




ORIGINAL ARTICLE

A real-world experience of subcutaneous and transvenous implantable cardiac defibrillators—comparison with the PRAETORIAN study

Dibbendhu Khanra MD, DM  | Abdul Hamid MRCP | Peysh Patel PhD, MRCP | John Tomson MRCP | Ahmed Abdalla MBBS  | Nasrin Khan MBBS | Rory Dowd MRCP | Nakul Chandan MRCP | Christopher Osagie MBBCh | Tomilola Jinadu MRCP | Selvakumar Velu MBBS, MRCP | Anita Arya MD, FRCP | Charles Spencer MD, FRCP | Craig Barr MD, FRCP | Sanjiv Petkar MD, DM, FRCP 

New Cross Hospital, Heart and Lung Centre, Division of Electrophysiology and Devices, Royal Wolverhampton NHS Trust, UK

Correspondence

Sanjiv Petkar, New Cross Hospital, Heart and Lung Centre, Division of Electrophysiology and Devices Royal Wolverhampton NHS Trust, WV10 0QP, UK.

Email: sanjiv.petkar@nhs.net

Abstract

Background: PRAETORIAN is the first randomized controlled trial that demonstrated the noninferiority of subcutaneous ICD (S-ICD) in comparison with transvenous ICD (TV-ICD). We retrospectively reviewed electronic records of patients with ICD implanted over the past 6 years, with the primary objective to compare our real-world single tertiary center experience with the randomized data from the PRAETORIAN study.

Methods: Seventy S-ICD patients were compared with 197 TV-ICD patients, from July 2014 to June 2020 retrospectively, over a median period of 1304 days (296–2451 days). Primary composite endpoints included inappropriate shocks and device-related malfunctions.

Results: Patients with S-ICD implantation were younger than those who received TV-ICD (mean, 49.7 years vs 63.9 years, $p < .001$). About 31.4% of S-ICDs were implanted for secondary prevention, and 58.6% of S-ICD patients had ischemic cardiomyopathy (ICM) with a median left ventricular ejection fraction of 32.5% (range: 10–67%). S-ICDs and TV-ICD had statistically similar inappropriate shocks (4.3% vs 4.6%, $p = .78$), device-related complications (11.4% vs 9.1%, $p = .93$), and the overall primary endpoints (15.7% vs 13.7%, $p = .68$). The findings remained the same even after age and gender adjustments and time-dependent analysis.

Conclusion: Although single-center experience with a small number of S-ICD patients, results of the PRAETORIAN study has been replicated in our real-world experience of S-ICD and TV-ICD implantations across diverse etiologies, indications, and age groups confirming the comparable performance of S-ICD and TV-ICD when implanted in selected patients.

Dibbendhu Khanra and Abdul Hamid contributed equally.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2022 The Authors. *Journal of Arrhythmia* published by John Wiley & Sons Australia, Ltd on behalf of the Japanese Heart Rhythm Society.

KEYWORDS

device-related complications, inappropriate shocks, PRAETORIAN study, subcutaneous ICD, transvenous ICD

1 | INTRODUCTION

The implantable cardioverter defibrillator (ICD) is the standard of care for primary or secondary prevention of sudden cardiac death; however, transvenous leads can be the “trouble monger” with complications that include lead failure, pneumothorax, tricuspid valve injury, lead displacement, cardiac tamponade, and even, infective endocarditis.^{1–6} Subcutaneous ICD (S-ICD) was originally developed as an alternative to transvenous ICD (TV-ICD) with challenging vascular anatomy³ but with a growing evidence base, improved hardware, and more sophisticated software, the scope of S-ICD implantation has continually expanded.⁷ Although S-ICD technology is limited by its inability to deliver chronic pacing therapy, either in the context of bradycardia or in the antitachycardia pacing (ATP), American Heart Association (AHA)/American College of Cardiology (ACC), and the European Society of Cardiology (ESC) guidelines stipulate class IIa recommendations for S-ICD over TV-ICD in patients without indication for bradycardia pacing, ATP, or cardiac resynchronization.^{8,9} Safety and efficacy of S-ICD have predominantly emerged from large prospective registries.^{10–13}

PRAETORIAN was the first randomized controlled trial (RCT) comparing S-ICD with TV-ICD, which concluded that S-ICD was noninferior to TV-ICD with respect to device-related complications and inappropriate shocks.¹⁴ However, RCTs may not necessarily reflect clinical practice and the results of an RCT may not be generalized due to stringent study design. Real-world studies comparing outcomes of S-ICD and TV-ICD are handful, but none validated the findings of the PRAETORIAN study.^{14–19} The aim of this retrospective study was to analyze the real-world experience of a tertiary care hospital (NX) on outcomes between S-ICD and TV-ICD implantation among patients with similar inclusion criteria to the PRAETORIAN study. The primary objective of this study was to (1) compare baseline characteristics, safety, and efficacy between TV-ICD (TV-ICD Group NX) and S-ICD (S-ICD Group NX) at our center and the secondary objectives were to (2) compare S-ICD implants at our center (S-ICD Group NX) with the S-ICD arm of the PRAETORIAN study (S-ICD Group PS) and (3) TV-ICD at the center (TV-ICD Group NX) to the TV-ICD arm of the PRAETORIAN study (TV-ICD Group PS).

2 | METHODS

2.1 | Study design

This study was performed in a tertiary care center (NX) in the United Kingdom which started complex cardiac rhythm device implantation in 2004 and has been one of the early adopters of S-ICD implantation since 2014. We retrospectively assessed complex device

“What's new”

In the retrospectively analyzed data of ICD implantations from our center over the last 6 years, transvenous (TV-ICD) and subcutaneous ICD (S-ICD) patients, selected and compared similar to the PRAETORIAN study protocol, inappropriate shocks, and device-related complications were found to be statistically comparable between TV-ICD and S-ICD groups despite 31.4% secondary preventions and 58.6% ischemic cardiomyopathy in our S-ICD cohort. Replication of the findings of the PRAETORIAN study in our real-world ICD data strengthens the comparable performance of S-ICD to TV-ICD in patients needing ICD without indication for brady pacing, ATP, or cardiac resynchronization.

implantation in our center using the electronic database to compare our experience of S-ICD versus TV-ICD implantation dated from February 2014 till June 2020, with follow-up till March 31, 2021. A comparison of our real-world data with that of the PRAETORIAN study was also performed.

2.2 | Inclusion and exclusion criteria

The inclusion and exclusion criteria of the study were similar to the PRAETORIAN study.²⁰ Patients of age ≥ 18 years undergoing ICD implantation as per class I or IIa ESC recommendation were included in the PRAETORIAN study.^{14,20} Patients requiring bradycardia pacing (for sinus bradycardia, sinus pause, bifascicular block, prolonged PR interval, and necessary drugs causing bradycardia), ATP (monomorphic ventricular tachycardia with rate < 170 bpm), and resynchronization therapy (QRS > 120 ms and interventricular conduction delay) were excluded in the PRAETORIAN study.^{14,20}

2.3 | S-ICD implantation

Although procedural technique and hardware evolved, all S-ICD implantation procedures were carried out by one of three experienced operators. The majority of S-ICDs were implanted under general anesthesia (GA) or serratus anterior (SA) block, utilizing two or three-incision technique at the operator's discretion. The device was placed in the intermuscular plane between latissimus dorsi and serratus anterior and sutured to the muscle bed to avoid migration. Air was removed carefully from the lead tunnels and device header. Defibrillation threshold (DFT) tests were performed at the end of

the procedure unless prohibited (thrombus, atrial fibrillation without anticoagulation, or part of PRAETORIAN DFT trial²¹) and shock impedances were recorded. Patients were mostly discharged on the same day as per trust protocol and followed up in the device clinic. Chest radiography was done immediately postimplant to assess lead position with respect to sternum and position of a can with respect to scapula.

