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Comparative Evaluation of Safety Outcomes of Different Prosthetic Valves in Indian Subjects.

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Review Article

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ABSTRACT

Prosthetic heart valves are commonly used in the treatment of valvular heart disease. Choice of heart valve in the developing countries is an unsettled issue due to illiteracy and noncompliance related increase in incidences of stuck valve and anticoagulant related bleeding and as such international guidelines may not be wholly applicable. The aim of our study was to compare outcomes after mitral, aortic or double valve replacements with mechanical versus bioprosthetic valves. The outcomes will include incidence of mortality, reoperations, bleeding, thromboembolism, and endocarditis.

INTRODUCTION

The introduction of valve replacement surgery in the early 1960s has dramatically improved the outcome of substitutes are now implanted in patients with valvular heart disease. Approximately 280 000 worldwide each year; approximately half are mechanical valves and half are bioprosthetic valves. Despite the marked improvements in prosthetic valve design and surgical procedures over the past decades, valve replacement does not provide a definitive cure to the patient. Instead, native valve disease is traded for “prosthetic valve disease,” and the outcome of patients undergoing valve replacement is affected by prosthetic valve hemodynamics, durability, and thrombogenicity. Nonetheless, many of the prosthesis-related complications can be prevented or their impact minimized through optimal prosthesis selection in the individual patient and careful medical management and follow-up after implantation [1].

Prosthetic heart valves used for the definitive treatment of disease and dysfunctional native heart valves. They are broadly divided into mechanical heart valves (MHVs) and bioprosthetic heart valves (BHVs). MHVs are made of synthetic material (e.g., polymers, metal, and carbon), whereas BHVs are made of biologic tissues which are mounted on a fabric covered plastic frame, called a stent. MHVs are more durable, but their thrombogenicity and need for long-term anticoagulant therapy make them unsuitable for patients in some age groups especially older age groups. In contrast, BHVs are safe to implant, functionally similar to the native aortic valve, do not require long-term anticoagulant therapy, and are hence associated with reduced risk of hemorrhage. Since their introduction in the mid-1960s, BHVs have gone through many modifications, in their handling from time of harvesting to availability for implantation. Many tissues and different animal species aortic valves have been tried with varying results. Today, the most commonly used BHVs are those from porcine aortic valves and from calf pericardium. While the use of either one may be guided by patient age and other considerations, the trend in the India and Europe has been towards greater use of tissue rather than mechanical valves [2].

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Types of Prosthetic Heart Valve Design

Mechanical Valves

The current designs for the aortic and mitral positions include ball-and-cage valves, single tilting disc prostheses, and bileaflet prostheses. The bileaflet prostheses are manufactured by St. Jude, CarboMedics, ATS Medical, and On- X and are the most commonly used mechanical prostheses in the aortic position. They are unlike the other mechanical prostheses because they are mechanically stable and are hemodynamically efficient.

Mechanical prosthetic valves are intended to last a lifetime, decreasing the risk of reoperation. A disadvantage to mechanical valves is the risk of thromboembolism. Warfarin, an anticoagulant must be taken concurrently for the duration of the patient's life. Warfarin requires constant monitoring of the prothombin time and international normalized ratio (INR) which requires frequent postoperative follow-up appointments. Also, because warfarin is a blood thinner, the risk of bleeding is higher.

Three basic types of mechanical valve design exist: bileaflet, monoleaflet, and caged ball valves (Figure 1A, 1B, and 1C).

