For nearly 3 decades, the implantable cardioverter-defibrillator (ICD) has been available to patients who survived life-threatening rapid heart rhythms or are at risk of experiencing them. The ICD comprises a device generator coupled with a defibrillation lead. Traditional ICDs are implanted under the skin with the generator positioned beneath the collar bone. The defibrillation lead is inserted through the veins in the chest that course to the heart, permitting direct attachment to the inside of the heart, specifically the right ventricle. Figure (A) shows an x-ray of an ICD and leads.

The Subcutaneous ICD
Versus the Traditional ICD
The subcutaneous ICD (SICD) is a novel defibrillator developed over the past decade that has become available to patients in the United States this year. The SICD provides an alternative option for patients whose physicians are recommending an ICD. Manufactured by Boston Scientific, Inc, a company that makes and sells ICDs, the SICD consists of an ICD generator and a defibrillation lead, similar to a traditional ICD. However, the defibrillation lead remains completely outside the chest cavity. Figure (B) shows an x-ray of the SICD. The SICD is implanted under the left breast, and the lead is placed under the skin along the left side of the breastbone. Early experience with the SICD has shown that it can terminate life-threatening rapid heart rhythms within seconds of their detection.

Patients who are candidates for an ICD should understand the differences between a traditional ICD and the SICD. The greatest advantage of the SICD is that the lead does not course through the central veins in the chest, nor is it attached to the tissue within the heart chambers. Patients who opt for an SICD avoid the need for possible lead removal, or extraction, from the central veins and heart cavity. Lead extraction is recommended in cases of lead infections, fractures, or other mechanical problems that prevent safe and effective ICD shock therapies. Although extraction remains an infrequent necessity among implantation patients, it is associated with significant risks, including death.

A comparison of the SICD to a traditional ICD follows.
Device Size
The SICD device is substantially larger because it requires a larger battery to deliver stronger shocks during life-threatening rapid rhythms. A higher shock energy is necessary because the SICD system shocks the heart entirely from outside the chest wall.

Pacemaker Function
A substantial number of patients requiring an ICD also require protection from slow heart rates (pacemaker therapy) or may benefit from implanted leads in veins coursing to the surface of the heart to improve heart function (cardiac resynchronization therapy). The SICD cannot provide pacemaker or resynchronization therapy. However, both are available with traditional ICDs.

Alternative Rapid Rhythm Therapy
Traditional ICDs have improved ability to detect and treat rapid rhythms. These devices have programmable features that discriminate between life-threatening and non-life-threatening rapid rhythms. This can help to reduce the occurrence of inappropriate shocks for non-life-threatening rhythms, which unfortunately can occur in ICD recipients. Traditional ICDs can also incorporate a rapid pacing treatment, or antitachycardia pacing, to terminate
rapid rhythms. The SICD has limited discriminator functions and lacks antitachycardia pacing.

Expanded Programmability
Programming that allows lower shock energies and the ability to evaluate an implanted device with wireless technology from a patient’s home are standard features now in traditional ICDs. Adjusting shock energy delivery is limited in the SICD. The SICD lacks remote monitoring capabilities.

Battery Life
Device battery replacement is necessary for all patients with implanted devices. The SICD battery life is not as long as that of the traditional ICD. In general, this means that the SICD device will need to be surgically replaced sooner than an ICD would need to be replaced. When devices are replaced, the original leads are detached from the original device and placed in a new one. Postprocedural hospitalization is occasionally needed. Replacement procedures can be complicated by infections or inadvertent lead damage.

Implantation Risks
Implant-related complications appear to be roughly equivalent between the SICD and ICD. Both are implanted without significant adverse issues in the vast majority of patients.

In What Patients Would the SICD Be Reasonable to Consider?
Patients in whom an SICD may be considered include those who lack the traditional channels through the chest veins that course back to the heart. These include patients who have developed blockages of the veins as a result of prior procedures or whose veins already have leads used for pacemakers or ICDs. Some individuals require their central veins for hemodialysis, and others require long-term intravenous drug therapy for cancer or other conditions. Individuals with metal heart valves in the chambers where

<table>
<thead>
<tr>
<th></th>
<th>ICD</th>
<th>SICD</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implantation procedure</strong></td>
<td>Requires x-ray</td>
<td>X-ray use not mandatory</td>
<td>Overall low risk of significant complications</td>
</tr>
<tr>
<td><strong>Implanted components</strong></td>
<td>Leads course through chest veins, Potential need for lead extraction</td>
<td>All components outside the chest cavity, Probable shorter battery life</td>
<td>Risk of infections</td>
</tr>
<tr>
<td><strong>Available functions</strong></td>
<td>Antitachycardia pacing, Remote monitoring capabilities, Pacemaker therapy</td>
<td>Limited defibrillation functions, No remote monitoring capabilities, No pacemaker therapy</td>
<td>Risk of inappropriate device shocks for non-life-threatening rhythms</td>
</tr>
<tr>
<td><strong>Defibrillation efficacy</strong></td>
<td>Robust population experience, demonstrates effective treatment</td>
<td>Effective defibrillation at implantation, Limited real-life experience</td>
<td></td>
</tr>
</tbody>
</table>

ICD indicates implantable cardioverter-defibrillator; and SICD, subcutaneous implantable cardioverter-defibrillator.

Figure. A, Chest x-ray of a standard implantable cardioverter-defibrillator (ICD). The ICD generator is positioned below the left collar bone. There are 2 leads connected to the ICD that course through the central veins in the chest to the heart. The defibrillator lead is positioned in the right ventricle and a pacemaker lead is positioned in the right atrium of the heart. B, Chest x-ray of the subcutaneous ICD. The generator is positioned on the side of the chest wall. The defibrillator lead is tunneled under the skin, along the chest wall, to lie adjacent to the breastbone.
patients, the SICD is a very promising alternative.

Finally, for individuals who have experienced complications from serious lead, device, or heart valve infections and remain at high risk of recurrent infection, the SICD is the device of first choice.

The SICD can also be implanted in patients meeting an indication for an ICD with preserved venous connections and usability. In these cases, the SICD is used as a means of providing the protective benefits of an ICD without having to use the central veins, thereby preserving their use for the future.

How Well Does the SICD Work?

Unlike standard ICD implants, 95% of SICD implants do not require x-ray use during the implantation process. Early experience with testing the SICD during implantation also indicates that it terminates life-threatening rhythms as well as an ICD.

There are limited data on the real-life ability of the SICD to terminate life-threatening rhythms after it has been implanted and over its battery life. The reason is that the device is newly approved for use and lacks a robust population like that of the standard ICD population, which currently includes tens of thousands of patients. However, an international registry following up SICD patients indicates that the device is working well.

The Table lists the potential advantages and disadvantages of the SICD compared with the ICD.

Conclusion

Like all therapy options, the decision about what device is best for an individual should be made after careful consideration and discussion between the ICD candidate and the medical team. With new therapy options like the SICD, it is critical to consider current and potential future issues that could come into play once the device is implanted and over its battery life. The significance of the SICD today is that it provides patients needing an ICD with a safe alternative option.

Disclosures

None.

References


Subcutaneous Implantable Cardioverter-Defibrillator
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