Literature Review
CHOOSING A PROSTHETIC HEART VALVE

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ABSTRACT

The heart is a vital part of human anatomy because it functions as a pump to circulate blood throughout the body. Heart valves allow the heart to pump blood to specific locations efficiently. These valves are prone to disease and malfunction, and can be replaced by prosthetic heart valves. The two main types of prosthetic heart valves are mechanical and bioprosthetic. The mechanical valves are excellent in terms of durability, but are hindered by their tendency to coagulate the blood. Bioprosthetic valves are less durable and must be replaced periodically. When one of the valves of the heart becomes infected with a disease, it can be replaced with one of several different types of prosthetic valves. No prosthetic valve is ideal. None of the available mechanical or biologic valves has the performance and durability of the native human semilunar and atrioventricular valves. Therefore, the selection of a valve must take into account the relative advantages and disadvantages of a particular prosthesis and how to apply to the patient's risk profile.

Keywords: *valve, prosthetic valve, mechanical valve, bioprosthetic*

INTRODUCTION

The development of heart valve prostheses has dramatically chanced the care of patients with valvular heart disease (Wernly, 1991). It is 40 years since Starr and Edwards description of successful prosthetic valve replacement in 1961. Some patients who underwent valve replacement with the original Starr-Edwards prosthesis in the 1960s are alive to this day. Each year more than 6000 patients in the UK and 60.000 in the USA alone undergo valve replacement surgery (Bloomfield, 2002).

There are two classes of heart valves: mechanical prostheses, with rigid, manufactured occluders, and biological or tissue valves, with flexible leaflet occluders of animal or human origin (Grunkemeier, 2001). Prosthetic valves differ from one another with regard to several characteristics, including durability (longevity), thrombogenicity, and hemodynamic profile (Vongpatanasin, 1996). Since the 1950s more than 80 models of prosthetic heart valves have been developed and use (Vongpatanasin, 1996). The variety of available prostheses attests to the inability of any single existing design to fulfill the requirements of an ideal prosthesis. An ideal prosthesis: adequate flow characteristic, durability, biocompatibility, resistance to thrombosis, ease of insertion, and silence (Wernly, 1991).

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The clinician who manages patients with valvular heart disease faces key decisions when referring patients for surgery. First, should the valve be repaired or replaced? And for replacement, what type of prothesis should be chosen? (Thamilarasan, 2002). Whenever possible, a repair procedure that preserve the patient's native valve while restoring valve function is preferable to implantation of a prosthetic valve (Otto, 2004). If valve repair is not feasible and replacement is needed, both mechanical prostheses and bioprostheses are available (Thamilarasan, 2002).

Choice of operation and the prosthesis used for those undergoing valve replacement is important for each individual patient and ideally should be made together by the patient, cardiologist, and surgeon (Bloomfield, 2002). This article reviews the characteristics of the most commonly used valve prostheses and concludes with guideline for the selection of a prosthesis for an individual patient.

TYPES OF PROSTHESIS AVAILABLE

A. MECHANICAL PROSTHESES

The pioneering efforts of Dr. Charles Hufnagel, who made the first successful placement of a totally mechanical valvular prosthesis, started the era of artificial heart valves. Hufnagel achieved this feat in 1952, by inserting a Plexiglas cage containing a ball occluder into the descending thoracic aorta. The first implant of a mitral valve replacement in its anatomic position took place in 1960, when the Starr-Edwards

prosthesis was put in the clinical use. A number of similar caged ball designs appeared subsequently; like the Magovern-Cromie, DeBakey-Surgitool, Smeloff-Cutter prostheses. Even though caged ball valves have proven to be durable, their centrally occluding design result in a larger pressure drop accros the valve and higher turbulent stresses, distal to the valve. Their relatively large profile increases the possibility of interference with anatomical structures after implantation. This led to the development of low profile caged disc valves in the mid-1960s. The cross-Jones, Kay-Shiley and Beall caged-disc design were introduced during 1965 to 1967. These valves were used exclusively into the atrio-ventricular position. However, because of high complication rates, the model soon fell into disuse (Nair, 2003).

The next significant development was the introduction of tilting disc valves by Bjork-Shiley in 1967. The original Bjork-Shiley prosthesis employed a Delrin (polyacetal) accluder, which later replaced by pyrolitic carbon. The Medtronic-Hall prosthesis was introduced in 1977. The first bileaflet valve was introduced by St. Jude Medical Inc. in 1978 (Nair, 2003).

During the last fifty years, many valve designs have been tried in laboratories. Few of them have gone through extensive stages of evaluations and reached clinical use. Of these few only three variants are currently in clinical use; viz. the caged ball, tilting disc and the bileaflet designs (Nair, 2003):

1. Caged Ball Valves

Several modifications of this design have been used, but only the Starr-Edwards valve has endured; it has been used more than 200,00 times (Bonow, 1998; Grunkemeier, 2001). The ball is a silicone rubber polymer impregnated with barium sulfate for radio-opacity that oscillates in a cage of cobalt chromium alloy (Bonow, 1998). A silastic ball which seated in the sewing ring when closed and moved forward into the cage when open (Bloomfield, 2002). Antegrade blood flows around the ball with a typical velocity of 2 m/s. Turbulent and shear stresses reach levels associated with damage to the endothelium and blood cells, factors that contribute to the high thrombogenicity of this valve (Otto, 2004).

The Starr-Edwards valve is easy to insert but requires a somewhat generous space because of its large cage, which is a disadvantage in patient with small left ventricles or narrow aortas. The transvalvular gradients are generally larger than those of a tilting disc or bileaflet valve of equivalent diameter, but with the exception of the small valve sizes, the hemodynamic function is satisfactory. Long-term experience with this valve for up to 20 years reveals excellent durability statistics (Wernly, 1991).

