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ORIGINAL ARTICLE

Predictors of morbidity and in-hospital mortality following procedure-related cardiac tamponade

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Abstract

Background: Cardiac tamponade (CT) can be a complication following invasive cardiac procedures. We assessed CT following common cardiac electrophysiology (EP) procedures to facilitate risk prediction of associated morbidity and in-hospital mortality.

Methods: Patients who underwent various EP procedures in the cardiac catheterization lab (ablations and device implantations) were identified using the International Classification of Diseases, Ninth and Tenth Edition, Clinical Modification (ICD-9-CM and ICD-10-CM, respectively) from the Nationwide Inpatient Sample (NIS) database. Patient demographics, presence of comorbidities, CT-related events, and in-hospital death were also abstracted from the NIS database.

Results: The frequency of CT-related events in patients with EP intervention from 2010 to 2017 ranged from 3.4% to 7.0%. In-hospital mortality related to CT-related events was found to be 2.2%. Increasing age was the only predictor of higher mortality in atrial fibrillation (AF) ablation and cardiac resynchronization therapy (CRT) groups (OR [95% CI]: AF ablation = 11.15 [1.70–73.34], $p = .01$; CRT = 1.41 [1.05–1.90], $p = .02$).

Conclusions: In the real-world setting, CT-related events in EP procedures were found to be 3.4%–7.0% with in-hospital mortality of 2.2%. Older patients undergoing AF ablation were found to have higher mortality.

KEYWORDS
cardiac tamponade, electrophysiological procedures, mortality

1 | INTRODUCTION

Percutaneous cardiac interventions are increasingly utilized with varying procedure complexity and ongoing technological innovations.[1] Specific steps during procedures (e.g., transseptal puncture) increase the risk of developing pericardial effusion, which may then lead to cardiac tamponade (CT).[2] Coronary interventional (CI) procedures and complications like guidewire-related coronary perforation, intracoronary balloon rupture, and atherectomy device-related rupture can lead to pericardial effusion and CT, requiring acute, life-saving intervention.[3,4] Electrophysiology procedures (EP), such as device implantations (including left atrial appendage occlusion [LAAO]) and ablation procedures may also be complicated by

pericardial effusion and CT.[5] Most EP procedures are performed using venous access (low pressure), except ablations done in the left atrium or left ventricle, whereas coronary interventional procedures generally involve the arterial (high pressure) side of the circulation.

There have been individual studies based on complications of a few interventional coronary and EP procedures, with pericardial effusion being a significant finding in most of these.[6–12] We assessed the incidence of CT and associated morbidity and mortality outcomes following common EP procedures using a large US database. This data will be helpful for the clinician when communicating possible complications associated with these procedures and thus facilitate informed consent.

2 | METHODS

2.1 | Database selection

The study was conducted using the Nationwide Inpatient Sample (NIS) of the HCUP dataset between 2010 and 2017.[13] The NIS data include inpatient care and readmissions and is the largest "real-world" all-payer claims dataset in the United States. Each entry contains information on the demographics, primary and secondary procedures, hospitalization outcome, length of admission, and the number of days for readmission after the discharge, where relevant. The data correlate well with other hospitalization discharge databases in the United States. The information is stored with safeguards to protect the privacy of patients, physicians, and hospitals involved.

The population selected from the NIS dataset for this study are patients who developed periprocedural CT after interventional EP procedures from 2010 to 2017. This data include all adult patients (>18 years of age). This study was considered exempt from Institutional Review Board approval because HCUP-NIS contains de-identified patient information and is publicly obtainable.

2.2 | Variables

NIS data were queried using the International Classification of Diseases, Ninth and Tenth Edition, Clinical Modification (ICD-9-CM and ICD-10-CM, respectively) to identify the patients undergoing EP interventions and looked for the patients who developed CT as a periprocedural complication. We also abstracted the information regarding types of arrhythmia, types of treatments, intervention-related events, and interventions for CT (Table S1). Briefly, the patients with intervention-related events after the EP procedures were defined as the patients who had CT, hemopericardium, acute posthemorrhagic anemia, hemorrhage complicating a procedure, or hematoma complicating a procedure. Of patients with events, moreover, we regarded the patients with severe events as the patients who died or required cardiac surgery (i.e., pericardiocentesis, incision of heart, cardiotomy, pericardiotomy, or pericardiectomy). Data regarding EP procedures (including LAAO), including demographics, hospital details, and medical charges of these procedures were also abstracted from the database. The presence of comorbidities and the use of anticoagulant therapy in the patients were defined using ICD-CM codes as shown in Tables S2 and S3, respectively. The data for LAAO was analyzed from 2015 since the first device was FDA-approved in 2015.

2.3 | Statistical analyses

Descriptive statistics are presented as median (inter quantal range; IQR), number (percentage), and odds ratio (95% confidence interval) (OR [95% CI]). Baseline characteristic data were compared using Fisher's exact test and a Kruskal–Wallis equality-of-populations rank test after a Kolmogorov–Smirnov test. For the estimation of a 95% confidence interval for the frequency of cardiac intervention-related events in patients with EP procedures, we calculated the Clopper-Pearson's exact confidence interval. A Cochran–Armitage test was used for the estimation of the P-trend on binary data. For multivariate linear analysis, a logistic regression analysis was used to identify potential predictors of harmful events. The variables used for the logistic regression analysis were age, sex, nonelective admission, race, primary payer, hospital region, hospital bed size, anti-coagulant therapy, arrhythmias, comorbidities, and admitting year. Statistical analysis was performed using STATA v.15.1 (Stata-Corp). A two-tailed a priori p-value of $<.05$ was regarded as significant.