2.4 | S-ICD screening

At our hospital, patients requiring complex devices are routinely discussed in the multidisciplinary team meetings (MDT) consisting of device consultants, interventional cardiologists, heart failure specialists, general cardiologists, imaging consultants, and cardiothoracic surgeons. All patients who were considered for S-ICD underwent QRS-T-wave analysis for vector screening and had to pass at least one vector to be eligible to receive an S-ICD. Patients who did not pass the screening for S-ICD underwent TV-ICD implantation.

2.5 | Periprocedural anticoagulation

Most of the device implantations were performed on minimally interrupted warfarin, keeping INR <3, or minimally interrupted DOAC, 24 hours if renal function is normal and 48 h if renal function is impaired. Antiplatelets had been continued uninterrupted as per local trust guidance. The majority of operators used diathermy during the procedure. Elective patients were discharged on the same day of the procedure with a limited supply of analgesics.

2.6 | Data extraction

Data on baseline characteristics including age, gender, diabetes, hypertension, body mass index (BMI), atrial fibrillation (AF), New York Heart Association (NYHA) class, left ventricular ejection fraction (LVEF), underlying cardiac etiology, and an indication of ICD implantation were collected using electronic records. All the patients had their first device checked 6 weeks postimplant and followed up regularly on-site or virtually. Appropriate or inappropriate therapies (ATP or shocks), device-related complications (details outlined later), and hospitalization due to heart failure (HHF) and mortality were gathered using electronic records. Findings from the PRAETORIAN study were directly extracted from the published results.¹⁴

2.7 | Device programming

TV-ICDs were programmed in three zones (monitor, VT, and VF), and attempts were made to minimize shocks and to have ATP therapies for TV-ICD by setting higher rate cutoff and duration delay for detecting VT-like MADIT-RIT study.²² S-ICD were programmed

as conditional shock zone at 200 bpm and shock zone at 230 bpm. SMART-pass filter was switched on in all the S-ICD devices.²³ The S-ICD vector was left the same as the successful DFT, at least till the first follow-up at 6 weeks. All the ICD patients underwent home monitoring by LATITUDE.²⁴

2.8 | Outcome measures

Primary composite endpoints included inappropriate shocks and device-related malfunctions. Secondary endpoints included the individual components of the primary endpoint, death from any cause, appropriate ICD therapy (including ATP), and hospitalization for heart failure. Device-related malfunctions include lead displacement, lead-related cardiac perforation, thrombosis, device upgrades, clinically significant pneumothorax, bleeding, infections, and failed DFT, as defined by the PRAETORIAN study protocol.²⁰ Patients with unavailable follow-up data or LATITUDE malfunction were omitted from the analysis. The time to diagnosis of complications was collected retrospectively from the electronic database as appeared first in the clinical note or electronic correspondences. In our hospital, patients have their first on-site follow-up routinely in 6 weeks after device implantations, unless indicated for an early checkup. Thereafter, patients are seen every 3 months, alternating between on-site and virtual follow-ups. Thus, we divided the time to diagnosis of complications as early (within 6 weeks), intermediate (6 weeks–3 months), late (3 months–1 year), and very late (after 1 year).

2.9 | Definitions of complications

Outcome measurements were similar to the PRAETORIAN study protocol.²⁰ Inappropriate shock was defined as shock therapy for a reason aside from VT or VF, including supraventricular tachycardia (SVT) with fast ventricular rate, sinus tachycardia, and atrial fibrillation (AF), T-wave oversensing, detection of physiological or other noncardiac activity, and lead or device failure. ICD-related infection was defined as an infection involving the subcutaneous pocket containing the device and/or leads that required lead or device extraction. Clinically significant hematoma was defined as a swelling of the pocket with the need for reoperation, blood transfusion, or prolonged hospitalization. Lead displacement was defined as the displaced lead in which a new procedure had to occur for lead repositioning. Failed DFT was defined as an induced VF episode that failed to be terminated with 65 J shock followed by 80 J shock and needed to be externally cardioverted.

2.10 | Statistical analysis

Statistical analyses were performed using IBM SPSS statistics 20.0 (SPSS Inc.). Continuous variables were expressed as mean \pm standard

deviation (SD), whereas categorical variables were given as numbers (percentages). Comparisons between the groups were done by Mann–Whitney *U* test for continuous variables and by the Chi-squared test for categorical variables. *p* value of <.05 was considered statistically significant. Findings from PRAETORIAN study results¹⁴ were directly compared with the findings of NX S-ICD and TV-ICD patients. With regard to the continuous variables from the PRAETORIAN study (e.g., age, LVEF, BMI, QRS duration), mean/SD were derived directly from the median/interquartile range using Box–Cox transformation²⁵ in R studio (2020)²⁶ with “estmeansd” package. Statistical analyses of S-ICD and TV-ICD of the NX group were also undertaken with age and gender adjustments using the “match” function in the R platform.²⁶

3 | RESULTS

A total of 758 complex devices were implanted in our center during the study period (July 15, 2014–June 15, 2020) of which 394 (52.0%) were new ICD implants (TV-ICD: 320/394 [81.2%], S-ICD: 74/394 [18.8%]) (Figure 1). A total of 127/394 (38.5%) patients were excluded as they either did not meet the PRAETORIAN study inclusion and exclusion criteria, underwent generator replacement only, and were upgraded to an ICD from previous permanent pacemaker implantation or because no follow-up data were available. The remaining patients (TV-ICD: 197, S-ICD: 70) were suitable for analysis. The median duration of the follow-up for all patients was 1304 days (296–2451 days).

3.1 | S-ICD Group NX vs TV-ICD Group NX

Patients in the S-ICD NX group were significantly younger than in the TV-ICD NX group (median 50 years vs 66 years, *p* <.001).

One-third of our S-ICD cohort had implants for secondary prevention. The duration of follow-up was shorter (median 1048 days vs median 1463 days, *p* <.001). There were no differences between the two groups with regard to median BMI, NYHA class, the proportion of patients with ICM, AF, and median QRS duration (Table 1).

The primary composite endpoints (15.7% in S-ICD vs 13.7% in TV-ICD) and the individual primary endpoints of inappropriate shocks (4.3% in S-ICD vs 4.6% in TV-ICD) and device-related complications (11.4% in S-ICD vs 9.1% in TV-ICD) did not differ significantly between the groups (Table 2, Figure 2A). Only 4.3% (3/70) of patients with S-ICD received appropriate shocks in comparison with appropriate shocks received in the TV-ICD group (20/197, 10.1%). Although all-cause mortality was similar in both the groups, hospitalizations due to heart failure (HHF) were significantly more in the TV-ICD (20.3%) group than S-ICD group (2.8%). Of note, 16.2% and 9.6% of patients received ATP from TV-ICD for ventricular arrhythmia and SVT, respectively (Table 3).

Selection of patients for S-ICDs was naturally skewed to a relatively younger age group. However, in a comparative analysis between S-ICD and TV-ICD implanted patients at NX after age and gender adjustments, which limited the total number of matched patients to only 62, the primary and secondary endpoints were found to be similar (Table S1).

