Use of pulsed electron avalanche knife (PEAK) PlasmaBlade™ in patients undergoing implantation of subcutaneous implantable cardioverter-defibrillator

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ABSTRACT

Introduction: Surgical implantation of subcutaneous implantable cardioverter-defibrillators (S-ICD) requires preparation of a deeper and larger pocket. Infection and bleeding complications are reported, particularly in patients requiring antiplatelet therapy (APT) or being on oral anticoagulation (OAC), with rates up to 25%. The pulsed electron avalanche knife (PEAK) PlasmaBlade™ has been reported to reduce bleeding complications. The purpose of this study was to evaluate the safety and feasibility of a PEAK guided S-ICD implantation with respect to perioperative complications.
Methods and results: We enrolled 36 consecutive patients (75% male; mean age 52.1 ± 14.4 years) undergoing S-ICD implantation. Periprocedural safety endpoints comprised major complications including pocket hematomas, wound infections, bleeding (BARC ≥2) or events requiring interventions. Patients were divided into three groups according to management of their anticoagulation: i.) APT, n = 15 (41.7%); ii.) OAC, n = 10 patients (27.8%); iii.) none (neither OAC nor APT), n = 11 (30.6%). Mean procedure duration was 33.1 ± 13.4 min. Mean length of hospital stay was 3.3 ± 2.1 days. Overall analysis showed no differences between the 3 groups with respect to major complications, major bleeding episodes or other procedural parameters, beside a trend towards more minor hematomas in the OAC group (OAC: 22.2% vs. APT: 11.4% vs. none: 9.1%; $p = 0.15$).
Conclusion: The results of our pilot study suggest that intermuscular S-ICD implantation using PEAK is safe and potentially beneficial in patients receiving OAC or APT with respect to prevention of bleeding complications. These results support the rationale for large prospective controlled trials evaluating a beneficial effect of PEAK use in S-ICD implantation procedures.

1. Introduction

Subcutaneous implantable cardioverter defibrillator (S-ICD) developed as an alternative option in defibrillation therapy for prevention of sudden cardiac death (SCD) during the last years [1–3]. Despite advantages of a complete extracardiac ICD system the S-ICD implantation procedure does require preparation of a deeper and larger pocket. Pocket preparation is one potential risk factor for relevant hematoma which may lead to an increased risk for infection [4]. In addition,

many patients requiring defibrillator therapy present often multiple co-morbidities such as coronary artery disease (CAD) and/or atrial fibrillation, necessitating the use of antiplatelet and anticoagulation therapy. The perioperative use of any antithrombotic therapy is associated with increased bleeding risk after cardiac implantable electronic device (CIED) implantation. While pocket hematoma is per se a relatively common complication in CIED procedures (reported rates between 2% and 5%) [5–7], dual antiplatelet therapy (DAPT) increases the risk fivefold [8]. As mentioned above the most common procedure-related complications for the S-ICD are mainly related to the device pocket including infection, hematoma, and skin erosion. Therefore, potential tools or techniques preventing bleeding complication might be beneficial in patients with high bleeding risk in a setting requiring antithrombotic therapy while undergoing S-ICD implantation.

The pulsed electron avalanche knife (PEAK) PlasmaBlade™ is a novel low-thermal-injury electrosurgical device. It uses very brief, precise pulses of radiofrequency (RF) energy to cut and coagulate soft tissue without the thermal damage to surrounding tissues that is normally

seen with traditional electrosurgery. Thermal injury depth, inflammatory response and scar width appear to be reduced upon PlasmaBlade™ incisions in comparison to conventional electrocautery [9]. A postulated advantage of the electrosurgical device seems to be an improved bleeding control based on the electrical cutting and cauterization technique, which generates less damage and better direct coagulation of injured vessels thereby allowing quicker wound healing [10,11]. With respect to CIED surgery the use of PlasmaBlade™ might accelerate wound healing and thereby reduce the rate of infections and bleeding complications. In the present manuscript we describe our initial experience with PEAK PlasmaBlade™ in patients undergoing implantation of S-ICD using the intermuscular technique with respect to infection and bleeding complications and in relation to a potential antithrombotic therapy with antiplatelet agents (AP) or oral anticoagulants (OAC).

2. Methods

2.1. Study design

From February 2016 to September 2018 36 patients underwent de novo S-ICD (Boston Scientific, Natick, MA) implantation and were included in this retrospective observational study. The study was performed in accordance with the 1975 Declaration of Helsinki and approved by our ethical review board (Ethics committee of the University of Duisburg-Essen, 19-8716-BO). We routinely recorded data to evaluate the safe and effective management of all patients. All parameters were entered into an internet-based electronic case report from the center. Patient data was analyzed anonymously.

