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Note informative

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Evaluation of subcutaneous-lead implantable cardioverter-defibrillators

English summary

Québec

This is the English summary of the guidance entitled Évaluation des défibrillateurs cardiaques implantables avec sonde sous-cutanée published in November 2016.

The complete version of this guidance (in French) is available on the website of INESSS in the *Publications* section.

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SUMMARY

Technology

The implantable cardioverter-defibrillator (ICD) is recognized for preventing sudden death in patients with heart disease at high risk of this event (primary prevention) and those who have experienced a malignant ventricular arrhythmia (secondary prevention). It consists of a generator implanted in a subcutaneous pocket and connected to one or more transvenous leads (TV-ICD) or, more recently, a single subcutaneous lead (S-ICD). The present evaluation only concerns S-ICDs.

The U.S. Food and Drug Administration (FDA) approved first- and second-generation S-ICDs in September 2012 and March 2015, respectively, while Health Canada approved first-generation S-ICDs in 2014 and second-generation S-ICDs in August 2015. The second-generation device is smaller than its first-generation counterpart, has a longer lifespan and can be monitored remotely.

An ICD can be associated with adverse events, such as implantation-related complications, inappropriate shocks, lead displacement or infection. The shocks produced by ICDs can also lead to psychological symptoms for patients, notably anxiety.

The S-ICD is a new technology presently being used in the six Québec hospitals that implant such devices.

Objective

The objective of this evaluation is to document the current state of knowledge regarding the use and performance of the S-ICD in order to determine its added value in relation to the TV-ICD, to specify its indications and to identify issues that may arise from its use.

This literature review is part of a more extensive project that includes a health technology assessment report and a field evaluation concerning the replacement of ICDs and cardiac resynchronization devices (CRT). It will serve as a basis for developing recommendations regarding the use of and replacement of these devices in Québec.

Methodology

A literature review was conducted regarding: 1) indications for the S-ICD; 2) efficacy and safety of the S-ICD; 3) health professional-related and organizational issues; 4) costs associated with the device; and 5) ethical aspects of the use of this technology. The methodology adhered to the production standards for systematic reviews of the Institut national d'excellence en santé et en services sociaux (INESSS).

The literature search targeted clinical practice guidelines (CPGs), health technology assessment (HTA) reports, Canadian consensus conference publications, systematic reviews with or without meta-analyses, and primary research studies that were not included in the former publications. The search was conducted in three databases (PubMed, EMB Reviews and Embase) and in international registries of current clinical trials. The search was complemented by consulting websites of the Guidelines International Network (G-I-N) and the National Guideline Clearinghouse (NGC), and by querying the technology assessment databases of the International Network of Agencies for Health Technology Assessment (INAHTA) and the Centre for Reviews

and Dissemination (CRD) (University of York). Lastly, Google and Google Scholar search engines were used to identify other relevant publications. Study selection and quality assessment were performed by two research professionals. Data extraction was conducted by a single person and validated by a second professional.

Information provided by stakeholders on the use of S-ICDs in Québec was also considered.

The members of the advisory committee and an external reviewer assured the project's scientific validity.

Results

Numerous studies of S-ICDs have been published in the past few years. Most of these are descriptive case series, some of which are based on registry data. Only a few compare S-ICDs and TV-ICDs. The studies are generally of short duration and involve small samples. Studies with a follow-up of at least 5 years – enabling a better evaluation of particular aspects of the technical performance of S-ICDs – are rare.

The present report includes the interim results of ongoing clinical studies (cohort studies and randomized controlled trials, RCT). Final results are expected in a few years.

Eleven synthesis studies and three observational studies, that are not included in the synthesis group, were retained for this report. The synthesis documents present the results of a varying number of primary studies. For the most part, they are technology assessment reports and analyses intended for making coverage decisions regarding these devices. The three primary studies use data from the same registry, EFFORTLESS (Evaluation oF FactORs ImpacTing CLinical Outcome and Cost EffectiveneSS), and pool these with data from the IDE (Investigational Device Exemption) study. The primary studies include cohort (n=1) and case series (n=2) investigations.

