Outcomes in heart failure patients referred for consideration of implantable cardioverter defibrillator for primary prophylaxis of sudden cardiac death: What are the risks of waiting?

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BACKGROUND: Clinical trials have confirmed that implantable cardioverter defibrillators (ICDs) reduce mortality in patients with a left ventricular ejection fraction below 30%. The 'real-world' prognosis before ICD implantation in such patients is not known. The estimated risk of death is 0.8% per month, and this forms the basis for wait-time recommendations.

OBJECTIVES: To determine the consequences of waiting for ICD implantation among heart failure patients eligible for primary prophylactic ICD.

METHODS: The present retrospective study evaluated consecutive patients who were deemed eligible for primary prophylactic ICD implantation. Survival outcomes were tracked for patients who declined an ICD, those who accepted and received an ICD, and patients who accepted an ICD but died while waiting.

RESULTS: Of 470 patients referred for evaluation, 218 were deemed eligible for an ICD. A total of 174 of 218 patients (79.8%) accepted an ICD; 39 (17.9%) declined, and five (2.3%) were deemed to be at too great a risk for the procedure. The mortality rate at two years among patients who accepted an ICD was 18.8% before ICD implantation and 12.2% after ICD implantation. Among patients who declined ICD implantation, the two-year mortality rate was 5.3%. Among patients waiting for an ICD, five of 19 deaths were out-of-hospital sudden deaths. Of 12 patients who died after ICD implantation, there were no documented out-of-hospital sudden deaths.

CONCLUSION: Consistent with current estimates, the mortality rate at two years among patients who accepted and were waiting for an ICD implant was 18.8%. After receiving an ICD, the mortality rate was 12.2% at two years.

Key Words: Implantable cardioverter defibrillators; Sudden death; Wait times

It is well established that implantable cardioverter defibrillators (ICDs) for primary prophylaxis in patients with heart failure symptoms and left ventricular ejection fraction (LVEF) of 30% or less, significantly reduce all-cause mortality compared with standard medical therapy (1-5). National and international guidelines recommend an ICD for such patients (class 1 recommendation) (6,7). Most studies have shown that ICD use in this setting is associated with a 1.5% to 3.0% per year absolute mortality reduction (8). Identification of a patient as a candidate for primary prophylactic ICD marks a time point from which the patient's risk of sudden cardiac death has the potential to be offset by receipt of an ICD. In a real-world, resource-limited setting in which referral to an electrophysiologist may comprise the first

Les issues d'insuffisants cardiaques aiguë pour évaluer la possibilité d'implanter un défibrillateur à synchronisation automatique : Quels sont les risques de l'attente ?

HISTORIQUE : Les essais cliniques confirment que les défibrillateurs à synchronisation automatique (DSA) réduisent la mortalité chez les patients ayant une fraction d'éjection ventriculaire gauche inférieure à 30 %. On ne connaît pas le pronostic réel de ces patients avant l'implantation d'un DSA. Le risque estimatif de décès s'élève à 0,8 % par mois, ce qui jette les bases des recommandations relatives aux temps d'attente.

OBJECTIFS : Déterminer les conséquences de l'attente avant d'implanter un DSA à des insuffisants cardiaques admissibles à l'implantation prophylactique primaire de ce dispositif.

MÉTHODOLOGIE : La présente étude rétrospective visait à évaluer des patients consécutifs jugés admissibles à l'implantation prophylactique primaire d'un DSA. Les chercheurs ont retracé les issues de survie des patients qui avaient refusé l'implantation, de ceux qui l'avaient acceptée et reçue et de ceux qui l'avaient acceptée, mais étaient décédés en attendant.

RÉSULTATS : Des 470 patients aiguës vers une évaluation, 218 étaient jugés admissibles à l'implantation d'un DSA. Au total, 174 des 218 patients (79,8 %) l'avaient acceptée, 39 (17,9 %) l'avaient refusée et cinq (2,3 %) étaient présumés trop à risque pour subir l'intervention. Le taux de mortalité au bout de deux ans chez les patients qui l'avaient acceptée s'élevait à 18,8 % avant l'implantation et à 12,2 % après l'implantation. Chez les patients qui avaient refusé l'implantation, le taux de mortalité au bout de deux ans s'élevait à 5,3 %. Chez ceux en attente de l'implantation, cinq des 19 décès étaient des morts subites survenues hors de l'hôpital. Chez les 12 patients décédés après l'implantation, on ne documentait pas de mort subite hors de l'hôpital.

