CARDIAC DEFIBRILLATORS

INTRODUCTION — It is estimated that 200,000 to 400,000 people die suddenly in the United States; the majority die as a result of heart rhythm abnormalities known as ventricular tachycardia and ventricular fibrillation. An implantable cardioverter-defibrillator (ICD) is a battery-powered device that significantly improves the chances of survival in people at high risk for these arrhythmias.

Cardiac arrest, also known as sudden cardiac death, occurs when an abnormal heart rhythm prevents the heart from working normally to deliver blood the brain and other vital organs. A heart attack occurs when a blood vessel is partially or completely blocked, preventing blood flow to the heart, causing heart muscle to die. Cardiac arrest is not the same as a heart attack, though patients can be at a higher risk for cardiac arrest during or after a heart attack.

These dangerous arrhythmias often occur without warning and can be fatal within minutes, making them difficult or impossible to treat with conventional methods. There are many individuals with heart disease who have not experienced rhythm abnormalities but are at high risk for having them. An ICD continuously monitors the heart's rhythm and, upon sensing a potentially serious rhythm disturbance, electrically paces or administers a shock to the heart to stop the arrhythmia and restore a normal heartbeat. Thus, an ICD does not prevent the abnormal rhythm from occurring, but it rapidly detects and treats the abnormality, restoring a normal heart rhythm before the event becomes life-threatening.

FUNCTIONS — Modern ICDs are sophisticated devices that are able to perform three general functions: treatment of dangerous ventricular arrhythmias, record the hearts activity in the device memory, and standard pacemaker functions. Older devices may not have all of these capacities.

Treatment of ventricular arrhythmias — The primary functions of an ICD relate to the treatment of potentially fatal ventricular arrhythmias (VT and VF). The ICD is highly effective in the treatment of these arrhythmias, and a number of studies have demonstrated that people who have had such arrhythmias, or selected patients who have not had, but are felt to be at risk of such arrhythmias, survive longer with an ICD. The ICD does not prevent heart disease and does not prevent arrhythmias from occurring, but when potentially lethal arrhythmias do occur, the ICD can terminate the arrhythmia, often saving the patient's life.

The ICD treats these arrhythmias in one of three ways:

- Cardioversion
- Defibrillation
- Anti-tachycardia pacing

Cardioversion and defibrillation are both forms of high-energy shocks that terminate dangerous arrhythmias and restore a normal heart rhythm. If the patient is conscious (awake) at the time of the shock, it is painful and usually described as feeling like a kick in the chest.

Anti-tachycardia pacing is an alternative method of terminating ventricular arrhythmias. It involves delivering a short series (eg, 5 to 10) of paced beats. This is not painful and may be unnoticed by the patient, although some patients may feel a brief burst of palpitations. Anti-tachycardia pacing can be very effective for some slower ventricular arrhythmias (eg, 150 to 180 beats per minute), and is often programmed as the initial therapy for these arrhythmias. High-energy shocks are often programmed as the initial therapy for very fast rhythms (eg more than 180 to 200 beats per minute) or as rescue therapies if anti-tachycardia pacing fails.

ICDs can usually distinguish between different arrhythmias, such as atrial fibrillation and VT. This is important as atrial fibrillation causes a rapid heart rate but does not always require a shock.

Records the heart's activity — A record of the heart's activity is kept by the ICD. The record can be retrieved during an office visit, enabling the healthcare provider to monitor any underlying conditions causing abnormal heart rhythms. This allows the provider to make adjustments to ICD programming and recommend or change other treatment measures (eg, antiarrhythmic medications).

Pacemaker — In addition to treatments for dangerous rapid arrhythmias, all modern ICDs also have the ability to function as standard cardiac pacemakers. However, pacemakers do not perform the functions of an ICD..

Combination therapy — A healthcare provider may recommend the use of additional (adjuvant) therapies for some patients with ICDs, depending upon the frequency of the arrhythmia, the underlying cause, the type of device used, and other factors. Antiarrhythmic drugs provide incomplete protection from VT, VF, and sudden death, and are never used alone; an ICD is the only available treatment option to terminate VT/VF. Adjuvant therapies may include treatment with antiarrhythmic drugs, lipid lowering medications, and catheter ablation.

