

CARDIAC PACING

Pacemaker-Implantation Complication Rates: An Analysis of Some Contributing Factors

VICTOR PARSONNET, MD, FACC, ALAN D. BERNSTEIN, ENGScD, FACC,
BRUCE LINDSAY, MD*

Newark, New Jersey and St. Louis, Missouri

An examination of 632 consecutive pacemaker implantations performed at a single institution by 29 implanting physicians over a 5 year period was made to determine which factors affected the 37 perioperative complications experienced. The introducer method of vein access contributed significantly to the complication rate, which was also related to the number of physician implanters on the staff

and the makeup of the implantation teams. Of greatest interest was the substantially large incidence of complications experienced by implanters who performed fewer than 12 implantations per year, and particularly the incidence of lead-related complications.

(*J Am Coll Cardiol* 1989;13:917-21)

Personal experience and common sense tell us that, in the performance of any craft, technical facility and judgment improve with practice. Differences in the quality of performance may be obvious in tasks of immense difficulty and less obvious in those that are technically simple. This study was performed to identify, if possible, differences in the quality of pacemaker implantation surgery as reflected by intraoperative and early postoperative complications.

Methods

Sources of data. Since 1970 a monthly report has been prepared at this center summarizing all pacemaker complications. The report includes the patient's name, the implantation date, the implanters' names, the make and model of the pacemaker implanted, any in-hospital complications, any corrective action taken and the immediate results of such action. All reports from 1982 through 1986 were reviewed, and the pertinent data were entered into a computerized data base for subsequent analysis. All questionable data were restudied by review of hospital and outpatient clinic charts. Perioperative complications were categorized as described

as follows, and correlations were sought with various factors, such as the pacemaker type (single or dual chamber) and the makeup of the implantation team.

A complication was defined as any untoward event that required or might have required surgical intervention, such as wound hematoma, pneumothorax, hemothorax, air embolus, infection or electrode malposition. Late events and complications (≥ 6 weeks after implantation) such as inappropriate pacing-parameter choice, failure to pace or sense, conductor fracture or delayed infections were not counted, nor were reoperations unless they involved the implantation of a completely new pacing system on the opposite side and the complication was related to the new side. Antitachyarrhythmia devices and automatic implantable cardioverters or defibrillators were not included in the study.

Pacemaker implantations. A total of 632 operations were performed by 29 different implanters. With rare exceptions, all operative procedures were performed by a team of two, a surgeon and a nonsurgeon. Implantation privileges were granted only to those physicians who had completed cardiology or surgery residency and a fellowship program, and who documented that they had personally performed at least 25 primary implantations and 10 pulse generator replacements during the training period (1).

Stimulation thresholds and electrogram signal characteristics were measured on an oscilloscope by a trained biomedical engineering technician according to methods previously described (2). The electrical integrity of the lead or leads was verified, and the output characteristics of the pulse generator were measured. All findings were recorded for

From the Department of Surgery and the Pacemaker Center, Newark Beth Israel Medical Center, Newark, New Jersey and the *Cardiology Division, Washington University School of Medicine, St. Louis, Missouri.

Manuscript received June 8, 1988; revised manuscript received November 9, 1988; accepted November 30, 1988.

Address for reprints: Victor Parsonnet, MD, Department of Surgery, Newark Beth Israel Medical Center, 201 Lyons Avenue, Newark, New Jersey 07112.

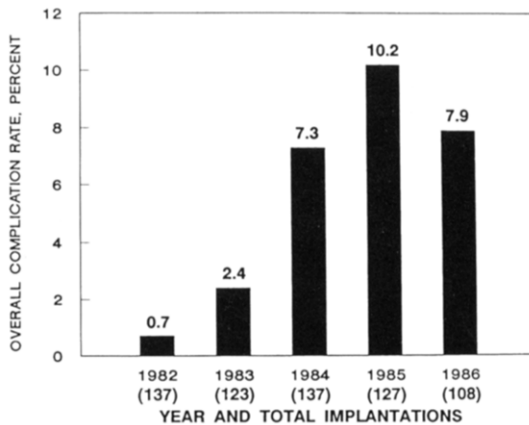


Figure 1. Overall complication rate over a 5 year period. Ratios of complications encountered are above the bars and the number of pacemaker implantations performed are shown below in parentheses.

permanent hospital and pacemaker clinic records. All pulse generators were tested and programmed provisionally within 48 h of implantation and definitively 4 to 6 weeks later.

