

# Retrospective Study of Patients Who Undergo Pacemaker Implantation in Short-Stay Ambulatory Surgery. Long-Term Follow-up and Cost Analysis

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**Introduction and objectives.** The aim of this study was to analyze data concerning mortality, morbidity, the number of re-admissions, complications, and cost per patient after pacemaker implantation, in groups of patients with different postoperative follow-up regimens.

**Patients and method.** Data from 2108 patients with permanent pacemakers implanted between January, 1991 and December, 2001 were analyzed retrospectively. We took into account the length of hospital stay and pacemaker dependence: group I, non-pacemaker dependent ambulatory patients with no hospital admission (NPMD) (n=710); group II, pacemaker-dependent patients with a short hospital stay of up to 48 hours (PMD) (n=779); group III, non-pacemaker-dependent patients with routine hospitalization for more than 48 hours (NPMD) (n=289); and group IV, pacemaker-dependent patients with routine hospitalization for more than 48 hours (PMD) (n=330).

**Results.** Total mortality was 3.9% (n=83), and no deaths were directly related to surgery. The cause of death was cardiac in 1.4% (n=30), non-cardiac in 2.3% (n=49), and unknown in 0.2% (n=4) of the patients. Mortality was early (<30 days) in 38 patients (1.8%) and late (>30 days) in 45 patients (2.1%). Total mortality was the same in Groups I and II (0.2%), and morbidity was 0.75%, and 0.9%, respectively. There were no early deaths in these first 2 groups. In groups III and IV, mortality rose to 1.5% and 2% and morbidity to 0.9% and 1%. The total number of re-admissions (early and late) was higher in Groups III (6 re-admissions) and IV (9 re-admissions). The average total cost per patient, considering the sum of the average unit costs of the activities in each one of the medical processes which

were studied (i.e., hospitalization, home visits, surgical activity, re-admissions, and second operations) was 117 euros in group I (ambulatory surgery) and 280 euros in group II (short stay). In both groups III and IV (hospitalization) the average total cost rose to 917.80 euros.

**Conclusions.** Major ambulatory surgery may be an economical and efficient procedure for the health care system if it is used in carefully screened patients who require cardiac stimulation.

**Key words:** Ambulatory surgery. Pacemaker. Surgery. Cost-benefit analysis.

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## Estudio retrospectivo de pacientes sometidos a implante de marcapasos en cirugía mayor ambulatoria y de corta estancia. Seguimiento a largo plazo y análisis de costes

**Introducción y objetivos.** El objetivo de este estudio es el análisis retrospectivo de los datos de mortalidad, morbilidad, número de reingresos, complicaciones y coste por paciente tras el implante de marcapasos, obtenidos en distintos grupos de pacientes, según la pauta de recuperación.

**Pacientes y método.** Se han analizado retrospectivamente los datos resultantes de 2.108 pacientes con implante de marcapasos definitivo entre enero de 1991 y diciembre de 2001. Estos datos se han analizado teniendo en cuenta los siguientes grupos, según la duración de la estancia hospitalaria y la dependencia del marcapasos: grupo I, con 710 pacientes ambulatorios sin ingreso que no dependen del marcapasos; grupo II, formado por 779 pacientes con ingreso de corta estancia, hasta de 48 h, dependientes del marcapasos; grupo III, con 289 pacientes hospitalizados sistemáticamente con una estancia de más de 48 h y sin dependencia del marcapasos, y grupo

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## ABREVIATIONS

SS: short-stag.  
 MAS: major ambulatory surgery.  
 PMD: pacemaker-dependent.  
 NPMD: non-pacemaker-dependent.

IV, con 330 pacientes con hospitalización sistemática y una estancia de más de 48 h, dependientes del marcapasos.

