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Bleeding Risks for Patients on Chronic Anticoagulation Undergoing Cardiac Im-Plantable Electronic Device (CIED) Lead Extraction

Megan Borchers[1]
Melissa J. Snider[1*]
Michael Boyd[1]
Diana Vinh[1]
Mahmoud Houmsse[1]

[1]*The Ohio State University Wexner Medical Center 452 West 10th Ave Columbus, OH 43210*

Abstract

Background: About 40% of patients undergoing a Cardiac Implantable Electronic Device (CIED) lead extraction procedure is on chronic anticoagulation (AC). Previous literature has identified patients on chronic AC may be at a higher risk of adverse events. However, no literature reports the potential risk during hospitalization, the risk of bridge therapy, or the risk of using Direct Oral Anticoagulants (DOACs).

Objective: The purpose of this study was to assess in-hospital adverse events and readmission rates for patients on various chronic AC strategies (e.g. vitamin K antagonists (VKA), DOAC, and bridge therapy) versus those not on chronic anticoagulation.

Methods: This is a single-centre, retrospective, exploratory study of patients who underwent CIED lead extraction from January 1, 2012 to September 30, 2017. 1176 patient underwent this procedure during the study period with 41% on chronic anticoagulation. The most common device lead extraction was ICD (55%).

Results: There was no statistically significant difference in adverse events between those patients on chronic AC versus those not on chronic AC (OR 0.90, 95% CI 0.52 – 1.53, P = 0.85). In addition, there was no statistically significant difference between type of AC strategy (VKA with or without bridge therapy versus DOAC therapy) (P = 0.97).

Conclusion: This study shows that patients on chronic AC may not be at a higher risk of in-hospital adverse events compared to those not on chronic AC.

Keywords: Lead Extraction; Anticoagulation; Cardiac Implantable Electronic Device; Pacemaker; Implantable Cardioverter Defibrillators; Vitamin K Antagonists; Direct Oral Anticoagulants; Bridge Therapy

Introduction

As the number of patients obtaining a Cardiac Implantable Electronic Device (CIED) continues to increase, the number of patients having to undergo lead extraction also continues to rise. A survey completed in 2009 estimated 1.25 million pacemakers (PPM) and 410,000 Implantable Cardioverter Defibrillators (ICD) were placed worldwide compared to an estimated 550,000 PPMs and 1,500 ICDs in 2005 [1]. Of the patients undergoing lead extractions, about 40% are on long-term oral anticoagulation [2]. The CIED lead extraction procedure is considered a high-bleeding risk due to the chance of tearing the surrounding blood vessels or perforating the heart [3,4,5]. Therefore, according the 2012 American College of Chest Physician perioperative

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[*]**Corresponding Author:** Dr. Melissa J. Snider, The Ohio State University Wexner Medical Center 452 West 10th Ave Columbus, OH 43210. Telephone: (937) 903-8482; Fax: 614-293-8260; Email: mgnborchers(at)gmail.com

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guidelines, patients on vitamin K antagonist (VKA) therapy at high risk for thrombosis should be bridged with parental agents (i.e. Low-Molecular Weight Heparin (LMWH), Unfractionated Heparin (UFH)), while those with low risk of thrombosis, anticoagulation should be held for the procedure [6]. Literature suggests bridge therapy leads to a higher bleeding risk than uninterrupted anticoagulation in CIED implantation without showing a difference in embolic risk [3,8]. However, no literature reports the risks versus benefits of bridge therapy surrounding lead extractions. Literature does suggest that patients on chronic anticoagulation (AC) undergoing lead extraction have higher risk for adverse events.2,9 In 2014, Brunner M, et al. evaluated over 5000 extractions and found significant multivariable predictors of major complications including INR ≥ 1.2 [OR 2.7, 95% CI 1.2-5.7, P=0.012] [9]. Additionally, Regoli et al. suggest chronic oral AC as an independent risk factor for any adverse event [HR 2.09, 95% CI 1.35-3.22, P=0.001] and system-related adverse event [HR 2.38, 95% CI 1.21-4.68, P=0.012] after CIED lead extractions [2]. For patients with atrial fibrillation on chronic AC using direct oral anticoagulants (DOACs), a consensus statement from the Journal of American College of Cardiology recommends interrupting therapy based on the patient's renal function.7 No study has compared lead extraction adverse events for patients on various chronic AC strategies including VKA, DOAC, and bridge therapy versus those not on chronic AC. This study will address in- hospital adverse events and readmission rates in these two groups.

