality after MVR was similar (81% vs. 79%);
3. There was no SVD with the mechanical valve.
4. Primary valve failure occurred mainly in patients <65 years; it began at 5 to 6 years after MVR and at 7 to 8 years after AVR; its incidence was higher after MVR (44 8% vs. 23 5%);
5. More than 10 years of follow-up was needed to determine the incidence and deleterious effects of SVD with use of porcine valve;
6. The primary valve failure rate between bioprosthesis and mechanical valve was not significantly different in those 65 years after AVR.
7. Use of a bioprosthetic valve resulted in a lower bleeding rate.
8. There were no significant differences with regard to other valve-related complications.



Conclusions from Edinburgh trial

1. There was a trend toward an improved survival with the Bjork-Shiley valve.
2. Reoperation rates were low and non significant at 5 years; at 12 years there was a higher reoperation rate with the porcine valve versus mechanical valve (AVR, 22.6 5.7% vs. 4.22.1%;MVR, 43.1 6.0% vs. 9.9 3.2%); younger patients were more likely to require reoperation, with “relative risk of reoperation increasing 55% for each 10 years, continuously over the whole range of ages studied”.
3. The incidence of thromboembolism and of endocarditis were not statistically significantly different.
4. The bleeding rate was higher with the mechanical valve versus porcine valve after AVR (32.6 6.1% vs. 9.7 4.7%,)but



AVR:	Bjork-Shiley	109	92	85	78	72	68	58	51	46	37	20
	Porcine	102	83	81	77	67	60	44	33	25	17	7
MVR:	Bjork-Shiley	129	99	85	76	71	63	53	44	40	32	19
	Porcine	132	101	90	81	69	39	27	16	10	6	3

Meta analysis I

The included 38 valve series relative to specific prosthetic valve types

	No. of patients	Total follow-up (patient-y)	Death rate %/patient-y
Mechanical valve series			
St Jude bileaflet disc, N = 10.	4069 (93-773)	24,356 (383-6419)	4.35 (1.52-8.88)
Mixed disc valve, N = 3†	2957 (222-1755)	17,368 (865-9302)	2.88 (2.48-6.13)
Medtronic-Hall tilting disc, N = 2	1552 (736-816)	12,814 (5120-7694)	4.82 (4.73-4.87)
Bioprosthetic valve series			
CE Perimount pericardial, N = 6	1852 (75-589)	9643 (470-2556)	5.81 (4.04-8.30)
CE porcine standard, N = 5	1792 (94-572)	10,465 (862-3375)	5.14 (1.77-6.84)
CE porcine supra-annular, N = 3	1307 (75-1108)	5918 (513-4735)	8.25 (5.52-8.79)
Hancock II and MO porcine, N = 3	1645 (132-843)	10,807 (857-5093)	5.96 (4.94-7.09)
Mitroflow pericardial, N = 3	643 (113-403)	2673 (572-1270)	7.48 (5.29-8.90)
Mixed biologic N = 2‡	602 (133-469)	2726 (349-2377)	8.99 (8.31-9.09)
Biocor porcine, N = 1	1029	5049	6.28

- The largest and more recent study
- Includes only series of valves that are currently available for AVR
- Operations were performed between 1975 and 2002
- There was a large difference in mean age distribution between mechanical and biologic valve series but with a considerable overlap. Adjusting for an age impact on mortality without obscuring any real effect was thus possible.

Lund O, Bland M. Risk-corrected impact of mechanical versus Bioprosthetic valves on long-term mortality after aortic valve replacement.
J Thorac Cardiovasc Surg. 2006 Jul;132(1):20-6

