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Chapter

Pacemakers and Defibrillators Implantation

Kamran Ghods, Mohammad Forozeshfard, Shahrzad Aghaamoo, Narges Amini and Hoda Zangian

Abstract

Since the introduction of pacemakers and defibrillators in the 1960s, many lives have been saved. The technologies used in the development and implantation of such devices are constantly improving, making the procedures increasingly effective and safe. However, the complexity of such implantations makes it one of the most important procedures that need high levels of expertise, knowledge, and experience on the part of the entire surgery team. There is a wide range of devices used for different purposes with various features and characteristics to suit different patients. They range from single-chamber and dual-chamber pacemakers to pulse generators and biventricular pacemakers. The present review chapter seeks to elaborate on the steps of pacemakers and defibrillators implantation, starting from patient selection to post-surgery care and patient education. It outlines all necessary measures in the preoperative, intraoperative, and postoperative stages to ensure the utmost safety, prevent infection, and avoid and treat further complications. The procedures used by our team have demonstrated satisfactory results for patients with a wide variety of conditions.

Keywords: pacemaker, defibrillator, PPM implantation, ICD implantation, anesthesia care

1. Introduction

Cardiac pacemakers (PPM) and implantable cardioverter defibrillators (ICD) are electrophysiological devices that affect different aspects of patients' lives. Research and implantation of PPM and ICD began in the early 1960s. Nowadays, their role in the medical world is widely accepted because of advancements in new technologies and their widespread use, in addition to the improved life expectancy and quality of life in cardiac patients. Few companies produce and supply PPMs and ICDs.

They are a common treatment for irreversible bradycardia and tachyarrhythmias with specific indications. Cardiac pacemakers are made of a pulse generator that produces the electrical current required for the stimulation of the myocardium. One or two electrodes (leads) transmit the electrical activity from the pulse generator to the atrium and ventricle muscle.

As with other surgical procedures, patients require a precise evaluation and special care in preoperative, intraoperative, and postoperative periods. Implantation must be performed under anesthesia care. Anesthesia management plays a vital role as it involves general and local anesthesia.

Undoubtedly, despite the numerous benefits of using PPMs and ICDs, various local and cardiovascular complications may occur. Local complications include pain, swelling, wound hematoma, wound infection, and ipsilateral hemopneumothorax. Cardiovascular complications include lead displacement, lack of sensation and pacing, atrial and ventricular perforation, myocardial hematoma, diaphragmatic pacing, and cardiac tamponade.

Postoperative care should be short-term and long-term, which include wound care, patient education, taking medications, and periodic follow-up. The improvements in the patients' quality of life are very impressive after implantation and could be affected by programming compatibility and psychological, social, and economic behaviors.

2. Patient selection

Patients are nominated for pacemaker (PPM) and implantable cardiac defibrillator (ICD) implantation according to the patient's history, symptoms and signs, physical examinations and other documents, cardiac imaging (echocardiography) in case of bradycardia/tachycardia, and based on the 2021 European Society of Cardiology (ESC) guidelines on cardiac pacing and cardiac resynchronization therapy, which was developed by the Task Force on cardiac pacing and cardiac resynchronization therapy [1].

A majority of all pacemaker implantations are indicated to patients above 60 years old. After admitting the patient and obtaining informed consent, the necessary blood tests, chest X-ray, and electrocardiography are taken, and then the patient is prepared for the procedure. The patient is transferred to the electrophysiology laboratory, where it is essential to have properly functioning equipment. In addition, standard air conditioning is crucial in controlling air infections. In the era of the Covid-19 pandemic, we need to consider health protocols and guidelines for the personal protection of staff and patients. If there is no emergency condition, pacemaker and ICD implantation should be delayed; otherwise, we must follow all the instructions and protocols related to the prevention of the disease.

3. Types of devices

- Single-chamber pacemaker, which has one lead that connects the pulse generator to the right ventricle or atrium.
- Dual-chamber pacemaker, which has two leads that connect the pulse generator to the right atrium and ventricle, modifying the rhythm of the heart.
- Biventricular pacemaker, which is also known as a cardiac resynchronization therapy (CRT) device and has three leads connecting the pulse generator to the right atrium and both ventricles, which is indicated in advanced heart failure.
- Implantable cardioverter defibrillators (ICD), which include single-chamber and dual-chamber.
- Pulse generators, which are implanted subcutaneously and their leads are divided into three categories: endocardial, epicardial, and subcutaneous. We generally apply endocardial leads with extensive experience in this field of medicine.

