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

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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. This study conducted on 477 patients during their hospitalization and eight weeks after their discharge. Complete heart block was the most frequent indication for pacemaker implantation (48.8%).The most frequent early complications of implantations were hematoma (2.1%), hemothorax (0.5%). The most frequent malfunctions were lead displacement (1.9%), exit block (1.5%) and atrial undersensing (1%). There were no significant difference between single and dual chamber PPM in regard to complications and malfunctions (p=0.56). 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.

Key words: Pacemaker, complication, malfunction, single-chamber, dual-chamber

INTRODUCTION

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 as well as to identify patient and implant-related factors that might be risk factors for these complications.

METHODS AND MATERIALS

This study was done in our center from April 2002 to February 2003. During this period, the patients, who had indications for implanting permanent pacemaker, according to AHA/ACC guidelines, were included .The study comprised 477 patients (235 men and 242 women) with 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 laboratory tests, Electrocardiography (ECG), 24 hrs Holter monitoring and electrophysiological study when it was necessary. Data entry forms were completed for each patient. Patients gave written informed consent for implantation and/or electrophysiological evaluation.

Implant procedure: All procedures were performed by or under close supervision of a cardiac electrophysiologist at the electrophysiologic laboratory in a fasting state after receiving a dose of 1.5 g cefazolin and 60 mg gentamicin intravenously. Aspirin, heparin and other anticoagulants had been discontinued before the procedure. In all patients procedure was performed under local anesthesia with lidocaine hydrochloride (10 mg mL^{-1}).

The different devices were used, with selection based on their availability. A single incision was made at

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the left or right infraclavicular area and a subcutaneous pocket was manually formed for 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 procedures. During implantation the pocket of pacemaker was rinsed with a solution of cefazolin.

After implantation of the pacemaker, 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 2 gr cefazolin was administered intravenously. After surgery ECG and Chest X ray (CXR) were also carried out for all patients for evaluation of 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, patient was discharged two days later. Before discharge, alarming signs and symptoms were explained to all patients.

Follow-up: All patients were reexamined at follow-up visits at the out patient 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 data was done with SPSS software. Our findings were compared by using chi-square, 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 were 65±16years. Most of the patients were in the eighth decade of life (71-80years). There was no significant difference between males and females (p=0.34). The patient characteristics showed in Fig. 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 patients. The second common cause for implanting pacemakers was sinus node dysfunction (18.9%). The third cause was second degree Atrioventricular Block (AVB) (11.1%). In 15.9% of patients the previous generator was replaced due to end of life condition and in 1.5% of patients upgrading of pacemakers were carried out. In 1.5% of them, cardiac

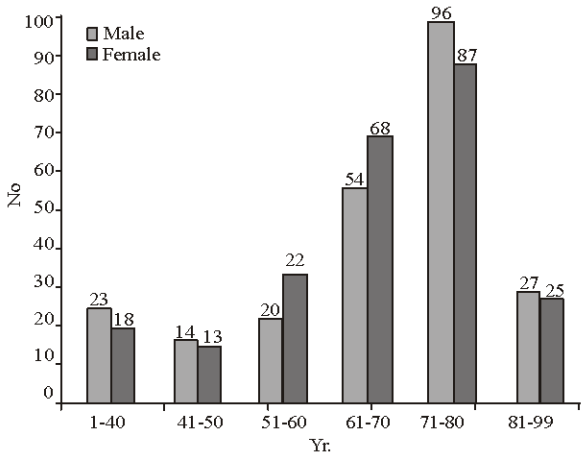

Fig. 1: This figure shows the characteristics of studied patients

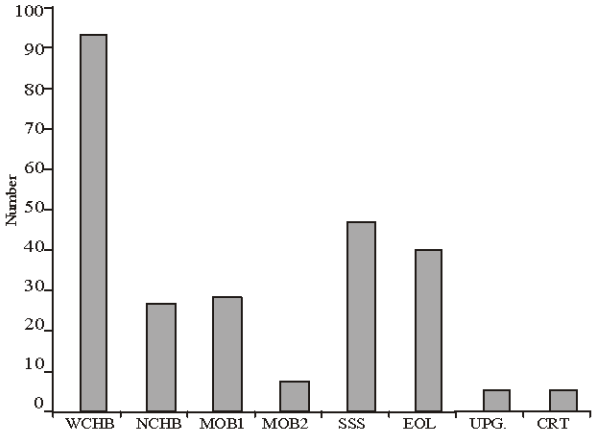

Fig. 2: This diagram shows frequency distribution of different indications of pacemaker implantation

resynchronization therapy (CRT) was performed. (Fig. 2). PPMs were successfully implanted in all 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 were performed in 63.3, 35.2 and 1.5%, respectively. (Fig. 3).

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 1). 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

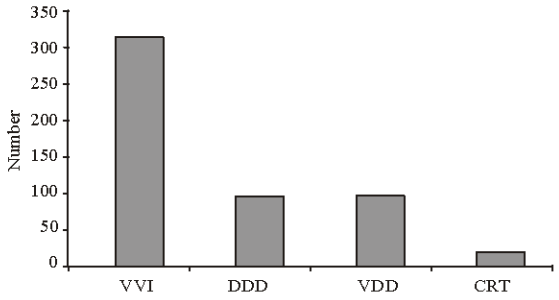

Fig. 3: Types of pacemaker implanted in our center

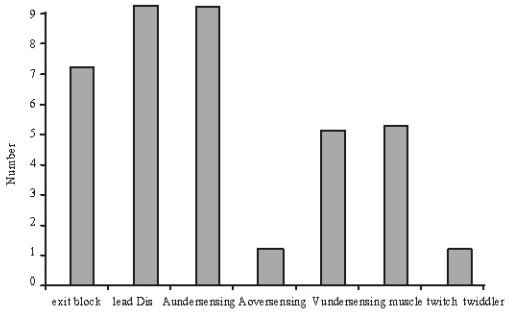

Fig. 4: Frequency of pacemaker malfuncation in population

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%) (Figure4). Most of the complications were found in the sixth decade (51-60years) of life (17.3%) and the fewest complications were in the patients less than 40 years old (7.3%). There was no correlation between the age and the rate of complications (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 patients underwent generator and/or lead replacement (p=0.15) or in those for whom a TPM was implanted before the procedure (p=0.66).

DISCUSSION

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

Table I: Frequency of Pacemaker-related complications

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

Pacemaker infection poses a serious problem and usually can be treated by removal of complete system. In our practice, during 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 patients were given antibiotics on a prophylactic basis. The attention to these factors could help to prevent infection.

The rate 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 continuation of ASA or heparin before procedure in those patients who needed these medications. The patients characteristics (frequency of age and sex), indications for pacemaker implantation and the type of generators (single versus dual chamber) were similar with those reported in other studies.[4-12]. Chauhan *et al.*[13] showed lower rate of early complications in single chamber PPMs than dual chamber PPMs. They also found a correlation between the rate of early complications and the need to TPM implantation. Our results indicated no difference in rate of complications between single versus dual chamber pacemakers. The present study also showed that 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 of sterile conditions in the electrophysiology laboratory, prophylactic administration of intravenous antibiotics and irrigation of pocket with antibiotic solutions may be the most important causes for the rarity of infectious complications in our study.

CONCLUSION

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

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