

# Prospective evaluation of health status, quality of life and clinical outcomes following implantable defibrillator generator exchange

Faisal M Merchant<sup>1,✉</sup>, John Larson<sup>2</sup>, Leon Darghosian<sup>1</sup>, Paige Smith<sup>1</sup>, Soroosh Kiani<sup>1</sup>, Stacy Westerman<sup>1</sup>, Anand D. Shah<sup>1</sup>, David S. Hirsh<sup>1,3</sup>, Michael S. Lloyd<sup>1</sup>, Angel R. Leon<sup>1</sup>, Mikhael F. El-Chami<sup>1</sup>

1. Section of Cardiac Electrophysiology, Emory University School of Medicine, Atlanta, GA, USA; 2. Department of Medicine, University of Michigan School of Medicine, Ann Arbor, MI, USA; 3. Grady Health System, Atlanta, GA, USA

✉ Correspondence to: [faisal.merchant@emory.edu](mailto:faisal.merchant@emory.edu)

<https://doi.org/10.11909/j.issn.1671-5411.2021.09.007>

## ABSTRACT

**BACKGROUND** Little is known about health status and quality of life (QoL) after implantable cardioverter-defibrillator (ICD) generator exchange (GE).

**METHODS** We prospectively followed patients undergoing first-time ICD GE. Serial assessments of health status were performed by administering the 36-Item Short Form Survey (SF-36).

**RESULTS** Mean age was  $67.5 \pm 14.3$  years, left ventricle ejection fraction (LVEF) was  $36.5\% \pm 15.0\%$  and over 40% of the cohort had improved LVEF to  $> 35\%$  at the time of GE. SF-36 scores were significantly worse in physical/general health domains compared to domains of emotional/social well-being ( $P < 0.001$  for each comparison). Physical health scores were significantly worse among those with medical comorbidities including diabetes, chronic obstructive pulmonary disease and atrial fibrillation. Mean follow-up was  $1.6 \pm 0.5$  years after GE. Overall SF-36 scores remained stable across all domains during follow-up. Survival at 3 years post-GE was estimated at 80%. Five patients died during follow-up and most deaths were adjudicated as non-arrhythmic in origin. Four patients experienced appropriate ICD shocks after GE, three of whom had LVEF which remains impaired LVEF (i.e.,  $< 35\%$ ) at the time of GE.

**CONCLUSION** Patients undergoing ICD GE have significantly worse physical health compared to emotional/social well-being, which is associated with the presence of medical comorbidities. In terms of clinical outcomes, the incidence of appropriate shocks after GE among those with improvement in LVEF is very low, and most deaths post-procedure appear to be non-arrhythmic in origin. These data represent an attempt to more fully characterize the spectrum of QoL and clinical outcomes after GE.

The decision to perform an implantable cardioverter-defibrillator (ICD) generator exchange (GE) at end of battery life is complex, and should incorporate potential survival benefit associated with on-going ICD therapy, along with overall health status, quality of life and goals of care.<sup>[1]</sup> Whereas multiple randomized trials support the survival benefit associated with initial ICD implantation,<sup>[2,3]</sup> there are no prospective data to support routine ICD GE. In the absence of high-level data to inform decisions at the time of ICD battery depletion, GE is frequently performed as a

matter of routine clinical course, with little consideration given to whether it's the right decision for an individual patient. A handful of studies have attempted to identify predictors of overall survival and ICD shocks after GE,<sup>[4-8]</sup> with the hope of determining which patients are most, or least, likely to benefit from the procedure. However, a major limitation of these studies has been lack of data on cause of death after GE. Given that the benefit of an ICD is dependent on the balance between competing risks of arrhythmic and non-arrhythmic mortality,<sup>[9]</sup> identifying causes of death is crucial to understand-

ing the potential benefit from GE.

The decision to replace an ICD generator is further complicated by the fact that many individuals place greater emphasis on quality, rather than quantity, of life as they age and continued ICD therapy may no longer be consistent with their goals of care.<sup>[1]</sup> However, little is known about trajectories in health status and quality of life (QoL) after ICD GE and therefore, opportunities to incorporate these factors into the decision to perform GE are limited.