3 | RESULTS

A total of 58 761 097 patients were admitted from 2010 to 2017, out of which 304 715 were admitted for either a coronary or EP intervention. Finally, 144 810 patients were included in the analysis after the exclusion of patients as shown in Figure 1. EP/device interventions were carried out in 144 810 (52.7%) of the admissions having cardiac procedures—permanent pacemaker (PPM) implantation formed the largest group amongst device implantation (45 600 [31.5% of all the EP procedures]), whereas AF ablation formed the largest group among patients undergoing ablations (18 611 [12.9% of all EP procedures]) (Figure 1).

3.1 | Baseline characteristics of the patients presenting with postprocedural CT

Detailed baseline characteristics of all the patients are provided in Table S4. Among the EP procedures, the patients undergoing cardiac resynchronization therapy (CRT) had the highest proportion of DM, HTN, and HF ($p < .0001$) as compared to all other procedures. Prevalence of CT ($p < .0001$) and requirement

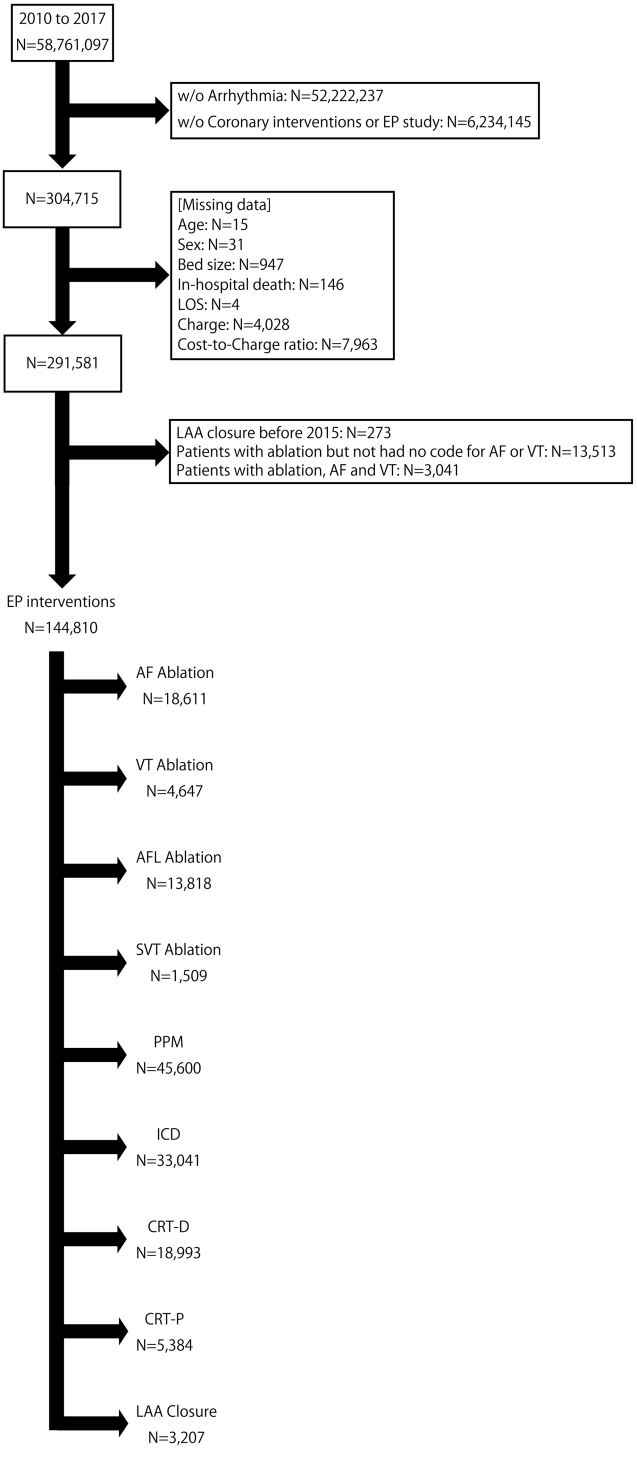

FIGURE 1 Study flow diagram. AF, atrial fibrillation; AFL, atrial flutter; CRT-D, cardiac resynchronization therapy-defibrillator; CRT-P, cardiac resynchronization therapy-pacemaker; CTO, chronic total occlusion; EP, electrophysiological procedure; ICD, implantable cardioverter defibrillator; LAA, left atrial appendage; LOS, length of stay; *N*, number; PPM, pacemaker; PTCA, percutaneous transluminal coronary angioplasty; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

for surgical interventions ($p < .0001$) and in-hospital mortality ($p < .0001$) were highest in the ventricular tachycardia (VT) ablation group (Table 1).

3.2 | Predictors of morbidity and mortality—EP Procedures Group

Admission for nonelective (emergency) procedure was found to increase the overall CT events and the events requiring intervention ($p < .0001$) without any significant increase in overall mortality, in all the subgroups of device implantation or EP procedure (Tables 2–4).

