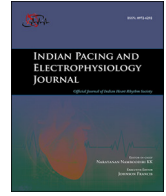




Contents lists available at ScienceDirect

Indian Pacing and Electrophysiology Journal

journal homepage: www.elsevier.com/locate/IPEJ

Interaction between shock coils increased the incidence of inappropriate therapies and lead failure in implantable cardioverter defibrillator



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ARTICLE INFO

Article history:

Received 20 August 2017

Received in revised form

21 September 2017

Accepted 24 October 2017

Available online 28 October 2017

ABSTRACT

Aims: Shock coil interaction in patients with multiple implantable cardioverter defibrillator (ICD) leads is occasionally observed. We aimed to evaluate the incidence of shock coil interaction and its clinical relevance.

Methods and results: All ICD patients (646 patients) who came to follow up control in our ICD ambulance between January 1, 2011, and December 31, 2011 in the department of cardiology in Bad Berka hospital were retrospectively evaluated in this study. All baseline demographic, clinical, and procedural characteristics and postoperative chest x ray in postero-anterior and lateral view as well as clinical and ICD follow up data were evaluated.

Among 646 patients 42 had multiple ICD leads (6.5%) of whom 36 patients (5.5% of total cohort patients and 85.7% of patients with multiple ICD leads) had shock coil interaction and presented the study group (Group I). The control group (Group II) consisted of 610 patients without coil-coil interaction including patients with single shock lead (604 patients) or patients with multiple leads but without interaction between shock coils (6 patients).

Inappropriate anti-tachycardia therapies and RV lead revisions were more frequent in patients with interaction between shock coils (Group I vs Group II: 27.7% and 5.7%; $p = 0.049$ and 30.6% vs 6.4%; $p = 0.0001$, respectively).

Conclusions: Interaction between shock coils may be one of possible causes of lead failure and resulted in inappropriate therapies and subsequent lead revision.

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1. Introduction

Over the last decades the number of implantable cardioverter defibrillator (ICD) implantations and revisions has considerably increased, long-term reliability of ICD leads remains a significant problem [1]. Lead design and material as well as implantation technique may contribute to lead failure and subsequent inappropriate ICD therapies consecutively leading to surgical revision [2]. Lead to lead interaction in ICD systems was first reported between ICD and pacemaker leads caused mainly by over sensing [3].

Sometimes this lead-lead interaction was detected during safety margin testing and could be corrected with repositioning of the new lead [4]. Another possible mechanism of lead-lead interaction is friction between retained and new leads, which may lead to abrasion and insulation defect of the new lead [5]. Holubec et al 2015 analyzed the contribution of implantation technique on lead failure and showed that lead-lead interaction was not associated with more lead failure [2]. Shock coils are larger and more prone to crush in comparison to other parts of cables. The incidence and clinical impact of coil to coil interaction is not well studied. Therefore we aimed to assess the incidence and clinical relevance of coil to coil interaction in a large cohort of ICD recipient.

2. Patients and methods

We included in this study retrospectively all ICD recipients (646

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Peer review under responsibility of Indian Heart Rhythm Society.

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patients) presented in the defibrillator ambulance between January 1, 2011 and December 31, 2011 in the department of cardiology in Bad Berka hospital. All baseline demographic, clinical, and procedural characteristics were evaluated. The most recent chest x ray was analysed to detect patients with interaction between shock coils and the site of interaction (right ventricle or superior vena cava or both). A coil to-coil interaction is defined if one coils overly another coil in both posterior-anterior and lateral X-ray view (Fig. 1). All available medical records of those patients were reviewed to assess the incidence of inappropriate (shock or anti-tachycardia pacing for supraventricular arrhythmias or due to over sensing) and appropriate anti-tachycardia therapies of ICD and lead revision when lead failure supposed to be due to lead fracture or loss of insulation according to ICD control parameters.

We divided the patients into two groups: study group (Group I) consisted of patients with evidence of interaction between shock coils in the postoperative chest x ray in both posterior-anterior and lateral views. The control group (Group II) consisted of patients in whom ICD had been implanted without interaction between shock coils including patients with single shock lead or patients with multiple shock leads but without interaction between coils.

2.1. Statistical analysis

Continuous variables were reported as median and interquartile ranges (25th–75thpercentiles). Categorical variables were presented as absolute (n) and relative (%) frequencies. Normal distribution of variables was assessed using the D'Agostino-Pearson omnibus normality test. The Mann-Whitney-test and the Fisher's exact test were used for appropriate comparisons. All tests were two-tailed and a probability value of $p \leq 0.05$ was considered to be statistically significant. Statistical analysis was performed using the GraphPad Prism version 6.02 for windows (GraphPad Software, La Jolla, California, USA).

