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Low-temperature electrocautery for high-risk cardiac implantable electronic device procedures

Maciej Dyrbuś et al., Plasma blade for secondary device procedures

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With rising numbers of cardiac implantable electronic devices (CIEDs) implanted each year, the population of patients with those devices is growing extensively [1]. Large numbers of those patients will eventually require secondary procedures, including device replacements, or upgrades. As during past years , the implanted systems become surrounded by adhesive tissue and fibers, the secondary procedures have been historically associated with a higher risk of short-and long-term complications, most often including lead damage. Moreover, due to comorbidities, a high percentage of patients with CIEDs are treated nowadays with anticoagulants, which increases the risk of bleeding and pocket hematoma. Thus, electrocautery is used to mitigate the risk of periprocedural bleeding. However, the use of conventional electrocautery can risk lead dysfunction due to its thermal injury.

The low-temperature electrocautery has been proven to improve local outcomes [2]. Few reports were published to date on its utilization in CIED-related procedures [3–5]. The aim of this analysis was to summarize its safety and efficacy in higher complication-risk procedures performed in a tertiary Polish center.

Between July 2021 and July 2022, a total of 150 CIED-related procedures considered as higher complication risk were performed with the use of PlasmaBlade™ low-temperature electrocautery (Medtronic, Inc., Minneapolis, MN). A higher complication risk was defined as any secondary procedure (e.g. generator replacement, device upgrade, transvenous lead extraction [TLE]), or subcutaneous implantable cardioverter-defibrillator (sICD) implantation. The choice of electrocautery was at the discretion of the operator. All similar procedures performed between January 2020, and June 2021, with the use of conventional electrocautery served as a control group.

All procedures including preprocedural antibiotics administration and management of anticoagulation were performed according to the established standards [6]. The periprocedural strategy, including capsulectomy and lead liberation were at the discretion of the operator. After completion of all procedures in the study period, each operator was asked to fill the survey on the perception and satisfaction with both types of electrocautery.

In all patients, the clinical and periprocedural characteristics were documented and summarized. As all patients after the procedures are routinely monitored in the device-focused outpatient clinic, the lead-related outcomes at follow-up could be analyzed based on the electronic records and were defined as any significant rise in lead impedance, or in pacing threshold, or the necessity for lead extraction or repeat procedure due to any causes. The routine scheme of visits places the post-procedural outpatient in-person visits at 2 weeks, 3 months, and after 6 or 12 months, depending on the type of device. The minimum follow-up was 6 months and the median 12 months. The research was performed as part of the Medical University of Silesia grant number PCN-1-083/N/0/K.

Of 150 patients, who underwent procedures with low-temperature electrocautery, the majority (90.7%) underwent secondary procedures, including TLE, and the remaining were sICD implantations (Table 1). The median (Q1–Q3) number of years between implantation of the first device and the index procedure was 7 (4–8) years. Generator replacements constituted the majority (58.7%) of the procedures, among them, the most prevalent were pacemaker (51.1%) and cardiac resynchronization therapy (27.3%) replacements, and there were 37 TLE procedures. In general, the procedures performed in the control group were comparable, with a slightly higher rate of generator replacements (72.4%), and a numerically lower rate of TLEs (15.8%).

The median duration, radiation doses and reductions in hematocrit during the hospitalization were comparable in both groups. However, the rates of bleeding were numerically lower in the studied group, with respectively 1.3% and 1.8% of patients in the

control group requiring blood transfusion. No other major periprocedural complications were reported in the study group, with 0.9% rate of acute lead dysfunctions noted in the control group. Neither significant lead-related outcomes, nor local or systemic CIED-related infections were reported in the post-discharge follow-up of the studied group, and none of the patients required any following device-related procedures. In the control group, the rate of long-term complication was also low, with 1.6% rate of lead dysfunctions and 1.3% of device infections. The results of the query dispatched among the operators indicate that 4 of 5 would choose low-temperature electrocautery, what could be attributed to the subjectively higher lead safety and lower risk of tissue damage.

