Short-term implantation-related complications of cardiac rhythm management device therapy: a retrospective single-centre 1-year survey

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Aims
The aim of this study was to evaluate the current short-term (<3 months) complication rate related to cardiac rhythm management (CRM) device implantations.

Methods and results
We analysed data of the complications related to all CRM device implantations during 1 year (2006) in a tertiary referral university hospital. In 567 device implantations, pacing system upgrade procedures, or lead revisions, 78 complications occurred in 69 (12.2%) patients. Lead dislodgement, pocket haematoma or bleeding, pneumothorax, and infection were the most common accounting for >80% of all complications. The complication rate was more than twice as high in bradycardia pacemaker (PM) implantations performed by cardiology trainees (17.4%) than by experienced cardiologists (7.7%, \( P = 0.001 \)). When performed by experienced cardiologists, the complication rate was not higher in implantations of more complex devices compared with that of bradycardia PMs. Fifty-two of the 69 patients needed additional surgical procedures. Altogether, the complications required 504 additional treatment days in hospital.

Conclusion
In conclusion, our retrospective 1-year single-centre survey shows that short-term implantation-related complications of contemporary device therapy are still frequent, occur much more frequently by trainees than by cardiologists, require a large number of additional surgical procedures, and substantially prolong the hospital stay.

Keywords
Pacemaker • Implantable cardioverter-defibrillator • Cardiac resynchronization therapy • Complications

Introduction
Cardiac rhythm management (CRM) devices include bradycardia pacemakers (PMs), implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy devices with pacing only (CRT-P) or also with defibrillation capability (CRT-D). Device therapy has developed rapidly during recent years, improves quality-of-life, haemodynamics, and physical capability, and often prolongs life. With expanding indications for ICDs and CRTs, the use of these more complex devices has increased rapidly. The target population often has severe congestive heart failure and various co-morbidities making them different from bradycardia PM populations. In addition, new implantation techniques like axillary vein puncture for venous access\(^1,2\) and alternative site ventricular pacing\(^3,4\) have been introduced and widely applied.

Furthermore, many cardiac patients are nowadays treated with antiplatelet and anticoagulation agents. Thus, complications related to implantations may have changed and become more variable. Large randomized device therapy trials provide estimates of implantation-related complication rates, but these may not be applicable to everyday practice because of selection bias in regard to operators and patients.

The purpose of the present study was to evaluate the current short-term (<3 months) complication rates related to CRM device implantations. We performed a retrospective analysis of all implantations during 1 year (2006) at the Helsinki University Central Hospital in Finland. In addition, we tried to identify some clinical, procedure-, and device-related determinants of the complications and evaluate the impact of complications.

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Methods

Study population
The study population was identified from the institution’s cardiac device registry. A total of 825 permanent CRM device implantations and replacements were performed in the year 2006. Of these, 554 were primary implantations, 11 pacing system upgrade procedures, 12 lead revisions, and the remaining were generator replacements. We excluded replacements and also those patients who were not followed in our hospital and who died from causes unrelated to device implantation, leaving 567 implantations for the study.

Study protocol
The pre-discharge evaluation was carried out the day after the implantation and included assessment of the PM pocket, an ECG, chest X-ray, as well as device interrogation, measurements, and programming. The follow-up visits were for PMs 3 months and for ICDs and CRT devices 1 and 3 months after implantation. History of symptoms, an ECG, device interrogation, and measurements were assessed. An additional chest X-ray was taken at 3 months for ICD and CRT-D devices. All evaluations were carried out by a dedicated cardiologist or a cardiology trainee under supervision, and pertinent data from the follow-up were documented in electronic patient files.

Data were collected from the time of implantation to the 3-month follow-up. We retrospectively reviewed patient files for pre-defined complications (see below) and for selected clinical and procedure-related characteristics that might predispose to complications. The clinical variables included diabetes, chronic renal insufficiency (serum creatinine >130 μmol/L), chronic heart failure, immunosuppressive medication, infection before implantation, temporary endocardial pacing, and the use of antplatelet [acetylsalicylic acid (ASA) or clopidogrel] and anticoagulation therapy [warfarin or low-molecular weight heparin (LMWH)]. The procedure-related variables included type of the implanted device, venous access route, lead fixation mechanism (active or passive) and ventricular lead position (apical or septal), and implantant’s experience (cardiologist or trainee).

The study was approved by the local Ethics Committee.

