_ TECHNOLOGY BRIEF _

IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICD)

Submitted to the
Ministre de la Santé et des Services sociaux du Québec

by the

Conseil d'évaluation des technologies de la santé

December 1992

(Version française disponible)

Legal Deposit - 4th. quarter 1992
Bibliothèque nationale du Québec
National Library of Canada

ISBN 2-550-26508-4

How to cite this document:

Conseil d'évaluation des technologies de la santé du Québec (CETS). Implantable cardio-verter defibrillators (ICD): a technology brief. Montreal: CETS, 1992. 8 p.

IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICD)

A TECHNOLOGY BRIEF

TABLE of CONTENTS

PAGE

_ TECHNOLOGY BRIEF _

A TECHNOLOGY BRIEF is a short overview of the present status of a rapidly evolving technology. It is not a comprehensive review of all the available information and is not a formal evaluation of the *Conseil d'évaluation des technologies de la santé du Québec.*

≡ ACKNOWLEDGMENTS ≡

Le *Conseil d'évaluation des technologies de la santé du Québec* acknowledges with gratitude the contribution of the following individuals who have reviewed this report.

Pr. A.J. Camm	Department of Cardiological Sciences St. George's Hospital Medical School London, England
Dr. Denis Roy	Chef, Département de médecine Institut de cardiologie - Montréal
Dr. Marc Dubuc	Département de cardiologie Hôpital du Sacré-Coeur - Montréal
Dr. Michael Rosengarten	Cardiology Division Montreal General Hospital

The contribution of members and staff of the *Conseil* who have contributed to this review, are also gratefully acknowledged.

IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICD)

The implantable cardioverter defibrillator (ICD) is an electronic device with two principal functions. It is a monitor which recognizes extremely rapid, life-threatening disturbances of heart rhythm, "ventricular fibrillation" (VF) or "ventricular tachycardia" (VT). When these disturbances are detected, the instrument then functions as a defibrillator or cardiovertor by delivering an electric shock to the heart which terminates the arrhythmia and allows a normal rhythm to resume.

The first ICD was implanted into a human in 1980 [1]. It soon became apparent that these instruments were capable of saving lives and their use has since spread rapidly, particularly in the USA where it is estimated that over 12,000 instruments will be installed in 1992 [2].

≡ CLINICAL BACKGROUND ≡

"***Ventricular fibrillation***" (VF) is a disturbance of the rhythm of the heart which effectively abolishes the heart's ability to develop coordinated contractions. Following the onset of VF, the heart stops pumping and the patient falls unconscious. In the absence of any intervention, death rapidly follows. When a defibrillator has been implanted, it immediately detects the rhythm disturbance and delivers a powerful electric shock to the heart, thus permitting regular normal coordinated contractions to resume.

"***Ventricular tachycardia***" (VT) describes a succession of rapid regular coordinated heart beats arising in the ventricles. Ventricular tachycardia can occur at different rates. When it is very rapid, the heart no longer has time to fill and empty adequately and its pumping action fails. This arrhythmia is not always fatal. However, patients may lose consciousness and fatal ventricular fibrillation may supervene. The implanted defibrillator is also capable of terminating this rhythm disorder.

The patients at greatest risk of sudden death due to VF and VT are those who have already survived such episodes, (except when they occurred in the context of an acute myocardial infarction, or an acute intoxication). Several options are available for the management of such patients. The most frequently used are medical management with amiodarone or sotalol, or the implantation of an ICD. However, certain arrhythmias in patients with good ventricular function can be effectively managed by catheter ablation or surgical resection of portions of endocardium, while severe ventricular dysfunction may be best managed in suitable patients by cardiac transplantation.

≡ THE INSTRUMENT ≡

ICDs are somewhat larger than contemporary cardiac pacemakers, due to the greater power source

required. They are installed subcutaneously over the abdomen. The devices usually weigh between 210 and 280 g and have a maximum output of between 30 to 40 J. Most are now programmable for rate and for output. Lithium-vanadium pentoxide batteries have, up to now, provided a life span of 1 to 2 years. However, they are now being replaced by lithium-silver vanadium oxide cells which, it is estimated, will have a life span of 3 to 5 years.

