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# The Incidence of Reoperations in Pacemaker Recipients

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## ABSTRACT

**Objective.** To evaluate the incidence of reoperation due to complications or battery depletion in patients who underwent endocardial permanent pacemaker implantation during an 8-year period.

**Methods.** All pacemaker implantation and related procedures from January 1996 to June 2003 were retrospectively collected and entered into a database. During this time period a total number of 3856 operations with 2242 primary implantations and 1614 redo operations were performed at our department. As 809 patients were referred from another hospital, where the primary operation was done, these patients were excluded from further analysis. The mean follow-up time was 48 months, ranging from 6 to 96 months.

**Results.** A total of 547 patients underwent 805 reoperations during this 8-year period. The most common cause for reoperation was lead malfunction, which occurred in 326 patients (8.4%). Atrial leads were affected more commonly (206 patients, 63%) than ventricular leads (120 patients, 37%). Eighty percent of lead failure occurred during the first 3 months after implantation and was due to dislocation of the lead, whereas the remaining 20% occurred more than 3 months after implantation and were caused by lead fracture, insulation failure, and exit block. Elective replacement indication of a pacemaker was necessary in 312 patients (8%), and pacemaker pocket erosion or infection required reoperation in 167 patients (4%).

**Conclusion.** Permanent pacemaker implantation is now accepted as a highly effective and safe procedure. However, cost effectiveness and the relatively simple procedure have to be weighed against the need of reoperations due to system malfunction or replacement indication.

## INTRODUCTION

Permanent pacemaker technology has evolved considerably since its implementation in the late 1950s. Today, optimal selection of the appropriate pacemaker device is based not solely on the type of rhythm disturbance, but also on the cost-benefit effectiveness. For example, it has to be considered that new devices with increased function parameters and ongoing miniaturization will need repeated device exchange for battery depletion [Kiviniemi 1999]. Moreover, through the use of increasingly sophisticated pacing systems, the complication and device malfunction rate increases accordingly, which greatly impacts the quality of life of every single patient [Brunner 2004]. This study was undertaken to assess the incidence of reoperations in patients who underwent first time implantation during an 8-year period at the Medical University of Vienna.

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## MATERIAL AND METHODS

### *Study Population*

We retrospectively analyzed all available data from patients who had undergone operations at our department and were followed at our cardiology department from January 1996 to June 2003. During this time period a total of 3856 pacemaker-related operations were performed at our department. Mean age of the total study population was 74 ± 16 years with a male-to-female patient ratio of 58% to 42%. Indication for primary pacemaker implantation is listed in Table 1.

Primary implantations were performed in 2242 patients (58.1%). A total number of 805 reoperations in 547 patients were performed during this time period. More than 2 reoperations were necessary in 134 patients and more than 4 reoperations in 41 patients.

### *Surgical Technique*

All procedures were performed by staff cardiothoracic surgeons in an operating room in the ambulatory setting using portable fluoroscopic equipment. Perioperative intravenous antibiotics were administered as a single shot, usually an aminobenzylpenicillin and beta lactamase inhibitor combination (amoxicillin and clavulanacid, 4.4 g). In cases of penicillin hypersensitivity, we used a lincosamide (clindamycin, 900 mg). For lead introduction the subclavian vein was used, predominantly on the left side with a subcutaneous generator pocket. The decision regarding the type of system being implanted was made by the surgeon, and the referring physician was also consulted. Whether active or passive fixation bipolar leads were used depended on the preference of the implanting surgeon. The position of the atrial lead was rou-

Table 1. Indications for Primary Pacemaker Implantation (N = 2242)

| | Number of Patients | Percentage |
|---|---|---|
| Sick sinus syndrome | 610 | 27 |
| Sick sinus syndrome and atrioventricular block | 146 | 6 |
| Atrioventricular block | 774 | 35 |
| Atrial fibrillation | 608 | 27 |
| Other | 104 | 5 |

tinely the atrial appendage, and in cases of previous cardiac surgery the lead was positioned in the lateral free wall. The preferred ventricular lead position was the right ventricular outflow tract or the ventricular septum. Postimplantation pacemaker interrogation and programming was done the morning after surgery at the cardiology department. Follow-up was also scheduled by the cardiologists. Only in case of surgical-related complications or problems was the patient referred to the cardiothoracic department.

### *Statistical Analysis*

Statistical analysis was performed using SPSS Sigma stat version 2.03 for Windows (Chicago, IL, USA). Continuous variables were expressed as mean ± standard deviation. Categorical variables were presented as percentages. Univariate analysis of variance was performed to test differences between the groups. A $P$ value less than .05 was considered significant.