- A new generation of PPM was introduced by Medtronic Company in 2016, offering leadless transcatheter pacing systems for bradyarrhythmia management. It is applied percutaneously via a minimally invasive approach, directly into the right ventricle, and does not require leads.

4. Surgical instruments and equipment

In the setting of device implantation by a cardiac surgeon, the required instruments for better management of the procedure are as illustrated in **Figure 1**. We have achieved desirable results using standard surgical techniques for gentle and homeostatic manipulation of tissue.

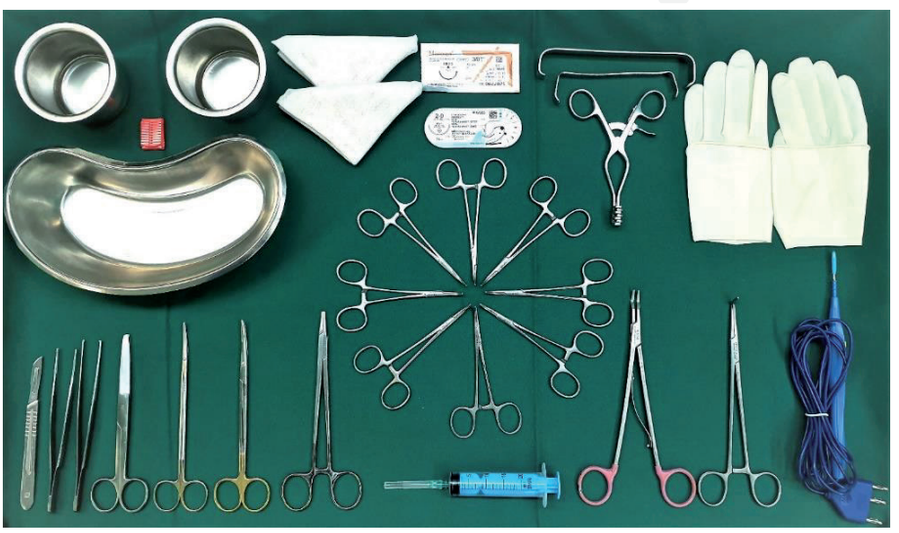

Figure 1.
Surgical instruments required for surgical pacemaker and ICD implantation.

5. Anesthesia considerations in patients undergoing PPM and ICD implantation

5.1 Pre-anesthesia care

The electrophysiology laboratory (EP lab) should be equipped with the following: anesthesia machine, air mask bag unit (patient-ventilator), electrocardiogram (ECG or EKG), pulse oximetry, defibrillators, emergency trolley, suction machine, external pacing equipment, capnography, airway management equipment. Moreover, emergency medications, including dantrolene for malignant hyperthermia, intralipid for toxicity due to local anesthetics, and antidotes drugs (naloxone, neostigmine, sugammadex, flumazenil), resuscitation drugs (epinephrine, atropine), anesthetics (propofol, etomidate), sedatives (midazolam), analgesics (fentanyl), antiarrhythmic drugs, and inotropes should be available. In addition to inspecting and preparing the equipment, an experienced and trained staff (including an anesthetic team who are sufficiently skilled in resuscitation) should be present. All patients seeking pacemaker and ICD implantation require preoperative evaluations, including (ECG), chest radiograph, blood tests (complete blood count and differentiation, BUN, CR, PT, PTT, INR), and electrolyte levels (K, Na, Ca) (**Figure 2**).

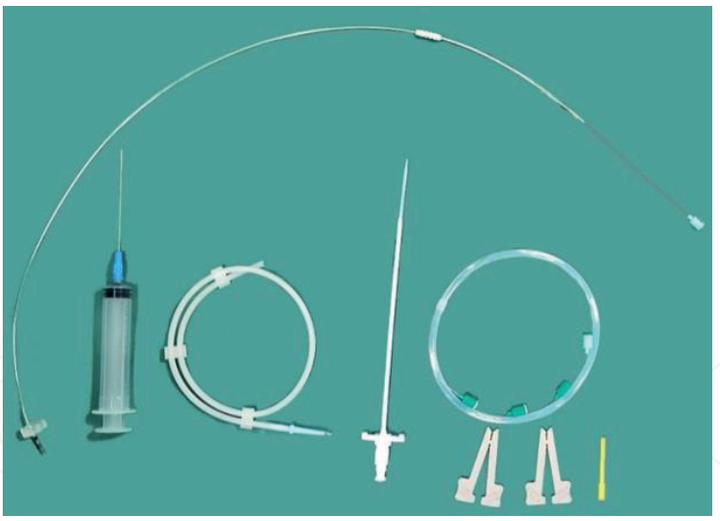

Figure 2.
Instrument setup for lead implantation based on Seldinger technique.