The 14 studies that were retained discuss indications for S-ICDs and the device's efficacy and safety. There is little discussion of the organizational, economic and ethical aspects related to use of S-ICDs. The available cost analyses arise from the United States, Australia and the United Kingdom. They take into account a unit cost for S-ICDs that is equal to or even less than that for TV-ICDs. The cost of using S-ICDs would be similar to that of using TV-ICDs in these three countries. Such results are not applicable to the Québec context, however, where the cost of an S-ICD is almost three times greater than that of a TV-ICD.

On the basis of the literature reviewed, S-ICDs can be an alternative to TV-ICDs for certain patients who meet one or more criteria for an ICD implantation but who also have other very specific clinical indications. The S-ICD avoids the main drawbacks of the TV-ICD, which requires vascular access and implantation of an intra-cardiac lead. It also permits avoidance of certain risks associated with TV-ICDs.

The preliminary and short-term results are promising and support the use of S-ICDs among carefully selected patients. However, they are based on non-comparative studies. The equivalence or superiority of S-ICDs compared to TV-ICDs has not been demonstrated. RCTs with long term follow-up are necessary to clearly define the risks, benefits and costs of S-ICDs.

The observed rate of appropriate detection of spontaneous ventricular arrhythmias by a S-ICD is between 84% and 100%, with the treatment success rate also being very high (96% to 100%). Successful conversion is achieved with the first shock in the majority of cases, (58%[1] to 98%), and

[1] The data in this S-ICD study arise mostly from 4 patients who received shocks [Aydin *et al.,* 2012].

its ability to discriminate between ventricular and supraventricular arrhythmias reaches 98%, compared to 77% and 68% for a single- and double-chamber TV-ICD, respectively.

Despite these benefits, an S-ICD – like a TV-ICD – can lead to infection (0 to 10% of cases in comparison with 0.4% to 12.3% for TV-ICD) and inappropriate shocks (approximately 8% for S-ICDs compared with 5% for TV-ICDs in the latest studies). The frequency of these adverse events thus appears comparable for both devices. As with TV-ICDs, T-wave over-detection is the most common cause of inappropriate shocks for S-ICD patients. Improved programming of the device and increased health professional experience with the technology can considerably reduce the incidence of inappropriate shocks. Indeed, studies show a lower rate of complications and inappropriate shocks when the implanting physicians have greater experience.

The cited studies use first generation S-ICDs for which the anticipated life span is 5 years. Second generation S-ICDs, which last for about 7 years, are already being used in Québec. However, there are currently no studies of these more recent models.

Finally, the National Institute for Health and Care Excellence (NICE) considers the efficacy of S-ICDs to be adequate for the prevention of sudden cardiac death in the short- and medium-term, but states that the collection of longer-term data is necessary.

Conclusions

Based on the present review of the scientific literature, INESSS concludes that:

- the S-ICD is a promising technology that provides the option of a defibrillator to certain specific patient populations for whom the TV-ICD is contraindicated;
- the S-ICD is an innovative technology whose efficacy and safety evidence in the short- and long-term (6 months to 5.8 years) is based on observational studies, most of which are descriptive; long-term results are currently the focus of research (cohort studies, RCTs) and are expected to be published in the next few years;
- the health professional-related, organizational, economic and ethical issues, including the patient's perspective, have been little examined in the published literature and merit an analysis in the Québec context;
- the S-ICD plays a role in the primary and secondary prevention of sudden arrhythmic cardiac death in carefully selected patients who meet criteria for ICD implantation but for whom cardiac stimulation and CRT are not indicated; and for whom a TV-ICD is contraindicated due to one or more of the following:
    - difficult venous access or need to preserve venous access;
    - the patient has had a TV-ICD removed because of a complication;
    - the patient is young and needs an ICD for the long term. This last indication is based on expert opinion.

The conclusions drawn from the scientific literature will serve as a basis for future recommendations, developed by experts in this field, regarding the use and replacement of implantable cardiac devices in Québec.