

Fatal Leaflet Escape in an Edwards TEKNA® Aortic Prosthesis

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The case is reported of a 26-year-old male patient who died eight years after the replacement of an aortic valve with a bileaflet mechanical valve (TEKNA®; Edwards, USA). Following prosthesis implantation, the patient had been in a good state of health, and his death occurred unexpectedly. Forensic autopsy revealed a leaflet escape, with two fragments of the leaflet being found bilaterally in the common iliac arteries. Death occurred due to an acute cardiac insufficiency. Immunohistochemical investigations

The original Duromedics-Edwards bileaflet valve was withdrawn from the market in 1988 following 12 reports of leaflet escape (1). After modification, the revised Edwards TEKNA® valve was introduced in 1993, and has been sold worldwide, mainly in Europe. During a short-term study the TEKNA has shown excellent overall clinical performance, though long-term data to confirm its durability are not yet available (2). Herein is described the case of a 26-year-old male patient who died from acute cardiac insufficiency due to leaflet escape of a TEKNA aortic prosthesis which had been implanted eight years previously. The discussion focuses on the question of prophylactic replacement in affected patients, as over 18,000 of these valves were utilized until June 2000, at which time it was removed from the market (3).

Case report

In December 2003, a 26-year-old male patient died eight years after replacement of his aortic valve. This had been performed using a mechanical valve prosthesis, as recommended for congenital aortic stenosis. The aortic valve had been replaced with a 27-mm mechanical bileaflet prosthesis (Edwards TEKNA®;

revealed fresh myocardial fiber necroses. Stereomicroscopic and scanning electron microscopic investigations demonstrated surface erosions of the leaflet. Although the valve was withdrawn from the market in June 2000, it had previously been implanted in over 18,000 patients. Thus, from a clinical viewpoint, the question of using a prophylactic replacement in affected patients must be discussed.

The Journal of Heart Valve Disease 2006;15:97-99

model 3200A27, serial number VD 05486). The patient's postoperative course was uneventful, and he had remained in good health thereafter. On the evening before his death, which occurred between Christmas and New Year's Eve, the patient has picked up his dog and immediately felt retrosternal pain. Suffering from panic attacks, he was transferred to the local hospital where electrocardiography revealed the suspicion of fresh myocardial infarction. On physical examination, a loud diastolic-systolic murmur was detected. Echocardiography demonstrated prosthetic valve dysfunction, and heart catheter investigations performed the next morning revealed a leaflet escape. The patient was transferred to a specialized hospital, but died 12 h after onset of the painful event.

Autopsy findings

The forensic autopsy revealed a severe general arteriosclerosis. Furthermore, an edema of the lungs and an acute congestion of all inner organs was diagnosed. The heart weighed 490 g, and concentric hypertrophy of both ventricles was identified. The aortic valve prosthesis showed a leaflet to be absent. In fact, the leaflet had been broken in half and the embolized fragments (which were almost identical in size) were found bilaterally in the common iliac arteries (Fig. 1a and b).

Histology and immunohistochemistry

Histological investigations showed acute congestion of the inner organs, chronic congestion of the lungs

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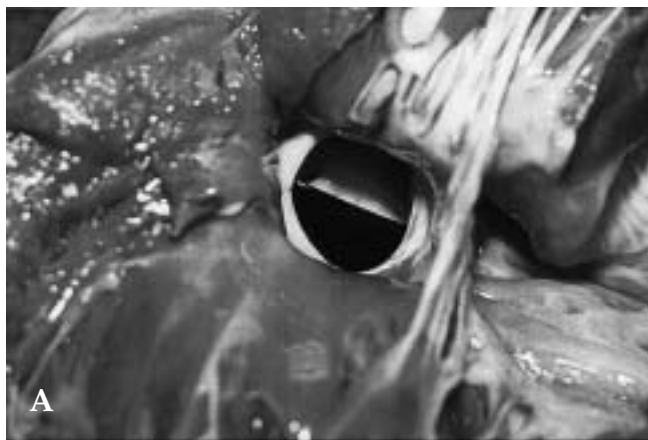


Figure 1: Autopsy findings. A) Edwards TEKNA® aortic valve after leaflet escape in situ. B) The leaflet fragments were located bilaterally in the common iliac arteries.

with intra-alveolar 'heart failure' cells, perivascular interstitial myocardial fibrosis and fresh myocardial fiber necroses, as well as siderosis of the proximal renal tubules of the kidneys. The cause of death was considered to be due to the extended fresh myocardial fiber necroses.

Stereomicroscopic and scanning electron microscopic investigations

Stereomicroscopic and scanning electron microscopic investigations (conducted by the Bundesanstalt für Materialforschung und -prüfung, Berlin; BAM) revealed cavitation-erosions on the surface of both leaflets in an area where the negative pressure during cardiac action is the lowest (Fig. 2).

Discussion

The Edwards TEKNA aortic valve is a bileaflet mechanical prosthesis with a self-irrigating hinge mechanism. The leaflet surfaces are coated with pyrolytic carbon, which is very hard and quite brittle.

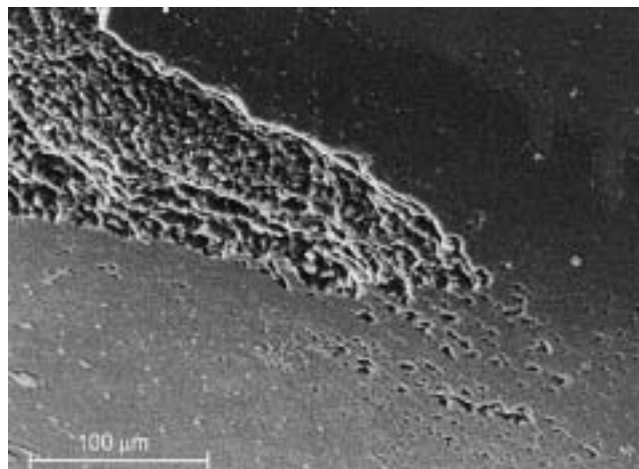


Figure 2: Scanning electron microscopic investigations. Surface failure of the fractured leaflet with material eruptions and fissures in the surrounding area (BAM).

The clinical performance of the valve had been reported by others to be quite satisfactory, with a low incidence of valve-related complications (4). However, problems of leaflet escape have been published (5-8), and irregularities in the structure of the material used, as well as pitting and erosion, had been considered as a reason for leaflet fractures.

In the present patient, cavitation-erosions were detected on the surface of both leaflets. Since the exact cause of the mechanical disruption remains speculative, and pyrolytic carbon is thought to be subject to fatigue fracture as well as to erosion damage (8), prophylactic replacement of the valve in affected patients should be considered.

A comparison of the risk of fractures versus elective reoperation was conducted in several publications, and the recommendation was that the overall mortality for elective reoperation outweighed the risk of death due to valve fracture (9-18). Most authors recommend individual decisions where factors such as age, state of health and type of prosthesis are important. With the introduction of non-invasive cineradiography, the detection of a valve fracture became easily possible (19-21).

However, in the present patient a catastrophic delay in treatment occurred due to problems in diagnosis. Therefore, all patients with implanted Edwards TEKNA mechanical aortic valves should be informed of the risk of leaflet break and examined closely at follow up.

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