Through the use of intravenous electrodes positioned in the superior *vena cava* near the base of the heart, in the right ventricle or coronary sinus, sometimes in association with a subcutaneous electrode near the cardiac apex, it is now usually possible to avoid intra-thoracic surgery. However, it is still sometimes necessary to use titanium mesh electrodes installed on the wall of the heart, a procedure which involves intra-thoracic surgery and the associated morbidity and mortality.

The newer instruments not only function as monitor/defibrillators, but also as pacemakers, capable of pacing the heart when it beats too slowly or stops, or of delivering appropriate bursts of extra-stimuli to interrupt rapid non-life threatening tachycardias [2].

≡ EFFECTIVENESS≡

The ability of these instruments to prevent sudden death due to VF and VT is now beyond doubt and numerous uncontrolled studies indicate that a lower than expected mortality will be found in patients in whom ICDs have been installed [3]. However, there is still debate as to whether they can significantly reduce overall mortality among arrhythmia-prone individuals when compared with the best available alternate therapies [8].

The patients who are prone to VT and VF are usually those who have extensive post-ischemic heart muscle damage resulting from coronary disease, with cardiac enlargement and a reduced ejection fraction. The life-expectancy of such patients is therefore limited irrespective of the risk of death due to VT or VF. One author recently concluded that even if sudden death due to these arrhythmias could be *completely abolished* by ICD, it could not reduce the overall annual mortality of such patients by more than 50% [5]. Complete elimination of sudden death is, however, extremely unlikely since some episodes of VF are related to renewed myocardial ischemia or infarction, events which carry their own mortality. Given that the trans-thoracic installation of the ICD is itself associated with a mortality estimated to be between 2 and 9%, these reviewers considered that the best reduction of overall mortality which could be expected would be 33% [5]. In view of the poor clinical status and limited life-expectancy of most of these patients, such modest reductions of mortality could not be either reliably detected or reliably excluded without a randomized trial of ICD compared to the best available medical treatment.

No such study has yet provided definitive evidence of the effectiveness of ICD. Most uncontrolled

series suggest that it is indeed an effective procedure. For example, in one study 270 patients who received ICDs after correction of VT or VF, followed for a minimum of 3 years, the 1 and 3 year sudden death rates were 1% and 4% respectively, while the non-sudden death rates were 8% and 18% [6]. There were no controls, but these results contrast favourably with those of an apparently comparable series of patients who received medical management with amiodarone. The 1 and 3 year sudden death rates for the amiodarone patients were 9 and 15% respectively [7]. However, the fact that non-sudden death rates were also nearly twice as high in the amiodarone series (28% and 41% at 1 and 3 years) suggests that the comparability of these 2 series was more apparent than real.

In a more recent trial, patients were divided after physiologic and pharmacologic testing into high-risk (inducible arrhythmias non-responsive to drugs) and low-risk groups (arrhythmias which could not be induced or which responded well to drug therapy). It was found that high-risk patients with ICD's had a comparable mortality to the low-risk group treated conservatively [8]. In general, comparison of sudden death mortality in series in whom ICD's were installed compares favourably with series treated medically [9].

Only one randomized control trial has as yet been reported [10]. Although the sudden death rate in this trial was lower in 60 ICD recipients than in controls (5% *versus* 10%), it is important to note that the non-sudden death rate was also significantly lower in recipients (17% *versus* 39%). This suggests that, in spite of a good study design, the 2 groups may, in fact, have not been equivalent in some important respect. (Alternatively, the presence of ICDs favourably influenced the non-sudden death rate).

Two randomized trials of ICD's are at present in progress: the Cardiac Arrest Study Hamburg (CASH) and the Canadian Implantable Defibrillator Study (CIDS). A third study has recently been authorised by the National Heart Lung and Blood Institute of the U.S.A. Confident evaluation of the effectiveness of ICD will have to await the outcome of these and other trials which are being planned.

