

Figure 1

mon comorbidity. Insufficient extent of BivP $\leq 98\%$ during the first year of CRT treatment is an independent predictor of poor outcome thus further supporting the use of 98% threshold of BivP, which should be attained in order to maximize the benefits of CRT. Adequate BivP appear to diminish deleterious impact of AF on prognosis.

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Lower annual operator volume is associated with higher risk of early cardiac implantable electronic device infection: insights from a contemporary, nationwide Danish cohort

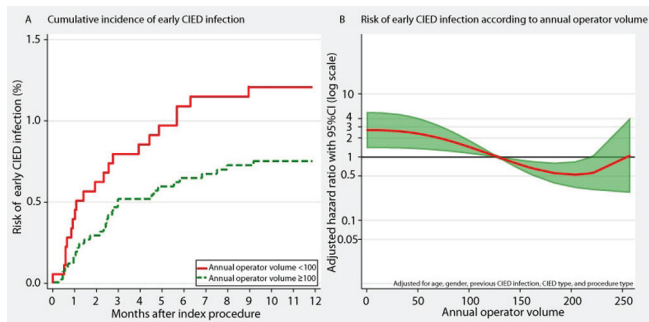
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Introduction: Cardiac implantable electronic device (CIED) infection is a serious complication associated with increased morbidity and health care costs. Few data exist on the influence of annual operator volume on CIED infection.

Purpose: We aimed to describe the association between annual operator volume and early CIED infection in a complete, contemporary, nationwide cohort of consecutive CIED patients.

Methods: A nationwide, cohort study was performed including all patients who underwent a CIED procedure in Denmark from May 2010 to April 2011. Data came from the Danish Pacemaker and ICD Registry. Study outcome was early CIED infection leading to CIED extraction within one year from the index CIED procedure in order to comprise surgical site infection. Cumulative incidence proportions for early CIED infection adjusted for competing risk (death) according to annual operator volume were generated. Cox proportional hazard regression analysis was used to estimate hazard ratio (HR) and 95% confidence interval (CI) for the association between annual operator volume and CIED infection (adjusted for age, gender, CIED type, index CIED procedure, and prior CIED infection) and the association further investigated by fitting fractional polynomials.

Results: The study population consisted of 5,918 consecutive patients; median age: 74 y (65–83), women: n=2,211, pacemaker: n=4,189, cardiac resynchronization therapy device: n=654, implantable cardioverter defibrillator: n=1,075, first implant as index procedure: n=4,355, reintervention as index procedure: n=1,563. During the study period, 68 physicians performed CIED procedures. Forty-one of



these were lower volume operators with <100 annual procedures (mean 44 annual procedures). Lower volume operators performed 30.2% (n=1,785) of procedures included in this study. Twenty-seven operators were higher volume operators performing more than 100 annual procedures (mean 150 annual procedures). A total of 51 patients (0.86%) had early CIED infection. The cumulative risk of infection was higher if the procedure was performed by a lower volume operator (Figure A). In multivariate analysis, increased risk of early CIED infection was observed in procedures performed by a lower volume operator, aHR 1.9 (95% CI 1.1–3.3, p value 0.03). This is further substantiated in Figure B where infection risk is depicted according to annual operator volume as a continuous covariate.

Conclusions: In a contemporary, nationwide cohort of consecutive CIED patients, risk of early CIED infection was low. Lower annual operator volume is an important predictor of early CIED infection. These data support a minimum of 100 annual CIED procedures per operator to minimise early infection risk.

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Healthcare resources utilization due to complications of cardiac implantable electronic devices: preliminary results from the IMPACT registry

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Background: While many evidence is currently available regarding incidence, type and treatment of complications related to cardiac implantable electronic devices (CIED), less is known regarding the impact of these complications on the healthcare system in terms of hospitalizations and related costs.

Purpose: To describe how CIED-related complications affect health care cost and resource utilization.

Methods: The IMPACT is a national registry promoted by the Italian Association of Arrhythmology and Cardiac Pacing (AIAC). All consecutive patients undergoing a CIED implant in one of the six enrolling centres between January 2010 and December 2012 were enrolled in the registry and followed-up for at least three years. We considered as a complication any event that was related to the CIED and that resulted in any of the following: a) unplanned surgical procedure (re-implant, upgrade, extraction, pocket surgery); b) unplanned hospitalization (device malfunctioning, inappropriate shocks or pacing therapy); c) unplanned out-of-hospital visit. Costs analysis was based on the Italian healthcare system, utilizing the standardized reimbursements for each of the ICD-9 diagnoses considered.