3. Results

During the study period 646 ICD patients underwent follow up control in our ICD ambulance between January 1, 2011, and December 31, 2011 in the department of cardiology in Bad Berka hospital were retrospectively included in this study. All baseline demographic, clinical, and procedural characteristics and most recent chest x ray in postero-anterior and lateral views as well as clinical and ICD follow up data were evaluated. The control group

(Group II) consisted of 610 patients (94.5% of all study patients). Group I consisted of 36 patients with interaction between shock coils (5.5% of all study patients and 89.7% of patients with multiple ICD leads). There were no significant differences between the two groups at baseline (Table 1). More than half of our patient in bot groups received biventricular ICD, the implantation of single chamber ICD was more prevalent in the control group and dual chamber ICD was more prevalent in coil-coil interaction group (Table 2). The site of coils interaction was in 16.7% in superior vena cava, 44.4% in right ventricle and in both of them in 38.9% (Table 2).

The median follow-up was 29 months in group I vs 26 months in group II. During this follow up period a total of 110 patients received anti-tachycardia therapies (44.4% of Group I and 15.4% of Group II). The incidence of appropriate therapies was not significantly different between the groups (37.5% of Group I and 62.8% of Group II; $p = 0.09$). The incidence of inappropriate therapies was significantly higher in Group I (27.7% and 5.7%; $p = 0,049$). 50 patients (7.7%) underwent lead revision, the incidence was significantly higher in patients with coil-coil interaction compared to patients without coil-coil interaction (Group I vs Group II: 30.6% vs 6.4, $p = 0.0001$). Inappropriate anti-tachycardia therapies and lead revision were not related to the site of interaction. Mortality did not differ between the groups (see Table 3). Subgroup analysis of patients with multiple shock leads revealed a higher incidence of inappropriate therapies (27.7% and 0%) and subsequent lead revision (30.6% vs 16.7%) in patients with coil interaction. The data are shown in Table 4.

4. Discussion

Our study represents a large data set evaluating the incidence and impact of coil-coil interaction. In particular, the relevant findings of this study are first the incidence of coil-coil interaction was common in patients with multiple shock leads (36 patients 85.7% from 42 patients with multiple shock lead); second the incidence of inappropriate therapies was significantly increased among patients with coil-coil interaction; third the need of lead revision/repositioning was significantly more frequent among such patients. Sometimes in shock lead revision operation it is difficult to avoid this interaction especially if leads were implanted at apical position which is common practice in our institution and may beside the lack of awareness of this problem explain this high incidence of coil-coil interactions in patients with multiple shock leads.

ICD lead failures and subsequently lead revisions were detected

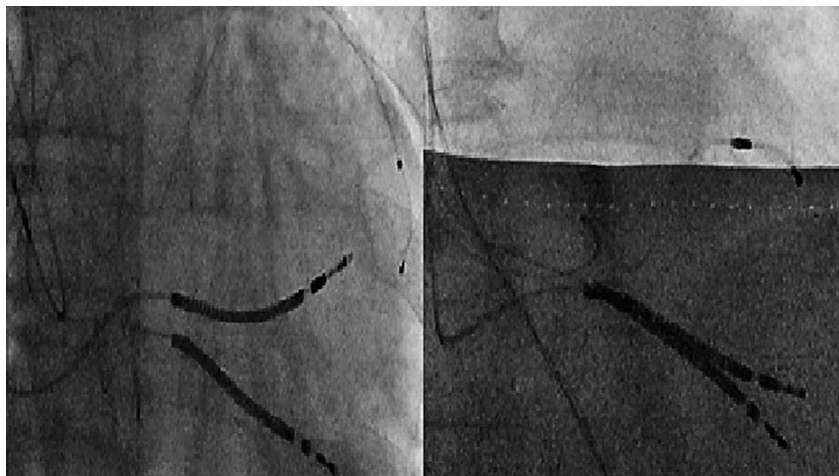


Fig. 1. To right post operative chest x ray showed a coil coil interaction, to left tow shock electrodes with out coil interaction.

Table 1
Comparison between the groups as regard baseline characteristics.