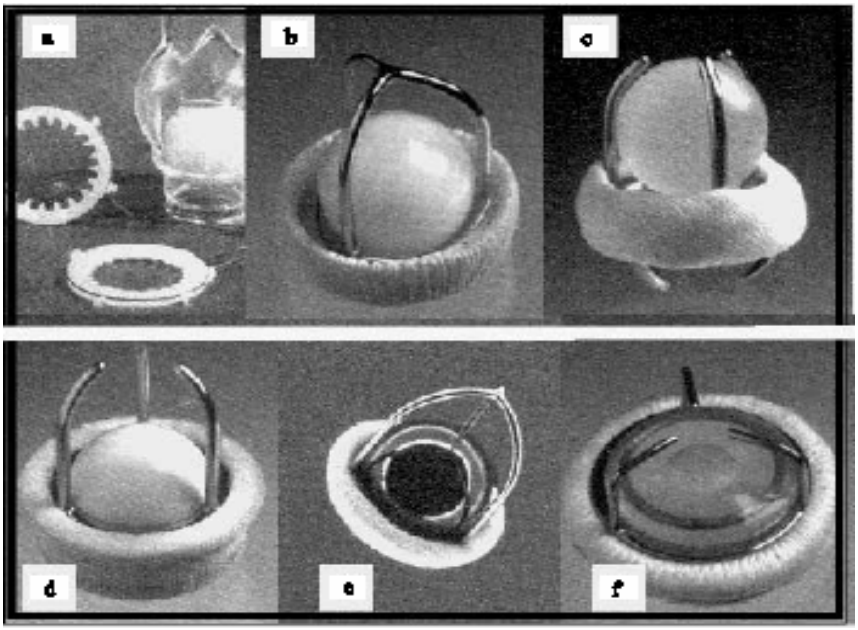

Figure 1. Caged Ball valves. (a) Hufnagel-Lucite valve, (b) Starr-Edwards, (c) Smeloff-Cutter, (d) McGovern-Cronic, (e) DeBakey-Surgitool and (f) Cross-Jones

2. Tilting-Disc Valves

The first successful low-profile design was the Bjork-Shiley tilting-disc valve, introduced in 1969. The original design was modified in the early 1980s to increase the angle of opening and to change the disc to convexo-concave shape (cc model). It evolved through several design refinements, and about 360,000 valves were implanted (Grunkemeier, 2001; Bloomfield, 2002). Available valves include the Medtronic Hall, Bjorrk Shiley, and Omniscience valves (Otto, 2004).

Tilting-disc valves employ a circular disc as an occluder. It is retained by wirelike arms or closed loops that project into the orifice. The discs are graphite with a coating of pyrolytic carbon, and the housings are stainless steel or titanium (Grunkemeier, 2001). The opening angle of the disc relative to the valve annulus ranges from 60-80 degrees, resulting in two orifices for antegrade flow (Otto, 2004). When the disc opens, the primary orifice is separated into two unequal (major and minor) orifices (Grunkemeier, 2001). The major orifice is semicircular in cross-section, with a typical antegrade velocity of approximately 2 m/s. Flow though the minor orifice consist of two jets separated by a well-defined wake behind the tilted disc but with a velocity in the minor orifice similar to that of the major orifice. Tilting disc valves have a small amount of normal regurgitation (5-9 mll per beat), with regurgitation originating from small gaps around the perimeter of the valve. Even this normal pattern of regurgitation is associated with high turbulent stresses (Otto, 2004).

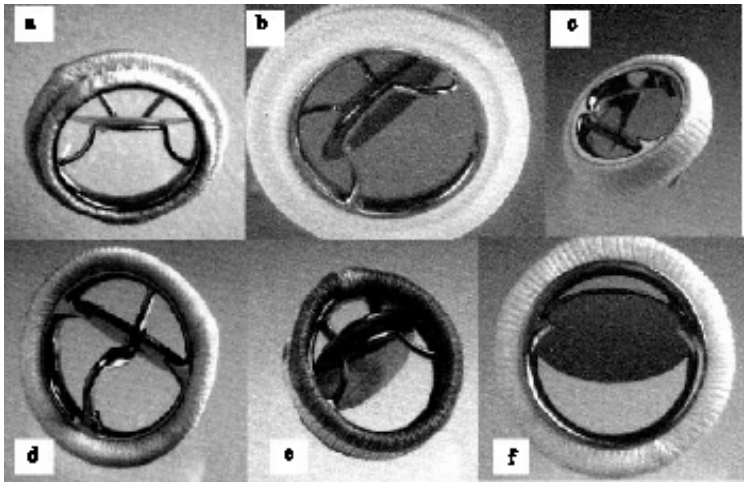

Figure 2. Tilting disc valves of the 1970s. (a) Bjork-Shiley Delrin valve, (b) Bjork-Shiley standard, (c) Lillehei-Kater, (d) Medtronic-Hall, (e) Zorin and (f) Omniscience.

3. Bileaflet Valves

The bileaflet principle, a hinge mechanism, and a low profile are basic to the design features of bileaflet heart prosthesis. They have two semicircular leaflets retained within the ring by hinges. The potential for impeded leaflet movement due to interference with cardiac structures is slim, as the open leaflet are positioned in the middle of the blood stream and enclosed within the ring in the closed position. Bileaflet valves are the most protected as the leaflets hardly protrude from the valve ring, even during maximum opening. The large effective orifice area of the bileaflet valves, contributes tp creating a flat, nearly normal flow profile with far les obstruction and turbulence, as compared with earlier generations of replacement valves (Nair, 2003).