Study Design

We conducted a retrospective, exploratory study at a high-volume lead extraction centre. We enrolled 1176 patients who underwent CIED lead extraction from January 1, 2012 to September 30, 2017. Patients were divided into two groups. Group 1 included all patients on chronic AC (n=477). Chronic AC was determined if the patient obtained VKA or DOAC during hospitalization or found to be on other chronic AC (LMWH) after complete chart review for patients with an adverse event. It is assumed most of the patients that obtained VKA and DOAC within the hospitalization have been on these agents chronically. Group 2 (n=699) included all patients that are not on chronic AC. All patients with an adverse outcome or readmission underwent a complete chart review to determine the anticoagulation strategy utilized. The study has been approved by The Ohio State University Institutional Review Board (IRB).

Study Procedure

Per the Ohio State Wexner Medical Centre Electrophysiology Procedural Guidelines in collaboration with a pharmacy-based anticoagulation clinic, patients on VKA, held the VKA for 2-3 days to achieve an INR < 1.7. Of those in the VKA with bridge group, they followed the same protocol as those in the without bridge group except were given either a LMWH or UFH until the procedure as well as after depending on patients' bleeding and embolic risk. Finally, for patients in DOAC group, the DOAC was held for two days or was adjusted based on renal function per the 2017 ACC Expert Consensus Decision Pathway [10].

Outcomes

The primary outcome is the composite adverse events for patients in Group 1 and Group 2 who underwent a lead extraction procedure. Adverse events and readmissions included any reported adverse outcome to The Ohio State Wexner Medical Centre Electrophysiology Outcomes Database. The secondary outcomes include the individual components of the adverse events for patients in Group 1 and 2, a comparison between each AC strategy in Group 1 for patients with the composite adverse events, the composite of reasons for readmission for patients in Group 1 and 2, and the individual components of reasons for readmission.

Statistical Analysis

The primary analysis was analysed using descriptive analysis as well as chi-squared analysis and all secondary outcomes were described with descriptive analysis, chi-squared analysis, Fisher's exact two- sided test as well as a multivariate analysis with statistical significance set at 0.05.

Results

There were 1176 patients included in the study, 477 in Group 1 and 699 in Group 2. There were 250 (52.4%) ICDs in Group 1 and 400 (57.2%) ICDs in Group 2. There was 69.4% male in Group 1 and 65.2% in Group 2. Patients in the Group 1 cohort were older (mean, 65.6 versus 60.7, P < 0.001). Group 1 had a higher INR (1.4 versus 1.1, P < 0.001), lower haemoglobin (12.1 versus 12.6, P < 0.001), lower haematocrit (36.6 versus 38.1, P < 0.001), and worse renal function (48% with GFR <60 mL/min/1.73m2 versus 38%, P = 0.0015). Table 1 summarizes the baseline characteristics for these 2 groups. There were 68 out of 1176 (5.8%) patients with a reported adverse event in both groups. There was no statistically significant difference in the primary outcome. There were twenty-six patients (5.5%) in Group 1 and 42 patients (6.0%) in Group 2 (odds ratio (OR) 0.90, 95% confidence interval (CI) 0.52 - 1.53, P = 0.85) [Figure 1]. There was no statistical significance between the two groups regarding the individual adverse events of the primary outcome. The most commonly reported individual adverse events of the primary outcome in both groups were: newly implanted lead dislodgement post extraction (34%), tamponade (15%), and bleeding at the chest site (10%) [Table 2]. There were three deaths recorded, one in Group 1 and two in Group 2.

There was no statistical difference in composite adverse events in the patients in Group 1 regardless of the AC strategy. The adverse event rates between patients on VKA or DOAC as well as with or without bridge therapy (P = 0.97) [Figure 2]. Nineteen readmissions were reported, four patients (1.0%) in Group 1 and 15 patients (2.0%) in Group 2 (OR 0.39, 95% CI 0.09 - 1.24; P = 0.14). The three most commonly reported reasons for readmissions

where: infection related to device (26%), acute heart failure (26%), and newly implanted lead dislodgement post extraction (16%) [Table 3].