CONCLUSIONS : Conformément aux estimations, le taux de mortalité au bout de deux ans s'élevait à 18,8 % chez les patients qui avaient accepté l'implantation d'un DSA et attendaient de le recevoir. Après l'implantation, le taux de mortalité correspondait à 12,2 % au bout de deux ans.

of many phases before implantation actually occurs, wait times and their effect on patient survival may have an impact on patient outcomes. There are currently no national registries of ICDs in Canada and benchmarks for wait times can only be extrapolated from trial and industry data (9).

To estimate a suitable wait time for patients accepted for primary prophylactic ICD implantation, Simpson et al (9) applied the principle currently used for patients on a waiting list for coronary artery bypass grafting – that the preventable waiting list mortality should not exceed 0.5%. Total mortality for patients eligible for ICD was estimated to be 0.8% per month, of which, 0.3% per month was potentially preventable by ICD insertion. Based on this observation and the suggestion to limit

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TABLE 1
Baseline characteristics of patients who accepted or declined an implantable cardioverter defibrillator (ICD)

	Accepted ICD	Declined ICD	P
Age, years, mean $\pm$ SD	64.9 $\pm$ 12.7	66.3 $\pm$ 10.3	0.5
QRS duration, ms, mean $\pm$ SD	143.9 $\pm$ 38.7	133.6 $\pm$ 37.9	0.13
LVEF, %, mean $\pm$ SD	24.8 $\pm$ 6.4	26.8 $\pm$ 5.2	0.07
Male sex, %	85.6	74.4	0.97
Previous myocardial infarction, %	80.0	79.0	0.83
Diabetes, %	32.7	41.0	0.35
Hyperlipidemia, %	69.5	76.9	0.44
Atrial fibrillation, %	35.3	29.7	0.57
Ongoing smoking, %	15.2	16.2	0.81
Dialysis, %	2.0	0.0	1.00
Beta-blocker use, %	83.8	74.4	0.17
ACE or ARB use, %	92.4	92.3	1.00
Amiodarone use, %	22.2	15.4	0.39
Cardiac disease, %			
Ischemic heart disease	80.2	82.0	
Nonischemic heart disease	15.2	15.4	
Valvular heart disease	1.0	2.6	0.53
New York Heart Association class, %			
I or II	54.5	69.2	
III or IV	45.5	30.8	0.11

ACE Angiotensin-converting enzyme; ARB Angiotensin receptor blocker; LVEF Left ventricular ejection fraction

waiting list mortality to the benchmark of 0.5%, Simpson et al suggested that the wait time for ICDs should not exceed eight weeks.

The impact of wait time on mortality (ie, the risk of waiting for ICD implantation) and the accuracy of the above estimate has not been corroborated by real-world data. We sought to determine the risk of wait time on patient outcome by following patients referred for primary prophylactic ICD from the time of referral, recorded during a time of major resource constraints, to ICD implantation.

METHODS

Study sample

The present retrospective study evaluated 218 consecutive patients with chronic left ventricular dysfunction who were referred to the Electrophysiology Service at St Michael's Hospital (Toronto, Ontario) between January 1, 2003, and December 31, 2005, and deemed eligible for primary prophylactic ICD implantation (based on existing guidelines). Patients were followed from the time of the initial assessment. Data on these patients were collected from clinic visits, existing clinic databases and chart review. Demographic characteristics, comorbidities, use of heart failure medications, functional status, QRS duration and ejection fraction were recorded for all patients. At the outset of their first consultation with the Electrophysiology Service at St Michael's Hospital, patients were asked to consent to the use of nonidentifier data for research purposes. The present retrospective project was approved by the St Michael's Hospital Research Ethics Board.

Outcome measures

The cohort included patients who were offered an ICD at the time of initial consultation and patients who were deemed to be at too high a risk to be offered an ICD. Patients who were offered an ICD and accepted were placed on a waiting list. The mortality outcome was collected for three groups of patients: those accepting and receiving an ICD, those accepting an ICD but who died while waiting, and those who declined an ICD. Mortality rates for those awaiting or declining an ICD implant were recorded from the date the patient was deemed eligible by the evaluating electrophysiologist. For those implanted, mortality was recorded from the date the patient received an ICD implant. All

TABLE 2
Time intervals between stages of patient care

Time interval	Days		
	Mean $\pm$ SD	Range	Median
Date of referral to date of evaluation by an electrophysiologist	60.7 $\pm$ 50.6	0–372	51.5
Date of evaluation by electrophysiologist to date of decision to implant an ICD	54.8 $\pm$ 160.7	0–1176	0
Date of decision to implant to date of ICD implantation*	287.3 $\pm$ 188.1	1–864	280

*Includes only patients who were deemed eligible for implantable cardioverter defibrillator (ICD) insertion, agreed to ICD implantation and received an ICD

deaths were reviewed and the presumed cause of death was classified according to the criteria described by Hinkle and Thaler (10). For those who accepted an ICD, the number of days to ICD implantation was recorded.

