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ORIGINAL ARTICLE

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The clinical and economic impact of extended battery longevity of a substernal extravascular implantable cardioverter defibrillator

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Abstract

Introduction: The extravascular implantable cardioverter defibrillator (EV ICD) has extended projected battery longevity compared to the subcutaneous implantable cardioverter defibrillator (S-ICD). This study used modeling to characterize the need for generator changes, long-term complications, and overall costs for both the EV ICD and S-ICD in healthcare systems of various countries.

Methods: Battery longevity data were modeled using a Markov model from averages reported in device labeling for the S-ICD and with engineering estimates based on real life usage from EV ICD Pivotal Study patient data to introduce variability. Clinical demographic data were derived from published literature. The primary outcomes were defined as the number of generator replacement surgeries, complications, and total healthcare system costs due to battery depletion over the expected lifetime of patients receiving EV ICD or S-ICD therapy.

Results: Average modeled battery longevity was determined to be 7.3 years for the S-ICD versus 11.8 years for the EV ICD. The probability of a complication after a replacement procedure was 1.4%, with an operative mortality rate of 0.02%. The use of EV ICD was associated with 1.4–1.6 fewer replacements on average over an expected patient lifetime as compared to S-ICD and a 24.3%–26.0% reduction in cost. A one-way sensitivity analysis of the model for the US healthcare system found that use of an EV ICD resulted in a reduction in replacement surgeries

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of greater than 1 (1.1–1.6) along with five-figure cost savings in all scenarios ($18 602–$40 948).

Conclusion: The longer projected battery life of the EV ICD has the potential to meaningfully reduce long-term morbidity and healthcare resources related to generator changes from the perspective of multiple diverse healthcare systems.

KEYWORDS

battery longevity, extravascular, implantable cardioverter defibrillator

1 | INTRODUCTION

Implantable cardioverter-defibrillator (ICD) therapy is associated with a mortality benefit for patients at risk for sudden cardiac death.[1–4] Understanding the costs of ICD therapy involves not only the costs of initial implantation but also the ongoing costs related to standard device follow-up, generator changes for battery depletion, and the management of device-related complications over the life of the patient. Innovations in ICD technology can impact these costs.

Compared to the subcutaneous ICD (S-ICD) with a lead above the sternum, the extravascular implantable cardioverter defibrillator (EV ICD) involves placement of a defibrillator lead under the sternum.[5] This lead position close to the heart results in lower defibrillation energy requirements and the ability to deliver asystole pacing, and anti-tachycardia pacing (ATP) to avoid shock delivery. These features of the EV ICD allow for a 45% reduction in generator size and a 60% increase in projected battery longevity compared to the S-ICD. The purpose of this study was to characterize the impact of projected EV ICD extended battery longevity on the need for generator changes, long-term complications, and overall costs from the perspective of multiple diverse healthcare systems in various countries.

2 | METHODS

2.1 | Model development

A Markov model was developed to simulate the time course of patients receiving EV ICD compared to S-ICD therapy with different projected battery longevities (Figure 1). Battery longevity data were modeled from averages reported in device labeling with engineering estimates based on real-life usage from EV ICD Pivotal Study patient data to introduce variability. Clinical demographic data were derived from published literature.

Non-geography-specific inputs to the model were comprised of the average age and gender of S-ICD recipients as derived from published evidence[6] and average battery longevity estimates from device labeling.[5,7] Local currency values were used for each geography with an annual discount rate of 3%.

Primary outcomes were defined as the number of generator replacement surgeries, complications, and total healthcare system costs due to battery depletion over the expected lifetime of patients receiving EV ICD or S-ICD therapy. Model inputs that are common across all countries are summarized in Table 1. Cost inputs that are country-specific are summarized in Table 2, with an assumption that S-ICD and EV ICD costs are equivalent as cost information is not yet