Available bileaflet valves include the St. Jude Medical and Carbomedics valves (Otto, 2004). The St. Jude bileaflet valve has been used over 900.000 times and the Carbomedics valve has been used about 300.000 times since its clinical introduction in 1986 (Grunkemeier, 2001). These valves consist of two pyrolytic carbon semicircular discs attached to a rigid valve ring by a small hinge. The opening angle of the leaflets relative to the annulus plane range from 75 to 90 degrees, with the open valve consisting of three orifices-a small, slit-like central orifice between the two open leaflets and two larger semicircular orifices laterally. Bileaflet valves typically have a small amount (5 to 10 ml per beat) of normal regurgitation (Otto, 2004).

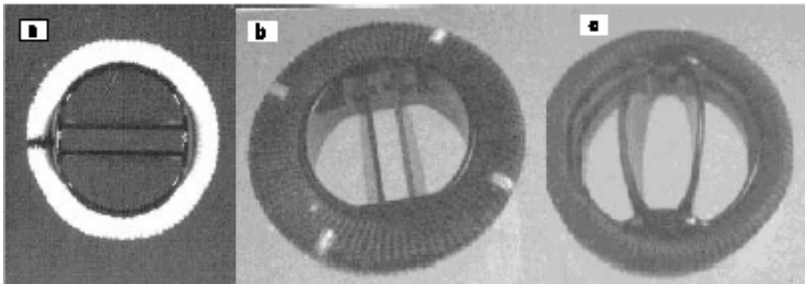

Figure 3. Bileaflet valve models. (a) St. Jude Medical, (b) Carbomedics and (c) Duramedics

B. BIOLOGICAL VALVES

Tissue valves (bioprostheses) have been developed primarily to overcome the risk of thromboembolism that is inherent in all mechanical prosthetic valves and the attendant hazards and in convenience of permanent anticoagulant therapy (Braunwauld, 2001). The modern era of bioprostheses was initiated by Alain Carpentier in Paris in 1968. He was the first to use glutaraldehyde for tissue preservation. Glutaraldehyde enhances the formation of collagen covalent cross-linkage bonds and increases tissue strength. At the same time, the tissue is rendered nonviable, and its antigenicity is markedly reduced. In 1970, Hancock Laboratories made commercially available a glutaraldehyde-treated porcine xenograft valve that had projected durability longer than other previous tissue valves. Edwards Laboratories subsequently offered the Carpentier-Edwards porcine bioprosthesis, which has become popular. Almost simultaneously, a tissue valve made of preserved bovine pericardium fashioned into a three-cusp valve was introduced by Ionescu in England in 1971. In 1976, this valve became commercially available from Shiley. Inc., and was renamed the Ionescu-Shiley valve. Newer bioprostheses have become commercially available in other countries, some are being implanted in the United States under investigation protocols. These newer valves have different fixation methods, newer mounting techniques, or addition of agents to retard calcification (Wernly, 1991).

There is a wide variety of biological valves. An autologous or autogeneous valve is fashioned from the patient's own tissue such as fascia lata or pericardium. An autograft valve is one translocated from one position to another-for example, when patient's own pulmonary valve is used to replace a diseased aortic valve. A homograft (or allograft) valve is one transplanted from a human donor, for example a donor's aortic or pulmonary valve into a recipient's aortic or pulmonary position. A heterograft (or xenograft) valve is a transplant from another species, either an intact valve, e.g., a porcine aortic valve, or a valve fashioned from heterologous tissue, e.g., bovine pericardium (Bonow, 1998; Grunkemeier, 2001; Bloomfield, 2002).

1. Autologous Valves

In the 1970s valves were fashioned freehand from the patient's own fascia lata in the operating theatre. The procedure was technically demanding, the valves had very limited durability, and this approach has been abandoned. More recently frame mounted valves constructed from the patient's pericardium in the operating room using a commercially produced kit have been developed-for example, The Carpentier-Edwards Perimount pericardial prosthesis (Bloomfield, 2002). Long-term durability appears to be excellent; in 267 patients undergoing isolated aortic valve replacement, the 14-year actuarial freedom of need for re-replacement because of structural valve dysfunction was 85 percent. Good result has also been reported for this valve in the mitral position (Braunwauld, 2001).

2. Autograft Valves

First describe in 1967, this operation is called the Ross procedure (Bonow, 1998; Braunwauld, 2001; Grunkemeier, 2001; Bloomfield, 2002). In, this operation, the patient's own pulmonary valve and adjacent main pulmonary artery are removed and used to replace the diseased aortic valve and often the neighboring aorta, with reimplantation of the coronary arteries into the graft. A human pulmonary or aortic homograft is then inserted into the pulmonary position (Braunwauld, 2001).

Advantages of the pulmonic autograft procedure include excellent hemodynamics, tissue viability, and resistance to infection. In addition, the pulmonic autograft is noiseless, non thrombogenic, and has shown growth potential in children. Disadvantages of the pulmonic autograft procedure include the technical difficulties of harvesting the pulmonic valve. Another concern about the pulmonic autograft procedure is the need for two valve procedures, which prolongs the operation and

increases risk of prosthetic valve dysfunction. In addition, use of the pulmonic autograft is usually limited to children and young adults (typically younger than 50 years of age, although it has been performed successfully in some older patients) because of changes with age in tissue quality, the relative size of the pulmonic annulus relative to the aortic annulus, and an increasing frequency of comorbid disease (Otto, 2004).

Long-term hemodynamic results are good, with a peak gradient of 6 ± 4 mmHg and no cases of moderate or severe regurgitation in a series of 100 patients followed for an average of 2.8 years. Recent series suggest a low rate of structural failure, with a 5-year freedom from reoperation of 89 % ± 3 %. The major long-term problem with the pulmonic aotograft procedure has been degeneration and failure of the right-sided homograft. Approximately 15 % to 29 % of survivors have required reoperation within 20 years, most often for right-sided valve failure (Otto, 2004).