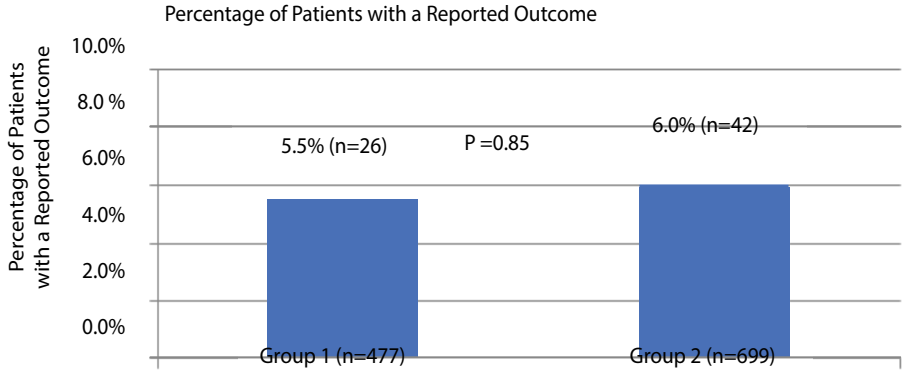

Figure 1: Primary Outcome - Patient with a Reported Outcome During Hospitalization

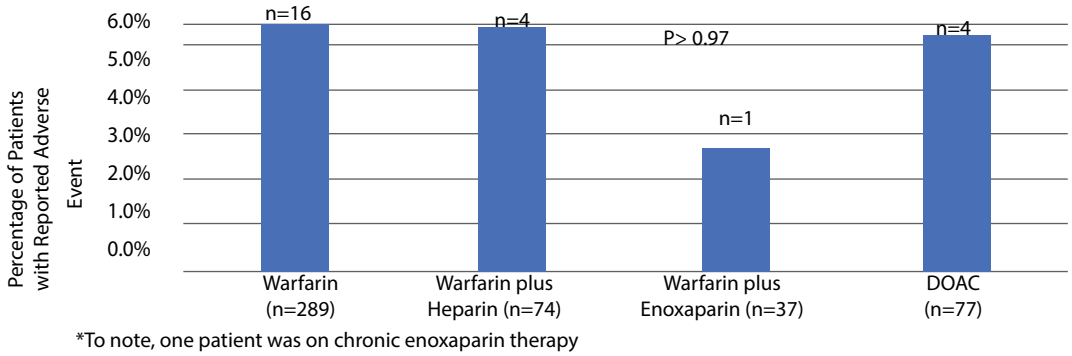

Figure 2: Anticoagulation Strategies for Patients with Reported Adverse Event in Group 1.

Table 1: Baseline Characteristics of patients stratified by patient's on chronic AC versus those not on chronic AC during hospitalization during lead extraction

Characteristic	Group 1 (n=477)	Group 2 (n=699)	P value
Age, year [mean (sd)]	65.6 (13.5)	60.7 (15.5)	<0.001
Male [n (%)]	331 (69.4%)	456 (65.2%)	0.15
White [n (%)]	424 (88.9%)	621 (88.8%)	0.16
Mean Body Mass Index (BMI), lbs/in^2 [mean (sd)]	30.6 (7.5)	30.5 (9.4)	0.90
ICD [n (%)]	250 (52.4%)	400 (57.2%)	0.12
Antiplatelet Therapy [n (%)]	366 (76.7%)	524 (75.0%)	0.53
Mean International Normalized Ratio (INR) [mean (sd)]	1.4 (0.4)	1.1 (0.1)	<0.001
Hemoglobin, g/dL [mean (sd)]	12.1 (2.3)	12.6 (2.2)	<0.001
Hematocrit, % [mean (sd)]	36.6 (6.7)	38.1 (6.4)	<0.001
Platelets, K/uL [mean (sd)]	206.5 (75.4)	204.1 (80.0)	<0.60
GFR, mL/min/1.73m^2 [n (%)] · >60 · 30-60 · 15-30 · <15	 246 (51.6%) 185 (38.8%) 32 (6.7%) 14 (2.9%)	 434 (62.1%) 201 (28.8%) 38 (5.4%) 26 (3.7%)	 0.0015

