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# Analysis of Complications of Permanent Transvenous Implantable Cardiac Pacemaker Related to Operative and Postoperative Management in 717 Consecutive Patients

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## ABSTRACT

A retrospective study on complications especially related to operative or postoperative management was carried out in 1000 pacemaker implantations in 717 patients between September, 1972 and December, 1986. In 33 of our series (4.8%), 24 pacing failure occurred within two weeks of implantation. Flange-type leads had the highest incidence of complications. Wedging the electrode close to the longitudinal axis of the heart was found to be the best placing, assuming that the tip of the electrode and the section immediately adjacent were pointing downward. There were 6 cases of diaphragmatic pacing which could not be corrected through programming. No relation with the position of the electrode could be found. We recommend using bipolar pacing to lower the incidence of diaphragmatic pacing. We also had 9 patients with lead fractures (1.3%); these included 3 cases with silicone insulation breaks and 6 cases with wire fractures which occurred closely proximal to the area where the lead was fixed to the vessels. No relationship between the ratio of lead fractures and their brand was found.

Five patients developed infections, all of them late postoperatively, over a period of 8 months to 5 years postop. Of these, there were 3 cases with postoperative prolonged hematoma at the pocket site, and 4 cases which had required lead repositioning because of pacing failure. The incidence of infection in our series was low when compared to previous reports, probably due to local use of one gram of Kanamycin during the operation and active chemotherapy performed short term postoperatively. To manage infection of the skin pocket, the pacemaker was removed and a new pacemaker was implanted in the opposite side.

There was 7 early postoperative deaths. One of them due to cardiac tamponade caused by perforation of the cardiac wall by temporary electrode lead. The resustation was unsuccessful.

***Key words:*** *Pacemaker, Complication*

1000 pacemaker (PM) implantations on 717 patients were performed at Hiroshima Prefectural Hospital between September, 1972 and December, 1986. Today, we perform safe implantations with a good record of postoperative recovery. This, however, does not mean that we have not also had our share of various complication with PM implantation. We report here our retrospective observations on the operations and operative techniques, with emphasis on the probable causes of resulting problems.

## MATERIALS AND METHODS

The 1000 operations in 717 cases we are reporting on took place at Hiroshima Prefectural Hospital. As shown in Fig. 1, there were slight annual variations, but generally the number of cases increased until by 1983 when there were generally about 100 cases of new PM implantation or generator replacement per year. The distribution of indications for PM implantation was as follows: A-V block (AVB) in 302 cases (42%); Sick Sinus Syndrome (SSS) in 317 cases (44%); Af bradycardia in 94 cases (13%) and also paroxysmal supraventricular tachycardia and venticular extrasystole 4 cases (0.6%).

Our general PM implantation procedure began with an incision of 4 cm along a line 1 cm below the clavicle. In early years, we used the left cephalic veins; alternately, during the last several years the subclavian vein has been used. After fluoroscopic confirmation of the lead's position, we implanted a generator under the sheath of the major pectral muscle after sprinking one gram of Kanamycin in the skin pocket. The wound was closed with subcutaneous sutures and a drain placed

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for 1-2 days in the pocket, particularly in cases where hemorrhage during operation was remarkable.

Postoperative management consisted of;

i) An elastic bandage applied on the incision.
ii) Bed rest in the semi-Fowler position on the day of the operation, followed by sitting one day postoperatively. On the second day the patient was allowed to stand up and walk.
iii) Antibiotics were prescribed for 5 to 7 days postoperatively.
iv) The drain was usually removed 2 days postoperatively.
v) If hematoma developed, it was removed with suction by syringe.

There were 117 complications among the 717 cases (Table 1).