**Resultados.** La mortalidad total fue de 3,9% (n = 83) y ninguna relacionada directamente con el implante. El número de muertes por causas cardíacas fue del 1,4% (n = 30), por causas no cardíacas del 2,3% (n = 49) y por causa desconocida del 0,2% (n = 4). La mortalidad fue precoz (< 30 días) en 38 pacientes (1,8%) y tardía (> 30 días) en 45 pacientes (2,1%). En el análisis, la mortalidad total fue la misma en los grupos I y II (0,2%) y la morbilidad del 0,75 y 0,9%, respectivamente. En estos primeros 2 grupos no hubo ninguna muerte precoz. En los grupos III y IV la mortalidad ascendió al 1,5 y 2% y la morbilidad a 0,9 y 1%. El número total de reingresos (precozes y tardíos) fue más elevado en los grupos III (6 reingresos) y IV (9 reingresos). El coste total medio por paciente, considerando la suma de los costes medios unitarios de las actividades que intervienen en cada uno de los procesos asistenciales objeto del estudio, es decir, la hospitalización, la visita de atención domiciliaria, la actividad quirúrgica y las reintervenciones y los reingresos, fue de 117 euros en el grupo I (cirugía mayor ambulatoria) y 280 euros en el grupo II (corta estancia); en los grupos III y IV (hospitalización) ascendió a la misma cantidad de 917,80 euros.

**Conclusiones.** La cirugía mayor ambulatoria puede constituir un procedimiento económico y ágil para la institución sanitaria si se aplica a la estimulación cardíaca, seleccionando adecuadamente los pacientes.

**Palabras clave:** *Cirugía ambulatoria. Marcapasos. Cirugía. Análisis coste-beneficio.*

## INTRODUCTION

The complexity of today's hospitals, which, for example, involve clinical departments formed from different specialties, multidisciplinary teams, and state-of-the-art technology, combined with society's preference for this type of institution and influenced by economic and political factors has led to a healthcare explosion. There is now a huge demand for emergency services, lengthy waiting lists, and a shortage of beds. In this situation, major ambulatory surgery, which is defined as "a type of healthcare that

combines all the resources of modern medicine with the emotional, social and psychological support of the patient's family and home; it is suitable for patients who need professional care but not the full range of services available at a general hospital,"<sup>1</sup> could contribute to relieving hospital congestion, improving healthcare quality, and easing healthcare costs by reducing the length of hospital stays.

In the area of cardiac stimulation, significant advances have taken place since Elmqvist and Senning<sup>2</sup> first implanted a complete cardiac pacemaker system in 1958. Miniaturized intracardiac devices have replaced earlier external systems and epicardial electrodes, which were difficult to set up. These advances, combined with technological and pharmacological progress in the areas of surgery and anesthesia, have both made possible and stimulated the search for alternatives to traditional hospitalization in this field.

A previous study carried out by our group,<sup>3</sup> which involved a follow-up analysis of 854 pacemaker implantations, showed that there was a very low incidence of complications with pacemakers using dual-chamber stimulation. Currently, there is still insufficient information about the results of early discharge in patients who require treatment by electrical cardiac stimulation.<sup>4</sup> In the present study, we analyzed data on pacemaker implantation carried out in selected patients who were treated within a program of major ambulatory surgery or surgery with a short hospital stay. We conducted a retrospective analysis of the medical histories of patients who underwent pacemaker implantation at our center over a period of 11 years. Patients were divided into groups according to their level of pacemaker dependency and existing risk factors, and data on mortality, morbidity, hospitalization, and complications were analyzed. Similarly, patient costs were calculated for the different patient groups.

## PATIENTS AND METHODS

Between January 1991 and December 2001, 2108 permanent pacemakers were implanted by the Servicio de Cardiología at the Consorcio Hospital General Universitario de Valencia in Spain. All patients, irrespective of age, were given the opportunity to be included in a program of major ambulatory surgery (MAS) or surgery with a short hospital stay. Once accepted into the program, patients were divided into 2 groups according to whether they were non-pacemaker-dependent (NPMD) or pacemaker-dependent (PMD). Group I comprised NPMD patients who underwent MAS, and group II, PMD patients who had a short hospital stay.

Patients who did not want to be included in the program (n=371) underwent routine hospitalization

after implantation, as did those who satisfied one of the social exclusion criteria ( $n=248$ ). These criteria included insanitary living conditions, no access to a telephone, no suitable means of transport, having a long way to travel to hospital, or having no one to look after them.

The study analysis was carried out on 4 groups of patients who were divided according to their length of stay in hospital and whether or not they were pacemaker-dependent. All data were recorded on a computerized database (FileMaker Pro 4.0):

- Group I: NPMD patients who underwent pacemaker implantation but who did not stay overnight in hospital ( $n=710$ ).

- Group II: PMD patients, in whom the failure of cardiac stimulation could have serious consequences, who remained in hospital for a maximum of 48 hours after implantation ( $n=779$ ).

