First Successful Transfemoral Implantation of an Edwards Sapien XT Valve in a Direct Flow Valve After Early Restenosis

Christian Butter, MD, Grit Tambor, MD, Michael Neuss, MD, Hidehiro Kaneko, MD, Thomas Schau, MD, Frank Hoelschermann, MD

A 76-year-old woman was transferred to our institute due to recurrent severe aortic stenosis (AS). Seventeen months ago, severe AS was treated with a transfemoral 25-mm nonmetallic Direct Flow valve (Direct Flow Medical, Santa Rosa, California) (Figures 1A and 1B). After this procedure, the mean aortic valve pressure gradient (PG) decreased from 31 to 13 mm Hg. However, her symptoms gradually worsened. Transesophageal echocardiography demonstrated the recurrence of AS and a calcified conglomerate without any leaflet motion (Figure 1C). Although she had no medical conditions related to the severe calcification such as renal dysfunction or history of radiation therapy, computed tomography images before Direct Flow valve implantation revealed a dominant bulky calcification close to the right coronary cusp adherent to the coronary supra-annular wall.

A second balloon aortic valvuloplasty (BAV)/transcatheter aortic valve implantation was considered. Due to a deformed Direct Flow valve, BAV was technically difficult. Moreover, the aortic valve PG increased immediately after BAV, and the residual aortic valve regurgitation was also remarkable. Therefore, we decided to implant a 20-mm Edwards Sapien XT valve (Edwards Lifesciences, Irvine, California). Aortography showed that the Sapien XT valve was implanted in the optimal position with no aortic valve regurgitation (Figure 1D). After the procedure, mean aortic valve PG decreased from 59 to 11 mm Hg. The second procedure was successfully finished without any complications.

We suppose that an early recoil of polymer-filled rings caused by reduced resistance to outer force changed the leaflet geometry, leading to an early degeneration. To our knowledge, this is the first experience of successful implantation of a balloon-expandable Sapien XT valve in a polymer-filled Direct Flow valve.

From the Department of Cardiology, Heart Center Brandenburg in Bernau, Bernau, Germany. The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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Figure 1  Sapien XT Valve Was Implanted in Direct Flow Valve Due to Early Restenosis

(A) Fluoroscopic image of the Direct Flow valve implantation. (B) Transesophageal echocardiography after the Direct Flow valve implantation. (C) The Direct Flow valve was deformed by compression. (D) A Sapien XT valve was successfully implanted in the Direct Flow valve. AR = aortic regurgitation.