National registry data on implantable cardioverter defibrillator treatment: what are they useful for?

Jens Cosedis Nielsen*

Department of Cardiology B, Aarhus University Hospital, Skejby Sygehus, Brendstrupgaardvej, 8200 Aarhus N, Denmark

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This editorial refers to ‘Impact of the main implantable cardioverter-defibrillator trials in clinical practice: data from the Italian ICD Registry for the years 2005–07’ by A. Proclemer et al., on page 465

Proclemer et al. report real-life data from a large cohort of more than 35,000 patients treated with implantable cardioverter defibrillator (ICD) therapy during the period 2005–07. These data document that the use of ICD treatment as primary prevention increased markedly during this period, in absolute numbers more than 50% from 2005 to 2007. In contrast, the number of patients treated with an ICD as secondary prevention remained stable without any increasing trend. These results indicate that the findings from randomized trials and the recommendations given in recent guidelines on the use of ICD therapy are changing our clinical practice over years. Primary preventive ICD therapy is increasing in the community.

As compared with the usage of primary preventive ICD therapy in the USA, the number of patients receiving this therapy in Italy as well as in most other countries is far behind. In the US registry cited in the paper by Proclemer et al., the indication for ICD implantation was primary prevention in 79% of the patients. Large national or regional ICD registries are necessary to make such comparisons, the results of which could lead to the question: how many patients should we treat with primary preventive ICD in the future? Is the high numbers already reached in the USA what we should aim for also in Europe? Recently, a critical review put into question whether the clinical benefits of ICD have been overestimated, whether the risks associated with ICD treatment have been underestimated, and whether the cost-effectiveness of ICD therapy also may have been overestimated. Regular reporting of the most recent data from the national ICD registries is a prerequisite for such discussions.

Furthermore, registry data are important, as the populations treated clinically are different from the cohorts included in randomized controlled trials, and the treatment outcome in the clinically treated populations may differ markedly from that found in clinical trials.

In the Italian registry, reporting to the registry was voluntary. Based upon comparison with the sales data, the present report represents data on 90% of the total Italian ICD activity during this period. The data, therefore, can be considered fairly representative for the Italian ICD population. However, the data missing in such voluntarily based registries may be different from the data reported. The data missing may hide a different patient population with a different clinical outcome. Therefore, the future reporting to national device registries should be mandatory to complete the data, if necessary implemented by coupling the reporting of data to reimbursement.

In Italy, a very large number of implanting centres report a low activity with less than 26 ICD implantations per year. In the present report, no comparisons were made between centres with a low implantation activity and centres with a high implantation activity. It would have been interesting to know whether the implantation rates actually had increased similarly in the populations served by low-volume centres when compared with those served by high-volume centres, and whether the distribution between primary and secondary prevention was similar between high- and low-volume centres. Thereby, registry data may promote an equal implementation of guidelines and recommendations across low- and high-volume centres in a country in the future.

The national ICD registry data enable a surveillance of device function after implantation; in the present paper, data on ICD longevity were reported together with indications for ICD explantation. Such a ‘post-marketing surveillance’ done across different manufacturers and allowing comparisons between manufacturers independent of the data collected by and owned by the device industry is very valuable for the medical community. It may be a little surprising that median ICD longevity was as low as 2.4–3.8 years for the devices explanted during the years 2005–07.
however, these data are similar to the recent report by Biffi et al. on longevity of ICDs.\textsuperscript{5} This short device longevity is in contrast to the longer expected battery longevity of older as well as new ICD models. In the present report, more than one-third of the devices were explanted due to other causes than battery exhaustion, explaining at least part of this discrepancy. A regular independent reporting of ICD longevity data as well as indications for ICD explantation is important for a continuous correct estimation of the relative risk–benefit ratio of ICD therapy and for the estimation of the cost-effectiveness of ICD therapy.

Implantable cardioverter defibrillator therapy has proven to be an effective treatment to prevent sudden death in selected patients. With the current trend of an increasing use of ICD therapy in lower-risk populations, the relative benefit of this device therapy may decline and the risk–benefit ratio rise. Therefore, the optimization of ICD therapy becomes even more important in the future. Implantable cardioverter defibrillator therapy has inherent risks including procedural complications, infections, device and lead malfunctions,\textsuperscript{6} and inappropriate shock therapy, which can adversely influence the patient’s quality of life, morbidity, and even mortality. In the future, the national ICD registries should be employed in the work of reducing these risks. For this purpose, these follow-up data have to be recorded in the registries and reported regularly. In the latest report from the Danish ICD register, national data on the incidence of appropriate as well as inappropriate ICD therapy have been reported for the first time. A total of only 2.8% of the 3300 ICD patients followed experienced inappropriate shock therapy during the year 2007.\textsuperscript{3} This incidence, which is less than previously reported, reflects the current risk of inappropriate shock therapy in ICD patients of today, the majority of whom are followed in highly experienced high-volume centres.

In conclusion, reporting of data from national ICD registries is important to monitor the use of this treatment, and in the future follow-up data from the ICD registries should be used more widespread also for optimization of ICD therapy.

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**References**