Results: We enrolled 2811 consecutive patients (age 71±14 years, 66.7% males), of which 1413 (50.3%) undergoing a pacemaker (PM) implant, 815 (29%) an implantable cardioverter defibrillator (ICD) implant and 583 (20.7%) a cardiac resynchronization therapy (CRT-D) implant. During follow-up (median 56.9 months) we observed 283 complications in 263 patients: 31.5% lead dislodgment, 15.1% pocket hematoma, 14.3% pocket infection, 11.8% pocket decubitus, 11.3% lead fracture, 8.0% device malfunctioning, 5.5% pneumothorax, 2.5% cardiac e-fusion. The annual complication rate was 2.2% per year, and ICD and CRT-D implants had significantly more complications when compared to PM (3.1% and 2.6% vs 0.9% respectively; p<0.001). Male gender, NYHA class, ischemic cardiomyopathy, left ventricular ejection fraction, oral anticoagulation, and CRT were all independently associated with an increased risk of complications. The patients experiencing a complication had twice the number of hospital admissions (2.3 vs. 1.1; p<0.001) and spent in hospital four times more time (15.7 vs. 3.6 days;

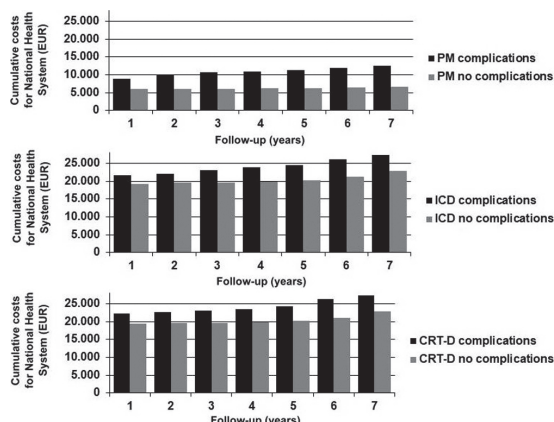


Figure 1

p<0.001) than CIED patients with no complication. A single CIED complication during follow-up is associated with a 28.3% increase in healthcare cost. The relative increase is much higher in PM patients (89.4%; 12.459 vs 6.577 Euro; p<0.001) and less in ICD (20.2%; 23.371 vs 22.775 Euro; p<0.001), and CRT-D patients (18.9%; 27.222 vs 22.897 Euro; p<0.001). Figure 1 details cumulative costs for every year after CIED implant.

Conclusions: CIED-related complications have a large impact on healthcare utilization and related costs. These data underline the importance of adopting specific protocols and preventive measures in order to reduce CIED complications and improve their management.

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Lead extraction in children and young adults - indications, complications, effectiveness and technical problems; the comparison with adults

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There is a considerable controversy regarding safety of transvenous lead extraction (TLE) in young patients due to different anatomy, intensive connecting tissue scar and earlier calcification. The Objective: The comparison of safety and feasibility of TLE in young and adult patients.

Methods: Using standard mechanical systems we have extracted ingrown PM/ICD leads from 50 children (<19 years old), and 2064 adult patients (40–79 years, especially selected control group) within the last 12 years. Patients over 80 years old and young 19–39 years old were excluded from the study.

Results: Results are presented in the table.

Impression: Children with old ingrown intracardiac leads form an extremely differentiated group. TLE in children is a different challenge (intensive tissue scar, frequent calcification or mineralization). Rare occurrence of pocket infection in children may be explained by implantation procedure performed in operation room (not in an EPS lab).

	<19 years	40–79 years	P		
Number of patients	50	2064			
Patient's age, years (SD)	14.8	3.2	66.3	9.3	S
Sex (% of male patients)	34	68.0%	1283	62.1%	NS
Infective indications (LRIE & pocket infection)	5	2.0%	729	35.8%	S
Number of leads in heart before lead extraction (SD)	1.43	0.56	2.00	79.00	S
Number of extracted leads in one patient (SD)	1.29	1.04	1.67	0.79	S
(ICD) lead extraction	7	14.0%	590	28.6%	S
Number of abandoned leads (SD)	0.13	0.40	0.18	0.52	S
Sum of dwell time of extracted leads, years (SD)	9.8	5.0	14.2	12.3	S
Technical problems during TLE	19	38.0%	395	19.1%	S
Major complications	1	2.0%	33	1.6%	S
Procedure related death	0	0.0%	6	0.3%	S
Full radiological success	39	78.0%	1986	96.2%	S
Clinical success	48	96.0%	2525	98.1%	NS
Full Procedural success	40	80.0%	1969	96.4%	NS

Conclusions: Infective indications are much less frequent in children. In spite of presence of simple systems in children, the effectiveness of TLE remains lower; a break of non-extractable distal lead fragment or a tip of a lead occurs in about 25% TLE. Young age does not influence on the appearance of major complications and procedure related death, however, the frequency of technical problems is increased.

