

Which Type Of Prosthetic Valves To Offer To Our Patients In Developing Countries

HASSAN RAFFA*

SUMMARY

701 cardiac valve replacements were performed between 1982-1987 by our Cardiac Team in four countries - 639 in Saudi Arabia, 27 in Yemen, 30 in Mauritius and 5 in Sudan. There were 398 aortic valve replacements (AVR). 326 patients received mechanical aortic valves and 72 bovine aortic valves. 417 patients underwent mitral valve replacements (MVR). 176 received bovine mitral pericardial valves and 24 mechanical mitral valves. Both AVR and MVR groups included 114 double valve replacement (AVR and MVR). 38 patients died perioperatively (average mortality rate of 5.4%). Prosthetic valve endocarditis of early onset occurred in 11 patients. Paravalvular leak in 4 patients (0.5%), thromboembolic episodes in 4 patients with AVR (1%) and in 8 patients with MVR (2%), acute catastrophic thrombosis in 3 patients with AVR (0.7%) and 2 patients with MVR (0.4%). Valve dysfunction occurred in 18 patients (2.5%) of which 9 had bioprosthetic and 3 mechanical valves.

The choice of valve prostheses depended on a multifactorial scheme including age, sex, origin, feasibility of anticoagulation, LV size, psychological makeup and intelligence of the patient respectively, awareness, literacy and availability of laboratories to estimate Prothrombin time. The choice of a cardiac prostheses for the patients in developing countries is a difficult but challenging and rewarding task.

INTRODUCTION

A cardiac valve is a device which allows the flow of blood in only unidirectional manner. Starr¹ implanted on September 21st, 1960 the first long-term successful mitral valve replacement with a caged ball valve in a 52-year old man with mitral stenosis and regurgitation. Successful implantations were enthusiastically performed all over the world and four basic types of cardiac valve prosthesis, caged ball, caged disc, tilting disc and tissue valves were developed. However, soon, many potential complications of even fatal nature, such as thromboembolism², degeneration³, calcification⁴, dysfunction^{5,6} metal fatigue⁷ with breakage, infections⁸ and outgrowing a prosthesis⁹ were

encountered. Branunwald defined an ideal prosthetic valve as one that is non-thrombogenic, non-obstructive, non-hemolysing, durable, not liable to infections and that present good hemodynamics. It is obvious that no prosthetic cardiac valve would fulfil all these criteriae and that the best available valve is still as before the patient's own native valve. However, on many occasions, the native valve is destroyed and its replacement offers the best palliative improvement in quality and quantity of the patient's life, and, in fact, may save his life. The Cardiac Surgeon is charged with the responsibility of determining which heart valve is best suited for a particular patient.⁽¹⁰⁾

*Assistant Professor of Cardiac Surgery, King Abdulaziz University Hospital, Jeddah, Saudi Arabia Chief of Cardiac Surgery, Saudi Heart Center

PATIENTS & METHODS

701 patients underwent open heart surgery for replacement of their cardiac valves in Saudi Arabia, Sudan, Yemen and Mauritius by the same surgical team which performed 10 overseas open heart projects outside the Kingdom of Saudi Arabia between 1981-1987. 262 were males (37%) and 439 were females (62%) 152 patients were children below the age of 14 years (21%). Indications for valve replacement were severe fibrosis and dystrophic changes in 668 patients, advanced calcification in 14 patients, infective endocarditis with ulceration and perforation of valve cusps in 13 patients, and failed trials of reconstructive surgery in 6 patients.

The choice of valve depended on the following parameters age and sex of the patient, geographic origin of the patient, medical condition and presence or absence of indications respectively, contraindications to anticoagulation such as gastroduodenal ulcer disease, hypertension and bleeding diathesis. The psychological status of the patient was also considered and so was his compliance to treatment, illiteracy and availability of Prothrombin estimating laboratories in rural areas. Finally, the size of the left ventricle is also a determining factor in the choice of valve prosthesis.