## RESULTS

### *Study Population*

The mean age of the total study cohort was 74 ± 16 years (female-to-male patient ratio was 40% to 60%), with a steady decrease in age from 77.9 ± 15.7 years in 1996 to 71.8 ± 15 years in 2003, which was statistically significant ($P = .002$). The percentage of patients over 70 years of age fell from 86.9% in 1996 to 74.1% in 2003. The mean follow-up time was 48 months, ranging from 6 to 96 months. Routine follow-up visits were 3 months after implantation and then yearly thereafter until the battery charge was low, after which the follow-up visits were scheduled between 3 months and 6 months.

### *Mode Selection*

During the study period, a total of 12 VDD, 1013 VVI and VVIR, 1631 DDD and DDDR, 100 DDDRP, and 88 biventricular devices were been implanted. Not surprisingly, there was a trend toward dual-chamber system implantation during the study period. In particular, younger patients with a mean age of 75.7 ± 14.8 years received a dual-chamber device (Figure A). Patients with a single-chamber device were on average 5 years older (mean age, 78.5 ± 17.1 years; Figure B). The underlying reason might be that older patients were commonly referred to pacemaker implantation for atrial fibrillation, whereas the underlying disease in younger patients was mainly atrioventricular (AV) block or sick sinus syndrome. With the introduction of pacemakers with antitachycardia function (DDDRP) and biventricular pacing, the use of these devices has increased steadily over the last 5 years: DDRP, from 7 in 2000 to 23 in 2001, and from 41 in 2002 to 22 through June 2003 (Figure C). The corresponding values for biventricular devices are: 1999, 9 patients; 2000, 10 patients; 2001, 16 patients; 2002, 30 patients; and until June 2003, 22 patients (Figure D). The Figure shows the changing trends in mode selection.

### *Reoperation Rate*

During the study period a total number of 3856 pacemaker-related operations were performed. There were 2242 patients who underwent first time implantation. A total of 1614 reoperations were performed. From those, 809 patients were referred from different hospitals, where the primary operation was performed. These patients were excluded from further analysis, as this study focused on a single-center experience. Excluding these patients, 805 reoperations were performed in 547 patients, which results in a reoperation rate of 24.3%. More than 2 reoperations were necessary in 134 patients (24.5%), and more than 4 reoperations in 41 patients (7.5%) (Table 2). This study focused on all reoperations due to lead, infection, or generator complications as well as normal replacement indications. Therefore acute complications such as pneumothorax and hematoma were not included. It is interesting to note that reoperations are occurring for an increasing number of pacemaker procedures each year. These values increased from 38% in 1996 to 45% in 2003 (Table 3). Univariate analysis revealed a statistical difference with $P < .001$.

