

Extracardiac Inappropriate Shocks in Subcutaneous Implantable Cardioverter Defibrillator: Management in Emergency Department



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Abstract

Background: The subcutaneous implantable cardioverter defibrillator (S-ICD) is an established treatment for the prevention of sudden cardiac death. In the S-ICD studies, inappropriate shocks (IAS) rate were reported to range between 5% to 25% and to be mainly due to cardiac and noncardiac oversensing.

Objective: This review highlights data on IAS complications of the S-ICD and is aimed to help in identifying the causes of extracardiac oversensing to facilitate safe and effective emergency management and to reduce the incidence of adverse outcomes.

Methods: Literature between January 2010 and March 2020 on IAS and S-ICD was identified by database search. We included studies assessing IAS rates due to extracardiac oversensing. We identified 12 eligible articles including meta-analysis and 28 selected case reports.

Results: The total population included 2654 reported patients. Of these, 84 patients received extracardiac IAS. The malfunction of S-ICD due to extracardiac oversensing was related, in particular, to myopotentials (34%) and electromagnetic interferences (29%). The meta-analysis demonstrates an overall high prevalence of extracardiac IAS of 22% (95% CI 8% - 50%); the prevalence was 6% (95% CI 3% - 12%) in patients without the SP (SMART-Pass) filter and 46% (95% CI 12% - 84%) in patients with the SP filter (P=0.047).

Conclusion: Our findings show the high prevalence of extracardiac IAS in patients with S-ICD and demonstrated that the SP is unable to prevent the IAS due to extracardiac reasons. It is important in the Emergency Department for the appropriate management of IAS to identify the various causes.

Keywords: Subcutaneous defibrillator; Inappropriate shock; Extracardiac oversensing; Lead complications; Myopotentials; Electromagnetic interferences

Introduction

Cardiovascular mortality due to ventricular fibrillation (VF) or ventricular tachycardia (VT) represents a significant health problem despite improvements in the prevention and management of underlying cardiovascular disease. Survival of patients with out-of-hospital cardiac arrest worldwide remains poor. In a meta-analysis of Yan et al. [1] the pooled incidence of return of spontaneous circulation was 29.7% (95% CI 27.6-

31.7%), the rate of survival to hospital admission was 22.0% (95% CI 20.7-23.4%), the rate of survival to hospital discharge was 8.8% (95% CI 8.2-9.4%), the pooled 1-month survival rate was 10.7% (95% CI 9.1-13.3%), and the 1-year survival rate was 7.7% (95% CI 5.8-9.5%). The survivors have various therapeutic options such as anti-arrhythmic drugs, radiofrequency or surgical ablation, or implant of implanted cardioverter defibrillator

(ICD). Currently, recently introduced S-ICD systems represent an alternative to the implantation of transvenous implanted cardioverter defibrillator (T-ICD) provided that the patient does not require anti-bradycardia pacing or cardiac resynchronization therapy (CRT), recurrent monomorphic VT responsive to antitachycardia pacing (ATP), or pre-existing unipolar pacemaker leads. S-ICD is particularly indicated for primary prevention in younger patients with cardiomyopathies or channelopathies [2]. Furthermore, S-ICD represents the preferred therapy for patients who are at high risk of infection (AHA/ACC/HRS guidelines, Class I recommendation) and for patients without the need of cardiac pacing (Class IIa) [3]. This device reduces VT or VF without direct contact between the implanted system and the vasculature or the endocardium. A can, inserted in the left lateral thoracic wall, and a coil, located anterior to the thoracic cage rib and to the left lateral edge of the sternum [4]. Although initial reports indicated an acceptable rate of IAS when compared to T-ICD [5], novel mechanisms of noise oversensing have recently been reported [6]. After 2016, an automated screening tool (AST) (Boston Scientific) is used to choose the best sensing configuration and through noise detection and double detection algorithms determines whether oversensing is present [7,8]. The S-ICD sensing algorithm comprises 3 phases: 1) detection phase: this phase filters the input signals to reduce T wave oversensing (TWO); 2) certification phase: the sensed events are classified as certified QRS complexes or as suspected oversensing events. A morphology algorithm based on frequency and slew rate analysis ensures that the signal is cardiac in origin and refuses myopotentials (MP) and electromagnetic interferences (EMI); 3) therapy decision phase: it discriminates between treatable and other high-rate using two programmable zones: conditional and shock zone. In the shock zone, the device analyzes arrhythmia only based on heart rate. In the conditional zone, the device makes supraventricular tachycardia (SVT)-VT discrimination based on static ECG morphology, QRS duration and dynamic ECG morphology. The last function identifies shockable tachyarrhythmias when beat-to-beat morphology varies to indicate that arrhythmia is polymorphic. The SP filter (Boston Scientific) was endorsed on 2016. The SP filter was retroactively installable for A209 systems through an upgrade. The SP filter could be activated following the device setup process and selection of the optimal sensing vector [9,10]. The aim of this algorithm was to reduce IAS without compromising detection of VT. SP reduces the amplitude of lower frequency signals such as T-waves by using a high pass filter. Higher frequency signals such as R-waves, VT and VF remains mostly unchanged. This review summarizes the available data on complications of the S-ICD and aims to help identifying the extracardiac causes of oversensing and the correct management of this device in the ED. We also aimed to evaluate the impact of SP filter on the pooled proportion of extracardiac IAS to the total number of shocks delivered.