5.2 Preoperative evaluation

1. Medical history and medications: The patient's past medical history (type of arrhythmia, history of myocardial infarction (MI), stroke, heart failure, valvular heart disease, previous cardiac revascularization, obstructive sleep apnea (OSA), COPD (chronic obstructive pulmonary disease), difficult intubation), ECG, current medications (anticoagulants, antithrombotic drugs, antihypertensive drugs, antiarrhythmic agents, diuretics), and any medication associated with the prolongation of VT (ventricular tachycardia) should be carefully evaluated.

2. Physical examination: The patient must be examined for devices such as IABP (intra-aortic balloon pump), VAD (ventricular assist device), other implantable heart devices; surgical scar; symptoms of compensated heart failure, vital signs, electrolytes, kidney function, and TTE (transthoracic echocardiogram) to rule out heart thrombosis and assess ventricular function and valvular heart disease.

3. The procedure should be explained to the patient to reduce her/his anxiety before getting informed consent.

4. The American Board of Anesthesiology recommends that patients should not eat solid food for at least 8 hours before a procedure and should not drink even clear liquids for at least 2 hours prior.

5.3 Anesthesia care

The anesthesia team's performance is vital for the management of patients with multiple risk factors and older ages. The medical team must be prepared for potentially catastrophic events such as cardiac arrest, cardiac tamponade, and unstable arrhythmias. Therefore, make sure that surgical instruments and anesthesia support measures are ready for emergency sternotomy.

In these patients, the relationship between the EP physician and the anesthesiologist is crucial. The type of anesthesia is determined based on the patient's medical history and condition and might involve monitored anesthesia care (MAC),

sedation, regional anesthesia, or general anesthesia. The patient's position is usually supine so that the right or left shoulder (according to the surgeon's decision) is elevated by a pad. Also, the positions of the head and neck are very important and should be in a way that the patient feels comfortable. The patient's head is rotated to the opposite side of the surgical site for easier access to the subclavian vein. The airway should be easily accessible because of intravenous sedation. Most patients undergo local anesthesia with intravenous sedation by applying oxygen through a non-rebreather mask. The hands should be neutrally placed on either side. Standard vital signs monitoring is performed with ECG, pulse oximetry, non-invasive blood pressure monitoring (NIBP), and capnography.

The patient should be constantly monitored for airway obstruction and respiratory failure regardless of the anesthetic technique. In case of airway obstruction, the chin-lift and jaw-thrust maneuvers are immediately performed. Excessive restlessness, anxiety, and pain intolerance due to electric shock are the reasons for choosing general anesthesia with intravenous sedation. The arterial line should be established for patients with severe conditions.

5.4 Post-anesthesia care

Postoperative care and monitoring are mandatory due to the probability of surgical and anesthesia complications caused by an underlying disease.

6. Implantation procedure

6.1 Antibiotic prophylaxis

According to the European Society of Cardiology (ESC) guidelines on cardiac pacing and cardiac resynchronization therapy, antibiotic prophylaxis is recommended in PPM and ICD implantation procedures to prevent *Staphylococcus aureus* species. The risk of infection is significantly reduced with a single dose of prophylactic antibiotic (cefazolin 1–2 g I.V. or flucloxacillin 1–2 g I.V.) applied within 30–60 minutes before the procedure [2].

6.2 Surgical incision

To get better anatomical access to the central vessels of the heart, we use local anesthesia with the administration of 4.5 mg/kg of 2% lidocaine for the sake of the patient's comfort. Then, an incision is made (2.5 inches for PPM and 3.5–4 inches for ICD) with a number 15 blade in the distal third of the right infraclavicular region of the anterior chest wall (**Figure 3**). The subcutaneous tissue is opened and dissected in a layer under the pectoralis major fascia with accurate homeostasis using electrocautery (**Figure 4**). The development of a subpectoral pocket may be advisable in patients with a low body-mass index and for esthetic reasons.

6.3 Central venous access

Tran's venous lead implantation is commonly performed through venous access via the right or left cephalic, subclavian or axillary vein. In case clinical signs of a venous occlusion of deep veins of the upper extremity are observed, preoperative assessment (colored Doppler sonogram, venography, or chest CT scan) may be useful to determine optimal venous access or find an alternative access way.

