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Real-world evidence for the use of subcutaneous implantable cardioverter–defibrillators in China: A single-center experience

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Abstract

Background: Subcutaneous implantable cardioverter–defibrillators (S-ICDs) have been shown to be non-inferior to transvenous ICDs in the prevention of sudden cardiac death (SCD), but there is still a lack of evidence from clinical trials in China. We investigated whether S-ICD implantation in the Chinese population is safe and feasible and should be promoted in the future.

Methods: Consecutive patients undergoing S-ICD implantation at our center were enrolled in this retrospective study. Data were collected within the median follow-up period of 554 days. Data concerning patient selection, implantation procedures, complications, and episodes of shock were analyzed.

Results: In total, 70.2% of all 47 patients (median age = 39 years) were included for secondary prevention of SCD with different etiologies. Vector screening showed that 98% of patients were with > 1 appropriate vector in all postures. An intraoperative defibrillation test was not performed on six patients because of the high risk of disease deterioration, while all episodes of ventricular fibrillation induced post implantation were terminated by one shock. As expected, no severe complications (e.g., infection and device-related complications) were observed, except for one case of delayed healing of the incision. Overall, 15 patients (31.9%) experienced appropriate shocks (AS) with all episodes terminated by one shock. Two patients (4.3%) experienced inappropriate shocks (IAS) due to noise oversensing, resulting in a high Kaplan–Meier IAS-free rate of 95.7%.

Conclusion: Based on appropriate patient selection and standardized implantation procedures, this real-world study confirmed the safety and efficacy of S-ICD in Chinese patients, indicating that it may help to promote the prevention of SCD in China.

Keywords
Subcutaneous implantable cardioverter–defibrillator · Sudden cardiac death · Efficacy · Safety · Chinese population

Sudden cardiac death (SCD) is a life-threatening challenge worldwide, although substantial progress has been made for the treatment of SCD, for example, with implantable cardioverter–defibrillator (ICDs). A transvenous ICD (TV-ICD), which is effective in reducing the risk of SCD in both primary and secondary prevention [1], is associated with many acute or long-term complications (e.g., pneumothorax, infection, lead malfunction, etc.; [2, 3]). Therefore, a less invasive but more effective system is needed.

As expected, subcutaneous ICD (S-ICD), a device that is totally implanted outside the thoracic cavity, has been demonstrated

The authors Lei Zhang, Xiao Li, and Yixiu Liang contributed equally to the manuscript.

Table 1 Clinical characteristics of the patients included in the study

Characteristic	Patients (*N* = 47)
Age, years; median (IQR)	39 (28, 61)
Female; n (%)	10 (21.3)
BMI; mean (SD)	23.4 ± 2.8
Diagnosis; n (%)	
Ischemic cardiomyopathy	8 (17)
Dilated cardiomyopathy	13 (27.6)
Hypertrophic cardiomyopathy	7 (14.9)
ARVC	3 (6.4)
Genetic arrhythmia syndrome	3 (6.4)
Idiopathic VT/VF	8 (17)
Congenital heart disease	2 (4.3)
Myocarditis	2 (4.3)
Alcoholic cardiomyopathy	1 (2.1)
LVEF, %; median (IQR)	48 (35, 65)
Secondary prevention; n (%)	33 (70.2)
High risk of infection for TV-ICD; n (%)	4 (8.5)
History of hypertension; n (%)	13 (27.7)
History of diabetes mellitus; n (%)	9 (19.1)
History of atrial fibrillation; n (%)	2 (4.3)
> 1 appropriate vector in all postures (right and/or left parasternal position); ***n*** (%)	46 (97.9)

IQR interquartile range, *BMI* body mass index, *SD* standard deviation, *ARVC* arrhythmogenic right ventricular cardiomyopathy, *VT* ventricular tachycardia, *VF* ventricular fibrillation, *LVEF* left ventricular ejection fraction, *TV-ICD* transvenous implantable cardioverter–defibrillator

to be non-inferior to TV-ICD in terms of the safety and efficacy both in randomized controlled trials and in real-world studies [4–8]. The results of these studies indicated S-ICD as an alternative choice to TV-ICD for patients with an indication for defibrillator therapy but without an indication for antitachycardia pacing (ATP) or backup pacing.

