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Techniques of Permanent Pacemaker Implantation

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<http://dx.doi.org/10.5772/48639>

1. Introduction

Currently available permanent pacemakers contain a pulse generator and one or more pacing leads. Early in the era of pacemaker implantation, this procedure was only performed by the cardiac surgeons because of the initial mandate for epicardial lead implantation. Further advancements in the pacing hardware and percutaneous venous catheterization simplified the implantation technique and made it feasible to implant the transvenous leads. Simultaneously, further innovations in the pulse generator and its circuitry extended the utility of the percutaneous technique even in the very young patients.

All device trainees will require basic skills in pacemaker implantation. However, first step is to identify whether a patient needs a permanent pacemaker. This chapter will summarize the necessary equipments, patient preparation, and implantation techniques. Like any practical skill it is only possible to give a flavor of the methodology in writing, and nothing can replace the practical tuition of an experienced implanter in the pacing theatre during a number of pacemaker implants.

2. Equipments

The pacemaker implantation can be performed in electrophysiology (EP) laboratory, catheterization laboratory, or operating room [1]. Pacemaker implantation by interventional electrophysiologist in EP lab or catheterization laboratory resulted in a significant reduction in medical cost and hospital stay [2].

Minimum required personnel for pacemaker implantation consist of implanting physician, scrub nurse, and circulating nurse or technician. Scrub nurse is required to help the implanter throughout the procedure. The circulating nurse or technician is required to prepare and administer medications, and to operate pacing system analyzer.

Fluoroscopy and electrocardiography (ECG) are necessary equipments in every device implant. Single-plane fluoroscopy via anteroposterior, 30° right anterior oblique, and 45° left anterior oblique views is usually adequate for transvenous implantation from either the right or the left pectoral approach. Currently, initial lead sensing and capture measurements are obtained by pacing system analyzers (Figure 1), which may be stand-alone or built into the pacer programmer.

Figure 1. Built-in pacing system analyzer

Apart from the fluoroscopy equipment and vital observation monitors, there are a number of sterile surgical instruments and equipment that are needed (Figure 2). Suture materials include both nonabsorbable material for lead and device anchoring and absorbable material for pocket closure. Antimicrobial flush and saline for pocket irrigation should be available. If venography is to be performed, an appropriate intravenous contrast agent must be available.

Figure 2. Minor surgical tray for permanent pacemaker implantation

3. Patient preparation

Before pacemaker implantation, an informed consent should be obtained. Any anticipated risks and benefits should be honestly discussed with patient or the patient's family. The indication for pacing should be thoroughly described to the patient. The need for lifelong follow-up should be emphasized and patient should be informed about the generator change and possible lead replacement in the future. Any physical or occupational restrictions related to the pacemaker implantation including rules regarding the driving should be discussed in detail with the patient.

Routine pre-implant lab tests are 12-lead ECG, chest x-ray, complete blood count, prothombin and partial thromboplastin times, serum electrolytes, blood urea nitrogen, and serum creatinine. Many of the patients requiring a pacemaker may be on oral anticoagulant [3]. Perioperative management of these patients is often challenging and needs special experience. In the past, standard practice was to discontinue warfarin 48 hours before the procedure, bridge with intravenous heparin, and then reinstitute warfarin the day of the procedure or even the night before. This practice has been associated with higher risk of

hematoma formation compared with that encountered in unanticoagulated patients (up to 20%) [4]. Recently, there has been an increasing interest in performing the pacemaker implantation without reversal of the anticoagulant. This practice was associated with lower risk of pocket bleeding and shorter hospital stay [3, 5-7].

Antibiotic prophylaxis is a controversial issue, but most implanters prefer to give oral or intravenous (IV) antibiotics to decrease the incidence of local or systemic infections based on limited data available [8]. Although there is a distinct lack of either national or international guidance in this area, meta-analysis of the randomized trials suggests a benefit from pre-procedure intravenous antibiotics [9]. Our routine practice is to give 1 gram of cefazolin or vancomycin (in penicillin-allergic patients) one hour before the procedure.

