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Incidence, predictors and outcomes of hematoma after ICD implantation: An analysis of a nationwide database of 85,276 patients

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ABSTRACT

Background: Pocket hematoma is one of the most common complications following cardiac device implantation. This study examined the impact of this complication on in-hospital outcomes following Implantable Cardioverter Defibrillator (ICD) implantation.

Methods: Data from Nationwide Inpatient Sample (NIS) 2010 was queried to identify all primary implantations of ICDs and Cardiac Resynchronization Therapy Defibrillators (CRT-D) during the year 2010 using ICD-9 codes. We then identified the patients who experienced a procedure related hematoma during the hospital stay. We compared the outcomes of the patients with and without a hematoma complication. All analyses were performed using SPSS 20 complex samples using appropriate weights to adjust for the complex sampling design of the national database.

Results: Out of a total of 85,276 primary ICD implantations in the year 2010, 2233 (2.6% of the implantations) were complicated by a hematoma. Increased age ($p < 0.001$), and comorbidities such as congestive heart failure (odds ratio (OR) − 1.86, $p < 0.001$), coagulopathy (OR - 2.3, $p < 0.001$) and renal failure (OR - 1.52, $p < 0.001$) were associated with an increased risk of pocket hematoma formation. Patients who developed a hematoma had a longer hospitalization (9.1 days versus 5.5 days, $p < 0.001$) and higher in-hospital costs ($56,545 versus $47,015, $p < 0.001$) compared to patients who did not have a hematoma. Overall mortality associated with ICD implantation was low (0.6%), and hematoma formation did not adversely affect mortality (0.6% versus 0.4%, $p = 0.63$).

Conclusion: Hematoma occurs infrequently after ICD implantation, however, it adversely impacts the cost of procedure and length of stay.

1. Introduction

Implantable Cardioverter defibrillator (ICD) devices are widely used for preventing sudden cardiac death. The first ICD was implanted in the year 1980 and subsequently randomized clinical trials have established the role of ICD's in both primary and secondary prevention of sudden cardiac death [1–4]. The use of the cardiac devices has significantly increased in the recent years; between 2006 and 2010, around 367,153 ICD devices were implanted across the country [5].

Implantation of these devices is associated with minor and major complications. Minor peri-procedural complications include pocket hematomas, lead dislodgement, conduction block and

Abbreviations: ICD, Implantable Cardioverter Defibrillator; CRT-D, Cardiac Resynchronization Therapy- Defibrillators; NIS, Nationwide Inpatient Sample.

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phlebitis [6]. Major peri-procedural complications include hemothorax, pneumothorax, cardiac perforation, device infection, myocardial infarction, stroke, valve damage, pericardial effusion, arterio-venous fistula and cardiac arrest [6]. The peri-procedural adverse events were estimated to be 3.6%, of which pocket hematomas and lead dislodgement were the most commonly observed adverse events [6]. These complications have been shown to result in prolongation of hospital stay and increased mortality [6]. The nationwide incidence of pocket hematomas; predictors of hematoma formation and its impact on mortality, length of hospital stay and utilization not been systematically studied before for ICD devices.

2. Methods

2.1. Data source

We used the discharge data from the Nationwide Inpatient Sample (NIS) database for the year 2010 to identify all the patients who underwent an ICD implantation during their hospital stay. The NIS database is developed by the Agency for Healthcare Research and Quality (AHRQ) as part of the Healthcare Cost and Utilization Project (HCUP) [7,8]. NIS is the largest available inpatient database in the United States and it contains a 20% stratified sample of all the discharges from nonfederal short-term general hospitals, subspecialty hospitals and public hospitals [7]. The sample is stratified based on the number of beds, ownership, hospital teaching status, region, and state [7]. This database accounts for 90% of all the hospitalizations and the stratification method ensures that the sample is truly representative of the United States population in general [7]. National estimates can be obtained using appropriate discharge weight assigned to each record [7]. This database contains demographic information and can include a maximum of 15 diagnostic and procedure codes based on the International Classification of Diseases 9th revision, Clinical Modification (ICD-9-CM) and outcomes based on patient discharge records [7]. The data includes hospital characteristics such as geographic location, bedsize, teaching status and also outcome variables such as length of stay, cost of hospitalization, and in hospital mortality for each hospitalization. Each record is for a single hospitalization and thus multiple records are possible for an individual with recurrent hospitalizations.