Increasing age [OR (95% CI): 1.10 (1.01–1.19), $p = .02$], female sex [OR (95% CI): 1.46 (1.27–1.19), $p < .0001$], a presence of PVD [OR (95% CI): 1.57 (1.23–2.00), $p < .0001$] and coagulation defects [OR (95% CI): 1.78 (1.31–2.41), $p < .0001$] predicted higher CT events in the patients undergoing AF ablation, whereas, the presence of HF [OR (95% CI): 0.66 (0.53–0.82), $p < .0001$] was associated with significantly lower CT events in this group. Females had a higher number of CT events in the VT ablation group compared to males [OR (95% CI): 1.39 (1.05–1.85), $p = .02$]. The patients undergoing ablation for atrial flutter (AFL) had a higher number of CT-related events with increasing age [OR (95% CI): 1.12 (1.02–1.23), $p = .02$], female sex [OR (95% CI): 1.35 (1.14–1.61), $p = 001$] and presence of PVD [OR (95% CI): 1.88 (1.43–2.48), $p < .0001$]. As expected, the presence of coagulation defects predicted higher CT events in all types of device implantation procedures [OR (95% CI): PPM—1.97 (1.67–2.33), $p < .0001$, ICD—1.92 (1.62–2.28), $p < .0001$, CRT—1.86 (1.63–2.12), $p < .0001$, LAA—2.58 (1.27–5.27), $p = .009$]. The patients undergoing ICD and CRT had a higher number of CT events with increasing age [OR (95% CI): ICD—1.10 (1.04–1.15), $p < .0001$, CRT—1.07 (1.02–1.12), $p = .003$], but the events were lower in the diabetic group [OR (95% CI): ICD—0.80 (0.69–0.92), $p = .002$, CRT—0.82 (0.73–0.91), $p < .0001$]. Female patients undergoing ICD implants had a higher number of events [OR (95% CI): 1.29 (1.14–1.46), $p < .0001$]. Obesity was associated with lower CT in the PPM and CRT groups [OR (95% CI): PPM—0.82 (1.69–0.99), $p = .03$, CRT—0.82 (0.71–0.95), $p = .007$]. (Table 2).

The patients requiring intervention for CT were lower in those with PVD [OR (95% CI): 0.50 (0.29–0.85), $p = .01$] and obesity [OR (95% CI): 0.64 (0.44–0.94), $p = .02$] in the AF ablation group. VT ablation patients with chronic pulmonary disease required a higher rate of intervention to treat the CT [OR (95% CI): 3.24 (1.40–7.52), $p = .006$], whereas female patients had significantly lower intervention rates [OR (95% CI): 0.50 (0.26–0.96), $p = .04$]. CT-related interventions were higher in females undergoing AFL ablation [OR (95% CI): 1.71 (1.16–2.53), $p = .007$], whereas lower with associated HF [OR (95% CI): 0.41 (0.23–0.73), $p = .003$] and PVD [OR (95% CI): 0.39 (0.19–0.81), $p = .01$]. Among device implants, female patients undergoing PPM or CRT implants required more interventions [OR (95% CI): PPM—1.57 (1.10–2.24), $p = .01$, CRT—1.55 (1.16–2.08), $p = .003$]. Surprisingly, the presence of previous cerebrovascular disease (CVD), PVD, or diabetes, lead to a lower number of CT-related interventions in the patients undergoing PPM and CRT {CVD[OR (95% CI): PPM—0.37 (0.16–0.84), $p = .02$, CRT—0.48 (0.25–0.92), $p = .03$: PPM—0.38 (0.19–0.76), $p = .006$, CRT—0.49 (0.29–0.83), $p = .008$]}. (Table 3) The adverse events associated with CT in each of these groups have been compared in Table S5.

TABLE 1 Electrophysiological Interventions with postprocedural cardiac tamponade.

	All	AF ablation	VT ablation	AFL ablation	SVT ablation	PPM	ICD	CRT-P	CRT-D	LAA	*p*-value
Number	144 810	18 611	4647	13 818	1509	45 600	33 041	5384	18 993	18 993	–
DM, *N* (%)	40 691 (28.1)	3722 (20.0)	1067 (23.0)	3570 (25.8)	313 (20.7)	12 767 (28.0)	10 301 (31.2)	1565 (29.1)	6607 (34.8)	779 (24.3)	<.0001
HTN, *N* (%)	99 370 (68.6)	11 843 (63.6)	2606 (56.1)	9387 (67.9)	869 (57.6)	34 400 (75.4)	21 959 (66.5)	3677 (68.3)	12 511 (65.9)	2118 (66.0)	<.0001
HF, *N* (%)	73 987 (51.1)	5039 (27.1)	2224 (47.9)	4583 (33.2)	508 (33.7)	17 400 (38.2)	21 569 (65.3)	4189 (77.8)	17 274 (91.0)	1201 (37.5)	<.0001
Obesity, *N* (%)	19 843 (13.7)	2991 (16.1)	636 (13.7)	2350 (17.0)	235 (15.6)	5422 (11.9)	4676 (14.2)	620 (11.5)	2435 (12.8)	478 (14.9)	<.0001
Coagulation defect, *N* (%)	1011 (0.7)	86 (0.5)	21 (0.5)	77 (0.6)	11 (0.7)	301 (0.7)	306 (0.9)	43 (0.8)	146 (0.8)	20 (0.6)	<.0001
Adverse events, *N* (%)											
Number o events	6413 (4.4)	1067 (5.7)	335 (7.2)	690 (5.0)	71 (4.7)	1560 (3.4)	1382 (4.2)	232 (4.3)	941 (5.0)	135 (4.2)	<.0001
Severe events[a]	1232 (19.2)	394 (36.9)	159 (47.5)	199 (28.8)	21 (29.6)	184 (11.8)	120 (8.7)	29 (12.5)	77 (8.2)	49 (36.3)	<.0001
In-hospital death[a]	140 (2.2)	16 (1.5)	22 (6.6)	9 (1.3)	1 (1.4)	42 (2.7)	18 (1.3)	4 (1.7)	24 (2.6)	4 (3.0)	<.0001

