Defibrillator Devices for the Treatment of Cardiac Conditions

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Abstract

Implantable cardiac shock devices called cardiac defibrillators are used to treat arrhythmias and prevent sudden cardiac death. The most recent generation of these devices offers a variety of memory properties, but there are still procedural concerns for the short- and long-term. A completely subcutaneous defibrillator device might make implanting it easier while reducing the drawbacks of transvenous leads. Backup pacing and emergency defibrillation are the two medical procedures that most efficiently stop sudden cardiac death. Risk factors for congestive heart failure include persistent congestive heart failure, a recent myocardial infarction, and fast "ventricular tachycardia" that progresses to "ventricular fibrillation." The best sort, fundamental concepts, elements, and regulatory clearance pathways are discussed.

Keywords: Implantable cardiac Defibrillator, Sudden cardiac deaths, ventricular tachycardia, ventricular fibrillation, Defibrillation threshold.

Introduction

A device called an implantable cardiac defibrillator (ICD) can identify a heartbeat that is alarmingly fast and fatal. Arrhythmia is the medical name for this irregular heartbeat. If that occurs, the ICD promptly provides an electrical shock to the heart. The shock recovers the beat to its original state. Defibrillation is the acronym for this [1]. Although such a device has proven to be more effective than anti-arrhythmic medications in preventing fatal cardiac arrest in both primary and secondary prevention, there are still short- and long-term procedural hazards. The implant process could be made further simpler by using a fully subcutaneous ICD (S-ICD) device, which would also lessen any drawbacks associated with transvenous ICD leads [2].

Medical experts decide whether to recommend ICD implantation relying on the patient's attributes and the available data [3]. Patients with high blood levels of natriuretic peptides are more likely to die, and ICDs may only be useful for those with LVEF 30% and QRS length >120ms [4]. ICDs are a significant kind of treatment for Long QT Syndrome (LQTS) [5]. Backup pacing and emergency defibrillation are the two therapeutic modalities [6] that is the most effective medication to avoid sudden cardiac death (SCD), which is the most prevalent cause of mortality in Europe, although it is linked to long-term problems [7]. Risk elements for SCDs include persistent congestive heart failure, recent myocardial infarction, fast 'ventricular tachycardia' (VT), or VT that becomes 'ventricular fibrillation (VF)'.

The regulatory channels for approval, the technique of activity, elements, Discoveries, Proactive measures, and the best type will all be covered in this review.

Regulatory Regulations

The US United States Food And drug (FDA) reviews high-risk medical devices like implantable cardiac defibrillators through a process called premarket approval (PMA), in which manufacturers submit data from clinical trials attesting to the safety and effectiveness of their products [8]. It is common practice to approve modifications to high-risk equipment that are already on the market using supplements for premarket approval. Additional clinical testing for these supplements is not necessary. Based on the sort of change being adopted, there are five separate review tracks for PMA supplements & Different supporting information is needed for each kind [9]. PMA Supplements are forms of communication and FDA engagement for modifications to a medical device that has received PMA approval. Whereas PMA Supplements (180 days) demand a major modification in components, materials, design, specification, software, color additives, or labeling, Panel-Track Supplements demand significant clinical data and a thorough PMA assessment. Clinical evidence offered in support of conventional device approval ought to still be relevant. Changes to the device that raise concerns about its efficacy and safety may need a thorough PMA assessment. Real Time supplements are for minor device modifications, whereas Special PMA supplements are for improvements to the device's safety or the safety of its usage. Before receiving an official FDA order allowing them, these supplements may be put into use.

The technique of Activity [10]

A medical device known as an implanted cardioverter defibrillator (ICD) is put surgically under the chest skin. It has a battery inside and uses microscopic leads placed into the heart chambers to regulate the rhythm. ICDs are employed to treat arrhythmia, halt sudden cardiac arrest, and gather data on the functioning of the heart. At a hospital or clinic, an automated ICD procedure typically takes a few hours to perform. An ICD shock can be set up to provide high- or low-energy shocks.

The most important details are that an implanted cardioverter defibrillator (ICD) continuously monitors your heartbeat and rhythm and shocks you with electricity if it notices an unusual rhythm. Risks include bleeding or bruising, pneumothorax, blood vessel injury, infection at the site of the incision, device malfunction, device movement, and edema. Recovery and prognosis involve notifying healthcare providers, having a card in your wallet, and being mindful of the items that might cause the device to malfunction.