2.2. Study population

NIS database for the year 2010 was analyzed to identify all the patients who underwent an ICD implantation during their hospital stay. Patients who underwent implantation of Implantable Cardioverter Defibrillator (ICD) or CRT-D were identified using the appropriate ICD-9 codes (ICD- 3794; CRT-0051) in the discharge records; and were included in the study. We included only denovo implantation of the devices, and did not include generator changes, redo, revisions etc. Since there is no universal defining ICD-9 code for ICD hematoma formation, we did our best to identify the ICD-9 codes which are most consistent with hematoma formation and used them in the setting of a preselected population of denovo ICD device implantation. (99,811–99813 - Hemorrhage or hematoma or seroma complicating a procedure). The study group was then categorized into patients with and without hematomas. Different demographic, clinical and hospital characteristics of the individual discharge records were then delineated and compared between the patients with and without a pocket hematoma complication. Clinical comorbidities of the patients receiving ICD implant were identified through comorbidity measures derived from the AHRQ comorbidity software [8](Supplementary File 1 for ICD 9 codes for different clinical co-morbidities). In hospital outcomes including length of stay, mortality and hospital charges were also compared between the two groups.

2.3. Data analysis

Statistical analysis was carried out using SPSS complex samples software (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). National estimates were projected after applying appropriate hospital and discharge level weights to NIS sample for the year 2010. Categorical variables are represented as n (%) and continuous variables are represented as mean ± SD. The differences in the two groups with and without pocket hematomas were compared using chi-square or *t*-test as and when appropriate. Regression analysis was then carried out to determine the factors favoring pocket hematoma formation. Factors that significantly favored hematoma formation on univariate regression were then included in the multivariate regression. A p value of less than 0.05 was considered statistically significant.

3. Results

During the year 2010, a total of 85,276 patients underwent a denovo ICD implantation across the nation. These patients formed our study population. Of these 50,041 were ICD implantations and 35,235 were CRT-D.

3.1. Baseline characteristics

Mean age our study population was 65.8 years and 30% of the patients were >75 years of age. The study population was predominantly male (71.9%). When implantation were stratified by race, we note that Caucasians constituted for the majority of device implantation (62%), followed by African Americans (14.3%) and 1other ethnic group (10.6%). Higher number of ICD implantations were performed in teaching hospitals (60%) compared to non-teaching hospitals (40%).

3.2. Incidence and predictors of hematoma formation

A total of 2232 (2.7%) ICD implantations were complicated by pocket hematomas. There was no difference in the rates of hematoma formation in ICD versus CRT-D implantations (2.5% versus 2.9%, $p = 0.18$).

3.2.1. Demographics

Hematomas formed more frequently in higher age groups (Table 1, p value for trend <0.001 by ordinal regression). There was no difference in hematoma formation between the two gender groups (2.5% versus 2.9%, $p = 0.2$). When stratified by racial categories, African Americans (3.0%) had a slightly higher occurrence of pocket hematomas compared to Caucasians (2.7%) and others (2.9%), however this difference was not statistically different ($p = 0.83$).

3.2.2. Hospital type

Urban hospitals tended to have a higher incidence of hematomas than rural hospitals (2.7% versus 1.9%, $p = 0.18$), however, only 5.4% of the ICD implantations were performed in the rural hospitals. The teaching status didn't affect the hematoma formation significantly; teaching (2.3%) versus non-teaching hospitals (2.8%), $p = 0.11$. We stratified hospitals based on their volume of device implantations into four quartiles and we didn't find any significant difference in the incidence of hematoma across these four quartiles ($p = 0.21$).

3.2.3. Clinical comorbidities

Univariate analysis showed that congestive heart failure (OR 1.86, $p < 0.001$), coagulopathy (OR 2.3, $p < 0.001$), renal failure (OR 1.52, $p < 0.001$) and peripheral vascular disease (OR 1.4, $p = 0.01$) were strongly associated with increased risk of hematoma formation (Table 2).