Note: Events: cardiac tamponade, hemopericardium, acute posthemorrhagic anemia, hemorrhage/hematoma complicating a procedure. Severe Events: in-hospital mortality or requirement for cardiac surgery (i.e., pericardiocentesis, incision of heart, cardiotomy, pericardiotomy, or pericardectomy). Numbers in red indicate <10 event number.

[a]The population of the analysis is patients who had cardiac intervention-related events.

Increasing age was the only predictor of higher mortality in the AF ablation group [OR (95% CI): 11.15 (1.70–73.34), $p = .01$] and the patients undergoing CRT [OR (95% CI): 1.41 (1.05–1.90), $p = .02$]. The presence of chronic pulmonary disease increased mortality in all device implantation procedures [OR (95% CI): PPM—2.20 (1.10–4.41), $p = .03$, ICD—3.98 (1.05–15.01), $p = 0.04$, CRT—2.06 (1.18–3.60), $p = .01$] (Table 4).

3.3 | Temporal trends in cardiac intervention related CT

The patients undergoing device implantation ($p < .0001$) had a decreasing trend, which was driven by reduced complications with PPM ($p = .02$) and ICD implantation procedures ($p < .0001$) (Figure 2A,B). Ablation procedures ($p < .0001$) were found to be increasingly associated with CT over these years, which was mainly driven by increasing CT events in the patients undergoing ablation for AF ($p = .0001$) and AFL ($p = .01$) (Figure 2A,B).

4 | DISCUSSION

Our study, to the best of our knowledge, is the first report assessing the prevalence and outcomes (morbidity and mortality) associated with CT following EP procedures, based on an analysis from a "real-world" NIS database from 2010 to 2017. It is the largest data reported in this regard with a number of important findings. First, increasing age, female sex, and presence of PVD predicted higher events in the patients undergoing AF and AFL ablations. Second, the presence of coagulation defect predicted higher events in all the patients undergoing device implantations (viz. PPM, ICD, CRT, LAAO). Fifth, female patients undergoing PPM/CRT implants had a higher number of severe events, where the presence of CVD, PVD, or diabetes appeared to be protective against these events in the patients undergoing PPM/CRT. Finally, increasing age predicted higher mortality only in the AF ablation and CRT groups.

Pericardial effusion and CT complicating the invasive cardiac procedure have previously been studied in specific subsets of patients namely postinvasive EP procedures,[14] post-AF ablation alone,[15] percutaneous coronary interventions,[16] and devices[17]). In our study, we have compiled the complications in EP interventional procedures in a large sample size (144 810 patients), including the patients undergoing LAAO. The incidence of these complications post EP procedure has been reported to be 0.6%–0.98% in recent studies,[14,18,19] which is very low compared to our findings (3.4%–7.0%). There may be several reasons for this—inclusion of patients with low comorbidities in these studies, exclusion of older age group patients, strict monitoring of anticoagulation regimen of patients enrolled in studies, and possible underreporting of the complication in routine clinical practice.

In the patients undergoing emergency procedures (device implantation or ablation), the risk of CT and the complications due to

TABLE 2 Predictors of incidence of any cardiac tamponade-related events.