3.2 | S-ICD Group NX vs S-ICD Group PS

We compared our experience of S-ICD patients with the S-ICD arm of the PRAETORIAN study (PS). Patients in the S-ICD Group NX were significantly younger (median age of 50 years vs 63 years, *p* <.001) with 1 in 8 patients (10/70, 14.3%) being below 30 years. More patients in the S-ICD Group NX underwent an implant for secondary prevention (22/70, 31.4% vs 80/426, 18.8%, *p* = .01)

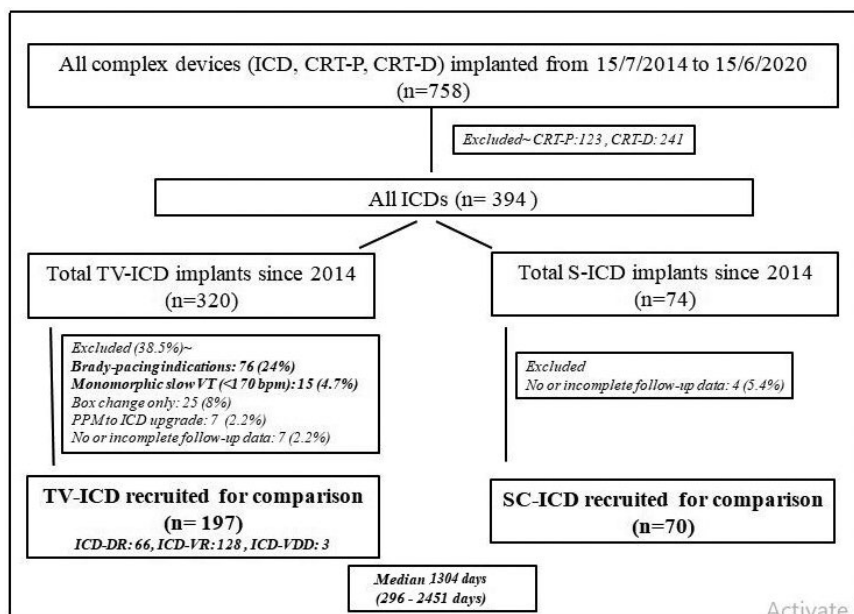


FIGURE 1 Flow diagram of patient selection for the comparison between subcutaneous and transvenous ICD. (bpm: beats per minute; CRT: cardiac resynchronization therapy with [CRT-D] and without defibrillator [CRT-P]; ICD: implantable cardiac defibrillator; ICD-DR: double chamber ICD; ICD-VR: single-chamber ICD; ICD-VDD: ventricular paced dual-sensed ICD; PPM: permanent pacemakers; S-ICD: subcutaneous ICD; TV-ICD: transvenous ICD)

TABLE 1 Comparison of baseline characteristics between patients selected for subcutaneous (S-ICD) and transvenous ICD (TV-ICD) in New Cross hospital group (Group NX) and PRAETORIAN study group (Group PS)

Parameters	S-ICD Group NX: N = 70	TV-ICD Group NX: N = 197	S-ICD (NX) vs TV-ICD (NX)		S-ICD (NX) vs TV-ICD (NX) p value	S-ICD Group PS: N = 426	TV-ICD Group PS: N = 423	S-ICD NX vs PS p value	TV-ICD NX vs PS p value
			OR (95% CI)	MD (95% CI) ^a					
Median age (years, range) [mean, SD]	50 (18-78) [49.7, 15]	66 (24-86) [63.9, 12.5]	14.1 (10.1 to 18.1) ^a	14.1 (10.1 to 18.1) ^a	<0.001	63 (54-69) ^b	64 (56-70) ^b	<0.001	0.21
Female gender (n, %)	12 (17.1)	37 (18.8)	0.89 (0.43 to 1.83)	0.89 (0.43 to 1.83)	0.96	89 (20.9)	78 (18.4)	0.65	0.92
HTN (n, %)	25 (35.7)	47 (23.8)	1.77 (0.98 to 3.19)	1.77 (0.98 to 3.19)	0.05	227/424 (53.5)	240/419 (57.3)	0.006	<0.0001
DM (n, %)	16 (22.8)	42 (21.3)	1.09 (0.56 to 2.10)	1.09 (0.56 to 2.10)	0.78	112 (26.3)	126/421 (29.9)	0.54	0.02
Median BMI (Kg/m ²) [mean, SD]	30.8(13.5-44.3) [27.8, 6.2]	29 (17.9-58.6) [29.54, 6.3]	1.02 (-0.93 to 2.99) ^a	1.02 (-0.93 to 2.99) ^a	0.30	27 (24.5-30.5) ^b	279 (25.2-31.7) ^b	0.34	0.03
AF (n, %)	13 (18.5)	46 (23.4)	0.75 (0.37 to 1.48)	0.75 (0.37 to 1.48)	0.08	115 (27)	93/420 (22.1)	0.13	0.73
VKA (n, %)	12 (17.1)	47 (23.9)	0.66 (0.32 to 1.33)	0.66 (0.32 to 1.33)	0.36	NA	NA	—	—
DOAC (n, %)	11 (15.7)	33 (16.8)	0.92 (0.44 to 1.95)	0.92 (0.44 to 1.95)	0.05	NA	NA	—	—
DAPT (n, %)	19 (27.1)	62 (31.5)	0.81 (0.44 to 1.48)	0.81 (0.44 to 1.48)	0.21	NA	NA	—	—
Median LVEF (% range) [mean, SD]	32.5 (10-65) [35.3, 14.7]	31 (10-67) [33.8, 12.7]	-1.43 (-1.98 to -5.36) ^a	-1.43 (-1.98 to -5.36) ^a	0.47	30 (25-35) ^b	30 (25-30) ^b	<0.001	<0.001
NYHA stage I (n, %)	36 (51.4)	78 (39.6)	1.61 (0.93, 2.79)	1.61 (0.93, 2.79)	0.13	144/ 423 (34)	136/421 (31.8)	0.01	0.07
ICM (n, %)	41 (58.6)	135 (68)	0.64 (0.36 to 1.13)	0.64 (0.36 to 1.13)	0.13	298 (70.4)	298 (70.4)	0.05	0.62
NICM (n, %)	21 (30)	46 (23)	1.40 (0.76, 2.58)	1.40 (0.76, 2.58)	0.27	98 (23.1)	98 (23.1)	0.20	0.96
SNH (n, %)	8 (11.4)	16 (6)	1.45 (0.59 to 3.57)	1.45 (0.59 to 3.57)	0.40	27 (6.5)	27 (6.5)	0.12	0.79
Secondary prevention (n, %)	23 (32.8)	95 (48)	0.49 (0.27 to 0.87)	0.49 (0.27 to 0.87)	0.02	80 (18.8)	84 (19.9)	0.01	<0.001
Median QRS (ms) [mean, SD]	96 (67-170) [99.8, 22.2]	100 (45-200) [102.4, 22.0]	2.60 (to 3.45 to 8.65) ^a	2.60 (to 3.45 to 8.65) ^a	0.40	[105, 20]	[105, 20]	0.04	0.15
Follow-up duration	1048 (296-2378) 1079.2, 537.7	1463 (299-2451) 1387.5, 587.6	308.22 (156.49 to 459.95) ^a	308.22 (156.49 to 459.95) ^a	0.01				

Note: Significant relations are bold-faced

Abbreviations: AF, atrial fibrillation; BMI, body mass index; CKD, chronic kidney disease; DAPT, dual antiplatelet therapy; DM, diabetes mellitus; DOAC, directly acting oral anticoagulants; HTN, hypertension; ICM, ischaemic cardiomyopathy; LVEF, left ventricular ejection fraction; MD, mean difference; ms, milliseconds; NICM, non-ischaemic cardiomyopathy; NX, New Cross Hospital group; NYHA, New York Heart Association; OR, odds ratio; PS, PRAETORIAN study group; SD, standard deviation; S-ICD, subcutaneous ICD; SNH, structurally normal heart; TV-ICD, transvenous ICD; VKA, vitamin K antagonists.

^aExpressed in mean difference, 95% confidence interval.

