Acute and Mid-term Outcomes of Subcutaneous Implantable Cardioverter Defibrillator Therapy in Patients at Risk of Ventricular Tachyarrhythmia: A single-center experience in Japan.

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**Introduction**: Subcutaneous implantable cardioverter defibrillator (S-ICD; EMBLEM S-ICD, Boston Scientific, USA) was launched in February 2016 in Japan. S-ICD is characterized by no need for transvenous leads that can cause serious complications during implantation and long-term use of defibrillators. S-ICD has been expected to make patient care with defibrillators safer. However, our clinical experience with S-ICD is even less than that with conventional transvenous ICD (TV-ICD).

**Methods**: To investigate efficacy and safety of S-ICD, we retrospectively compared outcomes of two patient groups who underwent the implantation of defibrillators (S-ICD group, n=49, and TV-ICD group, n=69). TV-ICD group, set as a historical control, consisted of patients who received TV-ICD before the launch of S-ICD (from 2012 to 2106) and who had neither history of monomorphic ventricular tachycardia nor need for pacing for bradycardia. We investigated outcomes of the patient groups such as initial success rate of implantations, procedure time, types and incidence of acute and mid-term complications, and incidence of appropriate or inappropriate shock delivery.

**Result**: All S-ICD recipients passed the screening of surface electrocardiogram simulating sensing vectors of S-ICD in at least one vector. Defibrillators were successfully implanted in all patients of both groups. Procedure time was shorter in S-ICD group (95.4 ± 22 min. vs. 123 ± 36 min., p<0.01). There was no complication associated with implantation in the S-ICD group. In TV-ICD group, some acute complications occurred and most of them were associated with intravenous leads (lead dislodgement in 3 (4%), right ventricular perforation by the lead in 2 (3%), device infection in 1 (1%), and hematoma in the generator pocket in 1 (1%)). In the mid-term follow up, neither syncope nor sudden death due to improper detection or therapy of arrhythmia was observed in both groups. In the follow up of S-ICD patients for 690 days on average, appropriate shocks for ventricular tachyarrhythmias occurred in 4 patients (8%). Inappropriate shocks occurred in 3 (6%) due to supraventricular tachycardia or noise sensing. In 3 (6%) patients in S-ICD group, late-onset sensing malfunction (lowering of QRS wave amplitude or noise sensing) was observed on average 13 months after implantation and inappropriate shock was triggered by the noise in 1 patient.

**Conclusion**: S-ICD can be implanted with less risk and invasion compared with TV-ICD. All the
ventricular tachyarrhythmia events were properly treated with S-ICD. In some patients with S-ICD, late-onset sensing malfunction developed in their mid-term follow up. Thus, paying continuous attention to the status of sensing may be more important in the patient care with S-ICD. Long-term efficacy and safety outcomes of S-ICD need to be further investigated.