PARTS OF AN ICD — An ICD is approximately the size of a pager. The main parts include:

- The ICD — The ICD is powered by a battery and generates an electrical shock. It is also called the battery, the device, or the pulse generator. It is a single unit that is usually inserted into a "pocket" created under the skin (or muscle) in the chest below the collarbone (in the pectoral region). The longevity of the ICD is defined by the length of life of the battery (usually three to five years).

- The leads — Flexible, insulated wires, or leads, monitor the electrical impulses and report the heart's electrical activity back to the ICD. These leads deliver electrical charges from the generator to heart muscle when needed. During implantation, the ICD leads are passed through a vein (transvenously) into the heart.

The leads are connected to the ICD. When the ICD reaches the end of battery life and is replaced, the original leads are usually left in place and connected to the new device. The leads may last for 20 years or more.

WHO SHOULD CONSIDER AN ICD? — Specific recommendations have been established regarding the use of ICD therapy. The reasons for using an ICD have expanded in recent years because additional groups of patients have been shown to benefit from ICD therapy. Categories of patients in whom an ICD is recommended include the following:

- Patients who have experienced one or more episodes of spontaneous, sustained VT or VF (if it is not due to a transient or reversible cause).

- Certain patients who have not had prior episodes of VT or VF, but are felt to be at high-risk for experiencing one of these arrhythmias. The estimated risk for these arrhythmias is based upon a combination of several risk factors (for example, prior heart attacks, severely reduced heart function, and/or advanced heart failure). Patients with a very high risk profile may require an ICD based upon those features alone. Other patients with a combination of risk factors that puts them in a moderate risk category may be referred for an additional test, called an electrophysiology study, to determine if an ICD is necessary.

PROCEDURE — Before the procedure, a local anesthetic (numbing medication) will be given along with other medication to help the patient relax and feel sleepy. Some patients will be given general anesthesia, which is used to induce sleep while the procedure is performed.

The surgery involves making an incision below one of the collarbones. The leads will be placed into the heart through the vein that runs next to the collarbone. Up to two leads will be placed inside your heart. One lead will be placed in the ventricle (bottom chamber) and one may be placed in the atrium (top chamber), on the right side of heart.

During the operation, routine electrical measurements of the heart will be made to be sure that the leads are positioned correctly. After the leads are in place, they are connected to the ICD. The device will be placed under the skin in the upper chest. The physician may start abnormally fast heartbeats several times and stop them by giving the heart electrical shocks from the ICD; this is done two to five times to make sure the ICD can stop the fast heartbeats. The procedure takes about 15 to 25 minutes to complete. A chest x-ray is performed after the procedure to be sure the leads are in the proper position.

Patients will usually need to stay in the hospital overnight. The first follow-up appointment to check the incision is usually one to two weeks after the surgery .

COMPLICATIONS — As with any therapy, patients should be aware that complications can occur with the placement or use of an ICD. Before ICD implantation, a doctor will explain the possible complications and specific risks based upon a patient's specific condition and the surgical procedure planned.

Complications can be divided into those that can occur around the time of surgery, and those that can occur well after surgery. The following list describes the most common complications.

Surgical risks

- Collapse of the lung (pneumothorax) occurs in about 1 percent of cases and can usually be treated by insertion of a chest tube.

- Perforation of the heart, causing a collection of blood to develop within the sac around the heart (pericardial effusion or tamponade). This occurs in less than 1 percent of cases and can usually be treated by placement of a drain in the sac around the heart.

- Bleeding can occur under the skin around the defibrillator and can require drainage. The risk of this complication is higher for patients who take blood thinners or have a tendency to bleed easily.

- The risk of infection is about 1 percent. Because the defibrillator is a foreign material, the entire system must usually be removed if an infection occurs. Removal is relatively easy if the device was recently implanted. If an infection occurs several months or years after implantation, there can be significant risk of removal of the device because the leads can become scarred to the blood vessels and the heart.

- Lead movement occurs in about 1 percent of patients, and is usually managed by repositioning the lead within the heart.

- The risk of death from implantation of a modern defibrillator is less than 1 in 500.

Long-term risks

- Infection or erosion of the device. In most cases, the entire system must be removed.

- Lead failure. The leads are the weakest part of the ICD system, and the mechanical stresses on the leads can lead to breakage of the wires within the leads or in the insulation surrounding the leads.

- Inappropriate detection and subsequent delivery of a shock. If patients experience a shock from their ICD, they are advised to immediately notify their doctor to ensure appropriate clinical evaluation and ICD assessment. Also, because most arrhythmic events require only one shock for termination, patients who receive frequent or clusters of shocks typically require hospital admission so that the cause can be determined. In some cases, programming and/or medications may need to be adjusted; less commonly, a malfunctioning lead may be detected.