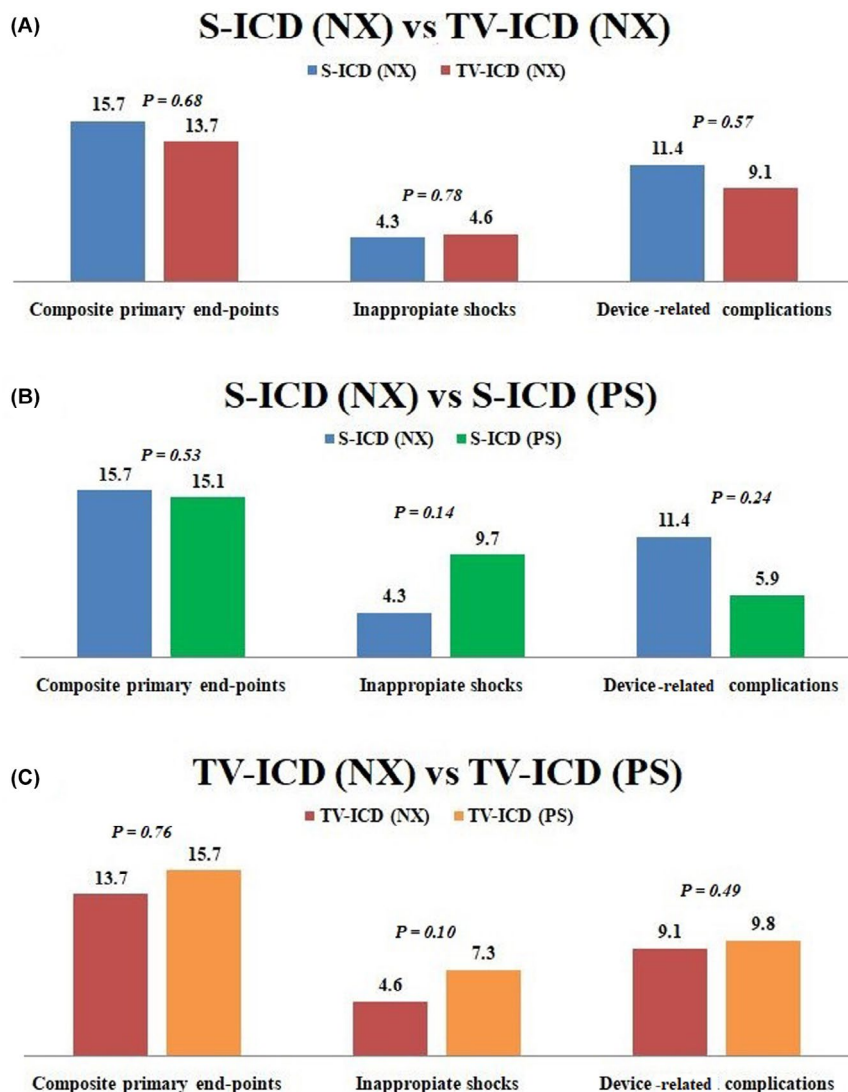
^bExpressed in median, inter-quartile range.

TABLE 2 Comparison of composite and individual primary end-points between patients selected for subcutaneous (S-ICD) and transvenous ICD (TV-ICD) in New Cross hospital group (Group NX) and PRAETORIAN study group (Group PS).

Parameters	S-ICD Group NX: N = 70 n (%)	TV-ICD Group NX: N = 197 n (%)	S-ICD (NX) vs TV-ICD (NX) OR (95% CI)	S-ICD (NX) vs TV-ICD (NX) p value	S-ICD Group PS: N = 426 n (%)	TV-ICD Group PS: N = 423 n (%)	S-ICD (NX) vs TV-ICD (NX) p value	TV-ICD (NX) vs TV-ICD (PS) p value
Patients with composite primary end-points	11 (15.7)	27 (13.7)	1.1 (0.5, 2.5)	0.68	68 (15.1)	68 (15.7)	0.53	0.76
Patients with inappropriate shock events	3 (4.3)	9 (4.6)	1.21 (0.30, 4.83)	0.78	41 (9.7)	29 (7.3)	0.14	0.10
AF/ SVT	1 (1.4)	7 (3.5)	—	—	15 (3.5)	27 (6.4)	—	—
Cardiac over-sensing	1 (1.4)	1 (0.5)	—	—	20 (4.7)	2 (0.5)	—	—
Non-cardiac over-sensing	1 (1.4)	1 (0.5)	—	—	8 (1.9)	0	—	—
Patients with device-related complications	8 (11.4)	18 (9.1)	1.3 (0.5, 3.1)	0.57	31 (5.9)	44 (9.8)	0.24	0.49
Infection	2 (2.8)	3 (1.5)	—	—	4 (0.9%)	8 (1.9)	—	—
Bleeding	1 (1.4)	2 (1)	—	—	8 (1.8)	2 (0.5)	—	—
Thrombotic events	0	2 (1)	—	—	1 (0.2)	2 (0.5)	—	—
Lead perforation	—	0	—	—	—	4 (1)	—	—
Pneumothorax	—	2 (1)	—	—	—	4 (1)	—	—
Lead repositioning	0	6 (3)	—	—	2 (0.4)	4 (1)	—	—
Lead replacement	1 (1.4)	2 (1)	—	—	3 (0.7)	9 (2.1)	—	—
Device or sensing malfunctions	1 (1.4)	1 (0.5)	—	—	8 (1.8)	6 (1.4)	—	—
Pacing indications	1 (1.4)	—	—	—	5 (1.1)	1 (0.2)	—	—
CRT upgrade	1 (1.4)	1 (0.5)	—	—	—	2 (0.5)	—	—
DFT failure	1 / 65 (1.5)	—	—	—	3 (0.7)	3 (0.7)	—	—
Pain / discomfort	1 (1.4)	2 (1)	—	—	2 (0.4)	2 (0.5)	—	—

Abbreviations: AF, atrial fibrillation; CRT, cardiac resynchronization therapy; DFT, defibrillation threshold test; NX, New Cross Hospital group; OR, odds ratio; PS, PRAETORIAN study group; SNH, structurally normal heart; SVT, supraventricular tachycardia.

FIGURE 2 Comparison of composite and individual primary endpoints between patients with (a) subcutaneous (S-ICD) implantation at New Cross Hospital (NX) versus the PRAETORIAN study (PS) group; (B) transvenous (TV-ICD) implantation at New Cross Hospital (NX) versus the PRAETORIAN study (PS) group; (C) TV-ICD versus S-ICD implantation in New Cross Hospital (NX) group (numbers expressed in percentages)



(Table 1). In the S-ICD Group NX, among the different etiologies, previous mitral valve repair (1), tetralogy of Fallot repair (1), device closure of atrial septal defect (1), Brugada syndrome (1), long QT syndrome (2), hypertrophic cardiomyopathy (HCM, 6), arrhythmogenic right ventricular dysplasia (ARVD, 1), and sarcoidosis (1) were present. In the S-ICD Group NX, 22 (31.4%) patients had BMI > 30 kg/m² and 4 (5.7%) patients had BMI > 40 kg/m². Two- and three-incision techniques were used as per the operator's discretion, but, overall, both the techniques were used in an equal number of patients.

The composite primary endpoints were statistically similar between S-ICD Group NX and S-ICD Group PS (15.7% vs 15.1%, $p = .51$) (Table 2, Figure 2B). The individual components of the composite primary endpoints, that is, inappropriate shocks and device-related complications, also did not differ between the two groups (Table 2, Figure 2B). The three patients with inappropriate shocks in the S-ICD Group NX were due to (a) oversensing of AF in one patient in whom SMART-pass filter was not enabled, (b) T-wave oversensing (TWOS) in another patient which resolved with a change of vector, and last, (c) caudal displacement of the S-ICD generator

causing downward traction and thus displacement of the lead in a patient with postmitral valve repair (MVRe) leading to myopotential oversensing. This patient subsequently underwent a TV-ICD. All three cases of inappropriate shocks occurred between 3 months and 1 year period after device implantation with median (range) 136 (101–350) days. One S-ICD patient had oversensing of noise without inappropriate shock on the second day of implantation, presumably due to the trapping of air between the sternum and the S-ICD lead, which was massaged out, and no device-related problems occurred thereafter.

