Advantages of Quality Management in Pacemaker Therapy

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Summary

The financial limitations of public medical welfare are in conflict with the rising costs of modern health services. However, increasing efforts for pre-operative examinations and perfection in surgical technique might be closely related to a reduction in post-operative complications and corresponding period of hospitalization. This report presents our experience with the implementation of a clinical quality management system and its consequences. Since the first pacemaker implantation at St. Georg Community Hospital in 1970, the number of implantations per year has increased in two phases to more than 600 in 1998. In order to handle this increase properly, a reorganization of clinical routine was indispensible. It was the main target to put into practice the relevant national and international guidlines for pacemaker therapy, concerning implantation and follow-up treatment, published in 1991/92. Therefore, treatment of bradyarrythmia is now split into 5 consecutive steps. Comparison of the first and second phase of growth reveals a significant reduction of complication rate (1981-83: 2.8 ± 3.0%; 1995-98: 0.7 ± 0.8%), a remarkable increase in dual chamber implantation (1998: 57%) and a reduction in hospitalization duration. Despite the increasing number of external follow-up examinations, the correction of postoperative malfunction takes less time than before. Centralization of bradyarrhythmia treatment - including pre- and postoperative examination as well as the implantation itself - improves pacemaker therapy by optimizing the examination methods and implantation procedure. Hence, the complication rate and corresponding costs are reduced, and the patients' benefit is guaranteed.

Key Words

Quality management, pacemaker implantation, complication rate

Introduction

Modern pacemaker therapy sets high quality standards that must be fulfilled in the determination of indications, the choice of pacemaker systems, the implantation and follow-up (compare the relevant national and international guidelines for pacemaker therapy). There is no systematic research in how the number of pacemakers implanted in a hospital corresponds to the quality of pacemaker therapy. There are a number of reasons for the lack of this sort of study. At this time, for example, there is no generally accepted and clinically practicable procedure for comparing the success of pacemaker therapy of one hospital with another.

Another reason might be, that cut of financial resources for public health are in conflict with the costs of modern health care.

Extensive diagnostics and operative expertise are directly related to a reduction in the postoperative complication rate and the period of hospitalization. Competent follow-up care reduces the number of reoperations required.

Rigorous quality management is of major impact for cost reduction, successful treatment and contented patients.

Our experience in the field of quality control began in 1974. Because of the EDP system implemented by the pacemaker study group of the Society for Cardiology and Angiology of the GDR, it was possible to compare the data from all 34 implantation centers existing at that time. This evaluation process led to a steady improvement in pacemaker therapy.

In 1972, 44 out of one million inhabitants received first-implantations; in 1988 this figure amounted to 220.
Due to numerous inadequacies in the current registration system, present implantation rates can no longer be determined exactly.
In close collaboration with the Department of Cardiology at the 1st Clinic for Internal Medicine, responsible for extensive diagnostics, indication and follow-up care, a total of 12,690 pacemaker operations were carried out in 8,263 patients before end of 1998. Out of these, 8,263 were first-implantations, all other were system replacments or corrective operations.

Methods

Since the first pacemaker implantation at the St. Georg Community Hospital in Leipzig in 1968, the number of first implantations per year has increased in two steps:

1. Until 1982 the number rose up to 400, then dropped to 187 in 1989. The reason for this development was the complete reconstruction of the operating room, which made a temporary transfer of pacemaker surgery to a different center necessary.
2. In the following years up to 1998, the number of first implantations increased up to 603.

The second phase was characterized by a reorganization of the clinical routine, in order to improve the consideration of the diagnostic guidelines, the implementation of pacemaker implantation, the education, and follow-up.
The treatment of bradyarrhythmias was split into 5 successive phases, each with its own section:

1. Extensive diagnostics with careful analysis of cardiac rhythm disturbances and underlying pathology.
2. Strict determination of indications with selection of suitable systems and exclusion of temporary symptoms.
3. Optimal conditions for scheduled and emergency implantations at any day and night time, with an operating surgeon and an implantation team conducting at least 100 operations/year, as well as an operating room specifically designed for implant surgery.
4. Continuous postoperative monitoring at a cardiology-oriented ward for early recognition of complications.
5. Regular, competent pacemaker follow-up at the referal center in cooperation with the admitting cardiologists and peripheral clinics.

The reorganization included the extension of available diagnostics, the medical care, and the cooperation between our hospital and the admitting hospitals or practicing physicians. This also applies to further professional training.

Results

The comparison between the first and second phase of development shows a significant reduction in the rate of complications:

- The number of primary infections decreased from about 0.8% in 1980 to about 0.3% in 1995 (Figure 1a);
- The number of secondary infections fell from a maximum of 6% in 1978 to 0.9 % in 1997 (Figure 1b);
- The dislocation rate for ventricular leads, especially macro-dislocations, fell to 1.1%, and the rate for atrial leads fell to 5.2 % (1% of these were macro-dislocations);
- The implantation of the optimal pacemaker system is demonstrated by an increase in the number of dual-chamber pacemakers up to 53%.