Although S-ICDs have already been extensively used for decades, they were certified for use in China only recently, in 2018. Moreover, prior studies regarding S-ICDs were mostly performed without the enrollment of patients from Asia, resulting in the limited implantation of S-ICD in Chinese patients and insufficient application evidence among this population. Thus, we performed this retrospective study with patients in our center to verify the safety and efficacy of S-ICD in Chinese patients. We also attempt to provide the real-world experiences for the optimized application of this device in the future.

Methods

Study design

In this retrospective analysis, all patients who underwent S-ICD implantation at the Zhongshan Hospital of Fudan University (Shanghai, China) were considered eligible and included consecutively. Data were collected from patient files, while follow-up information was acquired both from regular face-to-face outpatient monitoring and via telephone contact. Ethical approval for this research was granted by our local medical ethics committee.

Vector screening

Electrocardiogram recordings of potential patients were collected in the supine and siting/standing positions at rest. Patients were considered suitable for S-ICD implantation if at least one sensing vector was acceptable in all tested postures that were analyzed by an automated screening tool (AST) or a manual screening tool (MST; [9]).

S-ICD implantation

Patients were anesthetized after the appropriate location for the device and lead implantation was confirmed and marked via preoperative fluoroscopy. The procedure was typically performed using either the two- or three-incision technique: one incision for the device pocket and xiphoid, with or without a superior sternal incision.

The device was placed in the intermuscular plane between the latissimus dorsi and serratus anterior and sutured to the muscle bed to avoid migration. The distal sensing electrode was positioned adjacent to the manubriosternal junction and the proximal sensing electrode was placed adjacent to the xiphoid process. Air was removed carefully from the lead tunnels and device header. Defibrillation threshold (DFT) tests were performed at the end of the procedure unless foreseeable high risks or shock impedances were recorded. Chest radiography was performed immediately postimplantation to assess the position of the lead and pulse generator [10].

Postoperative programming

A shock zone at 230 bpm and a conditional shock zone at 200 bpm or 10–20 bpm less than the previous ventricular tachycardia (VT) rate were programmed. A SMART-pass filter and the function of pacing after defibrillation (50 bpm for 30 s) were switched on in all devices [11].

Follow-up

Follow-up was performed at in-office visits and/or through phone calls. Device-related complications were observed (including infection, lead replacement, device malfunction, delayed surgical incision healing, etc.). Both appropriate and inappropriate shocks were recorded and analyzed.

Statistical analysis

Descriptive statistics are reported with mean ± standard deviation (SD) or median interquartile range (IQR) for continuous variables and frequency and percentage for categorical variables. Kaplan–Meier analyses were made to estimate event-

Table 2 Operation procedures

Characteristic	Patients (*N* = 47)
Intravenous anesthesia; ***n*** (%)	47 (100)
Two-incision technique; ***n*** (%)	18 (38.3)
Lead in right sternal border; ***n*** (%)	25 (53.2)
Intraoperative DFT; ***n*** (%)	41 (87.2)
Successful VF induction; ***n*** (%)	39 (95.1)[a]
Successful defibrillation; ***n*** (%)	38 (100)[b]
Shock impedance; mean (SD) ohms	67 ± 13
Procedure time; mean (SD) min[c]	46 ± 22

DFT defibrillation test, *VF* ventricular fibrillation, *SD* standard deviation
[a] Among the 41 patients who underwent intraoperative DFT
[b] Another patient of induced VF with restored sinus rhythm before shock
[c] Operation time from skin incision to skin suture

Table 3 Follow-up data

Characteristic	Patients (*N* = 47)
Median duration (IQR); days	***554 (257, 934)***
Device-related complication; n (%)	***1 (2.1)***
Infection; ***n*** (%)	0 (0)
Bleeding; ***n*** (%)	0 (0)
Thrombotic events; ***n*** (%)	0 (0)
Lead replacement; ***n*** (%)	0 (0)
Device malfunction; ***n*** (%)	0 (0)
Delayed surgical incision healing	1 (2.1)
Need to replace S-ICD with other devices; n (%)[a]	0 (0)
SMART pass algorithm; n (%)	47 (100)
Total shocks; no. of patients/times[b]	17/77
Appropriate shock; no. of patients (%)	15 (31.9)
Successful defibrillation with one shock; n (%)[c]	72 (100)
Inappropriate shock; no. of patients (%)	2 (4.3)
Cardiac oversensing; ***n*** (%)	0 (0)
Noncardiac oversensing; ***n*** (%)	2 (4.3)