Elements for implantable cardiac shock devices [11]

Power Source

ICDs are powered by common lithium iodide batteries, which are also utilized in permanent pacemakers. Battery life in early ICDs, despite their great size, was only about 2 years due to the higher requirements of ICDs compared to pacemakers. Due to advancements in circuit and cell layout, cell durability has increased to the extent that it is currently anticipated to be between five and nine years, reliant on shocks and pacing-based patterns, despite a significant shrinkage of the pulse generator.

Central Systems

ICD systems have three primary purposes: sensing (often known as “rate sensing”), “pacing”, and “defibrillation”. Earlier Such devices made use of “epicardial” probes that use to be sewn straight in the left-hand ventricle during a chest surgery as separate leads for rate sensing and shocking. Later, hybrid devices were created, which combined epicardial patches and defibrillation coils with endocardia1 rate sensor leads (nearly matching the leads used in enduring pacemakers). A significant development that eventually resulted in nonthoracotomy, ICD implants was the creation of combined lead arrangements which are united with rate-based

detection conductors with defibrillation loops in a solo catheter. Compared to traditional epicardial patch electrodes, these non-thoracotomy devices initially had greater DFTs, frequently requiring dermal cover arrangements. The development of the bi-layered signal, however, made non-thoracotomy systems practical for routine implantation. Two-phased wave patterns, novel catheter locations (such as the "coronary sinus"), and the usage of inverted polarisation (where the right-side ventricle's loop was established as the positive electrode contrasting to the negative electrode, as was customary in durable pacemakers) all aided in the diminution of DFTs to some significant degree. Due to the device shrinking to enable pectoral implants, the circuit barrel can also be deployed as one of the shock conductors (the heated container), especially when paired with a twin coiled lead (triad arrangement), which has further diminished DFT.

Bradycardia built Pacing

Entirely all such devices currently on the market can pace bradycardia. This device-based Pacing remained designed to avoid characteristic bradyarrhythmia, particularly the gaps that followed ICD discharges. Before, just the WI mode was accessible. Intermittent WI-established pacing might be poorly tolerated on or after a hemodynamic standpoint (pacemaker syndrome*), as has been observed with permanent pacemakers, and is linked to a higher prevalence of atrial arrhythmias. Frequent ICD pacing caused early battery depletion, necessitating occasionally the embedding of a dissimilar two-chambered everlasting pacing-built system. The most recent ICD generation can rate responsiveness and dual-chamber pacing in addition to having a distinct control source for pacing, which extends the life of the pulsation source.

Anti-tachycardia-built Pacing

In order to provide a more comfortable manner of tachycardia termination, anti-tachycardia-created pacing was added to such a device, as previously indicated. A reentrant arrhythmia must be effectively terminated by dispersing the circuit and rendering it intractable so that such impulse cannot be transmitted and is destroyed. The ability to pace dismiss ventricular tachycardia, first described in the 1970s, was typically given up as a stand-alone therapy due to

the risk of accelerated tachycardia. Several pacing algorithms (such as ramp and burst) can be created with the presumption that a shock will be administered if the tachycardia worsens or if anti-tachycardia pacing is ineffective (e.g., after a certain preset intermission or several pacing trials). Since “ventricular fibrillation’’ and speedy polymorphic “tachycardias” cannot be concluded by pacemakers, anti-tachycardia pacing can be helpful.

Memory

Modern ICDs can detect electrograms during arhythmical events (usually in combination with treatment delivery), and these electrograms can continue to be gathered even after the device has been probed. Retained electrograms provide valuable, ground-breaking information about the physiology of arrhythmias, which has proven crucial in assessing therapy efficacy, identifying problems, and other areas.

Discoveries

The displacement of the ICD, pneumothorax, hemorrhage, and infection are all possible side effects. The total complication rate for ICDs in RCTs was 9.1%, with device displacement at 3.1%, pneumothorax at 1.1%, hematoma at 1.2%, and infection at 1.5%, according to regular analysis and meta-analysis of the problems [12]. One of the driving forces for the creation of innovative defibrillation techniques is the aim to lessen complications (Table 2).

