CHOICE OF CARDIAC VALVE PROSTHESES IN VALVULAR HEART DISEASES

M.S. ESSAY PRESENTED BY

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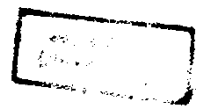

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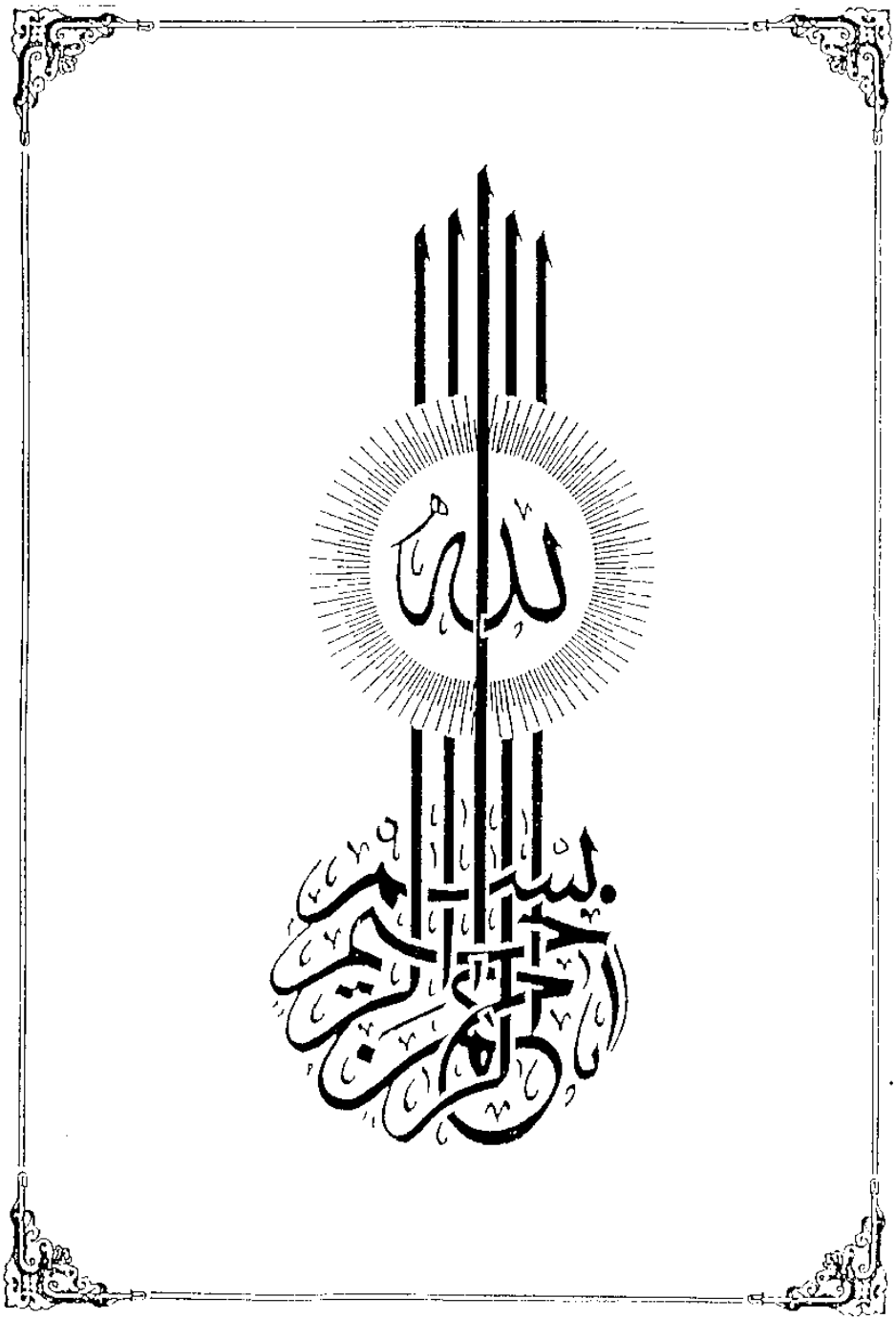

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INTRODUCTION

INTRODUCTION

Historic Aspects of Cardiac Valve Replacement:

Although closed valve operations had have good results in cases of mitral stenosis, results were poor in aortic valve disease and mitral incompetence (1)(2)(3)and surgeons became interested in improving their "blind" procedures for these lesions. On September 1952, Hufnagel ignited the fire of prosthetic valve implantation by successfully inserting a caged ball valve into the descendingthoracic aorta of a patient with severe aortic regurgitation (3). In 1953, John Gibbon excited the entire field of medicine by his first successful use of total cardiopulmonary bypass for intracardiac surgery in man (4)(55). Lillehei revitalised the surgical approach to chronic valvular disease by performing the first successful open mitral commisurotomy in 1956 (5). Also in 1956, Lillehei performed open annuloplasty operations for severe mitral regurgitation (5). The especially rewarding results were in those patients in whom the leaftets pliability was preserved. Poor results occurred most often in patients with loss of valve tissue due to fibrosis and contraction of the leaflets (5). To approach this problem of deficient valve substance, Lillehei (5) sutured tubular immobile prostheses near the destroyed posterior leaflet to serve as buttresses against which the anterior mitral leaflet would approximate during systole. This technique was not helpful in the majority of patients in whom the rheumatic inflammatory process had produced stiff, thickened and calcified valves.

Also during this period, open-heart operations were performed on the aortic valve similar to the mitral valve (9).

Two important problems were noted: many valves were contracted and calcified, and the restonsis rate after commissurotomy was high. Thus, development of implantable valve substitutes would be absolutely necessary. Barnard used a flap-type silastic prosthesis to replace the posterior mitral leaflet in dogs. Leaflets were also fashioned from pericardium, or Teflon (14). None of these partial valve replacement techniques were successful because of problems of dehiscence, thrombosis, and loss of compliance of the leaflets.

In 1960, Hufnagel gave Harken some of his hollow mylon-silicone rubber covered poppets. Harken used them as ball poppets in a stainless steel double caged prosthesis (21). Harken's first aortic valve replacement was unsuccessful.

His second patient, a 32 year old women, underwent successful aortic valve replacement on March 10, 1960 (21). This patient developed later on periprosthetic leakage and the prosthesis was replaced in 1963 (132). The second successful operation was performed in June 1960. The patient developed prosthetic endocarditis in 1985 and the prosthesis was replaced (132). Thus, the initial prosthesis was in place for 25 years, the longest duration recorded for any valve. Neither of Harken's first two successful aortic replacement received anticoagulation and neither had embolic complications (132).

The first successful mitral valve replacement was performed by Albert Starr in September 1960. Star used also a caged ball prosthesis. His first patient died after operation by an air embolus, but the second patient survived

for 15 years later (55). Starr and his engineering associate, Lowell Edwards, started a laboratory for manufacturing caged ball prostheses, the Edwards Laboratories (132).

Types of Cardiac valve prosthesis:

(A) Mechanical prostheses:

a. Caged ball design: (24, 25)

(1) Starr-Edwards valve: This prosthesis has many models. In the mitral position models 6000, 6120, 6300, 6310, 6320, 6320, 6400

In the aortic position models 1000, 1200, 1260, 2300, 2310, 2320, 2400.

(2) Smeloff - Cutter prostheses (56)

(3) Magovern-Cormie valve (68)

(4) Braunwald-Cutter valve (76)

(5) De-Bakey-Surgitool valve (55)

b. Central disc occluder prostheses (Non-tilting disc)

(1) Kay-Shiley valves (93)

(2) Beal-Surgitool valve model 102, 103, 104, 105, 106 (106).

(3) Starr-Edwards disc valves model 6500, 6520 (118).

(4) Cooley-Cutter valve (122).

c. Tilting disc valves

(1) Björk-Shiley disc valves: It passed many modifications

- Björk-Shiley with Derlin disc.
- Bjork Shiley with Pyrolyte carbon disc (129).

- Björk-Shiley convexo concave model (143)
- Björk-Shiley integral monostrut model (136).

(2) Lillehei-kaster valve (195).

(3) Omniscience valve (197).

(4) Medtronic-Hall valve (Hall-Kaster) (205).

(5) St. Jude Medical bileaflets device (209).