(a) Ablation	AF ablation		VT ablation		AFL ablation		SVT ablation	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Age per 10 years	1.10 (1.01–1.19)	.02	1.08 (0.98–1.20)	.13	1.12 (1.02–1.23)	.02	1.22 (0.96–1.55)	.11
Female	1.46 (1.27–1.19)	<.0001	1.39 (1.05–1.85)	.02	1.35 (1.14–1.61)	.001	1.39 (0.80–2.41)	.24
Nonelective admission	1.97 (1.66–2.31)	<.0001	1.85 (1.42–2.40)	<.0001	2.12 (1.76–2.56)	<.0001	3.67 (2.01–6.67)	<.0001
Comorbidities								
Heart failure	0.66 (0.53–0.82)	<.0001	1.34 (0.93–1.949	.12	0.90 (0.71–1.14)	.38	1.09 (0.46–2.59)	.84
Cerebrovascular diseases	0.74 (0.47–1.18)	.21	1.34 (0.64–2.81)	.43	1.14 (0.73–1.76)	.57	1.87 (0.46–7.60)	.38
Chronic pulmonary disease	0.99 (0.80–1.22)	.90	1.10 (0.75–1.62)	.62	0.97 (0.76–1.24)	.83	1.36 (0.58–3.17)	.47
Peripheral vascular diseases	1.57 (1.23–2.00)	<.0001	1.22 (0.82–1.80)	.33	1.88 (1.43–2.48)	<.0001	1.24 (0.44–3.52)	.69
Liver diseases	0.67 (0.30–1.50)	.33	0.84 (0.24–2.96)	.79	1.41 (0.62–3.18)	.41	0.85 (0.09–8.20)	.89
Diabetes	1.03 (0.83–1.27)	.81	0.85 (0.58–1.25)	.40	0.92 (0.72–1.17)	.48	1.03 (0.41–2.58)	.95
Renal diseases	1.14 (0.83–1.56)	.43	1.46 (0.87–2.46)	.16	1.32 (0.94–1.84)	.11	2.21 (0.69–7.13)	.18
Hypertension	1.06 (0.91–1.23)	.45	0.97 (0.74–1.28)	.85	0.94 (0.78–1.14)	.53	0.68 (0.38–1.22)	.19
Coagulation defects	1.78 (1.31–2.41)	<.0001	1.53 (0.90–2.59)	.12	1.40 (0.97–2.01)	.07	1.78 (0.59–5.35)	.30
Obesity	1.12 (0.94–1.34)	.22	0.76 (0.51–1.14)	.19	1.05 (0.84–1.32)	.65	1.01 (0.46–2.18)	.99
(b) Implants and LAAO								
	PPM		ICD		CRT		LAAO	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Age per 10 years	1.02 (0.96–1.08)	.61	1.10 (1.04–1.15)	<.0001	1.07 (1.02–1.12)	.003	1.18 (0.91–1.54)	.21
Female	1.12 (1.00–1.25)	.047	1.29 (1.14–1.46)	<.0001	1.08 (0.99–1.18)	.10	1.39 (0.93–2.06)	.11
Nonelective admission	1.48 (1.28–1.72)	<.0001	1.51 (1.31–1.74)	<.0001	1.41 (1.27–1.57)	<.0001	2.01 (0.97–4.18)	.06
Comorbidities								
Heart failure	0.94 (0.82–1.06)	.31	0.95 (0.82–1.10)	.52	1.02 (0.92–1.14)	.67	1.06 (0.60–1.89)	.83
Cerebrovascular diseases	0.82 (0.67–1.00)	.06	0.80 (0.62–1.03)	.09	0.91 (0.77–1.07)	.26	0.45 (0.12–1.68)	.24
Chronic pulmonary disease	0.90 (0.78–1.03)	.11	0.92 (0.80–1.07)	.29	0.88 (0.79–0.98)	.03	1.00 (0.57–1.78)	.99
Peripheral vascular diseases	1.13 (0.96–1.34)	.14	1.14 (0.96–1.36)	.14	1.12 (0.98–1.27)	.10	1.31 (0.72–2.36)	.38
Liver diseases	0.92 (0.60–1.40)	.70	1.23 (0.85–1.78)	.27	1.39 (1.03–1.86)	.03	N/A	–
Diabetes	0.88 (0.77–1.01)	.07	0.80 (0.69–0.92)	.002	0.82 (0.73–0.91)	<.0001	0.70 (0.39–1.26)	.24
Renal diseases	1.05 (0.90–1.23)	.50	1.01 (0.84–1.21)	.92	1.01 (0.89–1.15)	.87	1.42 (0.69–2.92)	.34
Hypertension	0.90 (0.79–1.02)	.10	0.93 (0.81–1.06)	.25	0.93 (0.85–1.03)	.19	0.86 (0.54–1.36)	.51
Coagulation defects	1.97 (1.67–2.33)	<.0001	1.92 (1.62–2.28)	<.0001	1.86 (1.63–2.12)	<.0001	2.58 (1.27–5.27)	.009
Obesity	0.82 (0.69–0.99)	.03	0.85 (0.71–1.02)	.09	0.82 (0.71–0.95)	.007	0.94 (0.54–1.62)	.81

CT is significantly higher, which emphasizes the fact that stabilization before any such procedures would be beneficial. In cases where stabilization is not possible due to some unavoidable circumstances, the patient and the relatives need to be counselled regarding this heightened risk.

We confirm the findings from smaller studies evaluating the incidence of CT in patients undergoing device implantation where the elderly were more prone to this complication[20,21] and the trend for a higher proportion of women and higher comorbidities predicting more CT events.[20,22] The presence of PVD having higher CT events in the patients undergoing AF/AFL ablation is a new finding from our study and is likely to be related to the need for arterial access in many of these procedures and associated complications in those with significant atherosclerosis. Further evaluation in prospective studies may provide further insight. Also, the patients with obesity were protected against CT in the patients undergoing PPM and CRT. This may be related to the higher protection offered by high epicardial fat in these patients with obesity.[23]

We have also studied the complications that can occur in these patients post CT (viz. requirement for cardiac surgery [i.e., pericardiocentesis, incision of heart, cardiotomy, pericardiotomy, or pericardiectomy]). The presence of heart failure was found to be protective in the patients undergoing AF ablation procedures, as per

TABLE 3 Predictors of incidence of severe cardiac tamponade-related events.

