Quality Of Life in Implantable Cardioverter Defibrillator recipients

Thesis
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Life-threatening arrhythmias remain a leading cause of death in the United States and Europe. In nearly all European countries, 40% of deaths are caused by a life threatening arrhythmia, underscoring the major health significance of these episodes **(Holmberg et al., 1999).** Those who have undergone successful resuscitation are at approximately 50% risk of another episode within 5 years. The optimal treatment today for life-threatening arrhythmias is the internal cardioverter defibrillator (ICD). These devices have reduced the risk of recurrence life-threatening arrhythmias to approximately 5 % **(Domanski et al., 1997; Schlepper et al., 1995).**

Therefore, the survival benefit of the ICD is clear and unequivocal which has led to an increased implantation of ICDs not only for secondary prevention but also for the primary prevention of life-threatening arrhythmias in certain high risk groups **(Moss el al., 2002; Buxton et al., 1999).**

With the pioneering work of Michel Mirowski, the first automatic implantable cardioverter (ICD) was implanted in 1980 **(Mirowski et al., 1980).** In the ensuing 25 years, there has been a tremendous increase in the use of ICDs after several large clinical trials demonstrated their ability to effectively reduce mortality in selected populations with cardiac disease **(Goldberger et al., 2006).**

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Overview of Implantable Cardioverter- Defibrillator

Historical background:

The first life-saving defibrillation therapy took place in 1947 when Dr Claude Beck, a thoracic surgeon at Western Reserve Hospital in Cleveland, Ohio, was operating on a 14-year-old adolescent boy to correct pectus excavatum. Near the end of the procedure when the chest was being closed, the patient experienced a cardiac arrest from VF, possibly secondary to anesthesia. Dr Beck opened the chest, initiated cardiac massage, and sent his resident to Dr Carl Wiggers' nearby laboratory in Western Reserve University for the animal cardiac defibrillator that Dr Beck had developed while working in Dr Wiggers' animal laboratory many years earlier. After more than a half hour of cardiac massage, the defibrillator arrived in the operating room. Internal electrical defibrillation was successfully applied with conversion of the fatal heart rhythm to sinus rhythm. The patient fully recovered without neurologic or cardiac residua, and the findings were rapidly published **(Beck et al., 1947).**

This life-saving success with intraoperative, open-chest defibrillation led to its immediate acceptance throughout the world and to the subsequent development of external and implantable defibrillators.

Electrical device therapy with pacing and defibrillation rapidly developed during the 1950s and early 1960s. Dr Paul Zoll used external cardiac pacing for the treatment of patients with

heart block beginning as early as1952. Zoll subsequently focused on external defibrillation, and in 1956, he performed the first successful human external defibrillation using a device with a 15-A alternating current that produced 710 volts across the chest for 0.15seconds **(Zoll P et al., 1956).**

In the early 1960s, Dr Bernard Lown demonstrated the superiority and safety of direct current vs. alternating current for external, transthoracic defibrillation **(Lown B et al., 1962).**

The implantable pacemaker was developed by Senning and Elmquist of Sweden **(Elmquist R et al., 1960)** with the first patient implant in 1958.

In 1959, Wilson Greatbatch and William Chardack improved upon the Swedish pacemaker by creating a smaller and more efficient implantable unit that used mercuric oxide zinc cells for its energy source to drive an oscillating circuit that produced fixed-rate electrical discharge through electrodes placed into the myocardium using a thoracotomy approach **(Chardack et al., 1960).**Subsequent development of transvenous electrodes led to cardiac pacing as we know it today.

Dr Michel Mirowski and associates miniaturized the components of the external defibrillator into a device small enough to be implanted in humans and coupled it with a unique sensing algorithm to discriminate between normal rhythm and VF. After documenting the safety and efficacy of automatic internal cardiac defibrillation in animals, they reported clinical success in 3 patients in 1980. This success ushered in the

implantable defibrillator era that led to a series or randomized trials documenting the improved survival of high-risk cardiac patients with an implantable cardioverter/defibrillator (ICD) **(Mirowski M et al., *1980).***

Drs Mirowski and Mower continued their innovative work and subsequently focused their investigations on ways to improve ventricular contractility through appropriate pacing of the left ventricle in hearts with dyssynchronous contractile patterns. This electrical resynchronization therapy, patented in 1990, **(Mower et al., 1990)** became the treatment of choice for patients with advanced heart failure due to mechanical dyssynchrony.