- Group III: NPMD patients who underwent routine hospitalization for more than 48 hours ( $n=289$ ).

- Group IV: PMD patients who underwent routine hospitalization for more than 48 hours ( $n=330$ ).

Patients and their families were informed about the timescale and conditions of the study at its outset. Once they were accepted for participation in the program, patients were included in the MAS or short-stay group.

The following procedure was implemented in patients in the MAS group on the day of implantation and in short-stay patients on the day of discharge: patients were given instructions on home care that were appropriate for their clinical condition, were transferred home by ambulance if they did not have their own vehicle, were assigned a date for a follow-up visit in their home by a member of the medical team, and were assigned a date for a hospital check-up. In addition, they were provided with a permanent 24-hour telephone contact number for use in an emergency and for inquiries.

The human resources utilized in the program of MAS or short-stay surgery comprised members of the arrhythmia and pacemaker unit of the cardiology department: a cardiologist, a surgeon, and 2 nurses, plus a part-time auxiliary nurse and an ambulance driver, who were requested when necessary. The medical equipment available included that normally used for pacemaker implantation (i.e., an electrophysiological laboratory) and a suitably equipped ambulance, which had a mobile telephone, a portable electrocardiograph, a magnet, and a first-aid kit.

The study patients were followed up during regular outpatient consultations at 15 days for the removal of stitches from the surgical wound and for pacemaker programming, at 3 months to reduce the stimulating output voltage once the threshold level was considered to be fixed, and, subsequently, every year. If patients did not attend a follow-up consultation, they were

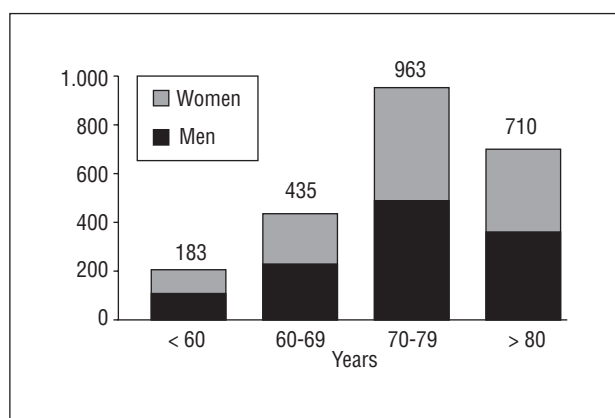
telephoned to obtain information. If this was not successful, details of the patient's clinical history held in the hospital's central records were reviewed. All complications and deaths that occurred after implantation were registered.

With the aim of assessing the acceptability of the program, the psychology department at our center mailed a questionnaire to the first 200 patients randomly selected from the different groups. The questionnaire included 13 questions that covered patients' opinions about the medical staff who treated them, about the information and treatment they received before, during and after implantation, about home visits, and about the instructions they received at discharge. In addition, their personal level of satisfaction, personal feelings, and willingness to take part in another similar program should it be necessary were also recorded.

A register was kept of the total length of the hospital stay, in both the coronary care unit and hospital ward, from the day of admission until final discharge of all 2108 patients included in the study.

In performing the cost analysis, unit costs provided by the hospital accounting department were used. These included operating theater costs, which were the same for all patient groups, and the cost of home visits (i.e., for the surgeon, driver and ambulance) for patients in groups I and II, as well as the cost of readmissions and of any repeat interventions required to treat complications.

A statistical analysis was carried out to compare morbidity and mortality in the MAS and short-stay groups and to compare any difference in morbidity and mortality between these 2 groups and groups III and IV, who were hospitalized. Quantitative variables were analyzed using an analysis of variance (ANOVA) and qualitative variables using a chi-squared test for comparing proportions.



