

Clinical Guidelines for the use of Implantable Cardiac Defibrillators for Prognostic Reasons in Patients with Impaired Ventricular Function Without Known Ventricular Tachyarrhythmias in Public Hospitals in NSW

Safety

The Medical Services Advisory Committee (MSAC)¹ report on Implantable Cardioverter Defibrillators (ICDs) in March, 2006 found that the short-term safety profile for the insertion of an ICD plus optimal pharmacological therapy (OPT) is acceptable.

The success rate for implantation of an ICD is very high (98%) and the rate of complications is low at 0.5 - 3% as reported in clinical trials.

No differences were reported in the mortality rates within 30 days of implantation of an ICD when comparing groups with ICD plus OPT and those who only received OPT.

Indications

Prophylactic implantable defibrillators are recommended for patients with:

1. Previous myocardial infarction (MI) with LVEF <36%^{2,3}, or
2. Dilated cardiomyopathy with Class 2 or 3 heart failure who have received optimal pharmacological therapy (ACE inhibitor or Angiotensin blocker, beta blocker and aldosterone antagonist in some cases) for 3 months followed by estimation of ejection fraction showing LVEF <36%^{4,5}, or
3. Expected longevity \geq 3years.

Provisos

1. If the patient has Coronary Artery Disease (CAD), ischaemia should be adequately investigated and treated.
2. The ICD should be implanted more than 1 month after the most recent acute MI⁶.

Note

Patients within 1 month of an acute MI who have inducible sustained monomorphic Ventricular Tachycardia (VT) at Electrophysiology Study (EPS) should receive an ICD as the capacity to support VT has been demonstrated and there is data to show this group is at high risk^{7,8,9,10,11,12,13,14,15}.

3. Patients with Class 4 heart failure should not receive an ICD unless cardiac resynchronisation is performed (*Class 4 either excluded or numbers too small in current studies, but benefit shown in COMPANION ICD trial¹⁶ when CRT was also performed*).

It is also recommended that all patients receiving a public hospital funded ICD should be included in a registry with basic information on indications, cardiac data and comorbidity. Outcomes should be analysed using data from death certificates and other information if available and the results studied by the Electrophysiology Subcommittee of the GMCT Cardiac Network.

These indications align with those recommended for funding by the US Centers for Medicare and Medicaid Services¹⁷ published in January, 2005 and the National Institute for Health and Clinical Excellence guidance¹⁸. The indications are also the same as the recommendations in the MSAC Report on ICDs with one additional indication ie insertion of ICDs for patients within 1 month of an acute MI who have inducible sustained monomorphic Ventricular Tachycardia (VT) at Electrophysiology Study (EPS).

Cost Effectiveness

There are a substantial number of patients who are eligible for ICDs and the implantation of these devices will have a significant impact on the budgets of the hospitals where these procedures take place. As more evidence becomes available, it may be appropriate to offer these devices to other groups of patients which will further increase expenditure.

It is possible that high risk groups may be identified on the basis of inducible VT at electrophysiological studies, ambulatory ECG monitoring or other non-invasive parameters that would reduce significantly the number of patients needing ICDs.

It is suggested that a study is commenced at the major implanting institutions (Westmead Hospital, Royal Prince Alfred Hospital, The Royal Newcastle Centre and others who wish to participate) in conjunction with the Centre for Health Economics Research and Evaluation (CHERE) using these potential screening tests in all patients receiving a prophylactic ICD. Analysis of the outcomes would assist in determining the value of these filters and the cost-benefit ratios in the various groups.

The decision to implant an implantable cardiac defibrillator must be a clinical judgement based on individual patient assessment and the complexity of each case.

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