Statistical analysis

The baseline characteristics of all patients who accepted an ICD and all patients who declined an ICD were examined. Data are expressed as mean $\pm$ SD. One-way ANOVA was used for comparison of continuous variables, and categorical data were compared using χ^2 or Fisher's exact tests, as appropriate. Hazard ratios (HRs) and 95% CIs were estimated based on a competing risks Cox model for patient destination (patient receiving an ICD, patient declining an ICD or patient dying while waiting for an ICD). Survival curves were estimated using the Kaplan-Meier method. Cox proportional hazard models were used to determine whether the survival of patients was influenced by other baseline patient characteristics. The Kaplan-Meier analysis was completed with R software version 2.5.0 (11).

RESULTS

Patient characteristics

A total of 218 patients were deemed by the consulting electrophysiologist to be eligible for primary prophylactic ICD based on existing indications. All patients underwent a multigated acquisition scan to quantify LVEF, and treatment decisions were based on this measured value. Thirty-nine (17.9%) of these patients declined to have an ICD implanted at the time that an ICD was offered. Of the 218 patients, 174 (79.8%) agreed to undergo implantation and five (2.3%) were deemed to be at too high of a risk for the procedure. The baseline demographic characteristics of the groups declining or accepting ICDs are presented in Table 1. The majority of patients who agreed to an ICD or declined ICD implantation were men (85.6% and 74.4%, respectively), had ischemic cardiomyopathy (80.2% and 82.0%, respectively), and were taking angiotensin-converting enzyme inhibitors or angiotensin receptor blockers (92.4% and 92.3%, respectively) and beta-blockers (83.8% and 74.4%, respectively). There was a non-significant trend toward a lower LVEF in the patients who accepted an ICD compared with those who declined an ICD (24.8 $\pm$ 6.4% versus 26.8 $\pm$ 5.2%, $P=0.07$). A similar proportion of patients in both groups had diabetes, ischemic cardiomyopathy, hyperlipidemia and atrial fibrillation, and were current smokers.

Time intervals between stages of patient care

The median time from date of referral to date seen by the consulting electrophysiologist was 51.5 days (Table 2). The median time from the date of the final decision to the date of ICD implantation was 280 days. Multiple factors contributed to the interval between the final decision date and the implantation date (data not shown). These include resource limitations of the institution, interval hospitalization of the patient, patient request, and the need for additional cardiac and noncardiac testing.

TABLE 3
Mortality and causes of death in respective patient groups

Cause of death	Deaths, n		
	Patients declining ICD (n=39)	Patients accepting ICD before implant (n=174)	Patients accepting ICD following implant (n=149)
All causes	3	19	12
Cardiac, sudden*	2	5	0
Cardiac, nonsudden†	0	8	7
Noncardiac	0	2	2
Unknown	1	4	3

*Refers to sudden, out-of-hospital deaths; †End-stage heart failure. ICD Implantable cardioverter defibrillator

Mortality

Of the 174 patients who were eligible for and accepted an ICD, 149 received an ICD, 19 died while awaiting ICD implantation and one was lost to follow-up. Of the 149 patients who received an ICD, 12 died during the follow-up period. Of the patients who declined ICD implantation, three died during the follow-up period. Mortalities at one and two years, respectively, were as follows (Table 3): 7.7% and 18.8% in all patients accepted for an ICD (mortality before implant); 8.7% and 12.2% in patients who were implanted (mortality after implant); and 5.3% and 5.3% for patients who declined an ICD. The causes of death are listed in Table 3. Of the 19 patients who died while waiting for an ICD, five deaths (26%) were sudden and out of hospital, and in another four, the cause of death could not be classified due to insufficient data. Of the 12 patients who died after an ICD was implanted, there were no documented sudden, out-of-hospital deaths, but there were three cases with insufficient data to classify.

