Implantable Defibrillators for Secondary Prevention of Sudden Cardiac Death in Cardiac Surgery Patients With Perioperative Ventricular Arrhythmias

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Background—Randomized studies of implantable cardioverter defibrillators (ICD) have excluded sudden cardiac death survivors who had revascularization before or after an arrhythmic event. To evaluate the role of ICD and the effects of clinical variables including degree of revascularization, we studied cardiac surgery patients who had an ICD implanted for sustained perioperative ventricular arrhythmias.

Methods and Results—The electronic database for Southern California Kaiser Foundation hospitals was searched for patients who had cardiac surgery between 1999 and 2005 and an ICD implanted within 3 months of surgery. One hundred sixty-four patients were identified; 93/164 had an ICD for sustained pre- or postoperative ventricular tachycardia or fibrillation requiring resuscitation. Records were reviewed for the following: presenting arrhythmia, ejection fraction, and degree of revascularization. The primary end point was total mortality (TM) and/or appropriate ICD therapy (ICD-T), and secondary end points are TM and ICD-T. During the mean follow up of 49 months, the primary endpoint of TM+ICD-T and individual end points of TM and ICD-T were observed in 52 (56%), 35 (38%), and 28 (30%) patients, respectively, with 55% of TM, and 23% of ICD-T occurring within 2 years of implant. In multivariate risk analysis, none of the following was associated with any of the end points: incomplete revascularization, presenting ventricular arrhythmia, and timing of arrhythmias.

Conclusion—Our data supports the recent guidelines for ICD in this cohort of patients, as the presence of irreversible substrate and triggers of ventricular arrhythmias, cannot be reliably excluded even with complete revascularization. Further studies are needed to understand this complex group of patients. (J Am Heart Assoc. 2014;3:e000686 doi: 10.1161/JAHA.113.000686)

Key Words: implantable defibrillator • perioperative ventricular arrhythmias • revascularization
to focus our study on 1 group: those who had surgical revascularization.

Methods

The study protocol was reviewed and approved by the Internal Review Board Committee. The central electronic database for all of Southern California Kaiser Foundation hospitals containing demographic variables, coded clinical diagnoses, and procedures/operations performed was searched for all patients who underwent CABG—alone or combined with valve surgery—and had an ICD between January 1999 and December 2005.

Patients included were those admitted with ventricular tachycardia/ventricular fibrillation (VT/VF), had CABG (alone or combined with valve surgery) during that admission, and had an ICD within 3 months of cardiac surgery, as well as all post-CABG patients (alone or combined with valve surgery) who developed VT/VF postoperatively and had an ICD within 3 months of cardiac surgery. Patients excluded were those in whom a reversible cause such as electrolyte imbalance or medications was identified.

From a total of 2877 patients who had an ICD implanted between 1999 and 2005, 164 patients were identified, 93/164 had an ICD implanted for secondary prevention of SCD due to sustained monomorphic or polymorphic VT or VF requiring resuscitation.

ICD was implanted in 53/93 for preoperative, and in 40/93 for postoperative ventricular arrhythmias.

In both groups, the ventricular arrhythmias were not related to reversible causes such as electrolyte imbalance or medications.

Patients were followed up until December 2010. The records were reviewed for the following: results of the preoperative angiograms that were performed in all 93 patients, the status of revascularization (complete or incomplete; eg, vessels that could not be bypassed, poor targets or quality of vessels used in grafting), postoperative course, pre and postoperative left ventricular ejection fraction, results of programmed electrical stimulation study for inducible ventricular arrhythmias, indication and date of ICD implant, medications used including β-blockers (BB), angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, statins, and anti-arrhythmics. The ICD clinic records of the follow-up visits every 3 to 4 months, and the ECGs of the events triggering ICD therapies were reviewed by a certified electrophysiologist. Time to first event, and type of ventricular arrhythmia were noted. The records of deceased patients were reviewed to identify the cause of death. The end points defined were TM and/or appropriate ICD therapies (ICD-T) for VT/VF, and the individual outcomes of TM and ICD-T.

