Transcatheter Aortic Valve Implantation for Chronic Dialysis Patients in Japan

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It is well-known that end-stage renal disease (ESRD) requiring chronic dialysis is associated with cardiovascular diseases. According to the report of the Japanese Society for Dialysis Therapy (JSDT), the number of patients requiring chronic dialysis in Japan increased from 36,397 in 1980 to 310,007 in 2012, representing a more than 8-fold increase over 30 years (Figure 1), and the leading cause of death is cardiovascular disease, including heart failure, cerebrovascular accident, and myocardial infarction (Figure 2).¹ (The data depicted in the Figures were provided by the JSDT. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy or interpretation of the JSDT.)

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Aortic stenosis (AS) is one of the common cardiovascular diseases in dialysis patients. Calcification of the aortic valve is present in approximately 28–55% of dialysis patients, with an average age of onset that is 10–20 years lower than that of patients with normal renal function.² Although surgical aortic valve replacement (AVR) has been the gold standard approach for patients with severe AS, it carries considerable risk for patients with advanced age, frailty, or high comorbidity. Okada et al³ retrospectively analyzed the clinical data from 89 dialysis and 317 nondialysis patients undergoing AVR in Japan.

Figure 1. Annual numbers of hemodialysis patients in Japan. (Adapted from the Japanese Society for Dialysis Therapy (JSDT).¹⁴)

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Figure 2. Annual changes in causes of death of Japanese dialysis patients. AMI, acute myocardial infarction; CVA, cerebrovascular accident; MT, malignant tumor. (Adapted from the Japanese Society for Dialysis Therapy (JSDT).¹⁴)

The overall survival was significantly worse in the dialysis patients (63% vs. 85% at 5 years; $P < 0.001$), and freedom from structural valve deterioration (SVD) of bioprosthetic valves was lower in the dialysis patients (82% vs. 100% at 5 years; $P < 0.001$). The life expectancy of dialysis patients differs considerably among countries, as well as the causes of renal failure and comorbidity. The survival rates of dialysis patients in Japan are superior to those in Europe or the United States.

Transcatheter aortic valve implantation (TAVI) has been increasingly used as a treatment option for patients with severe symptomatic AS who are considered at high risk for surgical AVR.^{4–9} In this issue of the Journal, Maeda et al¹⁰ report early outcomes in Japanese dialysis patients with severe AS undergoing TAVI with SAPIEN XT or SAPIEN (THV 9000). They studied 17 dialysis patients (mean age, 76.7 ± 5.0 years). Mean logistic EuroSCORE and STS score were 25.0 ± 19.0 and 15.4 ± 12.3 , respectively. Although 1 patient required a valve-in-valve procedure on the 187th postoperative day, device success rate was 87.5%; clinical efficacy and the overall mortality at 1 year were 69.2% and 0%, respectively. There are several recent reports on TAVI for dialysis patients in Western countries. Oguri et al¹¹ assessed the clinical data of 2,929 consecutive patients undergoing TAVI in the FRANCE 2 registry. The mean age of the 96 patients in chronic kidney disease (CKD) stage 5, including 82 dialysis patients, was 79.6 ± 7.1 years, the mean logistic EuroSCORE and STS score were 26.4% and 13.8%, respectively. CKD stage 5 was associated with very high 30-day (24.2%) and 1-year (39.9%) mortality rates. Ferro et al¹² also analyzed the clinical outcomes on 3,980 patients undergoing TAVI in the UK TAVI registry. The mean age of the 99 patients in CKD stage 5, including 81 dialysis patients, was 78 years, and the mean logistic

EuroSCORE was 27.9%. Cumulative 1- and 3-year mortality rates of the CKD stage 5 patients were 39.4% and 86.4%, respectively. Compared with these large registries, the early outcomes in Japanese dialysis patients reported by Maeda et al are promising, despite the small patient volume.

At present, TAVI for dialysis patients is not reimbursed in Japan. In the near future, however, can TAVI be considered as the treatment of choice for dialysis patients with severe symptomatic AS? The indications for TAVI and the durability of the transcatheter valve can be concerned with the question. With respect to the indications for TAVI, the mean age and the degree of risk measured by logistic EuroSCORE and STS score in the patients of Maeda and colleagues' study are similar to those in the subjects of the reports from France and the UK. This may mean that consensus has almost been achieved on the indications for TAVI. On the other hand, the durability of prosthetic valves has affected valve selection in surgical AVR. We still have controversy over valve selection, especially in patients with ESRD on dialysis because both adverse events following mechanical valve implantation and SVD of bioprosthetic valves are not infrequent. In the United States, the life expectancy of chronic dialysis patients in their 6th, 7th, and 8th decades is 5.3–6.2 years, 3.8–4.5 years, and 2.7–3.2 years, respectively.¹³ In consideration of these circumstances, the durability of current transcatheter valves may be acceptable, although the life expectancy of dialysis patients in Japan is much better than that of patients in the USA. The study conducted by Maeda et al shows the safety and efficacy of TAVI for dialysis patients in Japan for the first time. Further studies on more patients are warranted to establish the role of TAVI for the treatment of high-risk patients.

Disclosures

The authors declare no conflicts of interest.

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