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Duration of hospital admission, need of on-demand analgesia and other peri-procedural and short-term outcomes in sub-cutaneous vs. transvenous implantable cardioverter–defibrillators☆

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ABSTRACT

Background: Post-procedural recovery following sub-cutaneous ICD (S-ICD) implantation is feared to be more painful and to require more prolonged hospital admission. The purpose of this study was to compare peri-procedural and short clinical outcomes of the S-ICD vs. the Transvenous ICD (TV-ICD).
Methods: We conducted a single-center cross-sectional study including all consecutive patients who underwent S-ICD implantation by the same operator since January 2016 and a gender and age-matched control group with all single chamber TV-ICD implanted patients over a contemporary time period.
Results: Thirty-one patients (sex ratio 1/5; mean age 58.7 ± 13.2 years) with S-ICD were compared to 31 matched TV-ICD patients. Duration of the implant procedure was significantly longer for the S-ICD (58.0 ± 24.4 min vs 41.7 ± 20.8 min TV-ICD, $p < 0.01$). Mean fluoroscopy time for the TV-ICD was 3.5 ± 3.6 min vs 0.1 ± 0.01 min for all S-ICD patients ($p < 0.01$). Requirement of on-demand analgesia administration, and duration of hospitalization (1.5 days for both groups; p = NS) were similar in the two groups. No peri-procedural events were reported, and after a mean follow-up of 6 months, the only complication was a pocket infection requiring reintervention in the TV-ICD group.
Conclusions: The S-ICD appears to be as effective and safe as the conventional single chamber TV-ICD. Duration of hospital admission and need of on-demand analgesia are also comparable for S-ICD patients.

1. Introduction

The Subcutaneous Implantable Defibrillator (S-ICD) is a promising technology developed to overcome many of the limitations of the conventional Transvenous single-chamber ICD's (TV-ICD) [1,2].

Based on several randomized clinical studies that demonstrated a low complication rate and an excellent efficacy for conversion of ventricular tachyarrhythmias [3], a Class IIa recommendation for the S-ICD has been added to the most recent European Society of Cardiology (ESC) Guidelines as an alternative to the TV-ICD, in the absence of pacing or resynchronization indication [4].

However, and despite the fact that most ICDs do not have a pacing or CRT indication, the TV-ICD is still the most widely used in most of the European centers [5]. Interestingly, the rationale for preferring a TV-ICD is generally not supported by strong reasons, such as the need for permanent pacing or anti-tachycardia pacing, and is not always very clear. This behavior may be explained by the lack of experience or availability of the S-ICD in some centers, but also by a more conservative approach by physicians who are still not entirely convinced of the real-world results of this technology, or may think that this procedure is associated with a more painful and prolonged recovery, as a result of the extensive subcutaneous tunnelization for the ICD lead and the different pocket location.

In this study, we aimed to compare peri-procedural and clinical outcomes after implantation of the S-ICD or the TV-ICD based on a cross-sectional study including S-ICD implanted patients and an age and gender-matched control group of patients implanted with TV-ICD, with focus on procedure duration, pain assessment and duration of hospitalization, perioperative complications and short-term follow-up.

2. Methods

We conducted a cross-sectional study, including all consecutive patients who underwent S-ICD implantation, from January to December 2016 at Clinique Pasteur,

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Toulouse, France, and an age and gender-matched control group of patients implanted with a TV-ICD system in the same center. The study complies with the ethical guidelines of the 1975 Declaration of Helsinki. All patients gave written informed consent allowing the use of their medical data.

2.1. Patient selection

Patients implanted with an S-ICD were compared with a similar number of controls implanted during the same time period, with a conventional TV-ICD system. The "nearest neighbor" method was used for matching S-ICD cases and TV-ICD controls, and for each S-ICD patient, we assigned the first subsequent gender and age-matched, single-chamber TV-ICD patient implanted within a time-interval of 30 days, without pacing or CRT indication. All the devices included in this study were implanted by the same operator, having an experience of >20 years for the TV-ICD and >2 years for the S-ICD.

All patients had an indication for ICD implantation according to the American College of Cardiology/American Heart Association [6] and European Society of Cardiology guidelines [4] for primary and secondary prevention of cardiac arrhythmias (see Fig. 1).

Screening was performed in all S-ICD candidates [1,2]. This consisted of using a dedicated screening tool to confirm their eligibility by analyzing the surface electrocardiogram signals in both supine and standing positions. In patients passing screening, a detailed discussion with the implanting physician about the pros and cons of both technologies took place, and selection of the device was performed in accordance with the patient's preference. Written informed consent was obtained for all patients.

Importantly, the only exclusion criteria for this S-ICD vs. TV-ICD comparison was requirement of pacing and/or resynchronization requirement.

The Emblem™ S-ICD (Boston Scientific©, St. Paul, MN) was implanted in all cases. In the TV-ICD group, all devices were single-chamber, and all existing manufacturers and models were used.