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ICD therapy in primary prevention with mid-range LVEF in the painFree SST Study

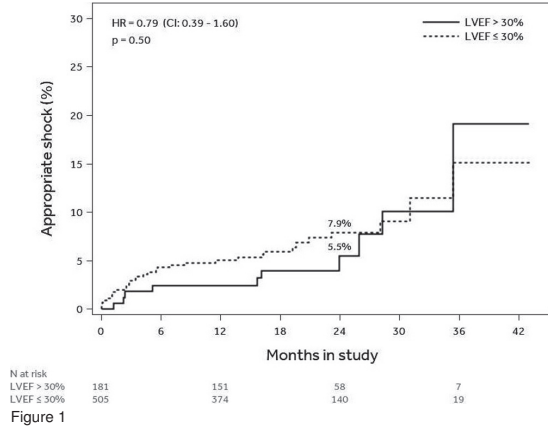
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Background: ESC guidelines recommend an implantable cardioverter defibrillator (ICD) for primary prevention of sudden cardiac death in patients with a history of myocardial infarction (MI) and reduced left ventricular ejection fraction (LVEF). However, evidence of benefit of ICD in patients with LVEF >30% is limited.

Method: This sub-analysis of the PainFree SST trial evaluates ICD therapy in primary prevention patients with prior MI, comparing LVEF ≤30% versus >30%.

Results: A total of 686 primary prevention patients with a history of MI were included, of which 505 had LVEF ≤30% and 181 had LVEF >30%.

>30% group, 87.3% of the patients had LVEF ≤40%. All devices included advanced shock reduction features and 80.4% had prolonged detection programming. At 24 months post-implant, the incidence of appropriate ICD shock was similar among the two groups (7.9% in LVEF ≤30% patients vs. 5.5% in LVEF >30% patients, HR = 0.79, 95% CI: 0.39–1.60, p=0.50, Figure). The incidence of appropriate ATP was also not significantly different among the two groups (10.7% in LVEF ≤30% patients vs. 5.4% in LVEF >30% patients, HR = 0.48 95% CI: 0.23–1.03, p=0.055). No significant differences were observed with regards to delivery of inappropriate therapy.



Conclusion: Among primary prevention patients with prior MI, the incidence of appropriate ICD therapy tended to be higher in patients with LVEF ≤30% compared to LVEF >30%, but differences were not significant and the therapy rate in patients with LVEF >30% was fairly high.

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Benefit and harm during 10-year ICD-therapy: temporal trends during the last 25 years

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Aim: Aim of the study was to evaluate the benefit and harm of long-term ICD therapy and to describe the temporal trends during the last 25 years.

Methods: Among 1955 patients of a prospective single-centre ICD-registry a total of 490 (25%) patients had a 10-year ICD therapy and were selected for the present analysis. Patients were divided into three groups according to the implantation year: 1991–1999 (group 1), 2000–2005 (group 2) and 2006–2008 (group 3).

Results: After 10 years of ICD therapy 58% of patients had an appropriate ICD therapy whereas 67% suffered from ICD complications.

Table 1. Baseline characteristics, benefit and harm of 10-year ICD therapy stratified according to the implantation year

	Group 1: implantation 1991–1999 (n=152)	Group 2: implantation 2000–2005 (n=238)	Group 3: implantation 2006–2008 (n=100)	p-value
Age (years)	58±9	59±11	59±11	n.s.
Female	18%	20%	25%	n.s.
EF <30%	25%	44%	62%	<0.0001
Primary prophylactic ICD	16%	40%	60%	<0.0001
Coronary artery disease	58%	59%	45%	n.s.
CRT device	1%	16%	28%	<0.0001
10-year ICD-therapy benefit				
ICD-therapy	70%	54%	49%	0.001
Appropriate ICD shocks	59%	35%	31%	<0.0001
Appropriate ATP therapy	49%	46%	35%	n.s.
10-year ICD harm				
ICD-complications	73%	66%	60%	0.03
Pocket or lead infection	7%	8%	9%	n.s.
Inappropriate shocks	43%	41%	32%	0.07
ICD lead defect	49%	33%	43%	0.005

Conclusions: Every 4th patient undergoing ICD implantation had a 10-year ICD-therapy. More than half of the patients profited from ICD therapy, but two thirds of patients had ICD-complications at the same time. The temporal trend over the last 25 years showed a significant decline of beneficial ICD therapy whereas there was only a slight decrease of the complication rate over time.