Implantation of pacemaker usually involves a combination of local anesthesia and conscious sedation. Infiltration of skin and subcutaneous tissue at the implant site with 1-2% lidocaine provides sufficient local anesthesia for the majority of implant procedures. However, to obtain optimal anesthesia, conscious sedation in the form of carefully titrated IV midazolam and fentanyl is recommended. On rare occasions, general anesthesia may be required in an extremely uncooperative patient.

Implant area from the angle of jaw to the nipple line bilaterally should be completely cleansed and shaved. Placement of an IV line ipsilateral to the intended implant site is routine for administration of prophylactic antibiotics, administration of IV analgesia/sedation, and potentially to perform venography.

On entering the procedure room, the patient is usually placed on his or her back with the arms tucked and physiologic monitoring (ECG, pulse oximetry, and noninvasive blood pressure) should be quickly established to detect any arrhythmia or hemodynamic abnormality. Preparing the procedure field is also crucial to minimizing complications. Sterility is obviously of paramount importance; the chest is prepared with an antiseptic solution, and the area is covered with sterile drapes to keep the incision area as clean as possible.

4. Implant techniques

4.1. Central venous access techniques

A central vein (ie, the subclavian, internal jugular or axillary vein) is accessed via a percutaneous approach. Alternatively, target vein is accessed via direct visualization by a cut down technique (most commonly, cephalic vein). Figure 3 shows a standard prepackaged introducer set for implantation. In patients in whom this is technically difficult because skeletal landmarks are deviated, an initial brief fluoroscopic examination will greatly reduce the time and complications associated with obtaining the access (Figure 4).

Figure 3. Introducer set used for percutaneous access to central veins

Figure 4. Target area for subclavian vein puncture is marked by white arrow.

Subclavian vein puncture is the first choice technique for most operators. The needle is advanced (gently aspirating on an attached syringe as with any other indirect puncture), aiming for the space below the clavicle and over the first rib until either the vein is cannulated or the rib is struck. The subclavian vein is typically accessed at the junction of the first rib and the clavicle. On occasion, venography may be required to visualize the vein adequately or to confirm its patency (Figure 5). This approach is associated with minimal incidence of pneumothorax.

Figure 5. Contrast venography performed from left brachial vein. The figure clearly shows axillary vein, cephalic vein, subclavian vein

Other important alternative central vein techniques for lead implantation are cephalic vein cut down and axillary vein puncture. The cephalic vein resides in the sulcus between the deltoid and pectoral muscles. This area is easily identified by palpation and is occupied by loose connective tissue and fat, which can be dissected to identify the cephalic vein. Occasionally, the vein is deep or consists of a plexus of tiny veins. In these circumstances, other routes should be used for lead insertion. After vein isolation for 1 to 2 cm within the groove, it is ligated distally. A ligator is placed around the proximal part of the vein for hemostasis. The vein can be entered using venotomy or with 16- or 18-gauge peripheral IV catheter. The axillary vein can be accessed by blind percutaneous puncture by entering the pectoral muscle just medial to the acromion process on anteroposterior fluoroscopy. The

needle then is directed to the point at which the lateral border of the first rib appears to cross the inferior margin of the clavicle. Alternatively, the axillary vein can be accessed using contrast venography.

After venous access is obtained, a guide wire is advanced through the access needle, and the tip of the guide wire is positioned in the right atrium or the venacaval area under fluoroscopy. The needle is then withdrawn, leaving the guide wire in place. If indicated, a second access will be obtained in a similar fashion for positioning of a second guide wire.

Sometimes, a double-wire technique is used, whereby 2 guide wires are inserted through the first sheath and the sheath then withdrawn, so that 2 separate sheaths can be advanced over the 2 guide wires. This technique can cause some resistance or friction during sheath or lead advancement.