Two patients in the S-ICD Group NX developed serious infections, one who was dialysis-dependent as a result of chronic renal failure and had multiple arteriovenous fistulas and the other in the above-described post-MVRe patient. In both these cases, the S-ICD devices were explanted after 45 and 350 days of implantation, respectively. The same dialysis-dependent patient also had a clinically significant hematoma and was on warfarin for AF. The other patient with clinically significant hematoma was on triple antiplatelet therapy including ticagrelor and warfarin. For both the patients with significant hematoma, they were taken to the lab for exploration of the

TABLE 3 Comparison of secondary end-points between patients selected for subcutaneous (S-ICD) and transvenous ICD (TV-ICD) in New Cross hospital group (Group NX) and PRAETORIAN study group (Group PS)

Parameters	S-ICD Group NX: N = 70 n (%)	TV-ICD Group NX: N = 197 n (%)	S-ICD (NX) vs TV-ICD (NX) OR (95% CI)	S-ICD (NX) vs TV-ICD (NX) p value	S-ICD Group PS: N = 426 n (%)	TV-ICD Group PS: N = 423 n (%)	S-ICD NX vs PS p value	TV-ICD NX vs PS p value
Patients with appropriate shock events	3 (4.3)	20 (10.1)	0.3 (0.06-1.2)	0.08	83 (19.2)	57 (11.5)	0.0006	0.17
VT	1 (1.4)	10 (5.1)	0.3 (0.03-2.1)	0.22	68 (16)	41 (9.7)	—	—
VF	2 (2.8)	11 (5.5)	0.3 (0.03-1.9)	0.18	32 (7.5)	22 (5.2)	—	—
Patients with ATP therapies	—	42 (21.3)	—	—	—	NA	—	—
For VT	—	32 (16.2)	—	—	6 (1.4)	54 (12.8)	—	<0.00001
For SVT	—	19 (9.6)	—	—	1 (0.2)	30 (7.1)	—	0.27
Recorded death ^a	4 (5.7)	21 (10.6)	0.1 (0.01-1.1)	0.06	83 (19.5)	68 (16.1)	—	0.02
Hospitalization due to heart failure	2 (2.8)	40 (20.3)	0.2 (0.02-1.7)	0.15	79 (18.5)	74 (17.7)	—	0.0001

Abbreviations: ATP, anti-tachycardia pacing; NX, New Cross Hospital group; OR, odds ratio; PS, PRAETORIAN study group; SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia.

^aData on death may be incomplete in Group NX.

wound and stayed in the hospital for more than 48 hours. DFT test was not performed in five patients at the time of procedure; two patients were part of the PRAETORIAN DFT trial and randomized to the no DFT arm of the study, two patients had left ventricular thrombus, and one patient was discovered to be in AF at the time of the implant and was not previously anticoagulated.

All these patients underwent DFT testing later successfully. Based on available data (65/70), the median shock impedance was 65 Ω (range 55–115 Ω) which is indicative of a good implantation technique. In the patient with a shock impedance of 115 Ω , the generator was placed inferiorly and DFT was repeated which resulted in a shock impedance of 105 Ω . Only one patient had DFT failure when both 65 J and 80 J shocks failed to convert VF into sinus rhythm and had to be externally cardioverted. Patients with secondary endpoints were only a few in comparison with S-ICD Group PS and only three patients received appropriate shocks in the entire S-ICD Group NX during the median follow-up period of 3 years (Table 3) and all of them were secondary prevention S-ICDs. Two of the S-ICD patients had to undergo device upgradation between 6 months to 1 year after device implantation; one patient to CRT-D (due to heart failure with LBBB morphology on ECG) and another patient to dual-chamber TV-ICD due to pacing indication. In both cases, S-ICD system was left in situ but was deactivated.

3.3 | TV-ICD Group NX vs TV-ICD Group PS

Distributions of age, gender, etiology, or presence of AF were similar between our group (TV-ICD Group NX) and Group PS. Prevalence of HTN has been surprisingly high in the PS, in both S-ICD and TV-ICD groups, and is more than twice that in our study. However, the prevalence of diabetes mellitus is significantly higher in Group NX TV-ICD with respect to PS. Secondary prevention TV-ICD was higher in Group NX compared with Group PS (95/197 [48%] vs 84/423 [19.9%], respectively, $p < .001$) (Table 1). Among the different etiologies, mitral valve surgery (6), Brugada Syndrome (2), long QT syndrome (2), ARVD (1), HCM (10), and sarcoidosis (1) were present.

Composite primary endpoints and their individual counterparts were statistically similar between Group NX and Group PS (Table 2, Figure 2C). Two patients needed reexploration due to hematoma, both were on uninterrupted triple antiplatelet therapy due to ICM and LV thrombus. Three patients had infected wounds, one had swelling and erythema and responded to prolonged oral antibiotic therapy; one had a displaced atrial lead and underwent repositioning and later developed an infected wound, underwent surgical explantation and reimplantation of TV-ICD from the right side later; and one patient had vegetation on the RV lead and underwent surgery and later reimplantation of TV-ICD as directed by guidelines. Six patients with TV-ICD underwent lead repositioning, all within the first 7 days. Pneumothoraxes were low in our experience as we routinely attempt implantation through a cephalic/axillary venous approach.

Appropriate shocks in TV-ICD were numerically lower but statistically similar among Group NX and Group PS; however, ATP therapies for VT were statistically higher in Group NX than Group PS ($p < .00001$). A number of deaths ($p = .02$) and patients needing hospitalization for heart failure ($p = .0001$) in our experience were significantly lower than Group PS (Table 3).

3.4 | Time-dependent analysis of primary endpoints

Most of the complications (72.7% of all complications in S-ICD NX group vs 60% of all complications in the TV-ICD NX group) were recorded within the first 3 months of device implantations. Of note, the composite and individual primary endpoints (namely inappropriate shocks and device-related complications) did not differ between S-ICD and TV-ICD with respect to the time of diagnosis of the complications (Figure 3, Table 4). In the S-ICD NX group, all the inappropriate shocks (3) took place between 6 weeks and 3 months after implantation. No complications were detected after 1 year of S-ICD implantation, whereas five patients with TV-ICD received inappropriate shocks after 1 year of implantation with median (range) 782 (690–1511) days. Two patients with TV-ICD had to undergo system explantation due to device-related infective endocarditis after 113 and 164 days. Device upgrades (S-ICD 2, TV-ICD 1) or TV-ICD lead replacement (2) were performed between 3 months and 1 year after implantation. Pocket hematomas (S-ICD 2, TV-ICD 3) were detected within the first 6 weeks uniformly in our experience, whereas pocket infections underwent wound explorations (S-ICD 2, TV-ICD 1) after 6 weeks.

Although we selected TV-ICD patients from the same time frame when S-ICD implants were started at NX (i.e., 2014), due to a low number of S-ICD implants initially, the overall follow-up duration of S-ICD patients was lower than TV-ICD patients. Thus, we filtered 108 patients with the total follow-up duration of 1500 days or more following implant (which is nearly twice the follow-up duration of median time to diagnosis of very late TV-ICD complications). Analyses of primary and secondary endpoints between S-ICDs and TV-ICDs in this group revealed similar results (Table S2).

4 | DISCUSSION

Although S-ICDs have been on the market for nearly 10 years, it still has only class IIa indications for selected patients needing defibrillators.^{8,9} The safety and efficacy of S-ICD have been proven in large registries but its adoption into practice is limited. Although observational studies explored the comparability of S-ICD to TV-ICD, PRAETORIAN is the first to conduct a randomized head-to-head trial.^{11–14} Our center was one of the early adaptors of S-ICD implantations in the United Kingdom and has been implanting S-ICDs since 2014. In the wake of the PRAETORIAN trial, we looked back into the patients with S-ICD in our center and compared them with the patients with TV-ICD with similar indications. In our real-world experience, inappropriate shocks and device-related complications were found to be comparable, mirroring the findings of the PRAETORIAN study.

4.1 | Baseline

In our retrospective data, patients aged ≤ 50 years constituted 26.6% (71/267) of total patients, including 48.6% (34/70) in the S-ICD group and 18.8% patients (37/197) in the TV-ICD group, which is strikingly different from the patient profile in PS,¹⁴ which were relatively older, especially in the S-ICD group. Young patients with SNH were preferred for S-ICD as per trust guidelines, unless contraindicated, depending on patient choice and the result of vector screening.

In our study, 44.2% (118/267) of ICD implantation was for secondary prevention of sudden cardiac death, with 32.8% of S-ICD (23/70) and 48% (95/197) of TV-ICD, which is significantly higher than the PS with underrepresentation of secondary prevention in both the ICD groups.¹⁴ Interestingly, 34/47 primary prevention S-ICD and 7/23 secondary prevention S-ICD patients had ICM. Although there was broadly low LVEF among the ICD patients in our study, the majority were NYHA class I, probably due to the high proportion of secondary prevention ICDs.

