HAUTE AUTORITÉ DE SANTÉ

REVIEW OF HOMOGENEOUS CATEGORIES OF MEDICAL DEVICES

Assessment of cardiac defibrillator leads

Summary

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Haute Autorité de Santé
Communications and Information Department
5, avenue du Stade de France – F 93218 Saint-Denis La Plaine Cedex, France
Tel.: +33 (0)1 55 93 70 00

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Contents

Abbreviations and acronyms

AE	Adverse effects
AHA	*American Heart Association*
APODEC	Association of Cardiac Defibrillator Wearers
CCAM	Joint classification of medical procedures
CNEDiMTS	Medical Device and Health Technology Evaluation Committee
CRT-D	*Cardiac Resynchronisation Therapy-Defibrillator*
FDA	*Food and Drug Administration*
HRS	*Heart Rhythm Society*
ICD.	Implantable Cardioverter Defibrillator
LPPR	List of products and services qualifying for reimbursement
LVEF	Left Ventricular Ejection Fraction
MD	Medical device
RCT	Randomised controlled trial
SCD	Sudden cardiac death
SNITEM	National Union of the Medical Technology Industry
VF	Ventricular fibrillation
VT	Ventricular tachycardia

Summary

Background

Sudden cardiac death (SCD) continues to be a major public health problem in industrialised countries, with between 350,000 and 700,000 deaths a year in Europe, of which 40,000 to 50,000 in France.

Adult sudden cardiac death is defined as an unexpected death occurring in the hour following the onset of initial symptoms. Clinically and aetiologically, cardiac rhythm disorders are responsible for the large majority of sudden deaths; in adults, in 90% of cases cardiac arrest is linked with a rhythm disturbance called ventricular fibrillation.

One of the means for managing SCD is afforded by the implantable cardioverter defibrillator (ICD) comprising one, two or three intracavitary leads (right atrium, right ventricle, coronary sinus) and a pulse generator positioned in the left or right pectoral region. The purpose of the ICD is to detect and treat tachycardia and ventricular fibrillation. An ICD is able to stimulate the right ventricle as a stimulator or deliver an electric shock and so restore the sinus rhythm of a subject with fibrillation or ventricular tachycardia. Occasionally, especially in cases of ventricular tachycardia, the ICD may intervene without delivering any electric shock, simply by triggering its function of providing rapid stimulation.

In this system, the cardiac defibrillator lead, positioned in the right ventricle, plays a vital role by enabling cardiac signals to be sent to the pulse generator (detection function), and the device's electrical treatments to the heart (stimulation and shock-treatment function).

This assessment concerns the cardiac defibrillator leads included in the list of products and services qualifying for reimbursement (LPPR).
This assessment follows on from:
- the Order of 14 December 2015, which fixes the date when implantable cardiac defibrillator leads cease to be covered at 31/07/2018;
- the submission of 10 December 2015 calling upon CNEDiMTS to come to a decision on this product category as a matter of priority.

Objectives – Working Method

The principal objectives of this assessment were to provide answers to the following questions:

- Is there a technological difference between each cardiac defibrillator lead, and does each one of them have something specific to offer?
- Is there a particular type of cardiac defibrillator lead to be recommended (for example in terms of calibre or stiffness) depending on a specific anatomy?
- What are the factors behind the mechanical/operational failure of certain cardiac defibrillator leads?
- How often do cardiac defibrillator leads need to be renewed?
- What is the healthcare process for children management?
- Is there any way to keep tabs on every type of cardiac defibrillator lead according to its brand name to make it easier to identify patients in the event of a medical device vigilance alert?
- What are the minimum technical specifications for cardiac defibrillator leads defining a sufficient level of requirement?

The working method used is based on a systematic review of the literature, analysis of the manufacturers' data, and calling on the expertise of arrhythmia specialists who declared any conflicts of interest at the outset and for the duration of the project.

Assessment – Analysis of the Data

Among the references identified during the literature search over the period from January 2005 to April 2016, an analysis of the efficacy data was conducted initially based on professional recommendations, a technological assessment and three randomised controlled studies that satisfied predefined selection criteria. Afterwards, an analysis of data from the medical device vigilance system and market surveillance was performed, based on the ANSM's report as well as on a meta-analysis and a study comparing the databases listing failures of leads currently on the market and relevant to this assessment.

