Complications leading to surgical revision in implantable cardioverter-defibrillator patients: comparison of patients with single-chamber, dual-chamber, and biventricular devices

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Aims

Implantable cardioverter-defibrillator (ICD) technology has become more complex, particularly with respect to biventricular resynchronization devices. The incidence of hardware-related complications in single (SC)-, dual (DC)-, and triple (BiV)-chamber devices requiring surgical revision has not been investigated systematically.

Methods and results

We analysed data from consecutive ICD recipients implanted between January 2000 and December 2007 with respect to the need of surgical re-intervention for device- or lead-related complications. Generator exchanges due to normal battery depletion were not considered. From 816 patients (81% male, 69% ischaemic cardiomyopathy, 48% secondary prevention ICDs) followed for 31.1 + 24 months (2118 cumulative patient-years), 98 patients underwent 110 revisions (5.2% per patient-year). Complications included lead-related revision procedures in 81 cases and generator-related problems in 29 cases. The annual incidence of surgical revision due to complications was 11.8% in BiV compared with 4.9% in SC and 4.1% in DC patients (P = 0.002). This higher revision rate was mainly caused by lead-related complications. Implantation of a BiV system was an independent risk factor of the need for surgical revision (relative risk 2.37, 95% confidence interval 1.38–4.04).

Conclusion

Even with long-lasting operator experience, complications requiring surgical revision remain a clinically important problem of ICD therapy. The incidence of complications is significantly higher in BiV resynchronization devices than in SC and DC systems.

Keywords

Implantable defibrillator • Complications • Surgical revision • Cardiac resynchronization therapy • Lead complication

Introduction

Implantable cardioverter-defibrillator (ICD) therapy is the mainstay in the prevention of sudden cardiac death.1,2 Over recent years, modern ICD systems have become increasingly complex with a significant proportion of systems consisting of dual- or even triple-chamber (DC or BiV) devices. Implantable cardioverter defibrillators capable of biventricular stimulation improve quality of life, exercise capacity, and outcome in patients with heart failure of New York Heart Association functional class III–IV, left ventricular (LV) ejection fraction <0.35, and QRS duration ≥120 ms.3–6 This increasing complexity in ICD hardware may result in higher complication rates compared with single-chamber (SC) devices. However, specific data on this clinically relevant question are sparse.7–9

Accordingly, the purpose of this observational single-centre study was to analyse lead- and generator-related complications in patients treated with SC, DC, or biventricular ICDs necessitating surgical interventions.

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Methods

Patients

Implantation and follow-up data were retrospectively collected from consecutive patients who underwent transvenous ICD implantation between January 2000 and December 2007 at the J.W. Goethe University, Frankfurt, Germany. Indications for ICD and cardiac resynchronization therapy (CRT) were based on contemporary guidelines. Patients were followed up in 6 months intervals. In the case of surgical re-intervention, all information (clinical data, device interrogations, and surgical reports) was carefully collected and analysed.

Device implantation

All implantations were performed by electrophysiologists with a long experience in device therapy. At the time of initial device implantation, right ventricular (RV) and atrial (A) leads were implanted conventionally preferably using the cephalic vein. Left ventricular leads were implanted via lateral subclavian puncture with the intention to avoid subclavian crush of the lead. Defibrillation shock testing (successful defibrillation with energy at least 10 J lower than maximum output) was performed in haemodynamically stable patients.

Classification of causes leading to surgical revision

Regular generator replacements without additional surgical interventions (i.e., lead replacements) and lead-related complications, which could be resolved by reprogramming the device, were not considered for the present analysis. Early generator depletion was defined as generator replacement <4 years after implantation. The following classification of lead-related complications was applied: dislocation defined as X-ray-confirmed dislodgement of the lead combined with significant changes in sensing/pacing performance; exit block defined as failure to capture at reasonable device output without visible changes in the lead position or significant impedance rise; oversensing defined as sensing of artefacts (chaotic, far-field, T-wave, myopotential, and so on) without significant changes in lead impedance or visible changes in the lead position; and lead fracture defined as changes in impedance (>2000 Ω) with changes in sensing/pacing performance (intermittent or permanent), optionally confirmed by fluoroscopy.