IQR interquartile range, *S-ICD* subcutaneous implantable cardioverter–defibrillator
[a] Including need to pace for the treatment of bradycardia, to use anti-tachycardia pacing (ATP) therapy or cardiac resynchronization therapy (CRT)
[b] Two patients separately received 24 and 22 shocks induced by ventricular electrical storms
[c] Concerning appropriate shocks

free rates for appropriate shock (AS) and inappropriate shock (IAS). Learning-curve analysis was determined by logistic regression. All statistical analyses were performed using SPSS version 17.0.

Results

Study population

This study enrolled patients who met the aforementioned inclusion criteria in Zhongshan Hospital, Fudan University from August 21, 2018 to January 28, 2022. A total of 47 patients were enrolled consecutively, with a median follow-up duration of 554 days. The clinical characteristics of all patients are summarized in **Table 1**. Briefly, the majority of the patients were male (78.7%) with the median age of 39 years (IQR: 28, 61). The S-ICDs were implanted in patients eligible for ICD implantation but without predictable pacing requirements [12] and for various etiologies (e.g., ischemic cardiomyopathy, dilated cardiomyopathy, hypertrophic cardiomyopathy, etc.). Overall, 70.2% of the patients underwent implantation for secondary prevention, with a median left ventricular ejection fraction (LVEF) of 48% (IQR: 35%, 65%). Four of the 47 patients were highly advised to receive S-ICD implantation because of the high risk of infection associated with TV-ICD (one patient with previous TV-ICD-related infection and three with end-stage renal disease). Among the 47 patients considered suitable for S-ICD implantation, 46 patients had > 1 appropriate vector in both postures (three appropriate vectors in 57.4% of the patients).

Implantation procedure

The second-generation devices were all successfully implanted in the patients. To reduce the intensity of pain and to enable the patients to cooperate better with the operation, all patients received intravenous anesthesia. Specifically, general anesthesia (GA) by the combination of propofol and remifentanil along with mechanical ventilation were successfully applied to the first 19 patients, to avoid patient discomfort and awareness, especially at lead tunneling and the generator insertion sites. The rest of the patients were anesthetized by a combination of monitored anesthesia care (MAC) and local anesthesia at the site of implantation.

As shown in **Table 2**, intraoperative defibrillation testing (DFT) was not performed for six patients, due to the high risk of either atrial fibrillation-related thrombosis or aggravation of heart failure. One of the six patients received two appropriate shocks, and none of them received inappropriate shock. Moreover, ventricular fibrillation (VF) was successfully induced in 39 patients, all of which were terminated with one 65-J shock. Nonetheless, the PRAETORIAN score of the patients who did not undergo DFT or failed DFT was< 90 for all patients. The shock impedance was similar between patients who underwent DFT and those who did not (66 ± 14 vs. 72 ± 12 Ω, $p = 0.36$).

The leads were positioned to the right sternal border in half of the patients, which were determined by both preoperative fluoroscopy and sensing vector tests. Additionally, the increased number of implantations was accompanied by decreased procedure time (**Fig. 1**).