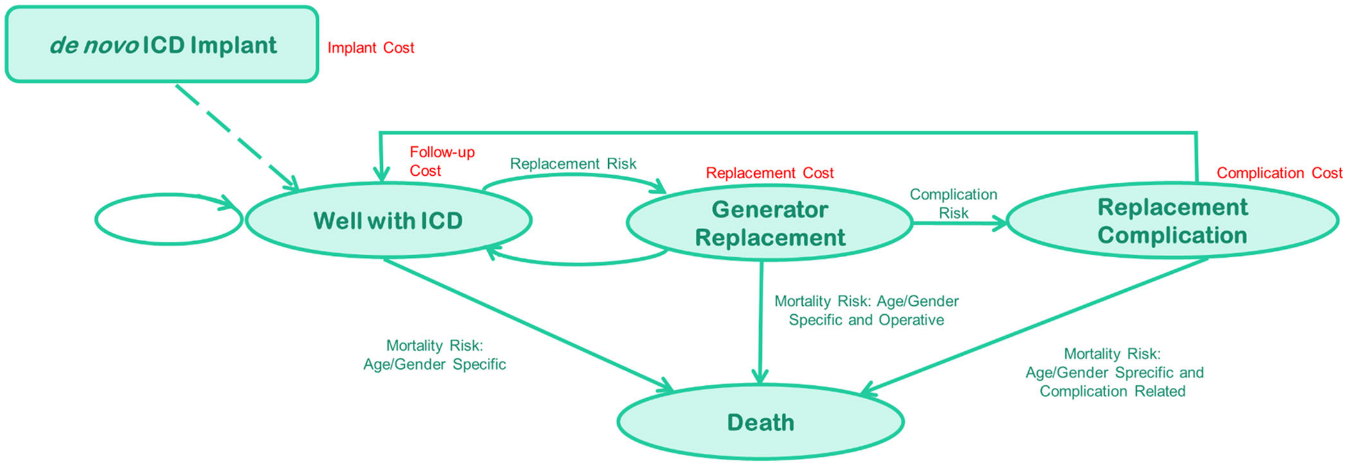

FIGURE 1 Markov model diagram. A Markov model showing the simulation of the time course of patients receiving an implantable cardioverter defibrillator (replicated for EV ICD and S-ICD). Model states are represented by ovals; arrows indicated transitions between states. EV ICD, extravascular implantable cardioverter defibrillator; S-ICD, subcutaneous-implantable cardioverter defibrillator.

TABLE 1 Common model input parameters.

Parameter	Base case value	Rationale
Age	52.5	Weighted average from published S-ICD trials
% Male	71	Weighted average from published S-ICD trials
Probabilities		
Mortality after replacement procedure (%)	0.02	NCDR Registry[8]
Complication after replacement procedure (%)	1.4	S-ICD complication rated after replacement surgery.[9]
Mortality after complication (%)	0.02	NCDR Registry[8]
Discount rate (%)	3	Standard economic assumption.
S-ICD average longevity (years)	7.3	S-ICD labeling.
EV ICD average longevity (years)	11.7	EV ICD labeling.

Abbreviations: EV ICD, extravascular implantable cardioverter defibrillator; NCDR, national cardiovascular data registry; S-ICD, subcutaneous-implantable cardioverter defibrillator.

available for the EV ICD (potential differences in cost between the systems are explored in the sensitivity analyses).

2.2 | United States

For the United States, age- and gender-specific background mortality rates were based on data from the Social Security Actuarial Life Table period 2019 (2022TR).[10] To represent a hospital cost perspective, the costs associated with S-ICD implant and replacement procedures were estimated from weighted average inpatient and outpatient historical costs in the Medicare 100% Fee for Service claims file. Since the cost of major complications is often driven by the cost of a replacement ICD system, they were estimated to be the cost of replacing the ICD system plus an additional 25% for labor and materials to treat the complication over and above the device replacement.

2.3 | France

For France, age- and gender-specific background mortality rates were based on data from the National Institute of Statistics and Economic Studies (INSEE) period 2019.[11] To represent a payer cost perspective, the costs associated with S-ICD and EV ICD implant and replacement procedures were estimated from weighted averages over S-ICD implant and ICD replacement procedures for 2021 in public hospitals, as recorded in the French national hospital discharge database (PMSI) and leveraging associated DRG tariffs. Since admissions for major complications related to ICD implants are often driven by the need to replace the ICD system, the cost of major complications was estimated to be similar to the cost of an admission for an ICD replacement.[12]

2.4 | Australia

For Australia, age and gender-specific background mortality rates were based on data from the Australian Bureau of Statistics Life Table period 2019–2021.[13] To represent a payer perspective, the costs associated with S-ICD and EV ICD implant and replacement procedures were estimated from Private Hospital Data Bureau

TABLE 2 Geography-specific model cost input parameters.