Methods

For the purpose of the present investigation, a comprehensive literature on this specific subject search between January

2010 and March 2020 was performed on PubMed, Cochrane central registry, and Google Scholar. The search terms were “subcutaneous implantable cardioverter-defibrillator and left ventricular assist devices,” “electromagnetic interference and S-ICD,” “Myopotential and S-ICD,” “inappropriate extracardiac shocks and S-ICD,” “chest compression and S-ICD”, “lead fracture and S-ICD”, “lead dislodgment and S-ICD”, “air entrapment and S-ICD”, “mechanical complications and S-ICD”. Demographic, extracardiac IAS, programming and actions data were extracted from the reports and authors as needed. The FDA Manufacturer and User Facility Device Experience (MAUDE) database was also queried for reports of S-ICD and EMI interactions. We included studies assessing IAS rates due to extracardiac oversensing by 3 investigators.

Studies selection and data extraction

Overall, 333 citations were identified after the removal of duplicates. The references were screened by two independent researchers (MP and GI) and, in case of disagreement, a third researcher (LI) was involved to resolve the differences. The selection process (PRISMA Flow Diagram) is displayed in Figure 1 [11]. Search criteria and methodology were approved by all authors. Titles and abstracts retrieved in the search were reviewed, and observational and comparative studies reporting extracardiac IAS rates in S-ICD were selected. For extracardiac review on causes analysis, articles, abstracts, meta-analysis and editorials were excluded. In the event that there were multiple publications from the same study, the latest study with the most complete data available was selected, and the other publications were not used in order to avoid overlapping cohorts. Because randomized controlled trials (RCT) and non-RCT were included in this meta-analysis, we used the Jadad scale to assess the quality of the RCT, whereas the methodological index for non-randomized studies (MINORS) scale [12] was used to assess non-RCT. If two independent evaluations conflicted, all authors participated in a discussion to resolve the controversy. For selected studies, only data on S-ICD patients were extracted. Extracted data included: number of patients, age, total shocks, number of extracardiac IAS and number of patients with extracardiac IAS. For the meta-analysis, the article type was limited to clinical trials. Twelve full length article were considered eligible for the meta-analysis. Moreover, we identified 28 case reports useful to calculate the percentage of extracardiac IAS in the last 10 years.

Statistical Analysis

Continuous variables were expressed as mean \pm standard deviation and categorical data as percentages. Differences between groups were analyzed by t-test or chi-square test, as appropriate. The main effect size of the meta-analysis was proportional to extracardiac IAS rate of the total number of shocks delivered during the specified follow-up. The user-written Stata metaprop-one package was used to pool proportions and to present weighted sub-group and overall estimates with inverse-variance weights. For this purpose the random-effects model

the logit transformation was applied, and the result displayed as forest plot. Study specific 95% confidence intervals (CI) were calculated using the Clopper-Pearson exact method. In between-study heterogeneity was evaluated with Cochran's Q and I square statistics or the likelihood test for random effect vs fixed effect meta-analysis as appropriate. Metaregression analysis was also performed. For this purpose, the extracardiac IAS rate was modeled on the log scale as a linear combination of the regression factors. P-values <0.05 were considered as statistically significant. The presence of publication bias was graphically assessed using a funnel plot, a simple graphical display of a measure of study size against logit of IAS rate. The interpretation of funnel plots is facilitated by the inclusion of diagonal lines representing the 95% confidence limits around the summary treatment effect, showing the expected distribution of studies in the absence of bias. To evaluate potential publication bias, we also performed the Egger weighted regression test and the Begg's rank test. Finally, percentage of cause of extracardiac IAS in the selected S-ICD studies and case-reports were calculated. Statistical analysis was performed using the Stata software 16.0 (StataCorp 4905 Lakeway Drive College Station, Texas 77845 USA).

Results

After excluding 580 articles for not meeting inclusion/exclusion criteria, 33 articles remained to be assessed for eligibility (Figure 1). Following assessment of the full-text articles, 21 were excluded for reasons such as: shocks were not specified or rates

of extracardiac IAS (rather than just shocks) were not specified. Thus, 12 articles considered eligible for the meta-analysis, and 28 case-reports were selected. The 12 studies included in the meta-analysis are reported in Table 1. The 28 selected case-reports were used for calculating the percentage of extracardiac causes of ICD dysfunction are reported in Table 2. In selected studies and 28 case-reports the malfunction of S-ICD due to oversensing caused by extracardiac signals were: electromagnetic interferences (29%), pectoral or diaphragmatic myopotentials (34%), chest compression (11%), lead damage (1%), air entrapment (23%), electrical interference (1%) and Twiddler syndrome (1%) (Figure 2). The causes of extracardiac IAS and the consequently actions were reported in Table 1 [9-48]. The final population for the meta-analysis included 2627 patients, 1329 without (Group 1) and 1298 with SP filter (Group 2). A total of 84 patients received 167 extracardiac IAS. The random effect meta-analysis of the select studies (9,10,13,14,18,25,27,33,35,42,43,47) demonstrated that in the overall study population the IAS percentage of total shocks delivered due to extracardiac oversensing represent 22% (95% CI 8% - 50%); the percentage was 6% (95% CI 3% - 12%) in patients without the SP filter and 46% (95% CI 12% - 84%) in patients with the SP filter (Figure 3). The funnel plot appears symmetrical (Figure 4), without evidence of bias using both the Egger weighted regression method (P= 0.763) and the Begg rank test (P= 0.304). At meta-regression analysis, the SP filter was significantly associated with a proportion of extracardiac S-ICD dysfunction (P= 0.047).

