Abstract

Background: It is recommended that patients and clinicians discuss end-of-life deactivation of their implantable cardioverter defibrillator (ICD) prior to device implantation and throughout the illness trajectory to facilitate shared decision-making. However, such discussions rarely occur, and little is known about patients' openness to this discussion.

Aims: The purpose of this study was to explore factors associated with patients' openness to discussing end-of-life ICD deactivation with clinicians.

Methods: This cross-sectional study recruited 293 patients with an ICD from outpatient clinics in the United States, Australia, and South Korea. Patients were classified into an open or resistant group based on their desire to discuss device deactivation at end of life with clinicians. Multivariable logistic regression was used to explore factors related to patients' openness to this discussion.

Results: About half of the participants (57.7%) were open to discussing such issues with their clinicians. Factors related to patients' openness to discussing device deactivation at end of life were living with someone, not having severe comorbid conditions (cancer and/or chronic kidney disease), greater ICD knowledge, and more experience discussing end-of-life issues with clinicians (Odds ratio: 0.479, 0.382, 1.172, 1.332, respectively).

Conclusion: Approximately half of the ICD recipients were reluctant to discuss device deactivation at end of life with clinicians. Unmodifiable factors were their living arrangement and severe comorbidity. ICD knowledge and prior experience discussing end-of-life issues were potentially modifiable factors in the future. These factors should be addressed when assessing patients' readiness for a shared discussion about device

deactivation at end of life.

Keywords:

Implantable cardioverter defibrillators, shared decision-making, patient preference, cross-sectional studies

Introduction

An implantable cardioverter defibrillator (ICD) is an effective therapy for treating life-threatening ventricular arrhythmia. An ICD continuously monitors patients' heart rhythms and delivers shocks when they experience lethal arrhythmias.[1] The implantation rate of ICDs has increased due to technological advances and clinical success,[2, 3] causing the mean age of the population and risk of greater comorbidity to also increase.[2, 4]

As a patient's illness deteriorates, physiological changes can lead to more arrhythmias, causing more frequent shocks.[5, 6] Westerdahl et al.[6] found that 32% of ICD recipients experienced ICD shocks in their last day of life and 10% of these patients received inappropriate shocks due to supraventricular tachycardia or over-sensing of the ICD. Shocks, especially inappropriate shocks, experienced during the dying process can cause distress for patients and their families.[7, 8] Thus, ICD deactivation can be a moral option for a more dignified death for terminally ill patients if it is consistent with the patient's wishes.[9-11] The European Society of Cardiology and the American Heart Association recommends that ICD deactivation at end of life be considered for terminally ill patients.[1, 7] To support this recommendation, experts recommend that clinicians and patients should have discussions about ICD deactivation at end of life before implanting the device and throughout the illness trajectory using a shared decision-making approach.[1, 7]

Shared decision-making is the responsibility of both the patient and the clinician,[12] making the patient an equal partner with the clinician. While clinicians have the responsibility to offer reasonable treatment options, patients have the responsibility

to articulate the goals and values of their treatment.[12] However, in reality, shared decision-making regarding ICD deactivation at end of life is relatively rare in clinical practice.[13-17] Although some patients are reluctant to discuss ICD deactivation at end of life,[18, 19] many studies examining discussions between the two parties focus on the clinician's perspective.[20-22] In addition, clinicians are usually asked to modify their orientation in forming a partnership with the patient.[10, 23]

Although insights on what patient-related factors are associated with ICD recipients' openness to end-of-life discussions can promote patient participation in future discussions, few quantitative studies have explored what patient-related factors are associated with how patients perceive discussions about end-of-life decisions. In addition, these studies have mostly focused on non-modifiable factors (e.g., a clinical variable).[24] Thus, to facilitate shared decision-making between patients and clinicians, it is important to explore patient-related factors in a comprehensive manner including modifiable factors.

In our previous study, ICD recipients' knowledge about ICD and their willingness to discuss ICD deactivation was examined using a sample from the United States and Australia.[25] Although the study found that insufficient ICD knowledge was associated with negative attitudes about discussing ICD deactivation, other related factors were not explored. The current study expands on our previous study by adding a Korean sample and exploring patient-related factors associated with recipients' openness to end-of-life discussions in a comprehensive manner. Thus, the purpose of this study was to explore patient-related factors associated with patients' openness to discussing ICD deactivation at end of life with clinicians in both a western and eastern context.

Methods

In this cross-sectional study, ICD recipients were recruited from cardiology clinics in tertiary hospitals including academic medical centers in the United States, Australia, and South Korea. Patients were eligible for this study if they had an ICD implanted for at least one year and had not been diagnosed with psychiatric diseases other than mood disorders. Patients were excluded if they were referred for heart transplantation, diagnosed with cognitive impairment, were institutionalized, or had a ventricular assist device (VAD).

Procedures

This study was approved by the Institutional Review Board in the United States (61699; 13.0666), Australia (215/15; 42-2015; 2015-165R), and South Korea (2-1046881-A-N-01-201412-HR-054). The investigation conforms with the principles outlined in the Declaration of Helsinki.

Data from three countries were concurrently collected between August 11, 2014 and September 1, 2016. Eligible patients were referred to the investigators by their clinicians. Patients provided signed, written, informed consent if they agreed to participate in this study after the research nurses explained the purpose and the detailed procedures of the study. Patients were also fully informed about their anonymity and given enough time to answer the questionnaire. After giving informed consent, the participants were given the option to take a copy of the questionnaire home to mail in after completing it at their leisure or to complete it during their clinical visit.