2.2. Indication for S-ICD and patient selection

S-ICD implantation was considered in all patients with primary and secondary ICD indication based on current recommendations [12]. Patients with negative screening, pacing or CRT indication and VT <170 bpm, whose arrhythmia might be suppressed by overdrive pacing were excluded. Possible S-ICD patients include those with an unacceptable risk of infection or an inadequate/limited vascular access including patients with congenital heart abnormalities and hemodialysis patients and those with previous transvenous ICD infection and lead malfunction, channelopathies at risk of sudden death but not of monomorphic VT, such as e.g. hypertrophic cardiomyopathy.

2.3. Implantation procedures

S-ICD implantation surgery was performed in a hybrid operating room under conscious sedation with local anesthesia [13]. All procedures were performed using the PEAK PlasmaBlade™ (Medtronic Inc., Minneapolis, MN, USA). Conventional electrocautery was not used. Direct oral anticoagulants (DOACs) were stopped at least 24–48 h before the procedure and were started at least 24 h after the procedure. In patients treated with vitamin K antagonist (VKA), uninterrupted VKA was recommended with a target international normalized ratio (INR) between 2.0 and 3.0 on the day of surgery. Antiplatelet therapy was not stopped.

Patients were first screened preoperatively with an automated screening tool (ATS) by considering electrograms in each of the three sensing vectors. S-ICD implantation was performed using the two-incision technique and all devices were implanted in an intermuscular pocket approach between musculus serratus anterior and musculus latissimus dorsi as described previously [14]. The generator pocket incision overlays the fifth to sixth intercostal space 4 cm lateral to the mid-clavicular line towards the mid-axillary line. The lateral pocket incision was made by the PEAK PlasmaBlade™ CUT mode 6 and the preparation of the intermuscular pocket was performed with COAG mode 8. Procedural goal was no sign of an overt residual bleeding within the pocket

region. The lead was tunneled subcutaneously from the generator pocket into a small incision at the inferior edge of the xiphoid process.

2.4. Definition of endpoints

The primary endpoint of our analysis was the incidence of clinically significant lateral pocket hematoma. A hematoma was considered clinically significant if it led to surgical evacuation, blood transfusion or/and prolonged hospitalization. Secondary endpoints were the occurrence of other periprocedural complications, e.g. pocket infection. Two categories of complications were defined. Minor complications were resolving spontaneously, without requiring intervention, re-hospitalization or prolonging the hospital stay. A major complication was defined as an adverse event resulting in prolonged hospitalization for >48 h, re-admissions or requiring medical intervention for treatment.

Complications were divided into wound healing problems, infectious complications (superficial infections, pocket infections and infections requiring complete device extraction) and device-pocket hematomas. Daily assessment of the device pocket and wound examination were performed until the patient was discharged from the hospital. Follow-up visits (including wound assessment) were scheduled 4 weeks and 3 months after the procedure in our outpatient clinic.

2.5. Statistical and data

Baseline characteristics, procedure-related data and procedure-related complications were recorded in a database. Patient tolerability of the procedure was also assessed. All statistical analyses were performed using SPSS version 24.0 (IBM SPSS, Chicago, IL, USA). Continuous variables are expressed as mean ± standard deviation in case of normal distribution, and as median and interquartile range in the cases of other types of distribution. Categorical variables are summarized as counts and percentages. The groups were compared using the Mann-Whitney U test. For all analyses, a p value of <0.05 was considered statistically significant.

3. Results

3.1. Patient and procedural characteristics

Baseline characteristics of the patients are listed in Table 1. Between February 2016 and September 2018, 36 patients underwent S-ICD implantation using the two-incision intermuscular technique by a single operator. Mean patient age was 52.1 ± 14.4 years and 27 (75.0%) patients were male. Indications for S-ICD implantation were primary prevention in 30 patients (83.3%) and secondary prevention in 6 (16.7%). Dilatative cardiomyopathy was present in 13 (36.1%), ischemic cardiomyopathy in 17 (47.2%), and hypertrophic cardiomyopathy in 4 (11.1%) patients. Two patients (5.5%) had idiopathic ventricular fibrillation with no overt structural heart disease. Mean ejection fraction (EF) was 27% ± 10%. Mean HAS-BLED-score was 3.19 ± 0.8. CAD was present in 61%, while six patients had a history of atrial fibrillation (AF, 16.7%). Furthermore, diabetes was present in 33% and renal impairment in 25% of the studied cohort.