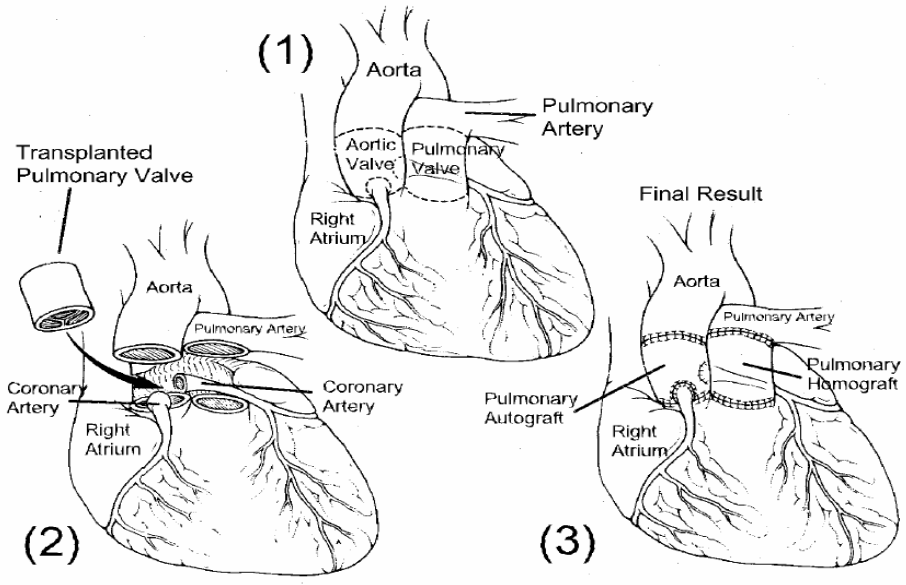

Figure adapted from: Kouchoukos et al, New England Journal of Medicine. 330(1):1-6, 1994 Jan 6.

Figure 4. Autograft (Ross Procedure)

3. Homograft (Allograft) Valves

Homograft valves were first use in the early 1960s (Bonow, 1998). These are harvested from cadavers, often along with kidneys, ussualy within 24 hours of donor death. They sterilized with antibiotics and cryopreserved for long periods at - 196° C (Braunwauld, 2001). The homograft valve is considered to be a preferred substitute for aortic valve replacement, especially in younger patients. It achieves excellent hemodynamics; there is no need for anticoagulation and it has low thrombogenicity. Three surgical techniques are used for aortic valve replacement (Grunkemeier, 2001):

1. Replacement of the valve only into the subcoronary position
2. Complete aortic root replacement with reimplantation of the coronary arteries
3. Miniroot replacement with part of the donor aortic wall inserted within the host aorta.

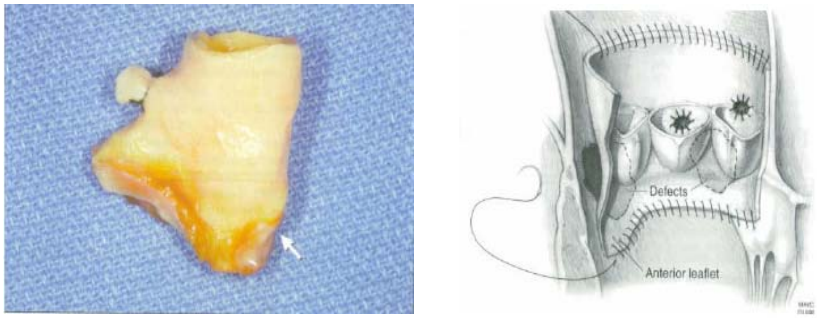

Figure 5. Homograft Valve

Although subcoronary implantation has the advantage that the coronary artery origins are undisturbed, this approach is technically difficult and results in suboptimal hemodynamics if even minor distortion of the 3D anatomy of the valve occurs. Thus, this approach is rarely used (Otto, 2004). Complete root replacement is technically simpler, provides reproducibly excellent hemodynamics, and is the procedure of choice at most centers, even though reimplantation of the coronaries into the homograft aorta is necessary (Otto, 2004).

Summarizing the data on the long-term outcome with homograft valve replacement is complicated by the differences between centers in harvesting, sterilization, and preservation of the homograft and differences in surgical implantation techniques. In early series using antibiotic-stored valves, midterm durability was impressive, with freedom from structural deterioration in 95 % of valves at 5 years and 78 % of valves at 10 years. However, after 10 years the rate of deterioration accelerated, with only approximately one half still functioning normally 15 years after implantation. Similar midterm results were found with cryopreserved valves at another center, with 85 % of valves free from leaflet failure 8 years after implantation (Otto, 2004).

Freedom from thromboembolism was 95 % at 10 years for isolated aortic homograft valve replacement, with or without concurrent coronary artery bypass grafting, but it was only 81 % for all homograft, including those with concurrent mitral or other valve surgery. Endocarditis is rare in patients with homograft valves, with 94 % ± 2 % of cryopreserved homograft valves free of endocarditis at 15 years (Otto, 2004).

4. Heterograft (Xenograft) Valves

A. Stented Heterograft Valves

Stented porcine aortic heterografts were developed for both the mitral and the aortic positions and have been in wide clinical use since 1965 (Braunwauld, 2001). The traditional design of a heterograft valve consists of three valve leaflets that open to a circular orifice in systole, resembling the anatomy of the native aortic valve (Otto, 2004). The Hancock valve is fixed and preserved in glutaraldehyde and is mounted on a dacron cloth-covered flexible polypropylene strut. The Carpentier-Edwards valve is pressure-fixed, preserved in glutaraldehyde, and mounted on a Teflon-covered Eljgiloy strut so as to minimize the septal shelf (Braunwauld, 2001).

