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Leaflet Escape in a New Bileaflet Mechanical Valve

TRI Technologies

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Background—Leaflet escape is a mode of structural valve failure for mechanical prostheses. This complication previously has been reported for both monoleaflet and bileaflet valve models. We report 2 leaflet escape occurrences observed in 2 patients who underwent valve replacement with a TRI Technologies valve prosthesis.

Methods and Results—At the University of Padua, between November 2000 and February 2002, 36 TRI Technologies valve prostheses (26 aortic and 10 mitral) were implanted in 34 patients (12 women and 22 men) with a mean age of 59.9 ± 10.3 years (range, 30 to 75 years). There were 5 deaths: 3 in hospital, 1 early after discharge, and 1 late. Two patients experienced a catastrophic prosthetic leaflet escape; the first patient was a 52-year-old man who died 10 days after aortic valve and ascending aorta replacement, and the second was a 58-year-old man who underwent a successful emergency reoperation 20 months after mitral valve replacement. Examination of the explanted prostheses showed in both cases a leaflet escape caused by a leaflet's pivoting system fracture. Prophylactic replacement was then successfully accomplished so far in 12 patients, without evidence of structural valve failure in any of them. Among other significant postoperative complications, we observed 3 major thromboembolisms, 1 hemorrhage, and 1 paravalvular leak.

Conclusion—These catastrophes prompted us to interrupt the implantation program, and they cast a shadow on the durability of the TRI Technologies valve prosthesis because of its high risk of structural failure. (*Circulation*. 2003;107:2303-2306.)

Key Words: valves, mechanical ■ prosthesis ■ leaflet escape ■ heart failure ■ surgery

Leaflet escape due to strut fracture of a mechanical valve prosthesis has been reported previously for monoleaflet (Omnicarbon, Björk-Shiley convexo-concave)^{1,2} and bileaflet mechanical prostheses (Tekna and Duromedics).³

The present report details the high propensity to structural valve failure of the TRI Technologies valve (TRI Technologies Prosthetic Heart Valve, Ltda; Belo Horizonte, Brazil), a mechanical valve prosthesis that recently has been released on the market. A leaflet escape, caused by pivoting system fracture, was the cause of death in 1 aortic patient and required a successful emergency reoperation in 1 mitral patient.

Methods

The TRI Technologies valve is a new low-profile mechanical bileaflet prosthesis composed of solid pyrolytic carbon and designed to rotate in situ. The two leaflets are identical and curved to reduce turbulence and enhance blood flow (85° in full open position). The leaflets are housed in the orifice ring by 2 tabs that are inserted into orifice hinges. A metal band reinforces the housing system. The swing ring, made of polyester, is covered by a small ledge of pyrolytic carbon, both in the proximal and distal surfaces.

Between November 2000 and February 2002, 401 patients underwent heart valve replacement at our Institute (279 aortic, 88 mitral,

3 tricuspid, and 31 double valve replacement). Of the implanted prostheses, 66% were tissue valves (Biocor, St Jude Medical; Carpentier-Edwards Perimount Baxter; Labcor; and Mosaic Medtronic), and 44% were mechanical valves (St Jude Medical, Sorin Bicarbon, TRI Technologies, and On-X). The 36 TRI Technologies valve prostheses (26 aortic and 10 mitral) were randomly implanted in 34 patients (22 men and 12 women) with a mean age of 59.9 ± 10.3 years (range, 30 to 75 years).

According to the Euroscore grading, 5 patients (14.8%) were at low risk, 15 patients (44.1%) were at medium risk, and 14 patients (41.1%) were at high risk.

The aortic prosthetic sizes were 19 Ø in 3 patients (11.5%), 21 Ø in 4 (15.4%), 23 Ø in 10 (38.5%), and 25 Ø in 9 (34.6%). The mitral prosthetic sizes were 27 Ø in 1 patient (10%), 29 Ø in 6 (60%), and 31 Ø in 3 (30%).

Seven patients (21%) had undergone a previous operation: valve replacement in 3 cases (1 aortic and 2 mitral) and valve repair in 4 (1 aortic and 3 mitral). Concomitant procedures included coronary revascularization in 2 patients (6%), ascending aorta replacement in 6 patients (18%), De Vega tricuspid valvuloplasty in 1 patient (3%), and radiofrequency pulmonary vein ablation in 4 patients (12%). Two patients (6%) underwent septal defect closure (1 atrial and 1 ventricular).

Surgical Technique

Median sternotomy, cardiopulmonary bypass, moderate hypothermia, and aortic cross clamping were used in all patients. Cardioplegic

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arrest was achieved by using antegrade and retrograde cold blood cardioplegia, repeated at 20-minute intervals.

