Original Research

Complications Related to Cardiac Rhythm Management Device Therapy and Their Financial Implication: A Prospective Single-Center Two-Year Survey

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Introduction: Cardiac rhythm management devices (CRMDs) have proven their clinical effectiveness for patients with heart rhythm disorders. Little is known about safety and complication rates during the implantation of these devices. This study demonstrated the complication rates related to CRMD implantation, and estimated the additional hospital stay and cost associated with the management of complications.

Methods: During a period of one year, a total of 464 consecutive recipients underwent CRMD implantation and were followed for 2 years. Finally, data were analyzed for 398 patients who completed the two-year follow up, resulting in a total of 796 patient-years.

Results: Of the 201 patients with initial pacemaker (PM) implantations, 6 (2.99%) had seven complications (5 patients had lead dislodgement, 1 of them twice), and 1 patient developed pocket infection. Of the 117 PM replacements, 1 (0.85%) patient developed a complication (pocket erosion). Two patients with complications (1 with an initial PM and 1 with a replacement) died before completing the follow up for reasons unrelated to cardiac causes. There were no complications in either initial implantations (69 patients) or replacements (11 patients) of implantable cardioverter-defibrillators. The average prolongation of the hospital stay was 7 days, ranging from 1 to 35 days, resulting in €17,411 of total additional direct hospital costs.

Conclusion: This study found relatively low rates of complications in patients undergoing CRMD implantation, initial or replacement, in our center, compared with other studies. The additional hospitalization days and costs attributable to these complications depend on the nature of the complication.

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The development of implantable technology for cardiac rhythm management remains one of the seminal achievements of the second half of the 20th century.[1] Pacemakers (PMs) decrease mortality and improve quality of life,[2] while implantable cardioverter-defibrillators (ICDs) have been shown to reduce mortality in patients at risk of sudden cardiac death, in both primary[3-5] and secondary prevention.[6,7] Nowadays, PMs and ICDs are implanted on a large and growing scale because of the introduction of new indications and the aging of the population.[8-12] However, prospective studies examining the risk of the implantation procedure or the complications after initial implantation or replacement of cardi-

ac rhythm management devices (CRMDs) are rare.[13]

The primary aim of the present study was to estimate prospectively the complication rates, over a 2-year follow-up period, associated with the initial implantation or replacement of CRMDs that were implanted during a 1-year period in one tertiary university hospital in Greece. A secondary goal was to examine the additional hospital stay due to these complications and their economic implications.

Methods

Study design and sampling

This is a single-center registry that formed part of a cost-of-illness study. We recorded data from a consecutive series of patients who underwent CRMD implantation or replacement during a period of 1 year. The implantations of ICDs were conducted after approval from the Central Council of Health, as required by Greek legislation. Oral informed consent was obtained from the patients at the initial visit, prior to proceeding with the study. The study was carried out in accordance with the Declaration of Helsinki of 1975, as revised in 2000.

Data collection

Three case report forms (CRFs)—one for the baseline data (CRF A), another for the follow-up data (CRF B), and the last one at the end of the study (CRF C)—for each enrolled patient were completed prospectively by the investigator of the study.

CRF A (baseline data) encompasses sociodemographic characteristics, measurements of anthropometric and clinical characteristics, type of device (manufacturer, serial number), number and type of electrodes (manufacturer, serial number), and finally the complications during the implantation procedure. All these data were recorded by the principal investigator of the study from face-to-face interviews with the patients, from their medical folders and their attending physician.

CRF B (follow-up data) records all the complications that were noted during the follow-up period.

CRF C represents the final report at the end of the study for each patient. In case of death, the date and cause of death were recorded.

Study population

In the study period a total of 464 patients underwent initial implantation or replacement of a CRMD. Of these, 29 were lost during the two-year follow-up period and 37 patients died for reasons unrelated to their devices or other cardiac cause. Finally, data from 398 patients were analyzed.

Definition of complication

We defined as complication any adverse event related to CRMD therapy requiring reoperation or additional diagnostic examination, with the subsequent need for prolongation of hospital stay.

Results

Complications at initial implantation of PM

From the 240 initial PM implantations, 16 patients were lost to follow up and 23 died from non-cardiac causes (Table 1).