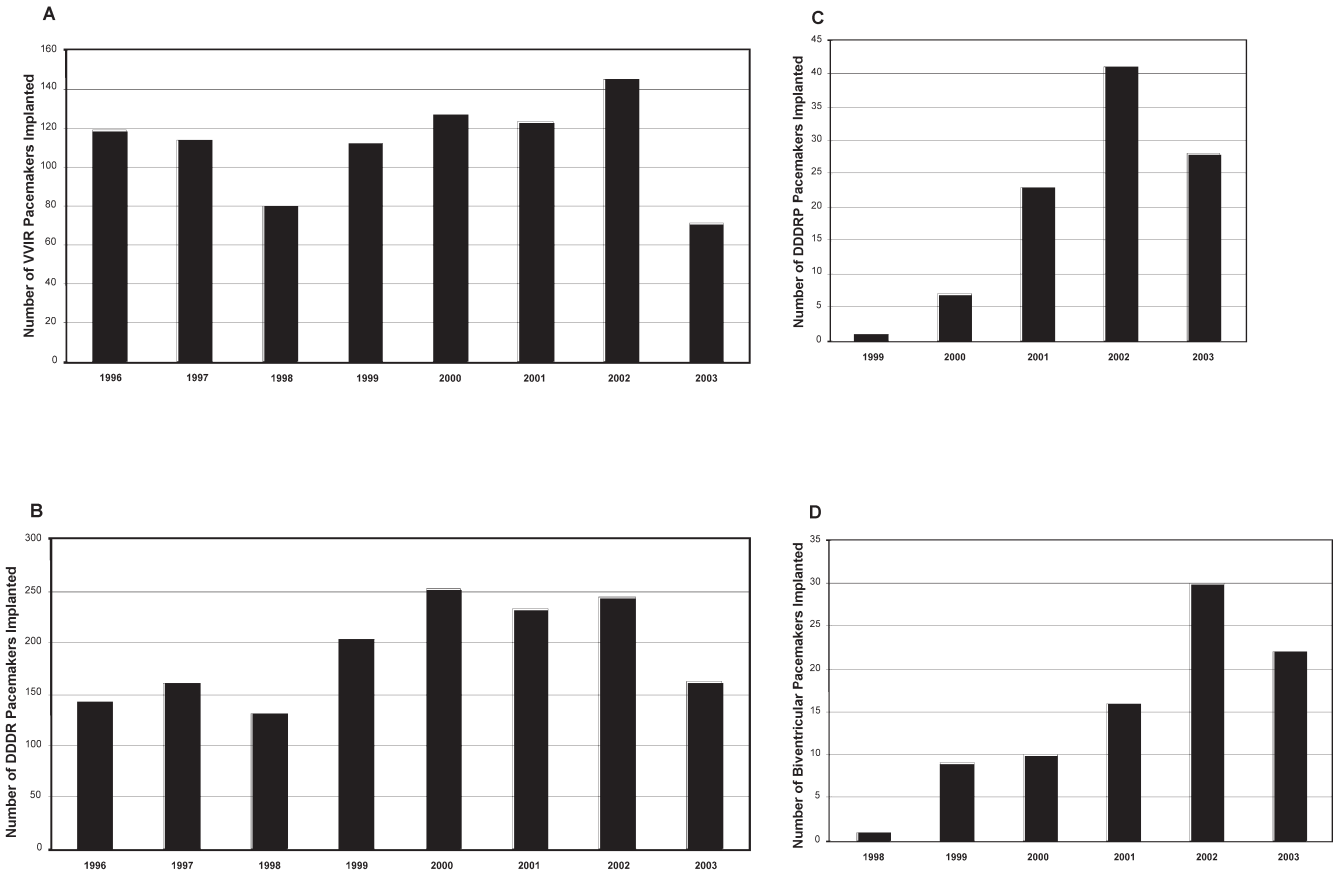
The most common cause for reoperation was lead dysfunction due to exit block or insulation failure and dislocation, which occurred in 326 patients (8.4% from all operations performed). Atrial leads were affected more commonly (206 patients, 63%) than ventricular leads (120 patients, 37%), $P > .05$. Eighty percent of lead failure occurred during the first 3 months after implantation and was due to dislocation of the lead, whereas the remaining 20% occurred more than 3 months after implantation and were caused by lead fracture, insulation failure, and exit block (Table 2). We detected no differences between atrial and ventricular leads in terms of dislocation rates as well as between active or passive fixation mechanisms, $P > .05$.

Elective replacement indication of a pacemaker was necessary in 312 patients (8% from all operations) and pacemaker pocket erosion and/or infection required reoperation in 167 patients (4% from all operations). The mean duration until elective replacement indication was 7.2 ± 3 years. No data was available for DDDRP and biventricular devices due to the short follow-up time in these patients (mean, 3 years).

## DISCUSSION

With the development of dual-chamber pacemakers, the ability to maintain AV synchrony and to rate the quality of life in pacemaker recipients has improved dramatically. Recent studies showed evidence that pacemaker therapy improves outcome, which results in a broadened indication spectrum [Sutton 1996; Daley 1998; Montanez 2003].

On the other hand, the need to introduce 2 leads results in a longer implantation time as well as higher dislocation rates.




Mode selection changes during the study period (2003 data until June).

Moreover, the modern, sophisticated pacing systems with multiple functions are prone to malfunction, and the cause is often difficult to locate. Furthermore, the trend of miniaturization of devices with multiple functions increases the need for repeated exchanges for battery depletion [Kawanishi 1996; Hildick-Smith 1998; Tobin 1999; Ellenbogen 2002; Wiegand 2003].

It was the aim of our study to assess the complication rate and the need of reoperation over an 8-year period. The total reoperation rate was 14.1% in our series of 3865 patients and included all complications (mainly of lead malfunction and infection) as well as elective pacemaker replacements for battery depletion. When we focused only on the complications we had a rate of 8.4%, which is in accordance with previously published studies by Kiviniemi et al, who reported a early complication rate of 6.7% and a late complication rate of 7.2% in a series of 571 patients [Kiviniemi 1999]. A study by Aggarwal et al [1995] reported a complication rate of 3.3%, but that lower rate may be due to the earlier date. The pacemaker systems