Implanting physicians were characterized as to years in practice, years in pacing and primary implantations performed per year. They were also graded on the general level of their competence and knowledge as judged from their involvement in follow-up clinics, attendance at courses and scientific meetings and general level of participation in the pacemaker service. Frequent implanters were defined arbitrarily as those who performed at least 12 primary implantations per year. The number of pacemaker implantations performed at other centers during the study period was taken into account in classifying the implanters as frequent or infrequent.

Results

Procedures performed. Over the 5 year period from 1982 through 1986, during which a total of 632 pacemaker implantations were performed, the overall complication rate ranged from 0.7% in 1982 to 10.2% in 1985 (Fig. 1). The mean

Figure 2. Number of implanting physicians active during the period of the study.

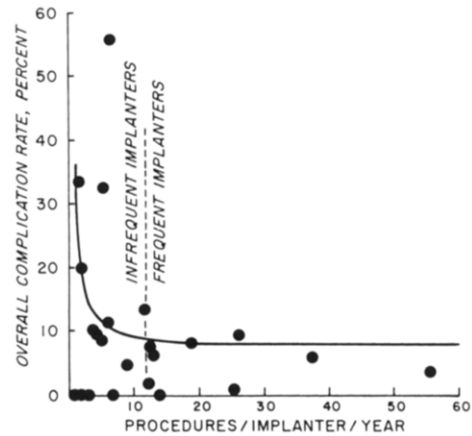
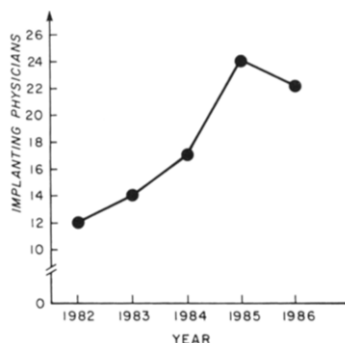


Figure 3. Overall complication rate for all pacemaker implanters as a function of implantations per implanter per year.

overall rate for the period was 5.7%. During the same period the total number of implanters having privileges to implant pacemakers more than doubled from 12 in 1982 to 26 in 1985 (Fig. 2).

Frequent and infrequent implanters. At the outset of the analysis, the overall complication rate for all implanters was plotted as a function of procedures per implanter per year (Fig. 3). A sharp increase in complication rate was seen for those implanters who performed fewer than 12 procedures/year, and the distinction between frequent and infrequent implanters was therefore made on this basis. Differences between frequent and infrequent implanters are summarized in Table 1. Frequent implanters performed 5 times the number of primary implantations as infrequent implanters and, on the average, had been in the practice of pacing almost 4 years longer.

Dual chamber pacemakers were used in 63% of the cases. The remainder were single chamber pacemakers, primarily VVI devices.* Atrial pacemakers (AAI or AAT) were used in only 2.6% of the cases. Utilization of dual chamber pacemakers decreased from 69.3% in 1982 to 55.1% in 1986. This change is plotted in Figure 4 as a ratio of dual to single chamber pacemakers. Frequent implanters were much more prone than infrequent implanters to utilize dual chamber pacemakers (64.6% versus 45.2%, $p < 0.000001$). When the implantation team was made up entirely of infrequent implanters, a dual chamber pacemaker was used in only 26.1% of cases, whereas frequent implanters working alone or in pairs used a dual chamber pacemaker in 68% of cases ($p = 0.000003$).