Table 1: The select studies that investigate the inappropriate Shocks due to oversensing of extracardiac signals.

Authors	Time	Age (years)	Total N shocks	IAS numbers	Cause	Actions
Bardy GH et al. [9]	2010	61±11	12	3	Myopotentials	Device reprogramming
Dabiri AL et al. [10]	2011	53±16	37	3	Pt 1: Myopotentials Pt 2: lead dislodgment	Pt 1: Device reprogramming, Pt 2: lead reposition
Aydin A et al. [13]	2012	42±15	70	3	Chest compression during CPR	S-ICD was removed and TV- ICD was implanted
Weiss R et al. [14]	2013	52±16	79	3	EMI	Device reprogramming
Burke MC et al. [18]	2015	50±16	328	7	EMI	Reprogrammed device
Boesma L et al. [25]	2017	48±12	366	22	EMI	Reprogramming device
Rudic B et al. [27]	2017	38±13	24	4	Pt 1: Myopotentials Pt 2: Air entrapment	Pt 1: Reprogramming device Pt 2: Spontaneous resolution
Afzal MR et al. [33]	2018	42±11	3	2	EMI	Pt 1: S-ICD was removed and T- ICD was implanted Pt 2: Reprogrammed device
Migliore F et al. [35]	2019	37±17	13	2	Pt 1: artifacts due to postural change Pt 2: myopotentials	Pt 1: Reprogramming device Pt 2: S-ICD was removed and T- ICD was implanted
Van den Bruch JH et al. [42]	2019	42±8	40	39	Myopotentials	Reprogramming device
Khazen C et al. [43]	2019	44±17	13	3	Pt 1: EMI in the bathroom Pt 2: Myopotentials Pt 3: Myopotentials	Pt 1: Recommendations Pt 2: Reprogramming device Pt 3: Reprogramming device

Ishida Y et al. [47]	2020	41±10	13	10	EMI	3 Pts Reprogrammed device 3 Pts S-ICD was removed and T- ICD was implanted 3 Pts S-ICD turned OFF 1 Pt Observation
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IAS: inappropriate Shocks; **S-ICD:** subcutaneous Implanted Cardioverter Defibrillator; **T-ICD:** Transvenous Implanted Cardioverter Defibrillator; **TENS:** Transcutaneous electrical nerve stimulation; **EMI:** Electromagnetic interference; **CPR:** Cardiopulmonary Resuscitation **Pt:** patient

Table 2: The select case-reports that investigate the inappropriate Shocks due to oversensing of extracardiac signals.

Authors	Time	Age (years)	EIASs numbers	Cause	Actions
Alvarez-Acosta LA et al. [15]	2014	32	3	Myopotentials	Device reprogramming
Zipse MM [16]	2014	56	7	Air entrapment	Device reprogramming
Gamble JH et al. [17]	2014	22	2	Air entrapment around the proximal sensing electrode	Spontaneous resolution once the air has been absorbed
Frommeyer G et al. [19]	2015	17	1	Electrical interference	Pt should be advised to avoid direct contact with electrically powered hardware
Corzani A et al. [20]	2015	58	1	Myopotentials	Device reprogramming
Miller MA et al. [19]	2015	24	1	EMI	Pt may still utilize TENS despite recommendations
Kooiman PA et al. [20]	2015	40	1	Twiddler's syndrome	Reimplantation of device
Yap SC et al. [22]	2015	37	2	Air entrapment	Spontaneous resolution
Chinitz JS et al. [24]	2015	56,73	2	Introduction of air along the sternal track as the lead is inserted and sheath is removed	Pt 1: spontaneous resolution Pt 2: reprogramming device
Lee S et al. [26]	2017	55	11	Residual air subxifoide node	Reprogramming device
Chieng D et al [28]	2018	61	1	Myopotentials	Device pocket revision
Turner SL et al. [29]	2018	41	1	EMI	Pt may still utilize TENS despite recommendations
Ahmed AS et al. [30]	2018	25	1	EMI	Reprogrammed device
Taguchi Y et al. [31]	2018	17	9	Air entrapment	Spontaneous resolution
Berkowitz EJ et al. [32]	2018	56	14	Chest compression during CPR	S-ICD was removed and dual chamber ICD was implanted
Saini H et al. [34]	2018	49	2	EMI	S-ICD was removed and T- ICD was implanted
Barnett A et al. [36]	2019	25	1	Seal plug damage	Device replacement
Sasaki T et al. [37]	2019	28	3	Myopotentials	Lead repositioning to the midline of the sternum
Yang YC et al. [38]	2019	58	1	Air entrapment	Reprogrammed device
Camm CF et al. [39]	2019	16	1	Twiddler's syndrome	Reimplantation of an S-ICD under general anaesthetic
Nishinarita R et al. [40]	2019	57	1	Air entrapment	Reprogrammed device
Adduci C et al. [41]	2019	40	2	Air entrapment	Reprogrammed device