To address these knowledge gaps, we performed a prospective study of patients undergoing ICD GE to evaluate health status, trajectories in QoL and clinical outcomes, including cause of death, after the procedure.

## METHODS

The Emory University and Grady Health System Institutional Review Boards approved the study protocol. We performed a prospective study of patients undergoing ICD GE at three sites across two institutions: Emory Healthcare (Emory University Hospital & Emory University Hospital Midtown) and Grady Hospital between October 2017 and April 2019. Only patients undergoing an elective, first time ICD generator exchange for end of battery life were included. Patients undergoing GE for other indications (system upgrade, hardware malfunction...) were excluded, as were patients with recalled leads, even if those leads were functioning normally and no intervention was planned at the time of GE.

The decision to perform a GE and all technical aspects of the procedure were at the discretion of treating physicians. A complete interrogation of the depleted ICD battery was performed at the time of GE in order to determine whether ICD shocks had occurred during the first battery life and whether those shocks were appropriate. Device clinic records were also reviewed to obtain supplementary arrhythmia history. Additionally, all patients underwent an assessment of left ventricle ejection fraction (LVEF) around the time of GE. If an assessment of LVEF by any modality had been performed as part of routine clinical care within 6 months prior to GE, that measurement was recorded. If no recent clinical assessments of LVEF had been performed, a

trans-thoracic echocardiogram was performed at the time of enrollment as part of the study.

ICD programming after GE was at the discretion of the treating physician. In general, our institutional approach has been to program ICDs with long detection intervals and high rate cut-offs, consistent with contemporary programming practices,<sup>[10,11]</sup> except in circumstances where a clinical history of ventricular arrhythmias would dictate alternative device programming. All patients in the study were enrolled in remote device monitoring systems and followed through the device clinics at the respective sites.

## Assessment of Health Status and Quality of Life

All patients underwent serial assessment of health status and QoL by completing the 36-Item Short Form Survey (SF-36). The SF-36 is a written, well-validated 36 question survey which assesses health status across 8 domains: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue and general health perceptions.<sup>[12]</sup> It also includes a single question assessment of perceived change in health status over the past year. Each domain is scored from 0–100, with 0 representing worst possible health and 100 representing perfect health. Although the SF-36 is not specific to patients with heart failure or devices, it has been used frequently for assessment of health status and QoL in patients with ICDs.<sup>[13–16]</sup>

Baseline SF-36 evaluations were completed in-person at the time of enrollment, prior to GE, in order to minimize the impact of post-operative factors such as pain. Follow-up SF-36 assessments were administered annually for up to 3 years of follow-up after GE. Follow assessments were administered by mail, email or telephone

## Follow-up Data Collection

Telephone calls were performed at 6 month intervals through up to 3 years of follow-up to collect data on clinical events. Additionally, institutional medical records were reviewed at 6 month intervals and device clinic records and remote device monitoring databases were queried every 6 months to determine if ICD therapies had occurred after GE



and whether they were appropriate. All device data was reviewed by certified device clinic engineers and over-read by board-certified cardiac electrophysiologists.

In the case of death, attempts were made to obtain relevant history from next of kin and by obtaining pertinent medical records and death certificates. If available, ICD device interrogations around the time of death were also analyzed. Cause of death was adjudicated using a modification of the Hinkle and Thaler classification.<sup>[17]</sup>

### Statistical Analysis

Continuous variables are presented as mean  $\pm$  SD and categorical data are summarized as frequencies and percentages. Correlates of SF-36 scores were identified using *t*-tests or Pearson correlation coefficients, as appropriate. Survival after GE was estimated using Kaplan-Meier analysis. A two-tailed *P* < 0.05 was considered significant. All statistical analyses were performed using Statistica<sup>®</sup> (Statsoft, Tulsa, OK).

