Early Complications and Malfunctions of Permanent Pacemaker Implantation: Single versus Dual-Chamber

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Abstract

Background- Implantation of transvenous permanent pacemakers (PPM) has become standard therapy for sinus node dysfunction and atrioventricular conduction abnormalities. It plays an important role in improving quality of life and preventing death in this group of patients.

Methods- This study was conducted on 477 patients during their hospitalization and eight weeks after their discharge.

Results- Complete heart block was the most frequent indication for pacemaker implantation (48.8%). The most frequent early complications of implantations were hematoma (2.1%) and hemothorax (0.5%). The most frequent malfunctions were lead displacement (1.9%), exit block (1.5%) and atrial undersensing (1%). There were no significant differences between single- and dual-chamber PPM in regard to complications and malfunctions (p=0.56).

Conclusions- PPM implantations in our center are associated with a low incidence of early complications and malfunctions in comparison with other qualified centers. There is no significant difference between early complications of single- versus dual-chamber PPMs***(Iranian Heart Journal 2006; 7 (3):38-42)***.

Key words: pacemaker ■ complication ■ malfunction ■ single-chamber ■ dual-chamber

Implantation of transvenous pacemakers has become standard therapy for sinus node dysfunction and atrioventricular conduction abnormalities.[1, 2] It plays an important role in improving quality of life and preventing death. Further studies are required to keep abreast with the rapid advances in the technology of PPMs. There are early complications which occur in the first 6 weeks after implantation. Their incidence is underestimated (up to 7%), as is their seriousness. There are also late complications. Some are responsible for pacemaker malfunction, the risk of which is proportional to the dependence of the patient on permanent cardiac pacing.[1] Infectious complications are also under-reported (less than 1%). The diagnosis is difficult because of the insidious symptoms. They may be life-threatening and require extraction of all of the implanted materials.[2]

The purpose of this study was to identify and characterize the frequency of lead and pacemaker-related complications in our center over a period of 12 months. We compared our experience with previous reports of pacemaker-related complications and malfunctions so as to identify patient and implant-related factors that might be risk factors for these complications.

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Methods

This study was conducted in our center between April 2002 and February 2003. During this period, the patients who had indications for implanting a permanent pacemaker according to AHA/ACC guidelines were included. The study comprised 477 patients (235 men and 242 women) at a mean age of 65.48 years (range 11 to 79). All the patients underwent the following work up: complete diagnostic tests such as routine lab tests, electrocardiography (ECG), 24-hour Holter monitoring and electrophysiological study when necessary. Data entry forms were completed for each patient. The patients gave written informed consent for implantation and/or electrophysiological evaluation.

Implant procedure

All the procedures were performed by or under close supervision of a cardiac electrophysiologist at the electrophysiology laboratory in a fasting state after receiving a dose of 1.5g cefazolin and 60mg gentamicin intravenously. Aspirin, heparin and other anticoagulants were discontinued before the procedure. In all the patients, the procedure was performed under local anesthesia with lidocaine hydrochloride (10mg/ml).

Different devices were used, with selection being based on their availability. A single incision was made at the left or right infraclavicular area and a subcutaneous pocket was manually formed for the placement of the pacemaker generator. The leads were introduced into the vascular system via left or right subclavian vein. Sensing and pacing characteristics as well as impedance and slew rates were assessed at the time of implantation. Electrocautery was not used during the procedures. During implantation, the pocket was rinsed with a solution of cefazolin.

After implantation of the pacemaker, the patients underwent physical examination with emphasis upon complications such as tamponade, pneumothorax, hemothorax, arterial rupture, arrhythmia due to lead implantation, etc. An additional dose of 2g cefazolin was administered intravenously. After surgery, ECG and chest X-ray were also carried out for all the patients both to evaluate lead positioning and to rule out pneumothorax. The day after the procedure, pacemaker analysis was performed and all sensing and pacing parameters were checked. If there was no problem, the patient was discharged two days later. Before discharge, alarming signs and symptoms were explained to all the patients.

Follow-up

All the patients were re-examined at follow-up visits at the outpatient clinic ten days after discharge for wound infection and eight weeks later for device analysis. Routine pacemaker analysis was performed every six months at the pacemaker clinic thereafter.