(a) Ablation	AF ablation		VT ablation		AFL ablation		SVT ablation[a]	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Age per 10 years	1.13 (0.97–1.36)	.17	0.88 (0.70–1.11)	.29	0.79 (0.63–1.00)	.052	N/A	—
Female	1.20 (0.90–1.60)	.20	0.50 (0.26–0.96)	.04	1.71 (1.16–2.53)	.007	N/A	—
Nonelective admission	1.53 (1.09–2.15)	.01	2.06 (1.16–3.66)	.01	1.47 (0.93–2.33)	.10	N/A	—
Comorbidities								
Heart failure	0.76 (0.48–1.21)	.25	0.74 (0.35–1.53)	.41	0.41 (0.23–0.73)	.003	N/A	—
Cerebrovascular diseases	1.20 (0.48–2.99)	.69	0.82 (0.16–4.32)	.82	1.34 (0.49–3.66)	.57	N/A	—
Chronic pulmonary disease	1.13 (0.71–1.81)	.60	3.24 (1.40–7.52)	.006	1.18 (0.64–2.18)	.59	N/A	—
Peripheral vascular diseases	0.50 (0.29–0.85)	.01	0.64 (0.27–1.50)	.30	0.39 (0.19–0.81)	.01	N/A	—
Liver diseases	0.38 (0.04–3.37)	.38	4.73 (0.28–80.47)	.28	0.35 (0.03–3.67)	.39	N/A	—
Diabetes	0.91 (0.58–1.44)	.69	1.00 (0.42–2.37)	.99	1.23 (0.68–2.24)	.49	N/A	—
Renal diseases	0.81 (0.41–1.60)	.54	0.79 (0.24–2.59)	.70	0.53 (0.22–1.25)	.15	N/A	—
Hypertension	0.94 (0.69–1.28)	.69	1.33 (0.75–2.37)	.34	1.01 (0.66–1.55)	.97	N/A	—
Coagulation defects	0.72 (0.40–1.30)	.28	1.53 (0.51–4.58)	.45	0.46 (0.19–1.12)	.09	N/A	—
Obesity	0.64 (0.44–0.94)	.02	1.31 (0.52–3.30)	.56	0.92 (0.54–1.59)	.78	N/A	—

(b) Implants and LAAO	PPM		ICD		CRT		LAAO	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Age per 10 years	1.10 (0.92–1.33)	.30	0.86 (0.73–1.02)	.08	1.07 (0.93–1.24)	.33	0.97 (0.53–1.80)	.93
Female	1.57 (1.10–2.24)	.01	1.36 (0.88–2.10)	.17	1.55 (1.16–2.08)	.003	1.25 (0.49–3.18)	.63
Nonelective admission	2.81 (1.89–4.20)	<.0001	2.29 (1.44–3.65)	<.0001	2.34 (1.72–3.18)	<.0001	2.89 (0.48–17.46)	.25
Comorbidities								
Heart failure	0.74 (0.50–1.10)	.14	0.60 (0.35–1.02)	.06	0.75 (0.54–1.04)	.09	0.70 (0.19–2.59)	.59
Cerebrovascular diseases	0.37 (0.16–0.84)	.02	0.54 (0.18–1.63)	.28	0.48 (0.25–0.92)	.03	1.08 (0.09–12.82	.95
Chronic pulmonary disease	1.19 (0.79–1.80)	.41	1.13 (0.68–1.89)	.64	1.21 (0.86–1.70)	.28	0.55 (0.14–2.07)	.37
Peripheral vascular diseases	0.38 (0.19–0.76)	.006	1.05 (0.56–1.94)	.89	0.49 (0.29–0.83)	.008	0.21 (0.05–0.88)	.03
Liver diseases	0.79 (0.22–2.92)	.73	1.11 (0.34–3.67)	.86	0.62 (0.21–1.83)	.39	N/A	—
Diabetes	0.60 (0.38–0.95)	.03	0.70 (0.40–1.24)	.22	0.63 (0.43–0.92)	.02	0.78 (0.20–3.03)	.72
Renal diseases	0.86 (0.55–1.35)	.52	1.20 (0.63–2.27)	.58	0.71 (0.48–1.05)	.09	0.15 (0.02–0.95)	.04
Hypertension	1.30 (0.87–1.95)	.20	1.16 (0.71–1.91)	.55	1.35 (0.97–1.88)	.07	1.33 (0.45–3.89)	.60
Coagulation defects	0.55 (0.31–0.98)	.04	0.71 (0.38–1.35)	.30	0.80 (0.53–1.29)	.31	0.16 (0.02–1.25)	.08
Obesity	0.76 (0.40–1.44)	.39	1.36 (0.75–2.48)	.31	1.17 (0.73–1.88)	.51	2.37 (0.58–9.73)	.23

[a]Due to few number of patients with severe cardiac tamponade-related events, the values cannot be estimated.

our results. This may be attributable to—the intensive care carried out in the periprocedural period in the form of adequate diuretic usage, meticulous fluid and anticoagulation management, and regular use of general anesthesia in all these patients. More severe events in female patients undergoing PPM/CRT implants, and higher in-hospital mortality in the AF ablation/CRT group are unique finding from our study. Higher mortality in AF ablation group at higher age may be related to the frailty in this patient population which puts them at a higher risk of complications. This fact should be kept into consideration and should be explained to the relatives at the time of the procedure in the elderly population. We also found that the patients with diabetes required a significantly lower interventions for CT. Most of the device implantation procedures are elective, so it is possible to control blood sugar levels before taking up the patients for the procedures.