## RESULTS

Sixty-three patients undergoing ICD GE were enrolled. Baseline characteristics are presented in Table 1. Mean age at the time of GE was 67.5  $\pm$  14.3 years, 67% were male and 57% had a history of coronary artery disease (CAD). However, 48% of the cohort was classified as having non-ischemic cardiomyopathy (NICM). In some cases, despite the presence of underlying CAD, the extent of left ventricle (LV) dysfunction was felt out of proportion to CAD and thus classified as primarily NICM. Among the 59 patients who had originally been implanted for LV dysfunction, 49 (83%) were implanted for primary prevention and the remaining had either secondary prevention or high risk features with positive electrophysiology study as the implant indication. The other four patients had originally been implanted with ICDs for arrhythmogenic syndromes including two with hypertrophic cardiomyopathy, one with long QT syndrome and one with cardiac sarcoidosis. Approximately 40% of the cohort had CRT defibrillators. Four patients were on continuous home inotrope therapy at the time of GE and one had a left ventricle assistance

**Table 1** Baseline characteristics (n = 63).

|   |                 |
|---|-----------------|
| Age, yrs                                      | 67.5 $\pm$ 14.3 |
| Male gender                                   | 42 (67%)        |
| Coronary artery disease                       | 36 (57%)        |
| Prior myocardial infarction                   | 14 (22%)        |
| Prior coronary artery by-pass grafting        | 17 (27%)        |
| Prior percutaneous coronary intervention      | 15 (23%)        |
| Non-ischemic cardiomyopathy                   | 30 (48%)        |
| Long QT syndrome                              | 1 (2%)          |
| Hypertrophic cardiomyopathy                   | 2 (3%)          |
| Cardiac sarcoidosis                           | 1 (2%)          |
| Left ventricle ejection fraction              | 36.5% $\pm$ 15% |
| Comorbidities                                 |                 |
| Hypertension                                  | 42 (67%)        |
| Atrial fibrillation                           | 26 (41%)        |
| Diabetes                                      | 18 (29%)        |
| Obstructive sleep apnea                       | 10 (16%)        |
| Chronic kidney disease (stage III or greater) | 12 (19%)        |
| Chronic obstructive pulmonary disease         | 8 (13%)         |
| Device type                                   |                 |
| Single chamber defibrillator                  | 19 (30%)        |
| Dual chamber defibrillator                    | 17 (27%)        |
| Cardiac resynchronization defibrillator       | 25 (40%)        |
| Subcutaneous defibrillator                    | 2 (3%)          |
| Medical therapy                               |                 |
| Beta blockers                                 | 60 (95%)        |
| Angiotensin antagonists                       | 46 (73%)        |
| Angiotensin receptor-neprilysin inhibitor     | 12 (19%)        |
| Aldosterone antagonist                        | 4 (6%)          |
| Diuretics                                     | 36 (57%)        |
| Long-acting nitrates                          | 14 (22%)        |
| Hydralazine                                   | 7 (11%)         |
| Anti-platelet agents                          | 43 (68%)        |
| Anticoagulants                                | 30 (48%)        |
| Statins                                       | 44 (70%)        |
| Home continuous inotrope therapy              | 4 (6%)          |

Data are presented as mean  $\pm$  SD or *n* (%).

device (LVAD) in place.

Assessment of LVEF at the time of GE was available in 61 out of 63 patients. Ejection fraction at the time of GE was 36.5%  $\pm$  15.0%. Among patients originally implanted with ICDs in the setting of LV dysfunction, 24 out of 59 (41%) had improvement in



LVEF to > 35% at the time of GE, and 6 (10%) had improvement to > 50%.

Nine patients in the cohort (14%) had a history of appropriate ICD shocks during the 1<sup>st</sup> battery (i.e., prior to GE) and three additional patients had a history of appropriate anti-tachycardia pacing (ATP) therapy but no prior ICD shocks. Three patients (5%) had experienced inappropriate shocks during the 1<sup>st</sup> battery life, of whom one had also experienced appropriate shocks.

### Health Status and Quality of Life

Baseline SF-36 scores are presented in Table 2. At the time of GE, SF-36 scores were significantly lower in domains of physical health (physical functioning:  $62.3 \pm 29.7$ ; limitations due to physical health:  $63.3 \pm 42.4$ ; energy/fatigue:  $60.5 \pm 19.4$ ) compared to domains of emotional/social well-being (limitations due to personal/emotional problems:  $82.8 \pm 32.4$ ; emotional well-being:  $81.4 \pm 18.1$ ; social functioning:  $81.0 \pm 24.8$ ) ( $P < 0.001$  for each comparison between categories of physical health compared to categories of emotional/social well-being).