Generator-related complications were defined as early generator depletion (<4 years after implantation), recalls, power reset, pocket bleeding, infection (pocket or endocardial), pocket ulceration, and lead connector problems.

Statistical analysis

Baseline variables were compared using the χ² test or the analysis of variance test where appropriate. Due to different mean follow-up durations of patients with SC or DC vs. biventricular devices, the sum of patient-years with implanted devices was calculated for the three device types. The rate of surgical revisions was normalized by the overall patient-years in the different groups. Survival times without the need of surgical revision in the three patient groups were estimated with the Kaplan–Meier method and compared with the Mantel–Cox test. Several clinical variables were evaluated as potential predictors of the need for device revisions by univariable and subsequently by multivariable Cox regression analysis. A two-sided value of P ≤ 0.05 was considered significant.

Results

Patients’ characteristics

Data from 816 consecutive ICD recipients were collected (Table 1). Patients receiving biventricular ICDs were older, had a lower ejection fraction, and had more often dilative cardiomyopathy and primary prophylactic ICD indications compared with those with SC or DC devices. The devices were implanted in a pectoral pocket in all patients.

Follow-up

Mean follow-up duration was 31 ± 24 months in 816 ICD recipients (2118 patient-years): 33 ± 26 months in 453 patients receiving SC devices (1267 patient-years), 35 ± 23 months in 234 patients receiving DC devices (682 patient-years), and 16 ± 14 months in 129 patients with biventricular ICDs (169 patient-years) (P < 0.001 compared with SC or DC ICDs). The normalized yearly mortality (4.6, 4.5, and 5.3%; P = ns) and the time to...
death (27 ± 18, 30 ± 18, and 21 ± 15 months; P = ns) did not differ in patients with SC, DC, or BiV devices, respectively.

Revision procedures
A total of 110 surgical revisions were performed in 98 patients, with 87 patients undergoing one, 10 patients two, and 1 patient three re-interventions. The normalized overall revision rates were 4.9, 4.1, and 11.8% per patient-year (P = 0.002 SC and DC vs. BiV). Survival free of device revision was similar for patients with SC and DC devices, those patients with biventricular devices had a significantly shorter revision-free follow-up time (Figure 1, P = 0.002).

In the univariable analysis, the relative risk (RR) for surgical revision was 2.44 [95% confidence interval (CI) 1.43–4.16, P = 0.001] for biventricular devices compared with SC devices and 2.39 (95% CI 1.32–4.31, P = 0.004) for biventricular devices compared with DC devices. There was no higher risk for revision for patients with DC devices, compared with SC (RR 1.02, 95% CI 0.64–1.63, P = 0.93). Univariate predictors of device revision were type of device and female gender (Table 2). In the multivariable Cox regression analysis, both factors remained significant (triple- vs. SC: RR 2.37, 95% CI 1.38–4.04, P = 0.002; triple vs. DC: RR 2.26, 95% CI 1.25–4.09, P = 0.007; female gender: RR 1.80, 95% CI 1.17–2.77, P = 0.007).