The most important benefits of low-temperature electrocautery during CIED-related surgical procedures are the reduction of the risk of lead damage during the liberation of the leads from surrounding tissues during the procedure and the reduction of the risk and intensity of periprocedural bleeding. Due to the different scheme of electrocautery pulse delivery, when compared with conventional electrocautery, it allows obtaining comparable tissue separation and cautery, while not exceeding the melting point of the majority of the materials constituting lead insulation [4]. In the sub-analysis of the WRAP-IT trial, its use was associated with a significant, 32% reduction in the incidence of any lead-related adverse events than the conventional electrocautery group [4]. In the other available literature sources evaluating low-temperature electrocautery, the risk of lead-related complications, ranged between 0.0% and 0.7%, which along with the present data, confirms that its utilization in generator replacement procedures yields high safety for leads [4, 5, 7].

The development of pocket hematoma has been identified as one of the most important risk factors of both pocket and systemic infection [8, 9]. Of 150 procedures performed in the current analysis with the use of low-temperature electrocautery, no clinically significant pocket hematoma developed, although almost 40% of patients were on anticoagulants. A recent study focused on the risk of bleeding in patients on anticoagulants after transcatheter aortic valve implantation demonstrated that the risk of pocket hematoma with low-temperature electrocautery was 1.2% [10]. As none of the patients from the studied group developed a clinically significant pocket hematoma, and the rates of hematomas from the prior studies with low-temperature electrocautery did not exceed 3.4%, it could be concluded that low-temperature electrocautery allows maintaining low risk of pocket hematoma and lead-related complications [4, 7].

Conflict of interest: None declared

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Table 1: Characteristics of patients and outcomes of procedures performed with the use of low-temperature electrocautery versus similar procedures performed in the years 2020–2021.

Demographics	**N = 150**	**N = 436**	**P**
Female gender	40 (26.7%)	152 (34.9%)	NS
Age [years]	71 (62–79)	74 (65–82)	NS
Procedural characteristics			
Secondary procedure (patient already with an implanted device), including TLE	136 (90.7%)	399 (91.5%)	NS
Time from baseline implantation to index procedure [years]	7 [4–8]	7 [4–9]	NS
Hematocrit at baseline [%]	41.0 [37.6–43.5]	40.5 (37.3–43.0)	NS
eGFR at baseline [mL/m^3]	60 [50–75]	60 [48–72]	NS
Lowest hematocrit during hospital stay [%]	37.6 [33.9–40.7]	37,5 (34.1–40.8)	NS
Maximal reduction in hematocrit during hospital stay [%]	2.5 [1.1–4.3]	2.6 [1.0–4.2]	NS
Hospitalization duration after the procedure [days]	1 [1–3]	2 [1–3]	NS
Procedural radiation dose [mGy]	0 [0–19]	1 [0–5]	NS
Procedural duration [min]	90 [65–130]	90 [50–100]	NS

AF on anticoagulation		62 (41.3%)	277 (63.5%)	<0.001
Procedure types				
Generator replacement		88 (58.7%)	316/436 (72.4%)	NS
	PM replacement	45/88 (51.1%)	195/316 (61.7%)	
	ICD replacement	19/88 (21.6%)	70/316 (22.1%)	
	CRT replacement	24/88 (27.3%)	51/316 (16.1%)	
Device upgrade		7 (4.7%)	3 (0.7%)	NS
Lead repositioning		3 (2.0%)	8 (1.8%)	NS
Pocket revision		1 (0.7%)	4 (0.9%)	NS
sICD implantation		14 (9.3%)	36 (8.3%)	NS
TLE		37 (24.7%)	69 (15.8%)	NS
Immediate outcomes				
Pneumothorax		0/150 (0%)	0/436 (0%)	NS
Hemothorax		0/150 (0%)	0/436 (0%)	NS
Pericardial tamponade		0/150 (0%)	1/436 (0.2%)	NS
Bleeding, any		2/150 (1.3%)	10/436 (2.3%)	NS

Bleeding requiring transfusion	2/150 (1.3%)	8/436 (1.8%)	NS
Clinically significant pocket hematoma	0/150 (0%)	3/436 (0.7%)	NS
Lead dysfunction requiring acute implantation of the new lead	0/150 (0%)	4/436 (0.9%)	NS
Follow-up outcomes at 12 months			
Lead dysfunction	0/150 (0%)	7/436 (1.6%)	NS
Local or systemic CIED-related infection	0/150 (0%)	6/436 (1.3%)	
Need for pocket revision	0/150 (0%)	2/436 (0.5%)	

Data are shown as number (percentage) or median (minimum–maximum) or median [Quartile 1–Quartile 3]. Chi-square test and exact Fisher tests were used for the assessment of categorical variables, while non-paired Wilcoxon test was used to assess continuous variables after assessment of distribution normality in the Shapiro-Wilk test.