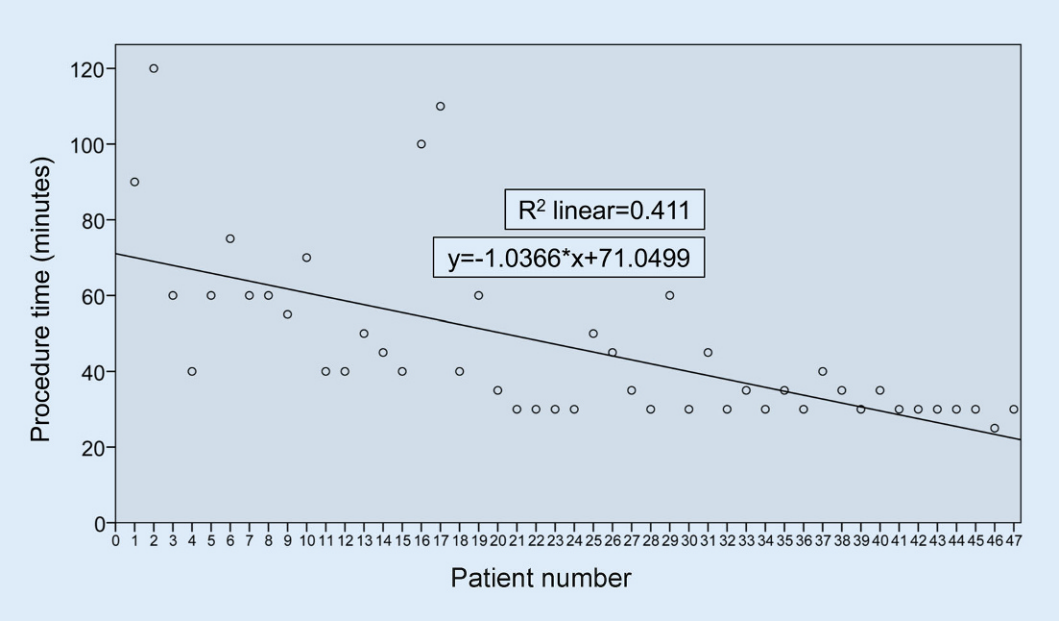

Fig. 1 ◄ Logistic regression analysis of skin-to-skin procedure time

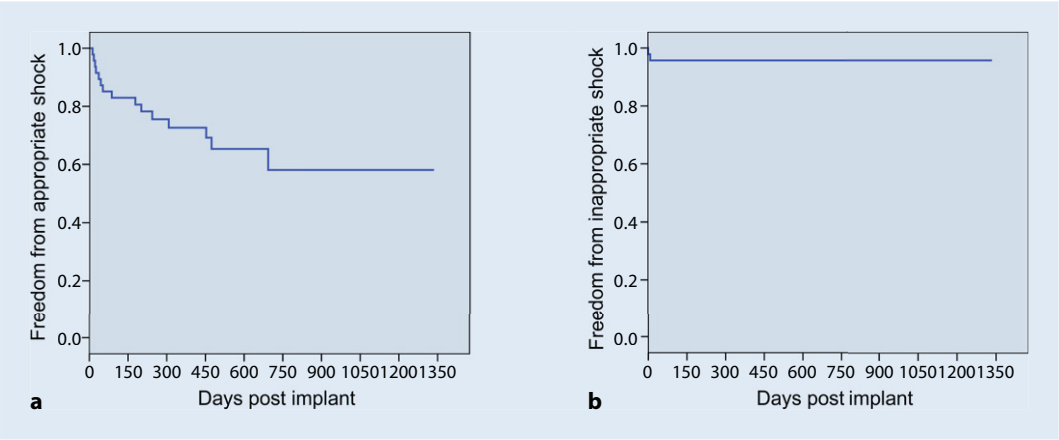

Fig. 2 ◄ Kaplan–Meier analysis of appropriate-shock-free rate (**a**) and inappropriate-shock-free rate (**b**)

Complications

During the median follow-up of 554 days (IQR: 257, 934), there was only one patient with delayed healing of the pocket incision but without infection. No other device-related complications were observed (e.g., infection, lead replacement, device malfunction, etc.), and no replacement was needed for the patients, regarding pacing for the treatment of bradycardia, using anti-tachycardia pacing (ATP) therapy or cardiac resynchronization therapy (CRT) (**Table 3**).

Appropriate shock

During the follow-up, 17 patients received a total of 77 shocks. Two of these patients received 24 and 22 shocks, respectively, due to ventricular electrical storms induced by either gynecological operation or excessive activities with inappropriate discontinuation of medical treatment. Appropriate shocks (AS) were delivered to 15 patients (31.9%) during the follow-up, while all episodes (VT/VF) were successfully terminated by the first shock (**Table 3**). Overall, 12 patients (80%) received their first AS within 1 year, and the Kaplan–Meier AS-free rate was 58.1% at 2 years (**Fig. 2a**).

Inappropriate shock

As shown in **Table 3**, only two patients (4.3%) experienced inappropriate shock (IAS) due to non-cardiac oversensing within 9 days of implantation, resulting in a high Kaplan–Meier IAS-free rate of 95.7% (**Fig. 2b**).