Device implantation
The indications for PM and CRT-P device implantations were according to guidelines.5,6 Implantable cardioverter-defibrillator and CRT-D devices were implanted mainly due to secondary prevention. As venous access for pacing leads, cephalic vein cutdown7 and axillary access sites is shown in Table 2.

In ICD and CRT-D implantations, vancomycin 1.0 g was administered intravenously prior to the procedure and thereafter ofloxacin 500 mg daily was used for 1 week.

Definitions of complications
A complication was defined as any adverse event requiring reoperation or additional diagnostic examinations with the subsequent need for prolonged hospital observation. Lead dislodgement was defined as inadequate capture or sensing with (macrodislocation) or without (microdislocation) a visible change of the lead position in the chest X-ray. Pneumothorax was defined as the absence of lung markings over the lung field ipsilateral to the PM pocket assessed from the pre-discharge X-ray. Pocket haematoma or bleeding was defined as swelling of the pocket with the need for reoperation or for prolonged hospital observation. Heart perforation was defined as procedure-related peri-cardial effusion or pericardial pain requiring prolonged post-operative surveillance or lead repositioning. Cardiac tamponade was defined as pericardial effusion causing haemodynamic compromise and requiring drainage. Symptomatic deep vein thrombosis was defined as a combination of symptoms with verification of the occlusion by contrast venography or ultrasonography. Device infection was classified as superficial wound infection or device system infection, defined as pocket infection or fever associated with positive blood cultures without an infectious focus elsewhere. Other non-pre-specified complications were noted.

The additional treatment days in hospital due to a complication were determined from the patients’ electrical records. If more than one complication occurred in a patient, the hospital days were counted for the most severe complication.

Statistical analysis
The absolute and relative frequencies were calculated for categorical variables and statistically tested with χ² or Fischer’s exact tests. A P-value of <0.05 was considered statistically significant.

Results

Implantation data
The age of the patients was 72 ± 14 years (range 16–100 years) and 291 of the patients (51.3%) were men. Of the included 567 implanted devices, 476 (84.0%) were bradycardia PMs and 91 (16.0%) were ICDs or CRTs (Table 1). Distribution of venous access sites is shown in Table 2. Bipolar active-fixation leads were used almost exclusively for the atria and in great majority for the ventricles. Implantable cardioverter-defibrillator leads were all with active fixation.

Clinical and procedure-related data are presented in Table 3. Of all the patients, 450 (79.4%) used more than one antiplatelet drug or anticoagulation therapy at the time of implantation. One-hundred and thirty-five patients (23.8%) had chronic heart failure.
Of all the device implantations, 325 (57.3%) were performed by a cardiologist and 242 (42.7%) by a trainee. Cardiologists implanted 234 (49.2%) of PMs and all ICDs and CRT devices.

Complications and their determinants
A total of 78 complications were detected in 69 (12.2%) patients with 8 patients having more than one complication (Table 4).

There were 69 complications in 60 patients receiving PM (12.6%) and 9 complications in 9 patients receiving ICD or CRT (9.9%). Complication rate in bradycardia PM implantations was 18 (7.7%) of 234 implantations by cardiologists and 42 (17.4%) of 242 implantations by trainees ($P = 0.001$). Complication rate was similar, 9 of 91 (9.9%) in ICD and CRT device implantations and 18 of 234 (7.7%) in bradycardia PM implantations when performed by cardiologists ($P = 0.52$). The overall implantation-related complication rate by cardiologists was 8.3%. The overall complication rate did not differ between single- and dual-chamber bradycardia PMs (11.8 vs. 13.3%, $P = 0.63$). No other clinical or procedure-related variable was statistically significantly related to higher overall complication rate.

The most common complication was lead dislodgement which occurred in 21 (3.7%) patients, all associated with PM leads. From these, 6 were macro- and 15 were microdislodgements. Dislodgement rate of the atrial lead (9 of 330, 2.7%) was not different from that of the right ventricular lead (12 of 535, 2.2%, $P = 0.65$).

The second most common complication was a pocket hematoma or bleeding occurring in 18 (3.2%) patients. They all were on antplatelet or anticoagulation treatment before implantation. Five patients had ASA alone, three patients ASA and clopidogrel, and one patient both ASA and LMWH. Warfarin was temporarily terminated in nine patients and substituted by LMWH in seven of them. Patients with chronic renal insufficiency did not have this complication more frequently than those without. Pocket hematoma or bleeding occurred more frequently in implantations by trainees (6.6%) than by cardiologists (1.5%, $P = 0.002$). All leads were successfully repositioned.

lead was of active-fixation type in all atrial and in three ventricular lead dislodgements. All dislodged ventricular leads were positioned apically. Dislodgement rate was higher in implantations by trainees (6.6%) than by cardiologists (1.5%, $P = 0.002$). All leads were successfully repositioned.