One patient underwent S-ICD implantation with a left ventricular assist device (LVAD) support. Over half of the patients had an ASA classification IV (n = 20, 55.5%).

3.2. Characteristics of antithrombotic therapy

The majority of the patients (69.4%) underwent S-ICD implantation on antithrombotic therapy, including AP and OAC (see Table 2). Patients were divided into three groups according to the management of their antithrombotic therapy: group A was defined as antiplatelet therapy (APT) comprising 15 patients (41.7%) with single (S) or dual (D) APT, group B comprised 10 patients (27.8%) with OAC ± APT, and group C

Table 1
Baseline demographic and clinical characteristics of the study population.

Patients	n = 36
Demographics	
Mean ± SD age at implant, years	52.1 ± 14.4 (18–74)
n (%) < 35 years	5 (13.9)
Male sex, n (%)	27 (75.0)
Body mass index (kg/m²)	28.40 ± 6.43 (14–45)
Medical history	
DCM, n (%)	13 (36.1)
ICM, n (%)	17 (47.2)
HCM, n (%)	4 (11.1)
IVF, n (%)	2 (5.5)
CABG, n (%)	2 (5.5)
Coronary artery disease, n (%)	22 (61.1)
Left ventricular ejection fraction, mean ± SD and range (%)	27 ± 10 (15–62)
Atrial fibrillation, n (%)	6 (16.6)
Renal insufficiency, n (%)	9 (25.0)
Diabetes, n (%)	12 (33.3)
ASA	
ASA III, n (%)	16 (44.4)
ASA IV, n (%)	20 (55.5)
HAS-BLED Score (mean ± SD)	3.19 ± 0.8
Indication for s-ICD implantation	
Primary prevention of SCD, n (%)	30 (83.3)
Secondary prevention of SCD, n (%)	6 (16.7)
No venous access, n (%)	1 (2.70)
Prior sternotomy, n (%)	3 (8.30)

Abbreviations: SCD sudden cardiac death, ASA, American Society of Anesthesiologists; DCM dilatative cardiomyopathy, ICM ischemic cardiomyopathy, HCM hypertrophic cardiomyopathy, IVF idiopathic ventricular fibrillation, CABG coronary artery bypass graft surgery.

included 11 (30.6%) patients with neither OAC or APT (Table 3). In the APT group 7 patients (19.4%) were on SAPT for the prevention of primary or secondary cardiac vascular disease, while 8 patients (5.6%) were on DAPT based on coronary intervention after drug-eluting stent implantation. Acetylsalicylic acid (ASA) was the most used drug (19 patients, 52.8%), followed by a combination of ASA and clopidogrel or ticagrelor in DAPT regime (22.2%). Among the 10 patients on OAC, eight patients were treated using vitamin K-antagonists (VKA), while two patients (5.6%) were on direct oral anticoagulants (DOAC). Only 2 patients required triple therapy (5.6%) combining OAC with APT. Of the VKA patients only one patient (12.5%) had INR < 2.0, while seven cases (87.5%) showed an INR < 2.0 at time of surgery. Mean INR at the time of the index surgery was 1.15 ± 0.29.

Between the three groups several differences could be noted (see Table 3). There were significant differences in age, history of AF and CAD. Patients who were taking OAC were older. APT group showed significantly higher rate of CAD history, while the OAC group showed more often a history of AF. We also observed a trend of an increasing HAS-BLED-Score with higher intensities of anticoagulation (OAC > APT > none). Comparisons regarding sex and body mass index (BMI) showed non-significant differences between the groups, although we

Table 2
Peri-interventional anticoagulation.

Oral anticoagulation or antithrombotic therapy, n (%)	25 (69.4)
SAPT, n (%)	7 (19.4)
DAPT, n (%)	8 (22.2)
OAC only, n (%)	4 (11.1)
VKA[a], n (%)	3 (8.3)
NOAC, n (%)	1 (2.8)
OAC + APT, n (%)	6 (16.7)
VKA + APT, n (%)	5 (41.2)
DOAC + APT, n (%)	1 (2.8)
None, n (%)	11 (30.6)

Abbreviations: VKA, vitamin K antagonist; SAPT, single antiplatelet therapy; DAPT, dual antiplatelet therapy; NOAC, no-VKA oral anticoagulant.
[a] Mean INR of patients on VKA at the time of the procedure was 1.15 ± 0.29.

