Perioperative management of oral anticoagulation in patients undergoing implantation of subcutaneous implantable cardioverter-defibrillator

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BACKGROUND The perioperative anticoagulation management during subcutaneous implantable cardioverter-defibrillator (S-ICD) implantation is still evolving.

OBJECTIVE The purpose of this study was to assess whether it is safe to perform S-ICD implantation with uninterrupted warfarin.

METHODS This is a single-center retrospective review of patients undergoing S-ICD implantation between October 1, 2012 and June 30, 2017. One hundred thirty-seven patients underwent successful S-ICD implantation during the study period. The most common indication for implantation was primary prevention of sudden cardiac death. In 24 (17.5%) patients, warfarin was continued without any interruption (warfarin group). In 113 (82.5%) patients, no warfarin was used in the perioperative period (nonwarfarin group). The incidence of clinically significant lateral pocket hematoma was compared in the 2 groups.

RESULTS The mean international normalized ratio was 1.83 ± 0.47 in the warfarin group and 1.09 ± 0.18 in the nonwarfarin group. A total of 8 patients developed a hematoma at the lateral pocket. No patient developed a hematoma at the parasternal pockets. Six patients (25%) in the warfarin group and 2 (1.5%) in the nonwarfarin group developed a significant lateral pocket hematoma ($P = .001$). The mean length of stay was longer in the warfarin group (1.23 ± 0.46 days) than in the nonwarfarin group (1.02 ± 0.18 days) ($P = .0008$). An international normalized ratio of >1.8 predicted the risk of hematoma. The concomitant use of dual antiplatelet therapy did not increase the risk of hematoma. None of the patients with a hematoma developed infection or required hematoma evacuation.

CONCLUSION Uninterrupted warfarin in the perioperative period during S-ICD implantation is associated with an increased risk of significant lateral pocket hematoma that results in prolonged hospital stay.

KEYWORDS Perioperative anticoagulation; Pocket hematoma; Subcutaneous implantable defibrillator; Sudden cardiac death; Uninterrupted warfarin

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Introduction

Subcutaneous implantable cardioverter-defibrillator (S-ICD) is the latest development in defibrillation therapy for prevention of sudden cardiac death (SCD). Large clinical studies have proven the efficacy and safety of S-ICD therapy similar to transvenous (TV) defibrillators for primary and secondary prevention of SCD.[1–3] Although S-ICD and TV devices have shown similar efficacy in SCD prevention, the perioperative management of patients undergoing S-ICD implantation is still evolving.

Many patients who require defibrillator therapy have significant comorbidities such as coronary artery disease and atrial fibrillation, necessitating the use of antiplatelet and anticoagulation (AC) therapy. Interruption of antiplatelet and AC therapy may pose serious risks such as stent thrombosis, myocardial infarction, or stroke in high-risk patients.[4,5] Contemporary experience with TV cardiac devices has demonstrated safety of uninterrupted warfarin; therefore, a majority of the operators perform TV device implantation despite therapeutic international normalized ratio (INR).[6] This approach has not been studied in patients undergoing

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implantation of S-ICD. The purpose of this study therefore was to compare the incidence of pocket hematoma in patients undergoing S-ICD implantation with vs without uninterrupted warfarin therapy.

Methods

Patient population

All patients (N = 137) who underwent successful implantation of S-ICD between October 1, 2012 and June 30, 2017 were included in this retrospective study. Patients were categorized according to whether warfarin was used in the perioperative period. In 24 (17.5%) patients, warfarin was continued without any interruption (warfarin group). In 113 (82.5%) patients, no warfarin was used in the perioperative period (nonwarfarin group). A total of 11 patients in the nonwarfarin group were receiving warfarin as outpatients. Warfarin was discontinued to allow the normalization of the INR before the procedure.

Device implantation

Patients underwent device implantation in the standard fashion using either a 2- or a 3-incision approach as described previously.[3,7–11] Briefly, the lateral pocket incision was made at midaxillary line between the fourth and the sixth intercostal space using a #10 blade. Meticulous dissection was performed with electrocautery. All devices were implanted subcutaneously and secured to the fascial plane covering the serratus muscle. None of the devices were implanted in the intramuscular space. A light retractor or surgical headlight was frequently used for better visualization inside the lateral pocket. Parasternal incisions (1 or 2) were also made in standard fashion. All patients were monitored overnight in the hospital after S-ICD implantation.

On postoperative day 1, all patients with newly implanted devices are examined by an advanced nurse practitioner. If the advanced nurse practitioner is concerned about the presence of hematoma or adequacy of pain control at the pocket site, the patient is examined by the rounding electrophysiology team that consists of a staff electrophysiologist, an electrophysiology fellow, and a general cardiology fellow. The decision on further management such as further inpatient monitoring or changes in pain control medication is dictated by the rounding team. In the case of hematoma, further management included application of pressure dressing, additional inpatient monitoring for surveillance of hematoma, pain control, or device pocket revision. Hemoglobin levels were measured to assess whether there is a significant drop. If there was no significant expansion of hematoma after additional surveillance in the hospital and pain was adequately controlled, patients were discharged with outpatient follow-up 7–10 days later.

End points

The study end points were the incidence of clinically significant lateral pocket hematoma, length of stay (LOS), and hemoglobin changes in the postoperative period. A hematoma was considered clinically significant if it was detected within 24 hours of the implantation procedure and led to either alteration of oral AC or antiplatelet drug management (ie, temporary discontinuation or dose reduction), prolonged LOS, wound dehiscence, or surgical evacuation of the hematoma, as described previously.[12]

Statistical analysis

A chart review was performed to collect demographic characteristics, clinical characteristics, procedural details, incidence of clinically significant hematoma, change in hemoglobin level, and LOS. The Fisher exact test and Student *t* test were used for the statistical analysis of categorical variables and continuous variables, respectively. A P value of $<.05$ was considered statistically significant. A regression analysis was performed to assess the predictors of clinically significant hematoma using STATA v14.0 data analysis and statistical software (StataCorp LP, College Station, TX). The institutional review board of the Ohio State University approved the study.

Table 1 Baseline characteristics of patients stratified by status of warfarin at the time of S-ICD implantation

Characteristic	Nonwarfarin group (n = 113)	Warfarin group (n = 24)	*P*
Age (y)	48.67 ± 15.4	50.96 ± 19.91	.57
Body mass index (kg/m^2)	30.2 ± 6.83	31.8 ± 8.6	.32
Preprocedural hemoglobin level (g/dL)	12.47 ± 2.24	11.98 ± 2.22	.98
Serum creatinine level	1.49 ± 1.49	1.48 ± 0.91	.96
Platelet count	228 ± 92	227 ± 62	.87
INR	1.09 ± 0.18	1.83 ± 0.47	.0001
LVEF (%)	39.95 ± 17.25	25.38 ± 7.88	.0001
Concomitant aspirin	37 (33)	13 (54)	.30
Concomitant DAPT	28 (25)	6 (25)	.99
Primary prevention	78 (69)	17 (71)	.96
Procedure duration (min)	142 ± 54	141 ± 64	.93

Values are presented as mean ± SD or as n (%).

DAPT = dual antiplatelet therapy; INR = international normalized ratio; LVEF = left ventricular ejection fraction; S-ICD = subcutaneous implantable cardioverter-defibrillator.