Up to 1995, there had been in excess of 60,000 units implanted worldwide **(AUSTIN, 1997; Fromer, 1999 and Olshansky, 2001).**

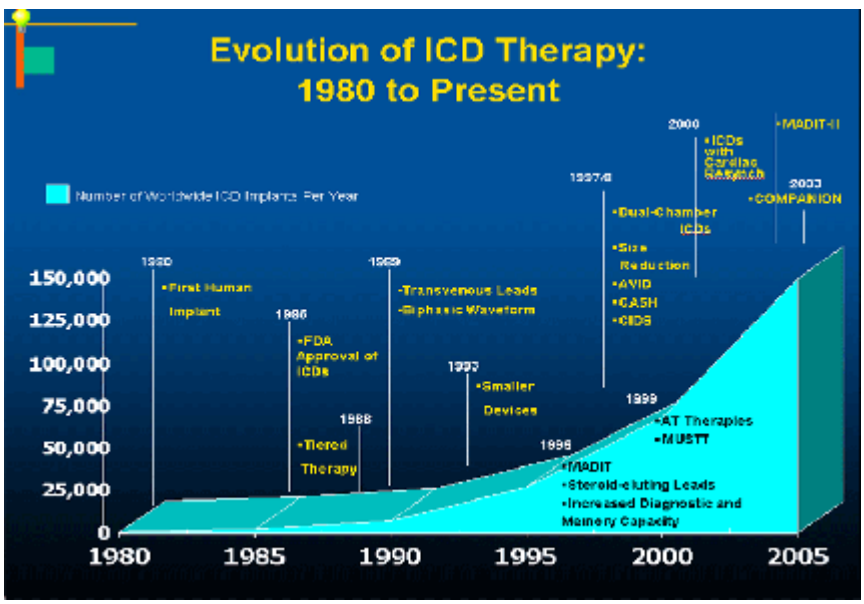

Fig. (1): Growth in number of patients who have received ICDs

The growth in the number of ICDs recipients are represented in (Fig 1).

Components of ICDs

[A] ICD Pulse Generator [PG]

Evolving ICD technologies have focused on decreasing the size of the pulse generators, which would allow pectoral implantation, improve patient comfort, and decrease the local pocket complications **(Mehara and Cybulski, 1994).** The bulk of pulse generator consists of the lithium silver vanadium oxide (Li/SVO) battery and the capacitor. The battery serves as the energy storage reservoir, and charges the capacitor to a significantly greater voltage, which can then be discharged across the myocardium. The size of the devices is directly related to the maximum available energy output. The ability to manufacture smaller devices while maintaining adequate available energy is mainly limited by advances in battery and capacitor technology. Current generators approach the size of permanent pacemakers, and some are less than 60cc **(Fig.2)**. A typical battery can store 1800 j/cc. **(Chen and Epstein, 2001).**

Besides the battery and the capacitors, the pulse generator also contains the operational circuits of the devices, which consists of low-power circuits (sensing, pacing, amplifiers, and microprocessors) and high-power charging and output circuits. The ICD generator must monitor electrical status through sense amplifier, analyze waveforms for abnormal arrhythmias, deliver

appropriate therapy, be reliable, and have a significant lifetime before battery depletion **(Chen and Epstein, 2001).**

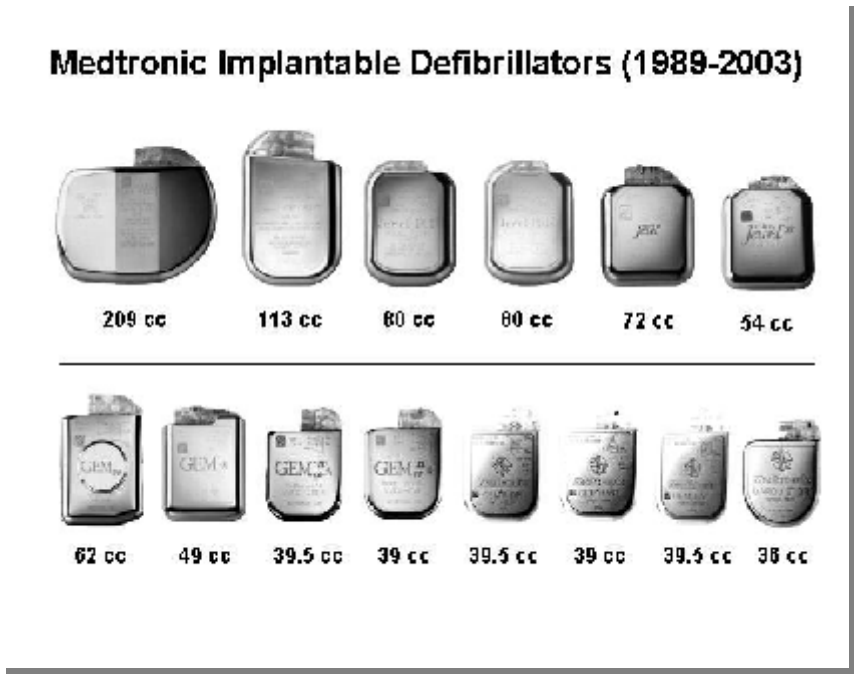

Fig (2): pulse generator sizes through a decade of evolution (Quoted from Medtronic Corporation web site)