There was no significant correlation between age and SF-36 score in the physical functioning domain ( $r = -0.133$ ,  $P = 0.307$ ) or general health ( $r = 0.223$ ,  $P = 0.08$ ). Similarly, there was no correlation between LVEF at the time of GE and physical function ( $r = -0.098$ ,  $P = 0.445$ ) or general health ( $r = -0.074$ ,  $P = 0.566$ ). History of ICD shocks (appropriate or inappropriate) was also not associated with health status in any domains. In contrast, scores in domains of physical function and general health were significantly lower among patients with medical comorbidities. Among patients with diabetes, scores were significantly lower in physical functioning

( $40.0 \pm 27.1$  vs.  $70.8 \pm 26.3$ ,  $P < 0.001$ ), energy/fatigue ( $51.9 \pm 17.0$  vs.  $63.8 \pm 19.5$ ,  $P = 0.031$ ) and general health ( $51.2 \pm 23.0$  vs.  $65.9 \pm 20.6$ ,  $P = 0.018$ ). Similar patterns were seen for those with chronic obstructive pulmonary disease (COPD) [physical functioning ( $34.0 \pm 18.6$  vs.  $66.0 \pm 29.0$ ,  $P = 0.006$ ); general health ( $37.1 \pm 22.3$  vs.  $65.0 \pm 20.2$ ,  $P < 0.001$ )] and atrial fibrillation (Afib) [physical functioning ( $54.1 \pm 31.8$  vs.  $68.0 \pm 27.2$ ,  $P = 0.07$ ); energy/fatigue ( $52.7 \pm 18.9$  vs.  $65.8 \pm 18.2$ ,  $P = 0.008$ )]. Conversely, general health scores tended to be better among those with CRT devices ( $67.7 \pm 19.7$  vs.  $57.1 \pm 23.1$ ,  $P = 0.059$ ).

Among patients who completed SF-36 assessments at 12 months after GE ( $n = 43$ ) and 24 months post-procedure ( $n = 23$ ), scores in all 9 domains remained similar between baseline and both 12 and 24 month assessments (Table 2). The pattern of lower scores in physical health domains compared to domains of emotional/social well-being persisted at 12 and 24 months.

### Clinical Outcomes

Mean duration of follow-up after GE was  $1.6 \pm 0.5$  years. There were no device infections or other significant procedural complications associated with the GE procedure. Four patients (6%) experienced appropriate ICD shocks during follow-up. Of the patients who experienced appropriate shocks, LVEF at the time of GE remained impaired in three (15%, 23%, 35%) and had improved to 40% in the remaining patient. None of the four had experienced appropriate ICD shocks prior to GE. The incidence of appropriate ICD shocks based on LVEF at the time of GE was 3 out of 35 (9%) among those with LVEF  $\leq 35\%$ , 1 out of 18 (6%) among those with improved LVEF (35%–50%) and 0 out of 6 among those with

Table 2 SF-36 scores.

|                   | Physical health      |                                    |                   | Emotional health/social well-being             |                      |                    |                   |                   | Perceived change in health over past year |
|-------------------|----------------------|------------------------------------|-------------------|--|----------------------|--------------------|-------------------|-------------------|---|
|                   | Physical functioning | Limitations due to physical health | Energy/fatigue    | Limitations due to personal/emotional problems | Emotional well-being | Social functioning | Pain              | General health    |   |
| Baseline          | $62.3 \pm 29.7^*$    | $63.3 \pm 42.4^†$                  | $60.5 \pm 19.4^†$ | $82.8 \pm 32.4$                                | $81.4 \pm 18.1$      | $81.0 \pm 24.8$    | $73.2 \pm 28.4$   | $61.9 \pm 22.1$   | $55.6 \pm 23.3$                           |
| 12-month (n = 43) | $66.9 \pm 27.0^†$    | $74.3 \pm 34.5^†$                  | $59.1 \pm 17.3^†$ | $86.0 \pm 31.9^†$                              | $85.4 \pm 16.9^†$    | $86.1 \pm 20.3^†$  | $79.7 \pm 24.5^†$ | $58.3 \pm 22.7^†$ | $60.5 \pm 22.0^†$                         |
| 24-month (n = 23) | $60.4 \pm 33.3^†$    | $60.9 \pm 43.2^†$                  | $52.3 \pm 29.8^†$ | $78.3 \pm 39.7^†$                              | $77.3 \pm 20.5^†$    | $76.8 \pm 28.7^†$  | $77.5 \pm 27.2^†$ | $51.3 \pm 23.7^†$ | $55.4 \pm 21.3^†$                         |