Specifically, a 67-year-old male patient underwent S-ICD implantation due to ischemic cardiomyopathy. He experienced IAS without any discomfort before the shock at the third hour after the operation. A contentious baseline shift and frequent oversensing of low-amplitude signals were detected by device interrogation, which was followed by a shock (**Fig. 3a**). A similar baseline shift, which could be induced by pressing the two incisions, disappeared after massaging the skin along the tract and pocket, indicating that there was subcutaneous air surrounding the proximal electrode [13]. In addition, the sensing vector was changed from *secondary* to *alternate*, and further IAS was avoided.

Another 38-year-old male patient with Brugada syndrome experienced IAS while having lunch and being in his usual state

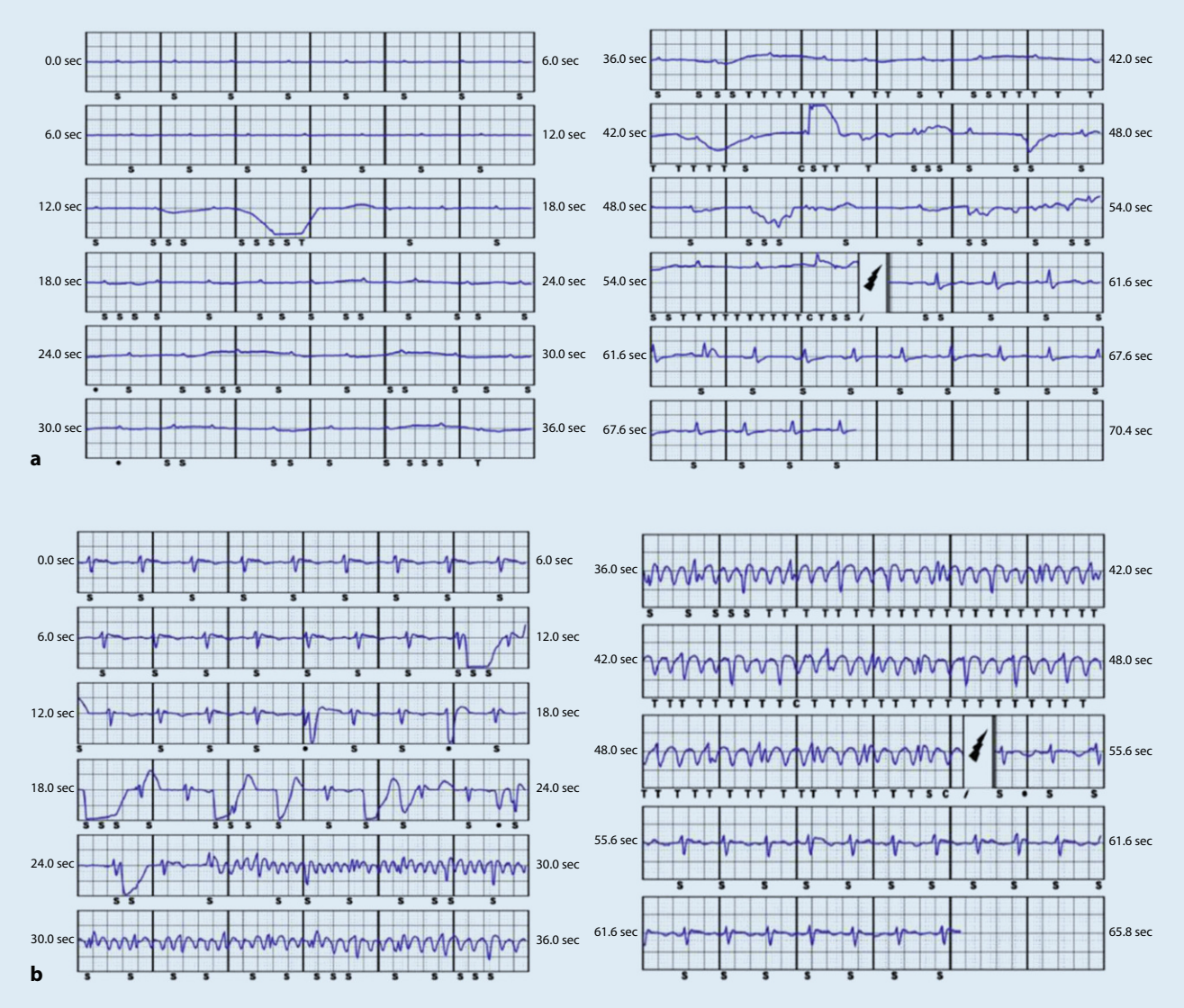

Fig. 3 ▲ Two subcutaneous electrocardiograms at the time of inappropriate shock. **a** An oversensing of low-amplitude induced shock; **b** a noise oversensing induced inappropriate shock. *S* sense, *T* tachycardia detection, *C* charge start, *lightning symbol* shock