Meta analysis II

	Mechanical valve series (N = 15)	Biologic valve series (N = 23)	*P* value
No. of patients	8578 (93-1755)	8861 (75-1108)	.1
Total follow-up (patient-y)	54,538 (383-9302)	47,281 (349-5093)	.008
Mean follow-up (y)	6.4 (3.9-10.8)	5.3 (2.6-10.1)	.05
Total No. of deaths	2178 (15-375)	2992 (25-416)	.6
Length of operation period (y)	16.2 (5-25)	12.5 (3-20)	.04
Mean age (y)	58.0 (48-75)	68.8 (50-77)	<.001
Women (%)	34.5 (21-54)	37.5 (15-57)	.3
NYHA classes III and IV (%)	64.6 (29-92)	69.6 (49-94)	.3
Aortic regurgitation (%)	28.7 (8-48)	16.5 (23-57)†	.001
Aortic stenosis (%)	50.9 (22-72)	68.6 (21-100)†	.002
Active endocarditis (%)	6.8 (0-11)	2.2 (0-5)	<.001
Concomitant CABG (%)	15.7 (0-57)	34.1 (0-100)	.006
Other concomitant procedures (%)	4.5 (0-20)	7.2 (0-16)	.2
Redo operation (%)	3.8 (0-10)	5.0 (0-15)	.2
Death rate (%/patient-y)	3.99 (1.52-8.88)	6.33 (1.77-9.09)	<.001

Final regression models of death rate analysis

Predictor variable	A b	SE	*P* value	B b	SE	*P* value
Mechanical vs bioprosthetic valve	−2.34	3.69	.5	0.94	0.082	.4
Higher mean age (per year)†	1.53	0.41	<.001	1.04	0.006	<.001
NYHA classes III and IV‡	28.7	7.36	<.001	/	/	/
Aortic regurgitation‡	−60.0	21.70	.01	/	/	/
Concomitant CABG‡	/	/	/	1.51	0.24	.01
Constant	−46.4	28.3	.11	/	/	/

There was no significant difference in death rate between mechanical and bioprosthetic valves when corrected for age and well-known risk factors with no interaction between age and valve type.

Long term mortality after AVR.
Non randomized studies

Author	Type of PHV	No. of Patients	Mortality at Yr	Mortality %
Orszulak et al.	Starr-Edwards	1,100	10	40.4
			15	55.1
			20	68.8
Lindblom et al.	Bjork-Shiley	1,753	10	30*
			15	46*
Lund et al.	St. Jude	694	10	42 ± 5
Butchart et al.	Medtronic Hall	736	10	36
			15	55
Peterseim et al.	St. Jude	412	10	50 ± 6
	C-E porcine	429	10	46 ± 3
Yun et al.	Hancock porcine	652	12	49 ± 2
	Hancock MO porcine	561	12	58 ± 3
	C-E porcine	389	12	56 ± 7
Jamieson et al.	C-E supra-annular porcine	1,335	10	40.6 ± 2.1
			12	45.8 ± 2.8
Cohn et al.	Hancock MO porcine	843	10	48 ± 2*
			15	72 ± 3*
Khan et al.	Hancock porcine/ Hancock MO porcine	243	10	45*
			15	64*
Frater et al.	C-E pericardial	267	14	60.7 ± 3.1*
David et al.	Hancock II porcine	670	10	39 ± 2
			15	53 ± 3

*Excluding operative mortality.
AVR = aortic valve replacement; C-E = Carpentier-Edwards; MO = modified orifice; PHV = prosthetic heart valve.

Mortality

- The 10- and 15-year mortality rates after AVR and MVR are high.
- The range is large, even with the use of the same brand of PHV, indicating the importance of factors other than the type of PHV.
- Risk factors for late mortality have included:
  - decade of age,
  - Left ventricular dysfunction,
  - heart failure,
  - NYHA functional classes III and IV,
  - Coronary artery disease (CAD),
  - coronary artery bypass grafting
  - (CABG), valve regurgitation
  - arrhythmias, male gender
  - pulmonary hypertension
  - comorbid conditions such as renal failure, lung disease, hypertension, and diabetes

Complications

1. There is no significant difference among the various mechanical valves for thromboembolism, and also among the various bioprostheses; this is also true for rates of thrombosis, bleeding, endocarditis, and leak;
2. The incidence of thromboembolism is higher in patients with mitral PHV than in those with aortic PHV;
3. Bioprostheses are not free of thromboembolic risk, but the risk is lower than with use of a mechanical valve;
4. Complication rates with use of the same brand of PHV varies widely;
5. The risk of SVD with all currently used mechanical valves is “negligible”.

These findings reconfirm that, with the use of approved PHV, these complications are largely related to factors other than the type of PHV.

Grunkemeier GL, Li H-H, Naftel DC, Starr A, Rahimtoola SH. Long-term performance of heart valve prosthesis. Curr Probl Cardiol 2000;25:73–156.

