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