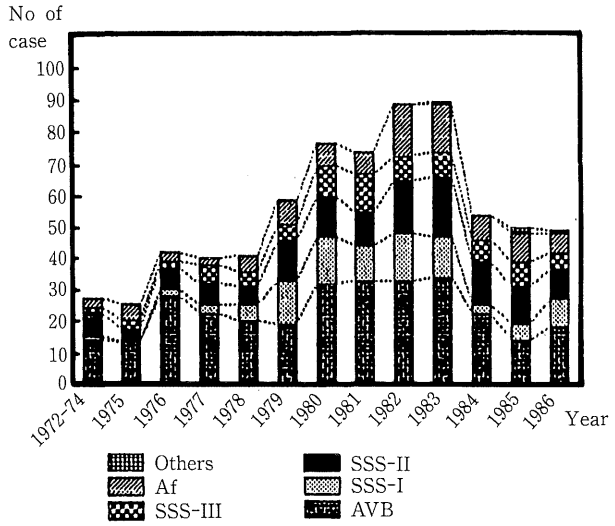


**Fig. 1.** Number of pacemaker implantations in chronological order

This study analyzes comlications related to operative procedure or postoperative management such as pacing failure requiring re-manipulation of PM leads, lead fractures, PM infection, skin necrosis and early postoperative death.

## RESULTS

In 42 PM out of the 717 cases, PM ventricular leads required re-manipulation. There were three categories: pacing failure due to malpositioning or dislodgement of the tip and/or an abnormal increase in the threshold in 33 cases (78.6%); diaphragmatic stimulation which could not be corrected by reprogramming in 5 cases (11.9%); pacing failure or its possibility due to the tendenty of slipping out in 4 cases (9.5%). The leads and tips were classified into 4 types as seen in Fig. 2: straight type, flange type, fin type and tined type.

Table 2 shows the incidence of pacing failure, diaphragmatic stimulation or tendency of slipping out according to the time of occurrence of the problem and type of leads. There were 24 cases of pacing

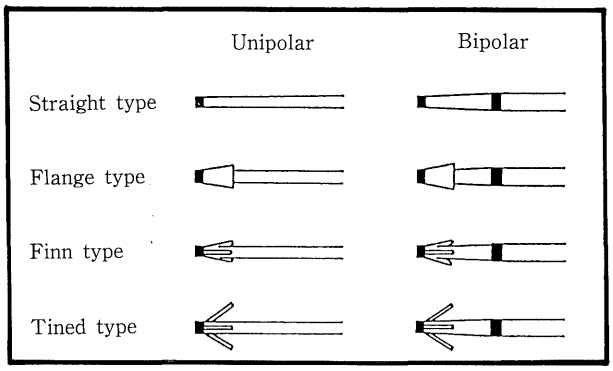


**Fig. 2.** Classification of electrodes

**Table 1.** Summary of postoperative complications in 717 cases

| | Complication | No of Case | (%) |
|---|---|---|---|
| Generator | Trouble of IC circuit | 17 | (2.4) |
| | Early battery consumption | 5 | (0.7) |
| | Ruptured generator capsule | 1 | (0.1) |
| | Malconnection of PM leads | 1 | (0.1) |
| Lead | Pacing failure | 33 | (4.6) |
| | Lead fracture | 9 | (1.3) |
| | Impending pacing failure due to pull on the lead (straightened PM lead) | 4 | (0.6) |
| Patient | Hematoma | 15 | (2.1) |
| | Diaphragmatic stimulation | 8 | (1.1) |
| | Elevation of threshold | 7 | (1.0) |
| | Cerebral embolism | 5 | (0.7) |
| | Infection | 5 | (0.7) |
| | Skin necrosis | 2 | (0.3) |
| | PM syndrome | 1 | (0.1) |
| | Stress ulcer | 1 | (0.1) |
| | Twiddler's syndrome | 1 | (0.1) |
| | Uncomfortable sensation on battery charging | 1 | (0.1) |
| Total | | 117 | (16.3) |

