The management of surgical complications of pacemaker and implantable cardioverter-defibrillators

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The rate of implantation of pacemakers and implantable cardioverter-defibrillators (ICDs) is ever-increasing. The relative ease of device implantation utilizing a relatively simple, expeditious, percutaneous approach, without the requirement for general anesthesia or long recuperation times, has fueled enthusiasm for implantation. However, the complication risk is ever-present and forms the subject of this pragmatic review, which is limited to the management of only the surgical complications of device implantation. The management of surgical complications related to the implantation of pacemakers and ICDs should include (1) awareness of potential complications, (2) a meticulous approach to the implantation procedure to avoid complications, (3) approach to diagnosis and (4) specific therapy. With a clear understanding of the accepted implant indications and potential complications, and a meticulous approach to the implant and post implant follow up, the incidence of complications can be minimized. Curr Opin Cardiol 2000, 16:66–71 © 2001 Lippincott Williams & Wilkins, Inc.

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Abbreviations

ICD implantable cardioverter-defibrillators
SVCS superior venacava syndrome

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The rate of implantation of pacemakers and implantable cardioverter-defibrillators (ICDs) is ever-increasing. This increase parallels the potential for more widespread indications pending the results of ongoing trials of pacing in heart failure and sudden death prevention. The relative ease of device implantation utilizing a relatively simple, expeditious, percutaneous approach, without the requirement for general anesthesia or long recuperation times, has fueled enthusiasm for implantation. However, the complication risk is ever-present and forms the subject of this review.

Complications may be surgical/hardware, programming/software, or normal device function related. Pacemaker specific complications include failure to pace (Table 1), failure to sense (Table 2), pulse generator failure (Table 3), pacemaker syndrome and pacemaker mediated tachycardia. Complications specific to the ICD include ineffective therapy, failure to deliver therapy, multiple shocks (both appropriate and inappropriate), and device proarrhythmia. Both pacemakers and ICDs may be subject to crosstalk, electromagnetic interference, and patient psychological issues. This review, however, limits discussion to surgical complications. Managing surgical complications related to the implantation of pacemakers and ICDs should include (1) awareness of potential complications, (2) a meticulous approach to the implantation procedure to avoid complications, (3) approach to diagnosis, and (4) specific therapy.

A recent publication of device complication rates showed an acute pacemaker implant complication rate of 4 to 5% [5]. Implantable cardioverter-defibrillators lead complications occur in 10 to 16% of patients [10], and even higher when programming and potential psychological complication data are considered. The nonthoracotomy implant technique portends a lower complication rate than the now superceded open thoracotomy, epicardial patch approach. Hardware and implantation related complications often require further surgical intervention. The incidence of device related implant complications has been shown to be implanter-experience related [3,5] and similar with single or dual chamber implantation [4].

An exhaustive list of potential complications is outlined in Table 4. Each *surgical complication* and specific management strategy will be dealt with in turn. Classification will be divided into venous access related,

Table 1. Causes of loss of capture

Lead dislodgment or malposition
Micro/macro-dislodgment
Perforation
Capture threshold elevation
Lead maturation
Metabolic/electrolyte abnormality
Drugs
Cardiac disease progression (infarction/cardiomyopathy)
Local electrode–myocardial interface damage
Electrocautery/defibrillation
Battery depletion
Circuitry failure
Inappropriate programming
Too low a safety margin
Pseudo–malfunction
Recording artifact mimicking pacing stimulus
Isoelectric evoked potential
Functional non-capture–output delivered during refractory period (true or functional undersensing)

Adapted from [18].

lead related, and pocket related. Infection is an extremely important complication that is discussed separately. Unless specifically stated otherwise, discussion incorporates complications applicable to both pacemaker and ICD devices.

Venous access related complications

Pneumothorax

This complication occurs uncommonly and is directly related to operator experience, the difficulty of the subclavian puncture, and is almost eliminated using the cephalic cut-down technique. However, these traditional comparisons may become obsolete as the axillary vein cannulation technique [16] threatens to eliminate this controversy. Often the pneumothorax is asymptomatic and noted on routine follow-up plain chest radiograph.