ADVERSE EFFECTS. As can happen with implanted cardiac pacemakers, the implant sites of ICDs can become infected. Similarly there can be electronic malfunction which could result in delivery of inappropriate shocks. These must be fairly rare events however, and none has yet found its way into the limited literature on this subject.

QUALITY OF LIFE. The unexpected discharge of these instruments does not cause pain, but rather the sensation of a "jolt", "thump" or "semi explosion" [15]. While this evidence of a functioning instrument, in a patient who, in its absence, would probably have died, is reassuring, the fear of unexpected shocks is also a cause of significant anxiety and depression [15]. In one study, 6 of 17 patients were found to be suffering from various degrees of anxiety or dependence syndrome [16]. However, for most, life returns to normal or near normal after the operation and the majority of those who were employed before the operation, return thereafter to full time employment [17].

PRESENT STATUS OF ICD. The ICD has now passed the "experimental" stage. It is certain that it is capable of functioning and saving life. However, it cannot yet be considered an "accepted" technology. While it is still evolving so rapidly, and until its applications have been precisely defined, it should be regarded as being in an "innovative" stage of development. As such, its use should be limited to a few designated centres possessing all the necessary resources and expertise to carry out these procedures and to report the outcomes.

≡ ESTIMATES OF COST AND COST-EFFECTIVENESS ≡

Even without use of ICDs the management of patients in whom sudden death is considered to be a probable event, is expensive. Whether an ICD is used or not, it will usually involve electro-physiologic testing in the heart catheterization laboratory, often on several occasions, with trials of different drugs and periods of in-hospital electrical monitoring. ICD installation involves instrument costs of the order of $22,000. Until recently, installation of an instrument required major intra-thoracic surgery. However, approximately 75% of procedures in Quebec are now performed with intravenous electrodes and do not require intra-thoracic surgery.

In the absence of quantitative estimates of effectiveness, studies of cost-effectiveness are premature. Nevertheless, a recent Canadian study based on costs in the British Health System are of interest. In this study, it was estimated that the total net discounted cost of installing an ICD per patient, treated to 20 years, compared to the cost of using amiodarone, would be approximately $50,000 [**Error! Bookmark not defined.**]. Estimates of effectiveness were made by artificially adjusting the sudden death rates in 2 of the studies mentioned above [6,7] assuming that non-sudden death rates were the same in both groups (which they were not). It also had to be assumed that any advantages in such adjusted sudden death rates would be reflected in overall mortality. With these and other assumptions, cost-effectiveness was estimated at approximately $31,000 per life-year gained (discounted at 6%) [**Error! Bookmark not defined.**].

≡ POTENTIAL DEMAND IN QUEBEC ≡

In 1991, 135 new ICDs were installed in Canada [18]. In the same year, 31 defibrillators were installed in Quebec. Estimates of potential demand in the future will depend on improvements that may be made in this and in competing technologies, such as anti-fibrillatory medication. In particular, demand will be influenced by the outcome of the 2 randomised controlled trials of effectiveness which are presently being carried out.

In the USA, between 8,000 and 9,000 ICDs were installed in 1991 [18]. It has been estimated that by 1992, 12,000 ICDs will be implanted per year and that by 1995 the frequency of implantation may be as high as 35,000 [2]. Adjusted proportionally for population size, this would be the equivalent of rates

of 336 and 980 in Quebec for 1992 and 1995, respectively. Even if these are gross overestimates, it suggests that the future need for this technology in Quebec may well be considerable.

A recent poll of Quebec cardiologists trained in electrophysiology and defibrillator therapy suggests that by 1995 the number of implantations in Quebec may be 85 to 100 (12). Other applications of this technology, such as their use for patients with poor ventricular function and non-sustained ventricular tachycardia may, if successful, further increase their use.

Finally, the same factors which favour the cleaning, testing, sterilisation and reuse of pacemakers [13,14] apply equally to the reuse of ICDs. It is to be hoped that the evolution of safe standardised procedures for the refurbishing of both pacemakers and ICDs may, in the future, reduce the demand for new instruments.