AF — atrial fibrillation; CIED — cardiac implantable electronic devices; CRT — cardiac resynchronization therapy; ICD — implantable cardioverter-defibrillator; NS — non-significant; PM — permanent pacemaker; sICD — subcutaneous implantable cardioverter-defibrillator; TLE — transvenous lead extraction

Title: Low-temperature electrocautery for high-risk cardiac implantable electronic devices procedures

Running title: Plasma blade for secondary device procedures

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Keywords: Cardiac implantable electronic devices; Generator replacement; Low-temperature electrocautery; PlasmaBlade; Secondary procedures

Word count: 9851,045

Cardiac implantable electronic devices (CIED) constitute a cornerstone of modern treatment of arrhythmias. With rising high numbers of cardiac implantable electronic devices (CIEDs) implanted each year, the population of patients with those devices is growing extensively [1]. Large numbers of those patients will eventually require secondary procedures, including device replacements, or upgrades. As during the years, the implanted leads systems and generators become surrounded by adhesive tissue and fibers, the secondary procedures have been historically associated with a higher risk of short-and long-term complications, most often including lead damage. Moreover, due to comorbidities, a high percentage of patients with CIEDs is nowadays treated with anticoagulants, which increases the risk of bleeding and pocket haematoma. Thus, electrocautery is used to mitigate the risk of periprocedural bleeding. However, the use of conventional electrocautery can risk lead dysfunction due to its thermal injury.

The low-temperature electrocautery has historically been proven to improve the local local outcomes in surgical procedures [2]. Few reports were published to date on its utilization in CIED-related procedures [3-5]. The aim of this analysis was to summarize its safety and efficacy in higher complication-risk procedures performed in the tertiary Polish centre.

Between July 2021 and July 2022, a total of 150 CIED-related procedures considered as of higher complication risk were performed with the use of PlasmaBlade™ low-temperature electrocautery (Medtronic, Inc., Minneapolis, MN). A higher complication risk was defined as any secondary procedure (e.g. generator replacements, pocket revisions, device upgrades, a transvenous lead extraction - TLE), or subcutaneous implantable cardioverter-defibrillator (sICD) implantation., due to a higher risk of lead damage, higher procedural complexity, or the risk of excessive bleeding associated with a need to create a larger, deeper pocket for the sICD. The choice of electrocautery was at the discretion of the

operator. All similar procedures performed between January 2020, and June 2021, with the use of conventional electrocautery served as a control group.

All procedures including preprocedural antibiotics administration and management of anticoagulation were performed according to the established standards [6]. The periprocedural strategy, including capsulectomy and lead liberation ~~, including either complete or incomplete dissection and mobilization~~ were at the discretion of the operator. After completion of all procedures in the study period, each operator was ~~obliged~~ asked to fill the survey on the perception and satisfaction with both types of electrocautery ~~(the Questionnaire is attached in the Supplementary Materials)~~.

In all patients, the clinical and periprocedural characteristics were documented and summarized. As all patients after the procedures are routinely monitored in the device-focused outpatient clinic, the lead-related outcomes at follow-up could be analysed based on the electronic records and were defined as any significant rise in lead impedance, or in pacing threshold, or the necessity for lead extraction or repeat procedure due to any causes. The routine scheme of visits places the post-procedural outpatient in-person visits at 2 weeks, 3 months, and after 6 or 12 months, depending on the type of the device. The minimum follow-up was 6 months and the median 12 months. The research was performed as a part of the Medical University of Silesia grant number PCN-1-083/N/0/K.

Of 150 patients, who underwent procedures with low-temperature electrocautery, the majority (90.7%) underwent secondary procedures, including TLE, and the remaining were sICD implantations (Table 1). The median (Q1-Q3) number of years between implantation of the first device and the index procedure was 7 (4-8) years. Generator replacements constituted the majority (58.7%) of the procedures, among them, the most prevalent were pacemaker (51.1%) and cardiac resynchronization therapy (27.3%) replacements, and there were 37 TLE procedures. In general, the procedures performed in the control group were comparable, with

a slightly higher rate of generator replacements (72.4%), and a numerically lower rate of TLEs (15.8%).