Hemothorax

This complication results from trauma to the great vessels rather than the lung. The risk can be minimized by direct inward and outward passes of the puncture needle rather than a side-to-side, potentially "lacerating" movement. If an arterial puncture is performed, recognition, withdrawal, and digital pressure are important. Never cannulate the artery with the introducer, a situation that should indicate vascular surgical removal. Avoid this situation by always checking the fluoroscopic path of the guidewire into the inferior venacava before introducer insertion.

Air embolism

Deep inspiration at the time of central venous access may cause significant air to be drawn into the venous system due to the physiological negative pressure developed. It can be prevented through operator care and using introducers with hemostatic valves. The diagnosis is obvious because it is heralded by a hissing sound as the air is sucked in and with the fluoroscopic confirmation that follows. Patients are surprisingly tolerant of this occurrence. However, respiratory distress, hypotension, and arterial oxygen desaturation may occur depending on the size of the embolus and 100% oxygen should be administered along with ionotropic support in some cases [7]. Aspiration of the embolus from the right heart has also been successful. However, usually no therapy is required, as the air is filtered and consequently absorbed in the lungs.

Lead-related complications

Perforation

The lead may perforate any of the great veins, the atria, or ventricle during the implant procedure. This complication almost always occurs in the cardiac chamber on lead manipulation or fixing a screw in lead, and consequently bleeds into the pericardial space. Perforation usually occurs without serious sequelae. However, a most devastating manifestation is *cardiac tamponade,* which requires prompt diagnosis and percutaneous pericardiocentesis, possibly followed by surgical intervention if the bleeding persists. An initial suspicion should be evaluated by fluoroscopy of the heart border, an immediately available diagnostic mechanism. Confirmation of the diagnosis is obtained by emergent bedside transthoracic echocardiography. This procedure is usually performed after emergency placement of the pericardiocentesis catheter because, on suspicion of this diagnosis, definitive therapy should not be delayed. Less dramatic manifestation may be poor

Table 2. Causes of undersensing

Poor intrinsic signal from implant
Signal amplitude and/or slew rate
Deterioration in signal over time
Lead maturation
Disease progression (cardiomyopathy, myocardial infarction, new left bundle branch block)
Respiratory or motion variation
Ectopic complexes not present at implant
Transient decrease in signal complex
Post cardioversion/defibrillation
Metabolic derangement (*eg,* hyperkalemia)
Component malfunction
Sensing circuit abnormality
Stuck reed switch
Battery depletion
Mechanical lead dysfunction
Insulation failure
Partial open circuit
Pseudomalfunction
Recording artifact
Normal device function–misintrepretation
Triggered mode
Fusion and pseudofusion beats
Functional undersensing
Long refractory periods
Blanking period
Safety pacing
Oversensing
Oversensing intiated functional undersensing

Adapted from [18].

Table 3. Causes of pulse generator failure

Battery depletion
Component malfunction
Direct trauma
Loss of hermeticity
Therapeutic radiation
Defibrillation/cardioversion
Lithotripsy

Adapted from [18].

implant pacing threshold and comparative differing unipolar versus bipolar sensing. Rarely, trauma to the great veins above the pericardial reflection may cause *bleeding directly into the mediastinum*. This is much more of a concern when extracting leads than implanting them and is an emergent indication for open chest surgery, which may still be inadequate to save the patient's life. These complications are most commonly seen with lead extraction procedures.

Dislodgment

In a recent series, this complication occurred in 2.5% of pacemaker implants [5,6]. With regard to ICDs, dislodgment may be associated with inadequate sensing or therapy. Dislodgment usually occurs very early post-implant (usually 24–48 hours) but may occur up to 3 months after initial implant [6]. Intermittent under-sensing or loss of capture on post-implant telemetry should prompt consideration of this complication. Confirmation is obtained by device interrogation revealing adverse changes in sensing and pacing thresholds compared to implant values, and often CXR evidence of macro-dislodgment. Lead repositioning or replacement is required.