There was no difference between SC (1.5%), DC (1.0%), and biventricular (1.8%) ICD patients groups regarding the yearly incidence of generator-related complications. The higher rate of revision procedures in patients with biventricular devices was predominantly due to a higher rate of lead-related complications (Table 3). Time to lead-related revision procedures was significantly shorter in patients with biventricular devices (Figure 2). When revisions for LV lead-related complications were excluded, there was no significant difference between the three patient groups in the surgical revisions per patient-year (4.9 vs. 4.1 vs. 7.9, P = 0.15) or in the time to first revision procedure (Mantel–Cox test: P = 0.20). A detailed description of lead-related causes for surgical revisions is shown in Table 4. Lead dislocations were most commonly observed during the first month after ICD implantation (11/21 cases); only one case of late LV lead dislocation occurred after 25 months (mean 0.9 months, 0.1–25). The dislocation rate was lower for RV (1.1%, 9/816 leads) and atrial leads (1.9%, 7/363 leads), compared with coronary sinus leads (4.7%, 6/129 leads, P = 0.03). The exit block occurred mainly (7/10 cases) within the first 3 months (mean 2.4 months, 0.3–14). Lead fractures (mean 23 months, 0.2–53 months) and oversensing problems (mean 23, 0.0–67 months) were mainly observed in RV leads with a more evenly distributed timing.

Discussion
Main findings
In the present large unselected ICD population, the annual rate of surgical revisions for hardware-related complications was ~12% in patients with biventricular ICDs when compared with 4–5% in those with SC or DC ICDs. This higher incidence of surgical revisions in patients with biventricular devices was predominantly due to lead-related complications, particularly related to the coronary sinus lead. Time to surgical intervention in patients with biventricular devices was significantly shorter compared with SC or DC ICD patients.

Complications of implantable cardioverter defibrillator therapy
The most common complications of ICD therapy are inappropriate shock deliveries (5–19%). Other complications include device malfunctions (1.4% per patient-year), lead problems (1.6%), and site infection (0.6%), according to a systematic review of randomized and observational ICD trials.13 Complications resulting in surgical revision (in the AVID trial 6% in the first year after implant)14 are of particular interest, given the risks of repeated surgical procedures including higher risk for device infection. The risk for a system infection is higher when more than two leads are present.15 A higher rate of complications with biventricular systems was previously presented;16 however,
these investigators had a much higher LV lead dislocation rate of 14%, which was probably related to their learning experience (6/43 patients). In a preliminary report of Gold et al., the incidence of the combined endpoint of mortality, patient injury, loss of system function, and system revision was higher in patients with biventricular systems compared with SC or DC devices. The difference remained significant even after excluding LV lead-associated complications, possibly because of the higher rate of mortality in the sicker patient population.

Lead-related complications

In our study, the majority of revision procedures were performed for lead-related complications (74%, 81/110). In the majority of all cases (58%, 64/110 revisions), RV lead complications prompted surgical intervention. Overall RV lead performance in our patient population was 93.5% at 24 months and 87% at 60 months. Published ICD lead performance data vary according to the definition of ICD lead survival (electrical, X-ray abnormalities, or the need of surgical revision) from 91 to 99% at 2 years and from 85 to 98% at 5 years. The performance of the leads may be dependent on the manufacturer and technical parameters of the lead.

Reported risk factors for defibrillation lead defects were younger age and female gender. In our series, the risk for revision was higher in patients with biventricular devices compared with SC or DC devices and in female patients. Inappropriate ICD shock delivery was the indicator of an RV lead defect in 41% (26 of 64 RV lead defects) in our series, which is within the range reported by other investigators.

The overall complication rate of DC ICD therapy may be higher than that of SC ICD therapy. However, DATAS showed only a non-significant trend towards higher procedure-related complication rate during DC ICD implantation. There was no difference in the lead-related complications between SC and DC ICD groups. We found no difference in our ‘hard’ endpoint surgical re-intervention between the two groups, possibly because the complications that could be managed with reprogramming of the device were excluded in our analysis. This was often the case in atrial lead-related complications, as threshold rise, suboptimal atrial signal amplitude, or rare oversensing episodes in the atrial channel did not lead to urgent revision. The revision of the atrial lead was postponed until the time of elective generator replacement.