**Table 2.** Summary of cases with pacing failure, diaphragmatic stimulation and tendency of slipping out of lead according to lead type

| Complication / Type of lead | Total No of lead | Days after operation 0 | 1-7 | 7-14 | 14-30 | 30-60 | 60- | Total (%) |
|---|---|---|---|---|---|---|---|---|
| Pacing failure | | | | | | | | |
| Straight | 6 | | | | | | | 0 |
| Flange | 357 | 3 | 9 | 6 | 3 | 2 | 3 | 26 (7.3) |
| Finn | 66 | | 2 | | | | | 2 (3.0) |
| Tined | 287 | | 3 | 1 | | | | 4 (1.4) |
| Unknown | 1 | | | | 1 | | | 1 |
| Total | 717 | 3 | 14 | 7 | 4 | 2 | 3 | 33 |
| Diaphragmatic stimulation | | | | | | | | |
| Straight | 6 | | | | | | | 0 |
| Flange | 357 | | 1 | 1 | | | | 2 (0.6) |
| Finn | 66 | | 1 | | | | | 1 (1.5) |
| Tined | 287 | | 1 | 1 | | | | 2 (0.7) |
| Unknown | 1 | | | | | | | 0 |
| Total | 717 | 0 | 3 | 2 | | | | 5 |
| Tendency of slipping out of lead | | | | | | | | |
| Straight | 6 | | | | | | | 0 |
| Flange | 357 | | | | | | | 0 |
| Finn | 66 | | 1 | | | | | 1 (1.5) |
| Tined | 287 | | | 1 | 1 | | 1 | 3 (1.0) |
| Unknown | 1 | | | | | | | 0 |
| Total | 717 | | 1 | 1 | 1 | | 1 | 4 |

failure which occurred within two weeks postoperatively, equivalent to 72.7% of all pacing failure problems. All cases of diaphragmatic stimulation occurred within 10 days postoperatively and no significant correlation between lead type and this problem was found.

Diaphragmatic stimulation was treated by changing the position of the lead tip, while according to chest X ray, there was not significantly discernible difference between the original position and the reposition which was undertaken to correct this trouble.

To analyze the ideal slack and running of the lead, two arbitrary lines were assigned as shown in Fig. 3, and hereafter, the angle formed at the intersection of these two lines is referred as the wedge angle. The authors made a comparison between the wedge angle in 18 cases of flange type lead with complication and that of 55 other cases of flange type lead without complication. Between the two groups, there was no significant difference according to clinical data. Moreover, the wedge angles immediately postoperatively and at the time of occurrence were not significantly different (Table 3).

It is difficult, therefore, to determine the cause of pacing failure from clinical data and chest X rays. We also compared the wedge angle of unipolar and bipolar leads in the cases of pacing failure with those of a control group with no pacing failure. The wedge angle in the unipolar group with good pacing was 7.3 ± 4.6 degrees, and that in the bipolar group with good pacing was 13.1 ± 4.6

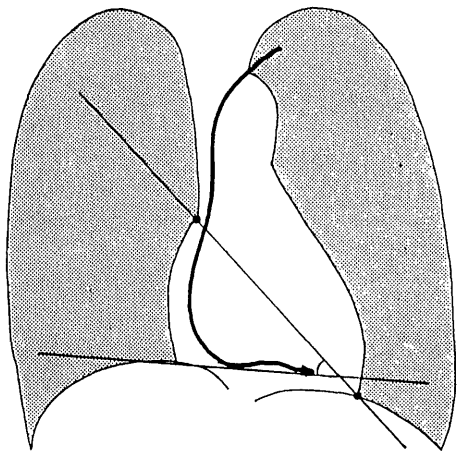

**Fig. 3.** Schematic illustration of relation between running of an electrode lead and longitudinal axis of the heart

**Table 3.** Comparison of clinical data in the cases of flange type lead with and without pacing failure.

| | Case with pacing failure | Case with good pacing |
|---|---|---|
| Number of case | 18 | 55 |
| Mean age, year | 67.8 | 64.9 |
| Sex, male/female | 6/12 | 27/28 |
| Mean R wave amlitude, mV | 12.1 | 10.2 |
| Mean stimulation threshold, mA/V | 1.3/0.9 | 1.0/0.7 |
| Mean lead impedance, | 676.9 | 700.0 |