Conventional ICDs

The conventional ICDs have cables (leads) connected to the heart after being inserted in the chest. Implant surgery necessitates extensive surgery [13].

Subcutaneous ICDs

S-ICD is inserted under the skin at the side of the chest, just below the armpit. It is connected to a breastbone-length electrode. Although an S-ICD is not attached to the heart, it is larger than a conventional ICD. It consists of a subcutaneously placed generator and a defibrillation coil [13]. With the help of two detecting electrodes and a pulse generator, it can identify ventricular arrhythmias and provide shock therapy when necessary [14].

Extravascular ICDs

A unique device being studied called the extravascular ICD (EV-ICD) uses substernal defibrillation lead to deliver pacing and defibrillation therapy [15, 16]. Using specialized instruments, the substernal lead is introduced into the anterior mediastinum through a small subxiphoid incision.

	Transvenous ICD	**Subcutaneous ICD**	**Extravascular ICD**
Safety	The total complication rate with such devices is 9.1%, the Chance of Device displacement from the location in the chest is 3.1%, the Possibility of Pneumothorax & Hematoma is 1.1 & 1.2% simultaneously, and Device linked Infection chance is 1.5% [12]	Upto 10.9% lead migration (Device dislocation from location), Upto 5.9% infection &1.4% chance of hematoma [17] coupled with such a device .	Understudy
Efficacy	The well-studied technique will be used as the standard when comparing the efficacy of S-ICD and EV-ICD	Similar rates of appropriate and inappropriate shocks in the treatment of Cardiac diseases when compared to TV-ICD [18]	Understudy
Benefits	Well-studied technique with widespread accessibility in the market	Can be implanted in patients at high risk for infection or without appropriate venous access.	Similar to S-ICD but is also capable of pacing and requires lower shock energy for action

Drawbacks	Requires intact venous system and also intravascular location may be problematic for patients with bacteremia	Current devices are unable to offer permanent pacing, though they do utilize temporary post-shock pacing for treatment.	Lack of safety and efficacy data

Table 2: Assessment of technologies

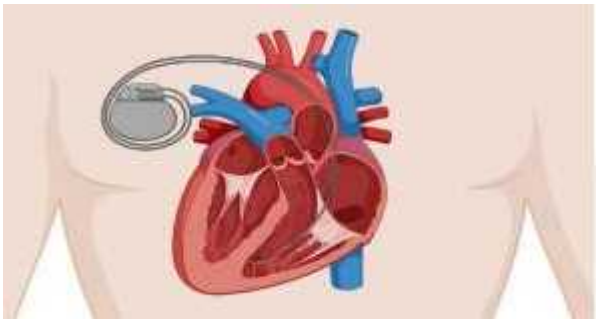

Figure 1: Conventional TV-ICDs, which have a ventricular lead in the RV apex.

Figure 2: S-ICDs (lead implanted subcutaneous)

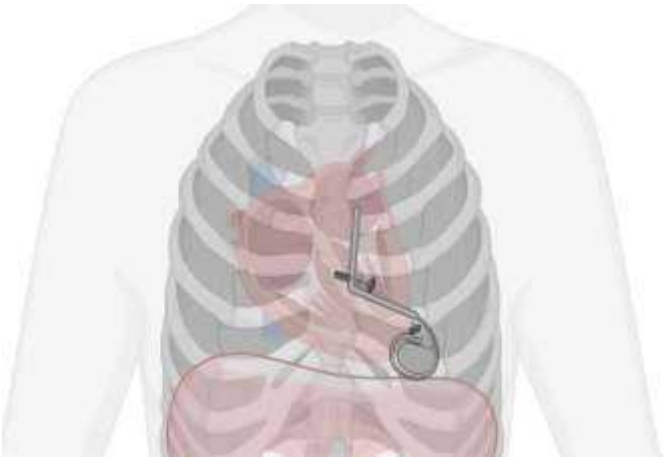

Figure 3: Anti-tachycardia leadless pacemaker with S-ICD called the EMPOWER Modular Pacing System made by Boston Scientific.