\* $P < 0.001$  for comparison between each category of physical health compared to each category of emotion health/social well-being;  $^†P > 0.05$  for comparison of each category between baseline and 12-months;  $^\ddagger P > 0.05$  for comparison of each category between baseline and 24-months.



LVEF > 50%. No inappropriate shocks occurred after GE. Seventeen hospitalizations occurred among 15 patients (24%) during follow-up, of which 8 hospitalizations were deemed to be primarily for cardiac causes (one for Afib and 7 for heart failure).

Five patients (8%) died during follow-up. Kaplan-Meier estimates of survival after GE were 97% at 1 year, 92% at 2 years and 80% at 3 years post-procedure (Figure 1). Two deaths were attributed to progressive heart failure and one to a stroke. In two cases, due to very limited information available from next of kin, no clear cause of death could be determined. There were no known ICD therapies delivered immediately prior to death, although post-mortem device interrogations could not be performed in these cases.

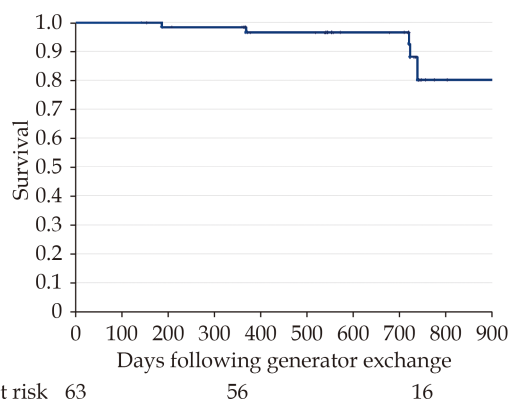
## DISCUSSION

This prospective registry demonstrates that patients undergoing ICD generator exchange have significantly worse health status and QoL in domains of physical health compared to domains of emotional and social well-being. The presence of medical comorbidities such as diabetes, COPD and atrial fibrillation was much strongly associated with poor physical health, in contrast to age or LVEF at the time of GE, which were not significantly correlated with physical health. However, overall health status and QoL were stable over the first couple of years after GE, without significant worsening in any domains. In terms of clinical outcomes, most patients who experienced appropriate ICD shocks after the procedure continued to have LVEF  $\leq$  35% at the time of GE. Only one patient with improvement in

LVEF to 40% at the time of GE experienced an appropriate ICD shock. Lastly, overall survival after GE was good, estimated at  $\sim$ 80% at 3 years. However, among patients who died, the majority of deaths were deemed to be non-arrhythmic in origin. These data represent an attempt to more completely understand the full spectrum of health status, QoL and clinical outcomes among patient undergoing ICD GE.

Over 60,000 new ICDs are implanted annually in the United States, the vast majority of which are done for primary prevention in the setting of impaired LVEF.<sup>[18]</sup> With improvements in medical and adjunctive therapy for heart failure,<sup>[19]</sup> survival has improved such that increasing numbers of patients are outliving the initial ICD battery and as a result, over 20,000 ICD GEs are performed each year.<sup>[18]</sup> Whereas decisions about *initial* ICD implantation are generally treated as significant, decisions about GE have received far less attention. Although GE is often performed as a default, several important differences exist in risk-benefit profile between initial implant and GE and suggest that the decision to exchange an ICD battery should be viewed as unique and independent.<sup>[1]</sup> First, the benefits of ICD therapy likely change over time. For most individuals, the proportional risk of arrhythmic death decreases over time, due to an age-related increase in competing risks of non-arrhythmic death.<sup>[9,20]</sup> Because ICDs are only able to prevent arrhythmic causes of death, it is likely that the benefit associated with ICD therapy wanes over time as patients grow older. This is further reinforced by the fact that over 40% of patients in this cohort had improvement in LVEF to > 35% at the time of GE, confirming the idea that the benefit of ICD therapy may have changed since initial implant. Second, some important procedural risks, such as device infection, are more common after GE than after initial implant.<sup>[21,22]</sup> Third, many individuals may prioritize quality over quantity of life over time and undergoing an elective surgical procedure to replace an ICD battery may no longer be consistent with their preferences.