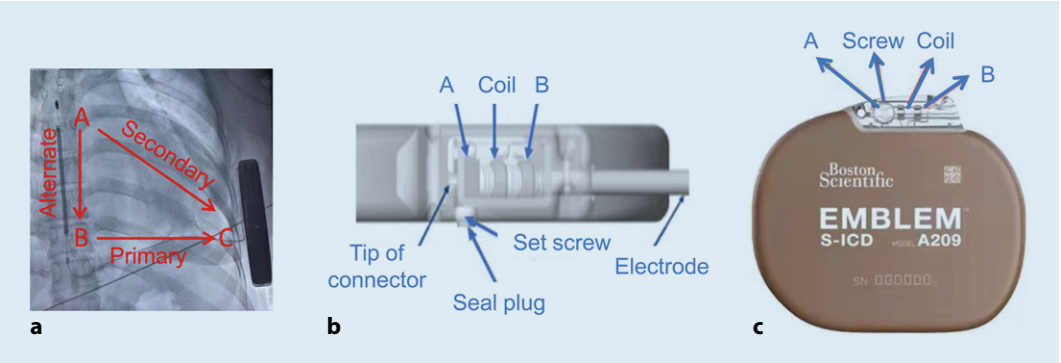

Fig. 4 ◄ Illustrations of sensing vectors. **a** Outer vectors; **b** Inner vectors (view from the top of the device). Point *A* is associated with both secondary and alternate vectors; **c** internal vectors (view from the front of the device)

of health 9 days after device implantation. Likewise, device interrogation revealed lead noise with evidence of noise oversensing (**Fig. 3b**), which is similar to a previously reported case, suggesting that noise oversensing might be triggered by fluid or air entrapment within the device header secondary to a physical breach of the seal plug [14]. The relationships between the sensing vectors and the points of lead connecting to the pulse generator are shown in **Fig. 4**. The impairment of the seal plug may affect the function of point A (**Fig. 4b,c**), which is associated with the secondary vector (**Fig. 4a**). Finally, the noise oversensing-induced IAS was resolved after reprogramming the sensing vector from secondary to primary, which is related to points B and C, but not point A (**Fig. 4**).

Discussion

Multiple studies have verified the safety and efficacy of S-ICD, and also proved that they are associated with lower risks of periprocedural complications as well as device-related complications and IAS, as compared with TV-ICD [15–18]. Regrettably, there is limited experience on this treatment in East-Asia populations, due to the significantly lower number of patients undergoing implantation, as compared with the increasing number of patients in other regions. This study confirmed the safety and efficacy of S-ICD in Chinese patients by providing the evidence from a single center.

Patient selection

In general, candidates for ICD therapy without backup pacing demand may be suitable for S-ICD treatment, especially for patients with a high risk of infection and young patients, regardless of whether for it used for primary or secondary prevention. The median age of patients who received S-ICD implantation at our hospital was 39 years, and in most cases it was for secondary prevention. This may also account for the high rate of AS in this study. As in previous studies, most patients underwent S-ICD implantation for primary prevention [4–6]. In view of the very low prevalence of ICD utilization in China (approx. only 1.5 device per 1 million people; [19]) this less invasive and well-accepted system may give an impetus to promote the prevention of SCD [20].

To further identify suitable patients for S-ICD implantation, vector screening should be performed; in this study, eligibility was defined by the presence of ≥ 1 appropriate vector in all postures. The majority of patients (98%) in this study had more than one appropriate vector in all postures, which made it possible to reprogram the sensing vectors in the two patients who experienced IAS. Thus, from our point of view, the location (right or left parasternal position) that has ≥ 2 appropriate vectors may be preferred for lead implantation, in the case of an unpredictable need for reprogramming the sensing vector in the future.