Table 3 Number of generator- and lead-related revisions and incidence of hardware complications associated with implantable cardioverter defibrillator discharges per patient-year of observation

<table>
<thead>
<tr>
<th></th>
<th>SC</th>
<th>DC</th>
<th>BiV</th>
<th>Total</th>
<th>P-value</th>
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<tr>
<td>Patient years</td>
<td>1267</td>
<td>682</td>
<td>169</td>
<td>2118</td>
<td></td>
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<tr>
<td>All revisions</td>
<td></td>
<td></td>
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<tr>
<td>(patient-year)</td>
<td>62 (4.9%)</td>
<td>28 (4.1%)</td>
<td>20* (11.8%)</td>
<td>110 (5.2%)</td>
<td>0.002</td>
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<tr>
<td>Generator-related revisions (patient-year)</td>
<td>19 (1.5%)</td>
<td>7 (1.0%)</td>
<td>3 (1.8%)</td>
<td>29 (1.4%)</td>
<td>0.89</td>
</tr>
<tr>
<td>Lead-related revisions (patient-year)</td>
<td>43 (3.4%)</td>
<td>21 (3.1%)</td>
<td>17* (10.0%)</td>
<td>81 (3.8%)</td>
<td>&lt;0.001</td>
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<tr>
<td>ICD discharge due to complications (patient-year)</td>
<td>20 (1.6%)</td>
<td>4 (0.6%)</td>
<td>2 (1.2%)</td>
<td>26 (1.2%)</td>
<td>0.165</td>
</tr>
</tbody>
</table>

There is no significant difference between the single- and dual-chamber group in any row. *P < 0.01 compared with single- and dual-chamber groups (Craddock–Flood's χ² test).

Figure 2 Left panel: time to first generator-related surgical revision in patients with single-chamber, dual-chamber, and biventricular implantable cardioverter defibrillator devices (Kaplan–Meier analysis). Right panel: time to first lead-related surgical revision in patients with single-chamber, dual-chamber, and biventricular implantable cardioverter defibrillator devices (Kaplan–Meier analysis).
Not unexpectedly, our data show that lead dislocation and exit block tend to occur early after implantation, mainly within 6 months, whereas problems related to oversensing or lead fracture are more evenly distributed over time.

Left ventricular lead dislocation

Adding a lead for LV stimulation increases complexity to the implant procedure and the incidence of lead-related complications during follow-up. The main reason for surgical revision of the LV lead was lead dislocation. The lead dislocation rate in our patient cohort was 4.7%. Similar dislocation rates of the coronary sinus lead were reported in the randomized trials.12,22 In single centre reports published in the last 4 years, LV lead dislocation rates varied between 0% (0/98 leads),23 1% (1/93 leads),24 3.9% (8/205 leads),25 4% (12/285 leads),26 and 7.5% (9/120 leads).27 In our study, after excluding LV lead-related complications, the difference in re-intervention rates between the three patient groups disappeared, emphasizing that the higher re-intervention rate in patients with triple-chamber ICDs was mainly due to the coronary sinus lead, predominantly lead dislocations. This observation is in agreement with the findings reported by others.28 To overcome dislodgement of LV leads, several methods for lead stabilization have been proposed.28–30 Although some of these studies reported favourable short-term results, no data concerning long-term performance are available.

Limitation of the study

Reporting complication rates as proportion per patient-year13 may overestimate the rates of complications, which are front-loaded, particularly when follow-up periods are short.

Conclusions and clinical implications

Even with long-lasting operator experience, complications requiring surgical revision remain a clinically important problem of ICD therapy. The incidence of complications is significantly higher in biventricular resynchronization devices compared with SC and DC ICD systems.

Before implantation of a biventricular device in heart failure patients, not only the more complex implantation procedure but also the higher surgical revision rates during follow-up need to be taken in consideration. Our data should be helpful for counseling heart failure patients in whom CRT is considered.

Conflict of interest: CWI is a consultant, investigator and member of the speakers’ bureau for Medtronic Inc., St. Jude Medical, and Ela Medical; SHH serves as a consultant, investigator and member of the speakers’ bureau for St. Jude Medical; GZD, JS and SCH have no conflicts of interest.

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References