Aortic prostheses were implanted through a transaortic approach. Mitral valves were replaced through a paraseptal left atrial incision. Valve prostheses were inserted by using multiple interrupted sutures of 2-0 Ticron reinforced by Teflon pledgets; the mitral mural leaflet was preserved whenever possible, and patients received continuous oral anticoagulation starting on the second postoperative day.

Patient Follow-Up

Patients were followed up at 1 and 6 months after discharge and on an annual basis, via direct visits, questionnaires, and telephone interviews. Cumulative follow-up time was 48.5 patient-years and was 100% complete. Median follow-up time was 19 patient-months (range, 1 to 26 months), and mean follow-up time was 17 patient-months. Data were prospectively entered into a database and updated. Patients were fully investigated by serial 2D echocardiogram and blood samples to evaluate hemolysis.

After the occurrence of the first prosthetic leaflet escape, the implantation program was discontinued on February 28, 2002. All patients were notified of their risk through direct interview and also underwent fluoroscopy to verify correct leaflet movement.

Statistical Analysis

Previously published guidelines for reporting morbidity and mortality were used for definition of postoperative complications and prosthesis-related events.⁴ The linearized rate of postoperative complications and prosthesis-related events was expressed as percent per patient-year (%/patient-year). Estimate of overall survival was calculated by use of the Kaplan-Meier method and expressed as percentage \pm SE or percentage \pm 95% confidence interval (CI). Actual freedom from leaflet escape was calculated by the Grunkemeier method.⁵ The actual calculations were made on a prosthetic basis (1 aortic and 1 mitral leaflet escape event).

Results

Among the 29 survivors, 72% (21 of 29 patients) were in New York Heart Association functional class I, 14% (4 of 29) were in class II, and 14% (4 of 29) were in class III. Moreover, 72% of patients (21 of 29) were in sinus rhythm, and 28% (8 of 29) were in chronic atrial fibrillation. All patients who underwent radiofrequency ablation for chronic atrial fibrillation were in sinus rhythm at the last follow-up. The serum value of lactic dehydrogenase was elevated in almost all patients, whereas the haptoglobin and reticulocyte counts were normal in all patients.

Hospital Mortality

There were 3 hospital deaths (8.8%); none of patients with a previous cardiac operation died. The first patient, a 61-year-old man with aortic stenosis associated with coronary artery disease and at medium operative risk according to Euroscore grading, died because of tamponade and cardiac arrest with neurological complication. The second patient, a 69-year-old man with isolated aortic valve stenosis and at high operative risk, died because of bowel infarction. The third patient affected by aortic stenosis, a 62-year-old man at medium operative risk, suffered from postcardiotomy low-output syndrome. He died early after heart transplantation.

Thirty-Day Mortality

A 52-year-old patient who underwent an uneventful replacement of the aortic valve and ascending aorta died at home 10 days after the operation. The pre-discharge transthoracic echocardiogram showed a normal prosthetic function (mean

transprosthetic gradient, 12 mm Hg) with improved cardiac function (preoperative left ventricular end-diastolic volume versus postoperative = 154 mL/m² versus 102 mL/m²; preoperative left ventricular ejection fraction versus postoperative = 55% versus 58%, respectively). The autopsy revealed a leaflet escape (see below).

Late Mortality

There was 1 late death (3.3%), which was valve related: a 72-year-old woman at high risk according to Euroscore, with chronic obstructive pulmonary disease, renal failure, systemic arterial hypertension, previous stroke, chronic atrial fibrillation, pulmonary hypertension, history of cancer, and previous cardiac surgery (commissuroplasty). She had undergone a mitral valve replacement because of mitral valve stenosis and De Vega tricuspid valve repair. This patient experienced a major embolic stroke 15 months after the surgery and died 21 months after the TRI Technologies valve prosthesis was implanted.

The overall 2-year Kaplan-Meier survival curve was 88 \pm 6% (71.4 to 95.4 CI). The actual death incidence was 13 \pm 6%.

Thromboembolism

Major thromboembolic events occurred in 3 patients (10%); linearized rate was 8.4%/patient-year. No prosthetic valve thrombosis was detected at 2D echocardiogram.

Hemorrhagic Events

One patient suffered from anticoagulation-related major hemorrhage (gastric bleeding) and was successfully medically treated; linearized rate was 2.8%/patient-year.