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Of all the device implantations, 325 (57.3%) were performed by a cardiologist and 242 (42.7%) by a trainee. Cardiologists implanted 234 (49.2%) of PMs and all ICDs and CRT devices.
trainees (5.0%) than by cardiologists (1.8%, \( P = 0.037 \)). Pocket haematoma needed surgical evacuation in seven (1.2%) patients, all having had two different anticoagulation or antiplatelet drugs before implantation.

Eleven patients (1.9%) developed pneumothorax related to the implantation procedure. Intercostal pleural drainage was needed in seven patients. This complication occurred more frequently in procedures by trainees (3.7%) than by cardiologists (0.6%, \( P = 0.011 \)). There were 10 pneumothoraxes in procedures by trainees. Five of these pneumothoraxes occurred with subclavian vein punctures and five with attempted axillary vein punctures. Pneumothorax did not occur with axillary vein puncture technique by experienced operators.

Eleven patients (1.9%) developed implantation-related infection. Nine were in bradycardia PMs and two in ICDs. Four of these were superficial wound infections, which responded to local measures and oral antibiotics. Seven (1.2%) were device system infections, which required removal of the generator with lead extraction and prolonged intravenous antibiotic treatment. Four of these infections were limited to the PM pocket and three patients also had signs of septic infection. Infection rates were 6.4% in patients with and 1.5% (\( P = 0.011 \)) without a temporary pacing lead before implantation. Two of the device system infections occurred after a reoperation due to lead dislocation.

Heart perforation occurred in four (0.7%) patients. All had the lead positioned in the right ventricular apex. Three occurred with pacing leads (two with active fixation) and one with an active-fixation ICD lead. Three patients needed repositioning of the lead and one pericardial drainage. Heart perforation with cardiac tamponade occurred in additional three patients (0.5%). All had right ventricular pacing leads with two in apical position and one in high septal position. Two were active-fixation leads.

Symptomatic deep vein thrombosis developed in four (0.7%) patients. All were subsequently anticoagulated and three patients became asymptomatic.

Other complications occurred in six (1.1%) patients. These included inadequate lead pin advancement to the connector in three patients, inadequate atrial sensing in a VDD PM, inadvertent ventricular lead placement in the coronary sinus, and a pectoral muscle haematoma after axillary artery puncture. The first five required corrective operation.

### Hospital stay after complications

The 78 complications in 69 patients resulted altogether in 504 additional hospital treatment days. The median prolongation of the hospital stay was 2 days ranging from 0 to 180 days. The mean prolongation due to complications was 0.9 day/patient. The additional hospital days according to complication type are indicated in Table 5.

### Discussion

#### Overall complication rate

Our observational retrospective 1-year survey from a single-centre shows that short-term implantation-related complications occur quite frequently in current cardiac rhythm device therapy. Complications requiring reoperation, additional diagnostic examinations, or prolonged hospital observation occurred in roughly one out of every eight patients (12.2%). In PM patients, complications occurred over two-fold more often in implantations by trainees than by cardiologists. Cardiologists had no obviously higher complication rate in ICD and CRT device implantations than in bradycardia PM implantations.

Estimation of the present implantation-related complication rate is relevant, since the implantation procedures have become more variable. Some new factors such as increasing number of trainees and more complex devices can potentially increase complications. On the other hand, improved lead technology and implantation techniques could decrease them. Implantation-related complication rates may be derived from randomized trials, retrospective surveys, and registries. However, data from recent randomized trials may not be applicable to everyday practice, since all these trials were performed in selected specific patient populations and the operators may have been more experienced limiting generalizability. Retrospective surveys provide complementary information on complication rates, but are surprisingly few with most reports focusing only on specific complications. In a study from early 1990s, Kiviniemi et al.\(^8\) found that in an unselected PM population, the overall complication rate was 14%, with 68% of these complications occurring within the first 3 months after implantation. A registry-based prospective multicentre PM study reported serious implantation-related in-hospital complications in 10.1% of the patients, which is similar to our overall 12.6% complication rate during 3-month follow-up concerning PMs only.\(^9\) These findings suggest that the net complication rate related to PM implantations has not decreased. On the other hand, in our institution, this rate is highly dependent on operator experience as seen also in other reports.\(^10,11\) More complicated device implantations did not affect the complication rate by experienced cardiologists. These findings suggest that with increasing number of trainees, the training process should be re-evaluated and possibly focused only on trainees likely to continue device implantations in their career.