**Figure .** Patients' age distribution (49% female, 51% male).

TABLE 1. Characteristics of the Different Study Groups

	MAS (Group I)	SS (Group II)	RH (Groups III and IV)	
	NPMD (n=710) Low Risk	PMD (n=779) Medium Risk	NPMD (n=289) Low Risk	PMD (n=330) Medium Risk
Women (49%)	351	382	140	159
Men (51%)	359	397	149	171
Age, years, mean±SD (73.7±11)	73.4±7	73.7±13	73.9±9	74.1±11
Diabetes (7%)	55	62	19	24
Arterial hypertension (12%)	97	103	36	39
Ischemic heart disease (30%)	293	289	48	57
Neurological disease (8%)	54	61	32	36
Cardiomyopathy (13%)	109	117	34	38
Valvular disease (7%)	56	61	20	23
Comorbid neurological, vascular, neoplastic or other disease (23%)	96	204	62	65
First implant (87.5%)	664	610	274	298
Right cephalic vein approach (92%)	687	756	229	275
Complications (n=76; 3.6%)	16	19	19	22
Readmission in <30 days (n=10; 0.5%)	0	0	4	6
Death at 30 days† (n=38; 1.8%)	0	0	17 (0.8%)	21 (1%)
Readmission in >30 days (n=6; 0.3%)	0	1	1+1	2+1
Death at >30 days (n=45; 2.1%)	4 (0.2%)	6 (0.2%)	14 (0.7%)	21 (1%)

\*MAS indicates major ambulatory surgery; SS, short stay; RH, routine hospitalization; NPMD, non-pacemaker-dependent; PMD, pacemaker-dependent; SD, standard deviation. †Unconnected with pacemaker implantation (if there was other disease, such as cardiac, neurological or neoplastic disease).

TABLE 2. Calculated Mean Hospital Stay and Cost per Patient\*

	MAS (Group I)	SS (Group II)	RH (Groups III and IV)	
	NPMD	PMD	NPMD	PMD
Patients	710	779	289	330
Days in hospital	0	1169	2312	2760
Total cost of hospitalization, euros	0	126 766 (19%)	250 820 (37%)	299 422 (44%)
Cost per patient of hospitalization, including complications, euros	0	162.70	867.80	867.80
Cost of home visit, euros	66.90	66.90	0	0
Cost of surgery and electrophysiology laboratory services, euros	50	50	50	50
Mean unit cost per patient, euros	117	280	918	918

\*MAS: major ambulatory surgery; SS: short stay; RH: routine hospitalization; NPMD: non-pacemaker-dependent; PMD: pacemaker-dependent

## RESULTS

### Study Population

The study included a total of 1076 men (51%) and 1032 women (49%) with a mean age of 73.7±11.0 years. The age distribution is shown in the Figure. The mean follow-up period was 50.9±33.6 months (range, 8–132 months).

Of the 2108 patients studied, 1109 were PMD (48%) and 999 were NPMD (44%). The main clinical diagnosis was ischemic heart disease in 30%, cardiomyopathy in 13%, and valvular disease in 7%. Half of the patients had electrocardiographic abnormalities without underlying cardiac disease.

Other comorbid complaints were found in 53% of patients: 12% had hypertension, 7% were diabetic, and 3% had both complaints. In addition, neurological disease was observed in 8%, and comorbid gastrointestinal, lung or urinary disease in 23%. Analyzed by group, these comorbid complaints were present in 27% of patients in group I, in 26% in group 2, in 21% in group III, and in 20% in group IV.

In total, 81% of the procedures involved first pacemaker implantations, comprising 93%, 78%, 95%, and 90% of procedures in groups I, II, III and IV, respectively. Some 12% involved replacement pacemakers, and 7%, a change in pacemaker operating mode; all these patients were included in group I. In



almost 85% of patients, the selected surgical approach taken was via the right or left cephalic vein, or both. In the remaining 15%, the electrode was introduced to the endocardium via the right or left subclavian vein, or both. The iliofemoral route was taken in only 4 patients, with the generator being lodged in the abdominal wall.<sup>5</sup> The pacemaker employed ventricular stimulation (VVI/R) in 33%, atrial sensing and ventricular stimulation (VDD/R) in 20%, dual-chamber stimulation in 46%, and atrial stimulation in 1%.

## Mortality

No death was a direct result of pacemaker implantation. The overall mortality rate in all patients monitored was 3.6% (n=83). In 38 patients, death was an early occurrence (i.e., in under 30 days), and, in 45, it followed later. The cause of death was cardiac disease in 30 patients (1.3%) and non-cardiac disease in 49 (2.3%), but could not be determined in the 4 remaining patients.

In groups I and II, there were no early deaths, although 10 patients died later due to causes unrelated to the pacemaker: 4 (0.2%) in group I and 6 (0.3%) in group II. There was no significant statistical difference between these 2 groups. In groups III and IV, both early (0.8% and 1%, respectively) and late (0.7% and 1%, respectively) mortality rates were higher than in groups I and II. Moreover, these differences were statistically significant ( $P<.01$  and  $P<.05$ , respectively).