Paravalvular Leak

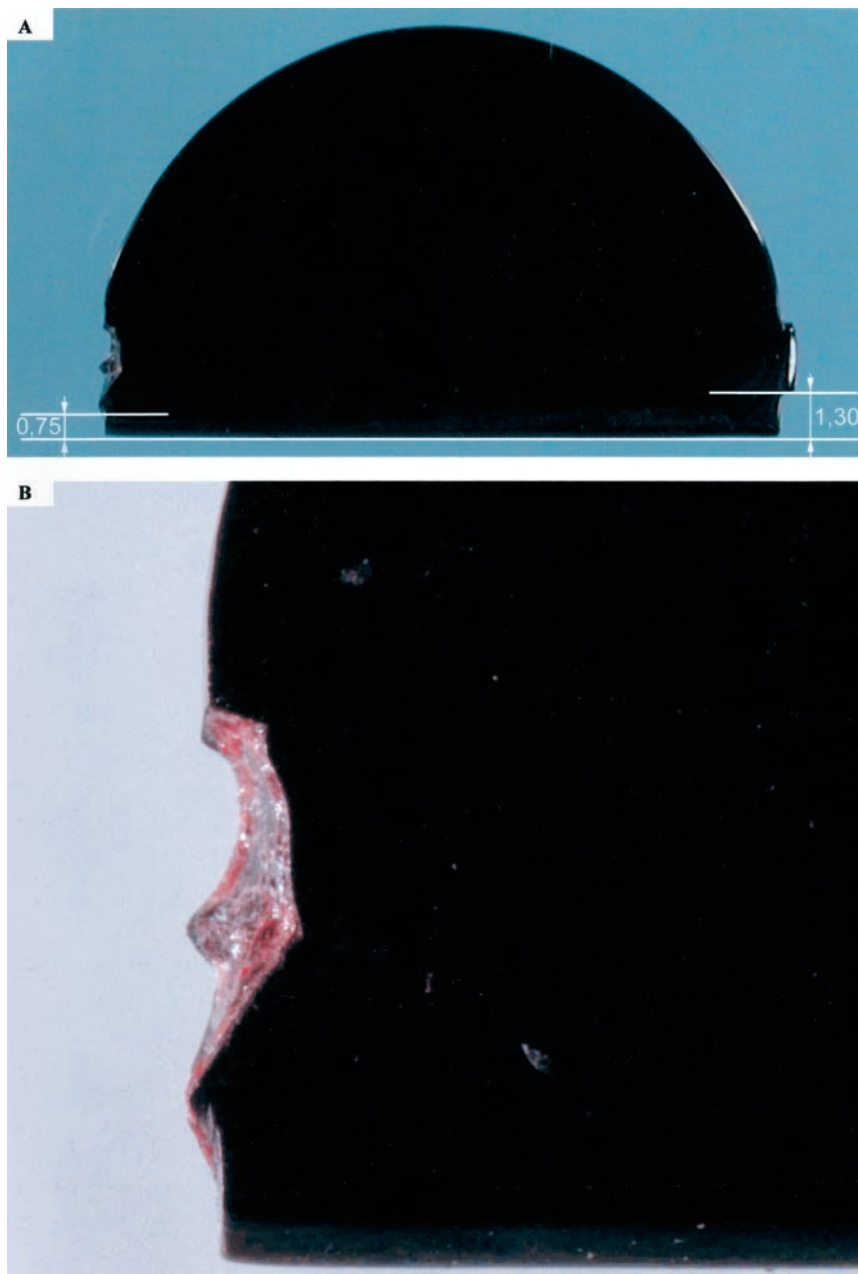
One mitral patient, a 52-year-old man at high risk according to Euroscore and at New York Heart Association class IV who underwent mitral valve replacement because of native valve endocarditis, had a paravalvular leak. The linearized rate was 2.8%/patient-year.

Leaflet Escape

This complication occurred in 2 patients, 1 aortic and 1 mitral patient, 10 days and 20 months after surgery, respectively. The linearized rate was 5.6%/patient-year.

The aortic patient with a 25-mm TRI Technologies valve prosthesis died suddenly, and the escaped leaflet was found at postmortem examination in the thoracic aorta. The mitral patient, who received a 31-mm TRI Technologies valve prosthesis and was affected by a prosthetic leak, underwent a successful prosthesis replacement in emergency condition. The leaflet was recovered in the abdominal aorta. In both cases, the cause of leaflet escape was a pivot system fracture with evidence of asymmetry in the distance between the tabs and the base of the leaflet (Figure).

The actual incidence of leaflet escape was 11.5 \pm 8.5%. The actual analysis of freedom from the combined events—death and leaflet escape—was 75.7 \pm 10% at 23 months.



Fatal leaflet escape in a 52-year-old man at 10 days after surgery (aortic valve and ascending aorta replacement). A, The escaped leaflet found in the thoracic aorta. Note the fracture of a pivot system with asymmetry of the tabs' height (0.75 mm of fractured tab versus 1.30 mm of nonfractured tab). B, Close-up, which highlights the fractured pivot system (stereoscopic view).