Statistical Analysis

Univariate analysis of the baseline clinical variables in patients with and without events, was performed using the 2-sample t test for continuous variables, Mann–Whitney test for nominal values with skewed distribution and the χ² test or Fisher’s exact test for categorical variables. Cox proportional hazards model was used for analysis of the factors independently associated with survival or time to events. Significant or borderline significant (P<0.05) baseline clinical variables from univariate results were used in the model. Due to limited sample size and power, there is an upper limit to the complexity of the model. To grant a stable model, the backward stepwise selection with substantive clinical knowledge was used to generate the final multivariable model. The survival analysis was performed using the Kaplan–Meier approach for nonparametric estimate of the overall survival probability of an event of interest: either death, ICD-T, or both. Kaplan–Meier curves were used to show the event-free survival over time.

Results

The clinical features of all 93 patients, the groups of patients with pre and postoperative ventricular arrhythmias, and the distribution of the clinical variables in the subgroups of patients with and without events are shown in Tables 1 through 3 respectively. In the preoperative arrhythmia group, 28 patients (53%) presented with monomorphic VT, 21 (40%) presented with VF, and 4 (7%) had unexplained syncope with inducible VT. In the postoperative arrhythmia group of patients; 18 patients (45%) had sustained monomorphic VT, and 22 (55%) had VF.

Clinical Events

During the mean follow-up period of 49 months, the composite primary end point of combined TM and appropriate ICD shocks was observed in 52/93 patients (56%); the TM rate was 35/93 (38%), appropriate ICD therapy occurred in 28/93 (30%), and 11 of the 35 patients who died also had appropriate ICD therapies.

In the preoperative group, the TM rate was 21/53 (39%), and 14/53 (26%) had appropriate ICD therapies for VT/VF. In the postoperative group the TM rate was 14/40 (35%), and 14/40 (35%) had ICD-T for VT/VF. Cardiac mortality accounted for 58% and 71% of the TM in the pre- and the postoperative groups, respectively. Fifty-five percent of deaths, and 23% of the appropriate ICD-T occurred within 2 years from the cardiac surgery (Figure).
Analysis of Clinical Characteristics and Clinical Outcome

In the univariate analysis, age, congestive heart failure (CHF) class III/IV, hypertension end stage renal disease (ESRD), and use of antiarrhythmic medication were associated with the combined outcome of TM+ICD-T (Table 1). In multivariable models, for every 1 year increase in age, there was 2% increase of combined events, patients who had CHF class III to IV, hypertension, and ESRD had 1.8 to 3 times higher...
| Characteristic | Total (n=53) | Non-events (n=25) | Combined Events (n=28) | P Value |
|---------------|--------------|------------------|------------------------|---------|
| Age, y (mean±SD) | 68.6±11.7 | 65.3±13.5 | 71.5±9.2 | 0.059* |
| Gender: male | 49 (92.5%) | 22 (88%) | 27 (96.4%) | 0.333† |
| Myocardial infarction | 47 (88.7%) | 23 (92%) | 24 (85.7%) | 0.672‡ |
| No. of patients with CAD | 47 (88.7%) | 23 (92%) | 24 (85.7%) | 0.672‡ |
| No. of vessels with CAD | | | | 0.826† |
| None | 6 (11.3%) | 2 (8%) | 4 (14.3%) | |
| 1 to 2 vessels | 9 (17%) | 4 (16%) | 5 (17.9%) | |
| 3 vessels | 38 (71.7%) | 19 (76%) | 19 (67.9%) | |
| No. of patients who had CABG | 46 (86.8%) | 23 (92%) | 23 (82.1%) | 0.426‖ |
| No. of grafts | | | | 0.398† |
| None | 7 (13.2%) | 2 (8%) | 5 (17.9%) | |
| 1 to 2 grafts | 9 (17%) | 4 (16%) | 5 (17.9%) | |
| 3 to 4 grafts | 37 (69.8%) | 20 (80%) | 17 (60.7%) | |
| Complete revascularization¶ | 16 (34.8%) | 8 (34.8%) | 8 (34.8%) | 1.000‡ |
| Preoperative LVEF (mean±SD) | 34.7±14.2 | 39.0±15.5 | 30.9±11.9 | 0.042‖ |
| Postoperative LVEF (mean±SD) | 38.9±14.3 | 42.6±14.7 | 36.4±13.7 | 0.185* |
| Congestive heart failure | | | <0.001‖† |
| Class I to II | 37 (69.8%) | 23 (92%) | 14 (50%) | |
| Class III to IV | 16 (30.2%) | 2 (8%) | 14 (50%) | |
| No. of patients who had valve surgery | 0.0 | | 1.00† |
| AVR | 5 (55.6%) | 1 (50%) | 4 (57.1%) | |
| MVR | 4 (44.4%) | 1 (50%) | 3 (42.9%) | |
| Preoperative arrhythmia | | | | 0.764† |
| VT | 28 (52.8%) | 11 (44%) | 17 (60.7%) | |
| VF | 21 (39.6%) | 11 (44%) | 10 (35.7%) | |
| Syncope | 4 (7.5%) | 3 (12%) | 1 (3.6%) | |
| Programmed electrical stimulation | 20 (37.7%) | 10 (40%) | 10 (35.7%) | 0.748§ |
| Hypertension | 46 (86.8%) | 20 (80%) | 26 (92.9%) | 0.234§ |
| Diabetes mellitus | 25 (47.2%) | 12 (48%) | 13 (46.4%) | 0.909‡ |
| End-stage renal disease | 8 (15.1%) | 0 (0%) | 8 (28.6%) | 0.005† |
| Atrial fibrillation | 22 (41.5%) | 8 (32%) | 14 (50%) | 0.184§ |
| β-blocker therapy | 40 (75.5%) | 19 (76%) | 21 (75%) | 0.933‡ |
| ACE inhibitor/ARB therapy | 44 (83%) | 23 (92%) | 21 (75%) | 0.148§ |
| Antiarrhythmic medication | 27 (50.9%) | 9 (36%) | 18 (64.3%) | 0.040‡ |
| Time between surgery and ICD implant, day (median [range]) | 8 (1.0 to 142.0) | 8.0 (1.0 to 142.0) | 9.0 (1 to 60) | 0.844§ |
| Duration of follow-up, months (mean±SD) | 57.1±37.7 | 88.4±19.5 | 29.2±26.2 | <0.001†† |