Anticoagulation requirements I

- Modern bileaflet mechanical prostheses have been shown to function safely at low levels of anticoagulation similar to those used in most of the atrial fibrillation trials.
- One randomised trial compared high and low intensities of anticoagulation in patients undergoing aortic valve replacement with the St Jude or Omnicarbon bileaflet mechanical prosthesis.
- All patients included in this trial were at low risk of thromboembolism as they were in sinus rhythm and had a small left atrium on echocardiography.
- The trial showed that a target INR of 2.0–3.0 was as effective as a target INR of 3.0–4.5 in preventing valve thrombosis and thromboembolism, but at a significantly lower risk of bleeding.

Acar J, Iung B, Boissel JP, Samama MM, et al. AREVA: multicenter randomized comparison of low-dose versus standard-dose anticoagulation in patients with mechanical prosthetic heart valves. Circulation 1996:94:2107–12.

Anticoagulation requirements II

- However, in unselected patients undergoing aortic AVR with the St Jude bileaflet mechanical prosthesis, thromboembolic events were only seen in patients with an INR of <2.5, and a target INR of 2.5–3.0 is therefore normally recommended for patients with bileaflet mechanical valves in the aortic position.
- Patients undergoing MVR are at a higher risk of thromboembolism than those undergoing aortic valve replacement; left atrial size is frequently increased and atrial fibrillation is common. A higher target INR of 3.0–3.5 is therefore recommended for patients with bileaflet mechanical valves in the mitral position.

British Cardiac Society and Royal College of Physicians. Valvular heart disease; investigation and management. Recommendation of a working group of the British Cardiac Society and the research unit of the Royal College of Physicians. London: Royal College of Physicians, July 1996.

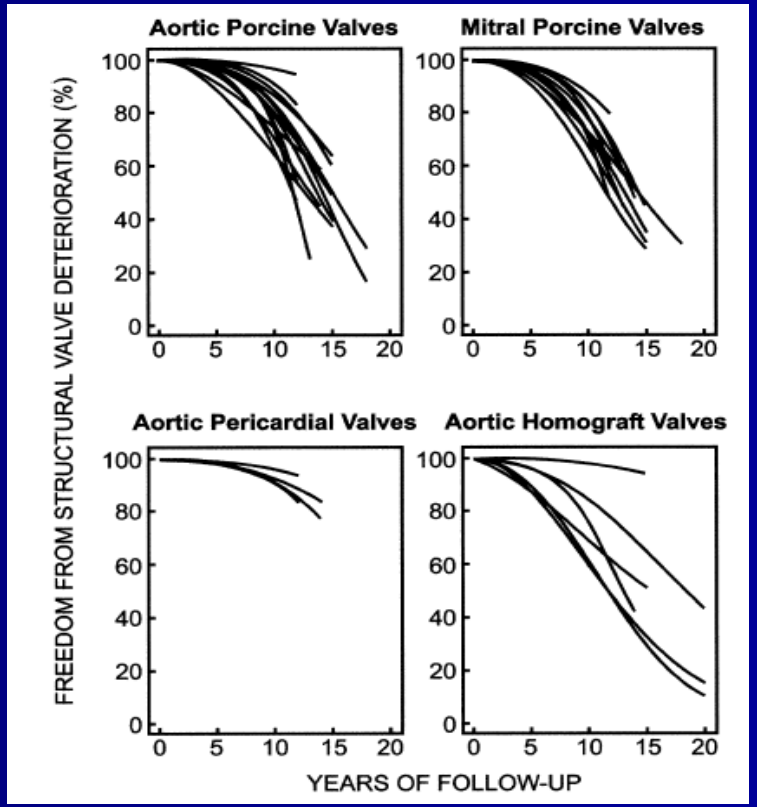
Anticoagulation requirements III

- The addition of low dose aspirin (75–100 mg daily) at these levels of anticoagulation appears to confer additional protection against thromboembolism, with only a small increased risk of bleeding.
- A meta-analysis of randomised trials comparing aspirin and warfarin with warfarin alone showed significant benefit with the combination of treatment.
- Aspirin may be of particular advantage in patients who have undergone concomitant CABG surgery at the time of valve replacement.

Masssel D, Little SH. Risks and benefits of adding anti-platelet therapy to warfarin among patients with prosthetic heart valves: a meta-analysis. J Am Coll Cardiol 2001;37:569–78.