Anesthesia for the operation

With the accumulation of surgical experience, and to minimize the drawbacks associated with GA such as procedure length, airway injury, and post-anesthesia care, MAC with dexmedetomidine hydrochloride and local anesthesia with lidocaine were simultaneously delivered to the rest of patients. Both of these anesthesia strategies are acceptable, while local anesthesia alone may not be preferred because of the difficulty to tolerate the pain during the whole operation. Additionally, device-related pain may be severe in the first 3 days postimplantation and could be successfully managed with nonsteroidal anti-inflammatory drugs [21].

DFT in implantation

Currently, DFT is recommended in S-ICD implantation to determine the ability of the device in terminating fatal ventricular arrythmia [22, 23]. In this study, 87.5% of the patients successfully underwent DFT, which is similar to reports from a previous study [24]. The PRAETORIAN score is a tool evaluating the implant position and predicting the defibrillation success of the S-ICD. Specifically, < 90 points represents a low risk, 90–< 150 points represents an intermediate risk, and ≥ 150 points represents a high risk of conversion failure [25]. The six patients who did not undergo DFT owing to a high risk of disease deterioration all had a PRAETORIAN score of < 90, and none of them experienced unsuccessful termination of VT/VF, indicating that the PRAETORIAN score is helpful in identifying patients at risk for ineffective shock conversion [25]. Additionally, it also implies that implantation of S-ICD without DFT may be safe and effective [26]. Moreover, it is doubted that DFT is still needed routinely at implantation, given the extremely high success rate of such procedures today [5, 27]. Therefore, the undergoing randomized controlled trial assessing DFT in the S-ICD should further elucidate the need for DFT [28].

S-ICD-related complications

During the longest follow-up period of 1334 days, no serious complications were observed except for delayed healing of the pocket incision in one patient. This is consistent with the superiority of S-ICD implantation presented in other studies, which reported fewer infections, thrombotic events, and wire-related complications [29, 30].

Compared with TV-ICD, making a device pocket for S-ICD is more traumatic, which may be more likely to result in local infection and bleeding. Thus, the intermuscular technique (between the latissimus dorsi and serratus anterior muscles) is regularly adopted to reduce pocket complications and infections. Moreover, ensuring optimal initial placement and securing of the device to the deep fascia so as to avoid migration into a more anterior pocket are of crucial importance to guarantee high shock efficacy [31]. Furthermore, perioperative management of anticoagulation may help minimize the events of pocket hematomas. It has been reported that antiplatelet therapy with clopidogrel appears to increase the risk for hematoma following S-ICD implantation [32]. Considering that uninterrupted use of warfarin is associated with an increased risk of lateral pocket hematoma [33], interruption of anticoagulation without bridging should be considered for patients with an acceptable risk status [32]. In conclusion, a risk–benefit assessment must be made when deciding to stop or continue anticoagulation.

Safety and efficacy

No significant prognostic differences were observed between S-ICD and TV-ICD regarding all-cause mortality, cardiac death, and non-cardiac death. [16]. Moreover, the safety and efficacy of S-ICD for discrete and storm episodes have been confirmed by long-term studies, with the first and final shock efficacy of more than 90% and 95%, respectively. [8, 31]. Likewise, all VT/VF episodes were terminated by the first shock in our study, which may be due to the relatively small number of the patients and short follow-up duration. The safety and efficacy of the therapy could be enhanced by improving controllable factors, such as suitable patient selection and standardized implanting procedure.

With the increased experience of operators in implantation and programming, as well as improvements in the detection, filtering, and discriminative algorithms, the incidence of IAS has decreased yearly to an annualized rate of less than 4% [31, 34, 35]. This is consistent with the promisingly high Kaplan–Meier IAS-free rate (95.7%) in our study. Moreover, unlike TV-ICD, S-ICD was found to be associated with a significantly lower risk of IAS due to supraventricular arrhythmias, but an increase risk due to oversensing [16], such as T wave oversensing and myopotentials [4, 36, 37]. Likewise, the IAS episodes experienced by two patients in our study were all induced by noise oversensing, which was eventually resolved by altering the sensing vector. Thus, conditionally reprogramming sensory vectors may reduce episodes of IAS or prevent future episodes once they are detected [38]. In addition, it should be emphasized that releasing any residual subcutaneous air through the incisions prior to closing and avoiding violent actions during the operation are also helpful to minimize noise sensing-induced IAS.