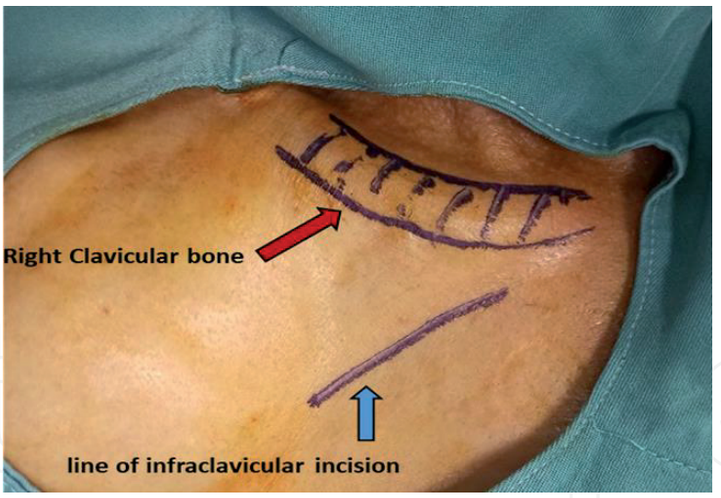

Figure 3.
Right infraclavicular incision region and marker.

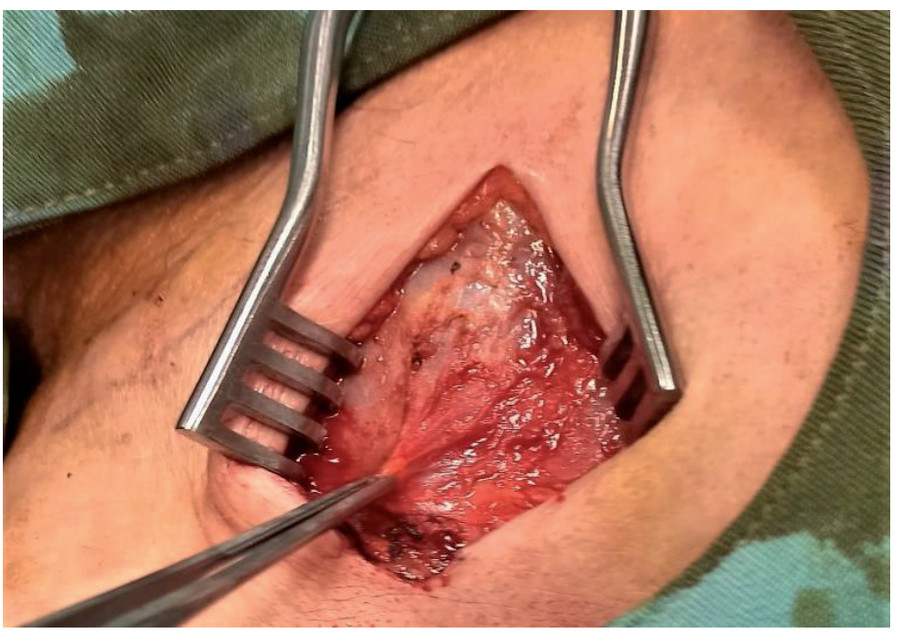

Figure 4.
Right pectoralis major fascia.

By applying the Seldinger technique, we first enter the right subclavian vein using a needle and syringe. Then, we insert a guide wire through the subclavian vein, superior vena cava, and the right atrium, determining the proper location using fluoroscopy. The lead introducer (7 French or 9 French) is sent through a guide wire and then the right ventricular (RV) lead (58 cm length) is passed through the introducer to the RV apex or interventricular septum, latter for patients who need more RV and LV contractile synchronization (**Figure 5**). The second guide wire is passed through the subclavian vein to the right atrium, and the 52 cm length lead is placed inside the right atrial appendage in the same manner and analyzed by a pacemaker programmer. An alternative technique is cephalic vein cut-down, which is occasionally performed by surgeons to reduce side effects. Subclavian vein access is associated with a 7.8-fold increased risk of pneumothorax [1]. In case subclavian venous access is not feasible, transfemoral lead implantation is alternatively performed, or leadless PPM or epicardial lead should be considered.