Structural valve deterioration I

- The SVD rate of bioprostheses is importantly related to:
  1. The site of PHV implantation (SVD in MVR>in AVR).
  2. The age of the patient at time of PHV implantation.
     - In patients age 16 to 39 years, at 10 years, SVD after AVR is 60% and at 16 years is 90%.
     - In patients 70 years, it is 15% at 15 years.
- The rate of SVD at 12 years in patients followed for more than 10 years is high with aortic and mitral porcine valves and with aortic homografts

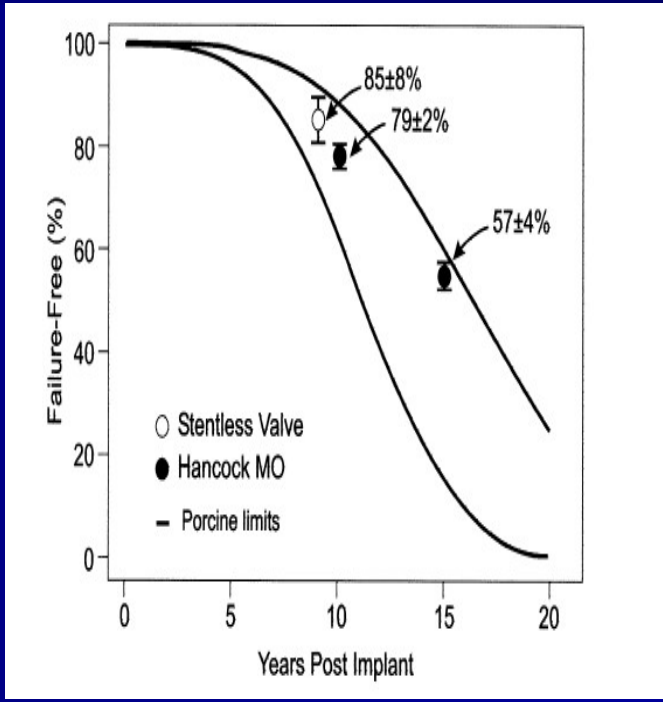


Yun KL, Miller DC, Moore KA, et al. Durability of the Hancock MO bioprosthesis compared with thestandard aortic valve bioprosthesis .Ann Thorac Surg 1995;60:S221–228.

Grunkemeier GL, Li H-H, Naftel DC, Starr A, Rahimtoola SH. Long-term performance of heart valve prosthesis. Curr Probl Cardiol2000;25:73–156.

Structural valve deterioration II

- In in vitro studies, the pericardial aortic valve has lower gradient and larger PHV area when compared with several other PHV and also a larger estimated aortic PHV area in patients in valve sizes 19 to 29.
- These data indicate that the pericardial aortic valve may be the bioprosthesis of choice in “older” people (60 to 65 years of age).
- Patients 65 to 70 years also have a lower rate of SVD after MVR.
- The rate of SVD is not significantly different for the standard Hancock, Hancock MO, and Carpentier-Edwards porcine valves.
- The rate of SVD of newer porcine valves (Hancock MO and the stentless porcine valve) at nine years is within the expected range of SVD of earlier stented porcine valves (Fig),



Bonow RO, Carabello B, deLeon AC Jr., et al. ACC/AHA guidelines for the management of patients with valvular heart disease. J Am Coll Cardiol 1998;32:1486–588.
Rao V, Jamieson WRE, Ivanor J, Armstrong S, David T. Prosthesis patient mismatch affects survival after aortic valve replacement. Circulation 2000;102 Suppl III:III5–9.
Grunkemeier GL, Bodnar E. Comparative assessment of bioprosthesis durability in the aortic position. J Heart Valve Dis 1995;4:49–55.