#### Pre-defined complications

The most common complication (3.7%) in our study was lead dislodgement with no difference between atrial and ventricular leads.
The dislodgement rate was similar to previous reports.\textsuperscript{8,12} Operator inexperience was associated with a four-fold risk of this complication. Interestingly, no right ventricular lead dislodged from the primarily targeted septal position even by less experienced implanters, suggesting that pursuing active-fixation septal lead positioning could reduce this complication.

Pocket haematoma or bleeding post-operatively occurred almost as frequently (3.2%), and roughly one-third of the haematomas had to be surgically evacuated. This incidence is also similar to what has been reported recently.\textsuperscript{8,13} Antiplatelet and anticoagulation therapy is common in contemporary CRM device implantation population with ~80% of the patients using more than one of these agents in our study. High-dose heparin treatment or combined ASA + thienopyridine antiplatelet therapy was found to predict these complications in a recent large study.\textsuperscript{13} All our patients who needed pocket haematoma evacuation had at least two different anticoagulation or antiplatelet medications administered before device implantation. Avoiding combinations of these drugs as well as, for example, the local use of flowable haemostat tended before device implantation. Avoiding combinations of these two different anticoagulation or antiplatelet medications administered before device implantation. Avoiding combinations of these drugs as well as, for example, the local use of flowable haemostat consisting of collagen/thrombin suspension in high-risk patients might reduce the incidence of this complication.\textsuperscript{14} Implanter’s experience decreased this complication, suggesting that better surgical technique for haemostasis is also important.

Pneumothorax occurred in 1.9% of all patients, despite an attempt to primarily use cephalic vein cutdown or axillary vein puncture for venous access, which rate was similar to previous reports.\textsuperscript{8,12,15} Pneumothorax was much more common by trainees and did not occur with axillary vein puncture technique by experienced operators.

The rate of implantation-related infection in our study was 1.9% and required removal of the entire pacing system in 1.2% of the patients, which is similar to other studies (0.7–1.8%).\textsuperscript{8,15} Our data support previous observations\textsuperscript{15} that temporary pacing leads and reoperations predispose to infections.

Heart perforation occurred in four (0.7%) patients and an associated cardiac tamponade in additional three (0.5%) patients, a figure similar to 0.4% incidence in a recent study.\textsuperscript{8} All except one of the leads were implanted in the right ventricular apex and the majority were of active-fixation type. Our results suggest that right ventricular active-fixation leads should be positioned in the septum, although one lead targeted to this position caused tamponade.

Symptomatic upper extremity deep vein thrombosis occurred infrequently in our study population (0.7%), as also in other studies.\textsuperscript{8,16} However, we did not seek asymptomatic vein thrombosis, which occurs more frequently.\textsuperscript{16}

Impact of complications on hospital stay

The complications required altogether 504 additional treatment days in hospital. It means that almost one additional day/patient was spent in hospital because of an implantation-related complication. Most of the complications required additional surgical procedures. Implantation-related infections caused the most additional treatment days for the hospital, whereas for the individual patient, cardiac perforation with tamponade prolonged the hospital stay the most.

Study limitations

Retrospective assessment of complications has some inherent methodological limitations. However, to obtain reliable information, we used pre-defined complication definitions. Data of exact individual training status and experience regarding device implantations could not be determined. To assess more reliably individual determinants of complications, the study population should be larger. The study was done in a tertiary referral centre and included patients who may have more co-morbidities and more complex device implantations than in other hospitals. Thus, the results may not be applicable to hospitals implanting only PMs. Because of the small number of implanted CRTs, the potential difference in complication rates between ICD and CRT implantations could not be reliably assessed.

Conclusions

Our retrospective 1-year single-centre survey shows that short-term implantation-related complications of contemporary device therapy are still frequent with an overall complication rate of 12.2%. Lead dislodgement, pocket haematoma and bleeding, pneumothorax, and infection are even in contemporary PM therapy the most common adverse events, accounting for > 80% of all complications. The complication rate is markedly higher when implanters are cardiology trainees than experienced cardiologists. The complexity of the present device implantations does not increase the complication rate when performed by experienced cardiologists. The impact of these complications on the length of the patients’ hospital stay is substantial.

Conflict of interest: none declared.

References