Complications experienced. The incidence of the complications most frequently encountered is shown in Figure 5. Complications were broken down into three categories: those related to venous access, those occurring in the pocket

*Pacing modes are represented throughout this report by the NASPE/BPEG Generic Code (3).

Table 1. Implanting Physicians, 1982 through 1986

	All	Frequent (≥12/yr)	Infrequent (<12/yr)
Number	29	12	17
Mean years in practice	7.45	10.67	5.18
Mean years in pacing	6.41	8.83	4.71
Mean procedures/yr	13.41	25.92	4.58
Median procedures/yr	13	26	5

(infection or hematoma, for example), and those related to electrode position (high stimulation threshold, electrode dislodgment or perforation, for example). The distribution was affected by the experience of the implanters (Fig. 6). Frequent implanters had fewer problems in every category than did infrequent implanters. The overall complication rates for the two groups differed significantly. (Unfortunately, the method used for vein access was not recorded in the reports, so it is not possible to analyze the complication rate as a function of access method.) Interviews revealed, however, that every implanter except one used the introducer method routinely. The one implanter who used the cephalic vein cutdown had the lowest complication rate of all the implanters (0.8%), but a cause and effect relation cannot be demonstrated purely on the basis of the data available (4).

An examination of the complication categories as a function of the makeup of the implanting team is shown in Figure 7. Access, lead and overall complication rates increased with increasing participation by infrequent implanters. Looking at the worst and best cases in which the least experienced implanters (<10 procedures/year) were compared with the most experienced (≥24/year), the differences were important, demonstrating statistical significance in overall complication rate and, especially, in the incidence of dual chamber pacemaker complications (Fig. 8).

An analysis of complication rates by specialty, comparing 6 surgeons with 23 nonsurgeons, revealed no significant differences, but a significant difference was found in comparing frequent with infrequent nonsurgeons (1.2% versus 5.4%, $p = 0.0074$).

Figure 4. Ratio of dual to single chamber pacemakers implanted.

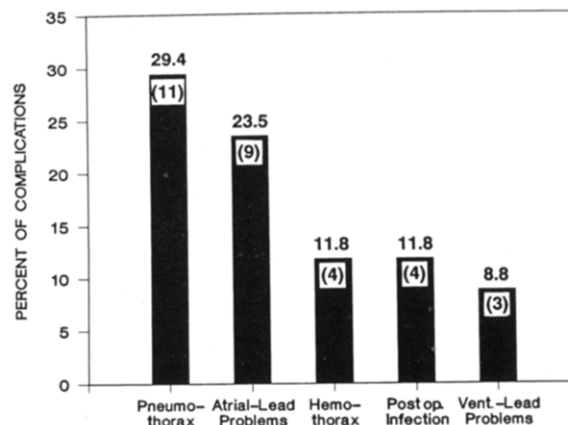
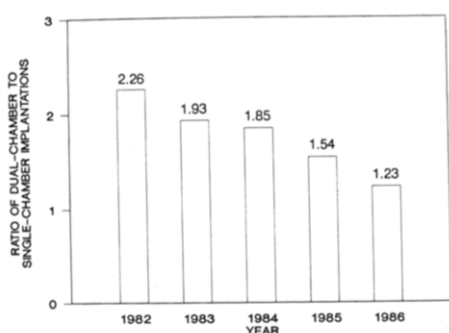
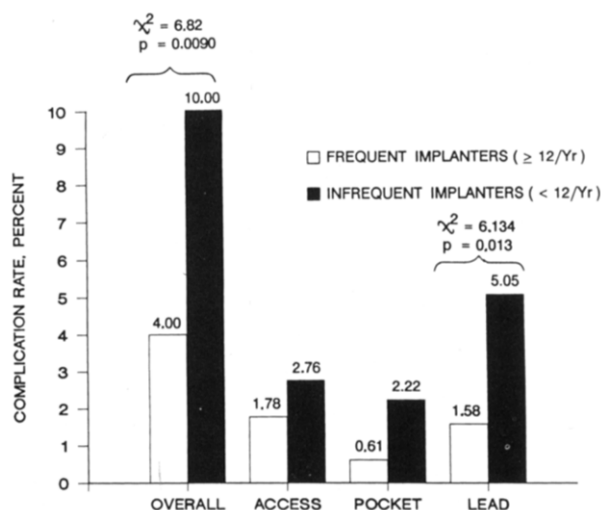


Figure 5. Incidence of the most frequent complications encountered. Post op. = postoperative; Vent. = ventricular.