PHV size and VP-PM

- An extensive review of VP-PM showed that, depending on its severity, VP-PM may result in higher valve gradients at rest and on exercise, less reduction of left ventricular mass, greater physical limitation, and higher morbidity and mortality.
- VP-PM is dependent not only on the small annulus/root but also on the size of the patient.
- For example, 19-mm valves produced only mild VP-PM in two studies from Asia, but, in a study from North America, almost half of the patients had moderate or severe VP-PM, the improvement in NYHA functional class was less, and, at five years, the incidence of clinical heart failure was significantly greater (15 3% vs. 7 2%)

Pibarot P, Dumesnil JG. Hemodynamic and clinical impact of prostheses-patient mismatch in the aortic valve position and its prevention. J Am Coll Cardiol 2000;36:1131–41.
Hachida M, Koyangi H, Nonoyama M, Bonkohara Y, Saitu S, Nakamura K. Serial hemodynamic study of aortic valve replacement inpatients with narrow aortic roots. J Heart Valve Dis 1998;7:81–5

Conclusions

- The results of valve surgery with regard to survival, complications, cardiac function, and functional class are importantly dependent on:
  - patient-related factors
  - type of surgery,
  - type of prosthesis, and
  - health care delivery related factors
- in patients age 60 to 65 years, SVD of bioprosthesis after AVR is very low and is low after MVR and, thus, bioprosthesis would be the PHV of choice in patients in these age groups;
- mortality up to 10 to 15 years is high after PHV implantation:
  - after AVR, 40% of the deaths and after MVR 40% to60% of the deaths are related to the PHV
  - mortality after PHV implantation is importantly related to the age of the patient at time of insertion of PHV and to associated cardiac and noncardiac comorbid conditions;
- severe VP-PM is an important clinical problem after AVR and after MVR; moderate VP-PM is a problem in some patients after AVR and after MVR; uncomplicated mild VP-PM is usually clinically not important.

Mechanical valves

- There is no good evidence that any one mechanical valve is superior with regard to patient outcomes (among FDA-approved PHV with good documented results at follow-up 15 years) when patient characteristics at baseline are identical or are similar
- they have an extremely low rate of SVD
- the major disadvantages with use of mechanical valves are the need for anticoagulant therapy and of bleeding and its consequences
- with good anticoagulation, the risk of thromboembolism with use of a mechanical PHV valve is similar to that with use of bioprosthetic PHV without anticoagulants.