Learning curve

Previous research showed that the complication rate and procedure time stabilized after > 13 implants, indicating a short learning curve for physicians adopting the S-ICD procedure [39]. Our experience also demonstrated that the technique could be well mastered by physicians shortly within 20 implantations, which is suggested by the shortened and stable procedure time.

Limitations

This study has several limitations. Firstly, it was a single-center study with a relatively small sample size, which carries inherent limitations. Secondly, the single-arm, retrospective design of the study did not allow for a comparative assessment of the safety and efficacy between S-ICD and TV-ICD. Thirdly, most of the patients enrolled were for the secondary prevention of SCD with different etiologies and therefore the results may not be translated to cases of primary prevention with specific etiology.

Conclusion

This real-world study confirmed the safety and efficacy of subcutaneous implantable cardioverter–defibrillators (S-ICD) in the prevention of sudden cardiac death (SCD). A high rate of successful appropriate shocks and a low rate of inappropriate shocks were achieved based on appropriate patient selection, standardized implanting procedures, and programming experience. Although S-ICD have been used in dozens of hospitals in China, the number of treated patients is still relatively small. Thus, S-ICD should be promoted in more centers to benefit more patients and enhance the prevention of SCD.

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Declarations

Conflict of interest. L. Zhang, X. Li, Y. Liang, J. Wang, M. Li, L. Pan, X. Chen, S. Qin, J. Bai, W. Wang, Y. Su and J. Ge declare that they have no competing interests.

This article does not contain any studies with human participants or animals performed by any of the authors.

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Zusammenfassung

Praktische Belege für den Einsatz subkutaner implantierbarer Kardioverter-Defibrillatoren in China: Erfahrungen aus einem Einzelzentrum

Hintergrund: Subkutane implantierbare Kardioverter-Defibrillatoren (S-ICD) haben sich gegenüber transvenösen ICD bei der Prävention des plötzlichen Herztods (SCD) als nichtunterlegen erwiesen, aber es fehlt bislang noch Evidenz aus klinischen Studien in China. Die Autoren untersuchten, ob die S-ICD-Implantation in der chinesischen Bevölkerung sicher und praktikabel ist und ob sie in Zukunft gefördert werden sollte.
Methoden: Konsekutiv sich zur S-ICD-Implantation vorstellende Patienten im Zentrum der Autoren wurden in die vorliegende retrospektive Studie einbezogen. Für eine mittlere Nachbeobachtungsdauer von 554 Tagen wurden dabei Daten erhoben. Ausgewertet wurden die Daten zur Patientenselektion, zu den Implantationsverfahren, zu Komplikationen und Schockereignissen.
Ergebnisse: Zur Sekundärprävention des SCD unterschiedlicher Ätiologie wurden 70,2 % aller 47 Patienten (mittleres Alter: 39 Jahre) in die Studie eingeschlossen. Das Vektorscreening zeigte, dass 98 % der Patienten > 1 entsprechenden Vektor in allen Positionen aufwiesen. Ein intraoperativer Defibrillationstest wurde bei 6 Patienten wegen des hohen Risikos einer Krankheitsverschlechterung nicht durchgeführt, während alle Phasen von Kammerflimmern, die nach Implantation auftraten, durch einen Schock beendet wurden. Wie erwartet, wurden keine schweren Komplikationen (z. B. Infektionen und gerätbezogene Komplikationen) beobachtet, außer in einem Fall eine verzögerte Abheilung der Inzisionsstelle. Bei 15 Patienten (31,9 %) wurden adäquate Schocks (AS) ausgelöst, wobei alle Phasen durch einen Schock beendet wurden. In 2 Fällen (4,3 %) kam es zu inadäquaten Schocks (IAS) aufgrund von Oversensing, was zu einer hohen IAS-freien Rate nach Kaplan-Meier von 95,7 % führte.
Schlussfolgerung: Auf der Grundlage einer entsprechenden Patientenselektion und standardisierter Implantationsverfahren bestätigte die vorliegende Real-World-Studie die Sicherheit und Wirksamkeit von S-ICD bei chinesischen Patienten als Hinweis darauf, dass diese Methode möglicherweise zur Förderung der Prävention des SCD in China beitragen kann.

Schlüsselwörter
Subkutaner implantierbarer Kardioverter-Defibrillator · Plötzlicher Herztod · Wirksamkeit · Sicherheit · Chinesische Bevölkerung