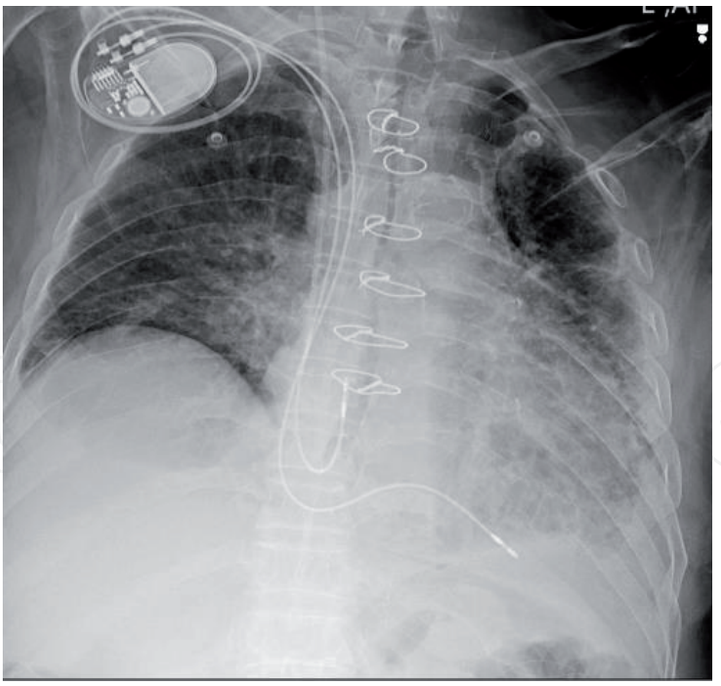

Figure 5.
Proper position of activated leads in right atrial appendage and right ventricular apex with noticeable tip position.

7. Analysis

7.1 Initial analysis

Pre-activation lead analyses have revealed the proper lead location and features as follows:

- Right ventricular (R) wave sensing: 5–20 Millivolts
- Right atrial (P) wave sensing: 1–5 Millivolts
- Lead impedance (resistance): 200–2000 Ohms
- Pacing threshold: <1 Millivolts

After initial analysis and making sure about proper leads position, the ventricular and atrial leads are screwed (activated), fixed, and re-analyzed. The same steps are carried out for RV lead-coiled (58 or 65 cm length) and should be more cautious of which can cause more endocardial trauma to the heart structures because of more stiffness. The ST-segment elevation (STE) diagram is checked in pace maker programmer. After screwing, the suture sleeve of the lead should be tied with a 3-0 black silk suture to pectoralis major fascia. Thus, each lead is fixed in two areas, the endocardium (screwed) and on the pectoralis major muscle. In the next step, after changing the surgical gloves and irrigating the subcutaneous pocket with a normal saline solution ensuring strict observance of sterility, the outer end of the RV and RA leads is connected to the pulse generator and securely screwed. The pulse generator is then placed in the subcutaneous pocket, so that the outer end of the leads is rounded beneath the generator with no bending and kinking. The PPM and the ICD function should be programmed using a sterile head or wireless programmer. The wound is

repaired in three layers following irrigation and homeostasis. The patient is then transferred to the recovery room for further vital signs monitoring. A sandbag weighing 1–3 kg can be placed on the wound site to prevent hematoma, and finally admitted to the OHICU. On the same day, chest X-ray and ECG tests are performed. Prior to discharge, we should make sure about wound healing and proper functioning of device (final analysis) and patient's general conditions to be satisfactory and provide the patient with all required information about new lifestyle and device dependency, accordingly those patients with ICD should be trained and aware of the painfulness of related shock. Scheduling for further visits and analyses is recommended.

7.2 Final analysis

Final analyses consist of the following items to achieve optimum results:

- Mood determination as recommended by the North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group (NASPE/BPEG)
- Lower rate limit
- Pacing amplitude
- Pulse width
- Sensitivity
- Upper rate limit for atrial track
- For ICD: determination of the VT and VF zone
- Configuration of leads (bipolar and unipolar)

8. Complications

Implantation can be associated with as many complications as other cardiovascular surgeries in the preoperative phase. In addition, the presence of the device inside the vessel and the heart itself is associated with early and late complications. The majority of complications occur in the hospital or within a few months after the surgery. Therefore, the cardiac surgeon should be trained about the proper management of complications and treating life-threatening conditions, and obviously, the more experienced the surgeon, the fewer the complications. The complexity of the device generally increases the potential risks. Nowadays, the device pocket is considered a source of major complications. Therefore, preventing pocket hematoma and infection has become a standard care measure. Complications are now described as early and late.