All Valve-Related Complications

The linearized rate was 22.2%/patient-year. According to prosthetic positions, 3 episodes occurred in the aortic position (1 embolism, 1 hemorrhage, and 1 leaflet escape), 3 occurred in the mitral position (1 embolism, 1 leaflet escape, and 1 perivalvular leak), and 1 occurred in a double-valve patient (1 thromboembolic stroke).

Reoperations

So far, 13 patients (13 of 29 patients; 45%) have undergone successful reoperation. One was reoperated on an emergency basis because of leaflet escape, and 12 underwent prophylactic replacement. Among the latter, there was an elective reoperation because of a suspected malfunction with delayed mural leaflet movement, which was detected by 2D echocardiogram and fluoroscopy in a 67-year-old mitral patient;

however, at surgery, the prosthesis revealed normal leaflet movements without impairment by subvalvular apparatus. The remaining 11 patients, 3 at medium and 8 at high operative risk, who were recipients of 12 TRI Technologies valve prostheses, underwent prophylactic valve replacement according to their own free will alone, without any evidence of valve dysfunction. Gross examination of the explants did not reveal any evidence of wear or fracture.

Discussion

Refinement in hemodynamic performances of mechanical valve prostheses is a continuous challenge; however, the ability to develop new, improved models might clash with the risk of structural failure.

The TRI Technologies valve prosthesis, a new bileaflet mechanical valve recently introduced on the market with the

aim of achieving better hemodynamics, unfortunately revealed an high propensity to leaflet escape as a result of pivoting system fracture.

In October 1998, the TRI Technologies valve prosthesis obtained the CE Mark from TÜV products service, which is a well-established testing and certification organization in Europe, independent of any manufacturing factory and therefore accredited and recognized as third-party certifier. In spite of this certification, 2 patients in our series experienced a prosthetic pivot fracture with leaflet escape, leading to an unacceptable rate of prosthetic failure. Only the case of aortic prosthetic leaflet escape was available for detailed examination including stereoscopy because all the explanted prostheses were thereafter sequestered by the legal authorities. One of the tabs of the escaped leaflet was detached with evidence of asymmetry in the distance between the tabs and the base of the leaflet. Thus, asymmetry of the tabs' height, attributable to a manufacturing flaw, might account for structural failure.

Lessons from the past seem to be not entirely helpful for drawing efficient guidelines for possible reoperation. Disk escape continues to be the Damocles' sword for $\approx 35\,000$ recipients of the Björk-Shiley convexo-concave^{6,7} and for many patients who received one of 3 other mechanical prostheses that presented the same mode of failure (Omnicarbon, Tekna, and Duromedics).^{1,3} At present, several studies are evaluating various risk factors associated with the use of these prostheses, determining the propensity of structural rupture with leaflet escape, and calculating the individual clinical risk for these patients connected with the prophylactic replacement.^{7,8} In the absence of recognized guidelines, certain physicians^{9–11} concluded that the benefit of replacing the prostheses outweighs the risk of prosthesis failure, whereas other physicians¹² claim that elective replacement of the valves involves a similar mortality rate. A combination of host and prosthesis factors was postulated.^{7,13}

Now, therefore, the identification of predictors of pivot fracture becomes crucial for the TRI Technologies recipients worldwide. In light of these regrettable incidents, we followed up all the patients by blood samples, 2D echocardiogram, and fluoroscopy to evaluate leaflet movements. The sole patient who was discovered to be affected by a probable prosthetic dysfunction with delayed leaflet movement underwent redo, and the replaced prosthesis has been found to be functioning well. Actually, we were unable to identify predictors of impending prosthetic failure by using common noninvasive investigations. Thus, we adopted the policy of performing prophylactic replacement only if chosen by the patient. Indeed, media pressure played a major role in prompting patients to demand prophylactic replacement of their TRI Technologies valve prostheses. The operative risk (Euroscore grading) for the 12 patients ranged from 4% to 43%, outweighing the calculated risk of structural failure in our series. According to data provided by the TRI Technologies manufacturers (Ivan Casagrande, MD, personal communication, November 18, 2002), the overall worldwide incidence of disk escape was 9 cases out of 3841 implants.

Nowadays, only careful planning of the reoperation allowed us to maintain our hospital mortality rate equal to 0%, but again we are dealing with an indisputable operative risk and with an unpredictable risk of prosthetic failure.

The incidence of thromboembolism was high when compared with other bileaflet valves¹⁴ and mostly occurred in the perioperative period.

In conclusion, this clinical experience casts a shadow on the durability, safety, and quality of the TRI Technologies prosthesis. We felt it mandatory to discontinue its clinical use, as well as to inform the scientific community.

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