AGE

In children and adults, only mechanical

valves are now implanted. In the beginning of our series from 1981-1983, tissue valves were implanted more as we were afraid of all the morbid complications associated with the use of anticoagulation with mechanical valves. The high rate of fibrosis, calcification and degeneration of bioprosthetic valves seen by us even in tissue valves treated with anticalcification agents, tanned with surfactant factor, treated with special Methylen Blue agents or fixed with low pressure fixation, methods which are supposed to reduce significantly the rate of accelerated degeneration of tissue valves, forced us to stop using all the xenoheterografts of both bovine or porcine origin in the young patient population and to use only mechanical valves in them. Implants of 325 mechanical valves of bileaflet type (Duromedic & St. Jude) in the aortic position, and 241 in the mitral position have given in our hands excellent results.

The hemodynamic performance of these valves even in small sizes is good. The orifice to annulus ratio is high, the transvalvular gradient at rest is minimal and on exercise is acceptable. Metal fatigue and breakage of struts or any components of these valves were not encountered. The children who had A. V. R. with bileaflet valves were only given antiplatelet drugs as prophylaxis against thromboembolism, and the embolic rate was 1-2%/patient/year. Ebert¹¹ has documented very low thrombogenicity with this prophylaxis. Sade^{1 2} has reported that the risk of thromboembolism in children

TABLE I:

Type and number of Valve Replacements carried on by the Saudi Team in 4 developing countries

	MVR	AVR	MVR/AVR MVR/TVR	PVR	Total	Deaths
Saudi Arabia	291	243	104	1	639	34
Yemen	4	23	—	—	27	3
Sudan	2	3	—	—	5	—
Mauritius	5	14	10	1	30	1
	302	283	114	2	701	38

CHOICE OF ARTIFICIAL CARDIAC VALVES:

Children & Young Adults

- AVR
- Only mechanical prosthesis with antiplatelet agents
- MVR
- Only mechanical
- with antiplatelet agents
- with anticoagulation

- Women**
- (Childbearing age)
- MVR
- desiring pregnancy
- : Mechanical with Calci-Heparine
- not desiring pregnancy
- : Mechanical
- AVR
- Only mechanical with anti-platelet agents

ADULTS

- | | |
|---|----------------|
| Males | Elderly |
| • AVR | • AVR |
| Mechanical | Mechanical |
| • MVR | • MVR |
| Mechanical unless anticoagulation contraindicated | Tissue |

Consider also the following factors:

- Psychological status
- Illiteracy
- Geography
- Size of L. V.
- Anaemia

given antiplatelet drugs is not greater than in those treated with full anticoagulation.

In our series, 3 children who underwent M. V. R. and had mechanical bileaflet valves implanted were not anticoagulated, but only given Dipyramidole and Aspirin and no major thromboembolic phenomenae were encountered. However, in one, transitional loss of speech was experienced twice which was an indication for full anticoagulation. 3 children who had tilting disk prosthetic valve implanted (2 Sorrin and 1 Bjork-Shiley) were given full anticoagulation as these valves are more prone to thrombosis.

All adult patients (above the age of 14 years) who undergo implantation of mechanical valve of any type at the mitral position are fully

anticoagulated as the risk of thromboembolism in the adult approaches 33% without anticoagulation and it is evident that prophylactic sole treatment with Aspirin and/or Dipyramidole (Persantin) does not give sufficient protection as in children.

SEX

Women in childbearing age who desire to become pregnant were always thought to present a good indication for usage of only tissue bioprosthetic valves if they undergo mitral valve replacement. In our experience, this is no more true today. Implantation of mechanical valves give superior hemodynamics and proven longer durability. In all female patients where pregnancy is no more desired or possible (status post-tubal ligation or hysterectomy etc.). Only

mechanical valves should be implanted in the mitral position.

For all female patients who required isolated aortic valve replacement, only mechanical aortic valves of bileaflet type should be implanted, as treatment with antiplatelet agents during pregnancy gives sufficient protection against thromboembolism and is not teratogenic.