Although the median BMI of our S-ICD groups was numerically higher than Group PS S-ICD, the DFT success rate was 98.5% with only one unsuccessful DFT which implies an adequate implantation

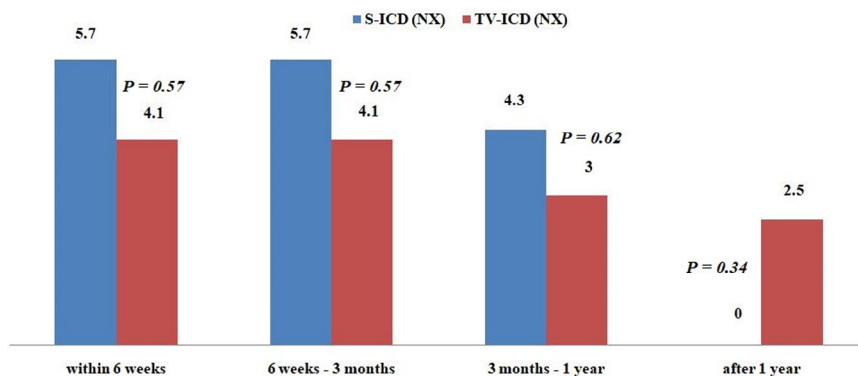


FIGURE 3 Comparison of composite primary endpoints between patients with subcutaneous (S-ICD [NX]) and transvenous ICD (TV-ICD [NX]) implantation at New Cross Hospital (NX) with respect to time of diagnosis following device implantation (numbers expressed in percentages)

TABLE 4 Comparison of composite and individual primary end-points between patients selected for subcutaneous [S-ICD (NX)] and transvenous ICD [TV-ICD (NX)] in New Cross hospital group with respect to time of diagnosis following device implantation

Complications	Time of diagnosis following device implantation	S-ICD Group NX (N = 70)		TV-ICD Group NX (N = 197)		OR (95% CI)	p value
		Number of patients (%)	Time to diagnosis Median (range) days	Number of patients (&)	Time to diagnosis Median (range) days		
Composite primary end-points	Within 6 weeks	4 (5.7)	1 (0-4)	8 (4.1)	0 (1-38)	1.43 (0.41-4.91)	0.57
	6 weeks - 3 months	4 (5.7)	64 (45-84)	8 (4.1)	61 (44-88)	1.43 (0.41-4.91)	0.57
	3 months - 1 year	3 (4.3)	136 (101-350)	6 (3)	140 (108-365)	1.42 (0.34-5.85)	0.62
	after 1 year	0	NA	5 (2.5)	782 (690-1511)	0.24 (0.01-4.54)	0.34
		Number of events (%)		Number of events (%)			
Inappropriate shocks	Within 6 weeks	0		0			
	6 weeks - 3 months	3 (4.3)		2 (1)		4.36 (0.71-26.69)	0.11
	3 months - 1 year	0		2 (1)		0.55 (0.02-11.69)	0.70
Device-related complications	after 1 year	0		5 (2.5)		0.24 (0.01-4.54)	0.34
	Within 6 weeks	4 (5.7)		10 (5)		1.13 (0.34-3.73)	0.83
		DFT failure 1 Hematoma 2 ^a Oversensing 1 ⁱ		Pneumothorax 2 ^d Hematoma 3 ^a Severe pain 2 lead dislodgement 3 ^e			
	6 weeks - 3 months	2 (2.8) Infection 1 ^b Severe pain 1		6 (3) Thrombosis 2 ^g , Infection 1 ^{b,f} lead dislodgement 3 ^e		0.93 (0.18-4.75)	0.93
3 months - 1 year	3 (4.3) CRT upgrade 1 Pacing 1 ^c Infection 1 ^b		6 (3) IE 2 ^{h,f} Lead replacement 2 CRT upgrade 1 Oversensing 1 ⁱ		1.42 (0.34-5.85)	0.62	
after 1 year	0		0				

Note: Day 0 stands for day of device implantation

Abbreviations: CI, confidence interval; CRT, cardiac resynchronization therapy; DFT, defibrillation threshold test; IE, infective endocarditis; OR, odds ratio; S-ICD, subcutaneous ICD; TV-ICD, transvenous ICD.

^aHematoma needing exploration of surgical wounds.

^bPocket infection needing exploration of surgical wounds.

^cPacing indication emerged, thus replaced to TV-ICD.

^dBoth pneumothoraces needed intercostals chest drain.

^eLead dislodgments needed lead revisions.

^fDevice explanted.

^gDeep vein thrombosis (confirmed by Doppler studies) of upper limb veins related to device implantation.

^hInfective endocarditis were confirmed by blood cultures and trans-oesophageal echocardiography.

ⁱICD leads oversensing noise (for S-ICD) and T-wave (for TV-ICD) without inappropriate shock.

technique. Although operators have evolved with regard to surgical techniques at our center over time, the number of patients with two and three-incision techniques was similar. In a study by Stujit et al., 5-year follow-up of the S-ICD cohort showed similar complication rates and effectiveness of the two-incision technique compared with the three-incision technique.²⁷

Six HCM patients received S-ICD (primary prevention) with high QRS amplitude and T inversions but all of them passed the vector screening test and none received inappropriate shocks. In the multicenter experience by Nazer et al. (HCM S-ICD study), inappropriate shocks were rare (3.8 inappropriate shocks/100 patient-years) and appropriate shocks were confined to secondary prevention patients.²⁸ In a German registry of genetic cardiomyopathy patients receiving ICD, the rate of annual appropriate and inappropriate shocks were 3.8% and 1.9% over a mean follow-up of 4.3 years, respectively, with inappropriate shocks and lead revisions being significantly lower in the S-ICD group compared with the TV-ICD group.²⁹ In our study with real-world data, proportions of inherited cardiomyopathies were low and none received any therapies.

Despite 23% and 16.5% of patients on minimally interrupted VKA and DOACs, respectively, and 30% of patients on uninterrupted DAPT, clinically significant hematomas were low in both S-ICD (one patient) and TV-ICD (two patients) groups, which reflects good hemostasis techniques including appropriate use of diathermy.

ICDs were implanted with one dose of preoperative intravenous teicoplanin 600 mg and most patients were discharged on the same day of the procedure, if elective, but the incidence of device-related infection was very low, with clinically significant infection needing device removal only in two and three patients, respectively, in S-ICD and TV-ICD groups in our experience. Both the patients with infected S-ICD were challenging implants and early in the procedural experience.

Okabe et al.³⁰ also demonstrated the suitability of the same-day discharge of S-ICD patients and mentioned that device-related pain can be severe in the first 3 days, which is true for our patients as well; however, most patients did well with analgesics with only one patient had an unplanned visit at 1 week due to severe pain, but no signs of infection or bleeding were noted and it responded with opioid analgesics.

4.2 | Primary endpoints

Basu-Ray et al.³¹ reported that inappropriate shocks from S-ICD were mainly due to T-wave oversensing (TWOS), however, only one patient in our S-ICD experience had TWOS, due to rigorous vector screening and use of the latest generation of device. In a large single-center study by Rudic et al.³² with 239 S-ICD implants with the mean follow-up of 34.9 ± 16.0 months, a total of 73 shocks occurred in 38 patients (6%). Forty-three (59%) shocks were considered appropriate, whereas 30 (41%) were inappropriate and occurred in 19 patients (8%) of which myopotential/noise

was the most frequent cause, followed by TWOS and undersensing of QRS. The prevalence of shocks is similar to our experience; however, appropriate shocks were much lower and etiologies for inappropriate shocks were different (Table 2). Myopotential oversensing has been also found as a major cause of inappropriate shock in S-ICD patients in the Japanese study by Tsutsui et al.³³; however, in our study, only one patient had noise due to device and lead migration. In our study, the inappropriate shocks in the S-ICD group were within 3 months of the device implantations, whereas, most (5/9) inappropriate shocks in the TV-ICD group were beyond 1 year after implantation.