Values are presented as no. (%), except indicated mean±SD or median (range). ACE indicates angiotensin converting enzyme inhibitors; ARB, angiotensin receptor blockers; AVR, aortic valve replacement; CABG, coronary bypass graft surgery; CAD, coronary artery disease; ICD, implantable cardioverter defibrillators; LVEF, left ventricular ejection fraction; MVR, mitral valve replacement; VF, ventricular fibrillation; VT, ventricular tachycardia. 
P value was based on: independent sample t test (*) or Mann–Whitney test (¶) for nominal variables with skewed distribution, and χ2 test (§) or Fisher’s exact (†) test for categorical variables with expected cell counts <5. ‡Revascularization applies only to those who had CABG surgery. §Statistically significant results at P<0.05.
| Characteristic                                      | Total (n=40) | Non-events (n=16) | Combined Events (n=24) | P Value  |
|---------------------------------------------------|--------------|------------------|------------------------|----------|
| **Age, y (mean±SD)**                              | 68.1±12.6    | 64.3±14.8        | 70.7±10.5              | 0.120*   |
| **Gender: male**                                  | 33 (82.5%)   | 14 (87.5%)       | 19 (79.2%)             | 0.681†   |
| **Myocardial infarction**                         | 33 (82.5%)   | 13 (81.3%)       | 20 (83.3%)             | 1.000†   |
| **No. of patients with CAD**                      | 32 (80%)     | 12 (75%)         | 20 (83.3%)             | 0.691‡   |
| **No. of vessels with CAD**                       |              |                  |                        | 0.615‡   |
| None                                              | 8 (20%)      | 4 (25%)          | 4 (16.7%)              |          |
| 1 to 2 vessels                                    | 8 (20%)      | 2 (12.5%)        | 6 (25%)                |          |
| 3 vessels                                         | 24 (60%)     | 10 (62.5%)       | 14 (58.3%)             |          |
| **No. of patients who had CABG**                  | 32 (80%)     | 12 (75%)         | 20 (83.3%)             | 0.691‡   |
| **No. of grafts**                                 |              |                  |                        | 0.336‡   |
| None                                              | 8 (20%)      | 4 (25%)          | 4 (16.7%)              |          |
| 1 to 2 grafts                                     | 9 (22.5%)    | 5 (31.3%)        | 4 (16.7%)              |          |
| 3 to 4 grafts                                     | 23 (57.5%)   | 7 (43.8%)        | 16 (66.7%)             |          |
| **Complete revascularization**‡                    | 14 (43.8%)   | 2 (16.6%)        | 12 (60%)               | 0.028‡   |
| **Preoperative LVEF (mean±SD)**                   | 36.2±15.3    | 35.2±16.4        | 36.9±14.8              | 0.731*   |
| **Postoperative LVEF (mean±SD)**                  | 39.2±13.7    | 43.5±13.9        | 35.9±12.9              | 0.093*   |
| **Congestive heart failure**                      |              |                  |                        | 0.602†   |
| Class I to II                                     | 23 (57.5%)   | 10 (62.5%)       | 13 (54.2%)             |          |
| Class III to IV                                   | 17 (42.5%)   | 6 (37.5%)        | 11 (45.8%)             |          |
| **No. of patients who had valve surgery**         |              |                  |                        | 1.000†   |
| AVR                                               | 12 (80%)     | 6 (85.7%)        | 6 (75%)                |          |
| MVR                                               | 3 (20%)      | 1 (14.3%)        | 2 (25%)                |          |
| **Postoperative arrhythmia**                      | 0.0          |                  |                        | 0.436‡   |
| VT                                                | 18 (45%)     | 6 (37.5%)        | 12 (50%)               |          |
| VF                                                | 22 (55%)     | 10 (62.5%)       | 12 (50%)               |          |
| **Time between surgery and arrhythmia**           |              |                  |                        | 0.021‡   |
| ≤3 days                                           | 14 (35%)     | 9 (56.3%)        | 5 (20.8%)              |          |
| >3 days                                           | 26 (65%)     | 7 (43.8%)        | 19 (79.2%)             |          |
| **Programmed electrical stimulation**              | 5 (12.5%)    | 2 (12.5%)        | 3 (12.5%)              | 1.000‡   |
| Hypertension                                      | 36 (90%)     | 13 (81.3%)       | 23 (95.8%)             | 0.283†   |
| Diabetes mellitus                                 | 17 (42.5%)   | 5 (31.3%)        | 12 (50%)               | 0.240‡   |
| End-stage renal disease                           | 3 (7.5%)     | 0 (0%)           | 3 (12.5%)              | 0.262‡   |
| Atrial fibrillation                               | 17 (42.5%)   | 5 (31.3%)        | 12 (50%)               | 0.240‡   |
| β-blocker therapy                                 | 33 (82.5%)   | 15 (93.8%)       | 18 (75%)               | 0.210‡   |
| ACE inhibitor/ARB therapy                         | 28 (70%)     | 13 (81.3%)       | 15 (62.5%)             | 0.297‡   |
| Antiarhythmic medication                         | 19 (47.5%)   | 6 (37.5%)        | 13 (54.2%)             | 0.301‡   |
| **Time between cardiac surgery and ICD implant, day** | 8.5 (1.0 to 122.0) | 7.0 (4.0 to 51.0) | 11.5 (1.0 to 122.0) | 0.166‡   |
| **Duration of follow-up, months (mean±SD)**       | 55.6±39.2    | 86.2±18.1        | 35.2±16.2              | <0.001‡  |