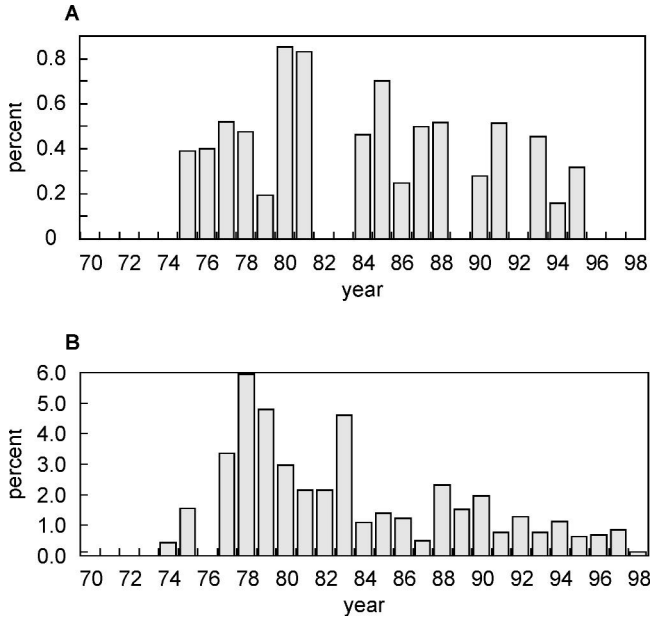

Figure 1. Percentage of primary infections after initial implants (A). Percentage of secondary infectious complications impending perforations (B).

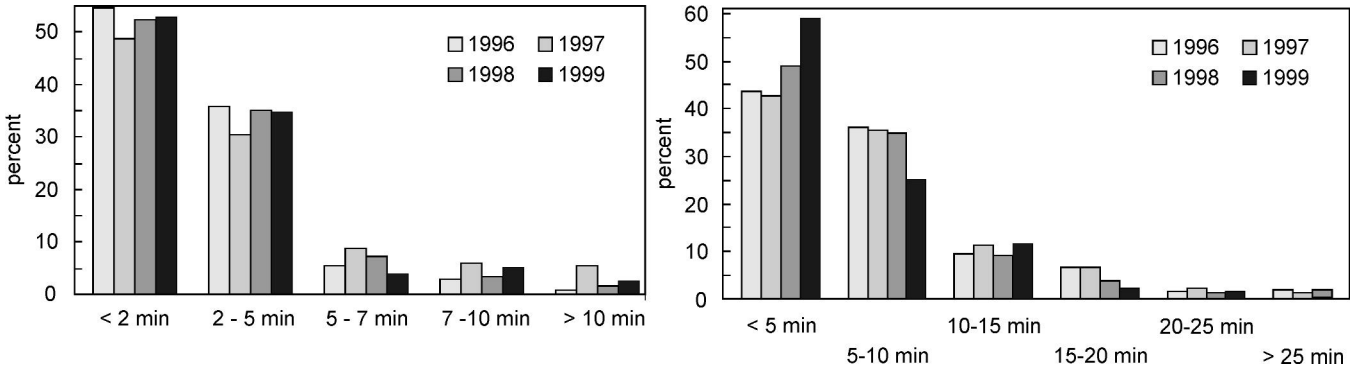

Figure 2. Percentage of fluoroscopy times for initial implantation of single- (left) and dual-chamber pacemakers (right).

- Concerning single-chamber implantations, X-ray exposure times are shorter than 2 minutes in 50% of all cases; concerning dual-chamber implantations exposure times are shorter than 5 minutes in 45% of all cases (Figure 3).
- Postoperative hospital stays were reduced to 2-7 days.
- Patient follow-up at fixed intervals after one and three months after implantation lead to early recognition of complications.
- Due to the reorganization of the clinical routine the reoperation rate, including system replacements, decreased from nearly 50% in the eighties to about 15% in the late nineties (Figure 4).
- Patient satisfaction and cooperation among partners brought about a steady increase in hospital admissions.

Discussion and Conclusion

The evaluation of the data shows that the investment made by the St. Georg Community Hospital for the optimization of pacemaker therapy as well as the other measures taken have led to a significant reduction in the rate of complications. An analysis of a short-term increase in the complication rate showed a correlation between implantation experience and complication rate. The unusual increase in number of implantations resulted in higher complication rates. This can be attributed to the fact that additional surgeon with no experience in pacemaker implantation had to be engaged because of the high amont of implantation.

As a consequence, the clinical routine was optimized, and the complication rate could be reduced.