(B) Bioprostheses:

(1) Aortic valve homografts (223).

(2) Autologus pulmonary valves (250).

(3) Dura mater homografts (254).

(4) Porcine valve xenografts: These are many types of the porcine xenografts:

1. Hancock porcine xenograft standard orifice (324).
2. Hancock porcine xenograft modified orifice (310).
3. Carpentier-Edwards porcine xenograft (297).
4. Carpentier-Edwards Supra Annular model xenograft (270).
5. Angell-Shiley valve (298).

(5) Bovine Pericardial xenografts: This include:

1. Ionescu-Shiley valve (343).
2. Carpentier-Edwards pericardial xenograft (300a)
3. Unicusp pericardial Meadox xenograft (358).

Characteristics of an ideal prosthetic valve:

There is no ideal prosthetic valve, yet he following criteria are the ideal characteristics that an ideal prosthesis should accomplish. They include the engineering principle, materials used, and ease of implantation(24)(57):

1-The valve orifice must permit adequate blood flow with a minimum pressure gradient. Table (1), (2) show natural valve areas compared with commercially available valve prostheses (Table 2).

Table (1) Adult human valve dimensions (29)

Natural heart valve	area (cm^2)	Natural heart valve	area (cm^2)
Aortic valve: male	4.81±1.30	Mitral valve male	8.7±2.03
female	3.73±0.98	female	6.94±1.41
Pulmonary valve male	4.88±1.25	Tricuspid valve male	11.9±2.72
female	4.32±1.03	female	9.33±2.02

Table (2) Orifice are of some of the most important commercially available cardiac prostheses size 21 mm

Valve name	in vtiro area (cm^2)	Valve name	in vitro area (cm^2)
Hancock stardard (264)	1-1.1	Ionescu-Shiley (310)	1.3
Hancock modified orifice (270)	1.6-1.4	Starr-Edwards (20)	1.0
Carpentier-Edwards (260)	1.3-1.4	Björk-Shiley (146)	1.3
Carpentier-Edwards pericardial valve (310)	1.4	St. Jude Medical (324)	1.4-1.5

2- The prosthesis should not cause clinically significant regurgitant flow (not more than 10% in the aortic position), or turbelence so as not to damage the red blood cells (24) (57).

3- Heart valves cycle at approximately 42 million times per year. So, heart valve prosthesis should be able to withstand cycling in this rate for a period of 25-30 years.

4- It should be designed in such a manner to minimize stagnation zone behind it to avoid thrombus formation (209).

5- The materials used in valve manufacturing must be compatible with tissue and blood so as not to corrode or initiate clots (57).

6- Mitral valve prostheses should not obstruct left ventricle outflow tract (26) and aortic valve prostheses should not compromise coronary flow (57).

7- The valve must operate independent of position of the patient i.e. on standing or lying down. This means that all floating parts should have a specific gravity (1014) close to that of blood (57).

8- McQueen and his associates used a computer in studying the performance of many mitral prosthetic design (273). The best overall valve has a radius of curvature equal to 1.5 times the diameter of the occluder and a pivot pont located 0.39 mitral-ring diameters from the anterior border of the mitral annulus. The maximum angle of opening of this optimal valve is limited to about 70 degrees. Nevertheless, the inclusion of a redundant stop in the mechanical design of the valve is indicated, since the computer experiments also reveal excessive opening and failure to close in valves with nearby parameter valve (273).

9- From the surgeon point of view, the prosthesis should be implantable with ease and withstand common hospital sterilization techniques (24). From the patient point of view the valve should operate quietly without noise (24).

Testing of artifical heart valves:

Before using any prosthetic valve in man, it should be subjected to several in vivo testing as well as animal implantation. The tests necessary for evaluation of any prosthesis are the following:

(I) In-vitro tests:

a. Steady flow studies.

b. Pulsatile flow studies.

c. Fatigue tests.

(II) In-vivo animal tests.

(III) In-vivo human evaluation.

(a) Steady-flow studies:

This simple method is used to compare the different valve types and to give a first impression of the relative hydrodynamic performance of a valve (57). To allow comparability the procedure should be standardized by using a standard average geometry of the test chambre or the use of a simple straight tube with constant diametr inside which the valve with its sewing ring is inserted. However, these tests ignore the systolic diastolic changes in cross-sectional areas of the heart during the cardiac cycle (57).