A major advantage of bioprosthetic valves is the low rate of thromboembolism, with recent series estimating the rate of thromboembolism at only 1.6 % per patient-year in the absence of chronic anticoagulation (Otto, 2004). The major problem with porcine bioprostheses is their limited durability. Cuspal tears, degeneration, fibrin deposition, disruption of the fibrocollagenous structure, perforation, fibrosis, and calcification sufficiently severe to require reoperation begin appear in some patients in the fourth or fifth postoperative year, and by 10 years the rate of primary tissue failure averages 30 percent (Braunwauld, 2001).

The rate of structural deterioration of bioprosthetic valves is related to patient age at the time of implantation. Degeneration of stented bioprosthetic valves is more rapid in children, young adults, and patients with abnormal calcium metabolism (e.g., renal failure). Tissue degeneration appears to be slower in elderly adults. In a study of 110 patients older than age 65, the rate of structural deterioration was only 0.95 % per year, with most deaths attributed to causes other than valve dysfunction (Otto, 2004). Re-replacement of a bioprosthetic valve should be carried out when significant and/or progressive structural deterioration is evident but before operation becomes emergency. The second operation, when carried out on an elective basis, may be associated with a surgical mortality rate of 10 to 15 percent (Braunwauld, 2001).

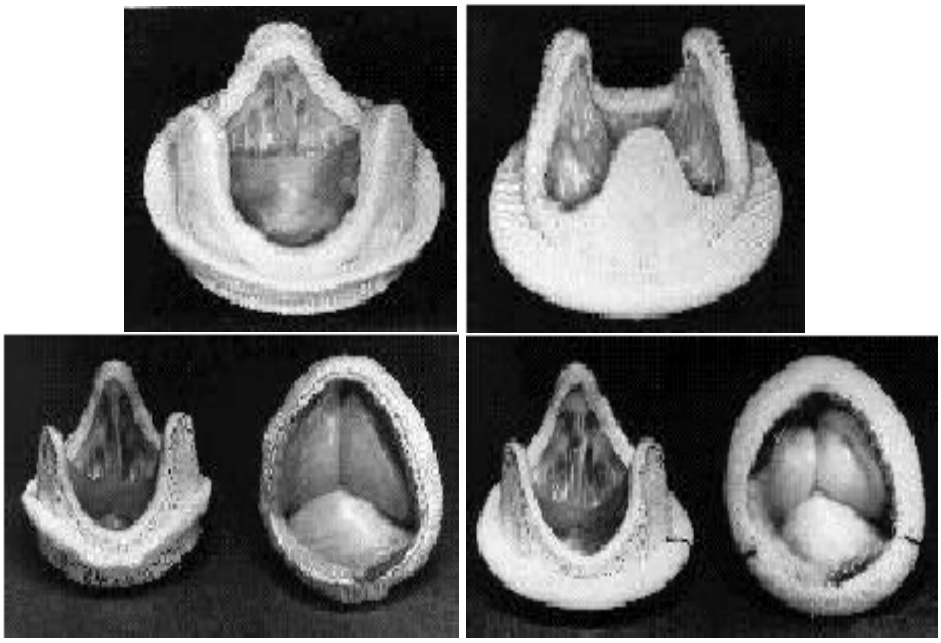

Figure 6. Hancock and Carpentier-Edwards. Hancock Aorta Valve (upper left) and Hancock Mitral Valve (upper right), Porcine Carpentier-Edwards (lower left), and Porcine Carpentier-Edwards Mitral Valve (lower right).

B. Stentless Heterograft Valves

Stentless bioprosthetic valves are typically manufactured from intact porcine aortic valves processed at low pressures to avoid fixing the collegen fibers in a stretched position. Some stentless valves are impregnated with agents to inhibit calcification, such as a-amino-oleic-acid. The addition of a layer of Dacron fabric around the graft adds support and aids implantation. These valves include the Toronto SPV Stentless valve (St. Jude Medical, St. Paul, MN), the Edwards Stentless valve (Edwards Life-Sciences, Irvine, CA), the Medtronic Freestyle valve, and the Cryolife-O'Brien (Cryolife International, Atlanta, GA). Stentless bioprosthetic valves have been used only in the aortic position, and the series to date have mostly included men with a mean age of 60 to 70 years.

The operative mortality rate for implantation of stentless bioprosthetic valves in the aortic position is only 3 % to 6 %. The incidence of postoperative complications by 12 months is low but does include endocarditis in 1 % to 2 %, thromboembolism in 2 % to 3 %, and hemorrhage in 1.5 % of patients. Compared with conventional stented bioprosthetic valves, stentless valves are associated with a greater and more rapid reduction in left ventricular mass, presumably related to a lower hemodynamic load imposed by the prosthetic valve (Otto, 2004).

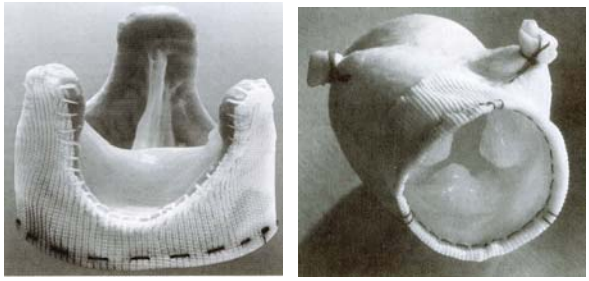

Figure 7. Stentless Heterograft Valves. Stentless Porcine (St Jude Toronto SPV, left) and Stentless Porcine (Medtronic Freestyle, right).

Currently, the most widely used prosthesis worldwide and FDA-approved prosthetic heart valves are shown in table 1.