The median ~~(Q1-Q3)~~ duration, radiation doses and ~~of all procedures was 90 (65-130) minutes, and median (Q1-Q3)~~ reductions in haematocrit during the hospitalization ~~was~~ were comparable ~~2.5%~~in both groups ~~(1.1-4.3)~~. However,~~, although only~~ the rates of bleeding were numerically lower in the studied group, with respectively 1.3% and 1.8% of patients in the control group ~~2 patients~~ requiring~~ed~~ blood transfusion ~~due to critical condition peri-TLE~~. ~~None of blood transfusions were directly related to the procedure.~~ No other major periprocedural complications were reported in the ~~analysed~~ study ~~sub~~group, with 0.9% rate of acute lead dysfunctions noted in the control group ~~including no cases of pneumo- or haemothorax, nor lead dysfunctions identified acutely after the procedure. Moreover, there were no pocket haematomas requiring invasive management nor prolonging the patients' hospitalization~~. N~~either~~o significant lead-related outcomes, nor local or systemic CIED-related infections ~~were reported in the post-discharge follow-up of the studied group, and none of the patients required any following device-related procedures. In the control group, the rate of long-term complication was also low, with 1.6% rate of lead dysfunctions and 1.3% of device infections. ~~No local or systemic CIED-related infections were noted in the median of 12 months of follow-up.~~ The results of the query dispatched among the operators indicate that 4 of 5 would choose low-temperature electrocautery, what could be attributed to the subjectively higher lead safety and lower risk of tissue damage.

The most important benefits of low-temperature electrocautery during CIED-related surgical procedures are the reduction of the risk of lead damage during the liberation of the leads from surrounding tissues during the procedure and the reduction of the risk and intensity of periprocedural bleeding.

Due to the different scheme of electrocautery pulse delivery, when compared with conventional electrocautery, it allows to obtain comparable tissue separation and cautery, while not exceeding the melting point of the majority of the materials constituting lead insulation [4]. In the subanalysis of the WRAP-IT trial, ~~the~~ its use ~~of low-temperature electrocautery~~ was associated with a significant, 32% reduction in the incidence of ~~risk of lead-related complications (36-month Kaplan-Meier estimation of 3.0% vs 3.9%, p=0.031), and in the multivariable analysis, the low-temperature electrocautery group had a 32% lower incidence of~~ any lead-related adverse events than the conventional electrocautery group [4]. In the other available literature sources evaluating low-temperature electrocautery, the risk of lead-related complications, ranged between 0.0% and 0.7%, which along with our data, confirms that its utilization in generator replacement procedures yields high safety for leads [4-5,7].

The development of pocket haematoma has been identified as one of the most important risk factors of both pocket and systemic infection ~~Despite the utmost efforts to reduce the risk of systemic infections, their development severely worsens prognosis in patients with CIEDs~~ [8~~-~~]. ~~The development of pocket haematoma has been identified as one of the most important risk factors of both pocket and systemic infection [~~9]. Of 150 procedures performed in our analysis with the use of low-temperature electrocautery, no clinically significant pocket haematoma developed, although almost 40% of patients were on anticoagulants. A recent study focused on the ~~periprocedural~~ risk of bleeding in patients on anticoagulants after transcatheter aortic valve implantation demonstrated that the risk of pocket hematoma with low-temperature electrocautery ~~demonstrated high safety with the risk of pocket haematoma of~~ was 1.2% [10]. ~~As in our population,~~ As nneither of the patients from the studied group developed a clinically significant pocket haematoma, and the rates of haematomas from the prior studies with low-temperature electrocautery ~~varied between 1.2%~~

~~and~~did not exceed 3.4%, it could be concluded that low-temperature electrocautery allows to maintain the low risk of pocket hematoma and lead-related complications [4,7].

Conflict of interest: No competing interests

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[1] Timmis A, Vardas P, Townsend N, Torbica A, Katus H, De Smedt D, et al. European Society of Cardiology: cardiovascular disease statistics 2021. Eur Heart J. 2022;43(8):716–99.

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Table 1: Characteristics of patients and outcomes of procedures performed with the use of low-temperature electrocautery versus similar procedures performed in the years 2020-2021.