(b) Pulsatile flow studies: (57) (143):

Numerous pulse duplicators have been designed. The designs usually involve two chambres to simulate left atrium and ventricle. A pump is used to create pulsatile flow through the valves. For comparing the results, fluid flow rates, viscosity, pulse rates and pressure curves should be defined.

The valve testing chambre in made of plexiglass so that valve action can be photographed. Cross-sectional areas molded from silicone rubber casts of human heart and aorta made at autopsy are used to give good three dimensional simulation. Water mixed with glycerin to a specific gravity and viscosity similar to blood, is used. A high speed camera can be used to photograph the motion of particles suspended in the liquid. Pressure gradients are measured by special transducers. The greatest disadvantage of the duplicators is the different designs and thereby the limited comparability of the results. The pulsatile flow tests give information about function of the valve opening and closing times and pressures; measurement of forward and backward flow through the valve, localisation of laminar or turbelant flow as well as the stagnation areas, and lastly the pressure gradient across the valve. Fig. (1) illustrates a pulsatile flow test apparatus that was used by Scotten et al. (143) in testing some low-profile valves.

(c) Fatigues tests: (57) (346):

Fatigues tests are done to evaluate material fatigue and wear. Accelerated fatigue tests are used to get faster results. However, the additional corrosion induced by body fluid can not be assessed and is only tested n vivo. It should be noted also that not all valves could be subjected to the same fatigue tests frequencies. For example, the valves manufactured by Edwards & Shiley laboratories are not tested by frequencies more than 500/min. Using higher frequencies, disturb the poppet function which remain in a medium floating position, kept by its inertia, and give unreliable data (57).

Animal Experimentation (55)

Animal experimentation in also important. The most common laboratory animal is the dog. Animal testing does not exactly simulate conditions in the human, for example, valves implanted in the dogs are much more likely to fail from clot formation. Also, the neointima growth over cloth covering of valve prosthesis in dogs are different from man (74).

In-vivo hemodynamic evaluation:

This is the most important single item in evaluating valve prosthesis. However, it is difficult to perform post-operative cardiac catheterisation studies routinely in asymptomatic patients who has successful valve replacement. There is increasing sophistication in the design of cardiac valves, but limited opportunity to substantiate improvement in valve performance by in vitro hemodynamic evaluation in patients with these valves. For purpose of comparability, Lawrance et al, suggested a standard protocol for intra-operative hemodynamic evaluation to permit comparing data (37). However, clinical and non-invasive methods are needed for practical following up of the patient. In a study done by Gray Mintz et al (31), to evaluate different non-invasive techniques in evaluation of prosthesis performance, it was found that in the mitral valve position the sensitivity of auscultation, echo-cardiography and cineflauroscopy were 94, 78, 88% respectively. In the abnormal aortic valve prosthesis, the sensitivities of auscultation, echo-cardiography, and cineflouroscopy were 92, 58, 33% respectively. In normal aortic valve prosthesis, the specificities were 100, 75, 92% respectively. Auscultation can detect almost all cases of malfunction of non-tissue

prosthetic valves. Echocardiography and cineflouroscopy can detect most cases of malfunction of mitral valve prostheses, but false positive results are common. They are less useful in detecting malfunction of aortic valve prosthesis (31).

Valvular prosthesis differ as regard durability, thrombogenicity haemodynamic effectiveness, suitability for different sized hearts, material competability and ability to cause hemolysis. The choice of a specific valve in a certain patient is dictated by many factors as age, sex, occupation, cultural level, accessibility to investigations necessary for follow up, heart size, as well as economic aspects. That is why choice may be difficult but a very important factor in determining the morbidity and mortality of the patient.

As there is no single valve of choice for all circumstances, cardiologist and surgeon have to match their best assessment of available prostheses against the clinical setting in which they are used (24) (25) (32) (281) (283). Follow up of the patient by a cardiologist who is aware of limitations and possible complications for each valve is mandatory.

THE AIM OF THE WORK

The aim of the work is review al types of limitations for each valve, as well as the different variables that determine the choice of specific valve to a specific patient.