Primary prevention by implantable cardioverter defibrillators: shock proof?

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In the last two decades, the focus of implantable cardioverter defibrillator (ICD) trials has mainly been on prophylactic implantation of ICDs in high-risk populations for the prevention of sudden cardiac death. In particular, prophylactic ICDs in high-risk post-MI patients with a depressed left ventricular ejection fraction has resulted in significantly improved survival. These benefits are in addition to those of optimal pharmacological therapy and ICD therapy should be considered the standard of care in these patients.

In recent years, the indications for implantable ICDs for the prevention of sudden cardiac death have been rapidly expanded. The new focus for ICD trials in 2009 and beyond will be on more selective and focused use of this therapy. This could be achieved by selecting ICD patients based on their pathophysiological and genetic risk. Increasing effort will also be placed on using the device for prevention of spontaneous malignant ventricular tachy-arrhythmias and the index clinical sudden death event. Clinically, the use of ICDs has been extended to patients with cardiac diseases prone to ventricular fibrillation such as hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia, Brugada syndrome and long QT syndrome. ICDs will be increasingly used in combination either with ventricular tachycardia ablation or ventricular fibrillation ablation using catheter techniques ('hybrid approach'). With the addition of cardiac resynchronisation therapy (CRT) in these devices, new clinical trials that use CRT as an early intervention in specific high-risk heart failure populations and refinement of the CRT technique are in progress. Finally, combining ICD devices and regenerative medicine approaches to myocardial replacement therapy are being explored.

Notwithstanding the unique benefits of ICD therapy, most clinical trial data were quickly implemented into the present guidelines without critical reassessment of the strengths and limitations of the evidence. ICD therapy has inherent risks including infection, inappropriate shocks, potential for proarrhythmias, device and/or lead malfunction, and procedural complications, which can adversely affect morbidity and quality of life. In addition, economical issues such as cost-benefit and cost-effectiveness ratios are at stake.

In the current issue of the NHJ, Wilde and Simmers question the appropriate indications for ICD implants for primary prevention in patients with depressed left ventricular function. Based on recent reviews and critical appraisals, the authors point to an overestimation of the clinical benefits and emphasise the need for a more rigorous risk stratification. They even plea for reconsideration of the existing guidelines. This is in line with data from the Leiden MISSION! AMI study which showed – using strict implementation of AMI and ICD treatment guidelines – that only 29/517 (5.6%) post-MI patients were eligible for ICD therapy. This finding reinforces the view that high-risk indicators for sudden cardiac death such as left ventricular ejection fraction assessed in the (sub)acute phase post-MI should be determined at least one month after AMI because of left ventricular remodelling. It is therefore clear that further risk stratification studies of post-MI patients will allow ICD therapy to be applied in a more cost-effective manner.

To summarise, a reappraisal of the benefits and potential hazards of ICD therapy will enable physicians to have a more mutually informed and balanced dialogue with colleagues and patients. Whether this should have impact on the ongoing debate concerning the considered necessary expansion of ICD implant centres in the Netherlands is an interesting topic to discuss. All stakeholders are encouraged to participate in this debate and express their own views on the appropriate use of ICD implants in patients prone to cardiac arrest. ■

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