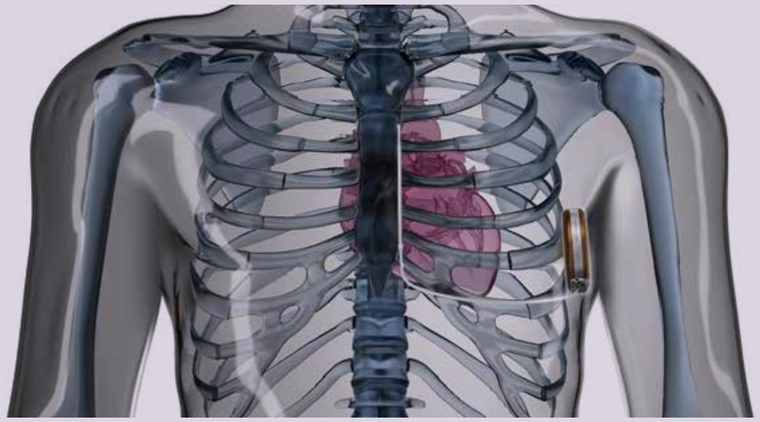
S-ICD technology continues to advance rapidly

The benefits of the Subcutaneous Implantable Cardioverter Defibrillator (S-ICD, Boston Scientific) over transvenous (TV)-ICD, including lower rates of lead-related complications and lower in-hospital complication rates in some instances, have been demonstrated in three recently published head-to-head studies by Friedman *et al* (*JAMA Cardiol* 2016;1:900–11), Honarbakhsh *et al* (*Int J Cardiol* 2017;228:280–5) and Brouwer *et al* (*JACC* 2016;68:2047–55). Additionally, a new technique (the 2-Incision technique) for S-ICD implantation and the launch of the EMBLEM S-ICD electrode (model 3501) are supporting optimisation of the technology for better patient outcomes. Jean-Benoît Le Polain de Waroux (Université Catholique de Louvain, saint Luc Hospital, Brussels, Belgium) and Jürgen Kuschyk (Medical Faculty Mannheim of the University of Heidelberg, 1st Department of Medicine, Mannheim, Germany), experienced implanters of the S-ICD, share with *Cardiac Rhythm News* their insights into these topics.



The S-ICD has been commercially available in Europe since September 2009 and in the USA since October 2012. Unlike TV-ICDs that require placement of at least one lead in the heart, the S-ICD lead is implanted subcutaneously and provides the patient with the same protection from sudden cardiac death without invading the heart and blood vessels. Since leads in the heart can be associated with serious complications, including lead displacement, fracture, systemic blood infections, or the need for lead extraction, there has been greater adoption from implanters towards the less invasive S-ICD System that has proved over the last years to be safer for patients.

Head-to-head comparison of S-ICD vs. TV-ICD

According to Boston Scientific data, more than 33,000 S-ICDs have been implanted worldwide and three recent head-to-head studies have proved the benefits of this technology over TV-ICDs.

Friedman *et al*, in the study "Trends and in-hospital outcomes associated with adoption of the Subcutaneous Implantable Cardioverter Defibrillator in the United States", which contains the largest single analysis of S-ICD recipients to date (3,717), highlights how the adoption of S-ICD therapy has increased almost nine fold. These results showed how S-ICD adoption is "rapidly increasing in the United States," Friedman *et al* wrote. In the analysis, the authors noted that the S-ICD recipients were on average secondary prevention patients, and were younger than TV-ICD patients (mean age 53.5 years compared with 62.1 for single chamber ICD and 66.5 for dual chamber ICD).

Safety and efficacy of S-ICD

Regarding complication rates, Friedman *et al* found that the S-ICD is associated with low in-hospital complication rates (0.9%), which are comparable to those with single chamber ICDs (0.6%), and lower than those with dual chamber ICDs (1.5%). The complication rate was lower than that of the EFFORTLESS registry (2% at one year), despite the high number of patients with comorbidities in this analysis. The efficacy of the S-ICD system was demonstrated with high rates of successful ventricular fibrillation conversion during defibrillation threshold (DFT) testing.

Honarbakhsh *et al*—in a second head-to-head comparison between S-ICD and TV-ICD—included 69 patients who underwent S-ICD implantation over a five-year period in a tertiary centre in London, UK, and who were propensity matched to 69 TV-ICD patients. The study found that relative risk of device-related complication was reduced by 70% in the S-ICD group compared with the TV-ICD group (Figure 1). The device-related complications in the TV-ICD group accounted mainly for by lead failures (n=20, 29% vs. n=6, 9%; p=0.004). Additionally, the authors noted that there were no implant-related complications (occurring within 30 days of implantation) in the S-ICD group compared to two in the TV-ICD group.