Discussion

Complication rates and technical competence. Nearly 100,000 new pacemakers are implanted in the United States every year by 7,000 physicians of varying specializations and degrees of skill (5). Little has been written about overall complication rates. New studies, however, have begun to document differences in competence, or at least in theoretical knowledge. The results of the first examination in pacing conducted by the North American Society of Pacing and Electrophysiology (NASPE) (ref. 6 and A. B. Campbell, private communication) in collaboration with the National Board of Medical Examiners show that physicians in the 1st decade after completion of their medical training scored significantly higher on the examination than did physicians in training or those long out of training. Similarly, high volume implanters scored better than did low volume implanters. Also, board-certified cardiologists scored better than board-certified surgeons.

Figure 6. Complications encountered by frequent and infrequent implanters, broken down by category.



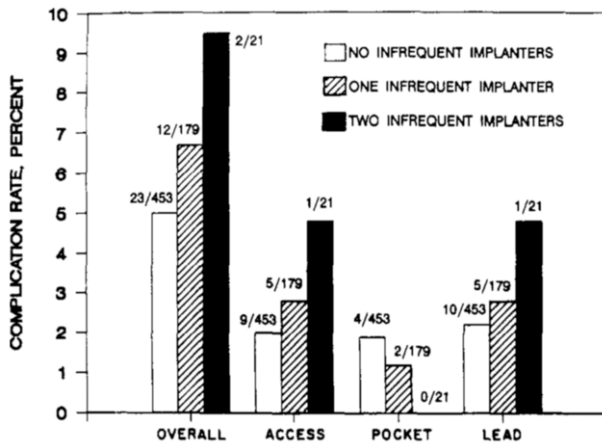
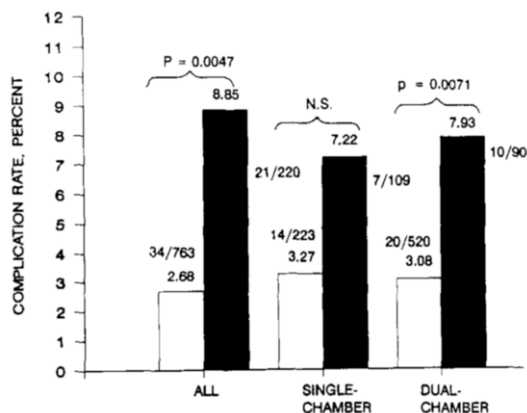


Figure 7. Frequency of complications by category as a function of the makeup of the implantation team.

Manual skills may be judged by the results of nationwide surveys such as those conducted in the United States in 1981 and 1985. In 1981, frequent implanters (defined at that time as those who performed >35 pacemaker implantations per year) had far fewer postoperative complications than did infrequent implanters (7). An earlier (unpublished) study conducted at this institution showed similar results.

Most frequent complications. Some of the complications most frequently encountered (access problems) were clearly related to the method of introducing the lead. Excluding pneumothorax and hemothorax, which do not occur with cephalic vein cutdown, and assuming that the frequency of complications unrelated to the use of the introducer would remain unchanged, the overall complication rate is 3.4% rather than 5.7%.

Figure 8. Complication rates of frequent and infrequent implanters, broken down by single chamber and dual chamber pacemakers. Open bars represent seven frequent implanters (≥ 24 implantations per year) and solid bars represent seven infrequent implanters (<10 implantations per year).