- Premature battery depletion or device failure. Although ICD systems are extremely reliable, they are like any other piece of electronic equipment and are occasionally subject to unpredictable failure. The mode of failure is variable, but usually Involves failure of an internal component.

There has been a recent increase in the number of devices found to have significant problems after manufacturing and implantation. In many cases, the problem is too rare to justify replacing the device. However, in some cases, the device must be recalled and replaced. The primary risk of replacement is infection.

The decision to replace the device depends on many factors, including the type and likelihood of device failure, the risk to the individual patient if failure were to occur, the risk of replacement, and the patient's preference. Manufacturers, doctor groups, and the federal government are paying increased attention to surveillance of ICDs after implantation as a result of the numbers of device failures.

FOLLOW UP — Patients with ICDs require regular monitoring, typically every three to six months throughout their lifetime. During this evaluation, the device is painlessly examined with a programmer that is placed on the area of the chest where the ICD is located. Stored information is retrieved to evaluate battery life, lead stability and function, programmed settings, assess pacing and shocks provided, and obtain data concerning the type of rhythm disturbances treated. Modern ICDs are able to continuously record the electrical activity of heart muscle and record the date and time of each episode and store graphs from such events. Such data assists in monitoring and diagnosing underlying conditions responsible for arrhythmias and making any necessary modifications to ICD programming to most appropriately suit the patient's needs.

ICD manufacturers are developing technology to allow patients to have ICD evaluation from their home using a telephone. This remote device follow up will likely change the way a patient's ICD monitoring is performed.

Regular monitoring will also indicate the status of the battery, providing time for replacement of the ICD before the battery ceases functioning. The ICD is usually powered by lithium batteries that last approximately three to five years . Replacing the ICD usually requires a simple procedure in which a repeat incision is made, the older ICD is removed, and a new ICD is implanted and joined with existing leads.

Fear of the ICD — Many patients describe the shocks from an ICD as severe and painful; however, most patients are willing to tolerate them because they are lifesaving. Patients may feel anxious or depressed because they fear ICD shock, device failure, or as a result of the need for decreased physical activity. Patients should speak with their healthcare providers for information

on supportive therapies (eg, relaxation and cognitive behavioral therapies) and support groups that may be helpful in reducing anxiety.

Avoiding electromagnetic interference — Since reliable ICD functioning depends upon proper sensing of the electrical activity of the heart, patients should take care to avoid electromagnetic interference from external sources.

Telephones — It is unlikely to have interference from wireless communication devices such as cellular telephones or wireless home telephones. However, it is recommended that patients should not carry or place digital cellular phones within 15 centimeters (6 inches) of the ICD.

Household appliances — Manufacturers do not recommend any special precautions when using common household appliances, such as televisions, radios, toasters, microwave ovens, and electric blankets.

Security systems — Electromagnetic security systems can be located in the workplace, airports, courthouses, or other high-security areas. Exposure to this type of security system has been shown to cause interference in some cases; interference may be related to the duration of exposure and/or the distance between the ICD and the security device. Experts advise that patients with ICDs be aware of the location of security systems, move through them at a normal pace, and avoid standing too close; in other words, the best recommendation is "Don't linger, don't lean."

External electrical equipment — The use of ICDs in certain workplaces, such as those with welding equipment or motor-generator systems, has not been shown to cause problems in the functioning of the ICD. However, because interference remains a concern, experts recommend that patients remain at least two feet from external electrical equipment, verify that the equipment is properly grounded, and wear insulated gloves when using electrical devices.

Diagnostic or therapeutic procedures — Although standard x-rays, computed tomography (CT) scans, and fluoroscopy do not interfere with the ICD, certain other diagnostic or treatment procedures may interfere. This includes magnetic resonance imaging (MRI), which should be avoided completely. Extracorporeal shock wave lithotripsy, often performed as a treatment for kidney stones, can damage an ICD, and the device should be turned off during this procedure. ICD function may also be altered during transcutaneous muscle or nerve stimulation (TENS), sometimes used for pain management.

Thus, patients should inform all doctors, dentists, and other healthcare team members about their ICD to discuss the benefits, risks, and alternatives of any planned procedure. Patients should carry or wear a medical identification bracelet or necklace in case of an emergency situation in which the patient cannot speak.