Lopez-Gil M et al. [44]	2019	24	1	EMI	Reprogramming device
Cmorej P et al. [45]	2020	30	several	Chest compression during CPR	Placement of a magnet failed
Ghrrair F et al. [46]	2020	50	1	Air entrapment	Reprogrammed device
Utkarsk K et al. [48]	2020	34	1	EMI	Pt may still utilize drill

IAsS: inappropriate Shocks; **S-ICD:** subcutaneous Implanted Cardioverter Defibrillator; **T-ICD:** Transvenous Implanted Cardioverter Defibrillator; **TENS:** Transcutaneous electrical nerve stimulation; **EMI:** Electromagnetic interference; **CPR:** Cardiopulmonary Resuscitation **Pt:** patient.

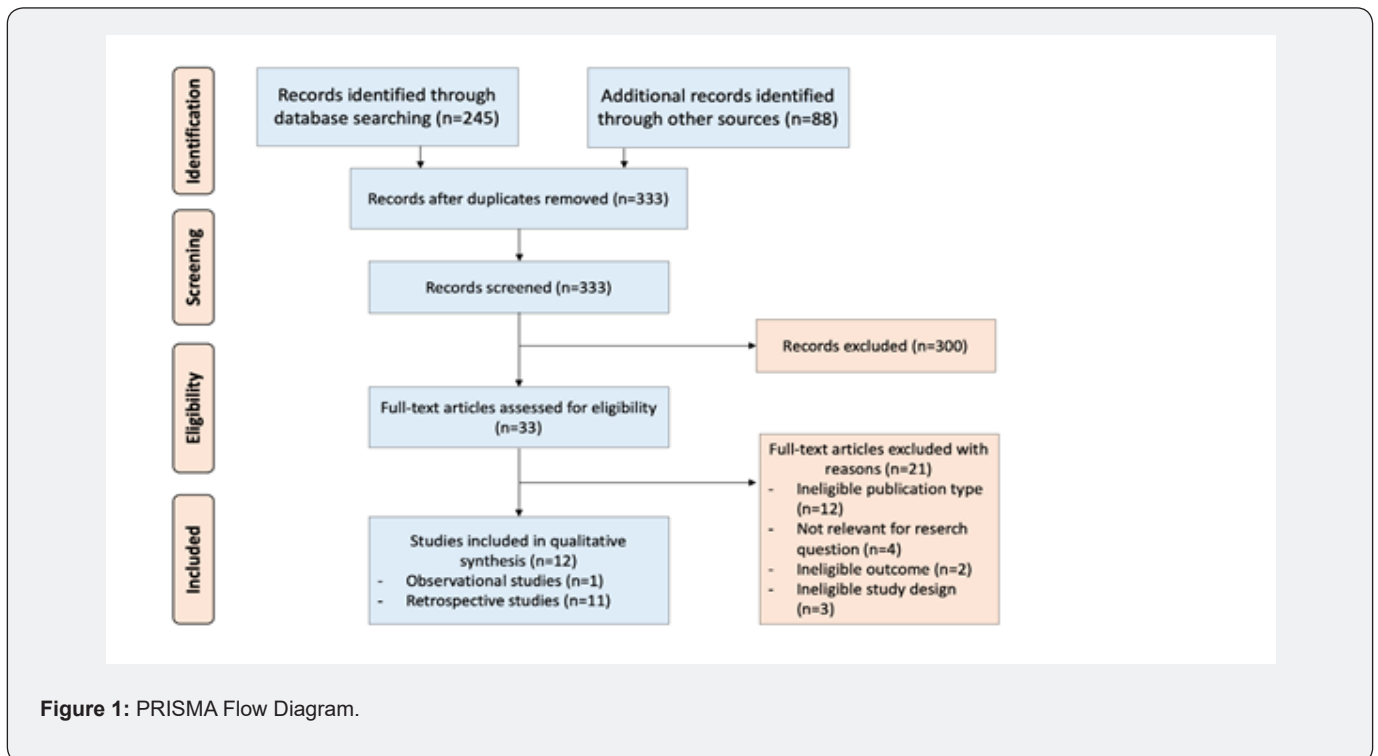


Figure 1: PRISMA Flow Diagram.

