Cardioverter-Defibrillator in the Primary Prevention of Sudden Death: for All or for a Few?

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The implantable cardioverter-defibrillators (ICD) have been used for more than two decades to prevent sudden death. Initially recommended for secondary prevention, currently their most common indication is the primary prevention.

A recent US report showed that, of the 108,341 implants carried in 2006, 85,823 (79.2%) were for primary prevention and only 22,518 (20.8%) were for secondary prevention[1]. Several clinical trials have sought to define which patients ought to have this form of treatment. The most recent and largest of these trials is the "Sudden Cardiac Death in Heart Failure" (SCD-Heft)[2], which followed 2,521 patients with CHF Functional Class II-III and EF $\leq$35% in 3 groups (placebo, amiodarone and ICD implant) for a mean follow-up of 45.5 months. This study showed a decrease in the total mortality of the group with ICD, with 23% decrease in the relative risk in the ICD group and no benefit with amiodarone use.

Considering that these clinical trials were carried out basically in developed countries, in an environment that is different from the Brazilian one, the applicability of these data is frequently questioned. The present study[3] sought to validate the results for the Brazilian population by comparing the patients from the SCD-Heft to those that met the inclusion criteria of the SCD-Heft and were from a Heart Failure Outpatient Clinic of a hospital in our country. The comparison between the groups showed small differences: the percentage of ischemic patients is slightly higher (63 *vs*. 53%, p=0.05) and the use of digoxin is lower among the patients of the present study (35 *vs*. 70%; p<0.001). Regarding the digoxin, no alterations in mortality are expected with its use, which makes this possible confounding factor less important. The slightly higher percentage of ischemic patients might have significance in terms of mortality, as these patients usually present higher rates than the non-ischemic ones; however, that was not observed.

The most important data from the point of view of alteration in mortality, such as ejection fraction and the use of beta-blockers and ACE inhibitors, are similar between the two studies. In the SCD-Heft, the benefit observed after the ICD implant occurred exclusively in patients with NYHA Functional Class II, which represented 70% of the total. This percentage was 67% in the present study, supporting the similarity between the populations. The conclusion that can be reached is that patients followed at the CHF outpatient clinic in our country are similar to the randomized ones in the SCD-Heft, indicating that the results of this clinical trial can be applied to our country.

However, another much discussed issue regarding the implant of the ICD in our country is the cost-effectiveness. The authors of the present study suggest that this therapy is not regularly used due to the economic impact that it would generate in our health system. This discussion is not a recent one and it is also present in developed countries[4-6]. Several clinical trials have assessed and compared the costs of using the ICD with other forms of treatment. The difference of costs for the implant varies from U$19,000, in the SCD-Heft[7], up to U$39,200, in the MADIT II[8]. The therapy cost must be appraised together with its benefit. Similarly to the costs, the NNT, necessary number of treated patients to prevent an outcome, varies largely. In the MADIT II, the NNT is 11 for 3 years, in the SCD-Heft it is 14 for 5 years; on the other hand, it is 3 for 5 years in the MUSTT and 4 for 2.4 in the MADIT[9-11]. Another information to be added to this calculation is that the cost-effectiveness must be adjusted to the patient's tolerance to treatment, i.e., adjusted to the quality of life. And, once again, the cost-effectiveness increase data adjusted to the quality-adjusted life year (QALY) are very different among the several studies. Considering a mean efficacy, the QALY values obtained are, in dollars, 34,000, 34,900, 54,100 and 70,200, for the MUSTT, MADIT, MADIT II and SCD-Heft studies, respectively[12]. Such different numbers generate different opinions. Whereas several suggest that the ICD implant is too expensive to be supported by the public health system, others do not agree with such affirmation.

Camm et al[13] consider that the cost increase would be of little relevance for the European Health System, even if the implants increased 3-fold. Additionally, they insist that the annual cost of ICD in Europe (0.49 billions of Euros) is insignificant when compared to other current therapies, such as the myocardial revascularization surgery (2.12 billions) or coronary angioplasty (2.7 billions), or with other costs, such as the lack of hospital administration efficiency (64 billions).

Perhaps, the most consistent information when analyzing the several studies is that the higher the risk stratification is, the better the NNT and the cost-effectiveness are.

Key Words

Defibrillators, implantable; primary prevention; health care costs; death, sudden

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However, the risk of using more specific stratification methods is the possibility of decreasing sensitivity, thus decreasing the number of people that could benefit.

Brazilian data evaluating the cost-effectiveness of ICD implants in the public health system for primary prevention are being studied, but are yet to be published*. A study carried out in the Hospital de Clínicas of Porto Alegre, state of Rio Grande do Sul, showed a difference in cost-effectiveness of the ICD in relation to the conventional treatment, in Brazilian Reais, of 72,280/QALY. If the price of the implant and the ICD generator change underwent a decrease of 50%, this ratio would be 38,436/QALY. And if the selected patients were only the higher-risk ones, such as in the MADIT study, this ratio would be 59,738/QALY.

The present study brings a significant contribution by showing that the data from a large clinical trial can be applied to our population. The cardioverter-defibrillators are useful in reducing mortality. The great challenge, in our country and around the world, is to find more precise methods of stratification, associated to less expensive and more durable ICD devices, in order to increase the number of patients who can benefit from a good cost-effectiveness.

** Personal communication*

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