**Table 4.** Summary of cases with lead fracture

| Case | Age yr | Sex | Postoperative duration, mths | Location of fracture | Cause | Treatment |
|---|---|---|---|---|---|---|
| 1. K.S. | 11 | M | 11 | Connector sheath | Belt | Repair with adaptor |
| 2. I.O. | 50 | M | 39 | Fixing* wire | | Lead exchange |
| 3. T.F. | 76 | F | 26 | Fixing* wire | | Repair with adaptor |
| 4. O.M. | 50 | M | 22 | Generator sheath | Trauma | Lead exchange |
| 5. G.K. | 87 | M | 88 | Fixing* wire | | Lead exchange |
| 6. S.A. | 79 | M | 24 | Generator side wire | | Lead exchange |
| 7. S.A. | 75 | M | 57 | Fixing* wire | | Lead exchange |
| 8. S.N. | 78 | M | 36 | Clavicle wire | | Repair with adaptor |
| 9. M.N. | 64 | F | 33 | Fixing* sheath | | Lead exchange |

* Close to the area where the lead was fixed to the vessels

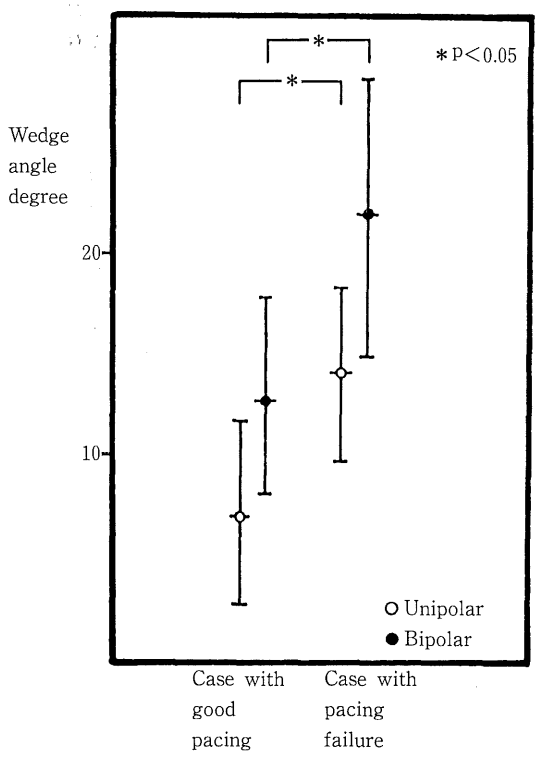


**Fig. 4.** Comparison of wedge angle of the electrode lead in cases with good pacing and cases with pacing failure according to type of electrode (unipolar and bipolar)

degrees, while that in the unipolar complication group was 14.2 ± 4.3 degrees and that in the bipolar complication group was 22.1 ± 7.1 degrees (Fig. 4).

Nine of our series had lead fractures (Table 4) which occurred between 11 months and 7 years 4 months postoperatively (mean 37.3 months). The causes varied. In one case it was assumed to be due to friction of the lead with the trouser belt and in another the severe impact of the steering wheel in a traffic accident. One patient's lead fracture was at the insertion site of the cephalic vein where the lead's silicone insulation was damaged. In other cases, the lead fractures occurred at the point behind the generator in the skin pocket, possibly because of friction with the hard generator case. One of the cases was simple insulation breaks and another was a complete fracture including the wire. In the last case, the postulated cause was pressure or abrasion by the clavicle.

Five of our series (0.7%) experienced PM pocket infection. These complications did not occur early postoperatively, but rather over a postoperative period from 8 months to 5 years (Table 5). In 3 out of 5 infection cases, hematoma had occurred early postoperatively and the duration of drainage was prolonged. These 3 cases required lead repositioning during the early postoperative course because of pacing failure. In all cases of infection, the pus was removed and the pocket was rinsed with a saline solution and antibiotics or Povidone-Iodine.

