Occasional single-beat regurgitation observed with the new Medtronic ADVANTAGE bileaflet heart valve

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The Medtronic ADVANTAGE prosthesis (Medtronic, Inc, Minneapolis, Minn) is a new bileaflet mechanical heart valve. The multicenter clinical trial to obtain worldwide regulatory approvals for the device began in November 1999. Currently, the study continues with the follow-up of all enrolled patients until US Food and Drug Administration approval is granted. In our series containing 61 study patients and 2 patients outside the study with an aortic prosthesis, we echocardiographically observed an intermittent regurgitation in 7 patients. The intermittent trivial to moderate aortic regurgitation occurring 1 to 30 times per minute shows higher velocities and a wider regurgitant jet than the physiologic washing jets in bileaflet valves through the hinge region.^{1,2} Neither the frequency nor the degree of regurgitation turned out to be progressive. To further investigate the possible underlying mechanism causing this phenomenon, we performed fluoroscopy and invasive blood pressure measurement in the ascending aorta.

Direct visualization of the leaflet motion showed intermittent, asymmetric incomplete closure of one of the valve leaflets, which could be either one of the 2 leaflets in the same prosthesis. Each incomplete closure that was visually detected led to a consecutive singular diastolic pressure decrease in the ascending aorta, reflecting the prosthetic insufficiency. Simultaneous electrocardiographic recordings proved that this phenomenon was not associated with arrhythmias (Figure 1).

Thrombotic or other material that might cause a disturbance of leaflet motion could not be detected. Further investigation is required to determine whether this is an intrinsic phenomenon of the ADVANTAGE aortic valve. In one of the study centers, an exploratory reoperation of an asymptomatic patient showing intermittent regurgitation during echocardiography was performed under suspicion for valve thrombosis. During the reoperation, the valve was observed to be normal in appearance and function and was left in place. In July 2005, Medtronic reported this reoperation as an unanticipated adverse device effect to the US Food and Drug Administration.

On the basis of our clinical data, we currently do not perform reoperations on these patients and follow-up these patients closely because they are in good clinical condition and apparently are not exposed to any risk, except for some intermittent single-beat regurgitation.

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Figure 1. Fluoroscopy of an ADVANTAGE bileaflet valve in the aortic position and recording of the invasive blood pressure measurement in the ascending aorta with electrocardiography (ECG). While one leaflet is completely closed, the second leaflet stays in a slightly open position during the whole diastole (*white arrow*). The housing and leaflet edges are radiolucent and cannot be visualized with this technique. Diastolic blood pressure decrease is associated with each pathologic leaflet motion (*black arrow*).

Complete excision of primary cardiac malignant fibrous histiocytoma involving the left atrial free wall and mitral annulus by modified autotransplantation

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A 44-year-old male patient was referred to our hospital for progressive dyspnea on exertion and a cardiac tumor disclosed by a computed tomographic image study (Figure 1, A). Operative exploration was per-

formed 3 days later, in which a wide-based tumor infiltrating the left atrial appendage, left atrial anterior free wall, anterior annulus of the mitral valve, and anterior mitral leaflet was found. Tumor debulking and removal of the left atrial appendage were performed to relieve obstruction by the tumor. Malignant fibrous histiocytoma was documented by microscopic examination. Follow-up computed tomography performed before his first hospital discharge revealed residual tumor existing at the anterior atrial wall.

The tumor grew fast, for 30 days, to reach a diameter of 3.6×3.6 cm² at his second admission for recurrent dyspneic symptoms. During the investigation process for possible cardiac allotransplantation, he suddenly experienced shortness of breath and collapsed in the ward because of nearly total obstruction of the mitral orifice by the rapid-growing tumor mass. Extracorporeal membrane oxygenation (ECMO) was set up on an emergency basis under cardiopulmonary resuscitation, and he was immediately sent to the operating room for a radical surgical procedure as his last chance.

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