Discussion

The Ohio State University Wexner Medical Centre is a highly experienced, high-volume, lead extraction centre, performing greater than 300 lead extractions per year. In addition, the collaboration between the anticoagulation pharmacy team and electrophysiologists in order to determine the final anticoagulation peri-procedural plan may make the high-risk lead extraction procedure safer. The overall risk of having any adverse event during the CIED lead extraction hospitalization at this centre was 5.8%. This is slightly better than percentage of major complications within 30 days by Regoli, et al. (6.6%). Patients in this study were found to have no difference in rate of adverse events following lead extraction as compared to those not on chronic AC. This is different than previous results showing an increased risk of adverse events for patients on chronic AC2 and having an INR ≥ 1.28. There are several plausible explanations for this difference.

Regoli, et al. utilized a different peri-procedural plan for patients taking VKA. The VKA was discontinued until a target INR < 1.6 was reached, and then patient was usually bridged with LMWH or UFH, subsequently discontinued at least two half-lives before the lead extraction procedure. Our results

Table 2. Individual Components of Primary Outcome.

Outcome	Group 1 (n=26)	Group 2 (n=42)	P value
Lead Dislodgement*	12	11	0.28
Tamponade	3	7	0.75
Bleeding at Chest Site	2	5	0.71
Pneumothorax	2	5	0.71
Pericardial Effusion	0	6	0.087
Death	1	3	0.65
Acute Renal Failure	0	2	0.52
Coronary Venous Dissection	1	1	1
Deep Vein Thrombosis	1	1	1
Stroke	1	0	0.40
Cardiac Arrest	1	0	0.40
Hematoma	1	0	0.40
Pseudo aneurysm	1	0	0.40
Cardiac Perforation	0	1	1

Table 3: Reported Reason for Readmission.

Outcome	Group 1 (n=4)	Group 2 (n=15)	P value
Infection Related to Device	3	2	0.40
Acute Heart Failure	1	2	0.80
Lead Dislodgement*	0	3	0.28
Deep Vein Thrombosis	0	2	0.52
Cardiac Perforation	0	2	0.52
Pulmonary Embolus	0	1	1
Bleed at Chest Site	0	1	1

*Dislodgement of the new implanted lead after extraction

show that only 23% of patients who underwent CIED lead extraction utilized a bridge strategy. Although, this trial did not show a difference across different strategies, this trial was not powered to identify this potential difference. Brunner, et al. reported having an INR ≥ 1.2 places patients at a higher risk for adverse events after reviewing 2999 procedures. They found 10 that patients had a major complication with an INR ≥ 1.2 with 6/10 [60%] on chronic anticoagulation for atrial fibrillation, and 5 of 10 (50%) on anticoagulation was held for the procedure. Therefore, the other 4 patients had elevated INR potentially due to another cause. In addition, there was no discussion around whether or not bridge therapy was utilized for any of these patients. No previous literature has evaluated a peri-procedural plan utilizing DOAC therapy. However, this study suggests there is no difference in risks between VKA with or without bridge in comparison to DOAC treatment.

In addition, no previous literature has evaluated outcomes likely to occur during CIED lead extraction hospitalization. Regoli et al., found a 0.8% risk of mortality, 4.3% risk of bleeding, and 0.8% of pneumothorax within 30 days of CIED lead extraction. Our findings are subject to the limitations inherent to retrospective studies, including possible confounders. This would include no evaluation of patient risk factors as identified by Brunner, et al. (i.e. cerebrovascular disease, ejection fraction ≤ 15%) or procedural related risk factors (i.e. use of mechanical/powered sheaths, type of lead extracted, duration since lead implantation, number of leads extracted) [9]. Our analysis did not complete a full evaluation of our guideline adherence as this was an exploratory study. Therefore, no assumption can be made that every patient followed the protocol as outlined in the methods and every individual must be evaluated with regard to bleeding and embolic risk.

Conclusion

This study shows that patients on chronic AC may not be at a higher risk of adverse events than those not on chronic AC. The authors do believe that the collaboration between the pharmacy-based anticoagulation clinic peri-operative AC strategy and the electrophysiologists showed comparable adverse events in patient on AC and those not on chronic AC. A randomized controlled trial is needed to further evaluate different peri-procedural plans for patients undergoing lead extraction procedures.

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