The anticoagulation can still be maintained during pregnancy by giving Calci-Heparine injections and avoidance of Warfarin in the first 12 weeks of gestation, as they may cause facial abnormalities. The Calci-Heparine subcutaneous prophylaxis gives enough protection against thromboembolism in the pregnant women with mechanical mitral valve, even though a hypercoagulability state exists during pregnancy. In the second trimester of pregnancy, Warfarin can be given orally and in the last trimester, 2 weeks prior to anticipated delivery, Calci-Heparine prophylaxis can be reinstated to avoid potential severe haemorrhage seen usually with prolonged use of Warfarin derivatives.

MEDICAL CONTRAINDICATIONS TO ANTICOAGULATION

Patients with evidence of gastro-duodenal ulcer disease, hypertension and bleeding tendency, especially elderly patients, should not have mechanical valves implanted in either the aortic or mitral positions, as severe, even fatal, complications can develop rapidly in them. We, therefore, recommend to implant bovine or porcine heterobioprosthetic valves, especially of the low profile in these patients as high profile mitral prosthesis may lacerate easily the thin and fibrotic myocardium of such elderly patients which can produce either a mid-ventricular rupture¹³ or a delayed subvalvular fibrotic aneurysm of the posterior left ventricular wall¹⁴, or even left ventricular outflow tract obstruction¹⁵.

PSYCHOLOGICAL STATUS

Emotionally unstable or neurotic patients cannot comply with the daily ingestion of anti-coagulative drugs or the necessity for repeated Prothrombin evaluation, illiterate patients who

are not reliable for proper consumption of necessary drugs. These variety of patients are at risk of thromboembolism if mechanical valves are implanted and should preferably receive bioprosthetic valves for the mitral position. Mechanical bileaflet prosthesis are recommended for aortic replacement as the risk of thromboembolism is low. Patients who come from rural areas where no facilities for Prothrombin estimation exist, should also have the same plan of management.

The author has seen on six occasions severe haemorrhagic complications related to non-compliance to proper anticoagulation. Brain haemorrhage in 3 children, gastrointestinal bleeding and genito-urinary bleeding in 3 illiterate patients who over-consumed the given oral anticoagulation drugs. Thromboembolic phenomena were also seen in 3 adult patients who stopped taking their prescribed daily con-maden drugs.

RESULTS

701 cardiac valve replacements were performed. Aortic valve replacement was performed in 398 patients and mitral valve replacement in 417 patients. 38 patients died postoperatively (within 30 days) reflecting an early mortality rate of 5.4%. 12 patients died later due to complications related to cardiac prosthesis (6 patients), Prosthetic valve endocarditis (2 patients), car accident (1 patient), electrocution (1 patient), leukaemia (1 patient) and unknown cause (1 patient) reflecting a late mortality rate of 2.3%/patient/year. Among the seen complications are prosthetic valve endocarditis of early onset (1%), thromboembolic events in AVR (1%) and in MVR patients (2%). Acute catastrophic thrombosis occurred in 0.7% of AVR patients and in 0.4% of MVR patients. Dysfunction of the prosthetic valves occurred in 18 patients (92.5%) of which there were 11 bioprosthetic valves and 8 mechanical valves. Reoperation to replace a dysfunctioning valve (13 patients = 2%), a thrombosed valve (6 patients 0.8%), an infected valve (5 patients 0.7%), and for paravalvular leak in 4 patients (0.5%). The actuarial survival rate for aortic valve replacement is 91% and for mitral valve replacement is 88% after 5 years.

TABLE 2 :

Type of Prosthetic Valves used in Saudi Cardiac Projects in 4 developing countries.