Statistic analysis

Statistical analysis of the data was done with SPSS software. Our findings were compared by using Chi-square and Fisher-exact in accordance with our purpose. P- values less than 0.05 were considered significant.

Results

This study comprised 477 consecutive patients (235 men, 242 women). Mean age of the patients was 65±16 years. Most of the patients were in the eighth decade of life (71-80 years). There was no significant difference between the males and females (P=0.34). The patient characteristics are shown in Figure 1.

Complete heart block (CHB) was the most common indication for pacemaker implantation (48.8%); wide QRS complex CHB was found in 38.9% and narrow complex CHB in 10.5% of the patients. The second common cause for implanting pacemakers was sinus node dysfunction (18.9%), and the third cause was second degree atrioventricular block (AVB) (11.1%).

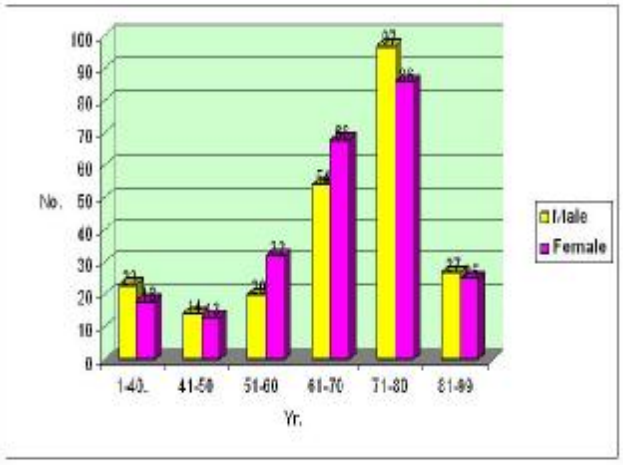

Fig. 1. This figure shows the characteristics of the studied patients.

In 15.9% of the patients, the previous generator was replaced due to end of life condition; and in 1.5% of the patients, upgrading of the pacemakers was carried out. In 1.5% of them, cardiac resynchronization therapy (CRT) was performed (Figure 2).

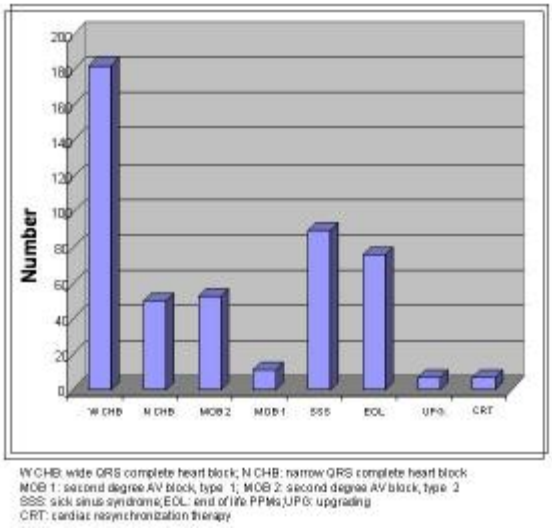

Fig. 2. This diagram shows the frequency distribution of different indications of pacemaker implantation.

PPMs were successfully implanted in all the patients at first attempt.

Single-chamber PPMs (VVI) were implanted in 302 patients (63.3%); dual-chamber PPMs including DDD and VDD were implanted in 83 (17.4%) and 85 (17.8%) patients, respectively. Overall, implantation of single-, dual- and three- chamber pacemakers was performed in 63.3%, 35.2% and 1.5%, respectively (Fig. 3).

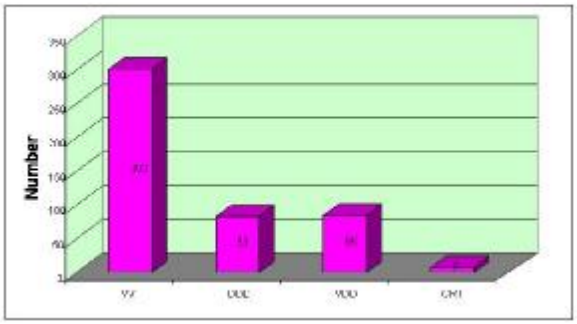

Fig. 3. Types of the pacemakers implanted in our center.