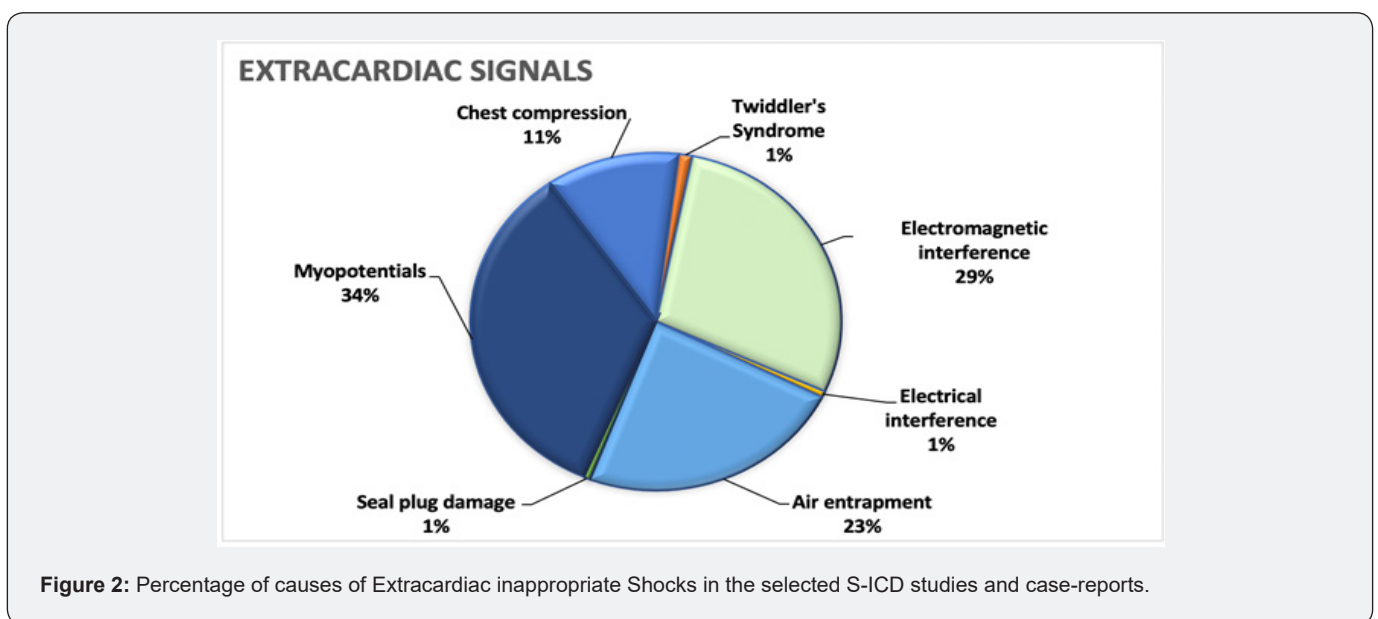


Figure 2: Percentage of causes of Extracardiac inappropriate Shocks in the selected S-ICD studies and case-reports.

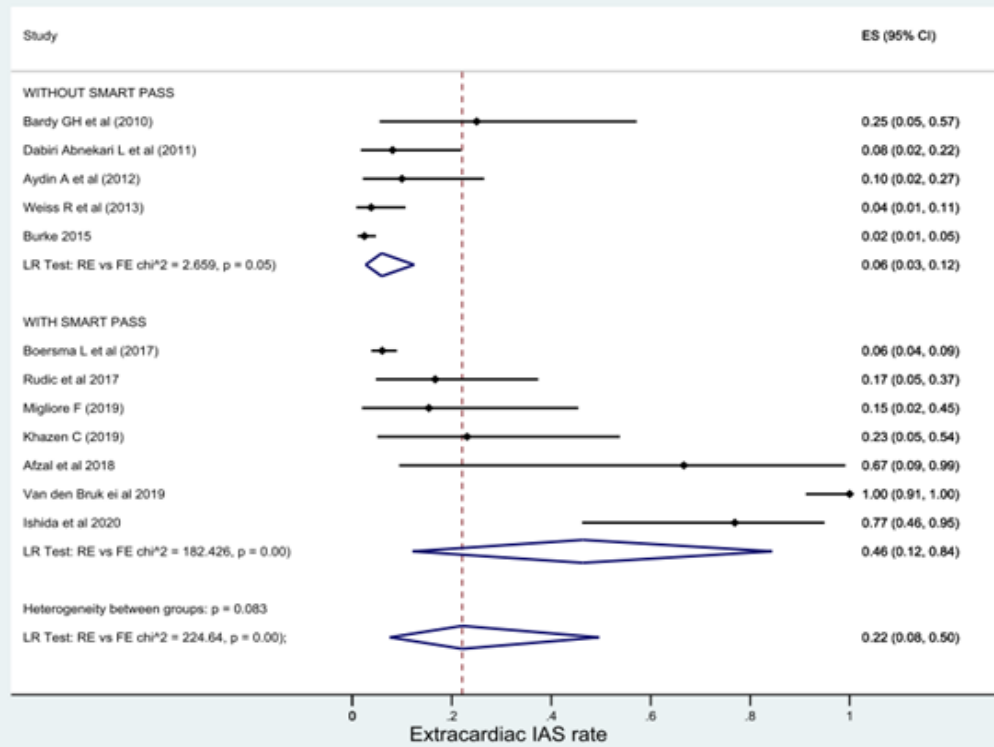


Figure 3: Meta-analysis of the patients with inappropriate Shocks without SMART Pass group and with SMART Pass group in the selected S-ICD studies.