Table 3
Clinical characteristics of the study population (APT vs OAC vs. none).

Number of patients	APT n = 15	OAC n = 9	None n = 11	p-Value
Age (mea ± SD)	56.3 ± 9.1	59.2 ± 11.7	41.7 ± 17.1	0.020
Male sex, n (%)	12 (80%)	9 (100%)	6 (54%)	0.056
BMI (kg/m²; mean ± SD)	26.9 ± 7.2	32.1 ± 6.2	26.8 ± 4.5	0.053
HAS-BLED Score	3.1 ± 17	3.6 ± 0.23	2.91 ± 0.3	0.103
ASA III or IV, n (%)	15 (100%)	9 (100%)	11 (100%)	
CAD, n (%)	13 (86.6%)	0 (0%)	9 (77.7%)	0.001
AF, n (%)	1 (6.6%)	5 (55.6%)	0 (0%)	0.002
DM, n (%)	5 (33.3%)	5 (55.6%)	2 (18.1%)	0.224
Renal insufficiency, n (%)	3 (20%)	4 (44.4%)	2 (18.1%)	0.338

observed trends that male sex and higher BMI lead to a higher probability of APT or OAC.

3.3. Procedural data

Table 4 provides an overview of the procedural characteristics of the overall cohort and the three subgroups. The mean overall procedure duration (time from first skin incision until the end of surgery) was 33 ± 13.4 min ranging from a minimum of 18 min and a maximum of 74 min for a de novo S-ICD implantation in intermuscular technique. There was no significant difference between the 3 groups with respect to procedural time. The mean length of postoperative hospital stay of all patients included in the study was 3.3 ± 2.1 days.

Regarding the primary endpoint of periprocedural complications no case of a significant device-pocket hematoma requiring surgical intervention was observed within all three groups independently from the use of an antithrombotic regimen. Minor pocket hematomas were noted in four patients with a non-significant trend for an increased rate of minor hematomas in the OAC group (n = 1/15 6.6% in group A, n = 2/9 22.2% in group B, n = 1/11 9.1% in group C). No patient with a hematoma required subsequent hematoma evacuation, blood transfusion or developed wound dehiscence or device infection during follow-up. In addition, there was no case of perioperative (<24 h) mortality in the three groups, and no patient died within 30 days. One patient presented to hospital 5 days postoperatively with multiple inappropriate shocks due to oversensing caused by air surrounding the proximal electrode. The device was reprogrammed to sense a different vector preventing any further inappropriate shocks. Patients quickly accommodated to the device in the intermuscular position without reporting any discomfort. There were no electrode or pulse generator migrations reported.

All patients but one (group C) underwent successful VF-induced defibrillation at 65 J shock. The patient with a defibrillation failure underwent external defibrillation with 200 J biphasic shock and, after repositioning of the pulse generator more dorsally, an effective internal shock was obtained in standard polarity.

4. Discussion

In this study we investigated the use of a novel surgical tool (PlasmaBlade™) with pulsed radiofrequency to generate a plasma-mediated discharge. We hypothesized that PlasmaBlade™ might be associated with low peri-procedural bleeding events, regardless of antithrombotic regimen. Our results show that the use of this new surgical tool is associated with a very low rate of adverse events – such as hematomas requiring intervention or wound infection. We assume that patients undergoing S-ICD procedures, which require anticoagulation or antithrombotic treatment might benefit from the use of the PlasmaBlade™ device with respect to bleeding complications. The study shows that in patients undergoing S-ICD implantation the use of PlasmaBlade is safe and might be beneficial in patients under antithrombotic therapy or OAC with respect to bleeding complications.

Table 4
Procedure-related results.

	Overall	APT n = 15	VKA n = 9	None n = 11	p-Value
Total procedure time, minutes	33.0 ± 13.4	34.7 ± 2.4	40.1 ± 5.6	36.1 ± 4.8	0.726
Length of postoperative hospital stay, days	3.3 ± 2.1	3.1 ± 0.6	3.5 ± 0.7	3.2 ± 0.5	0.717
Perioperative complications, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	
Lead dislodgement, n (%)	0 (0,00)	0 (0,00)	0 (0,00)	0 (0,00)	
Superficial infection, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	
Significant device-pocket hematoma, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	
Minor hematoma n (%)	4 (11.4%)	1 (6.6%)	2 (22.2%)	1 (9.1%)	0.149
DFT, n (%)	34 (97.2%)	15 (100%)	9 (100%)	10 (90.9%)	0.336

Device-pocket hematoma after CIED procedures is a complication that can lead to prolonged hospital stay, infection, and/or need for repeated surgical interventions. The incidence of bleeding complications has been reported to be significantly increased in patients undergoing surgery on clopidogrel treatment compared to aspirin monotherapy [15,16]. DAPT increases the risk of a device-pocket hematoma fivefold [5]. The rate of bleeding complications during CIED implantations can be as high as 40% with triple anticoagulation therapy [8]. The perioperative anticoagulation management during S-ICD implantation is still unclear and evolving.