The presence of coagulation defect has been found to be associated with higher events and mortality in the patients undergoing device implantations in this real-world study. The study by Fink et al. showed higher CT events in the patients with higher baseline activated clotting time (ACT).[14] Earlier analyses have also

TABLE 4 Predictors of incidence of cardiac tamponade events-related death.

(a) Ablation	AF ablation		VT ablation		AFL ablation[a]		SVT ablation[a]	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Age per 10 years	11.15 (1.70–73.34)	.01	0.73 (0.40–1.33)	.31	N/A	—	N/A	—
Female	0.80 (0.10–6.69)	.84	0.37 (0.05–2.71)	.33	N/A	—	N/A	—
Nonelective admission	0.01 (0.01–1.15)	.07	0.07 (0.007–0.75)	.03	N/A	—	N/A	—
Comorbidities								
Heart failure	2.21 (0.18–27.47)	.54	5.45 (0.55–54.27)	.15	N/A	—	N/A	—
Cerebrovascular diseases	N/A	—	0.10 (0.002–5.66)	.27	N/A	—	N/A	—
Chronic pulmonary disease	21.64 (1.23–380.05)	.04	5.40 (0.72–40.26)	.10	N/A	—	N/A	—
Peripheral vascular diseases	0.33 (0.02–6.77)	.47	5.78 (0.77–43.47)	.09	N/A	—	N/A	—
Liver diseases	N/A	—	2.09 (0.03–139.85)	.73	N/A	—	N/A	—
Diabetes	0.08 (0.001–6.22)	.26	0.29 (0.04–2.16)	.23	N/A	—	N/A	—
Renal diseases	0.05 (0.0005–4.62)	.20	0.36 (0.0–3.75)	.39	N/A	—	N/A	—
Hypertension	1.70 (0.20–14.28)	.63	0.24 (0.04–1.45)	.12	N/A	—	N/A	—
Coagulation defects	1.83 (0.15–22.15)	.63	1.53 (0.08–30.07)	.78	N/A	—	N/A	—
Obesity	3.00 (0.24–37.64)	.39	0.60 (0.07–5.36)	.65	N/A	—	N/A	—

(b) Implants and LAAO	PPM		ICD		CRT		LAAO[a]	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Age per 10 years	1.49 (0.99–2.25)	.06	0.73 (0.46–1.15)	.17	1.41 (1.05–1.90)	.02	N/A	—
Female	1.04 (0.53–2.02)	.92	1.21 (0.38–3.93)	.75	1.09 (0.63–1.88)	.75	N/A	—
Nonelective admission	0.97 (0.35–2.65)	.95	0.98 (0.23–4.24)	.98	0.82 (0.41–1.64)	.58	N/A	—
Comorbidities								
Heart failure	1.39 (0.66–2.93)	.39	0.41 (0.01–1.73)	.23	1.31 (0.69–2.51)	.41	N/A	—
Cerebrovascular diseases	0.64 (0.17–2.33)	.50	1.48 (0.12–18.93)	.76	0.61 (0.21–1.79)	.37	N/A	—
Chronic pulmonary disease	2.20 (1.10–4.41)	.03	3.98 (1.05–15.01)	.04	2.06 (1.18–3.60)	.01	N/A	—
Peripheral vascular diseases	0.25 (0.06–1.13)	.07	0.34 (0.04–3.16)	.34	0.45 (0.17–1.18)	.10	N/A	—
Liver diseases	0.69 (0.07–6.84)	.75	3.41 (0.23–50.32)	.37	0.36 (0.04–2.93)	.34	N/A	—
Diabetes	0.72 (0.32–1.62)	.42	0.40 (0.07–2.16)	.29	0.60 (0.31–1.18)	.14	N/A	—
Renal diseases	1.26 (0.59–2.68)	.55	16.30 (2.60–102.29)	.003	0.86 (0.45–1.64)	.65	N/A	—
Hypertension	1.14 (0.52–2.51)	.75	1.03 (0.26–4.07)	.96	1.05 (0.57–1.92)	.88	N/A	—
Coagulation defects	1.57 (0.69–3.58)	.28	2.20 (0.59–8.15)	.24	1.98 (1.07–3.67)	.03	N/A	—
Obesity	0.62 (0.17–2.28)	.47	2.28 (0.50–10.35)	.29	0.68 (0.23–1.96)	.47	N/A	—

[a]Due to few number of patients with in-hospital death, the values cannot be estimated.

shown that CT was found to be higher in the patients undergoing cardiac interventional procedures on periprocedural anticoagulation.[5,24] A closer look into these studies evaluating the association between anticoagulation and CT has found that the proportion of milder cases of pericardial effusion was similar, but larger effusions were higher with excessive anticoagulation.[25,26] It was considered that the excessively anticoagulated patients (more than therapeutic) were more prone to large effusions,[26] thus highlighting the importance of meticulous management of periprocedural anticoagulation.