Frequent versus infrequent implanters. As one might surmise, a relation was found between experience and outcome. The overall complication rate of 5.7% was beyond our expectations, but it was comforting to know that the exclusion of introducer-related complications brought the rate down to 3.7%, a somewhat more acceptable level. This issue alone raises questions regarding the advisability of the unrestrained use of the introducer as a method of vein access. Even though one of the authors (V.P.) was involved in the earliest report (8) of the widespread use of introducers for both single and dual chamber pacemakers, this technique is no longer used routinely by the same implanter because of the greater incidence of complications. Some years ago the Intersociety Commission on Heart Disease Resources (9) recommended that a complication rate of >5% should raise questions regarding the overall quality of an implantation program. Only frequent implanters maintained complication rates that met those guidelines. The incidence of complications related to the pacemaker pocket and to lead positioning was not as strongly affected by experience.

The most striking factor in the incidence of complications is the size of the implanting staff. As the number of physicians with pacemaker implantation privileges increased, so did the complication rates, even though all implanters had given evidence of adequate training in pacemaker implantation as a condition for operative privileges.

Frequent implanters were more likely to use the more complex pacemakers. It was of interest that dual chamber pacemakers were used less frequently in the latter part of the study than in the early part, probably because of increasing caution in the use of dual chamber pacemakers and, from 1985, the availability of adaptive-rate ventricular (VVIR) pacemakers.

The data show that complication rates were significantly affected by the experience and implantation volume of the implanting physicians. These effects were especially pronounced with respect to dual chamber pacemakers, although similar effects were noted concerning single chamber pacemakers as well. No differences in complication rates were found between surgeons and nonsurgeons, but there were significant differences between frequent and infrequent non-surgeon implanters.

This study has implications for hospital practice. It is apparent that infrequent implanters should not work with one another, but only with physicians who have considerable pacing experience. It would be wise to avoid the use of the introducer except when an adequate cephalic vein is not available.

Conclusions. Complication rates in pacemaker implantation rose significantly with increases in number of implanting physicians on the staff, the use of dual chamber pacemakers, and the participation of infrequent implanters in the operations. Overall complication rates increased sharply as individual implantation volume fell below 12 cases per year. The

introducer method of achieving vein access accounted for many of the complications and, therefore, should be used only as a second choice in the absence of a suitable cephalic vein.

References

1. Harthorne JW, Parsonnet V. Task Force VI. Training in cardiac pacing (17th Bethesda Conference: Adult Cardiology Training). *J Am Coll Cardiol* 1986;7:1213-4.
2. Parsonnet V, Myers GH, Gilbert L, Zucker IR, Shilling E. Follow-up of implanted pacemakers. *Am Heart J* 1974;87:642-53.
3. Bernstein AD, Camm AJ, Fletcher RD, et al. The NASPE/BPEG Generic Pacemaker Code for antibradyarrhythmia and adaptive-rate pacing and antitachyarrhythmia devices. *PACE* 1987;10:794-9.
4. Furman S. Venous cutdown for pacemaker implantation. *Ann Thorac Surg* 1986;41:438-9.
5. Parsonnet V, Bernstein AD, Galasso D. Cardiac pacing practices in the United States in 1985. *Am J Cardiol* 1988;62:71-7.
6. Furman S, Bilitch M. NASPExAM. *PACE* 1987;10:278-80.
7. Parsonnet V, Crawford CC, Bernstein AD. The 1981 United States survey of cardiac pacing practices. *J Am Coll Cardiol* 1984;3:1321-32.
8. Parsonnet V, Werres R, Atherley T, Littleford PO. Transvenous insertion of double sets of permanent electrodes: atraumatic technique for atrial synchronous and atrioventricular sequential pacemakers. *JAMA* 1980;243:62-4.
9. Parsonnet V, Furman S, Smyth NPD. Implantable cardiac pacemakers: status report and resource guidelines, Inter-Society Commission on Heart Disease Resources (ICHDR). *Circulation* 1974;50:21-35.