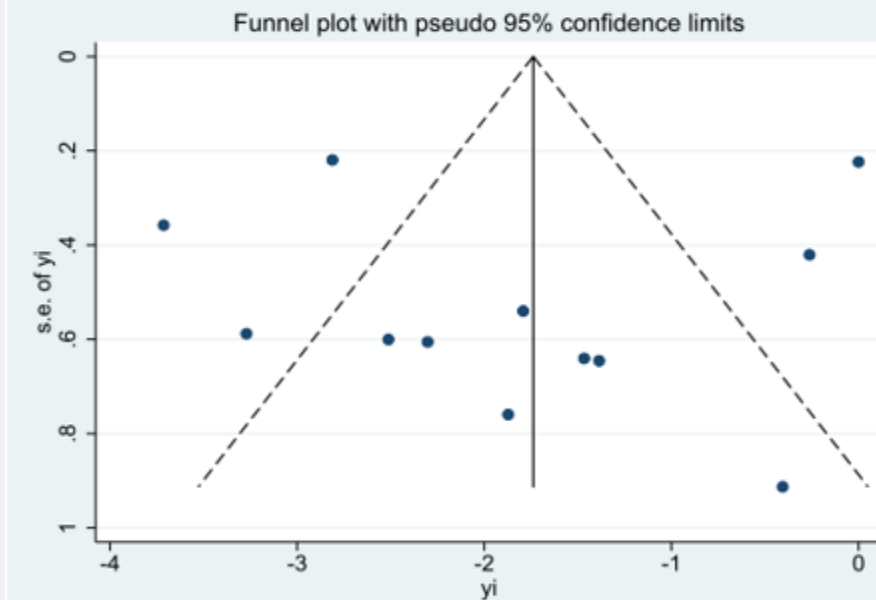


Figure 4: The funnel plot displays the study IAS rate on a logit scale against its standard error for each study included in the meta-analysis. The vertical line indicates the pooled estimate of the overall prevalence rate, with the diagonal lines representing the expected pseudo 95% confidence limits around the summary.

Discussion

Our study first systematically reviewed the percentage of causes of extracardiac IAS in full length and case-reports S-ICD studies. IAS derived from the activation of S-ICD therapy without a life-threatening tachyarrhythmia were evaluated in current English literature. During the initial experience with the S-ICD, the IAS rate was high, a prevalence of 4% to 25%, and IAS were associated with increase morbidity [49]. IAS predominantly result from oversensing of cardiac signals due to SVT misinterpreted as ventricular arrhythmias [50]. After addition of the SP filter and additional advancements, contemporary studies have reduced IAS rates from 6.4% to 3.5% annually [7] and the risk of IAS with T-ICD and with S-ICD comparable rates [49]. Theuns et al. [7] showed, with the LATITUDE remote control, that the group SP reduced the risk of the first IAS by 50% ($P < .001$) and the risk for all IAS by 68% ($P < .001$) in multivariate analysis adjusted for age and device programming. The incidence of IAS was 4.3% in the SP enabled arm vs 9.7% in the SP disabled arm. In particular, the incidence of extracardiac IAS was 0.5% in the SP enabled arm vs 2.3% in the SP disabled arm ($P=0.003$). But this study did not specify the causes of extracardiac episodes and the undertaken action. All shock episodes were systematically collected using the remote monitoring system. The EFFORTLESS S-ICD registry collected the data of 472 patients with S-ICD and reported a relatively low incidence of inappropriate therapy (rating of -7%), mostly due to inappropriate cardiac sensing (5.3%) and SVT (1.3%), with a very low incidence of extracardiac inappropriate sensing (0.009%) [51]. But a significant number of case-reports considered that the absence of extracardiac oversensing among patients with S-ICD is underestimated. There are several important reasons that might support such statement. In conclusion, the results of our meta-analysis demonstrate an overall high prevalence of extracardiac IAS of 22%. Interestingly, the summary prevalence was 6% in patients without SP and 46% in those with SP and the difference is statistically significant ($P=0.047$). The increase in prevalence of extracardiac IAS with SP may be due to recent spread of S-ICD in last years. There is only 10 years of experience with S-ICD. SP is able to reduce IAS from cardiac oversensing [7]. However, extracardiac IAS were already present in the first study of 2010 but for poorly cases suitable, they showed few numbers. Paradoxical effect of the increase in the prevalence of IAS with SP is due to increase in the device in more recent studies that SP can't avoid. This finding also suggests that, at this time, the SP is unable to eliminate the IAS due to extracardiac reasons. Extracardiac causes of shock are numerous, which effects the management of extracardiac IAS in the ED (Figure 5). In this contest, shock delivery is painful and reduces more battery life. In this report, the most frequent causes secondary to extracardiac signals were EMI (29%) and MP (34%). However, only limited data are available on the impact of EMI on S-ICD function. EMI was not immediately detected on standard device examination but detected on the Marker Channel.