3.2.4. Multivariate analysis

Multivariate analysis of all the appropriate demographic and clinical variables showed that Age ($p < 0.001$), congestive heart failure ($p = 0.02$), coagulopathy ($p < 0.001$) and renal failure (0.05) were the independent predictors of hematoma formation following ICD implantation.

3.3. Impact of hematoma formation on in-hospital outcomes

3.3.1. Length of stay

Overall mean length of stay associated with ICD device implantation was noted to be 5.56 days. The mean duration of hospital stay in patients with post procedural hematomas was significantly higher than those without hematomas; 9.1 versus 5.5 days ($p < 0.001$) (Fig. 1).

3.3.2. Cost of hospitalization

Overall mean cost of implantation was $47,257. Hospitalization costs were significantly increased in patients who developed hematomas; $56,545 compared to $47, 015 in patients without a hematoma ($p < 0.001$) (Fig. 1).

3.3.3. In-hospital mortality

The overall mortality in patients who underwent ICD implantation peri-procedurally was 0.6%. The overall mortality rate was not significantly impacted by hematoma complication (0.6% versus 0.4%, $p = 0.63$, Fig. 1).

4. Discussion

Main findings: Our study is the first investigation into the national incidence of post procedure hematoma after ICD implantation, predictors of this complication and its impact on in-hospital outcomes. To summarize the important findings of our study: ICD implantations are associated with a low rate of hematoma formation (2.6%). Hematoma formation does not adversely impact mortality, however, it significantly increases hospital length of stay (by 3.6 days) and cost of hospitalization (by 21%). Age, heart failure, pre-existing coagulopathy and renal failure significantly increase the risk of hematoma formation after ICD implantation.

Pocket hematoma is one of the most common peri-procedural complications associated with cardiac device implantations [6]. A few studies have reported the incidence of pocket hematomas after cardiac device implantations to be in the range of 1–5% [6,9,10]. Pocket hematomas in ICD implantations on a nationwide basis was reported by Peterson et al. in their study based on National Cardiovascular Data Registry (NCDR) ICD Registry [6]. In their study the incidence of pocket hematomas were seen in 1% of patients undergoing ICD implantation [6]. The higher rate of hematomas in our study is likely due to sampling differences between the NCDR and the NIS databases. The NCDR ICD database collects information on ICD implantation from hospitals reporting to NCDR, while the NIS database includes a nationwide stratified sample from discharge charts [7,11]. Therefore the NIS database is more likely to provide the best estimates for the general population.

Elderly patients appear to be at increased risk for hematoma formation. There was increase in the number of hematomas seen in patients >75 years and the highest risk was seen in patients >85 years [12]. The elderly patients therefore need to be observed closely for these complications because of the overall higher adverse events and in hospital mortality associated with ICD implantations in this age group [12]. Elderly individuals have loose subcutaneous tissues and poor muscle tone and this may likely contribute to pooling of blood around the device in these individuals. Hematoma formation was found to be similar in both the genders in our study. Peterson et al. in their study did not observe a difference in hematomas in the two genders [6]. These findings were further validated in a prospective study and thus gender does not affect hematoma formation in patients undergoing cardiac device implantation [13]. However, elderly females were at an increased risk of periprocedural complication and in-hospital mortality [12].

Congestive heart failure was strongly associated with increased risk for pocket hematomas in our study (OR 2). In an earlier study, congestive heart failure was not associated with increased risk of pocket hematomas [14]. Patients with congestive heart failure are likely to have other comorbidities. Additionally, congestive heart failure patients with comorbidities such as atrial fibrillation may require them to be on long-term anticoagulants. The above two reasons are the likely explanation for our findings. Renal failure increases the risk of hematoma and other complications in patients with cardiac devices [13]. In our study, renal failure increased the risk of pocket hematomas by 60%. Renal dysfunction has been shown to increase the risk of bleeding complications in patients undergoing cardiac procedures and is thought to be mainly due to platelet dysfunction from uremia [15–17]. Therefore patients with congestive heart failure and renal failure may need closer monitoring after the ICD implantation.

Coagulation abnormalities obviously increase the risk of bleeding complications such as pocket hematomas. Additionally, several patients undergoing ICD implantations have other indications for anticoagulation by means of antiplatelet agents or oral anticoagulants. Various studies estimate that nearly 14–35% of the patients who need cardiac devices are on long-term oral anticoagulation [3,18–21]. Device implantation in these patients

Table 1
Demographics, hospital and admission type.