The lifetime of the battery is dependent on the number of shocks, percentage of time spent in monitoring and pacing, and battery capacity **(Mehra and Cybulski, 1994)**. The elective replacement indicator (ERI) signifies that the battery is approaching end of life (EOL) and that a generator change should be scheduled. When a device reaches ERI, the time available for backup pacing and the number of shocks remaining is limited, but all other functions of the device operate as programmed until the battery reaches EOL. The battery has reached EOL once the ERI reserve battery capacity is used. At EOL, the device can provide only bradycardia pacing and maximum energy shocks. All other

function, such as anti tachycardia pacing and low-energy cardiversion, are no longer available **(Austin, 1997).**

Capacitor:

Capacitor store charges drawn from the battery. The most common capacitors currently used in ICDs are aluminum electrolytic capacitors. Capacitors are necessary because the battery itself cannot deliver a current fast enough for defibrillation and it cannot deliver a voltage high enough for defibrillation. Energy cannot be chronically stored in a capacitor so it must be charged just before defibrillation **(Chen and Epstein, 2001).**

Sensing circuitry:

Modern systems use bipolar electrograms (EGMs) and amplifying systems to permit accurate sensing of small EMGs such as seen in ventricular fibrillation (VF). As myocardium is activated, the change in electrical potential across the cell membrane results in depolarization; which can be detected as an electric signal. Local recordings of these electric signals are sensed from electrodes and processed through the sensing circuit **(Chen and Epstein, 2001).**

[B] Endocardial Lead System:

ICD leads have the function of delivering a high-voltage shock for defibrillation in addition to pacing and sensing function **(Austin, 1997).**

ICD leads are composed of electrodes, conductors, insulting coating, connectors, and a fixation mechanism. The distal tip of almost all ICD leads are incorporates an electrode that remains in electrical contact with the heart for sensing of cardiac activity. The conductors are the coils of wires that conduct the electrical currents between the electrodes and the ICD generator. The lead insulation is provided by biocompatible and biostable compounds, usually silicone or polyurethane. The connectors are the portion of leads that connect the lead to the ICD generator. The fixation mechanisms designed to stabilize the lead within the heart are classified as active or passive. Defibrillator leads with steroid-eluting tip electrodes are also available **(Kantharia et al., 2000).**

Fig (3): Steroid-Eluting, True Bipolar, Active Fixation ICD Lead (Quoted from Medtronic, Inc. 2008).

Rate sensing leads:

The endocardial transvenous rate-sensing lead can be a true (dedicated) bipolar or an integrated bipolar leads incorporating shocking and sensing elements **(Fig. 3)**. In the dedicated bipolar lea, sensing is accomplished between the electrode at the tip of the lead and a ring electrode placed 1 to 2 cm proximal from the tip. In the integrated sensing lead, rate sensing occurs between the tip of electrode and the RV defibrillation coil **(Kantharia et al., 2000).** The difference between dedicated bipolar and integrated sensing designs is largely a function of inter-electrode distance and size of proximal anodal electrode **(Goldberger et al., 2006)**.

Defibrillation Leads:

Endocardial defibrillation leads are almost exclusively used with the current available ICD systems. The availability of biphasic shocking waveforms delivered with the PG acting as one active electrode and an endocardial shocking coil as the other electrode virtually guarantees an acceptable defibrillation threshold (DFT) and a successful implant **(Neuzner et al., 1994).**