TYPE	No. of IMPLANTS	
	AVR	MVR
Mechanical Valves		
• Bileaflet Tilting disc valve		
• Duomedic	268	154
• St. Jude	76	38
• Sorrin	9	4
• Bjork	4	3
• Lillhei-Kastor	1	—
Caged Disc Valve		
• Cooley-Cutter	1	—
Bioprosthetic Valves		
: Heterografts		
: Bovine Ionescu-Shiley	37	189
: Porcine Carpentier-Edward	2	29
: Hommografts	—	—
Total:	398	417

DISCUSSION

Cardiac valve replacement with prosthetic valves is an event which is connected with a series of potential complications as the ideal prosthetic valve does not exist. Thrombogenicity, non-durability, liability to infections and obstructive and peripheral flow and other valve related complications are important factors restricting and prohibiting wide and generous valve replacement. A valve replacement is an ultima ratio and the last palliation. The decision to use any particular heart valve is often based on personal clinical experience, an experience complicated by the evolutionary nature of prosthetic heart valve design and the myriad of devices now available in addition, to a multi-factorial evaluation of age, sex, origin, compliance to anticoagulation, psychological makeup,

literacy, awareness, availability of facilities for Prothrombin estimation and different medical criteriae such as size of LV cavity, presence of anaemia or a bleeding diathesis, ulcer disease and hypertension. All these factors must be considered together, especially for cardiac patients in developing countries. Further, the decision whether to implant a mechanical or a biological valve is also important and often not an easy one. We, therefore, recommend to evaluate all the above factors thoroughly prior to implantation. A logical intelligent discussion with the patient can reveal many important hints. All children and young age adult patients should receive only mechanical or aortic valves implantations. Those with AVR receive only antiplatelet drugs, those with MVR full anticoagulation. If a child requires MVR and anticoagulation seems to be difficult, there

is still no need to implant a bioprosthetic valve and a mechanical valve with antiplatelet prophylaxis should be offered, as the risk of thromboembolic events in such children is not greater than in fully anticoagulated adults¹⁶.

FAILURE OF PROSTHETIC VALVES

A certain failure rate is unavoidable. The most commonly seen causes are thrombus formation preventing proper opening and closure of the disc. Acute catastrophic thrombosis is a feared and fatal complication leading to acute heart failure and pulmonary oedema. Metal fatigue and fracture of strut or the disc is also occasionally seen. Excessive granulation tissue pannus encapsulating the disc may form and interfere with its function, so also bulky vegetations in prosthetic valve endocarditis (PVE), especially in candida albicans infection. Disruption of annular anchoring sutures may cause paravalvular leak and severe valvular dysfunction due to acute regurgitation.

Among other problems seen with prosthetic cardiac valves, is hemolytic anaemia which is becoming less frequent today with the implantation of new models. In our experience, it occurred in less than 0.4% of patients who received either aortic or mitral bileaflet mechanical valves. It occurs more frequently today in cases where paravalvular leak due to suture disruption. Paravalvular leak is mainly related to technical causes (disruption of sutures) or occurrence of infection at the suture area. The incidence is less than 1-2% if careful attention to meticulous technique and sterile handling of the prosthesis during implantation respectively and washing it generously with saline after implantation. Patients who develop the last two complications of significant degree causing clinical disability should undergo a new valve replacement. Those with hemolytic anaemia evaluated well. If it is thought that the model of the implanted mechanical valve is rather hemolytic, another model of mechanical valve or eventually a bioprosthetic valve should be implanted.

NEW BIOPROSTHETIC VALVES

Barrat-Boyes, Yacoub and Ross have used

extensively homografts as substitutes for diseased aortic valves for the last 20 years and very good hemodynamic results, low or absent thromboembolism and long durability have been reported by them. Homografts, were always difficult to procure and sterilise. However, stented or free unstented homograft valves are now commercially available and may alter the choice of valves in the coming years. The economic situation in developing countries may also be an important political factor in choosing the prosthesis, although the bileaflet valves are the most expensive on the market, they may be the best to use in the long run in our patients as they have the least thrombosis, dysfunction, reoperation and hemolysis rate, so that a longer durability is probable with the least chance of the need for reoperation or admission for related complication and accordingly best economic cost/benefit ratio.

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