8.1 Early complications

Early complications include the following:

- Pain (surgical site or device-related)
- Wound bleeding: 0.5–3% [3]

- Pocket hematoma: accounting for over 3% of complications [4]
- Pericardial effusion or tamponade
- Pneumothorax: 0.5–2.2%
- Coronary sinus dissection or perforation: 0.7–2.1%
- Hemothorax: 0.1%
- Subclavian artery puncture
- Lead perforation: 0.8% [5]

8.2 Late complications

Late complications include the following:

- Superficial infection: 1.2%
- Pocket infection: 1.3% [4]
- Diaphragmatic pacing requiring reintervention: 0.55%
- Deep venous thrombosis
- Upper extremity edema
- Endocarditis
- Programming failure (vertigo, headache, palpitation, and blurred vision)
- Wound dehiscence
- Lead fracture
- Inappropriate shocks
- Skin erosion
- Pericarditis
- Lead dislodgment (**Figure 6**)
- Mortality (<30 days): 0.8–1.4%
- Systemic infection: 0.5–1.2%
- Tricuspid regurgitation: 16% [6]
- Pacemaker syndrome: 5–80% [7]
- Psychological problems: up to 35% of people develop anxiety disorder following ICD placement, although disabling problems necessitating admission are fairly uncommon [8]

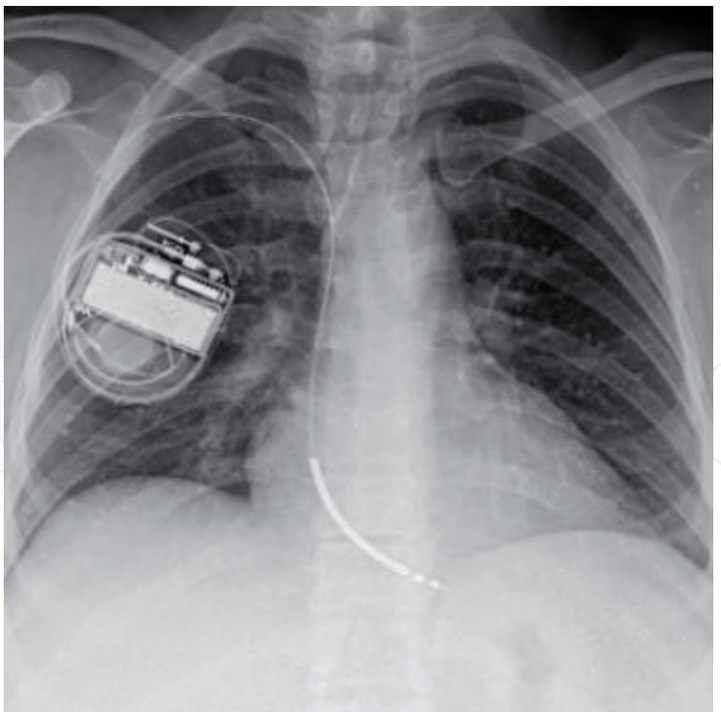

Figure 6.
Right ventricular lead-coiled dislodgment as late complication.

- Economic problems
- Replacement of pulse generator (4%) and with one or more additional lead insertions: 15.3% [1]
- Phlebitis or thrombophlebitis: 30–50% [9]

9. Post-discharge care and education points

The following points should be reminded and taught to patients for the post-discharge period.

- Keep the wound clean and dry. If you notice a swollen wound, seek medical help.
- You can take a shower 48 hours after the operation.
- Do not move your pacemaker under the skin and manipulate it.
- Do not move the arm on the same side of pacemaker implantation for up to 24 hours.
- You should not lift the arm above the shoulder for up to 4 weeks.
- The patient is instructed to seek medical support in case of fever and any discharge from the wound.
- Consume the medications according to the physician's instructions.
- The patient should not lift more than 4–7 kg.

- Avoid hitting, pressing, and sleeping on the operated site.
- Before going to spaces with strong magnetic fields and electrical circuits, consult with the treating physician and be analyzed if necessary.
- For periodic analyses, plan for 1 week, 1 month, 3 months, and 6 months later.
- Always carry your pacemaker profile card with you.

10. Conclusion

This review chapter provided a detailed outline of all the required steps involved in the implantation of pacemakers and defibrillators. The sensitive nature of the procedure requires an in-depth and careful analysis of the patient's medical history and present conditions to minimize the risk of future complications.

Extensive care and caution should be practiced in preoperative, intra-operative, and postoperative courses to ensure the risk of early complications, especially infection, are reduced. Patients need detailed instructions to learn how to live with their implanted devices. Patient-physician interaction would earn suitable long-life results.

Conflict of interest

None declared.

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