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EDITORIAL COMMENT

Who benefits from implantable cardioverter defibrillator therapy, and who pays the price?

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Implantable cardioverter defibrillators (ICDs) are an established therapy for the prevention of sudden cardiac death. Since the 1990s multiple primary and secondary prevention trials, such as AVID, MADIT-I and II and SCD-HeFT, have demonstrated a significant reduction in mortality in patients with ischaemic and non-ischaemic cardiomyopathy, especially in survivors of ventricular arrhythmias causing haemodynamic compromise. Today, expanding indications, mainly for prophylactic device implantation, cause a steep growth of ICD implantations worldwide [1]. However, not all patients eligible for prophylactic ICD therapy are likely to experience ICD therapy, and therefore benefit, within a reasonable time horizon. Assessment of multiple risk factors can more clearly identify patients at risk in whom ICD efficacy may be different from what was demonstrated in the large randomised ICD trials.

In this issue of the *Netherlands Heart Journal* Wijers et al. [1] present an extensive real-world clinical study in which they sought to determine in which patients sudden cardiac death was actually prevented with ICD implantation. They demonstrate that 21 % of the 1075 patients receiving an ICD between 2006 and 2011 (61 % primary prevention) received appropriate shocks during a median follow-up of 31 months. They report that ischaemic cardiomyopathy, an LVEF ≤25 % and male gender were independently associated with appropriate shock therapy. Also, they find that 14 % of the patients implanted with an ICD died during a 31-month follow-up, of whom 9.7 % did not receive prior appropriate therapy and 4.7 % died within the first year after ICD implantation. Predictors for mortality are, however, quite similar to the predictors for appropriate shocks [1]. ICD efficacy in terms of survival rather than in terms of appropriate therapy may therefore be questioned in high-risk subgroups of patients with multiple risk factors in whom the short-term risk of nonarrhythmic death may predominate despite ICD therapy. These risk factors are defined by Goldenberg et al. [2] as >3 of the following: NYHA class >II, age >70 years, impaired renal function, QRS duration >120 ms or atrial fibrillation. Conversely, there are also low-risk subgroups consisting of patients without any risk factors who actually have a very low annualised need for truly lifesaving therapy [2].

While the presumed benefit of ICDs is reflected in the indications for ICD implantation in the guidelines, which are predominantly based on the ICD efficacy, the associated harm (such as inappropriate shocks and implant and long-term complications) receives less attention. Multiple studies demonstrate that the inappropriate shock rate in the general ICD population is approximately 3 % per year, and higher numbers are reported in patients with a history of atrial fibrillation and, generally younger, patients with inherited or congenital heart diseases [3, 4]. This number of inappropriate shocks can safely and substantially be reduced by contemporary ICD programming, which Wijers et al. likewise suggest as an explanation for the low inappropriate shock rate in their study. ICD-related complications are reported in 5 % of the ICD patients per year and complication rates may increase with multiple lead and device replacements [3]. ICD patients are exposed to both implantation-related complications such as pneumothorax and heart perforation and long-term complications such as vein occlusions and consequences

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of lead fractures [3, 4]. Despite advances in ICD system design and manufacturing, devices remain imperfect. Failures of lead design, such as with the Sprint Fidelis and Riata lead, can lead to inappropriate sensing due to electrical noise with resultant inappropriate shocks. Complication rates are, however, not consequently reported in the large randomised ICD trials and appear to be a suppositious child, while substantially contributing to the morbidity and even mortality of ICD patients.

Moreover, ICD therapy may lead to a psychological burden. Studies consistently show impairments in health status and quality of life in ICD patients, with an elevated risk for anxiety and depression in up to 30 % of the patients. ICDs exacerbate psychological distress and the experience of one or more ICD shocks further negatively affects quality of life [5].

Finally, ICD therapy is expensive to society, with high costs at implantation. Earlier studies demonstrate a reasonable cost-effectiveness for prophylactic ICD therapy [6]. However, patient comorbidities affect long-term prognosis which might limit the cost-effectiveness whereas more extensive risk stratification could increase the effectiveness further. With increasing burden on health care budgets it should be questioned from a society perspective whether ICD therapy in patients who are less likely to benefit from ICD therapy is preferable.

Hence, when judging the price of ICD therapy, ICD-related adverse events, ICD-related psychological distress and cost-effectiveness need to be taken into account. This however, does not imply that prophylactic ICDs should not be implanted in patients in whom the indication can be debated, because the severity of the chance of sudden cardiac death may outweigh the chance of harm. An inappropriate shock or ICD-related complication may then be considered an acceptable, minor complication of ICD therapy in the context of prevention of sudden cardiac death, particularly in patients with concurrent appropriate shock therapy. However, patients with ICD harm but without appropriate shocks obviously pay the price for ICD therapy. Evolving technology may continuously change the balance between benefit and harm. This notwithstanding, risk taking is essential to success in any goal where the stakes are high. A patient-tailored risk stratification for a better benefit-harm equilibrium seems currently underdeveloped but certainly needed; and Wijers et al. should therefore be commended on clarifying which patients have the most benefit of their ICD [1].

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