## Complications

Only 76 patients (3.6%) experienced complications associated with pacemaker implantation, such as a displacement of the atrial or ventricular electrode or both, infection, pneumothorax, decubitus ulcer, hematoma, or atrial fibrillation during implantation. The numbers of complications that occurred in the different groups are shown in Table 1, and were: 16 in group I (0.75%), 19 in group II (0.9%), 19 in group III (0.9%), and 22 in group IV (1.0%). Among these 76 patients, there were 56 cases of electrode displacement that required repositioning (49 atrial and 7 ventricular), 12 hematomas of the surgical wound, 4 cases of infection, 2 cases of pneumothorax involving the apical lamina that did not require thoracic drainage and that were treated conservatively without the patient having to be hospitalized for more than 48 hours, and 2 cases of atrial fibrillation that occurred during implantation of an atrial electrode. There was no significant difference in the incidence of complications between the groups.

## Readmission

Only 16 patients (0.7%) who experienced complications associated with pacemaker implantation were readmitted. The remainder were dealt with as outpatients. Of these 16, 4 had infections (1 in group II and 3 in group III), 2 had decubitus ulcers (1 in group II and 1 in group IV), and 10 were admitted (8 early and 2 late) because they had atrial electrode displacement and wished to be readmitted for repositioning of the electrode (2 in group I, 3 in group II, 4 in group III, and 1 in group IV).

## Cost analysis

A detailed summary of costs in the different patient groups is shown in Table 2. In the 2108 patients combined, the total cost of hospitalization amounted to 677 008 euros and the overall expenditure (for hospitalization, home visits, and implants) was 869 432 euros. As the combined total duration of the hospital stays for all patients was 6241 days, the resulting unit cost per day in hospital was 108.48 euros.

For the 779 PMD patients in group II, the total number of days spent in hospital was 1169, which gives a total cost of 126 766 euros by applying the above unit cost.

The number of days spent in hospital by patients from groups III and IV were 2312 and 2760, respectively, at a cost of 250 820 and 299 422 euros, respectively. The number of days in hospital saved was not calculated by making a comparison with the group of patients who underwent routine hospitalization since this group was not included in the program and this could have led to abnormally long periods of hospitalization because of the patients' poor social conditions or comorbid complaints. Instead, a comparison was made with the mean hospital stay of a previously studied group of unselected patients,<sup>3</sup> which was 5.5 days. Therefore, compared with conventional surgery, the mean unit cost per patient is lowest with MAS, as can be seen from the data in Table 2. As a consequence, the total cost of the whole procedure is also lower. The largest saving that could have resulted from the use of ambulatory surgery would have been in its application to patients in group III, in whom the total medical cost was 250 820 euros.

## Questionnaire Findings

Some 97% of patients surveyed were very satisfied with the program, with the treatment and personal attention received, with the speed of the procedure and, in particular, with the rapid return to their homes, and concluded that they would be willing to be included in a similar program should it be necessary.

The remaining 3% complained, for example, about the clothing, food or telephone facilities provided or about having to share a 2-bedded room with another patient.

## DISCUSSION

Continuing progress in cardiac pacemaker technology makes it possible for each individual patient to have a device tailored to their needs. Moreover, this can be done in an increasingly cost-effective way. The steady rise in the use of pacemaker implantation for the treatment of rhythm and conduction abnormalities, coupled to the progress achieved by the introduction of alternative stimulatory systems, made it necessary to carry out this study. The study examined the potential benefits of using MAS or short-stay surgery for pacemaker implantation in patients who underwent the procedure during a period of 11 years from January 1991 through December 2001.

In 1986, Zegelman et al<sup>4</sup> published the results of a study of 781 patients who underwent pacemaker implantation. In 624 (79.9%) of them, ambulatory surgery was used and, in 157 (20.1%), patients underwent routine hospitalization. Few complications were observed in this study and the researchers concluded that the use of ambulatory pacemaker surgery for implanting either ventricular or dual-chamber pacemakers was safe and effective. In contrast, Irwin et al<sup>6</sup> found an increased number of complications, with 37% of patients experiencing early or late electrode displacement and 2.4% acquiring infections, in a group of 204 patients, which comprised 154 who received a first pacemaker and 50 who received a replacement pacemaker. These authors concluded that the financial savings achieved were not sufficient to justify the observed increase in morbidity and the high number of repeat interventions required. Finally, the studies carried out by Belott,<sup>7</sup> Hayes et al,<sup>8</sup> and Haywood et al,<sup>9-11</sup> although they involved fewer patients (181, 100, and 50 patients, respectively), confirmed Zegelman et al's data and showed that there was a high level of acceptance of the procedure among patients as well as considerable economic benefits.