Table 2. Causes of Reoperation (N = 805)

| | Number of Reoperations | Percentage |
|---|---|---|
| ERI | 312 | 39 |
| Infection | 167 | 21 |
| Lead complication total | 326 | 40 |
| Lead dysfunction | 160 | 20 |
| Atrial passive fixation | 50 | |
| Atrial active fixation | 49 | |
| Ventricular active fixation | 37 | |
| Ventricular passive fixation | 24 | |
| Lead dislocation | 166 | 21 |
| Atrial passive fixation | 60 | |
| Atrial active fixation | 47 | |
| Ventricular active fixation | 23 | |
| Ventricular passive fixation | 36 | |

Table 3. Primary and Redo Operations from 1996 to 2003*

| | Total | Primary Implant | No. of Reoperations | Univariate |
|---|---|---|---|---|
| 1996 | 515 | 337 | 178 (34.5%) | $P < .001$ |
| 1997 | 496 | 301 | 195 | 39.3 |
| 1998 | 494 | 297 | 197 | 39.8 |
| 1999 | 503 | 291 | 212 | 42.1 |
| 2000 | 583 | 323 | 260 | 45 |
| 2001 | 496 | 268 | 228 | 45.9 |
| 2002 | 425 | 226 | 199 | 46.8 |
| 2003 | 344 | 199 | 145 | 42 |
| Total | 3856 | 2242 | 1614 | |

*2003 data until June. Eight hundred nine redo procedures from different hospitals were excluded.

have substantially changed since 1995, and more sophisticated systems are more prone to complications. Furthermore, it should be noted that our study focuses on all causes of reoperation, which also includes pacemaker replacement due to battery depletion, which is not included in most reports.

In our study cohort, the most common cause for reoperation was lead dislocation, which occurred predominantly during the first 3 months after implantation. This timeframe is in accordance with the MOST trial and the Danish pacemaker registry, whose authors came to the conclusion that during the 3-year follow-up period complications most commonly occurred during the first 3 months after implantation, with atrial lead dislodgement leading the list [Harcombe 1998; Hildick-Smith 1998; Moller 2002; Ellenbogen 2003; Stambler 2003]. Furthermore, we, as well as others (Hildick-Smith, MOST trial), found no differences between active and passive fixation leads in terms of complication rate. However, in the study by Hildick-Smith an increased risk of complications in redo procedures was discernible [Hildick-Smith 1998; Ellenbogen 2002].

The number of reoperations and revisions are now reaching almost 45% of all pacemaker procedures. With the implementation of biventricular devices and the increased number of extremely small devices equipped with multiple function sets such as antitachycardia pacing, repeated device changes for battery depletion are expected to rise. Furthermore, patient life expectancy continues to rise due to medical advances and this should have clear implications on device selection for these long-term survivors. To avoid the risk and especially costs of repeated operations, the implantation of devices with a long battery life and the use of high resistance leads should be considered. The mean battery life is currently proposed to be 11.4 years as indicated by the North American Society of Cardiac Pacing and Electrophysiology (NASPE). However, through lead malfunction, particularly exit block, lead insulation failure and lead dislocation, battery life shortens considerably. The mean duration until elective replacement indication was 7.2 ± 3 years in our cohort, which is shorter than the current NASPE guidelines, but is due to the usually older devices (implanted from 1988 to 1995) that were replaced during the study period.

The cosmetic aspect improves with the use of smaller devices, and the number of reoperations with an associated increased risk of wound-related complications can be reduced [Hildick-Smith 1998]. During the 8-year period, there was a marked change from VVIR to DDDR pacemakers. However, the total number of VVIR pacemakers was nearly equal, as more patients with atrial fibrillation underwent single-chamber pacemaker implantation. We did not implant VVIR pacemakers in older patients when they had sinus rhythm so as to preserve AV synchrony [Stambler 2003]. On the other hand, patients who received a DDDR device were on average 5 years younger than patients with a VVIR pacemaker, but this reached no statistical significance in univariate analysis.

It was interesting to note that even with the factor of increased life expectancy the mean age of the patients did not increase but instead decreased from 78 years in 1996 to 71 years in 2003. This might be due to the broadened indication for pacemaker implantation since the implementation of devices with maintenance of AV synchrony and the introduction of biventricular devices for the treatment of heart failure, which affect mainly younger patients. However, younger patients will need more generator changes due to battery depletion and lead changes due to malfunction. In our institution, the number of patients with several leads in place who need removal is increasing. Lead extraction can be complicated and sometimes can be accomplished only by sternotomy and removal with cardiopulmonary bypass.

In conclusion, the cost effectiveness and the relatively simple procedure of pacemaker implantation must be seen in relation to the need for potential reoperations due to system malfunction and elective replacement indication. Even though the indication spectrum for pacemaker implantation has broadened due to the introduction of more sophisticated devices, the selection of a special lead and pacemaker has to be considered carefully in respect to the system's expected lifetime and long-term survival of patients.

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