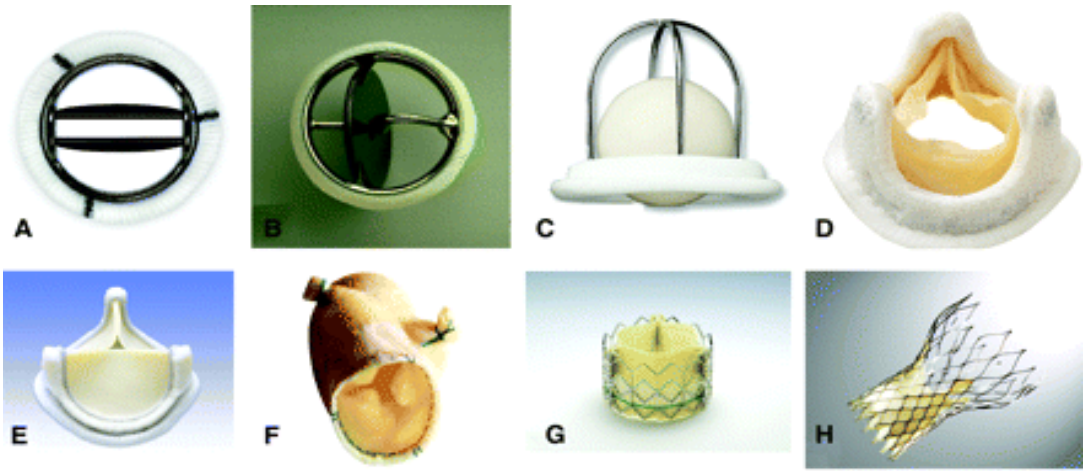

Figure 1

Different types of prosthetic valves. A, Bileaflet mechanical valve (St Jude); B, monoleaflet mechanical valve (Medtronic Hall); C, caged ball valve (Starr-Edwards); D, stented porcine bioprosthesis (Medtronic Mosaic); E, stented pericardial bioprosthesis (Carpentier-Edwards Magna); F, stentless porcine bioprosthesis (Medtronic Freestyle); G, percutaneous bioprosthesis expanded over a balloon (Edwards Sapien); H, self-expandable percutaneous bioprosthesis (CoreValve) [3].

Caged Ball Valves

Caged ball valves, which consist of a silastic ball with a circular sewing ring and a cage formed by 3 metal arches, are no longer implanted. However, several thousands of patients still have caged ball valves, and these patients require follow-up.

Monoleaflet Valves

Monoleaflet valves are composed of a single disk secured by lateral or central metal struts. The opening angle of the disk relative to valve annulus ranges from 60° to 80°, resulting in 2 distinct orifices of different sizes.

Bileaflet Valves

Bileaflet valves are made of 2 semilunar disks attached to a rigid valve ring by small hinges. The opening angle of the leaflets relative to the annulus plane ranges from 75° to 90°, and the open valve consists of 3 orifices: a small, slit-like central orifice between the 2 open leaflets and 2 larger semicircular orifices laterally.

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Bioprosthetic Valves

The bioprosthetic valves are treated chemically for transplantation to the human heart. Bioprosthetic valves are not as durable, have a shorter lifespan and are more susceptible to calcification than human and mechanical valves. Risk for reoperation is higher for younger patients receiving a bioprosthetic valve. The advantage to bioprosthetic valves is that unlike mechanical valves, they do not require lifelong anticoagulant therapy. Selection on the type of prosthetic valve is based on the age of the patient, valve position, comorbidity, and the risks and benefits of anticoagulation. Although, the selection process has some defined basis, much of the decision depends on the logic and experience of the surgeon.

The current recommendation by the American Heart Association/American College of Cardiology (AHA/ACC) is to perform a mechanical prosthesis for aortic valve replacement (AVR) in patients with a mechanical valve in the mitral or tricuspid position already in place or who is under 65 years old without contraindication to anticoagulants. In addition, a mechanical prosthesis should be considered for mitral valve replacement (MVR) in patients under 65 years old with long-standing atrial fibrillation.

Bioprosthetic valves are recommended in the aortic position in patients who are over 65 years old and thromboembolism risk free. In the mitral position, bioprosthetic valves should be considered in patients who are over 65 years old or are unable to take anticoagulants. The patient may choose either valve against the recommendations of the AHA/ACC guidelines or surgeon, as long as the risk of anticoagulant therapy versus reoperation has been discussed in detail with the patient.