Furthermore, Honarbakhsh *et al* performed a cost-efficacy analysis which showed that although initial implant costs were higher for the S-ICD group compared with the TV-ICD group (US$ 1,166,082 vs. US$741,749); overall S-ICD costs "may be mitigated vs. TV-ICDs over a longer follow-up period," the authors noted. This is due to costs of device-related complications (including hospital stay, procedure-related costs and the costs of generator and/or lead replacement) incurred in the TV-ICD group (total US$23,784 for S-ICD vs. US$199,251 for TV-ICD).

In a third head-to-head comparison analysis, Brouwer *et al* looked retrospectively at the long-term clinical outcomes of subcutaneous vs. transvenous implantable defibrillator therapy in 1,160 patients who underwent S-ICD or TV-ICD implantation in two high-volume hospitals in the Netherlands, between 2005 and 2014. The authors propensity matched 140 patients with S-ICDs and 140 with TV-ICDs. They found a complication rate of 13.7% at five years in the S-ICD group, compared with 18% in the TV-ICD group. It is relevant to note, Brouwer *et al* wrote, that the overall complication rates were not significantly different between the two groups, but that the nature of the complication differed. For instance, lead-related complications were significantly lower in the S-ICD group than in the TV-ICD group (0.8% vs. 11.5%), lead survival was also significantly higher in the S-ICD group than in the TV-ICD group (99.2% vs. 85.9%) and the incidence of appropriate and inappropriate shocks was similar in the two groups.

Overall, "this study demonstrates that the S-ICD has a significant benefit over TV-ICDs with respect to lead-related complications and this benefit may be greater with longer follow-up."

Experienced implanters' views

Commenting on the results of the three head-to-head studies, Le Polain, who started implanting the S-ICD over three years ago, says: "The key message of these studies is that the S-ICD is performing very well. The S-ICD is a technology that has been shown to be cost-effective if you count the number of lead-related complications you may encounter with TV-ICDs."

Regarding adoption of the S-ICD over the last years, he comments: "We definitely see an increasing rate of S-ICD adoption in the USA and also in

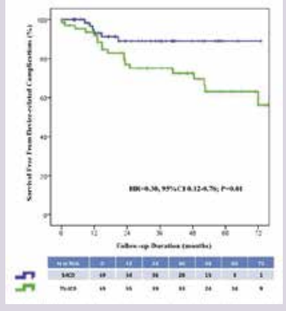


Figure 1: Kaplan Meier survival curves demonstrating the survival free from device-related complications in the S-ICD and TV-ICD groups . Source: Honarbakhsh *et al, Int J Cardiol* 2017;228:280–5

Jean-Benoît Le Polain de Waroux

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Europe. For example, in Belgium we have conducted the national registry on the use of the S-ICD and we have seen increased adoption of the technology over time by more than 300% per year." Particularly, at his centre he says: "We started using the S-ICD in some patients whose perceived lead-related risk was high, and in patients who did not need cardiac pacing. At that very early phase of experience we did not implant many patients with ischaemic cardiomyopathy because we were still thinking that those patients might be treated with antitachycardia pacing (ATP). But now, more and more ischaemic patients are also implanted with the S-ICD. So we came from something that was like 10% of our total number of ICD patients to nearly 50% of the patients who are currently implanted with the S-ICD."

From his personal experience, Le Polain attributes the increase of S-ICD implantations in his practice to the experience he has gained implanting this technology over time. He comments: "With more experience, I found the implantation of the S-ICD easier over time. [At our centre] we also changed our practice. At the beginning we used to use general anaesthesia for every case and now we are doing all our cases under local anaesthesia. And we have developed techniques of regional anaesthesia that facilitate the procedure. It is much quicker, we do not need an anaesthesiologist in the room, and that also helps to improve the comfort of the patient, which is very important."

He adds: "The implant technique has also changed. At a very early phase we were implanting the device subcutaneously and now we are always going inter-muscularly. And this also affects the perception of the patient, especially for young women whose device is now less visible."

Commenting on the relevance of implanting the S-ICD in young patients, Le Polain says: "The younger the patient the more important the benefits might be. The risk is a question of time, so the longer you have the TV-ICD lead in, the higher the risk. And sooner or later the patient will have a bacteraemia and if there is an infected lead that is hanging in the heart the risk for extraction gets worse."

With almost 10 years of experience implanting the S-ICD in over 300 patients, Kuschyk comments that he initially implanted the S-ICD in patients with difficult venous access or in patients who had an infection. However, "over the years, in terms of safety and efficacy, we have learned that the S-ICD is very comparable to TV-ICDs. So we see the vast majority of patients suitable for S-ICD and, based on 100% of patients who need an ICD, we are implanting nearly 80% with an S-ICD at our centre in Germany."

S-ICD optimisation

2-Incision technique

Based on published clinician experience with S-ICD, Boston Scientific has updated labelling to include the 2-Incision technique, which eliminates the superior parasternal incision. This technique is a more advantageous alternative to its predecessor in that it may reduce procedure time and can improve cosmetic outcome for patients. In the published study titled "Two-incision technique for implantation of the subcutaneous implantable cardioverter defibrillator" (*HeartRhythm* 2013;10:1240–43) Knops *et al* note that "the superior parasternal incision may be a risk for infection, a potential source of discomfort and cosmetically less appealing."