≡ CONCLUSION ≡

It is now beyond doubt that sudden death can be prevented by use of ICDs in selected patients.

It is a relatively expensive technology, even in comparison to medical management of such cases.

It is a technology which is evolving rapidly. Installation procedures, life span and costs of ICDs will continue to be the objects of rapid and continuing change for some years. Precise indications for the use of this technology are not yet defined.

However, there is already sufficient evidence, based on poorly controlled and non-randomised series, to make it highly probable that the use of ICD's can significantly lower mortality in some sub-groups of potential sudden death patients.

Three large randomised controlled studies, of which 2 are well advanced, should within 1-4 years provide the missing information concerning effectiveness, which is necessary for purposes of policy formulation.

At the present time, it would be premature to encourage the widespread use of this technology. It should be considered to be in an "innovative" stage of development and its application should be limited to special institutions where the appropriate resources and expertise exist.

≡ REFERENCES ≡

1. Mirowski M, Reid PR, Lower MM, et al. Termination of malignant ventricular arrhythmias with an implanted automatic defibrillator in human beings. N Engl J Med 1980;303:322-4.
2. Akhtar M, Garan H, Lehmann MH, Troup PJ. Sudden cardiac death: Management of high-risk patients. Ann Intern Med 1991;114:499-512.
3. Thomas AC, Moser SA, Smutka ML, Wilson PA. Implantable defibrillation: eight years clinical experience. PACE 1988;11:2053-8.
4. Fogoros RN. The implantable defibrillator backlash. J Am Coll Cardiol 1991;67:1424-7.
5. Connolly SJ, Yussuf S. Evaluation of the implantable cardioverter defibrillator in survivors of cardiac arrest: the need for randomised trials. J Am Coll Cardiol 1992;69:959-62.
6. Winkle RA, Mead RH, Ruder KA, et al. Long-term outcome with the automatic implantable cardioverter-defibrillator. J Am Coll Cardiol 1989;13:1353-61.
7. Herre JM, Sauve MJ, Malone P, et al. Long-term results of amiodarone therapy in patients with recurrent sustained ventricular tachycardia or ventricular fibrillation. J Am Coll Cardiol 1989;13:442-9.
8. Fogoros RN, Elson JJ, Bonnet CA, et al. Long-term outcome of survivors of cardiac arrest whose therapy is guided by electrophysiologic testing. J Am Coll Cardiol 1992;19(4):780-8.
9. Larsen GC, Manolis AS, Sonnenberg FA, et al. Cost-Effectiveness of the implantable cardioverter-defibrillator: Effect of improved battery life and comparison with amiodarone therapy. J Am Coll Cardiol 1992;19:1323-34.
10. Newman D, Sauve MJ, Herre J, et al. Survival after implantation of the cardioverter defibrillator. J Am Coll Cardiol 1992;69:899-903.
11. O'Brien BJ, Buxton MJ, Rushby JA. Cost effectiveness of the implantable cardioverter defibrillator: a preliminary analysis. Br Heart J 1992;68:241-5.
12. Roy D. Personal communication. 1992.
13. McGregor M. The reuse of cardiac pacemakers. Can J Cardiol 1992;8(7):697-701.
14. Conseil d'évaluation des technologies de la santé du Québec. The reuse of permanent cardiac pacemakers. Montreal: CETS, 1991. 26 p.
15. Cowley DE, Conway L, Hailey DM. Implantable cardiac defibrillators. Australian Institute of Health: health care technology series no. 5. Australian Government Publishing Service. Canberra. 1990. 30 p.
16. Friccione GL, Olson LC, Vlay SC. Psychiatric syndromes in patients with the automatic defibrillator: anxiety, psychological dependence, abuse and withdrawal. Am Heart J 1989;117:1411-1414.
17. Kalbfleisch KR, Lehman MH, Steinman RT et al. Re-employment following implantation of the automatic cardiovertor defibrillator. Am J Cardiol 1989;64:199-202.

18.Dorian P. Personal communication. 1992.