Lead malfunctions in implantable cardioverter defibrillators: where are we and where should we go?

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This editorial refers to ‘Complications leading to surgical revision in implantable cardioverter defibrillator patients: comparison of patients with single-chamber, dual chamber, and biventricular pacing’ by G.Z. Duray et al., on page 297

Implantable cardioverter defibrillators (ICDs) have become the standard of care for the prevention of sudden cardiac death and for the management of ventricular arrhythmias. In addition, the association of ICD with biventricular stimulation was demonstrated to improve quality of life and exercise capacity in patients with advanced New York Heart Association functional class, left ventricular ejection fraction <0.35 and QRS duration >120 ms.

These indications resulted in a 20-fold increase in annual device implants during the last 15 years, with a consequent rapid evolution of the device’s technology to answer to any different clinical situation (development of complex algorithm for pacing, for discrimination of arrhythmias, and for personalization of therapy).

The same improvement of technology was applied to ICD leads and to left ventricular leads, trying to offer the best performance and the easiest technique of the implant. Nevertheless, several studies demonstrated that the ‘Achilles heel’ of the ICD system is the long-term reliability of the leads. Leads must survive to millions of cardiac cycles and allow high voltage energy delivery for defibrillation when necessary. It is understandable that with the increasing age of the leads, the risk of malfunction also increases. In fact, the reported incidence of malfunction rate of the leads reaches 40% after 8 years. The most common abnormality reported by the studies is the insulation defect, which can result in a failure to detect and treat arrhythmias or in an inappropriate shock. This mainly affects patients’ safety, which depends on appropriate detection of potentially lethal ventricular arrhythmias and on successful delivery of therapy.

A big help in this context comes from the wireless home monitoring of the device that can immediately detect any abnormality in the function of leads, thus reducing the risk for patients.

Another point that could affect patients’ safety is the risk of re-intervention, which could increase the probability of system infection and introduce a not-trivial risk related to the extraction of previous leads.

Duray et al. investigated whether the increasing complexity in ICD technology, particularly with respect to a comparison between single-, dual-, and triple-chamber devices, may result in different complication rates. The authors collected retrospectively data from 816 patients who underwent transvenous ICD implantation between 2000 and 2007 at the Goethe University of Frankfurt, Germany. All implantations were performed by electrophysiologists with a long experience in device implantation using preferably cephalic vein for right ventricular and atrial leads and lateral subclavian vein for left ventricular leads. The authors collected only malfunctions of the system requiring surgical revision, whereas failure, which could be resolved by reprogramming the device, was not considered. After a mean follow-up of 31 ± 24 months, 98 patients underwent 110 revisions (5.2% per patients-year). The revision rate was mainly caused by lead-related complications that were significantly higher in biventricular resynchronization devices than in dual- or single-chamber devices (11.8 vs. 4.1 vs. 4.9%; P = 0.002).

Results, with respect to the incidence of malfunctions of ICD leads, are comparable with those recently reported by Eckstein et al. A rate of ~5% per patients-years of malfunction, observed by Duray et al., is ‘understandable’ considering the rapid evolution of the technology during the last 10 years, but not yet ‘acceptable’ considering the particular role of ICD. In fact, if it is true that ICD as well as any other technologies can be affected by malfunction, it is also true that the main role of ICD is reliability and any effort to improve this technology should be mainly directed to the reliability of the system more than to the complexity of the device.

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In addition, the authors observed that malfunctions are more frequent in ICDs with biventricular pacing due to a higher incidence of left lead dislocation. Probably, this issue is not ever well considered by the physicians, due to the fact that left lead dislocation is not considered to be associated with a relevant risk for the patient’s safety. Loss of capture of biventricular pacing, indeed, results in a minimum risk for patients, such as recurrence of heart failure. In contrast, we would like to remark that this relative high incidence of re-intervention, associated with \( \sim 30\% \) of the risk that patient will not respond to biventricular pacing, has a not-trivial impact on the evaluation of cost-effectiveness of this strategy. Therefore, indication to resynchronization therapy must be evaluated carefully, weighing up not only the risk/benefit ratio but also the cost/effectiveness ratio of this treatment in any single case.

In conclusion, despite the remarkable progress of ICD technology in the last 15 years, we need further significant improvement, especially in leads reliability and durability, in order to substantially reduce the rate of mid- and long-term complications of ICD therapy. Therefore, electro-medical companies should focus their efforts on increasing patients’ safety and improving, in this way, the credibility of ICD therapy among both general cardiologists and practitioners. We trust that, should this path of improvement be seriously pursued, the ICD indications would further extend with significant benefit for both patients and industries.

References