Due to the increased number product features in our

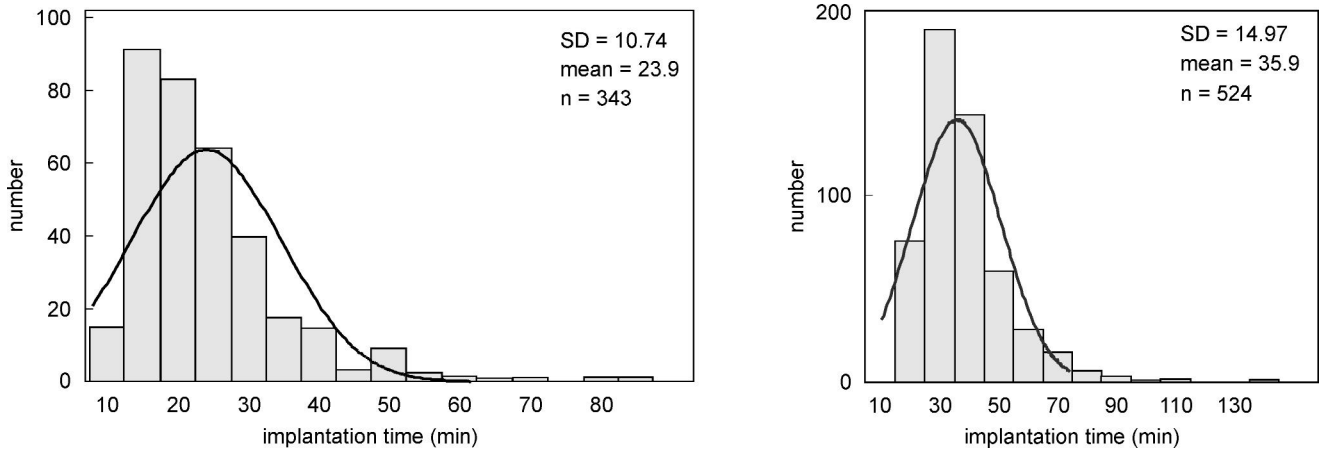

Figure 3. Implantation times for initial implantation of single-(left) and dual-(right) chamber pacemakers.

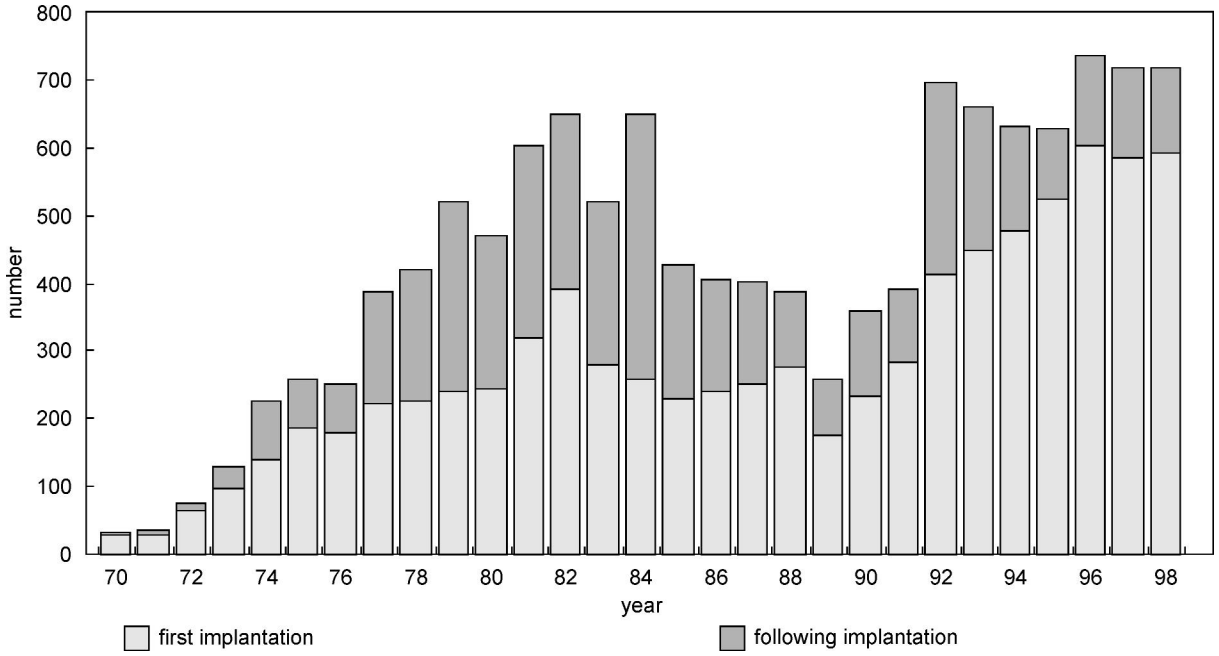

Figure 4. Number of pacemaker implantations and re-operations from 1970 to 1998.

days, the correction of postoperative pacing system malfunctions takes less time than previously. The achievement of these positive results is favored by the great progress in the field of pacemaker technology. Close collaboration with the admitting clinicians and general practitioners ensured that the pacemaker therapy can be quickly, efficiently and cost-effectively adapted to fulfill the patients' needs.

With the quality management in force it was possible to remedy all complications in the clinic itself. In addition, all indications for pacemaker therapy could be covered diagnostically and be treated with the appropriate system. Due to the large number of cases, it was possible to take the necessary time even for rarer indications and gain the experience needed to treat these patients optimally.