Malposition

Acute lead malposition is diagnosed by unacceptable implant pacing, sensing, and/or defibrillation thresholds, and remedied with repositioning during the initial implant. Often, particularly with atrial lead site selection in a patient post cardiac surgery and/or with significant structural heart disease, extensive intracardiac electrogram mapping may be required to determine the best site. In other cases, malposition may not be so immediately obvious. The presence of an intracardiac abnormality such as an atrial or a ventricular septal defect may allow passage of the lead from the right to the left heart. This occurrence is more likely with the ventricular lead, and because fluoroscopy during simple lead implantation is almost limited to the AP projection. Certainly, one must be alert to the resultant-paced ECG-QRS complex morphology. If right bundle, a left-sided ventricular lead position should be excluded. This is uncommon but can be excluded with post implant PA and lateral CXR review. Occasional cases of left ventricular endovascular lead placements have been recognized only at late follow up. The risk of surgical lead extraction then needs to be weighed against the possible risk of systemic thromboembolism and the perceived efficacy of long-term anticoagulation in this unusual situation.

Diaphragmatic stimulation is another possible manifestation of lead malposition. It is due to pacing adjacent to the phrenic nerve on the left with the right atrial lead, direct diaphragmatic stimulation from the right ventricular lead, or stimulation of the left phrenic nerve via a left ventricular lead utilizing a coronary sinus approach in biventricular pacing systems. This occurrence is uncomfortable for the patient and should be tested for, and is usually detected, at time of initial implant. The lead should repositioned at that time.

Venous thrombosis and superior venacava syndrome (SVCS)

Significant venous thrombosis of the innominate or subclavian veins has been demonstrated in up to 40% of

Table 4. Early complications

- Early complications related to implant procedure
  - Venous access
    - Pneumothorax
    - Hemothorax
    - Air embolism
  - Lead
    - Perforation
    - Malposition
    - Dislodgment
  - Pocket
    - Hematoma
    - Infection
    - Wound dehiscence
    - Pain
  - Generator
    - Loose set screw
- Delayed complications
  - Lead
    - Venous thrombosis/SVC syndrome
    - Exit block
    - Insulation failure
    - Conductor fracture (pacing/high voltage coil)
    - Pocket lead infection +/− endocarditis
  - Generator
    - Erosion
    - Device migration
    - Externally mediated damage (trauma, radiation)
- Device function issues
  - Pacing/sensing
    - Oversensing
    - Undersensing
    - Crosstalk
    - Pacemaker syndrome
    - Pacemaker-mediated tachycardia
  - ICD-specific
    - Failure to deliver therapy
    - Ineffective therapy
    - Inappropriate therapy
    - Device proarrhythmia
    - Psychological problems
  - Electromagnetic interference (EMI)

ICD, implantable cardioverter-defibrillators; SVC, superior venacava syndrome.

patients, with complete occlusion in up to 20% at 2 years post-implantation [1,8]. Almost all collected data are from pacemaker implantation. Manifestations vary from usually asymptomatic, acute symptomatic thrombosis, and even SVCS. Symptomatic venous thrombosis occurs in up to 5% of patients [9]. However, the incidence of SVC obstruction with symptomatic SVCS is rare, approximating 2 per 1000 implants. Predictive factors for the occurrence of SVCS have been reproducibly elusive, with variable association with the number of leads, whether the leads are intact or severed, the timing since initial implant or the presence of infection [2,8]. However, infection should be considered in all cases. There is some evidence to suggest variable contribution of difficulty gaining access at the initial implant with consequent trauma and associated inflammation as the culprit. There appears to be no difference in incidence when the cephalic cut-down approach is compared to subclavian puncture technique, and the use of lead insulation type [8].

The presence of arm swelling, collateral veins on the arm, thorax or abdomen and possible associated facial suffusion, cyanosis or edema with head and neck discomfort are classical. However, the diagnosis is more typically made in an asymptomatic patient at time of system revision when access to the venous system is difficult and venography shows varying degrees of obstruction, with possible complete occlusion. Routine preoperative venography to detect has been advocated before all device lead revision cases, so as alternative access can be considered [8].