Proactive Measures [30]

Before passing through airport security, you must let them know you have a pacemaker. Avoid spending too much time with the hand-held metal-detecting wand over the pacemaker if it is chosen for a more thorough inspection. Avoid magnetic resonance imaging (MRI) devices and other strong magnetic fields, and do not lean on or be close to the system for longer than is necessary. The majority of U.S.-made cell phones (less than 3 watts) are safe to use, but they should be kept at least 6 inches away from electronics. Keep MP3 player headphones at least 1.2 inches or 3 cm away from the device since they may contain a magnetic material that might obstruct device performance.
If a surgeon or dentist is performing a surgical procedure on you, tell the surgeon or dentist that you have a pacemaker or ICD. Shock wave lithotripsy can interfere with your device without proper preparation. Transcutaneous electrical nerve stimulation (TEN) to treat certain pain conditions may interfere with your ICD pacemaker. Therapeutic radiation, such as radiation used to treat cancer, can damage the circuits in your device. Appropriate precautions must be taken before radiation therapy, and wearing a physician alert bracelet or necklace is recommended if the device is available.
If you have any concerns about using equipment close to your pacemaker or ICD, you should always speak to your doctor or the device manufacture

Discussion

The primary disadvantage of transvenous ICDs is that it necessitates an integral vein system and that intravascular locations may present challenges for individuals with bacteremia.

S-ICDs have been shown to assist in stopping ventricular arrhythmias in ischemic 2cardiomyopathies, non-ischaemic cardiomyopathies, and inherited heart disorders [20]. Inappropriate shock rates for S-ICDs and TV-ICDs are comparable. S-ICDs frequently shock patients because of T-wave oversensing, whereas TV-ICDs frequently shock patients because of ‘’supraventricular tachycardias’[20, 21]. The primary drawback of S-ICDs is their inability to provide permanent pacing functionality. S-ICDs cannot provide anti-tachycardia pacing therapy for ventricular arrhythmias and can only pace for 30 s after device shock [20, 21]. This restriction might soon become obsolete because Boston Scientific is also working on leadless pacemakers that can deliver anti-tachycardia pacing [22]. The location of the device and patient habits significantly

impact S-ICD performance, with poor positioning and increased subcutaneous fat increasing the defibrillation threshold and conversion failure risk [23]. Subsequently, the PRAETORIAN score was created to forecast the success of defibrillation. It uses three measurements from common chest radiographs, including the anterior placement of the S-ICD generator, sub-coil fat, and sub-generator fat [23]. Low PRAETORIAN scores were found to accurately predict successful conversion in >99% of patients, in contrast to intermediate or high scores, which revealed a failure rate of 51% [23]. The ongoing PRAETORIAN-DFT trial aims to prospectively validate the score by contrasting the non-inferiority of S-ICD implantation without defibrillation testing (DFT) to S-ICD implantation with DFT in patients with low PRAETORIAN scores [24]. The PRAETORIAN trial is a prospective, randomized trial with 849 patients who qualified for an ICD but not for pacing. In terms of short- and long-term device issues as well as inappropriate shocks, the study showed that S-ICD is not inferior to TV-ICD. Additionally, it was discovered that S-ICD had much fewer lead-related problems than TV-ICD [25]. 1116 patients with LVEF ≤35% with an indication for an ICD for primary prevention but no requirement for pacing participated in the prospective, non-randomized UNTOUCHED study. According to the study, S-ICD is very safe and effective, and the rate of incorrect shocks was just 3.1% after a year [26].

In areas where TV-ICD and S-ICD might not be as successful, it is hypothesized that EV-ICD can be useful. Contrary to TV-ICD, EV-ICD is extravascular, allowing it to be placed in patients with limited vascular access or recurrent bloodstream infections. The EV-ICD can offer bradycardia pacing therapy, anti-tachycardia pacing for ventricular arrhythmias, and lower shock energy because of its location beneath the sternum and in front of the heart [27, 28]. No cardiac resynchronization or protection against bradycardia, no pacing for anti-tachycardia, higher requirements for shock energy, large-scale pulse generator, minimal diagnostic capabilities, Explicitly exposure to external injuries and lead migration/erosion risk is the danger associated [29].

Conclusion

The unique idea of extravascular ICD seems promising, but the main drawback is the paucity of safety and efficacy data. Of course, only time will tell if it will eventually displace subcutaneous and conventional ICDs. The goal may be to develop new kinds of defibrillators that can overcome some of the drawbacks of those now in use.

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Conflict of Interest

Authors claim to have no financial conflicts of interest.

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