Various studies estimate that nearly 14–35% of the patients who need cardiac devices are on long-term OAC [17–21]. In our selected S-ICD cohort we observed 35.7% being on APT and 23.8% being on OAC therapy, respectively. This underlines that the majority of our studied S-ICD patients were at a higher bleeding risk per se, which is also reflected by the relatively high HAS-BLED score with 3.19 ± 0.79 in this cohort. In addition, the surgical procedure of implantation of a S-ICD requires preparation of a deeper and larger pocket, which makes these patients prone to developing complications with respect to hematoma, bleeding events and/or infections.

The literature reports high rates of S-ICD pocket complications in conventional subcutaneous implantation technique ranging from 7.6% to 11.9% [22]. Anticoagulation and/or antiplatelet therapy with clopidogrel appears to increase the risk for hematoma [23]. We experienced no clinically significant pocket complication using PEAK PlasmaBlade for S-ICD implantation in intermuscular technique by using the PlasmaBlade™. Only four minor superficial hematomas were observed.

PlasmaBlade™ is a novel surgical tool that uses pulsed radiofrequency to generate a plasma-mediated discharge along the exposed rim of an insulated blade, creating an effective cutting edge while the blade stays near body temperature resulting in an effective bleeding control with less thermal tissue injury and damage. Furthermore, it provides atraumatic, scalpel- like cutting precision and electrosurgical-like hemostasis, while acute thermal injury depth is reduced by 74% [10]. PlasmaBlade™ incisions demonstrated reduced inflammatory response and scar width in healing skin compared with conventional electrocautery or scissors and reducing bleeding complications significantly (59%) [11]. Within the context of CIED surgery, the PlasmaBlade™ device might therefore provide clinical advantages over conventional electrocautery by accelerating the healing process, reducing the risk of infection and avoiding inadvertent lead damage. There is currently data supporting the use of PlasmaBlade™ in patients undergoing pacemaker or ICD generator replacement [24] or using PlasmaBlade™ for all types of CIED procedures [25].

Considering the retrospective analysis of the small patient cohort group and the lack of a control group under traditional electrosurgery it is not possible to conclude that this approach is safe per se, despite the absence of perioperative complications. However, our results with respect to high-risk groups of patients on APT and/or OAC therapy, can be put as hypothesis-generating, that patients at high bleeding risk may benefit from a procedure using PlasmaBlade™.

Despite of the above-mentioned advantages of the PlasmaBlade™ the acquisition costs of the PlasmaBlade™ are much higher than those of a conventional electrocautery unit. Further data demonstrating a reduction in the overall complication rate, procedure time and length of hospital stay in high-risk patients which might translate into cost savings are required to establish PlasmaBlade™ as an alternative to conventional electrocautery unit.

To date, no studies exist evaluating the use of the PlasmaBlade™ compared to conventional electrocautery for all types of CIED procedures. Therefore, our study is one of the first addressing this issue and highlighting the potential benefit of such a novel approach in S-ICD patients requiring blood-thinning therapy.

4.1. Limitations

The major limitation of our study is that it is a non-randomized, retrospective single-center study with a rather small number of patients. Furthermore, as PlasmaBlade™ was used in all patients, there was no control group in which conventional electrocautery as the standard of care was applied. Nevertheless, we could demonstrate the feasibility and high safety in the studied high-bleeding-risk cohort of patients undergoing S-ICD implantation in intermuscular technique using of the PlasmaBlade™ device.

5. Conclusions

Our findings suggest that intermuscular S-ICD implantation using PEAK PlasmaBlade™ is per se safe and co-administration of antithrombotic therapy is not associated with an increase of peri-procedural bleeding events. Further studies comparing PlasmaBlade™ and conventional electrocautery are warranted to evaluate whether PlasmaBlade™ is superior to conventional electrocautery for S-ICD procedures.

Ethics approval and consent to participate

The study was approved by the ethics committee of the faculty of medicine of the University of Duisburg-Essen (Reference no. 19-87.16-BO), Germany.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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