Specific therapy depends on thrombosis or fibrosis being causative and varies from heparin followed by warfarin or thrombolysis to percutaneous angioplasty or an open surgical procedure [2,8]. Early vascular specialist consultation should be sought. In summary, venous abnormalities occur frequently but they are rarely of clinical significance.

A rare associated complication is pulmonary thromboembolism that is potentially life-threatening. The presence of pulmonary embolism in a patient with a device should arouse the suspicion of thrombotic pacemaker (or ICD) lead source [9].

Conductor fracture

This complication refers to a discontinuity of the wire component of the lead. The pacing and sensing thresholds are not particularly affected in this particular situation because they use very small current compared to defibrillation, although pacing impedance typically increase. However, significant problems may occur with ICD lead conductor fracture. Partial implantable defibrillator conductor fracture will often deliver a shock with an increased shock resistance. Consequently, a lower current will be delivered, which may render the delivered shock ineffective. Conductor fracture of the sensing lead is associated with significant noise production with resultant inappropriate shocks. Partial fractures usually progress to complete, eventually impairing total lead function. It is also possible that the damaged conductor may penetrate the surrounding conductor insulation with the potential to cause adjacent intravascular perforation. Any point along the lead subject to stretching and crushing is susceptible to these complications. The diagnosis is suspected when pacing thresholds increase, defibrillation fails, shocks occur inappropriately, anti-tachycardia or anti-bradycardia pacing fails, or lead impedance rises substantially from previous measurements. This can be confirmed radiographically and ultimately, intraoperatively, at which time the lead should be replaced.

Lead insulation failure

Insulation fracture or erosion refers to an opening in the polymer surrounding the conductor. The insulation can be damaged at implant by instrumentation or overly tight tie-down sutures, or by rubbing against the device over time. The pacing impedance of the lead is markedly reduced. However, with ICD leads, the shocking impedance can be normal. The defibrillation threshold commonly increases due to shunting of electrical current away from the defibrillation electrode with decreased shock efficacy. With a bipolar lead system, checking the pacing impedance in the unipolar pacing mode may differentiate inner from outer insulation or conductor breach. In many ICD leads, the right ventricular shocking coil is also used as the anode of the right ventricular sensing lead. This "integrated bipolar" sensing/shocking system may not allow such differentiation of inner and outer system failures.

Both conductor and insulation failure are often caused by a medial subclavian vein puncture site at initial implant allowing compression of the lead by the first rib, clavicle and/or the subclavius muscle. Lead damage can be avoided by a more lateral subclavian vein insertion (including the cephalic cut-down approach), and the avoidance of very heavy upper limb exercise by the patient. The use of smaller diameter leads minimizes this complication, and similarly, is more common with ICD leads.

Definitive therapy is replacement of the lead. Occasionally, silicone rubber insulation fractures can be repaired.

Exit block

The development of fibrosis at the lead-myocardial interface over time can increase pacing threshold and is termed "exit block". This can often not be differentiated from a partial lead structural problem. However, the therapy is identical—lead replacement. The use of a steroid eluting lead may reduce this occurrence.

Generator-lead connection problem

Failure to adequately seat the proximal lead connection into the generator header may seem trivial but does occur. In this situation, the inadequate connection may generate electrical noise with consequent oversensing or a make-break connection problem with undersensing or failure to pace (partially open circuit). Similar concerns arise with ICDs with the added potential of failure to shock or inappropriate shocks. Attention should be given to this potential complication, because to remedy this situation necessitates a further surgical procedure.

Pocket-related complications

Hematoma

Pocket hematoma is an acute, relatively common complication. The site of bleeding maybe the pocket or back-bleeding around the lead venous entry site. The use of electro-cautery is useful to minimize pocket related bleeding. Bleeding from the venous entry site usually subsides during the procedure but ongoing bleeding is controlled by a firm suture placed through and around the lead entry/pectoral muscle interface.