Frequent use of the cephalic vein approach in our series, in 92% of patients, could have led to the lower number of complications.<sup>12</sup> Similarly, the surgical team's substantial experience could have had a positive effect, as Tobin et al<sup>13</sup> have recently pointed out.

In our study, the number of patients involved is greater than that in any previously reported study. The findings showed that the implantation of a permanent pacemaker by means of ambulatory surgery, when carried out using present-day methods and techniques of cardiac stimulation, is reliable, safe and feasible in the majority of patients. Out of a total of 2291 patients

who underwent pacemaker implantation at our center during the 11-year study period, 2108 (92% of the total) were given the opportunity to take part in the short-stay MAS program, of which, 1489 (65%) were accepted. The 619 patients who did not want to be included or who were excluded for social reasons made up study groups III and IV. These patients underwent routine hospitalization. Some 779 PMD patients were included in group II and 710 NPMD patients were included in group I.

The assignment of patients to their respective groups was important because, in PMD patients, it helped in the prevention or rapid treatment of possible complications. Data analysis showed that PMD patients did not experience complications more frequently than NPMD patients. The incidence of electrode displacement and hematoma was similar in the 2 groups, at around a very low value of 1%. This implies that PMD patients could also have been included in the MAS program and did not need to be admitted. In the previous studies listed in the references, patients were not allocated to groups according to whether or not they were pacemaker-dependent, irrespective of whether they were treated as outpatients,<sup>4,6,7</sup> or were admitted for 1 day<sup>8-10</sup> or for 48 hours.<sup>11</sup>

In our investigation, only 3.6% of patients experienced complications, with 0.9% requiring a second surgical intervention. Other authors have reported complication rates varying from 1.3% (Zegelman et al<sup>4</sup>) to 39.4% (Irwin et al<sup>6</sup>). The data obtained in our study are consistent with those previously reported,<sup>14</sup> in which the complication rate was between 4% and 7%, and with those found in a review of registry data in the United States, where 150 000 new pacemakers are implanted each year.<sup>15</sup> Although the patients in groups I and II were selected for an absence of serious comorbid complaints and for a willingness to participate in the program, both characteristics that could affect the validity of the findings, the incidence of complications was very low and much less than that in patients who underwent routine hospitalization. Thus, the selection of appropriate patients could be highly beneficial.

Only one short-stay patient had to be readmitted, compared with 15 patients in groups III and IV. No death resulted from pacemaker implantation in any of the groups. The long-term (>30 days) mortality rate was higher in patients who underwent routine hospitalization, but there was no significant difference between the mortality rates in groups III and IV, at 0.7% and 1.0%, respectively. In group II, the mortality rate was 0.2%; the same as in group I. Therefore, if there are no adverse social circumstances or high-risk comorbid complaints, the inclusion of patients in an outpatient program, whether or not they are pacemaker-dependent, is advantageous.

The mean financial saving attributable to use of the program of ambulatory or short-stay surgery is greater than 353 euros per patient. If all the patients who were not dependent on cardiac stimulation were included in MAS group I, there would have been a saving of 250 820 euros in hospitalization costs. If all PMD patients were included in group II, the saving would have amounted to 172 656 euros.

## Study Limitations

The main limitation of the study is that it was a non-randomized retrospective study in which patients were preselected for inclusion in the study groups. The conclusions cannot be generalized until randomized studies have been performed. Similarly, it is not possible to extrapolate the results of the cost analysis or the estimated savings made because, at our center, no account was taken of the major expense involved in employing staff throughout the normal working day.

## CONCLUSIONS

1. The use of major ambulatory surgery and early discharge could lead to better utilization of healthcare resources, thereby reducing the cost per patient.

2. The low complication and mortality rates observed in patients undergoing ambulatory or short-stay surgery in this study indicate that the selection of appropriate patients for pacemaker implantation within a program of major ambulatory surgery can be recommended.

3. The absence of complications in pacemaker-dependent patients who were hospitalized for less than 48 hours indicates that these patients could also have been included in study group I.

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