Parameter	US	France	Australia	Japan	South Korea
ICD implant	$31 600	€18 753	AUD 44 181	¥4 229 800	₩21 872 010
ICD replacement	$23 578	€16 120	AUD 37 379	¥3 450 100	₩16 710 000
Quarterly follow-up	$50	€111	AUD 124	¥30 000	₩60 000
Complication	$29 473	€16 120	AUD 37 379	¥3 450 100	₩16 710 000

Abbreviations: AUD, Australian Dollar; ICD, implantable cardioverter defibrillator; US, United States; $, USD; €, Euro; ¥, Yen; ₩, Won.

(PHDB) historical data for hospital and admission costs (Private Hospital Data Bureau: Annual Report 2020–2021 Table 7),[14] the current prostheses list reimbursement benefits for device costs,[15] and the Medicare Benefits schedule (MBS) for clinician fees (MBS items 38471 and 38472).[16]

2.5 | Japan

For Japan, age and gender-specific background mortality rates were based on data from the Life Table for Japan 2020 released by the Ministry of Health, Labor and Welfare.[17] To represent the payer perspective, the costs associated with S-ICD implant and replacement procedures were estimated based on (1) national medical fee service tariff and (2) diagnosis procedure combination/per-diem payment system. The cost of major complications was estimated to be the cost of replacing the ICD system as the cost of major complications is often driven by the cost of a replacement of the ICD system.

2.6 | South Korea

For South Korea, age and gender-specific background mortality rates were based on data from the Korean Statistical Information Service Life Table period 2021.[18] The costs associated with S-ICD implant and replacement procedures were identified from the NHIS (National Health Insurance System) database. Over 97% of the Korean population mandatorily subscribes to the NHIS, which is a single national insurer managed by the Korean government. The NHIS database is representative of the entire Korean population. Since the cost of major complications is often driven by the cost of a replacement ICD system, they were estimated to be the cost of replacing the ICD system plus an additional 25% for labor and materials to treat the complication over and above the device replacement.

2.7 | Model validation and statistical analysis

The model was validated by calculating the average device longevity predicted by the simulation and comparing it to the expected values for each device type. Deterministic model outputs are interpreted as mean values. A sensitivity analysis was performed for the US healthcare system as a series of one-way scenarios by individually varying model inputs to reasonable high and low values while holding all other inputs constant at the base case value. The inputs that were varied were age, gender, EV ICD implant cost, EV ICD replacement cost, EV ICD longevity, and S-ICD longevity. The input values for this sensitivity analysis are given in Supporting Information: Table S1. A value denoted as “high” is the high-end of the range for the variables and “low” is numerically lower than the base case value based on ranges for each parameter ascertained through the methods described above.

3 | RESULTS

The model started with an average age at de novo ICD implant of 52.5 years, with 71% male gender. Average modeled battery longevity was determined to be 7.3 years for the S-ICD versus 11.8 years for the EV ICD (Figure 2). The probability of a complication for both device types after a replacement procedure was 1.4%, with an operative mortality rate of 0.02%. The time horizon of the model was 30 years and costs were discounted at an annual rate of 3% to provide a net present value in 2022 currency.

3.1 | Base case analysis

The base case results for each country are shown in Table 3. The use of EV ICD was associated with 1.4–1.6 fewer replacement surgeries on average over an expected patient lifetime as compared to S-ICD. The use of EV ICD resulted in a 26.7%–29.8% reduction in costs, which represents a 24.3%–26.0% reduction when discounted into present value. The reduction in replacement surgeries and costs were similar in size and direction when simulated using mortality tables and costs associated with each additional country analyzed, with all countries experiencing at least a 25% reduction in discounted costs. Base case results are summarized in Table 3.