Complications

Procedure-related complications occurred in 9.9%. The most common complications were hematoma (2.1%), none of them necessitating surgical intervention; lead displacement (1.9%); and pneumothorax (1.3%, Table I).

Table I. Frequency of Pacemaker-related complications

Implant-related Complications	**Frequency (%)**
Pneumothorax	1.3
Subclavian artery Puncture	0.6
Hematoma	2.1
Hematoma requiring re-operation	0.0
Stitch abscess	0.4
Hemothorax	0.2
Hemopneumothorax	0.4
Impending erosion	0.2
Twiddler syndrome	0.2
Venous thrombosis	0.2
Lead-related complications	
Muscle twitch	1.0
Lead displacement	1.9
Exit block	1.4

There was no complication related to local anesthesia. It is noteworthy that only two cases of stitch abscess (0.4%) and one case of impending erosion of pacemaker lead developed in our series. We observed no wound infection either at first implant or in the case of generator replacement. The most common malfunctions were atrial undersensing (1.9%) and exit block (1.5%, Figure 4). Most of the complications were found in the sixth-decade (51-60 years) age group (17.3%) and the fewest were in the patients less than 40 years old (7.3%, P=0.49). The frequency of complications and malfunctions did not have any difference in the patients with single- or dual-chamber pacemakers (p=0.65). There was no significant difference in the rate of complications in the patients who underwent generator and/or lead replacement (P=0.15) or in those for whom a TPM was implanted before the procedure (p=0.66).

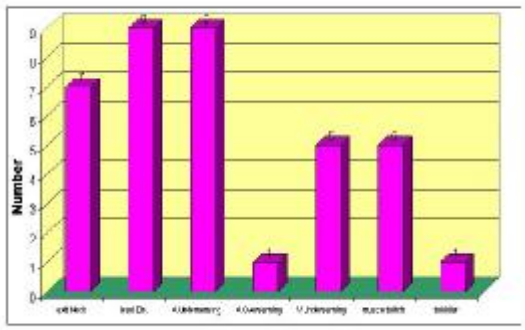

Fig 4. Frequency

Discussion

Pacemaker complications can be classified generally according to whether they primarily affect the pocket, the generator or the leads.[9] Acute complications resulting from permanent pacemaker implantation are well known and include perforation of the right atrium or right ventricle.[3]

Pacemaker infection poses a serious problem and usually can be treated by removal of the complete system. In our practice, during the operation all the implantable components were kept in their sterile boxes for as long as possible, the pocket was rinsed with solution of cefazolin and all the patients were given antibiotics on a prophylactic basis. The attention to these factors could help to prevent infection.

The rates of the procedure-related complications and malfunctions in our center were similar to those published in other series.[4-11] The most frequent complication found in our study, pocket hematoma, was related to the continuation of ASA or heparin before the procedure in those patients who needed these medications. The patient characteristics (age and sex), indications for pacemaker implantation and the type of generators (single versus dual chamber) were similar to those reported in other studies.[4-12] Chauhan et al.[13] showed a lower rate of early complications in single-chamber PPMs than that in dual-chamber PPMs. They also found a correlation between the rate of early complications and the need for TPM implantation. Our results indicated no difference in the rate of complications between single- versus dual- chamber pacemakers. The present study also showed that the insertion of TPM and the type of operation (first implant versus generator and/or lead replacement) did not increase the risk of complications. Also, the overall rate of complications and malfunctions were not only compatible with the standards set by other centers but also even better. Timelier discontinuation of anticoagulants before the procedure, better hemostasis and use of active fixation techniques could decrease the rate of complications and malfunctions even further.

Careful consideration to sterile conditions in the electrophysiology laboratory, prophylactic administration of intravenous antibiotics and irrigation of the pocket with antibiotic solutions may be the most important causes for the low rate of infectious complications in our study.

Conclusion

PPM implantations are associated with a low incidence of early complications and malfunctions. The procedure can be safely performed at the elctrophysiology laboratory. There is no significant difference between early complications of single- versus dual-chamber PPMs.

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