Experience with concomitant use of S-ICD and EMI is limited to only few published case reports with discordant results (14,18,25,29,30,33,34,43,47,48). Medical equipment which incorporates wireless technology, for example, some infusion pumps, monitoring devices, and ultrasound probes, should also be used at a distance from a S-ICD since these devices may provide a source of EMI. In the case-reports of Gupta et al. [52] and Raman et al. [53] the patient was observed monthly a tour LVAD clinic and no adverse event was seen. In contrast, Afzal et al. [33] and Ishida et al. [47] documented in LVAD patients with S-ICD, EM Interference in 12 patients. In these cases, EMI may be falsely interpreted as a shockable rhythm and results in 65 J biphasic shock delivery. The fundamental frequencies responsible for the EMI were directly proportional to the pump speed. This is important because there has been some disagreement in the literature regarding the relationship between pump speeds and EMI. Gupta et al. [52] and Raman et al. [53] postulated that the lower operational pump speeds of the LVAD were more likely to be recognized as noise, and less likely to cause sensing interference based on the S-ICD algorithm. Disabling the shock function of a device before exposure to EMI is therefore advised. Low amplitude of QRS complexes may have contributed to the inability to filter out the external noise. SP filter reduces amplitude of low frequency signals (T waves) but is not useful for high frequency signals like EMI. The EMI filter (non-programmable) of the device was set at 60 Hz. The band pass filter (3-40 Hz) was also enabled. Subcutaneous electrodes and engineered shielding protection have reduced the risk of EMI; however, sources of EMI around the patient should be avoided. If the device has been recently checked and the EMI source site is remote, the likelihood of malfunction is still persistent. For reducing these complications, the Boston Scientific have listed the EMI Compatibility Table for S-ICD [54]. In this document the manufacture recommended not to use the machines listed since then and is doing well. Offline analysis of the EMI events was invaluable. Educate patients to avoid the device causing the EMI or additional device reprogramming or repositioning is needed to overcome these problems. Although, in different studies and case-reports, we noted that the problem of oversensing related to MP was solved by setting a new configuration in device sensitivity (9,10,15,20,27,28,37,42,43). This is usually managed non-invasively via a change in sensing vector. In the study of Rudic et al. [27] 2 of 62 patients (3.2%) experienced IAS. In 1 patient oversensing of pectoral MP, caused by suboptimal position of the lead, was resolved by placing it toward the right side of the sternum. Reprogramming of the sensing vector resolved the problem. The second patient had 2 IAS in the first 24 hours after implantation and they are related to air entrapment inside the impulse generator pocket. The issue resolved spontaneously without intervention. Van den Bruck et al. [42] assessed 41 patients for MP inducibility. In nearly all patients (90.2%), MP were inducible during isometric chest press (ICP). Secondary vector (70.7%) and alternative vector (75.6%) were most affected during ICP; primary vector was most conditioned

during side plank exercise, supporting the body weight on the left arm (51.2%). However, for mechanical extracardiac causes of IAS, the fluoroscopy was clinically useful to demonstrate significant device movement [28]. In case of air entrapment, chest X-rays can often diagnose air entrapment when a large quantity of air sits inside a subcutaneous pocket or lead tunnel. Two kinds of artifacts are commonly seen with air entrapment. Both are related to the entrapped air insulating the sensing electrode. Recently, the two-incision technique is a simplified implant method. But, according to Chinitz et al. [24] and Khazen et al. [43] this new surgical technique predisposes to oversensing and IAS in the early post-implant period, possibly due to introduction of air along the sternal track as the lead is inserted and sheath is removed. This malfunction has been reported and requires only reprogramming the device and may be resolved spontaneously. If this complication does not resolve spontaneously, flushing the sternal track with saline, massaging the skin over the lead and suturing over the lead are suggested to minimize air entrapment [16,17,23,25,27,31,38,40,41,46]. Unexpectedly, the IAS were due also to oversensing of chest compressions in the setting of a profound postshock bradycardia. Aydin et al. [13] reported 40 consecutive patients of three institutions in Germany. Two episodes in the same patient stopped incorrectly because of under sensing during resuscitation and chest compression after ineffective shocks, respectively. The IAS in the cases reported by Berkowitz et al. [32] and Cmorej et al. [45] were due to oversensing of QRS artefacts that developed during chest compression. With increasing numbers of S-ICD

being implanted, the possibility of delivery shock during CPR is likely to represent a challenge in the management of cardiac arrest in S-ICD patients. Magnet deactivation of S-ICD is less reliable and should also be used during CPR maneuvers. In all the cases of malfunctions in emergency situations without a programmer (3200 model, Boston Scientific), the first step is to use a magnet to deactivate repeated shocks. Successful inhibition by the magnet is indicated acoustically as beeping for 60 seconds. Appropriate placement of the magnet depends on the device S-ICD model [55]. This variability in magnet placement increases the risk of failed deactivation. The magnet should be positioned off-center so that the curve of the “donut” magnet is over the top or the bottom end of the device. Improper magnet placement may hinder magnet activation and could lead to undesired delivery of shock therapy. Magnet application to temporarily deactivate the tachyarrhythmic therapy function is a simple procedure. We believe that consensus statements should consider whether a magnet should be placed over the S-ICD of all patients with IAS. If these conditions cannot be met, consideration should be given to reprogram the device “off” and appropriate precautions taken. Therefore, while the risk of S-ICD activation in the lower extremities is admittedly rare. This case calls into question prior to expert consensus opinion and to management of S-ICD in ED on the lower extremities. Although magnet applications result only in temporary alteration of S-ICD, it should be interrogated at the earliest opportunity to detect any possible programming changes [56].