Among the 201 patients who remained, seven complications occurred in 6 patients (2.99%). More specifically, 5 patients suffered 6 lead dislodgements (1 patient twice). In 3 cases the passive lead was replaced with an active one; in the other 2 cases the lead was repositioned, but in 1 of them it was replaced by a new active lead, as it was dislodged again. One of the patients who had lead dislodgement died

Table 1. Complication rates in patients undergoing PM and ICD during the procedure of implantation and in two years' follow up.

Device implantations	PM (n=370)		ICD (n=94)	
	Initial	Replacement	Initial	Replacement
Number of patients	240	130	80	14
Died in 2-year follow up (non-cardiac causes)	23	7	5	2
Lost to follow up	16	6	6	1
Completed follow up (2 years)	201	117	69	11
Patients with complication	6	1	0	0
Number of complications	7	1	0	0

from non-cardiac causes before he completed the follow up.

A pocket erosion was the most important complication that occurred in 1 patient, where the blood cultures revealed *S. epidermidis*. The entire system was extracted and the patient received the appropriate antibiotics for 4 weeks. A well-trained multidisciplinary team was needed in order to ensure an effective pacing system extraction.[14]

Complication at replacement of PM

From the 130 PM replacements, 6 patients were lost in the follow-up period and 7 patients died from non-cardiac causes (Table 1).

Of the remaining 117 patients, 1 female patient (0.85%) had an erosion in the pocket, which was revised successfully, but died from a non-cardiac cause before the end of the follow up.

Complication at initial implantation of ICD

From the 80 initial ICD implantations, 6 patients were lost to follow up and 5 died from non-cardiac causes. There were no complications (0.0%) among the remaining 69 patients who completed the 2-year follow up (Table 1).

Complication at replacement of ICD

From the 14 ICD replacements, 1 patient was lost to follow up and 2 patients died from non-cardiac causes. None of the remaining 11 patients who completed the 2-year follow-up period had any kind of complication (Table 1).

Time of occurrence of complications and additional hospital stay

In total (from initial implantations and replacements of PM and ICD), there were 7 patients (5 males and 2 females) who suffered eight complications. Regarding lead dislodgements, 3 of them occurred acutely (within 24 hours from the procedure) and reoperation was performed less than 48 hours after the procedure. The other 3 occurred 4, 5, and 19 days after the initial procedure. Reoperation was performed within 24 hours.

The pocket infection, which was revealed 400 days after the procedure in an 80-year-old male, was the seventh complication, while the last complication was a pocket erosion, revealed 100 days after a PM replacement procedure in an 81-year-old female.

All the complications resulted in 51 additional hospital treatment days. The average prolongation of the hospital stay was 7 days, ranging from 1 to 35 days.

Financial implications of complications

In an attempt to assess the financial implications of the complications, they were analyzed over a 24-month period after the procedure, in order to estimate the additional cost of complicated care.

We estimated the additional direct cost (hospitalization cost, medication cost, laboratory and imaging diagnostic examinations) using the bottom-up approach. Based on 2012 charges, we estimated the total additional cost due to complications to be €17,411.

Discussion

In our study, the percentage of complications over a follow-up period of 2 years in patients who underwent PM implantation was 2.99% for initial implants and 0.85% for replacements. In contrast, no complications were recorded in patients who underwent ICD initial implantation or replacement.

The most common complication was lead dislodgement, while the most serious complication was pocket infection and endocarditis, which occurred in 1 patient.

Compared to other studies the complication rates from our study are relatively low.[15-21]

Acute complications (atrial and/or ventricular lead displacement requiring repositioning, infection, pneumothorax, hemothorax, cardiac tamponade, acute myocardial infarction, and death) after initial PM implantations are not rare, ranging from 4-7%.[19]

A registry-based prospective multicenter study (FOLLOWPACE)[15] reported serious implantation-related in-hospital complication rates for patients undergoing initial PM implantation. Based on the first 1198 non-selected patients from this registry, 111 patients (10.1%) exhibited one or more complications. More recent data from the same study,[16] based on 1517 patients who underwent initial PM implantation, demonstrated a complication rate of 12.4% (during the procedure and within 2 months). Thereafter, over a period of 5.8 years, 140 (9.2%) patients experienced complications, mostly lead related (n=84).