Table 1. FDA-Approved Prosthetic Heart Valves

TYPE	MANUFACTURER	MODEL	YEAR OF FIRST CLINICAL USE	IMPLANTS* (thousands)
Mechanical				
Ball	Baxter-Edwards	Starr-Edwards	1965	200
Disc	Medtronic	Medtronic-Hall	1977	178
	Medical Inc.	Omniscience	1978	48
	Alliance	Monostrut	1982	94
Bileaflet	St. Jude	St. Jude	1977	580
	Baxter-Edwards	Duromedics	1982†	20
	CarboMedics	CarboMedics	1986	110
Biological				
Porcine	Medtronic	Hancock Standard	1970	177
		Hancock MO	1978	32
	Baxter-Edwards	CE Standard	1971	400
		CE SupraAnnular	1982	45
	St. Jude	Toronto Stentless (TSP)	1991	5
	Medtronic	Free Style Stentless	1992	5
Pericardial	Baxter-Edwards	CE	1982	35
Homograft	Noncommercial‡		1962	12
	Cryolife‡		1984	14
Autologous	Noncommerical‡	Pulmonary autograft	1967	2

*Approximate number of implants through part or all of 1994.
†Discontinued in 1988.
‡Does not require FDA approval for clinical use.
CE = Carpentier-Edwards; FDA = Food and Drug Administration; MO = modified orifice.
Adapted from Grunkemeier G, Starr A, Rahimtoola SH: Replacement of heart valves. *In* O'Rourke RA (ed): The Heart: Update I. New York, McGraw-Hill Publishing Co; 1996, pp 98–123. From Bonow RO, Carabello B, de Leon AC Jr, et al: ACC/AHA Guidelines for the management of patients with valvular heart disease. J Am Coll Cardiol 32:1486, 1998.

ADVANTAGES AND DISADVANTAGES OF MECHANICAL VALVES

A. The Advantages

1. Excellent durability and may last the patient's life time
2. Rates of structural failure are very low (except for the Bjork-Shiley convexconcave valve, which is no longer in use) (Wernly, 1991; Vongpatanasin, 1996)

B. The Disadvantages

1. The need for anticoagulation because they carry a significant risk of valve thrombosis and thromboembolism (most likely to develop thrombus when they are in the mitral and tricuspid positions, because flow velocity is lower than in the aortic valve)
2. Anticoagulation caries an inherent bleeding risk (1 % to 8.5 % per patient year, and it is highest in patients over 70 years old)

ADVANTAGES AND DISADVANTAGES OF BIOPROSTHETIC VALVE

A. The Advantages

1. The risk of thromboembolism is reduced but not eliminated. Embolism rates range from 0.2 % to 3.8 % per year for aortic valves and from 0.3 % to 5.1 % per year for mitral valves. Thrombosis rates are low.
2. The risk of anticoagulation-related bleeding is significantly reduced because many patients do not require chronic anticoagulation

B. The Disadvantages

The risk of primary tissue failure increases with time. At 6 to 7 years, valve failure-free rates in adult are 90 % to 95 %; by 10 years, they are approximately 70 % to 80 %

STUDIES EVALUATING DIFFERENT TYPES OF MECHANICAL PROSTHESES

Most studies results of mechanical valve replacement have been 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 randomized controlled trials comparing outcomes after mechanical valve replacement (Bloomfield, 2002).

Thromboembolism has been reported as occurring at a higher rate following Starr-Edwards replacement than Bjork-Shiley. Bileaflet prostheses such as the St Jude appear to have lowest risk of thromboembolism. Rates of thromboembolism are higher following mitral valve replacement than following aortic valve replacement (Vongpatanasin, 1996; Bloomfield, 2002). Likewise, in patients receiving adequate anticoagulation, the incidence of valve thrombosis is similar with cage-ball , single-tilting-disk, and bileaflet-tilting-disk valves (Vongpatanasin, 1996).

In general, structural failure of mechanical prosthetic valve is rare. However, in 1986 the Bjork-Shiley convex-concave single-tilting-disk valve was withdrawn from use after reports of fracture of the valve ring strut, resulting in dislodgment and embolization of the disk (Vongpatanasin, 1996).

STUDIES EVALUATING DIFFERENT TYPES OF BIOLOGICAL PROSTHESES

One study compared results with stentless porcine prostheses with stented prostheses in the aortic position in a non-randomized case-controlled study of patients undergoing aortic valve replacement, and showed apparently enhanced durability of the stentless prosthesis (David, 1998; Bloomfield, 2002). 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. How relevant this is in clinical practice when the vast majority of patients undergoing aortic valve replacement for calcific aortic stenosis are in their 60s, 70s or 80s is doubtful. To answer properly the question of whether stentless prostheses give superior long term results, a randomized controlled trial is needed (Bloomfield, 2002). A comparative study between porcine bioprostheses and bovine pericardial valves in the mitral position shows a clear advantage in valve durability at 10 years of the pericardial valve (Jamieson, 1999; Thamilarasan, 2002).

STUDIES COMPARING MECHANICAL WITH BIOLOGICAL PROSTHESES

The two major randomized clinical trials that have been reported are the Edinburgh Heart Valve Trial and the Veterans Administration (VA) Cooperative Study on Valvular Heart Disease. Both studies compared mechanical valves to porcine bioprostheses.

The Edinburgh trial compared the Bjork-Shiley standard valve to porcine valves-initially the Hancock and later the Carpentier-Edwards. It contains actuarial comparisons at 5 and 12 years for the 211 aortic and 261 mitral valve patients. The authors concluded that survival with a mechanical valve was better then with the bioprosthetic valve, but that this was somewhat offset by the increased risk of bleeding.