Highlighting the importance of S-ICD implantation techniques for the patient's benefit and therapy outcome, Kuschyk, who started using the 2-Incision technique over three years ago in all his patients, comments that implantation is the "most important step" in S-ICD therapy. "The implant technique is crucial for cosmetic reasons, for patient comfort and for efficacy of therapy," he notes.

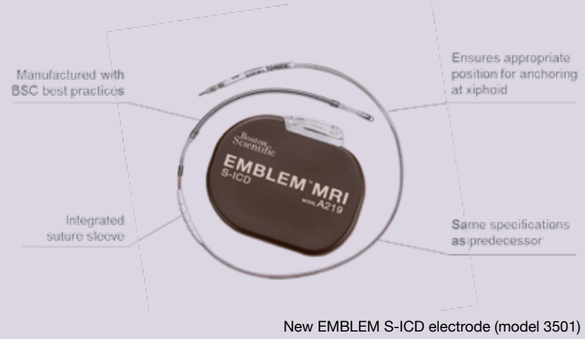
With a 100% success rate experience with the 2-Incision technique, Kuschyk considers this as his "preferred technique" and the technique of choice to teach S-ICD implantation.

Discussing the rationale to develop the 2-Incision technique, Kuschyk says that the most important reason is that it is easier to learn than the previous technique because it requires one incision fewer. It also reduces procedural time, "which means fewer infections," he comments. In the 3-Incision technique there were cases of superficial wound infections, he adds.

According to Boston Scientific's User's Manual for EMBLEM S-ICD and EMBLEM MRI S-ICD, the 2-Incision technique requires the same location of the pulse generator and subcutaneous electrode. Regardless of the surgical approach, the defibrillation coil must be positioned parallel to the sternum, in close proximity to, or in contact with, the deep fascia, below adipose tissue, and approximately 1–2cm from the sternal midline.

Discussing tips and tricks for physicians learning the 2-Incision technique, Kuschyk says that visualisations, with fluoroscopy, to verify if the lead is in the right position are very important during the first five to six procedures. He adds that close proximity to the sternum in the electrode positioning is very important to guarantee efficacy of defibrillation. He also recommends doing proctoring after training to get appropriate feedback for future procedures. As a pioneer implanting the S-ICD, Kuschyk advises new implanters to perform three to four procedures with training colleagues and to come back for help to the training facilities in case of difficult cases as part of their proctoring programme. He also advises physicians to continue performing a good number of procedures per year to become more skilled.

Kuschyk notes that the 2-Incision technique could be used in most patients. "There are some obese patients in whom it is potentially more difficult to implant the S-ICD with this technique. In those patients, colleagues sometimes cannot get close enough to the bone [the sternum], so perhaps in some of those cases a 3-Incision technique might be an alternative," he advises.



New EMBLEM S-ICD electrode (model 3501)

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In June 2017, Boston Scientific launched the EMBLEM S-ICD electrode (model 3501). The new electrode is built upon eight years of experience developing the technology.

Commenting on the key features of this new electrode, Kuschyk says: "The performance of the current S-ICD electrode is pretty amazing with regards to lead stability. The new electrode is very similar to its predecessor. However, now we have a suture sleeve already fixed to the lead at 0.75cm from the proximal pole. So, this is an advantage because it helps to reduce procedural time. The sleeve is designed in a way that you can push the lead with the suture lead through the introducer, and this is also a clear advantage. Additionally, there are fewer redundant conductors, which might contribute to an even higher lead longevity."

At the time of writing (May 2017), Kuschyk and Le Polain were about to start first implantations with this new electrode.

Future remarks

Looking to the future of S-ICD treatment, Le Polain says: "S-ICD use will continue to increase over time. The game-changer here is the ongoing development of implant techniques. For many cardiologists, having an anaesthesiologist during a procedure is a problem because of the time required for general anaesthesia. Implantation techniques that are more comfortable for the patient, that take no time, and that can be used by everybody without the use of an anaesthesiologist will become a game-changer. In terms of future development, having a leadless pacemaker which is able to communicate with the S-ICD and deliver either pacing or ATP is very valuable."

Kuschyk also shares Le Polain's view of the importance of having leadless pacemaker combined with S-ICD therapy including the possibility of biventricular pacing. Kuschyk already performs all S-ICD implantations with local anaesthesia and moderate sedation, and says that feasibility of local nerve blockades for the implantation is currently under investigation. He stresses that training programmes are of the greatest importance together with some new tools, and also foresees that evolution in battery technology and a standardised implantation technique might lead to miniaturisation of the device. He notes that "since closing and suturing of the wounds takes most time of the procedure, new tools for a quick wound closure would be of great value." In the future, Kuschyk sees the S-ICD as "a kind of headquarters in a device network communicating with other devices as leadless pacers and pressure sensors."