Implantable cardioverter defibrillators: even better than we thought?

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This editorial refers to ‘The effect of duration of follow-up and presence of competing risk on lifespan-gain from implantable cardioverter defibrillator therapy: who benefits the most?’[†], by C. Raphael *et al.*, on page 1676.

In certain parts of the world, cardiologists struggle on a daily basis to convince government-run health services to allow them to implant defibrillators into patients who have guideline indications for a device. The general opinion of the wider health service is that implantable cardiac defibrillators (ICDs) are expensive and our health systems cannot afford them. In recent years there is a general consensus between guidelines from Europe (European Society of Cardiology and European Heart Rhythm Association) and the USA (American Heart Association, American College of Cardiology and Heart Rhythm) for device implantation.¹ The indications for ICDs have appropriately expanded, based on excellent clinical data, to include wider indications for device implantation. This has made implementation of guidelines even less achievable for some countries, exacerbating the geographical variation in use.

Sudden cardiac death is one of the most prevalent causes of death in the USA, with 180 000–400 000 deaths per year,² with a higher incidence than death from stroke, lung cancer, and breast cancer.³ We know that ICDs are effective, that they are reasonably safe, and are better than standard pharmacological therapies. With this in mind, there is still a significant discrepancy between geographical location, ICD implantation rates, and implementation of guidelines. The USA has the highest rate of ICD implantation, despite the fact that only 50% of patients meeting guidelines are given an implant.⁴ The geographical discrepancy is not just between different continents (577 implants per million people in the USA compared with 155 per million people in Europe) or countries, but even within the same country there is a significant disparity in implantation rates.^{5–7}

Raphael *et al.* now report interesting data based on survival modelling.⁸ By projecting lifespan gain from ICD implantation over a longer period of time than the follow-up of 13 randomized controlled

trials, they propose that the lifespan gain from ICDs is largely underestimated.⁸ Lower risk patients stand to gain the greatest increase in lifespan. Based on their survival modelling, from trials performed in the early 2000s, the lifespan gain was 2–3 times greater at 5 years compared with the 3-year follow-up and 6–9 times greater at 10 years. As they mention, with improvements in medical therapies, earlier revascularization, better screening, ablation techniques, advances in autonomic modulation, optimization of device parameters (minimizing right ventricular pacing, single chamber device implantation, cardiac resynchronization therapy, and avoidance of therapies such as antitachycardia pacing and defibrillation), as well as advances in home monitoring mean that the number of patients with indications for devices and also the complications or risks related to ICDs may have also reduced.

One of the problems with increasing lifespan gain in the low risk group means that now there are more patients needing generator changes due to depleted batteries. In many health systems with limited resources, annual allocations of devices do not differentiate between new implants and generator changes, resulting in fewer *de novo* implants each year. So, although the guideline indications for devices have expanded, there is a serious concern that the number of *de novo* implants that some centres can perform has decreased.

The potential problem we will encounter with low risk patients is that the greater lifespan gain means more generator changes, potential lead explants, cumulative infection risk, and a greater potential for device malfunction over 20 years.⁹ Raphael *et al.*⁸ quote an Ontario ICD database study¹⁰ and a Medicare registry of ICD implantation outcomes¹¹ which followed up patients for 45 and 180 days, respectively, essentially reviewing acute and short-term complications. Thus the reported rate of complications was low but if long-term follow-up data were collected or the same statistical methods used by this group were used to calculate their 5-, 10-, and 20-year risk, the potential disadvantages of device therapy could be quite significant. Lead explants due to lack of compatibility with new devices or lead malfunction is not a simple undertaking. With the issues of requiring cardiothoracic back-up, accessibility to emergency cardiothoracic

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Table 1 If low risk patients benefit most from implantable cardioverter defibrillators then what are the potential implications for the patient and the health service?

bypass surgery when complications arise, and to expertise in lead explant, the potential risks of death are ever present.¹²

The patients not included in the landmark trials for ICD implantations are those who are likely to have the most lifespan gain from ICDs such as those with channelopathies, genetic cardiomyopathies such as hypertrophic cardiomyopathies, and right ventricular cardiomyopathies. These patients may present at a young age and without any other co-morbidities. The negative aspect of this is that they may experience significant issues over their lifetime related to multiple lead and generator changes, with the annual lead failure rate reaching 20% at 10 years.¹³

Although size and battery longevity are important factors in choosing a device for the patient, there is a need to resist the temptation to use the newest, multiple algorithm device for primary prevention patients in the absence of outcome data comparing these new features as many of these devices tend to add cost without any added benefits. Balancing cost-effectiveness with outcome data is our responsibility as physicians.

We also need to address the budgetary allocations in government-funded health systems, and cardiologists need to be better at public relations within our departments and our hospitals, at a governmental health service provision level and also internationally (Table 1). The inequity of access to a lifesaving therapy, such as an ICD, due to national economic status or a paucity of implant centres is hard to overcome. With improvement in registries and audits we will be able to understand this inequality better and hopefully be better equipped to tackle this problem. Finally, we must remember that choosing lifespan gain should be weighed against quality of life and potential cumulative risk of device-related complications.

Studies like this also remind us of the ever-present need to develop new therapies that go beyond the ICD as the tragedy of sudden death

is the millions of lives lost every year,¹⁴ with a vast majority of these deaths occurring in people with an ejection fraction >35%, a group that has ventricular function that is much too good to qualify them for a defibrillator! Improving this sobering statistic should be the focus for the future efforts of the field of cardiovascular medicine.

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CARDIOVASCULAR FLASHLIGHT

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Watch out for the WATCHMAN

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A 55-year-old man underwent percutaneous left atrial appendage (LAA) occlusion for recurrent bleeding during anticoagulation for atrial fibrillation. He had a history of myocardial infarction, ischaemic cardiomyopathy, hypertension, and end-stage renal disease with haemodialysis. Despite successful WATCHMAN implantation (Panel A), we noted a discrepancy between transoesophageal echocardiogram (no peri-device leak, Panel B) and CT scan (contrast filling in LAA, Panel C) during post-procedural follow-up at 8 weeks. In accordance with previous studies, we switched the anticoagulation therapy to the antiplatelet agent. At 22 months after LAA occlusion, the patient underwent heart transplantation due to progression of ischemic cardiomyopathy. During follow-up thereafter, the patient was free from bleeding and there was no cardioembolic event. Upon examining the explanted heart, we discovered that nearly half of the device was not covered by endocardium (Panel D), thereby demonstrating incomplete endocardial healing, even at 22 months after successful LAA occlusion.