In the UNTOUCHED registry,³⁴ 1116 S-ICD patients with 87.7% HF, 53.5% ICM, with LVEF of $26.4 \pm 5.8\%$, with 18 months follow-up, all-cause shocks were 9.4% with inappropriate shocks of 4.1% (3.1% at 1 year), and complication of 7.3% similar to our experience. The recent generation of devices, using the three-incision technique, no history of atrial fibrillation, and ischemic cause were found to be independent predictors of the low incidence of inappropriate shocks. With the high burden of AF in our S-ICD patients with a median of 4 years of follow-up, such low incidence of inappropriate shocks can be explained by good rate control, adequate implantation technique, latest generation device, and SMART-pass filter in the majority of cases.

Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database³⁵ reported 1604 S-ICD-related adverse events from 2016 to 2018, of which 542 (33%) instances of infections, 550 inappropriate shocks (34%), and 137 (8%) system migration. Our data suggest that out of 11 patients with complications in S-ICD, infections, inappropriate shocks, and system migration were, respectively, in two (22%), three (27%), and one (11%) patient, which is low in prevalence and suggests reasonably favorable outcome.

4.3 | Secondary endpoints

ATP therapies have been found to be successful in terminating both nonfast and fast VT among patients with various structural heart diseases in the real-world setting.³⁶ ATP therapy burden was higher in our TV-ICD patients as we programmed a higher total number of ATPs to minimize shocks. Overall, appropriate shocks from the TV-ICDs were low and similar to the TV-ICD group of PS, however, shocks due to VT were lower in comparison with PS TV-ICD group which may be due to a higher rate cutoff and duration delay for detecting VT-like MADIT-RIT study. With a median follow-up of nearly 4 years, only three S-ICD patients received an appropriate shock, all successfully terminated ventricular arrhythmia at the first instance.

Recorded deaths in both the ICD groups were found to be lower than PS, which could be explained by the overall younger age profile and relatively short follow-up in comparison with PS.¹⁴ Of note, the total number of deceased patients in our study was extrapolated from the electronic database and LATTITUDE and may not be always accurately reflect clinical occurrence.

Hospitalization due to heart failure in the S-ICD group in our study was remarkably low, indicative of careful patient selection, without wide QRS and left bundle branch block (LBBB) appearance, needing cardiac resynchronization therapy, however, only one patient in each group had CRT-D upgradation. Such lower incidence of CRT upgrades, in the maximum follow-up of 7 years, suggest appropriate patient selection which is reflective of appropriate trust pathways. Heart failure data may not be accurate, as some patients might have attended local heart failure outreach services. Only one patient in the S-ICD group developed symptomatic sinus node disease and received a dual-chamber permanent pacemaker system. We carefully selected patients for S-ICD without the need for brady pacing therapies, such as sinus bradycardia, prolonged PR interval, bi-, or tri-fascicular block.

4.4 | Future directions

One of the important considerations for S-ICD is the need for general anesthesia because of the larger device pocket in a richly innervated area, however, this can be circumvented by serratus anterior block under ultrasound guidance.³⁷ Also, a new substernal system of extravascular ICD is currently under evaluation.³⁸ The novel modular cardiac rhythm management (mCRM) system has already been described which consists of ATP-enabled leadless cardiac pacemaker and S-ICD, where there is an integrated wireless interbody communication between the two.^{39,40}

4.5 | Limitations

The study has several limitations. The sample size for S-ICD was relatively small. The S-ICD received regulatory approval from the Food and Drug Administration (FDA) only in 2012. New devices of this type, with a very different implant technique to conventional TV-ICDs (which has an implant technique similar to a pacemaker, a device that was first introduced in the 1960s) are expected to have a lag period before clinicians are trained to use them and also before national and international guidelines endorse their use. In our study, implants of S-ICDs and TV-ICDs were both dated from 2014, however, for the reasons mentioned above, the number of S-ICDs was lower (70) and the overall follow-up period was shorter in comparison with TV-ICDs. Not only the observation periods of S-ICD and TV-ICD in NX, but also the observation periods of NX and PS in each device are very different, but also the Kaplan–Meier in PS did not reach a plateau during the 4-year observation period; however, when S-ICDs patients were compared with TV-ICD patients at NX with more than 1500 days following implant, outcomes were still found to be similar. Age and gender-adjusted statistical analyses of outcome were performed at the remit of a limited number of matched samples. Logistic regression analysis was not performed as the number of patients

with composite primary endpoints was very low. For the comparison of outcomes, Kaplan–Meier curves were not analyzed as the implantation period and thus follow period spanned for nearly 6 years. As our center is not equipped with pediatric cardiology or grown-up congenital heart disease (GUCH) as specialties, patients younger than 18 years of age or patients with congenital heart diseases were excluded, and the results of our experience should not be generalized in these specific cohorts.

5 | CONCLUSIONS

Our real-world data replicate the findings of the PRAETORIAN study. In patients needing ICD but without the need for pacing or resynchronization, short- and long-term outcomes of S-ICD are comparable with that of TV-ICD. Thus, careful patient selection, rigorous vector screening, strict implantation technique, and utilization of the SMART-pass algorithm appear to enable S-ICD to be as safe and effective as TV-ICD without risks of lead-related complications.

CONFLICT OF INTEREST

None.

ORCID

Dibbendhu Khanra  <https://orcid.org/0000-0002-5446-4498>

Ahmed Abdalla  <https://orcid.org/0000-0002-0050-5653>

Sanjiv Petkar  <https://orcid.org/0000-0002-1699-7963>

REFERENCES

1. Moss AJ, Hall WJ, Cannom DS, Daubert JP, Higgins SL, Klein H, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter automatic defibrillator implantation trial investigators. *N Engl J Med.* 1996;335:1933–40.
2. Moss AJ, Zareba W, Hall J, et al. For the multicenter automatic defibrillator implantation trial II investigators. *N Engl J Med.* 2002;346:877–83.
3. Kirkfeldt RE, Johansen JB, Nohr EA, Jorgensen OD, Nielsen JC. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. *Eur Heart J.* 2014;35:1186–94.
4. Lee DS, Krahn AD, Healey JS, Birnie D, Crystal E, Dorian P, et al. Evaluation of early complications related to de novo cardioverter defibrillator implantation insights from the Ontario ICD database. *J Am Coll Cardiol.* 2010;55:774–82.
5. Ezzat VA, Lee V, Ahsan S, Chow AW, Segal O, Rowland E, et al. A systematic review of ICD complications in randomized controlled trials versus registries: is our “real-world” data and underestimation? *Open Heart.* 2015;2:e000198.
6. Kim EJ, Davogusto G, Huang S, Crossley GH III, Montgomery JA. Clinical and radiographic predictors of cardiovascular implantable electronic device lead failure at the time of initial implantation. *J Arrhythm.* 2021;37:1086–92.
7. Bardy GH, Smith WM, Hood MA, Crozier IG, Melton IC, Jordaens L, et al. An entirely subcutaneous implantable cardioverter-defibrillator. *N Engl J Med.* 2010;363:36–44.