Values are presented as no. (%), except indicated mean±SD or median (range). ACE indicates angiotensin converting enzyme inhibitors; ARB, angiotensin receptor blockers; AVR, aortic valve replacement; CABG, coronary bypass graft surgery; CAD, coronary artery disease; ICD, implantable cardioverter defibrillators; LVEF, left ventricular ejection fraction; MVR, mitral valve replacement; VF, ventricular fibrillation; VT, ventricular tachycardia.

For nominal variables with skewed distribution, P-value was based on: independent sample t test (*) or Mann–Whitney test (¶) for nominal variables with skewed distribution, and $\chi^2$ test ($) or Fisher’s exact (†) test for categorical variables with expected cell counts <5. ‡Revascularization applies only to those who had CABG surgery. §Statistically significant results at P<0.05.
hazard of combined events, and those on antiarrhythmic medications had \( \approx 1.7 \) times higher hazard of combined events (Table 4).

**Total Mortality Outcome**

In the univariate analysis, age, CHF class III to IV, hypertension, diabetes mellitus (DM), ESRD, and atrial fibrillation were associated with TM. After adjusting for all other variables in the models, for every 1 year increase in age, there was 2\% increase in mortality. Patients who had CHF class III to IV and ESRD had \( \approx 4 \) and 6 times higher hazard of death, respectively, whereas use of \( \beta \)-blocker therapy was associated with \( \approx 60\% \) lower mortality (Table 4).