However, the results were not favorable and both the generator and lead were removed, a new PM being inserted in the opposite side 10 to 14 days following the removal of the PM. Skin necrosis along PM pocket occurred in two cases (0.3%); one was an 88 year-old female who weighed only 30 kg and was suffering from malnutrition associated with AVB. One month postoperatively, pacing failure occurred resulting in reoperation. Eight months after, a fistula developed around the skin pocket with concurrent infection. The generator and lead were removed and a reimplantation of PM was performed utilizing a myocardial lead.

In the second case of skin necrosis, 1 year and 2 months after the first implantation, the replacement was performed because of battery consumption. Skin necrosis developed subsequent to this procedure, but the etiology of this case was not known.

Seven of the 717 cases died early potoperatively (Table 6). Four occurred due to unknown etiology, probably cardiac origin. A 70-year old male with AVB received temporary pacing for the control of Adams-Stokes attack prior to the insertion of permanent PM. It was suspected that there was the possibility of penetration of the cardiac wall by a temporary lead judging from the chest X ray. Since he had no symptoms of cardiac tamponade, a permanent PM was inserted with the transvenous method and the temporary pacing lead was re-

**Table 5.** Summary of cases with infection of skin pocket

| Case | Age yr | Sex | Postop. hematoma | History of reop. | Postop. duration | Treatment | Old lead |
|---|---|---|---|---|---|---|---|
| 1. T.O. | 86 | F | + | + | 2mo | Change to myocard. type | Remained |
| 2. T.N. | 42 | M | + | + | 4yr2mo | Replacement opposite side | Removed |
| 3. M.M. | 39 | M | + | + | 5yr6mo | Replacement opposite side | Removed |
| 4. M.K. | 49 | F | — | — | 5yr | Replacement opposite side | Remained |
| 5. Y.N. | 67 | F | — | + | 2yr | Replacement opposite side | Removed |

**Table 6.** Summary of cases postoperative early death

| Case | Age yr | Sex | Type of arrhythmia | Postop. duration day | Cause of death |
|---|---|---|---|---|---|
| 1. S.U. | 69 | F | A-V block | 7 | Pneumonia |
| 2. K.T. | 46 | M | Af, slow rate | 4 | Sudden death of unknown etiology |
| 3. G.K. | 75 | M | A-V block | 7 | Unknown |
| 4. R.A. | 76 | M | A-V block | 12 | Massive bleeding of G-I series |
| 5. H.N. | 73 | M | A-V block | 7 | Sudden death of unknown etiology |
| 6. M.H. | 56 | F | Af, slow rate | 5 | Heart failure |
| 7. S.M. | 70 | M | A-V block | 0 | Cardiac tamponade |

moved. There appeared postoperative symptoms of cardiac tamponade and an emergency thoracotomy was performed. It was found that the small perforation of the cardiac wall had indeed occurred. Unfortunately the resuscitation procedure was unsuccessful.

## DISCUSSION

The clinical effects and benefits of permanent PM are well known and we have reported on this subject previously[14,15].

With the increase in the number of PM insertions there is a concurrent increase in the number of PM insertions and thus there is more opportunity to observe them. The causes of complications can be related to three factors: the patient's condition, the generator or the battery, and the electrode or lead. The complications can be categolized also according to whether the complications occur early or late postoperatively. It was beyond the physician's capabilities to correct any electrical problems that occurred within the generators; however, we were able to correct or control complications that occurred due to operative technique or postoperative management. Thus, this paper primarily deals with the problems which we are able to correct or control.

Problems due to electrode malposition or slipping occurred relatively early postoperatively[7,11]. Clinically, electrode problems show up as pacing failures. On the other hand, pacing failure can also occur due to threshold increase. Pacing failure due to slipping or change in the position of the lead tip, possibly due to operative techique, should be considered separately from pacing failure which occurs because of an abnormal increase in threshold. However, since it is very difficult to distinguish the cause of pacing failure from chest X rays, it is difficult to differentiate clinically between the two problems.

It is generally assumed that the temporary increase in threshold occurs within two weeks postoperatively and thereafter it decreases and assumes a plateau value. This report analyzes 24 cases in which a high threshold occurred more than 2 weeks postoperatively. We found that the lead tends to be close to the heart's longitudinal axis in the patients with good pacing. Therefore, the best way to prevent threshold problems and pacing failure is to position the lead correctly.

