

Searching for the Truth: A Mechanical or a Tissue Valve?

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Mechanical heart valves, which were introduced commercially in 1962 (1) have excellent durability and hemodynamic performance, but require anticoagulation in order to reduce thromboembolism (2-6,10,17-20,22) and anticoagulation-related bleeding (2-7,10,17-20,22-27,29-33,40,42). Tissue valves were introduced to avoid anticoagulation, but undergo structural valve deterioration (SVD), with a reported life of between six and 12 years (7-17,22).

The major complications of modern-day valve replacement are thromboembolism, bleeding related to anticoagulation, SVD, and mortality associated with reoperation for SVD (3,6,8-11,13-23).

The purpose of this review is to provide information to assist the surgeon in heart valve selection.

Materials and methods

PubMed (21) citations were reviewed for reports of complications associated with FDA-approved heart valves. The review identified 45 relevant manuscripts and three web sites, which reported pertinent thromboembolism, bleeding, SVD and mortality data for tissue and mechanical valves (1-48).

Compilation and comparison of the linearized rates (% per patient-year; pt-yr) of thromboembolism, bleeding, SVD and mortality for both mechanical and tissue were analyzed.

Results

According to the 1998 FDA Objective Performance Criteria (OPC), the thromboembolism rate for mechanical valves was 1.8% per pt-yr (22). The mechanical valve thromboembolism rates ranged from 0.6 to 3.5%

per pt-yr (2-6,10,17-20,22-27,32-34,40,42,43,48), whereas the rates of thromboembolism for tissue valves ranged from 0.6 to 3.9% per pt-yr (8,10,11-17,23,48). Depending on the particular mechanical valve, the bleeding rates ranged from 0.6 to 4.0% per pt-yr (2-6,10,17-20,23-27,29-34,40,42,43). The bleeding rates reported for tissue valve patients were from 0.1 to 1.9% per pt-yr (6-10,11-17,23-27,29-33). Beginning at the eighth year post implantation, 10% of tissue valves were found to be replaced each year (6,8-17). Yu (16) reported that he replaced 56% of his previous tissue implants by year 12, while Jamieson et al. (14,17) indicated that patients receiving a bioprosthesis were five times more likely to have a reoperation and twice as likely to die when compared to patients who received a mechanical valve.

The linearized rate for reoperation was 3.4% per pt-yr for a tissue valve, with an associated mortality rate of 1.4% per pt-yr (10-12,14,17). This was compared to a reoperation and mortality rate of 0.7% per pt-yr for a mechanical valve ($p < 0.001$) (2,3,5,6,44).

Discussion

Valve replacement surgery is indicated when the risk of operative mortality and prosthetic valve complications is less than the risk of native valve disease. The most significant complications associated with an artificial valve are:

Thromboembolism

Bleeding events related to anticoagulation

Structural valve deterioration for tissue

Mortality from reoperation for SVD

Valve thrombosis, which historically is a disastrous complication, is unusual with modern mechanical valves (0.2% per pt-yr) (2-5,10,22,44). Prosthesis-patient mismatch - a term introduced by Rahimtoola (28) - occurs when the effective prosthetic valve area, after insertion into a patient, is less than that of a normal human valve. Prosthesis-patient mismatch results

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from an error in judgment by the implanting physician, and is not the fault of the prosthesis.

Mechanical and tissue valves have equivalent rates for thromboembolism (23,48), a probable explanation being that as tissue valves deteriorate they become a source for thromboembolism.

Tissue valve patients usually receive warfarin for the first three months after valve implantation, and anticoagulation is continued in a significant number of tissue valve patients for co-morbid conditions. The literature reports that 40-70% of mitral tissue patients and 15-35% of aortic tissue patients receive long-term warfarin therapy (6,7,11-17,29).

More efficient management of anticoagulation has been shown to reduce the rates of thromboembolism and bleeding. Examples include patient INR self-testing, self-testing and dosing, and the addition of antiplatelet agents to low-intensity INR protocols (23-27,29-32).

Each mechanical valve should have an optimal INR for both thromboembolism and bleeding (33). Valve construction materials can also make a difference; for example, the Omniscience valve - an all-pyrolytic carbon valve which is identical to its Omniscience predecessor - had a reported thromboembolism and bleeding rate of 1.4% per pt-yr, which was less than half of the rates reported for other FDA-approved valves. The Omniscience valve with a titanium housing and pyrolytic carbon disc had a thromboembolism and bleeding rate of 3.5% per pt-yr (34).

The two main types of mechanical valves in use are the tilting-disc (monoleaflet) and the bileaflet valve. A myth has been created that the posterior leaflet of the mitral valve can be preserved only with a bileaflet valve, but Aris and others (45-47) have pointed out that the posterior leaflet can be preserved with both types of valve. Though both valves have similar hemodynamics and similar late morbidity and mortality results, a tilting-disc valve creates less turbulence when properly oriented. High-intensity transient signals (HITS) - otherwise termed microembolic signals - are two-thirds fewer in number in a monoleaflet valve than in a bileaflet valve (35-39).

In conclusion, a tissue valve should be implanted if a patient has a history of bleeding or a predicted life expectancy of less than 10 years. Mechanical valves are durable, and should be implanted in patients who are expected to live more than 10 years, and also in patients already receiving anticoagulants or who are predicted to be anticoagulated.

More efficient anticoagulation management systems should be instituted to further reduce thromboembolism and bleeding.

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