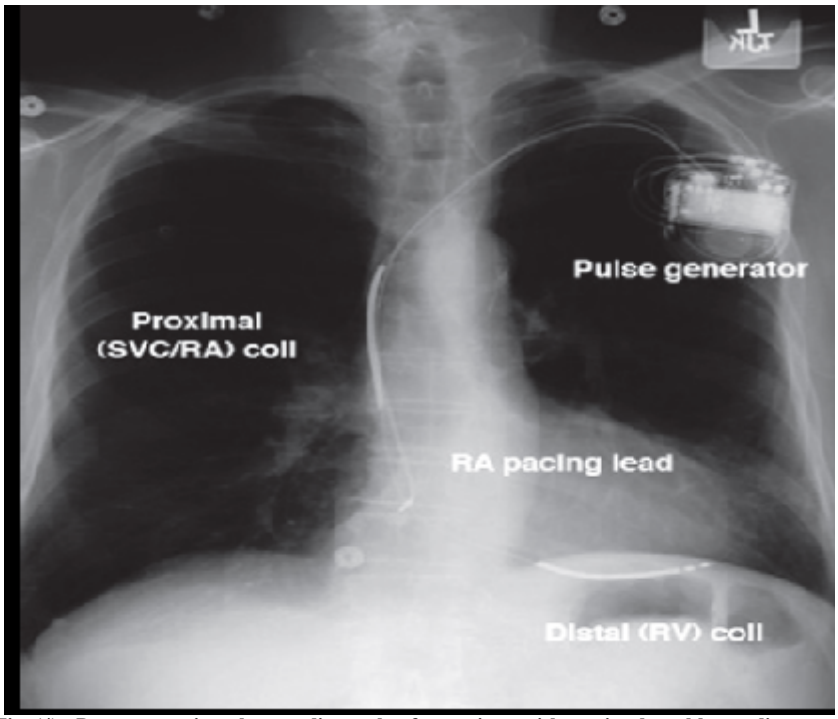

Fig (4): Posteroanterior chest radiograph of a patient with an implantable cardioverter-defibrillator (ICD). Components of the system include pulse generator, an ICD lead with proximal and distal shocking coils, and a right atrial (RA) pacing lead. RV, right ventricular, SVC, superior vena cava.

Functions of ICD System:

1. Detection:

Because ventricular tachyarrhythmias (VTAs) can be sustained or self limiting, hemodynamically stable or unstable, ICDs should be able to respond to each episode by a sequence of detection, confirmation, redetection if therapy is unsuccessful, and detection of non tachycardia rhythms after successful therapy to conclude the episode and to reset detection parameters**(Mehra and Cybulski,1994).**

The cutoff rate is defined as the heart rate above which the device will be triggered to deliver therapy **(Olson, 1994).** Devices today not only have programmable zones of detection, but different therapies can also be programmed for each zone, which is termed "tiered therapy"**(Chen and Epstein, 2001).** The ICD initiates therapy when it determines that detection criteria are met "Detection met" requires that: (a) the treatment zone's detection window becomes and remains satisfied, (b) the treatment zone's duration expires, (c) the detection enhancements are satisfied, and (d) the last detection interval remains in the treatment zone **(Guidant, 2000).**

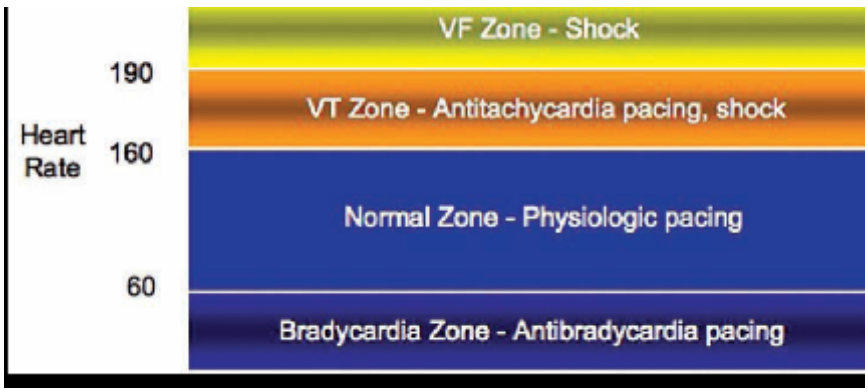

Fig (5): Therapy zones in an implantable cardioverter-defibrillator. At less than 60 beats per minute, the device provides backup pacing support. Between the lower rate limit and the lower edge of the ventricular tachycardia (VT) zone, 160 beats per minute, physiologic pacing occurs. Heart rates between 160 and 190 beats per minute are operationally called ventricular tachycardia and can be treated with antitachycardia pacing or high- or low-energy shocks. Heart rates more than 190 beats per minute are operationally called ventricular fibrillation and are treated with shocks.

Although detection based on cycle lengths of sensed ventricular electrograms alone is reliable, inappropriate shocks can sometimes occur. This most commonly occurs with atrial

fibrillation (AF), sinus tachycardia (ST), and other supraventricular tachycardias (SVTs) where the rate of these arrhythmias fall within the detection zones **(Grimm et al., 1992).** To decrease the risk of inappropriate shocks, the current devices offer additional detection parameters to increase the specificity of VT detection. These detection enhancements include: sudden onset criterion, rate stability criterion, and criterion based on electrograms width morphology **(Nisam and Fogoros, 1997)**.

The sudden onset criterion is intended to distinguish sinus tachycardia with a gradual increase in rate from VT with a sudden onset. With sudden onset turned "on", the device inhibits therapy if the rate increase is gradual. The ICD locates and measures a pair of intervals where the cycle lengths decreased the most (onset). If the difference between this interval and previously measured intervals is above the programmed onset value, the ICD classifies the onset as sudden. If the difference is below the programmed onset value, it classified as gradual, and therapy will be inhibited.

Therapy is then delivered only if the rate accelerates to a higher tachycardia detection zone. The obvious shortcoming of this enhancement is VT that begins during sinus tachycardia, such as onset of VT during exercise, which may be mistakenly classified as gradual onset and there for not detected **(Neuzner et al., 1995).**