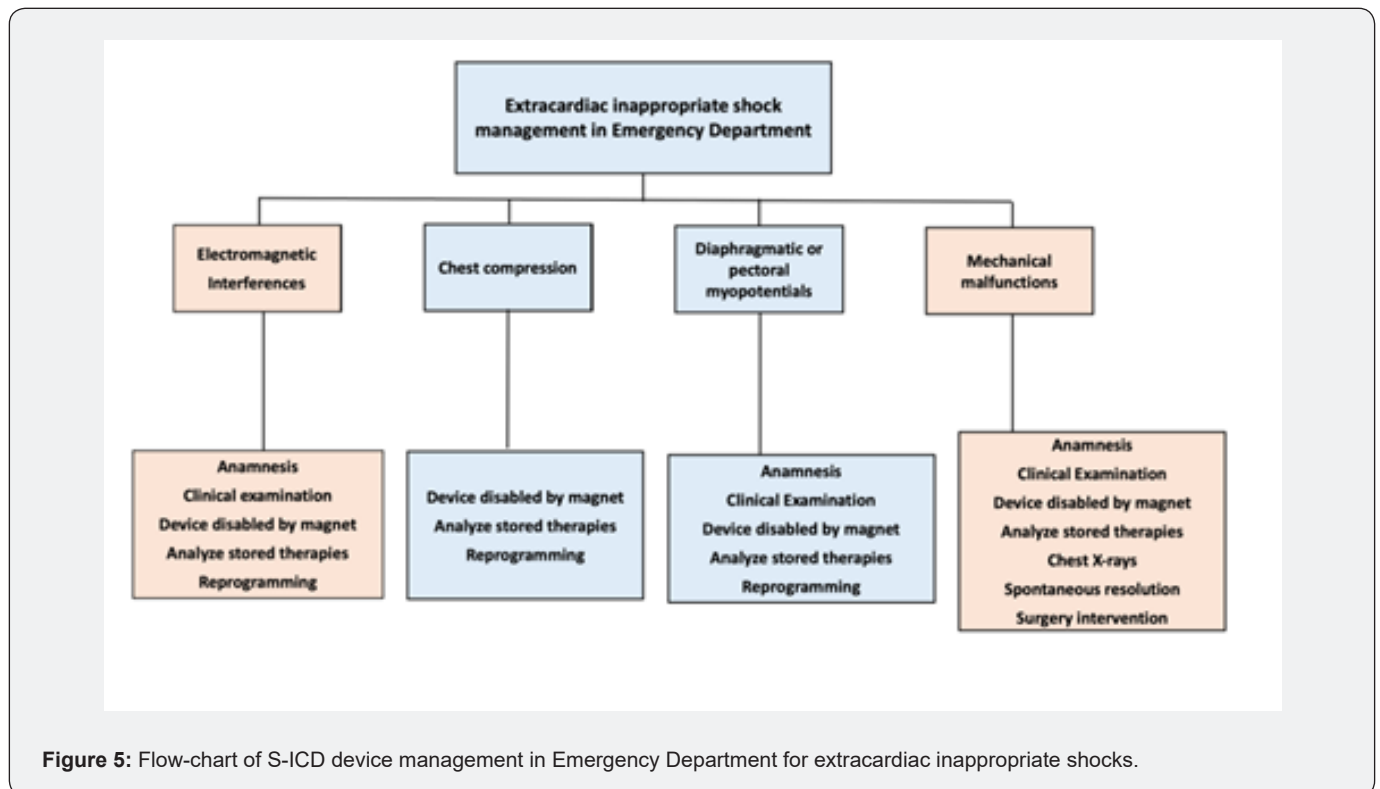


Figure 5: Flow-chart of S-ICD device management in Emergency Department for extracardiac inappropriate shocks.

Limitations

There were limitations to our study which need to be considered. First, the exact proportion of patients with S-ICD who experience extracardiac IAS is unknown. Also, there is a likely assertion bias because normal functioning devices are unlikely to be reported. In this regard, we only found twenty-two such reports of S-ICD with confirmed lack of EMI and MP in the literature [9,10,14,15,18-21,25,27,28-30,33-37,42,43,47,48]. It is noteworthy that the largest published patient series of S-ICD demonstrated that 0.5% to 8% of patients experienced EMI or MP [7,18]. Thus, it is likely that such interaction is not a rare event.

Conclusion

Data from reported clinical studies support that the technology of third-generation S-ICD with SP filter has reduced the risk of IAS related to cardiac signals, but do not eliminate the risk of IAS associated with extracardiac signals. Therefore, it is essential in the ED to help improving the management of IAS and to identify the different causes of cardiac and extracardiac IAS. These malfunctions were solved by different approaches: reprogramming device, surgical and education of patient.

Key Teaching Points

- The number of patients with S-ICD presenting in the Emergency Department is increasing.
- Our findings show the high prevalence of extracardiac IAS in patients with S-ICD and demonstrated that, at this time, the SMART-Pass is unable to prevent the IAS due to extracardiac reasons.
- For patient with S-ICD it is crucial to consider also the extracardiac signals as a cause of inappropriate shocks in emergency situation. Shock delivery is painful and utilizes more battery life. These malfunctions were solved by different approaches.
- In the Emergency Department, in case of inappropriate shock without suitable EMBLEM S-ICD 3200 Programmer, the specific Model 6860 or 4520 magnet must be placed above the upper or lower edge of the S-ICD device to inhibit shock delivery. Inhibition of shock delivery by the magnet is signaled acoustically as beeping.

Conflict of Interest

The author has no conflict of interest to disclose.

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