The activity and experience of operators are critical for the number and the type of complications. According to Parsonnet et al[22] and Tobin et al,[19] the relation between operator experience and complication rates is linear. Moreover, Tobin et al[19] reported that operators with more than 10 years' experience and more than 40 cases per year have the lowest percentage of complications.

In accordance with this, one study[21] reported that, in 234 PM implantations performed by cardiologists, the complication rate was 7.7%, whereas in 242 PM implantations performed by trainees, the complication rate was 17.4%. In total, 78 complications occurred in 60 patients (12.6%) and 8 patients had more than 1 complication. The most common complication in this study, during the PM implantation procedure and the follow-up period up to 3 months, was lead dislodgement in 21 (3.7%) patients (6 macro- and 15 microdislodgements). The overall complication rate did not differ between single- and dual-chamber PM devices.

It is not clear whether the complication rate was higher with dual- or with single-lead implantations. Some authors[20] have reported a higher rate of complications with dual-chamber than with single-chamber pacemakers. Others[24] have reported no increase in complication with dual-chamber pacemakers compared to single-chamber systems. A study from Papworth[20] reported higher late complication rates after elective unit replacement of dual-chamber systems.

At the same time, patients who underwent ICD implantation in our centre had no complications during 2 years' follow up, following either initial implantation or device replacement. It notable that no such results have been reported, either in any other similar study worldwide,[13,21,24-26] or in one systematic review of a randomized clinical trial.[27]

One single-center retrospective study[21] reported complication rates of 9.9% in patients undergoing ICD and CRT device implantations over a short-term follow up (<3 months). Another study,[28] which aimed to assess cardiac device implantations in the USA from 1997 through 2004 and to estimate perioperative outcomes until discharge, concluded that one or more complications occurred in 2-4% of new implantations.

The most important complication and the nightmare for operators and patients is infection, which can be associated with substantial morbidity and mortality.

The PEOPLE study[24] was a multicenter study from 44 medical centers, which evaluated the incidence and the risk factors of infectious complications over a follow-up period of 12 months after PM and ICD implantations in 6319 consecutive patients, 5866 with PM and 453 with ICD devices. Infections developed in 42 patients who underwent PM and ICD implantation, representing an incidence of 0.68 per 100 patients.

According to one survey,[29] which analyzed data from 48 centers of the European Heart Rhythm Association (EHRA) Research Network, the incidence of cardiovascular implantable electronic device infections showed a slight decrease from 2010 to 2011 in most centers and was substantially under 2% in the majority of centers interviewed. Fortunately, in our centre we had only 1 patient with pocket infection, which occurred long after the implantation procedure. However, it is clear that pocket infection is the complication with by far the longest additional hospital stay (35 days) and the greatest additional cost (€11,200).

The results from our study are very encouraging because of the low rates of complications. These low rates were mainly due to the high level of experience of the medical team. The team that has the responsibility for CRMD implantations receives continuous education on the technical, medical, and procedural levels and consists of cardiologists and electrophysiologists with a long experience in device therapy: more than 15 years of experience, and more than 5000 procedures involving implantation of such devices. The experienced operating room staff is also important. All of the above characteristics contribute to a careful and personalized clinical appraisal for each patient.

Study limitations

This study reflects complication rates from one center and the study population was relatively small. To assess more reliable individual determinants of complications, the study population should be larger, with a longer follow-up period. Ideally, all patients would be followed until death or need for replacement of the device. In addition, this study was not designed to evaluate the relationship of individual patient risk factors and subsequent complications. We present percentages of complications and compare those rates with the rates from other studies, but we cannot make accurate comparisons with those studies because of the differences in the follow-up period, in the types of devices, and the clinical and demographic profile of the enrolled patients.

Conclusion

This prospective survey demonstrates relatively low complication rates of in patients undergoing CRMD implantation, initial or replacement, in our center compared with other studies. The additional hospitalization days and the cost attributed to these complications depend on the nature of the complication.

The strength of the present report is that data were gathered in an organized, prospective fashion, within the confines of a randomized clinical trial. Quality assessment of therapeutic procedures of the CRMDs is essential in order to ensure a cost-effective health care system, especially today, in an era of sharp economic decline. Based on these complication rates, there is currently no evidence to support a change in practice.

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