Bioprosthetic replacement heart valves are derived from human (homograft) or animal (xenograft) tissues.

Homograft

These are derived from cadaveric (human) aortic valves. They are cryopreserved and are implanted into the aortic root without a stent. Autograft. Patient's own valve was taken from one site (pulmonary) and implanted at another site, for example, pulmonary valve grafted into the aortic site. This predominately occurs in children with diseased native aortic valves [4].

Xenograft or Heterograft

These are developed from animal tissues the most common being the porcine aortic valve followed by calf (bovine) pericardium.

Porcine aortic valve

In porcine BHV, the valve tissue is sewn onto a fabric covered metal wire stent, made from a cobalt-nickel or another alloy. A Dacron fabric covers the entire stent and a sewing skirt is fashioned and attached to the base of the wire stent. Contemporary models of these valves are durable and last for 10–15 years [4].

Bovine Pericardial Valve

Similar in design to porcine valves in that they imitate the tricuspid aortic valve, except that the metal cylinder joining the ends of stent wire is located in the middle of one of the stent post loops. At 10 years after implantation, the hemodynamics and durability of pericardial valves are equal to or greater than the porcine valves [5].

Stentless Valves

In bioprosthesis, as in MHV, the presence of the stent and the fabric sewing cuff leads to a residual stenosis of up to 20%. Stentless valves are meant to avoid this and to improve hemodynamics. They are made by removing the porcine aortic root and adjacent aorta en-block. The coronary arteries are tied off and the device can be trimmed as desired. The absence of a stent and sewing cuff avoids or at least minimizes residual stenosis and facilitates implantation of a larger BHV, which would enhance hemodynamics and patient survival [6].

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Ideal prosthetic valve

The ideal prosthetic valve that combines excellent hemodynamic performance and long-term durability without increased thromboembolic risk or the need for long-term anticoagulation does not exist. [7]Hence, patients and their physicians need to choose between a mechanical and a tissue (bioprosthetic) valve. In general, the advantageous durability of mechanical valves is offset by the risk of thromboembolism and the need for long-term anticoagulation and its associated risk of bleeding. In contrast, bioprosthetic valves do not require long-term anticoagulation yet carry the risk of structural failure and reoperation [8].

Valve-related complications

The initial concept that bioprostheses are associated with a lower embolic rate is disproven in patients who have similar baseline characteristics. This is also not surprising because there is a wide range of the incidence of these and other complications with the use of identical valve types [9,10] indicating complication rates are most likely due to patient related factors in the different studies and to differences in criteria of diagnosis and ascertainment of complications [10,11]. The patients in this trial had one or more risk factors for thromboembolism, which would be expected to be equally distributed between the mechanical and bioprosthetic groups in a randomized trial such as the present one. Furthermore, the follow-up in trial was 97% complete, and the determination of valve-related complications and causes of death were made by consensus of a committee of three who were blinded to valve type.

With the use of a mechanical valve, there were no primary valve failures with AVR and only one with MVR; the latter was not due to structural valve deterioration. The incidence of primary valve failure, reoperation and mortality was lower after AVR with use of the mechanical valve. With a lower rate of primary valve failure in those aged ≥65 years.

Safety parameters

An observational study by Khan et al. retrieved data from a computerized database, where the study enrolled patients who had undergone an aortic, mitral or combined aortic and mitral valve replacement with a bioprosthetic. In the first study, patients who underwent bioprosthetic and mechanical valve implantations for AVR and MVR reported having similar survival over a 20 year follow- up period. Reoperation was similar at 5 years between mechanical and bioprosthetic valves, but was notably different by 10 and 15 years. Bioprosthetic valve recipients had a higher rate of reoperation especially in patients who underwent double bioprosthetic valve replacement. The risk of reoperation increased progressively with time in isolated bioprosthetic MVR and AVR recipients. There was a higher incidence of bleeding in mechanical valve recipients in the aortic position, but incidence of bleeding in bioprosthetic and mechanical valve recipients was similar for MVR. Reported cases of embolism and endocarditis for AVR and MVR were insignificantly different in bioprosthetic and mechanical valve recipients.