The presence of strong data to support initial ICD implantation<sup>[2,3,23]</sup> may have resulted in a reluctance on the part of many physicians to recommend against replacing ICD generators.<sup>[9,24]</sup> As a result, the decision to exchange an ICD generator is often embedded in therapeutic inertia rather than clinical data. A handful of studies have looked at outcomes after ICD GE and have consistently demonstrated that



**Figure 1** Kaplan-Meier estimates of survival after defibrillator generator exchange.



patients whose LVEF remains impaired (i.e.,  $\leq 35\%$ ) at the time of GE, and those who experienced appropriate ICD shocks during the first battery, have higher mortality and are more likely to experience appropriate ICD shocks after GE compared to those in whom LVEF has improved or who have not experienced prior appropriate shocks.<sup>[4-7,25]</sup> Our data demonstrating an approximately 20% mortality rate at 3 years after GE are generally in line with the 3-year 27% mortality rate noted after GE in the National Cardiovascular Data Registry (NCDR) ICD Registry.<sup>[18]</sup> However, our data add important detail by demonstrating that more than half of the deaths in our cohort were judged to be non-arrhythmic. It is important that future studies continue to focus on understanding competing risks of arrhythmic and non-arrhythmic death after GE when attempting to understand the benefit of continued ICD therapy.

Our data are also consistent with prior studies which demonstrate that most patients who experience appropriate ICD shocks after GE continue to have impaired LVEF.<sup>[4,5,25]</sup> Only one patient in our cohort with improvement in LVEF to 40% experienced an appropriate ICD shock after GE. However, one of the challenges with using appropriate ICD shocks as a metric for determining the putative benefit of GE is that appropriate ICD shocks are not an ideal surrogate for estimating survival benefit. It is well-acknowledged that appropriate ICD shocks likely overestimate the true incidence of aborted sudden death,<sup>[26,27]</sup> in part because some ICD shocks may treat arrhythmias which would have eventually terminated spontaneously and not resulted in death. Additionally, some patients may experience appropriate shocks but go on to die soon thereafter due to progressive heart failure or other causes, with little overall impact on mortality from the ICD shocks. As a result, attempts to predict the benefit of ICD GE which depend primarily on predicting the incidence of appropriate ICD shocks after the procedure are unlikely to provide a sufficient overall assessment.

Our data also provide one of the first attempts to systematically evaluate trends in health status and QoL after GE. Our findings that patients undergoing GE tend to have significantly worse physical health compared to other domains is broadly consistent with findings among those undergoing initial ICD implantation.<sup>[13-15]</sup> Interestingly, in our cohort, the presence of medical comorbidities such as

diabetes, COPD and atrial fibrillation was much more closely correlated with impaired physical health, compared to either age or LVEF. The impetus to characterize health status and QoL among patients undergoing ICD GE is an acknowledgement of the fact that ICD therapy should be viewed as a preference-sensitive decision.<sup>[28,29]</sup> For some individuals, even if they meet Class I criteria for ICD implantation,<sup>[23]</sup> the decision to have an ICD implanted, or a generator exchanged, may not be consistent with their overall goals and preferences. The recent decision by the Centers for Medicare and Medicaid Services (CMS) to require shared decision-making prior to initial ICD implantation is an acknowledgement of the preference sensitive nature of these decisions.<sup>[30]</sup> Although the CMS requirement does not extend to GE, understanding the impact of ICD GE in the context of both quantity and quality of life is likely to yield decisions which are much better aligned with patient preferences. Our data suggest that particular attention should be paid to QoL considerations when making the decision to perform GE, particularly among patients with significant medical comorbidities. From a practical point of view, our data suggest that it may be particularly important to evaluate the presence and severity of medical comorbidities when making the decision to perform GE. Traditionally, GE decisions have tended to focus on LVEF and history of ICD shocks. While these factors are clearly important, they appear to have less impact on QoL than other comorbidities. Our data can help identify patients who are at-risk for poor QoL after GE, particularly in physical health domains, and in whom particular attention should be paid to QoL considerations when making GE decisions.