The VA trial compared the standard Bjork-Shiley valve to the Hancock Modified Orifice (size 21 to 23 mm aortic) or Hancock Standard (other sizes) porcine valves. The principal long-term findings of this randomized trial are:

1. Use of a mechanical valve resulted in a lower mortality and a lower reoperation rate after aortic valve replacement
2. The mortality after mitral valve replacement (MVR) was similar with the use of the two prosthetic valve types
3. There were virtually no primary valve failures with use of a mechanical valve
4. Primary valve failure after AVR and MVR occurred more frequently in patients with a bioprosthetic valve especially in patients aged < 65 years
5. The primary valve failure rate between bioprosthesis and mechanical valve was not significantly different in those aged = 65 years
6. Use of a bioprosthetic valve resulted in a lower bleeding rate
7. There were no significant differences between the two valve types with regard to other valve related complications including thromboembolism, and all complications

(Grunkemeier, 2001; Rahimtoola, 2003; Otto, 2004)

CHOOSING A PROSTHETIC VALVE

The choice between mechanical and bioprosthetic valves should be an early point of discussion between the cardiologist, the cardiac surgeon, and the patient. Multiple factors need to be considered in the decision-making process, including the age of the patient; the probability of future pregnancy in young women; and the patient's occupation, lifestyle, and life expectancy (Garcia, 2002). The major considerations in choosing a bioprosthesis versus a mechanical valve are the expected durability of the valve and the risks of anticoagulation. The other factors that influence the choice of valve include the expected hemodynamics for a specific valve size, anatomic considerations at the

time of surgery, patient preferences, lifestyle, and comorbid diseases that may affect longevity or the risk of anticoagulation. The specific choice of which bioprosthetic or mechanical valve to use depends on an assessment of the hemodynamics and ease of surgical implantation for each valve. Most cardiac surgical centers choose one type of valve in each category rather than using reserved for clinical situations in which noninvasive data are not diagnostic (Otto, 2004).

Because of the wide variation in results among and between various valve models, it is impossible to rank valves within valves types on the basis of complication rates. Some general recommendations, however, can be made with regard to valve selection (Grunkemeier, 2001).

A biological valve should be used when the patient cannot or will not take anticoagulants or has a short life expectancy. A mechanical valve should be used if the patient needs anticoagulant therapy (e.g., because of atrial fibrillation), has a mechanical valve in another position, previously had a stroke, requires double valve replacement, or has a long life expectancy. Mechanical valves should be considered for double valve replacement because the risk of structural deterioration for two porcine valves is additive, whereas the thromboembolic risk of two mechanical valves is not additive (Grunkemeier, 2001).

SPECIAL CONSIDERATION

A. AGE

Among the patient factors, age is one of the most important issues in valve selection because of the documented differences in durability of prosthetic valves, bioprostheses being less durable than mechanical prostheses. Consequently, all else being equal, mechanical valves are favored in younger patients and bioprostheses in older patients. What age distinguishes these two groups depends on the perceived life span of the individual since dysfunction of bioprostheses becomes more evident after 6 years. The incidence of valve dysfunction requiring reoperation approaches 30 % at 10 years after bioprosthetic valve implantation. Degeneration of bioprostheses is more common in younger patients for any valve replacement duration compared with that in older patients. Many recommend bioprostheses for patient older than 65 to 75 years and suggest mechanical prostheses for younger patients (Wernly, 1991).

Middle-aged or younger patients who wish to avoid long-term anticoagulation therapy and who require aortic valve replacement are good candidates for homograft or allograft replacement, because the durability of these valves appears to be greater than that of bioprostheses. It remains to be determined whether the durability of stentless porcine valves is comparable (Garcia, 2002).

B. PREGNANCY

For young women of childbearing age, wherever possible severe valvular lesions likely to cause problems during pregnancy should be corrected before pregnancy by treatments which avoid valve replacement-balloon valvuloplasty for mitral stenosis, mitral valve repair for mitral valve prolapse. If valve replacement is required the choice of type of prosthetic valve is difficult (Bloomfield, 2002). If valves replacement cannot be avoided, bioprosthetic valves should be used, because they carry a smaller risk of fetal and maternal complications (Garcia, 2002). The management of young women with valvular heart diseases who are contemplating a future pregnancy, the choice of prosthetic heart valves if one is necessary, and the management of such patients during pregnancy is outlined in figure 8 (Hung, 2003).

