Archives of Cardiovascular Disease (2017) xxx, xxx—xxx

Available online at ScienceDirect www.sciencedirect.com

Elsevier Masson France EM|consulte www.em-consulte.com/en

GUIDELINES

Recommendations for the implantation of leadless pacemakers from the French Working Group on Cardiac Pacing and Electrophysiology of the French Society of Cardiology

Recommandations du groupe de rythmologie et de stimulation cardiaque de la SFC concernant l'implantation des stimulateurs sans sondes ?

Pascal Defaye[a,*], Didier Klug[b], Frederic Anselme[c], Daniel Gras[d], Jean-Sylvain Hermida[e], Olivier Piot[f], Christine Alonso[g], Laurent Fauchier[h], Estelle Gandjbakhch[i], Eloi Marijon[j], Philippe Maury[k], Jérôme Taieb[l], Serge Boveda[m], Nicolas Sadoul[n], for the French Working Group on Cardiac Pacing and Electrophysiology

[a] *University Hospital of Grenoble-Alpes, 38043 Grenoble, France*
[b] *University Hospital of Lille, 59000 Lille, France*
[c] *University Hospital of Rouen, 76031 Rouen, France*
[d] *Nouvelles cliniques nantaises, 44000 Nantes, France*
[e] *University Hospital of Amiens, 80054 Amiens, France*
[f] *Centre cardiologique du Nord, 93200 St.-Denis, France*
[g] *Ambroise-Paré Hospital, 92200 Neuilly-sur-Seine, France*

Abbreviations: CE, conformité européenne; CNEDiMTS, Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé; CRT, cardiac resynchronization therapy; EU, European Union; MHRA, Medicines and Healthcare Products Regulatory Agency.

* Corresponding author at: Arrhythmia and Cardiac Pacing Service, University Hospital of Grenoble Alpes, CS 10217, 38043 Grenoble cedex 09, France.
E-mail address: PDefaye@chu-grenoble.fr (P. Defaye).

https://doi.org/10.1016/j.acvd.2017.10.002
1875-2136/

[h] University Hospital of Tours, 37044 Tours, France
[i] La Pitié-Salpétrière Hospital, 75651 Paris, France
[j] Georges Pompidou European Hospital, 75015 Paris, France
[k] University Hospital of Toulouse, 31059 Toulouse, France
[l] Hospital of Aix-en-Provence, 13616 Aix-en-Provence, France
[m] Clinique Pasteur, 31300 Toulouse, France
[n] University Hospital of Nancy, 54035 Nancy, France

Received 11 September 2017; received in revised form 27 October 2017; accepted 30 October 2017

KEYWORDS
Leadless pacemaker;
Recommendations;
Board-certified electrophysiologists

MOTS CLÉS
Stimulateur sans sonde ;
Recommandations ;
Rythmologues diplômés

Background

The Cardiac Pacing and Electrophysiology Working Group of the French Society of Cardiology has deemed it appropriate to revisit several points pertaining to the clinical evaluation and follow-up of implantable leadless cardiac pacing devices or leadless pacemakers.

The group intends to:

- outline the mandatory clinical evaluation required before the marketing of current devices;
- outline the mandatory clinical evaluation required after the introduction of current devices to the market;
- create a framework document intended for manufacturers, caregivers, health care institutions and organizations officially in charge of supervising the availability of this technique;
- define the optimal practice enabling its development under the safest conditions.

Conformité européenne (CE) marking and dissemination of leadless pacing

The CE marking of medical devices requires a compliance statement from the manufacturer, certified by the notified body of a member state of the European Union (EU), with the requirements imposed by the directives of the EU on medical instrumentation; this is required by law for the marketing of devices in the EU. CE marking for leadless pacemakers has, thus far, been based on limited clinical data, whether in terms of the number of patients enrolled in studies or the duration of follow-up [1—5].

Some competent European authorities have already given their opinion on leadless pacing. Whereas the Medicines and Healthcare Products Regulatory Agency (MHRA), the British competent authority for medical devices, has recognized leadless pacing as a major step forward compared with the devices used traditionally in the management of cardiac rhythm, it nevertheless considers it insufficiently validated and currently lacking clear indications. The MHRA has, therefore, formulated specific recommendations regarding the proper use of leadless pacing in the UK [6].

In that spirit, the office of the Cardiac Pacing and Electrophysiology Working Group of the French Society of Cardiology gathered a panel of experts in the management of cardiac arrhythmias, with personal experience in this field, with a view to formulating specific recommendations on the adoption of leadless pacing. Whereas it is important to acknowledge the novelty of this medical technological development, it seems as important, for the patients' welfare and for sound maturation of the technique, to define the clinical applications of leadless pacemakers. This requires close surveillance of possible complications, to verify that this technology is used appropriately, while tightly limiting the operative risk.

Recommendations regarding the reimbursement of leadless pacemakers have been issued for specific indications by the Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDiMTS)/Haute Autorité de santé (HAS) [7]. Firstly, in adults in need of a VVIR single-chamber cardiac pacemaker who are at high risk of lead-related complications and whose veins must be salvaged (patients with a history of lead fracture, patients undergoing chemotherapy, recipients of catheter chambers and patients undergoing haemodialysis), the CNEDiMTS granted a level III (moderate) improvement of expected services, compared with the implantation of a single-chamber ventricular pacemaker with an intracardiac lead. Secondly, in adults with an indication for a VVIR cardiac pacemaker without venous access or with a history of endocarditis or septicaemia, the CNEDiMTS granted a level II (high) improvement of expected services compared with the implantation

Please cite this article in press as: Defaye P, et al. Recommendations for the implantation of leadless pacemakers from the French Working Group on Cardiac Pacing and Electrophysiology of the French Society of Cardiology. Arch Cardiovasc Dis (2017), https://doi.org/10.1016/j.acvd.2017.10.002