The cumulative survival curves, from the day patients were evaluated by the treating electrophysiologist, for patients who declined an ICD and for all patients waiting for an ICD implantation (except for those who declined or who were deemed to be at too high a risk for the procedure) are shown in Figure 1A. Patients were censored from the Kaplan-Meier analysis if they received an ICD. The cumulative survival following ICD, from the date of implantation, is shown in Figure 1B. In this figure, day 0 corresponds to the date of implantation.

Multivariate analyses

Table 4 shows a multiple competing risks Cox model for one of three patient outcomes (patient declined an ICD; patient died while waiting for an ICD; or an ICD implantation was performed) up to and including the time an ICD was received. Female sex was associated with a lower HR for receiving an ICD (HR 0.47 [95% CI 0.24 to 0.89], $P=0.05$), and a trend toward a higher HR ratio for declining an ICD (HR 2.21 [95% CI 0.89 to 5.44], $P=0.05$). A functional status of New York Heart Association class III or IV was associated with an increased HR for dying while waiting for an ICD (HR 4.37 [95% CI 1.01 to 18.9], $P=0.03$).

To determine whether time was independently associated with an increased risk of death, a Cox model for 'time to death' following implantation (among those who received an ICD) was fit using a single explanatory variable – specifically, days waiting for implantation. The test of association between waiting time and death was nonsignificant ($P=0.62$). The HR per day of waiting was 1.00 (95% CI 0.997 to 1.01). The HR per week of waiting was 1.01 (95% CI 0.98 to 1.04).

DISCUSSION

In the present retrospective observational study of heart failure patients, the mortality rate was 18.8% at two years in patients accepting and waiting for an ICD implant. The mortality rate in patients following ICD implantation was 12.2% at two years. The study groups were similar to patients in prophylactic ICD studies with respect to their baseline clinical characteristics, suggesting that the rate

of survival in patients who received an implant was not entirely a reflection of the selection of patients with either higher risk profiles (and therefore, greater potential for benefit) or fewer comorbidities (and therefore, lower postprocedure mortality rates). Although the mortality rates in the two groups were not statistically compared, the natural history observed for patients being considered for primary prophylactic ICD in this real-world setting is comparable with that observed in large, randomized clinical trials. For example, in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) trial (3), the absolute reduction in the risk of mortality at five years was 7.2% in patients randomly assigned to receive an ICD compared with those randomly assigned to receive conventional therapy. In the Multicenter Automatic Defibrillator Implantation Trial (MADIT) II (2), after an average follow-up period of 20 months, the mortality rates in those assigned to conventional therapy were 19.8% compared with mortality rates of 14.2% in the defibrillator group. Furthermore, in our study, there was a smaller proportion of sudden, out-of-hospital deaths in patients who died after receiving an ICD compared with those who died while on the waiting list, an observation that is compatible with the expectation that an ICD should prevent sudden cardiac death. The rate of presumably arrhythmia-related deaths was very similar to that observed in previous randomized controlled trials of ICD therapy (2,3). Although the mortality rate after ICD implantation is not directly comparable with preimplant mortality, one would expect the annual mortality in the group as a whole to increase over time as the underlying disease progresses.

In the current study cohort, the time from the final decision to implantation was long (a median of 280 days). Multiple factors, such as patient request for delay, intercurrent illness and resource limitations, contributed to wait times. This duration of waiting was far greater than the recommended time (9). We could not accurately account for the interval between the time of diagnosis (the time when patients were first known to have coronary artery disease or cardiomyopathy and poor LVEF function) and the time of referral for consideration of an ICD.

In patients who declined an ICD, the mortality rate was low and relatively constant at one and two years. This suggests that ICD implantation in these patients would have been minimally effective in improving survival. There was a trend toward higher LVEF in patients declining compared with those accepting ICD insertion ($26.8 \pm 5.2\%$ versus $24.8 \pm 6.4\%$, respectively), but this difference did not achieve statistical significance ($P=0.07$). These data suggest that when a patient decides not to receive an ICD, the treating physician should carefully examine the patient's clinical profile.

The decision to implant a patient who qualifies according to current guidelines for ICD implantation is not necessarily straightforward. A recent study found that increasing age, the presence of noncardiac comorbidities and clinical heart failure are associated with an increased risk of death following ICD implantation (12). Whether the benefit conferred by ICD insertion outweighs the increased risk associated with these comorbidities is unclear. The presence of such factors likely increases the probability that the patient will eventually die from a cause other than sudden cardiac death. The observation that women in the present cohort were less likely to receive an ICD is similar to findings of recent larger observational studies (13,14). The present data seem to suggest that an increased rate of patients declining ICD implantation contributed partially to this outcome. However, given the small number of patients in our study, other factors, such as competing comorbidities between sexes, age differences between men and women, and perceived disparate benefits of ICDs between men and women on the part of health care providers, could have been present but were not detected.