Diaphragmatic stimulation is an even rarer condition but is another highly troublesome problem for the patients. This complication is commonly considered to be due to malposition such as positioning in the coronary sinus[13]. There were 8 cases with this complication. Over time, these symptoms decreased and some patients were able to tolerate the condition. However, other cases required repositioning of the lead. In cases of unipolar lead where repeated repositioning is required, lead type should be changed to bipolar. At any rate, improvements are being made in the electrode and lead, so the number of these complications concerning leads should decrease with time[1,10].

According to Green[8], there are three classifications of the electrode and lead problems: wire fracture without insulation break, both wire and silicone break, and silicone insulation break without wire fracture. Of these, the silicone insulation break is not as critical as the others, while the wire fracture is sometimes critical. The incidence of wire fractures and insulation breaks reported by other researchers[11] are higher than those in our series. With silicone insulation breaks there were occasionally associated contractions in the arm due to the proximity of the vein and the nerves controlling

this area[22].

In the cases of fracture, no sleeves had been used to fix the leads, and we found also that there were no lead fractures in any case in which the puncture method had been used. A lead fracture is sometimes reconnected the lead to the generator using a new connector[4], however, it might better to replace the lead entirely, owing to the likehood of another fracture[21]. Some authors have recommended limitation of arm movement to reduce the incidence of lead fracture. In our series we generally implanted the PM on the side opposite the most used hand, and now this procedure seems to be satisfactory in preventing lead fractures.

One patient in our series had Twiddler's syndrome which we recognized when we attempted to recharge the PM and found that the outward facing side was facing inward. In Twiddler's syndrome, the possibility of lead fracture is high, so the excess lead and the generator should be fixed securely in the skin pocket.

The incidence of infection concerning the PM ran from 3.9—8%[12,18,19]. In our series, infection and skin necrosis or erosion along the skin pocket occurred in 0.7% and 0.3% of all cases, respectively. This is a very low incidence, which we believe was due to one gram of Kanamycin which was scattered in the skin pocket at the time of the operation as well as the active chemotherapy which was performed for 5 to 7 days postoperatively. Bluhm[2] reported that in such cases antibiotics prophylaxis is necessary. Rao and Lima[17] also emphasized that infection in PM insertion was avoided with aseptic technique, adequate local and systemic antibiotics even in patients with risk factors of infection such as diabetes, heart failure and temporary pacing. Hematoma may contribute to later infection and skin necrosis, so bleeding during the operation was strictly controlled and, particularly in the case of hematoma in the skin pocket, we used two types of antibiotics.

For infection in the skin pocket, we rinsed the pocket with an antibiotic saline solution or Povidone Iodine solution and active chemotherapy was carried out for several days. In some cases where these therapies are not effective, it becomes necessary to remove the infected generator and lead, and reimplant a new PM on the opposite side[3,6].

In general, PM patients are advanced in age, and the usual cause of death is cardiovascular in nature or due to cancer or senility[16]. PM insertion procedure is simple and safe. However, 7 cases of death occurred postoperatively within one month. Among these, one case of cardiac tamponade was related to operation procedure. Cardiac tamponade due to perforation or rupture of the right ventricle has been reported in some of the literature[17,21]. Perforation of the right ventricle is related not only to cardiac tamponade but also to pacing failure and, therefore, the lead must be carefully and gently manipulated during the operation.

The 24-hour Holter monitoring device is now being more frequently used in diagnosing arrhythmias and in some cases the monitoring by 24-hour Holter discloses critical complications in pacing failure. Four cases, sudden death, among 7 postoperative early deaths in our series were of unknown etiology, probably cardiac origin, and so we recommend 24-hour Holter monitoring as a regular procedure for the PM patients before they are discharged from the hospital and return to their normal lives. Moreover, careful monitoring of the PM patient and checking of PM function should be carried through the PM clinic[5,9].

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