	No Hematoma	Hematoma	P value
Demographic variables			
Sex			
Male	59,748 (97.4%)	1565 (2.6%)	0.19
Female	23,244 (97%)	708 (3.0%)	
Age			
0–17	498 (99.0%)	–	0.001 (p trend)
18–44	5631 (98.5%)	83 (1.5%)	
45–64	28,040 (97.6%)	698 (2.4%)	
65–4	23,964 (97.5%)	604 (2.5%)	
>75	24864 996.0%)	883 (3.4%)	
Race			
Caucasian	51,452 (97.2%)	1455 (2.8%)	0.04
African American	118,144 (96.9%)	376 (3.1%)	
Others	8752 (97.1%)	265 (2.9%)	
Hospital Type			
Location			
Urban	4550 (98%)	93 (2%)	0.2
Rural	77,663 (97.3%)	2152 (2.7%)	
Teaching Status			
Non-teaching	33,025 (97.6%)	810 (2.4%)	0.17
Teaching	49,186 (97.2%)	1434 (2.8%)	
Admission Type			
Non Elective	50,503 (97.2%)	1446 (2.8%)	0.2
Elective	32,220 (97.5%)	818 (2.5%)	
Device Type			
AICD	48,778 (97.5)	1263 (2.5%)	0.18
CRT-D	34,226 (97.1)	1010 (2.9%)	

Table 2
Clinical characteristics.

Comorbidity[a]	Odds ratio for hematoma formation	P value
Rheumatoid arthritis/Collagen vascular diseases	1.4	0.35
Congestive heart failure	2.03	<0.001
Pulmonary disease	0.863	0.221
Coagulopathy	2.3	<0.001
Hypertension	0.957	0.67
Diabetes mellitus	0.86	0.123
Liver disease	1.4	0.359
Renal failure	1.6	<0.001
Peripheral vascular disease	1.4	0.01

Impact of different clinical comorbidities on hematoma formation following pacemaker implantation.
[a] Variables are AHRQ co-morbidity measures.