The current study suggests that wait times can have an adverse effect on patient survival. Patients, physicians and policy-makers should be aware of the potential implications of delaying ICD implantation on patient mortality. For example, the delegation of ICD implantation capabilities to large teaching institutions with dedicated

Figure 1 **A** Kaplan-Meier survival curve showing cumulative survival in patients who were eligible for an implantable cardioverter defibrillator (ICD) but declined implantation compared with those who were eligible for an ICD and agreed to implantation. Patients were censored from the Kaplan-Meier analysis once they received an ICD implant. Day 0 corresponds to the date on which the patient was evaluated by a St Michael's Hospital (Toronto, Ontario) electrophysiologist. One of the 39 patients declining ICD and 15 of the 174 patients accepted for ICD had missing follow-up data, which forced their removal from the Kaplan-Meier analysis. **B** Kaplan-Meier survival curve showing cumulative survival from time of implantation of patients who were eligible for an ICD and received an ICD implantation. Day 0 corresponds to the date of ICD implantation

TABLE 4

Multiple competing Cox regression analysis of factors associated with patient outcome before receiving an implantable cardioverter defibrillator (ICD)

	Factors associated with declining ICD implantation		Factors associated with death while awaiting ICD implantation		Factors associated with receiving an ICD implantation		P-value for interaction
	HR	95% CI	HR	95% CI	HR	95% CI	
Age (1 year)	1.01	0.97–1.04	1.00	0.94–1.06	0.98	0.96–1.00	0.15
Sex (female)	2.21	0.89–5.44	0.76	0.14–4.25	0.47	0.24–0.89	0.05
QRS	0.99	0.98–1.00	1.00	0.99–1.02	1.00	0.99–1.00	0.12
LVEF	1.04	0.98–1.10	1.02	0.93–1.12	1.00	0.97–1.03	0.27
NYHA (class III or IV)	0.71	0.30–1.68	4.37	1.01–18.91	1.18	0.73–1.90	0.03
Diabetes (no)	0.61	0.27–1.34	1.40	0.34–5.82	0.91	0.57–1.46	0.36
Hypertension (no)	0.84	0.36–1.98	1.86	0.50–6.91	1.75	1.09–2.79	0.16
Atrial fibrillation (no)	0.88	0.34–2.25	0.45	0.12–1.67	0.64	0.39–1.06	0.10
Beta-blocker use (no)	1.83	0.72–4.64	2.04	0.47–8.84	0.89	0.47–1.70	0.23
ACE/ARB use (no)	2.18	0.63–7.53	1.48	0.17–13.04	1.02	0.43–2.43	0.91
Amiodarone use (no)	1.09	0.35–3.36	1.13	0.28–4.60	0.71	0.40–1.28	0.37

ACE Angiotensin-converting enzyme; ARB Angiotensin receptor blocker; HR Hazard ratio; LVEF Left ventricular ejection fraction; NYHA New York Heart Association

electrophysiology programs has meant that patients from regions remote from these hospitals have lower implantation rates (15).

Limitations

The present study has several limitations. First, it was a retrospective study. Second, the characterization of patients who declined an ICD was limited by the small number of these patients and the possibility that there was insufficient power to accurately estimate their mortality. Third, it is possible that the lower rate of death in patients who received an ICD may have reflected a cohort that was 'healthy' enough to survive a long wait and therefore would be expected to have a lower rate of death regardless of whether they received an ICD. If this were the case, we would expect that patients who waited longer to receive an ICD would have had lower mortality rates following implantation than those who waited a shorter length of time. However, the likelihood of death after receiving an ICD was not significantly related to the time spent on the waiting list (HR 1.00 [95% CI 0.997 to 1.01] per day of waiting).

Despite these limitations, the present study is the first to document the consequences of wait time for ICD insertion on mortality. Increasing wait times are associated with appreciable mortality and a

substantial proportion of this mortality can likely be circumvented through timely ICD insertion. On the other hand, patients declining an ICD may have a better prognosis, although the reason for this is unclear. Further research is required to confirm this observation and to elucidate factors that may help risk-stratify patients currently eligible for primary prophylactic ICD.

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