Failure to incorporate health status, QoL and individual preferences at the time of ICD battery depletion may have important consequences. Data suggest that more than half of patients undergoing ICD GE are unaware that the decision to undergo the procedure is not mandatory and that at least a quarter would have considered not replacing the generator if given the option.<sup>[31]</sup> The time of ICD battery depletion represents an ideal time to reconsider the pros and cons of continued ICD therapy.<sup>[32]</sup> Not doing so results in patients growing older and older with active devices and many of them experiencing painful ICD shocks in the days and hours immediately before death with little likelihood of



these shocks having a meaningful impact on overall survival.<sup>[17]</sup> Failure to reconsider the benefits of ICD therapy over time results in ICDs becoming an indefinite commitment for many patients, with many potential unintended consequences as patients age with these devices.

## LIMITATIONS

Several important limitations should be noted. First, the data on health status and QoL in our cohort only apply to patients who were deemed to be candidates for GE and who chose to undergo the procedure. Some patients may choose not to undergo GE, or be deemed by their physicians not to be candidates for the procedure. Studying the outcomes of patients who elect not to undergo GE would be very useful; however, identifying these individuals in real-world datasets can be challenging. Our data also don't apply to patients with pacemaker dependence where the decision isn't elective. Second, in an attempt to study outcomes among the full spectrum of patients undergoing ICD GE in contemporary practice, we included patients with CRT devices. Cardiac resynchronization has a powerful impact on QoL and clinical outcomes and the decision to replace a CRT defibrillator generator should be viewed in a different context than replacing a non-CRT generator. Futures studies should attempt to more fully characterize differences in outcomes after GE for those with and without CRT devices. Lastly, the results of our data are entirely descriptive and represent an initial attempt to more fully describe outcomes of GE in the context of both QoL and clinical events. Further work is needed to determine how best to contextualize and present these data to patients so that they can make more fully informed decisions at the time of ICD battery depletion.

## CONCLUSIONS

In this prospective registry of patients undergoing ICD generator exchange, health status and quality of life were significantly worse in domains of physical health compared to emotional and social well-being. The presence of medical comorbidities including diabetes, COPD and Afib was most closely correlated with impairments in physical health. However, overall health status and QoL appeared relatively stable over the first couple of years

after GE. In terms of clinical events, most appropriate ICD shocks after GE occurred in patients whose LVEF remained  $\leq 35\%$ . Although overall survival after GE was relatively good, estimated at about 80% at 3 years post-procedure, most deaths were adjudicated as being non-arrhythmic in origin. These data provide important context on the full spectrum of health status, QoL and clinical outcomes among patients undergoing GE and should be used to develop approaches which enable patients and physicians to make more fully informed decisions at the time of ICD battery depletion.

## ACKNOWLEDGEMENTS

This work was supported by a Pilot Translational & Clinical Studies Program grant from the National Center for Advancing Translational Studies of the National Institutes of Health (UL1TR002378) and a FAME grant from the Emory University Department of Medicine.

## CONFLICTS OF INTEREST

None.

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**Please cite this article as:** Merchant FM, Larson J, Darghosian L, Smith P, Kiani S, Westerman S, Shah AD, Hirsh DS, Lloyd MS, Leon AR, El-Chami MF. Prospective evaluation of health status, quality of life and clinical outcomes following implantable defibrillator generator exchange. *J Geriatr Cardiol* 2021; 18(9): 720–727. DOI: 10.11909/j.issn.1671-5411.2021.09.007