3.2 | Sensitivity analysis

Figure 3 shows a Tornado chart resulting from the one-way sensitivity analysis of the model for the US healthcare system. EV ICD resulted in a reduction in replacement surgeries of greater than 1

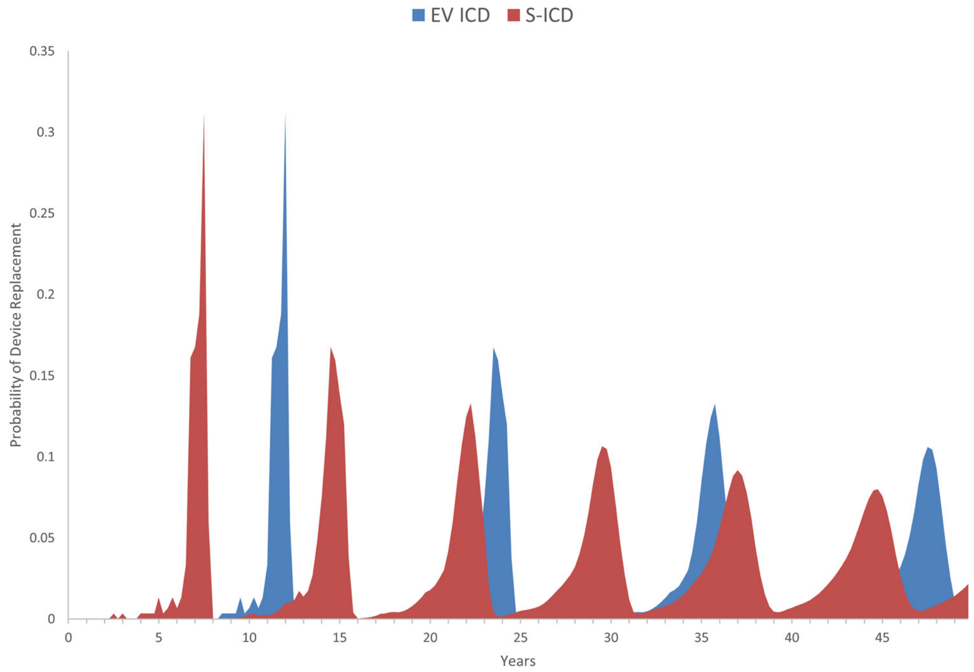

FIGURE 2 Replacement probability over time. The probability (*y*-axis) of having a device replacement is shown for EV ICD (blue) and S-ICD (red) patients over time in years (*x*-axis). Zero on the *x*-axis represents de novo device implant. The peaks represent the average time to replacement for each device. EV ICD, extravascular implantable cardioverter defibrillator; S-ICD, subcutaneous-implantable cardioverter defibrillator.

TABLE 3 Per-patient base case scenario results.

	US	France	Australia	Japan	South Korea
Replacement surgeries					
S-ICD	3.2	3.6	3.6	3.6	3.5
EV ICD	1.8	2.0	2.0	2.0	2.0
Difference	1.4	1.6	1.6	1.6	1.5
Undiscounted costs					
S-ICD	$112 990	€ 91 531	AUD 194 871	¥20 551 666	₩88 228 447
EV ICD	$79 341	€ 66 072	AUD 135 685	¥15 069 873	₩62 269 173
Difference	$33 649	€ 25 458	AUD 59 186	¥5 481 793	₩25 959 274
Discounted costs					
S-ICD	$80 546	€ 61 428	AUD 132 585	¥13 877 209	₩61 211 531
EV ICD	$59 207	€ 45 774	AUD 96 100	¥10 511 574	₩45 081 108
Difference	$21 339	€ 15 653	AUD 36 485	¥3 365 634	₩16 130 423

Abbreviations: AUD, Australian Dollar; EV ICD, extravascular implantable cardioverter defibrillator; S-ICD, subcutaneous-implantable cardioverter defibrillator; US, United States; $, USD; €, Euro; ¥, Yen; ₩, Won.

and five-figure cost savings in all scenarios. The difference in replacement surgeries varied between 1.1 and 1.6 procedures avoided, with the most variability caused by changes in patient age at implant and S-ICD longevity. The percentage difference in lifetime costs varied between $18 602 and $40 948 in cost avoidance, with the most variability associated with changes in the EV ICD implant/replacement costs and S-ICD longevity.