Analysis of efficacy data

The professional recommendations reveal a lack of clinical trials assessing cardiac defibrillator leads prior to marketing and of any follow-up after they have come onto the market.

The scope of adverse events (AEs) analyses remains limited by the quality of the available data. Early AEs were reported in observational cohorts, especially in the American NCDR-ICD registry with a high level of evidence, while the level of evidence remains low for later AEs.

In view of the small number of randomised controlled studies comparing the technical characteristics of cardiac defibrillator leads or implantation sites, no technical specification can be clearly displayed.

Analysis of the medical device vigilance system and market surveillance data

The meta-analysis and the study comparing the information extracted from two databases did not relate exclusively to the models and references of the cardiac defibrillator leads currently on the market and covered by this assessment; therefore, it is difficult to come to any conclusion concerning the observed results.

Detailed analysis of the incidents reported with cardiac defibrillator leads carried out by the ANSM has not shown up any particular issues that would justify taking any measures at this stage. However, these devices have to be carefully monitored considering their special therapeutic purpose and the various safety measures that have been implemented for several models of leads in recent years.

Opinions of professionals consulted

The professionals consulted pointed out the need to give preference to cardiac defibrillator leads that have a considerable hindsight and have few reported medical device vigilance incidents. The thinnest cardiac defibrillator leads are more problematic, with an increased medium- and long-term risk (abrasion, conductor externalisation). Cardiac defibrillator leads with barbs are scarcely ever used anymore, because they are associated with a high risk of septal perforation. The single-coil defibrillator leads are nowadays practically the only ones to be implanted. According to arrhythmia specialists, the leads with a DF-4 connector are safest, but they shall be monitored, like those with a DF-1 connector. The latter should always be available. MRI compatibility is an essential criterion when choosing a cardiac defibrillator lead, provided both components (pulse generator and associated cardiac defibrillator leads) are from the same manufacturer.

The professionals questioned did insist that the choice of cardiac defibrillator lead with DF-1/IS-1 or DF-4 connectors should be left to the discretion of the arrhythmia specialists.

The arrhythmia specialists' main nomenclature proposals concerned the following:

- updating the minimum technical specifications for cardiac defibrillator leads;
- the need, for the future nomenclature, to define a process for LPPR inclusion that would enable cardiac defibrillator leads to be monitored individually, in view of medical device vigilance alerts in the past. The purpose is to thus enable these cardiac defibrillator leads to be monitored with the aid of administrative databases.

General conclusions of the Medical Device and Health Technology Evaluation Committee (CNEDiMTS)

A nomenclature overhaul is proposed. The CNEDiMTS recommends deleting the current generic description and replacing it with an entry by brand name, differentiating between the various cardiac defibrillator leads according to the type of connector: DF-1/IS-1 or DF-4.

Relying on the literature analysis and the views expressed by the professionals consulted, the CNEDiMTS confirms the interest of cardiac defibrillator leads, without suggesting that one cardiac defibrillator lead is superior to another.

The CNEDiMTS recommends, according to the connector type – DF-1/IS-1 or DF-4 – an entry under the brand name for each model/reference of cardiac defibrillator lead. The aim is to enable these devices to be followed up individually.

Two categories are singled out for entry under the brand name:

1. right ventricular defibrillator leads with DF-1/IS-1 connectors;
2. right ventricular defibrillator leads with DF-4 connector.

The actual clinical benefit of these 2 categories is deemed to be sufficient.

For any cardiac defibrillator lead, a dossier needs to be submitted by the company concerned with a view to a specific assessment before the item can be considered for inclusion in the LPPR.

The CNEDiMTS does stress the need for all cardiac defibrillator leads included in the LPPR to be compatible with magnetic resonance imaging (MRI). In the absence of MRI compatibility, the CNEDiMTS expects to receive a well-argued dossier explaining this incompatibility.

Participants – Working group

► Stakeholders

- National Council for Cardiology (CNPC).
- College of Dispensing and Hospital Pharmacy (CPOPH).
- Association of Cardiac Defibrillator Wearers (APODEC).
- National Union of the Medical Technology Industry (SNITEM).

► Professionals consulted

Individual hearings

- S. Boveda, arrhythmia specialist, Toulouse.
- P. Defaye, arrhythmia specialist, Grenoble.
- D. Klug, arrhythmia specialist, Lille.

Proofreader

- JP. Depoix, anaesthetist, Paris.

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