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

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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.
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 anatomy7 but with a growing evidence base, improved hardware, and more sophisticated software, the scope of S-ICD implantation has continually expanded.8 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.9,9 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 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 latissiums 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

"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 prevention 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.

KEYWORDS

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

KHANRA ET AL.
the procedure unless prohibited (thrombus, atrial fibrillation without anticoagulation, or part of PRAETORIAN DFT trial\textsuperscript{21}) 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 who 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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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 dislocated 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 ± 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 results 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 transformation in R studio (2020) 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.

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)
| 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) | S-ICD Group PS: N = 426 | S-ICD NX vs PS p value | TV-ICD Group PS: N = 423 | TV-ICD NX vs PS p value |
|------------------------------------|------------------------|---------------------------|----------------------------|----------------------------|--------------------------|--------------------------|---------------------------|--------------------------|
| 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     | <0.001                     | 63 (54-69) b             | <0.001                   | 64 (56-70) b             | 0.21                     |
| Female gender (n, %)                | 12 (17.1)              | 37 (18.8)                 | 0.89 (0.43 to 1.83)        | 0.96                       | 89 (20.9)                | 0.65                     | 78 (18.4)                 | 0.92                     |
| HTN (n, %)                          | 25 (35.7)              | 47 (23.8)                 | 1.77 (0.98 to 3.19)        | 0.05                       | 227/424 (53.5)           | 0.006                    | 240/419 (57.3)           | <0.0001                  |
| DM (n, %)                           | 16 (22.8)              | 42 (21.3)                 | 1.09 (0.56 to 2.10)        | 0.78                       | 112 (26.3)               | 0.54                     | 126/421 (29.9)           | 0.02                     |
| Median BMI (Kg/m²) [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     | 0.30                       | 27 (24.5-30.5) b         | 0.34                     | 27.9 (25.2-31.7) b       | 0.03                     |
| AF (n, %)                           | 13 (18.5)              | 46 (23.4)                 | 0.75 (0.37 to 1.48)        | 0.08                       | 115 (27)                 | 0.13                     | 93/420 (22.1)            | 0.73                     |
| VKA (n, %)                          | 12 (17.1)              | 47 (23.9)                 | 0.66 (0.32 to 1.33)        | 0.36                       | NA                       | NA                       | NA                       | NA                       |
| DOAC (n, %)                         | 11 (15.7)              | 33 (16.8)                 | 0.92 (0.44 to 1.95)        | 0.05                       | NA                       | NA                       | NA                       | NA                       |
| DAPT (n, %)                         | 19 (27.1)              | 62 (31.5)                 | 0.81 (0.44 to 1.48)        | 0.21                       | NA                       | NA                       | 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   | 0.47                       | 30 (25-35) b             | <0.001                   | 30 (25-30) b             | <0.001                   |
| NYHA stage I (n, %)                 | 36 (51.4)              | 78 (39.6)                 | 1.61 (0.93, 2.79)          | 0.13                       | 144/423 (34)             | 0.01                     | 136/421 (31.8)           | 0.07                     |
| ICM (n, %)                          | 41 (58.6)              | 135 (68)                  | 0.64 (0.36 to 1.13)        | 0.13                       | 298 (70.4)               | 0.05                     | 298 (70.4)               | 0.62                     |
| NICM (n, %)                         | 21 (30)                | 46 (23)                   | 1.40 (0.76, 2.58)          | 0.27                       | 98 (23.1)                | 0.20                     | 98 (23.1)                | 0.96                     |
| SNH (n, %)                          | 8 (11.4)               | 16 (6)                    | 1.45 (0.59, 3.57)          | 0.40                       | 27 (6.5)                 | 0.12                     | 27 (6.5)                 | 0.79                     |
| Secondary prevention (n, %)         | 23 (32.8)              | 95 (48)                   | 0.49 (0.27 to 0.87)        | 0.02                       | 80 (18.8)                | 0.01                     | 84 (19.9)                | <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   | 0.40                       | [105, 20]                | 0.04                     | [105, 20]                | 0.15                     |
| Follow-up duration                  | 1048 (296-2378)        | 1463 (299-2451)           | 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) p value | S-ICD Group PS: N = 426 n (%) | S-ICD NX vs PS p value | TV-ICD Group PS: N = 423 n (%) | TV-ICD NX vs 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)                  | 0.53                   |
| Patients with inappropriate shock events | 3 (4.3)                     | 9 (4.6)                         | 1.21 (0.30, 4.83)                             | 0.78                         |                       | 41 (9.7)                   | 0.14                   |
| AF/ SVT                                | 1 (1.4)                     | 7 (3.5)                         | -                                             | -                            |                       | 15 (3.5)                   | -                      |
| Cardiac over-sensing                   | 1 (1.4)                     | 1 (0.5)                         | -                                             | -                            |                       | 20 (4.7)                   | -                      |
| Non-cardiac over-sensing               | 1 (1.4)                     | 1 (0.5)                         | -                                             | -                            |                       | 8 (1.9)                    | -                      |
| Patients with device-related complications | 8 (11.4)                  | 18 (9.1)                        | 1.3 (0.5, 3.1)                                | 0.57                         |                       | 31 (5.9)                   | 0.24                   |
| Infection                              | 2 (2.8)                     | 3 (1.5)                         | -                                             | -                            |                       | 4 (0.9%)                   | -                      |
| Bleeding                               | 1 (1.4)                     | 2 (1)                           | -                                             | -                            |                       | 8 (1.8)                    | -                      |
| Thrombotic events                     | 0                           | 2 (1)                           | -                                             | -                            |                       | 1 (0.2)                    | -                      |
| Lead perforation                       | -                           | 0                               | -                                             | -                            |                       | 4 (1)                      | -                      |
| Pneumothorax                           | -                           | 2 (1)                           | -                                             | -                            |                       | 4 (1)                      | -                      |
| Lead repositioning                    | 0                           | 6 (3)                           | -                                             | -                            |                       | 2 (0.4)                    | -                      |
| 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.
(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