4 | DISCUSSION

The main findings of this study are that the use of an EV ICD could avoid an average of 1.4 replacement surgeries over the expected lifespan of a patient, potentially avoiding complications related to those surgeries and avoiding $33 649 in related lifetime costs as compared to the use of an S-ICD. This finding was based on

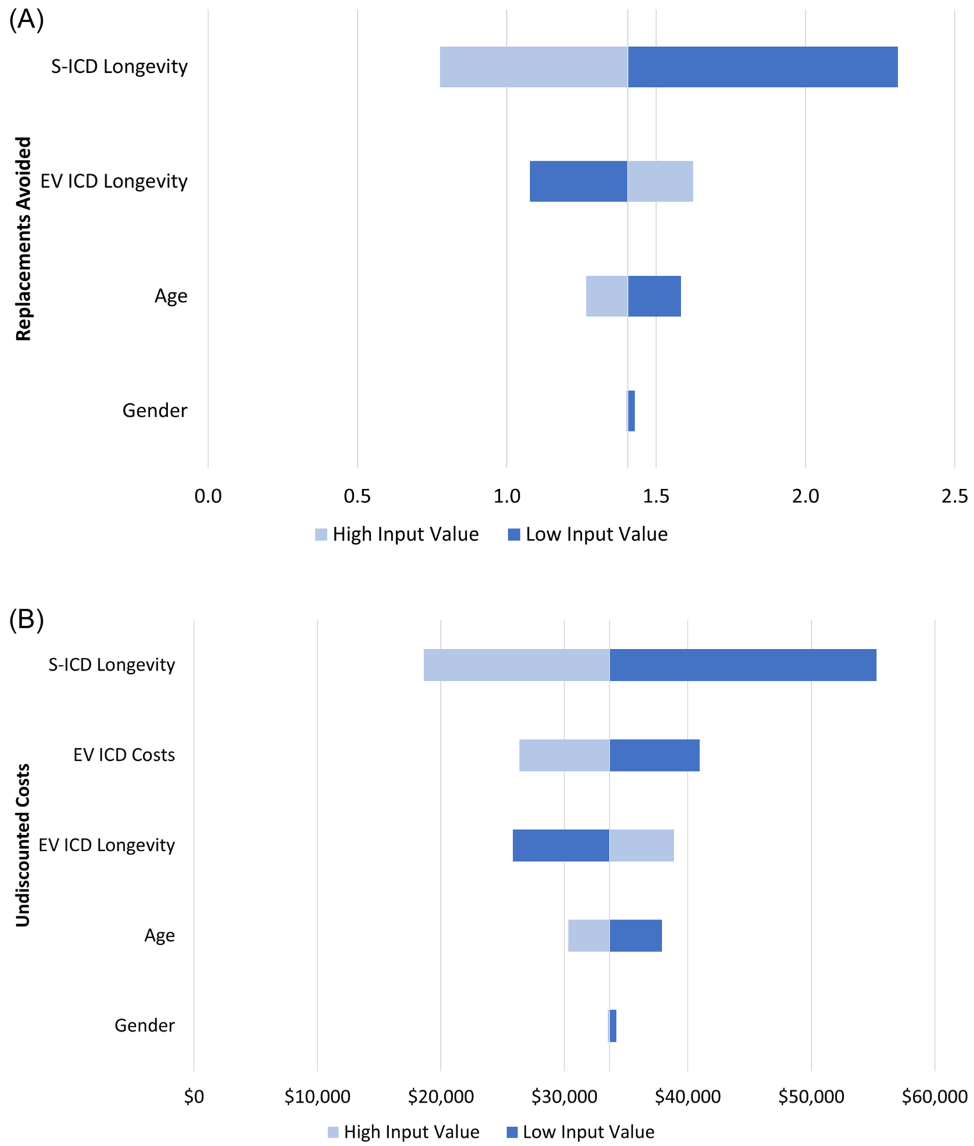

FIGURE 3 One way sensitivity analyses. A Tornado chart showing the one-way sensitivity analysis of the Markov model for total replacement surgeries (A) and undiscounted costs (B) in the United States healthcare system. Meaningful changes in replacements and cost savings persisted across all variations in model inputs.

real-world estimates of replacements costs specific to each healthcare system. These findings are robust, with similar results seen across four additional diverse healthcare systems in other countries and with substantial savings across all reasonable variations in model input parameters.