	Coil-coil interaction; n = 36	No coil-coil interaction; n = 610	p-Value
Age [years]			
Mean	66	67	0.83
Median (IQR)	66 (58–74)	69 (61–74)	
Sex [male]	31 (86.1%)	493 (80.8%)	0.52
Body-mass-index [kg/m ²]			
Mean	27	28	0.43
Median (IQR)	27 (25–30)	27 (26–30)	
Coronary artery disease	17 (47.2%)	386 (63.2%)	0.08
Prior coronary artery bypass grafting	6 (16.7%)	173 (28.4%)	0.18
Prior percutaneous coronary intervention	13 (36.1%)	297 (48.7%)	0.17
Hypertension	27 (75.0%)	511 (83.8%)	0.17
Diabetes	12 (33.3%)	252 (41.3%)	0.39
Chronic kidney disease	12 (33.3%)	199 (32.6%)	1.00
Cancer	3 (8.3%)	77 (12.6%)	0.61
DCMi	15 (41.7%)	213 (34.9%)	0.47
Valve dysfunction (> trivial)	6 (16.7%)	110 (18.0%)	1.00
Ejection Fraction [%]			
Mean ± SD	35 ± 13	31 ± 11	0.07
Median (IQR)	34 (30–40)	30 (25–35)	

IQR: interquartile range; DCMi ischemic dilated cardiomyopathy.

Table 2
Comparison between the groups as device characteristics.

	Coil-coil interaction; n = 36	No coil-coil interaction; n = 610	p-Value
Device type			
VVI-ICD	6 (16.7%)	216 (35.4%)	0.03
DDD-ICD	10 (27.8%)	83 (13.6%)	0.03
CRT-D	20 (55.6%)	311 (51.0%)	0.61
Indication for Device placement			
PP	26 (72.2%)	450 (73.8%)	1.00
SP	10 (27.8%)	160 (26.2%)	1.00
SSS	2 (5.6%)	40 (6.6%)	1.00
Atrial fibrillation	0 (0%)	12 (2.0%)	1.00
AV-Block	3 (8.3%)	42 (6.9%)	0.73
Binodal disease	0 (0%)	11 (1.8%)	1.00
CHF	20 (55.6%)	342 (56.1%)	1.00
Side of operation [left]	31 (86.1%)	576 (94.4%)	0.06
Device placement			
subcutaneous	0 (0%)	1 (0.2%)	1.00
sub-fascial	26 (72.3%)	489 (80.2%)	0.28
sub-muscular	10 (27.8%)	120 (19.7%)	0.28
Shock coil contact			
SVC	6 (16.7%)	0 (0%)	n/a
RV	16 (44.4%)	0 (0%)	n/a
RV and SVC	14 (38.9%)	0 (0%)	n/a

IQR: interquartile range; PP primary prophylaxis SP secondary prophylaxis, SSS Sick sinus syndrome; AV atrio ventricular; CHF congestive heart failure; SVC superior vena cava; RV right ventricle.

in 50 patients (7,7%) with mean follow up time of 25 months. This high Incidence of lead revision is in line with what reported by Kleemann et al. which reported 15% lead revision in 5 years after ICD implantation [6]. Other studies such as Eckstein et al 2008 showed relatively lower incidence of lead revision 2,5% in 5 years [7] which could be explained by different strategies to treat lead problems and the high incidence of single chamber ICD implantation which associated with lower incidence of lead failure in comparison with two chamber ICD and CRT D [8]. In our institution we try to resolve lead problem as oversensing and continuous increase of impedance as long as possible conservatively instead of immediate lead replacement. At the time of battery exchange we imply a more aggressive strategy aiming to reduce the incidence of reoperation. The high incidence of CRT implantation in our patients as well as long follow up time may be the main causes of relatively high incidence of lead revision in our patients.

Interaction between two endocardial leads is rare and uncommon in causing electrical noise [3]. There is some case report describe the interaction between shock electrodes as possible cause of lead failure [4,9]. Holubec et al 2015 studied the role of lead-lead interaction as a possible cause of lead failure but they showed that lead-lead interaction was not associated with more lead failure [2]. In this study we were more precise and studied coil-coil interaction because coils are more prone to be crushed, added to that tense fibrosis which occurred commonly around coils may lead to inside out abrasion because of sawing action of these cables under tension. In previous studies 80% of lead fractures occurred in the lead segment between shock coils. To the best of our knowledge, this study is the first one to show that the friction between shock coils is a possible cause of lead failure and subsequently lead revision.