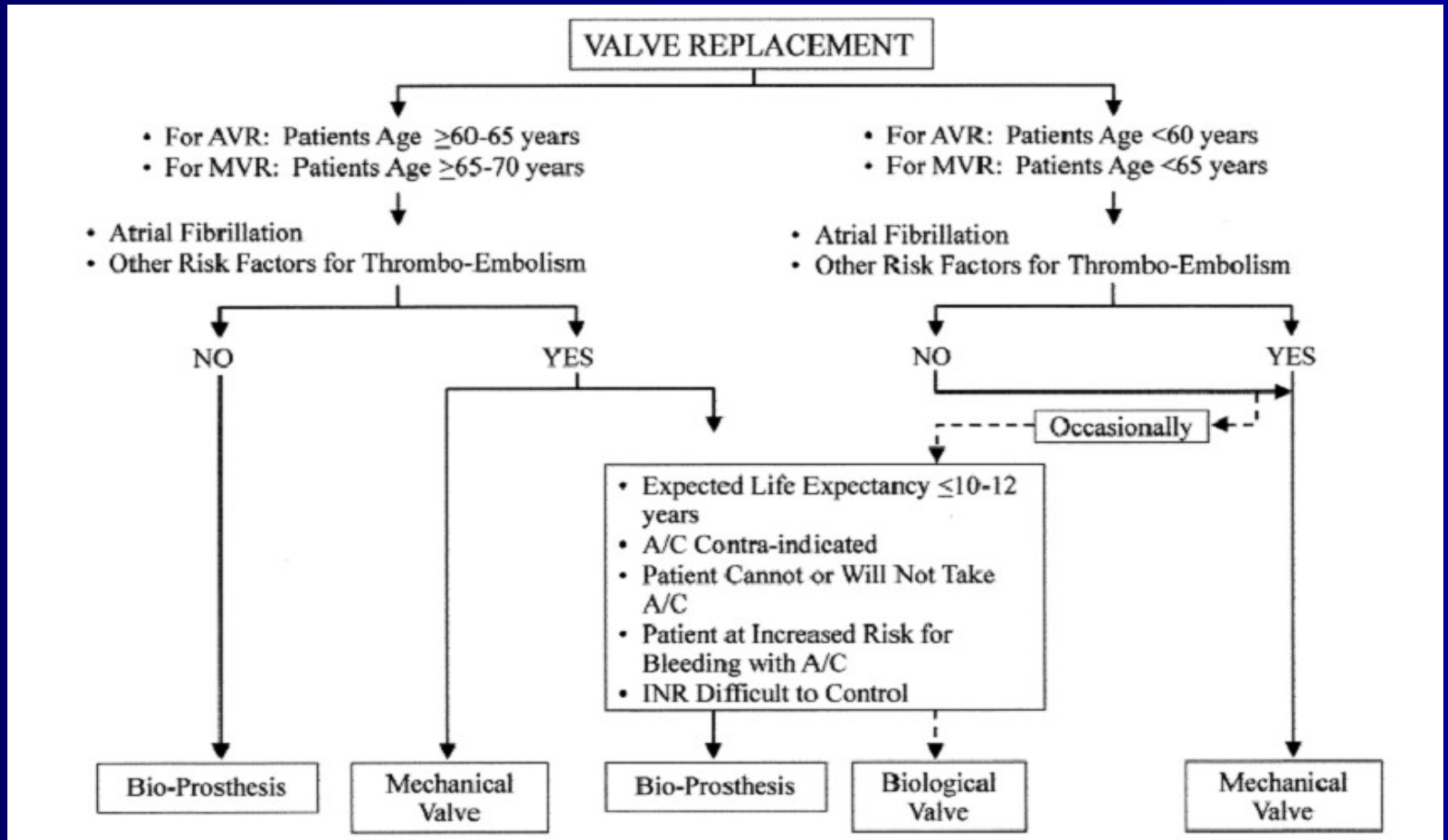
Bioprostheses

- There is no good evidence that any one porcine valve is superior with regard to patient outcomes (among FDA-approved PHV with good documented results at follow-up 15 years) when patient characteristics at baseline are identical or are similar;
- SVD begins at year 5 after MVR and year 8 after AVR;
- SVD is greater after MVR than after AVR;
- a minimum follow-up of 15 years is necessary to evaluate the incidence of SVD of FDA-approved PHV;
- the younger the patient at time of PHV implantation, the higher the rate of SVD;
- the major disadvantages with use of bioprosthesis are the incidence of SVD and of reoperation and their consequences including mortality;
- if patients with biological valves need anticoagulation, bleeding rates will be similar to that with use of mechanical valves
- the SVD of a stentless porcine valve is similar to that of a stented porcine valve
- data on patient outcomes 10 to 15 years after PHV using stentless porcine valves are needed;
- there is no proven benefit in patient outcomes and of SVD with use of a homograft when compared with a bioprosthesis;
- more good studies with follow-up of 15 years are needed in adults with use of pulmonary autografts

Recommendations

Recommendations for valve replacement with a mechanical prosthesis	Class
1. Patients with expected long life spans	I
2. Patients with a mechanical prosthetic valve already in place in a different position than the valve to be replaced	I
3. Patients in renal failure, on haemodialysis, or with hypercalcaemia	II
4. Patients requiring warfarin treatment because of risk factors* for thromboembolism	IIa
5. Patients ≤65 years for AVR and ≤70 years for MVR	IIa
Recommendations for valve replacement with a bioprosthesis	
1. Patients who cannot or will not take warfarin treatment	I
2. Patients ≥65 years needing AVR who do not have risk factors for thromboembolism*	I
3. Patients considered to have possible compliance problems with warfarin treatment	IIa
4. Patients >70 years needing MVR who do not have risk factors for thromboembolism*	IIa
5. Valve rereplacement for thrombosed mechanical valve	IIb

Class I There is evidence and/or general agreement that a given procedure or treatment is useful and effective.
Class II There is conflicting evidence and/or a disagreement of opinion about the usefulness/efficacy of a procedure or treatment.
Class IIa Weight of evidence/opinion is in favour of usefulness/efficacy.
Class IIb Usefulness/efficacy is less well established by evidence/opinion.
*Risk factors: atrial fibrillation, severe left ventricular dysfunction, previous thromboembolism, and hypercoagulable condition.
AVR, aortic valve replacement; MVR, mitral valve replacement.



An algorithm for choice of prosthetic heart valve. A/C = anticoagulation; AVR = aortic valve replacement; INR = international normalized ratio; MVR = mitral valve replacement.