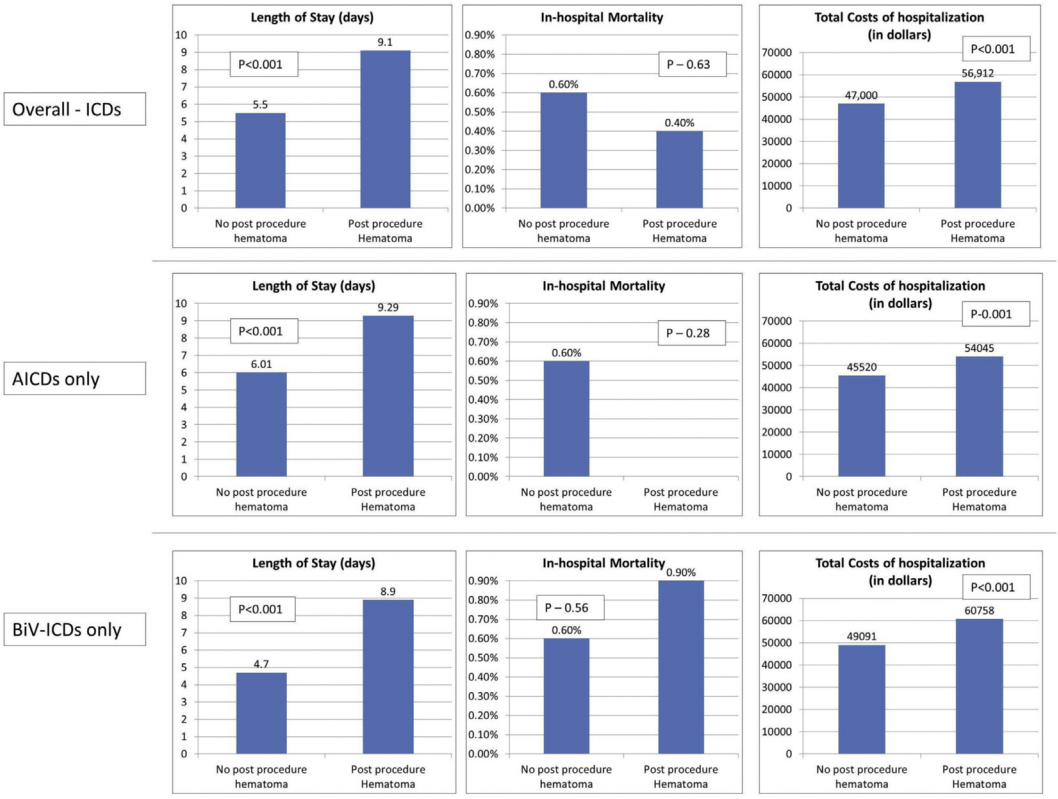

Fig. 1. Impact of Hematomas on length of stay, mortality and utilization costs.

automatically increases the risk of hematoma formation. Current guidelines recommend that patients be bridged to heparin peri-procedurally to decrease the risk of hematomas [22]. However, with this approach the risk of hematomas was still high [23–26]. A few studies have shown that ICD implantation without bridging with heparin decreased the risk of pocket hematomas [27,28]. BRUISE CONTROL a multicenter randomized clinical trial has observed that bleeding complications are higher with heparin bridging strategy compared to continued oral anticoagulation (16% vs 3.5%, $p < 0.001$) [21]. Few studies have suggested increase in hematoma formation with antiplatelet agents [14,29]. Other studies disagree with this evidence and suggest that this risk does not increase with antiplatelet agents [30,31]. Dual antiplatelet agents and periprocedural heparin increase the risk for pocket hematomas [32]. Our study was limited by the non-availability of drug history in the NIS database and therefore we could not differentiate the pocket hematomas based on intake of anticoagulant drugs.

Pocket hematomas could be benign or lead to further complications based on the size and other comorbidities. Minor consequences include discomfort and swelling. Major complications include infection of the hematoma, cardiac device infection and interventions (evacuation of the hematoma, blood transfusion, pocket revision or extraction and re-implantation of the device). Any or all of these will result in increased length of stay as well as increased costs. In our study, the mean cost of hospitalization increased by 21% following pocket hematomas. The incremental cost from hematomas as observed in another study was $7000 [33]. The mean length of stays increased by 3.6 days in our study. In an earlier study the length of stay following hematoma or bleeding complication increased by 2–3 days [14,33]. The length of stay in our study is higher compared to other studies, however, the possibility of additional complications (related and unrelated) cannot be ruled out.

In-hospital mortality from ICD hospitalization was estimated to be about 0.4–1% [6,33]. The mortality rates estimated in our study are similar to other studies. Mortality could be due to complications of pocket hematomas such as infection or additional interventional procedures needed to relieve the hematoma. It also has to be remembered that patients undergoing ICD implantation have severe heart failure and infections in these patients are likely to result in higher mortality.

Limitations

There are several limitations to our study. Firstly, our study database is an administrative database gathered from discharge records across the United States. We are therefore limited in terms of the variables that are contained in this database. Unavailability of clinical characteristics, medication history, severity of hematomas and the follow up tests and interventions done in these patients limits our understanding of the etiology and prognosis of these hematomas. Secondly, the documentation and coding errors that could occur during the individuals hospitalization could lead to erroneous results when using the NIS database [34]. Thirdly, the patients could have hematoma formation after the discharge from the hospital and these events are not included in the database for the individual's discharge and therefore are likely to be missed. Fourthly, the patients could have hematomas unrelated to the ICD implantation such as trauma from chest compressions, but could have been included in the database because these events occurred during the same hospitalization. Fifthly, the HCUP database does not include information on procedures which are done on outpatient basis that might have lesser complications. Lastly, the patients could have other adverse events that may have affected the length of hospital stay and therefore resulted in higher utilization costs. All the above factors could affect the results of our study.

5. Conclusions

Pocket hematomas following ICD implantation are infrequent and are not associated with significant increase in mortality. Elderly, congestive heart failure, renal failure and patients with coagulopathy are at higher risk of developing these pocket hematomas. Hematoma formation following cardiac device implantation prolongs the hospital stay significantly and is associated with increased utilization costs.

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The authors report no relationships that could be construed as a conflict of interest.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ipej.2016.10.005.

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