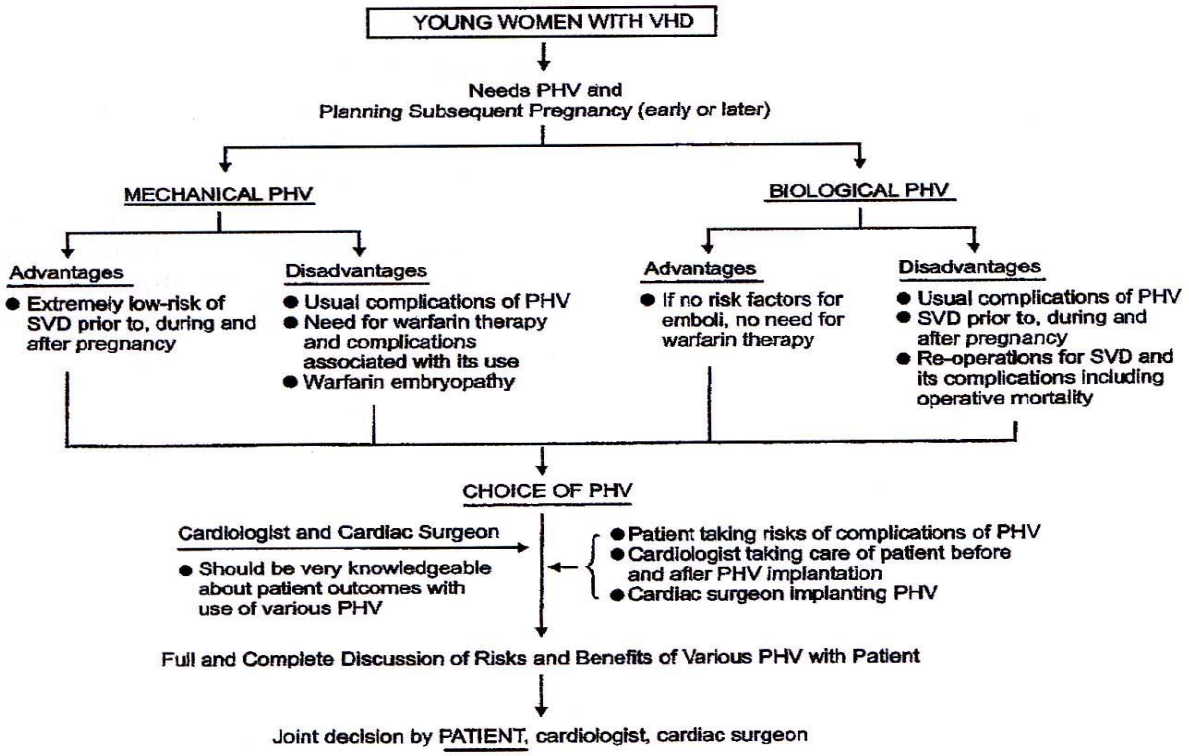

Figure 8. Algorithm the management of young women with VHD who are contemplating a future pregnancy

C. CHILDREN AND PATIENTS RECEIVING CHRONIC HEMODIALYSIS

The high incidence of bioprosthetic valve failure in children and adolescent and in patients on chronic hemodialysis virtually prohibits their use in these groups. In children, a mechanical prosthesis (generally the St. Jude valve) with is favorable hemodynamics is preferred despite the disadvantages inherent in the need for anticoagulants in this age group. Similarly, mechanical valve prostheses should be used in patients with chronic renal failure and/or hypercalcemia. Alternatively, if an experienced surgical team is available and the patient requires an aortic valve replacement, a pulmonary autograft may be employed (Braunwald, 2001).

D. TRICUSPID POSITION

The risk of thrombosis for all valves is highest in the tricuspid position because of the lower pressures and velocity of blood flow. This complication appears to be highest for tilting-disc valves, intermediate for caged-ball valves, and lowest for bioprosthesis, which are the valves of choice as tricuspid replacements. Fortunately, bioprostheses exhibit a much slower ate of mechanical deterioration in the tricuspid position than in the mitral or aortic positions (Braunwald, 2001).

MANAGEMENT AND FOLLOW UP OF PROSTHETIC HEART VALVES

Patients with prosthetic heart valves require regular examinations and echocardiograms, antithrombotic therapy, and appropriate antibiotic prophylaxis against endocarditis. Physicians must also be on the alert for several uncommon but potentially devastating complications: valve structural failure, thrombosis, embolism, endocarditis, paravalvular leak, and hemolytic anemia (Bettadapur, 2002).

Patients undergoing cardiac valve replacement should undergo Doppler echocardiographic evaluation at baseline is crucial, since it serves as a reference for subsequent examinations. Follow up visits in asymptomatic patients without complications and with a "normal" initial echocardiogram can be performed at yearly intervals and should consist of a detailed history taking and a physical examination. Any patient with a prosthetic heart valve who does not improve after

surgery or who later develops deterioration of functional capacity should undergo appropriate testing including transthoracic or transoesophageal Doppler echocardiography and, if ultrasound is not conclusive, cardiac catheterization and coronary angiography (Seiler, 2004).

Patients with prosthetic valves of any type have a 2 % to 6% lifetime risk of developing endocarditis, which carries a high risk of mortality. There are no data to suggest that prophylactic antibiotics for heart valve patients in certain high-risk situations: dental procedures and tooth cleaning, surgery involving the respiratory mucosa, some respiratory procedures, and some gastrointestinal and genitourinary procedures (Bettadapur, 2002).

Patients with mechanical valves are routinely treated with anticoagulants because without this therapy, they have a lifetime risk of thromboembolism that may be as high as 34 %. Ideally, anticoagulation therapy with warfarin would be started immediately after surgical implantation, but to prevent surgical bleeding, it is usually started a few days after surgery.

Patients with other risk factors for thromboembolism, such as left atrial thrombus, atrial fibrillation, decreased left ventricular function, multiple prosthetic valves, or any previous thromboembolic event, may be given aspirin in addition to warfarin.

For heterograft bioprosthetic valves, the need for warfarin is controversial. For mitral valves an international normalized ratio (INR) level of 2.5 to 3.5 is often recommended for the first 3 months after surgery until the valve is fully endothelialized. If the patient has additional risk factors (such as left atrial thrombus, atrial fibrillation, or a prior thromboembolic event), then anticoagulation should be continued beyond the first 3 months. For aortic valves, aspirin 325 mg daily is usually recommended for 6 to 12 weeks until the valve is endothelialized, though some guidelines recommend warfarin instead. For homograft bioprosthetic valves, no anticoagulation is necessary. However, as with any patient, anticoagulation therapy is required if there is atrial fibrillation, atrial thrombus, or previous thromboembolic events (Bettadapur, 2002).

SUMMARY

The development and the refinement of prosthetic valves during the last three decades have resulted in a remarkable improvement in survival and quality of life for millions of patients who have valvular heart disease. Replacement of a malfunctioning native valve with a prosthesis, however, substitutes one disease for another. No prosthetic valve is ideal. None of the available mechanical or biologic valves has the performance and durability of the native human semilunar and atrioventricular valves. Therefore, the selection of a valve must take into account the relative advantages and disadvantages of a particular prosthesis and how to apply to the patient's risk profile. However, there are several potential devastating complications that can occur in these patients. Recognizing these complications early is imperative to prevent serious morbidity and mortality. It is hoped that attention to these issues will lead to optimal care for patients with prosthetic valves.

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