**Appropriate ICD-T Outcome**

The average months of follow-up for those with and without ICD-T were 37.8 and 86.9, respectively. In the univariate analysis, patients with ICD-T had lower postoperative left ventricular ejection fraction (35\% versus 41\%), and in the multivariate analysis, DM patients were 50\% less likely to have ICD-T (Table 4).

**Discussion**

Experimental studies have shown that ischemicventricular arrhythmias are caused by focal (eg, automatic focal excitation) as well as non focal mechanisms (eg, reentry due to heterogeneity in refractoriness and conduction).\(^{17}\) Although in general implantation of an ICD is not recommended for patients with unstable VT/VF\(< 48 \) hours or \( >3 \) months post revascularization (patients who had ventricular arrhythmias 

<3 months post revascularization were not addressed) if they have reversible causes (eg, acute occlusion/infarct, restenosis) and undergo complete revascularization,\(^{10}\) these patients still have high mortality rates.\(^{18}\)

Studies of acute myocardial infarction patients presenting with VF show a high 90 day mortality rate in spite of having revascularization with PTCA\(^ {19,20}\) and although in some studies, CABG after SCD was associated with high survival rates and lower incidence of ventricular arrhythmia,\(^ {21,22}\) others studies yielded different results.\(^ {23,24}\)

Similar findings were found in patients with postoperative ventricular arrhythmias that can be triggered by reversible factors (eg, ischemia, metabolic causes, medications), but is still associated with high mortality rates as demonstrated by data from 2 different studies with \( >4000 \) patients.\(^ {25,26}\)

The available data from the Versus Implantable Defibrillators (AVID) study for ICD patients with preoperative ventricular arrhythmias is conflicting. Meta-analysis of the AVID registry patients who had CABG after presenting with ventricular arrhythmias showed that survival benefit from ICD was not diminished by surgical revascularization even though there was a significant reduction in mortality from having CABG alone.\(^ {11}\) However, meta-analysis of the AVID study concluded that patients who had revascularization after the index event (patients were allowed into the study if revascularization was deemed necessary by the treating physician) had better survival and were unlikely to benefit from ICD therapy.\(^ {12}\)

The 3-year survival rate in our study (\( \approx 73\% \)) is slightly lower than that of the AVID\(^ {1} \) and Canadian Implantable Defibrillator Study\(^ {2} \) trials (75\% and 77\%, respectively), that had a lower percentage of patients with CHF Class III to IV and other comorbidities (eg, hypertension, DM, atrial fibrillation), but also lower use of \( \beta \)-blockers, than this study.

We were unable to provide a matched control group (ie, cardiac surgery patients with perioperative ventricular arrhythmias not due to reversible causes without an ICD), given the guidelines for ICD therapy, which is considered the standard of care for many of these patients. The high event rates seen in the preoperative group, are more concordant with the AVID Registry results for patients who underwent surgical revascularization, whose clinical profile approaches that of our patients (CHF 35\%, DM 30\%, atrial fibrillation 20\%).\(^ {11}\) Of note, the meta-analysis report of the AVID study which showed limited benefit from ICD post revascularization, did not report on the clinical profile of patients who had revascularization and included in the analysis those who had CABG as well as PTCA.\(^ {12}\) We did not find a statistically significant difference among the subgroups of patients who had complete versus incomplete revascularization, those who presented with VT versus VF, or those who had valve repair/replacement.
Neither depressed left ventricular ejection fraction nor positive programmed electrical stimulation study predicted the higher-risk group of patients; however, age, CHF class III to IV, atrial fibrillation, DM, ESRD, and use of antiarrhythmics were all associated with high event rates, and are consistent with those observed in the AVID study as well as other ICD studies.27

In conclusion, our results support the role of ICD in this cohort of patients, particularly those with preoperative arrhythmias who may be overlooked, and highlight the recent published guidelines for appropriate use of ICD10 for patients with pre- and postoperative ventricular arrhythmias in whom the presence of irreversible substrate (including genetic predisposition) and triggers cannot be totally excluded even with complete revascularization.

The lack of randomized ICD studies in this cohort of patients (ICD were studied only for primary prevention in acute myocardial infarction but still excluded patients who had CABG or those who had ventricular arrhythmia before or >48 hours post myocardial infarction28,29) and the known limitations of programmed electrical stimulation study, highlight the need for further studies to understand the complex interaction of revascularization with other confounding variables.

Limitations
It is important to point out that this is a non-randomized retrospective study, with a smaller number of patients, and was conducted within 1 medical institute.

Disclosures
None.

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