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The Subcutaneous Defibrillator (S-ICD): Shock efficacy in induced and spontaneous ventricular tachyarrhythmias

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The subcutaneous implantable cardioverter-defibrillator (S-ICD) has established its place as an alternative to transvenous (TV-) ICD therapy especially in young and active patients, that are at high risk for lead complications but have no need for cardiac pacing. As it is still considered a relatively new therapy option, there is a reasonable amount of skepticism towards the safety and therapy effectiveness of the subcutaneous device. This study was designed in order to investigate the S-ICDs performance in one of the biggest single center cohorts in Germany as well as observing the learning curve and development based on growing experience with the system. Based on guideline recommendations, 218 consecutive patients have received an S-ICD at our University Medical Center between July 2011 and July 2017 for primary or secondary prevention of sudden cardiac death. Data collection took place among routine clinical diagnostics preceding and following S-ICD implantation as well as the implantation procedure itself. Furthermore, follow-up data was obtained through the routine procedure of device interrogation at least every six months, earlier in case of therapy delivery of any kind. Implantation technique and programming parameters were adapted according to latest scientific findings that have been published throughout the study. Within six years of S-ICD implantation, the duration of the implant procedure was reduced from 69.9 ± 9.2 to 37.9 ± 8.9 minutes (median: 46 minutes, $p < 0.001$). During intraoperative conversion testing, first shock conversion could be achieved in 90.5% of patients. Higher body-mass-index (27.8 ± 6.6 vs. 33.2 ± 8.3, $p = 0.002$) as well as shock impedance (79.5 ± 25.2 vs. 100 ± 25.7, $p = 0.008$) acted as confounders of ineffective first shock termination of induced ventricular fibrillation. Overall, conversion testing was successful in all patients. In the cohort, eleven percent of patients received appropriate S-ICD therapy throughout a mean follow-up duration of 24.7 ± 17 months. All episodes were successfully terminated by the S-ICD system. First shock efficacy in spontaneous episodes was 93.5%. Previously diagnosed atrial fibrillation ($p = 0.034$), time to shock after implant ($p = 0.009$) as well as patient age at first appropriate shock ($p = 0.045$) influenced first shock efficacy in spontaneous episodes. There were no reports of arrhythmic deaths in the cohort. With a safe and effective S-ICD performance, even in patients initially lacking first shock conversion in intraoperative testing, results from the ongoing PRAETORIAN-DFT trial are eagerly anticipated, possibly paving the way for omission of standardized S-ICD conversion testing as part of the initial S-ICD implantation. There were no lead related complications or technical failures of the device at any point of the study. Adverse events in this study included perioperative bleeding as well as wound erosion in a total of 2.7% of patients. Four patients (1.8%) had to have their device removed due to infection, which is within range of previously published data. Furthermore, there were no reports of serious bloodstream infection. Despite satisfying results regarding therapy effectiveness, there is still plenty of room for optimization of S-ICD therapy. Inappropriate shock delivery was experienced by seven percent of patients in the observed cohort and was most frequently attributed to over-sensing. The supplementation and improvement of the sensing algorithm is an ongoing process. Future trials will determine whether the unique subcutaneous sensing method will prevail. Results from the prospective, randomized TV-ICD vs. S-ICD PRAETORIAN-Trial will soon provide further insights on patient selection and therapy effectiveness.