Demographics	**N=150**	**N=436**	**p**
Female gender, n (%)	40 (26.7%)	152 (34.9%)	NS

Age, median (min – max), years	71 (62-79)	74 (65-82)	NS
Procedural characteristics			
Secondary procedure (patient already with an implanted device), including TLE, n (%)	136 (90.7%)	399 (91.5%)	NS
Time from baseline implantation to index procedureę, years, median [Quartile 1-Quartile 3]	7 [4-8]	7 [4-9]	NS
Haemoglobin Haematocrit at baseline, %, median [Q1-Q3]	41.0 [37.6-43.5]	40.5 (37.3-43.0)	NS
eGFR at baseline, ml/m3, median [Q1-Q3]	60 [50-75]	60 [48-72]	NS
Lowest haematocrit during hospital stay, %, median [Q1-Q3]	37.6 [33.9-40.7]	37,5 (34.1-40.8)	NS
Maximal reduction in haematocrit during hospital staty, %, median [Q1-Q3]	2.5 [1.1-4.3]	2.6 [1.0-4.2]	NS
Hospitalization duration after the procedure, days, median [Q1-Q3]	1 [1-3]	2 [1-3]	NS
Procedural radiation dose, mGy, median [Q1-Q3]	0 [0-19]	1 [0-5]	NS
Procedural duration, min, median [Q1-Q3]	90 [65-130]	90 [50-100]	NS
Atrial fibrillation on anticoagulation, n (%)	62 (41.3%)	277 (63.5%)	<0.001

Procedure types			
Generator replacement, n (%)	88 (58.7%)	316/436 (72.4%)	NS
PM replacement (n/N, %)	45/88 (51.1%)	195/316 (61.7%)	
ICD replacement (n/N, %)	19/88 (21.6%)	70/316 (22.1%)	
CRT replacement (n/N, %)	24/88 (27.3%)CRT replacement (n/N, %)	51/316 (16.1%)	
Device upgrade, n (%)	7 (4.7%)	3 (0.7%)	NS
Lead repositioning, n (%)	3 (2.0%)	8 (1.8%)	NS
Pocket revision, n (%)	1 (0.7%)	4 (0.9%)	NS
sICD implantation, n (%)	14 (9.3%)	36 (8.3%)	NS
TLE, n (%)	37 (24.7%)	69 (15.8%)	NS
Immediate outcomes			
Pneumothorax, n (%)	0/150 (0%)	0/436 (0%)	NS
Haemothorax, n (%)	0/150 (0%)	0/436 (0%)	NS
Pericardial tamponade, n (%)	0/150 (0%)	1/436 (0.2%)	NS
Bleeding, any, n (%)	2/150 (1.3%)	10/436 (2.3%)	NS

Bleeding requiring transfusion, n (%)	2/150 (1.3%)	8/436 (1.8%)	NS
Clinically significant pPocket haematoma, n (%)	0/150 (0%)	3/436 (0.7%)	NS
Lead dysfunction requiring acute implantation of the new lead	0/150 (0%)	4/436 (0.9%)	NS
Follow-up outcomes at 12 months			
Lead dysfunction, n (%)	0/150 (0%)	7/436 (1.6%)	NS
Local or systemic CIED-related infection, n (%)	0/150 (0%)	6/436 (1.3%)	
Need for pocket revision, n (%)	0/150 (0%)	2/436 (0.5%)	

*Significant in paired Wilcoxon signed-rank test ($p<0.001$)

Abbreviations: CIED - Cardiac implantable electronic devices; CRT - Cardiac resynchronization therapy; ICD – Implantable cardioverter-defibrillator; NS – Non-significant PM – Permanent pacemaker; sICD - Subcutaneous implantable cardioverter-defibrillator; TLE – transvenous lead extraction;

Caption: Chi-square test and exact Fisher tests were used for the assessment of categorical variables, while non-paired Wilcoxon test was used to assess continuous variables after assessment of distribution normality in the Shapiro-Wilk test.

~~**Table 1:** Characteristics of patients and outcomes of procedures performed with the use of low-temperature electrocautery~~

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223**~~Supplementary Materials:~~**

224~~Questionnaire dispatched among operators using plasma knife and conventional~~
225~~electrocautery.~~