ICD longevity depends on many factors. There are factors that are more dependent on clinical circumstances than device choice such as pacing and sensing thresholds, impedance, telemetry use, and patient need for high-voltage therapy. There are other factors that are modifiable based on device choice, including impact of lead position (subcutaneous vs. substernal) on energy required for shocks and pacing therapy, ATP capability reducing the need for high energy therapy, capacitor efficiency, circuit efficiency, required frequency of capacitor maintenance, and overall battery capacity. The S-ICD has a larger device volume (60 cm^3) as compared to EV ICD (33 cm^3), likely driven by battery and capacitor volume differences. However, since the EV ICD has a lead positioned under the sternum and closer to the heart, the efficiency of therapy delivery enables lower energy shocks and the additional capability of ATP terminating some episodes without a shock, all contributing to extended projected device longevity.

Device longevity has been shown to bring important benefits to patients and healthcare systems across multiple dimensions. Prior modeling work has established that increased ICD longevity results in fewer adverse outcomes for patients and lower healthcare costs,[19] which corroborates the findings in the present study. An earlier modeling study done with prior generation transvenous ICDs found that extending device longevity from 5 to 9 years resulted in a savings of €10 927 over a 15-year time horizon from the perspective of an average hospital in Europe.[20] Increased longevity has also been shown to be a strongly influential factor when determining the cost effectiveness of ICD therapy.[21,22] The current study demonstrates even greater clinical and economic benefits for recipients of extravascular ICD systems, as patients who receive these devices are substantially younger.[5] at the time of implant as compared to recipients of transvenous ICD systems.

Countries with universal healthcare and a single national payer system can take a long-term view when it comes to the benefits of extended longevity, but in a fragmented healthcare system those benefits do not necessarily accrue to the same stakeholder who pays the initial cost. It will take a shift in perspective, such as that provided by incentives in proposed healthcare reform in the US to align the interests of payers and providers to encourage investments that have a longer time to payoff. To begin with, even though the time horizon for this study was 30 years, the first replacement surgery can be avoided after only 8 years when the first S-ICD devices are being replaced.

To further gain perspective on the value of extended longevity, a focus on patient experience can help. To begin with, the Porter model of value in health care states that "achieving high value *for patients* must become the overarching goal of health care delivery."[23] Avoiding surgeries has multiple benefits that specifically help patients, including avoidance of the natural discomfort of surgery, reduced exposure to adverse events, reduced out of pocket costs, and less time spent out of daily life in the health care system. A recent patient survey revealed that when given a choice, patients expressed a strong preference for extended device longevity over other meaningful improvements in device characteristics.[24]

4.1 | Limitations

This analysis was an average analysis based on engineering estimates and patient characteristics from clinical study publications, specific longevity experienced by individual patients may vary. Individual data on variability of S-ICD were not available, so variability of the EV ICD longevity was used to model it. Modeled longevity was projected over a long period of time which could be impacted by changes in technology; however, confidence can be placed at least in the benefits of the first device. This analysis does not account for device upgrades, but this is conservative since the EV ICD will not need upgrades to enable ATP while the rate of upgrades to cardiac resynchronization therapy (CRT) and pacing devices should be similar across device types. Longevity projections are based on device labeling rather than real-life experience; however, projections found in device labeling for prior generation devices have been corroborated in recent product performance reports.[25] This analysis does not explicitly account for system replacements due to lead failures, but this is not expected to be significantly different between the two systems. It is possible that there could be cost differences between the EV ICD and the S-ICD implant procedure or device specific complications. The sensitivity analysis explored that possibility and revealed that significant cost savings remain even assuming differential costs.

4.2 | Conclusion

When compared to the S-ICD, the additional projected battery longevity of the EV ICD creates the opportunity to avoid replacement surgeries over the lifetime of a typical ICD recipient even in the setting of competing risks for mortality. There are substantial cost savings associated with these clinical benefits that persist even when analyzed in the context of a diverse set of healthcare systems.

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DATA AVAILABILITY STATEMENT

The data that support the findings will be available following an embargo from the date of publication to allow for commercialization of research findings.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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