8. Tracy CM, Epstein AE, Darbar D, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. 2013;61:e6–e75.
9. Priori SG, Blomstrom-Lundqvist C, Mazzanti A, Blom M, Borggrefe M, Camm J, et al. 2015 ESC guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. *Eur Heart J*. 2015;36:2793–867.
10. Weiss R, Knight BP, Gold MR, Leon AR, Herre JM, Hood M, et al. Safety and efficacy of a totally subcutaneous implantable cardioverter defibrillator. *Circulation*. 2013;128:944–53.
11. Lambiase PD, Barr C, Theuns D, Knops R, Neuzil P, Johansen JB, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS-S-ICD registry. *Eur Heart J*. 2014;35:1657–65.
12. Boersma LV, El-Chami MF, Bongiorno MG, et al. Understanding outcomes with the EMBLEM S-ICD in primary prevention patients with low EF study (UNTOUCHED): clinical characteristics and perioperative results. *Heart Rhythm*. 2019;16:1636–44.
13. Burke MC, Gold MR, Knight BP, Barr CS, Theuns DAMJ, Boersma LVA, et al. Safety and efficacy of the totally subcutaneous implantable defibrillator. 2-year results from a pooled analysis of the IDE study and EFFORTLESS registry. *J Am Coll Cardiol*. 2015;65:1605–15.
14. Knops RE, Nordkamp LRA, Delnoy PPHM, Boersma LVA, Kuschyk J, El-Chami MF, et al. Subcutaneous or transvenous defibrillator therapy. *N Engl J Med*. 2020;383:526–36.
15. Brouwer TF, Yilmaz D, Lindeboom R, Buiten MS, Nordkamp LRA, Schaliij MJ, et al. Long-term clinical outcomes of subcutaneous versus transvenous implantable defibrillator therapy. *JACC*. 2016;68:2047–55.
16. Friedman DJ, Parzynski CS, Varosy PD, et al. Trends and in-hospital outcomes associated with adoption of the subcutaneous implantable cardioverter defibrillator in the United States. *JAMA Cardiol*. 2016;1:900–11.
17. Köbe J, Reinke F, Meyer C, Shin DI, Martens E, Kääh S, et al. Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: a multicenter case-control study. *Heart Rhythm*. 2013;10:29–36.
18. Honarbakhsh S, Providencia R, Srinivasan N, Ahsan S, Lowe M, Rowland E, et al. A propensity matched case-control study comparing efficacy, safety and costs of the subcutaneous vs. transvenous implantable cardioverter defibrillator. *Int J Cardiol*. 2017;228:280–5.
19. Gold MR, Theuns DA, Knight BP, Lacy Sturdivant J, Sanghera R, Ellenbogen KA, et al. Head-to-head comparison of arrhythmia discrimination performance of subcutaneous and transvenous ICD arrhythmia detection algorithms: the START study. *J Cardiovasc Electrophysiol*. 2012;23:359–66.
20. Olde Nordkamp LR, Knops RE, Bardy GH, Blaauw Y, Boersma LV, Bos JS, et al. Rationale and design of the PRAETORIAN trial: a prospective, RANdomizEd comparison of subcuTaneOus and tRansvenous ImplANTable cardioverter-defibrillator therapy. *Am Heart J*. 2012;163:753–60.
21. Quast ABE, Baalman SWE, Betts TR, Boersma LV, Bonnemeier H, Boveda S, et al. Rationale and design of the PRAETORIAN-DFT trial: a prospective randomized comparative trial of subcutaneous implantable cardioverter-defibrillator implantation with and without defibrillation testing. *Am Heart J*. 2019;214:167–74.
22. Kutuyifa V, Daubert JP, Olshansky B, Huang DT, Zhang C, Ruwald ACH, et al. Characterization and predictors of first and subsequent inappropriate ICD therapy by heart rate ranges: result of the MADIT-RIT efficacy analysis. *Heart Rhythm*. 2015;12:2030–7.
23. Tachibana M, Nishii N, Banba K, Fujita S, Ikeda E, Okawa K, et al. SMART pass will prevent inappropriate operation of S-ICD. *J Arrhythm*. 2018;35:86–91.
24. Versteeg H, Pedersen SS, Mastenbroek MH, Redekop WK, Schwab JO, Mabo P, et al. Patient perspective on remote monitoring of cardiovascular implantable electronic devices: rationale and design of the REMOTE-CIED study. *Neth Heart J*. 2014;22:423–8.
25. Vélez J, Juan C, Fernando M. A new approach to the box-cox transformation. *Front Appl Math Stat*. 2015;1:1–10.
26. RStudio Team. RStudio: integrated development for R. Boston, MA: RStudio, PBC; 2020. <http://www.rstudio.com/>
27. van der Stuijt W, Baalman SWE, Brouwer TF, Quast ABE, de Groot JR, Knops R. Long-term follow-up of the two-incision implantation technique for the subcutaneous implantable cardioverter-defibrillator. *Pacing Clin Electrophysiol*. 2020;43:1476–80.
28. Nazer B, Dale Z, Carrassa G, Reza N, Ustunkaya T, Papoutsidakis N, et al. Appropriate and inappropriate shocks in hypertrophic cardiomyopathy patients with subcutaneous implantable cardioverter-defibrillators: an international multicenter study. *Heart Rhythm*. 2020;17:1107–14.
29. Kuschyk J, Müller-Leisse J, Duncker D, Tülümen E, Fastenrath F, Fastner C, et al. Comparison of transvenous vs subcutaneous defibrillator therapy in patients with cardiac arrhythmia syndromes and genetic cardiomyopathies. *Int J Cardiol*. 2021;323:100–5.
30. Okabe T, Miller A, Koppert T, Cavalcanti R, Alcivar-Franco D, Osei J, et al. Feasibility and safety of same day subcutaneous defibrillator implantation and send home (DASH) strategy. *J Interv Card Electrophysiol*. 2020;57:311–8.
31. Basu-Ray I, Liu J, Jia X, Gold M, Ellenbogen K, DiNicolantonio J, et al. Subcutaneous versus transvenous implantable defibrillator therapy: a meta-analysis of case-control studies. *JACC Clin Electrophysiol*. 2017;3:1475–83.
32. Rudic B, Tülümen E, Fastenrath F, Röger S, Goranova D, Akin I, et al. Incidence, mechanisms, and clinical impact of inappropriate shocks in patients with a subcutaneous defibrillator. *Europace*. 2020;22:761–8.
33. Tsutsui K, Kato R, Asano S, Ikeda Y, Mori H, Tawara M, et al. Myopotential oversensing is a major cause of inappropriate shock in subcutaneous implantable defibrillator in Japan. *Int Heart J*. 2020;61:913–21.
34. Gold MR, Lambiase PD, El-Chami MF, et al. Primary results from the understanding outcomes with the S-ICD in primary prevention patients with low ejection fraction (UNTOUCHED) trial. *Circulation*. 2021;143:7–17.
35. Zeitler EP, Friedman DJ, Loring Z, Campbell KB, Goldstein SA, Wegermann ZK, et al. Complications involving the subcutaneous implantable cardioverter-defibrillator: lessons learned from MAUDE. *Heart Rhythm*. 2020;17:447–54.
36. Chinushi M, Saitoh O, Furushima H, Aizawa Y, Noda T, Nitta T, et al. Anti-tachycardia pacing for non-fast and fast ventricular tachycardias in individual Japanese patients: from Nippon-storm study. *J Arrhythm*. 2021;8(37):1038–45.
37. Droghetti A, Basso Ricci E, Scimia P, Harizai F, Marini M. Ultrasound-guided serratus anterior plane block combined with the two-incision technique for subcutaneous ICD implantation. *Pacing Clin Electrophysiol*. 2018;41:517–23.
38. Crozier I, Haqqani H, Kotschet E, Shaw D, Prabhu A, Roubos N, et al. First-in-human chronic implant experience of the substernal extravascular implantable cardioverter-defibrillator. *JACC Clin Electrophysiol*. 2020;6:1525–36.
39. Tjong FVY, Brouwer TF, Kooiman KM, Smeding L, Koop B, Soltis B, et al. Communicating antitachycardia pacing-enabled leadless

pacemaker and subcutaneous implantable defibrillator. *J Am Coll Cardiol.* 2016;67(15):1865–6.

40. Gatto MC, De Sanctis V, Percoco F, et al. Combined therapy with subcutaneous implantable cardiac defibrillator and leadless pacemaker in a patient with persistent left superior vena cava and mega coronary sinus: a challenging case for the best treatment. *J Arrhythm.* 2021;37:1364–7.

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

How to cite this article: Khanra D, Hamid A, Patel P, Tomson J, Abdalla A, Khan N, Dowd R, Chandan N, Osagie C, Jinadu T, Velu S, Arya A, Spencer C, Barr C, Petkar S. (2022). A real-world experience of subcutaneous and transvenous implantable cardiac defibrillators—comparison with the PRAETORIAN study. *J Arrhythmia.* 2022;38:199–212. <https://doi.org/10.1002/joa3.12687>