4.2. Pocket formation

Although the pocket may be formed in the axilla or in the abdomen (for epicardial or femoral systems), the most common site is the pectoral region. In the latter approach, a 1.5- to 2-inch incision is made in the infraclavicular area parallel to the middle third of the clavicle, and a subcutaneous pocket is created with sharp and blunt dissection where the pacemaker generator will be implanted. Some physicians prefer to make the pocket first and obtain access later through the pocket or via venous cutdown; once access is obtained, they position the guide wires as described above.

4.3. Positioning of atrial and ventricular leads

Over the guide wire, a special peel-away sheath and dilator are advanced. The guide wire and dilator are withdrawn, leaving the sheath in place. A stylet (a thin wire) is inserted inside the center channel of the pacemaker lead to make it more rigid, and the lead-stylet combination is then inserted into the sheath and advanced under fluoroscopy to the appropriate heart chamber. Usually, the ventricular lead is positioned before the atrial lead to prevent its dislodgment.

Making a small curve at the tip of the stylet renders the ventricular lead tip more maneuverable, so that it can more easily be placed across the tricuspid valve and positioned at the right ventricular apex.

Once correct lead positioning is confirmed, the lead is affixed to the endocardium either passively with tines (like a grappling hook) or actively via a helical screw located at the tip. The screw at the tip of the pacemaker is extended or retracted by turning the outer end of the lead with the help of a torque device. Adequate extension of the screw is confirmed with fluoroscopy. Each manufacturer has its own proprietary identification marks for confirming adequate extension of the screw.

Once the lead is secured in position, the introducing sheath is carefully peeled away, leaving the lead in place. After the pacing lead stylet is removed, pacing and sensing thresholds and

lead impedances are measured with a pacing system analyzer, and pacing is performed at 10 V to make sure that it is not causing diaphragmatic stimulation. After confirmation of lead position and thresholds, the proximal end of the lead is secured to the underlying tissue (ie, pectoralis) with a nonabsorbable suture that is sewn to a sleeve located on the lead.

If a second lead is indicated, it is positioned in the right atrium via a second sheath, with the lead tip typically positioned in the right atrial appendage with the help of a preformed J-shaped stylet.

In a patient who is without an atrial appendage as a result of previous cardiac surgery, the lead can be positioned medially or in the lateral free wall of the right atrium. As with the ventricular lead, the atrial lead position is confirmed, impedance is assessed, the stylet is withdrawn, and the lead is secured to the underlying pectoralis with a nonabsorbable suture.

4.4. Lead connection and pulse generator insertion in the pocket

When the leads have been properly positioned and tested and sutured to the underlying tissue, the pacemaker pocket is irrigated with antimicrobial solution, and the pulse generator is connected securely to the leads. Many physicians secure the pulse generator to underlying tissue with a nonabsorbable suture to prevent migration or twiddler syndrome.

Typically, the pacemaker is positioned superficial to the pectoralis, but occasionally, a subpectoral or inframammary position is required. After hemostasis is confirmed, a final look under fluoroscopy before closure of the incision is recommended to confirm appropriate lead positioning.

4.5. Pocket closure

The incision is closed in layers with absorbable sutures and adhesive strips. Sterile dressing is applied to the incision surface. An arm restraint or immobilizer is applied to the unilateral arm for 12-24 hours to limit movement.

4.6. Post-procedural care

Pain levels are typically low after the procedure, and the patient can be given pain medication to manage breakthrough pain associated with the incision site. There is controversy over the routine use of IV or oral antibiotics after the procedure. A postoperative chest radiograph is usually obtained to confirm lead position and rule out pneumothorax. Before discharge on the following day, posteroanterior and lateral chest radiographs will be ordered again to confirm lead positions and exclude delayed pneumothorax. Pacemaker interrogation is also recommended to ensure proper pacing function before patient leaving the hospital.

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