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![Figure 2](https://example.com/figure2.png)

**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).
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.

### 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) p value | S-ICD (NX) vs TV-ICD (NX) OR (95% CI) p value | S-ICD Group PS: N = 426 n (%) | TV-ICD Group PS: N = 423 n (%) | TV-ICD NX vs PS OR (95% CI) 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)                   | 0.17                            |
| VT                                      | 1 (1.4)                      | 10 (5.1)                       | 0.3 (0.03-2.1)                               | 0.22                                          | 68 (16)                     | 41 (9.7)                    | NA                              |
| VF                                      | 2 (2.8)                      | 11 (5.5)                       | 0.3 (0.03-1.9)                               | 0.18                                          | 32 (7.5)                    | 22 (5.2)                    | NA                              |
| Patients with ATP therapies             | –                            | 42 (21.3)                      | –                                             | –                                            | –                           | –                           | NA                              |
| For VT                                  | –                            | 32 (16.2)                      | –                                             | –                                            | 6 (1.4)                     | 55 (12.8)                   | <0.00001                        |
| For SVT                                 | –                            | 19 (9.6)                       | –                                             | –                                            | 1 (0.2)                     | 30 (7.1)                    | 0.27                            |
| Recorded death                          | 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.

*Data on death may be incomplete in Group NX.*
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. 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. 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. 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, 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. 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.
| Complications | Time of diagnosis following device implantation | S-ICD Group NX (N = 70) | TV-ICD Group NX (N = 197) |
|---------------|-----------------------------------------------|-------------------------|---------------------------|
|               |                                               | Number of patients (%)  | Number of patients (%)    | OR (95% CI)   | p value |
|               |                                               | Time to diagnosis       | Time to diagnosis         |              |         |
|               |                                               | Median (range) days     | 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 |
| Inappropriate shocks | Within 6 weeks | 0 | 0 | 0 | 0 | 0.08 |
|               | 6 weeks - 3 months                            | 3 (4.3) | 2 (1) | 0.55 (0.02–11.69) | 0.70 |
|               | 3 months - 1 year                             | 0 | 2 (1) | 0.55 (0.02–11.69) | 0.70 |
|               | after 1 year                                  | 0 | 5 (2.5) | 0.24 (0.01–4.54) | 0.34 |
| Device-related complications | Within 6 weeks | 4 (5.7) | DFT failure 1 | 10 (5) | Pneumothorax 2<sup>a</sup> | 1.13 (0.34–3.73) | 0.83 |
|               |                                               | Hematoma 2<sup>a</sup> | Hematoma 3<sup>a</sup> | Severe pain 2 | lead dislodgement 3<sup>e</sup> |
|               |                                               | Oversensing 1<sup>i</sup> |                                               |               |         |
|               | 6 weeks - 3 months                            | 2 (2.8) | Infection 1<sup>b</sup> | 6 (3) | Thrombois 2<sup>f</sup> | 0.93 (0.18–4.75) | 0.93 |
|               |                                               | Severe pain 1           | Infection 1<sup>b</sup> | lead dislodgement 3<sup>e</sup> |
|               | 3 months - 1 year                             | 3 (4.3) | CRT upgrade 1 | 6 (3) | Lead replacement 2 | 1.42 (0.34–5.85) | 0.62 |
|               |                                               | Pacing 1<sup>c</sup> | IE 2<sup>h</sup> | CRT upgrade 1 |
|               |                                               | Infection 1<sup>b</sup> |                    | Oversensing 1<sup>i</sup> |
|               | after 1 year                                  | 0 | 0 | 0 | 0 | 0.08 |

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.

<sup>a</sup>Hematoma needing exploration of surgical wounds.
<sup>b</sup>Pocket infection needing exploration of surgical wounds.
<sup>c</sup>Pacing indication emerged, thus replaced to TV-ICD.
<sup>d</sup>Both pneumothoraces needed intercostals chest drain.
<sup>e</sup>Lead dislodgments needed lead revisions.
<sup>f</sup>Device explanted.
<sup>g</sup>Deep vein thrombosis (confirmed by Doppler studies) of upper limb veins related to device implantation.
<sup>h</sup>Infective endocarditis were confirmed by blood cultures and trans-oesophageal echocardiography.
<sup>i</sup>ICD 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.\(^\text{27}\)

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.\(^\text{28}\) 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.\(^\text{29}\) 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.\(^\text{30}\) 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.\(^\text{31}\) 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.\(^\text{32}\) 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.\(^\text{33}\); 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,\(^\text{34}\) 1116 S-ICD patients with 87.7% HF, 53.5% ICM, with LVEF of 26.4 ± 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) database\(^\text{35}\) 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.\(^\text{36}\) 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.\(^\text{34}\) 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, biventricular, 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. Also, a new substernal system of extravascular ICD is currently under evaluation. 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.

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.

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