In the second study by Hammermeister we found, survival was similar in bioprosthetic and mechanical valve recipients in the mitral position, but mechanical valve recipients in the aortic position had better survival. Reoperation was higher in patients who underwent a bioprosthetic valve implantation in the aortic position. In the mitral position, reoperation was similar.

Bleeding was reported more frequently in mechanical valve recipients in both aortic and mitral valve positions. Cases of embolism and endocarditis for AVR and MVR were insignificantly different in bioprosthetic and mechanical valve recipients.

In the last study by Oxenham et al., overall survival was similar in both bioprosthetic and mechanical valve recipients for AVR and MVR after a mean follow-up of 20 years. In addition, Oxenham et al. reported survival with the original prosthesis was better in mechanical valves for MVR. Reoperation was higher in bioprosthetic valve recipients than mechanical valve recipients for AVR and MVR.

Bjork-Shiley mechanical valve recipients reported higher incidence of bleeding than bioprosthetic valve recipients for AVR and MVR. Like the previous two studies by Khan et al. and Hammermeister et al., embolism and endocarditis cases were similar in numbers and insignificantly different in both bioprosthetic and mechanical valve recipients.

The principal long-term findings of randomized trial are:

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Use of a mechanical valve resulted in a lower mortality and a lower reoperation rate after AVR. The mortality after MVR was similar with the use of the two prosthetic valve types. There were virtually no primary valve failures with the use of a mechanical valve. Primary valve failure after AVR and MVR occurred more frequently in patients with a bioprosthetic valve, especially in patients aged <65 years. The primary valve failure rate between bioprosthesis and mechanical valve was not significantly different in those aged ≥65 years. Use of a bioprosthetic valve resulted in a lower bleeding rate. There were no significant differences between the two valve types with regard to other valve-related complications, including thromboembolism and all complications [12].

Mortality risk is not different after mechanical and after tissue valve replacement [13,14]. A 50-year-old patient should anticipate at least 1 reoperation after bioprosthetic valve replacement, but overall, valve-related morbidity is far higher after mechanical valve replacement.

Most studies of 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 [15]. There have been few randomised controlled trials comparing outcomes after mechanical valve replacement. Thromboembolism has been reported as occurring at a higher rate following Starr-Edwards replacement than Bjork-Shiley. 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 [16,17].

Several studies have identified porcine valve failure seven or more years after implantation, particularly in younger patients. 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. [18] Advocates of the stentless prosthesis point to its superior haemodynamics with an effective valve area some 10% larger than stented prosthesis of equivalent size.

CONCLUSIONS

Based on the evidence of this systematic review, the implications and recommendations for practice is to consider a mechanical prosthetic valve in patients, who have a life expectancy of at least 10 years and do not have contraindication to anticoagulant therapy. . Bioprosthetic valves should be considered in patients, who have a life expectancy of less than 10 years or have contraindication to anticoagulant therapy.

Better survival with a mechanical valve implantation in AVR and similar survival with bioprosthetic and mechanical valve replacement in MVR was reported in two studies, while the third study reported similar survival in both valve groups. The two randomized control trials reported higher occurrence of bleeding in mechanical valve recipients. The observational study reported higher occurrence in bleeding in mechanical valve recipient for AVR. There were no differences in the number of embolism or endocarditis cases between the two valve groups.

MHVs are more durable than BHVs. Patient age and compliance are the important factors which govern the use of prosthetic heart valves. Recently in India the trend favors the use of BHVs because they are safe to implant, similar to the native aortic valve both morphologically and functionally, do not require long-term anticoagulant therapy, and are associated with reduced risk of hemorrhage. Mechanical valves are associated with a significantly higher complication rate compared with biological valves in Indian patients. Biological valves thus maybe specifically suited to the Indian scenario. However, in choosing a prosthetic valve, patients' involvement and informed consent should take the utmost importance.

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