Some authors favorite complete extraction of the old one to avoid coil interaction [3] but the major concern with this approach

Table 3
Comparison between the groups as regard clinical end points.

	Coil-coil interaction; n = 36	No coil-coil interaction; n = 610	p-Value
Follow-up [months]			
Mean	35	34	0.76
Median (IQR)	29 (5–51)	26 (4–50)	
Tachyarrhythmia events	16 (44.4%)	94 (15.4%)	0.0001
Adequate therapies	6/16 (37.5%)	59/94 (62.8%)	0.09
ATP	2/16 (12.5%)	23/94 (24.5%)	0.52
Shock	4/16 (25.0%)	36/94 (38.3%)	0.40
Inadequate therapies	10/16 (62.5%)	35/94 (37.2%)	0.049
ATP	6/16 (37.5%)	11/94 (11.7%)	0.02
Shock	4/16 (25.0%)	24/94 (25.5%)	1.00
Revision	11 (30.6%)	39 (6.4%)	0.0001
Death	1 (2.8%)	29 (4.8%)	1.00
cardiac	1 (2.8%)	18 (3.0%)	1.00
non-cardiac	0 (0.0%)	9 (1.8%)	1.00

IQR: interquartile range; ATP anti tachycardia pacing.

Table 4
Subgroup analysis to compare between patients with multiple shock leads with and without coil interaction.

	Multiple leads with coil-coil interaction; n = 36	Multiple leads, but no coil-coil interaction n = 6	Single lead, no coil-coil interaction; n = 610
Device characteristics			
VVI-ICD	6 (16.7%)	1 (16.7%)	216 (35.4%)*
DDD-ICD	10 (27.8%)	3 (50.0%)	83 (13.6%)*
CRT-D	20 (55.6%)	2 (33.3%)	311 (51.0%)
Follow-up [months]			
Mean ± SD	35 ± 39	74 ± 58 [§]	34 ± 36
Median (IQR)	29 (5–51)	71 (29–107)	26 (4–50)
Shock coil contact			
SVC	6 (16.7%)	0 (0%)	0 (0%)
RV	16 (44.4%)	0 (0%)	0 (0%)
RV and SVC	14 (38.9%)	0 (0%)	0 (0%)
Arrhythmic events	16 (44.4%)	1 (16.7%)	94 (15.4%) [‡]
Arrhythmic events per person/year	0.15	0.03*	0.06*
Adequate therapies	6/16 (37.5%)	1/1 (100%)	59/94 (62.8%)
ATP	2/16 (12.5%)	0/1 (0%)	23/94 (24.5%)
Shock	4/16 (25.0%)	1/1 (100%)	36/94 (38.3%)
Inadequate therapies	10/16 (62.5%)	0 (0%)	35/94 (37.2%)*
ATP	6/16 (37.5%)	0 (0%)	11/94 (11.7%)*
Shock	4/16 (25.0%)	0 (0%)	24/94 (25.5%)
Revision	11 (30.6%)	1 (16.7%)	39 (6.4%) [‡]
Death	1 (2.8%)	0 (0%)	29 (4.8%)
cardiac	1 (2.8%)	0 (0%)	18 (3.0%)
non-cardiac	0 (0.0%)	0 (0%)	9 (1.8%)

IQR: interquartile range; SD: standard deviation; ATP anti tachycardia pacing. *p < 0.05. §p < 0.01. ‡p < 0.001 compared with patients with coil-coil interaction.

is the risk of complications that can be associated with extraction [9]. When extraction is not possible new lead should be implanted away from the old lead.

5. Limitations of the study

First, our study is subject to limitations inherent in observational studies, and in single center studies with relatively small number of patients. Second, all patients received ICD implantation with subclavian puncture and apical positioning of shock lead; therefore we cannot generalize our results to patients with alternative operative techniques. Finally, coil-coil interaction as the assumed cause of lead failure in our study group was not confirmed by direct examination of the lead, as lead extraction was not performed routinely in case of lead revision in our institution.

6. Conclusion

Friction between ICD shock coils may be one of possible causes

of lead failure and led to inappropriate shocks and lead revision.

Funding

None.

List of abbreviation

ATP	anti tachycardia pacing
AV	atrio ventricular
CHF	congestive heart failure
DCMi	ischemic dilated cardiomyopathy
ICD	implantable cardioverter defibrillator
IQR	interquartile range
PP	primary prophylaxis
RV	right ventricle
SP	secondary prophylaxis
SSS	Sick sinus syndrome
SVC	superior vena cava

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