Usually, hematomas are managed conservatively unless expanding in size, tense or painful. In these cases, reoperation to evacuate the hematoma and identify and arrest the site of bleeding is required. Evacuation was required in 1 to 2% of implant cases in a recent series [6]. The risk is increased in anticoagulated patients. The use of heparin appears to be associated with a higher risk of bleeding than warfarin. It has been shown that continuation of warfarin with an international normalized ratio (INR) of about 2.0 is safe and without devastating complication over a 15 year experience [17], although the most commonly, anticoagulation is discontinued for at least the duration of the procedure.

Wound pain

Minor wound pain is expected after device implantation, almost always controlled with simple analgesia, and settles quickly. In general, the pre-pectoral site is extremely well-tolerated. Continuing pain will usually improve or manifest an obvious infection eventually. However, pain that initially improves then recurs or occurs temporarily remote from the implant may suggest infection even in the absence of any outward localizing signs, and consequently may necessitate surgical exploration or even empirical removal and reimplant at another site. Alternatively, mechanical trauma from the device location adjacent to anterior chest wall structures maybe the culprit. In this situation, device relocation or pocket revision may be indicated.

Skin erosion

If the subcutaneous pocket fashioned at the time of initial implantation is too small for the device, undue tension on the overlying skin may cause gradual subcutaneous tissue, and possible eventual skin erosion. Care should also be taken when fashioning the pocket to create the pocket plane on the surface of the muscle, as if the pocket is too superficial, erosion may also occur. In the event of erosion, the associated potential for infection is paramount and complete extraction of the total device-lead system is usually advised.

Infection and extraction

The incidence of reported ICD system infection ranges from 2 to 8% [11]. Pacemaker infection is similar. The mortality of persistent infection when infected leads are not removed can be as high as 66% [12]. The physical manifestations range from mild systemic symptoms with no local reaction to fulminant life threatening sepsis. Early infections (more than 60 days from implant) tend to be more clinically evident as opposed to the more indolent course of late onset infection. These infections can present with only pain at the ICD site. When infection is present, complete device removal with transvenous lead extraction is followed by antimicrobial therapy with the device reimplanted at a later date. In our experience including both pacing and ICD leads, the median time for device reimplantation was 5 days with no subsequent evidence of recurrent or new infection at a mean follow-up period of 46 weeks [13•]. Partial system removal is associated with high recurrence rate and should be reserved for very selected cases. Once a strong clinical suspicion for infection is established, the whole system should be considered contaminated.

The method used for pacemaker and ICD lead extraction is very similar. In comparison with pacemaker leads, ICD leads are larger in diameter, more complex in design with multiple conductors increasing the rate of mechanical failure. A recent study from our institution showed a greater percentage of ICD leads extractions for lead failure [14] compared with pacemaker lead extractions, with a theoretical increase in the risk to the patient.

Telescoping polypropylene sheaths have been used traditionally for pacemaker and ICD lead extraction. These sheaths are relatively thin and kink easily. More recently, the laser sheath was introduced. This sheath appears to be a major advantage in removing ICD leads. Gentle advancement pressure is applied on the laser sheath combined with Excimer laser energy (5-second bursts) and withdrawal traction on the locking stylet. Implantable cardioverter-defibrillators lead extraction is significantly more difficult than pacemaker lead extraction implanted for the same duration.

In a recently published paper [15], the use of a 16 Fr laser to extract 128 ICD leads and 73 old pacemaker leads was evaluated. The complete and partial success rate was 90% and 2% respectively. Complications (cardiac tamponade, hemothorax, vascular or myocardial perforation) occurred in 6% with 0.6% periprocedure mortality.

The potential complications of implantable cardiac arrhythmia devices are significant and enormous, both in diversity and patient impact. For this reason, the decision to implant a device should be based on sound guidelines with definite expected patient benefit, because although it is a relatively simple procedure, the potential adverse outcome may, at times, be life-threatening. With a clear understanding of the accepted implant indications and potential complications, and a meticulous approach to the implant and post-implant follow up, the incidence of complications can be minimized.

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