2.2. Procedure

Because of Departmental regulation in our Institution, general anesthesia was used in all TV-ICD and S-ICD implantation procedures. General anesthesia management was at the discretion of the anesthetists. However, deep sedation with free ventilation was preferred when possible. The TV-ICDs were implanted in a pre-pectoral pocket. The S-ICDs were implanted in an intermuscular pocket, between the large serratus and the dorsal muscles. For the S-ICD, the left parasternal position of the shock coil with the pulse generator positioned over the sixth rib, in the left mid-axillary line, was recognized as the optimal configuration, and the incision strategy included a two incisions (left latero-thoracic and sub-xyphoidal) technique in all patients.

All S-ICD patients underwent a standardized intraoperative defibrillation test. The first shock energy was programmed to 65 J, resulting in a safety margin of at least 15 J. In case of ineffective first shock delivery, the second shock energy was set to 80 J with reversed polarity. In the event of failed cardioversion/defibrillation after the second internal shock, external defibrillation was attempted. As it is now a consensus not performing Defibrillation Threshold Testing (DFT) shock systematically [7], we only performed DFT, in the TV-ICD group, to specific patients for secondary prevention.

All patients had their devices interrogated the day after implantation, and optimization of detection vectors in 2 positions (sitting and lying) was performed in S-ICD patients.

A chest X-ray was obtained the first postoperative day after implantation to confirm stable lead position in all patients.

After the operation, we used a post-procedure pain management protocol where oral paracetamol (maximum dose: 4000 mg/day), oral tramadol (maximum dose: 400 mg/day), and endovenous or subcutaneous morphine (maximum dose: 0.5 mg/kg/day) were given on-demand, and in escalation according to the patient's level of pain.

After discharge, an exercise test was performed 4 weeks after implantation, and sensing vectors were checked again for preventing from T-wave oversensing during exertion in all S-ICD patients.

The programming of ventricular arrhythmias therapies was standardized to prevent inappropriate treatments: a shock only zone ≥220 bpm was set in both groups. Additionally, a monitor zone between 170 and 219 bpm with prolonged detection time was also programmed in the TV-ICD group.

2.3. Patient follow-up, clinical outcomes and study endpoints

Anthropometric and clinical data was collected for all patients, as well as information on procedural and/or peri-procedural complications. Total hospitalization duration in days (patients were always admitted the day before the operation, and kept at least for a night following the procedure for logistical reasons), and procedural (general anesthesia induction included) and fluoroscopy duration in minutes were collected (Fig. 1).

Pain management was assessed during the initial 24 h after implantation through comparison of the required doses of on-demand analgesia as requested by the patient.

Follow-up information was obtained following an initial outpatient clinical appointment at our center, 4 weeks after implantation for the exercise test (S-ICD patients only), 3 months after discharge (all patients), by remote monitoring, and through regular appointments every 4 to 6 months for device evaluation (all patients).

Different endpoints assessed during follow-up included: pocket/incision healing process, occurrence of appropriate therapies, inappropriate therapies and other complications (i.e. lead dislodgement or failure, etc.…), as well as overall and specific mortalities. Device

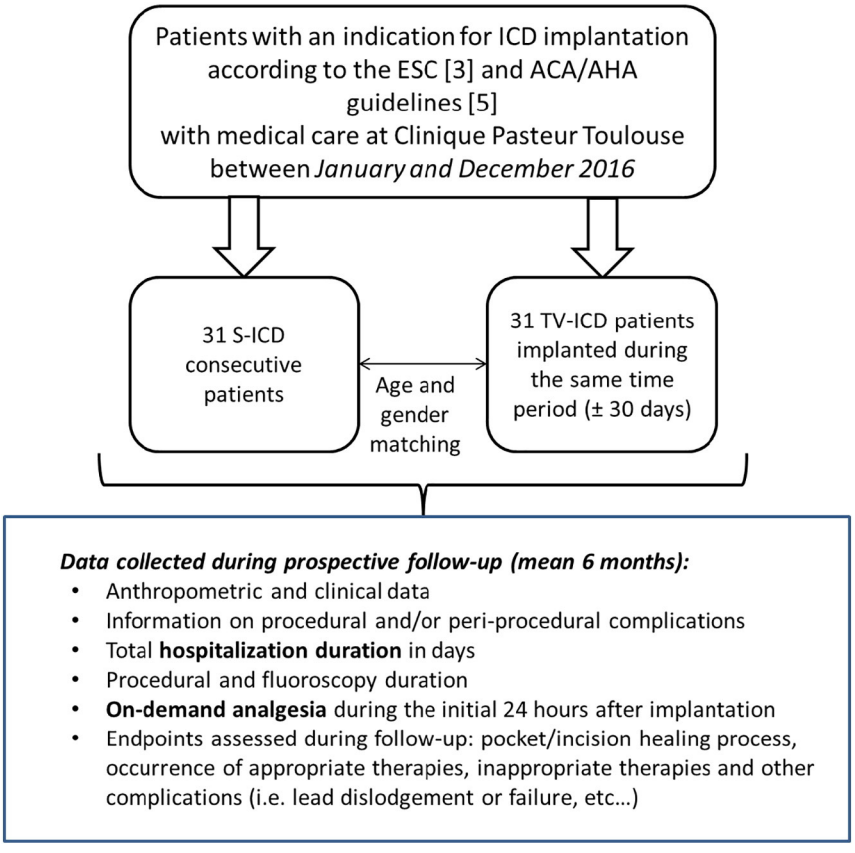

Fig. 1. Schematic description of the cross-sectional study.