The trend of CT-related complications has been shown to be increasing over the years in EP procedures in several previous studies.[18,20,22,27,28] This may be explained by more complex procedures being done in recent times in EP-related interventions and an increased number of older people undergoing the procedures. In contrast, our study shows that in the real-world setting, the complications have been on a decreasing trend in the patients undergoing PPM/ICD implantation, and it was more or less constant in CRT groups, from 2010 to 2017. This may be due to the improvement in the skill set of the operators and hardware used for the procedures. Although

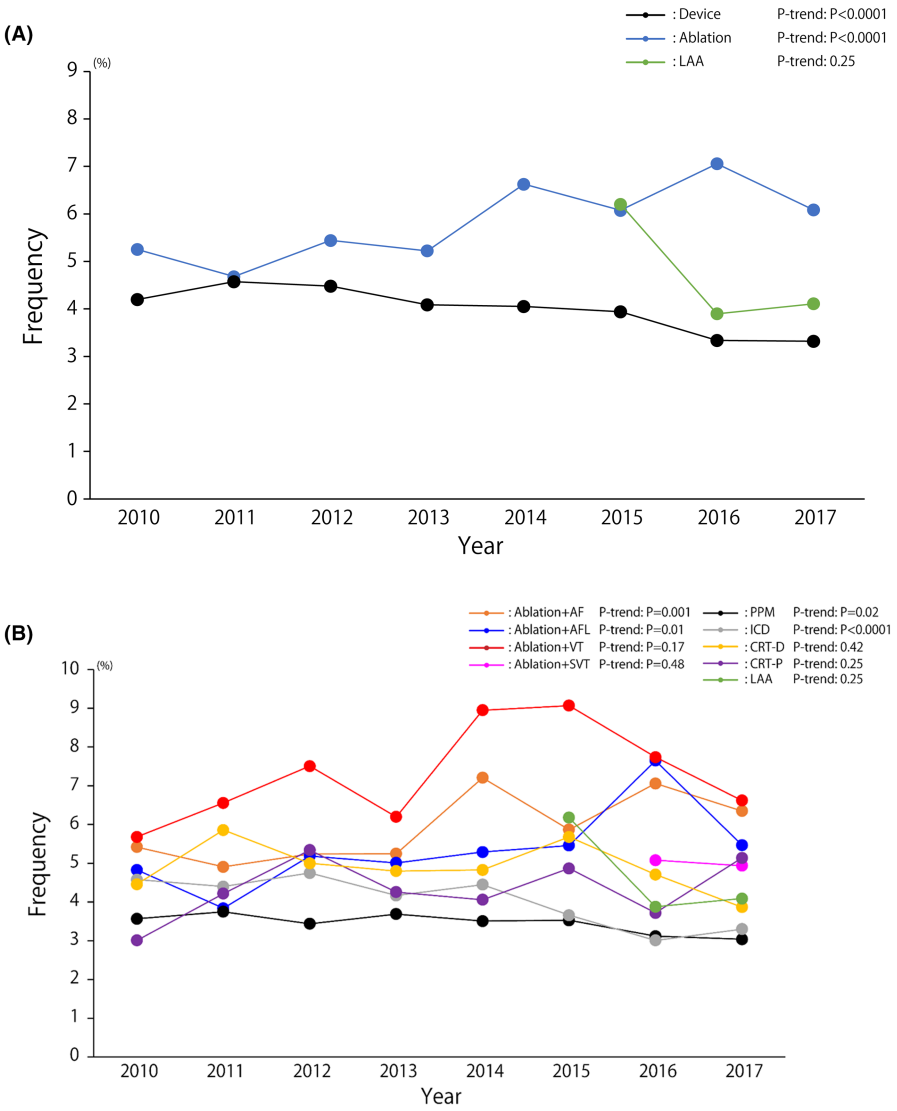

FIGURE 2 Temporal trends of cardiac intervention-related events in the patients who underwent coronary or electrophysiological interventions. (A) Trends of cardiac intervention-related cardiac events in the patients undergoing electrophysiological procedures. (B) Trends of cardiac intervention related cardiac events in the groups stratified by types of electrophysiological procedures. Events: cardiac tamponade, hemopericardium, acute posthemorrhagic anemia, hemorrhage/hematoma complicating a procedure. AF, atrial fibrillation; AFL, atrial flutter; CRT-D, cardiac resynchronization therapy-defibrillator; CRT-P, cardiac resynchronization therapy-pacemaker; EP, electrophysiological procedure; ICD, implantable cardioverter defibrillator; LAA, left atrial appendage; PPM, pacemaker; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

ablation procedures showed an increasing trend over the years, driven by AF/AFL ablation-related CT, similar to the study by Hamaya et al.[18]

The mortality attributable to CT ranged from 0% to 4% in EP procedures.[14,15,18,19] In our study, we found similar mortality rates (2.2% in EP procedures).

We recognize there are some limitations to this study. The effect of procedural characteristics in EP procedures was difficult to evaluate since the data in the NIS database does not contain these details, for example, use of transseptal access during the procedure, the hardware used during the procedure, etc. Laboratory data such as platelet count, prothrombin time, or international normalized ratio were unclear. Also, although the presence of comorbidities (e.g., heart failure, renal failure, liver diseases, etc.) was available the NIS data does not provide sufficient granularity to define the severity of these conditions.

5 | CONCLUSION

In the real-world setting, CT-related events in EP procedures were found to be 3.4%–7.0% and were found to be higher with the increasing complexity of the interventions. Of those developing CT, the mortality was found to be 2.2% for EP procedures. Older patients undergoing AF ablation were found to be having higher mortality.

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CONFLICT OF INTEREST STATEMENT

Authors declare no conflict of interests for this article.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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