Over 90% of the participants agreed to take the questionnaire home and return by post; the response rate was 82.7%. Of 401 patients, 108 were excluded due to incomplete data on the questionnaires, leaving a sample size of 293. When comparing the demographic characteristics between patients who were included and excluded in this study, there were no significant differences regarding gender. However, the patients included in this study were younger than the excluded patients.

Measures

Before conducting the study in South Korea, measurements with no Korean-translated version with sound psychometric properties were translated using Brislin's standard for cross-cultural translation method (i.e., forward and backward translations, and expert panel review for conceptual and semantic equivalence).[26]

Outcome variables

Patients' openness to discussing ICD deactivation. Data on patients' openness to discussing ICD deactivation at end of life with their clinicians were collected using one item from the Experiences, Attitudes and Knowledge of End-of-Life Issues in Implantable Cardioverter Defibrillator Patients Questionnaire (EOL-ICDQ)[27]: "I do not wish to have a conversation about turning off defibrillating shocks with my clinician." Response options to this item were "agree" or "disagree." Patients who answered "agree" were grouped into the "resistant to discussion group" (i.e., resistant group) and those who answered "disagree" were grouped into the "open to discussion group" (i.e., open group).

Variables related to the outcome variable

Factors related to patients' desire to discuss ICD deactivation at end of life (i.e.,

general experience related to ICD, ICD knowledge, prior experience of discussing end-of-life issues with clinicians, depressive symptoms, concerns related to ICD) were identified in accordance with previous studies.[15, 18, 19, 24, 25, 28, 29]

General experience related to ICD treatment. Patients' general experience related to ICD treatment was measured with one item ("In general, how would you describe your experience with your ICD?"), which was rated on a 4-point Likert scale (1=very bad, 4=very good).

ICD knowledge. The patients' knowledge regarding ICD treatment was evaluated using the knowledge subscale of the EOL-ICDQ.[27] This subscale has 11 statements about the functions of ICD, practical consequences and ethical aspects of ICD related to end of life. Patients answered each statement with "True, False, or Don't know." Each correct response received a score of 1 and each incorrect response, along with a "Don't know" response, received a score of 0. The total scores ranged from 0 to 11. The Korean version was translated for this study, and the internal consistency of the Korean version in this study was 0.69.

Prior experience discussing end-of-life issues with clinicians. Patients were asked whether they had ever discussed an end-of-life topic with their clinicians, using three items of the EOL-ICD Questionnaire.[27] End-of-life issues included replacing the ICD battery, ICD deactivation, and the illness trajectory of their cardiac condition. Each item had a binary response (0=no, 1=yes) and the total score was the sum of the three items, which indicated the number of end-of-life issues discussed with clinicians.

Depressive symptoms. Depressive symptoms were measured with the 9-item Patient Health Questionnaire-9 (PHQ-9).[30] Patients were asked how often they

experienced a particular depressive symptom over the past 2 weeks. The symptoms in the questionnaire were consistent with the symptoms of major depressive disorders according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition.[30] Each item was rated on a 4-point Likert scale (0=not at all, 3=nearly every day). The total scores, ranging from 0 to 27, were the sum the items. A score of 10 is used as a clinical cut-off score for clinically significant depressive symptoms.[31] For Korean patients, the Korean version of the PHQ-9 was used. The Korean version was translated and validated in a previous study.[32]

Concerns related to ICD. The 8-item version of the ICD-related Concerns Questionnaire (ICDC) was used to measure concerns related to ICD.[33] The ICDC asked patients how much they worried about the ICD firing. Each item was rated on a 5-point Likert scale (0=not at all, 4= very much) and the total scores were the sum of the items, ranging from 0 to 32. Higher scores indicated greater concerns related to ICD. The Korean version was translated for this study, and Cronbach's alpha of the Korean version in this study was 0.94.

Demographic and clinical information. Demographic (e.g., age, gender, education years, living arrangement, country of origin) and clinical information (e.g., years since implantation, number of shocks experienced, comorbid conditions) were obtained by participants' self-report. Comorbid conditions were assessed by asking patients to list the diseases they had. Among the list of diseases that patients reported, conditions were considered to be severe if the weight of the conditions were two or higher in the Charlson comorbidity index, which is a common instrument to measure comorbidity burden. The patients in our sample only reported chronic kidney disease and

cancer regardless of metastasis as severe comorbid conditions, based on the Charlson comorbidity index. Thus, in this study, patients with chronic kidney disease and/or cancer regardless of metastasis were defined as having severe comorbid conditions. Patients with no severe comorbid conditions were defined as patients who had conditions other than chronic kidney disease and/or cancer or those who had no chronic conditions.

Data Analyses

Data were analyzed using IBM SPSS 20.0 (Chicago, IL USA) and the a priori statistically significant level was set at a p-value of less than 0.05. The demographic, clinical, and ICD-related characteristics were compared based on patients' willingness to discuss ICD deactivation at end of life (open group vs. resistant group) using a chi-square test or two-tailed independent *t* test, as appropriate. A multivariable logistic regression analysis was used to explore factors associated with patients' openness to discussing ICD deactivation at end of life. Factors included in the model were the participant's age, gender, education level, living arrangement, country of origin, severe comorbidity, time since implantation, ICD shock experience, general ICD experience, ICD knowledge, prior experience discussing end-of-life issues with clinicians, depressive symptoms, and concerns related to ICD.

Results

Sample Characteristics

The mean age of the 293 ICD recipients was 59 (SD 14.0), with a range of 20 to 88, and 39.2% (115/293) were 65 years old or older (Table 1). The majority of the sample

were male with an education level of high school or higher. Overall, 68.6% (n=201) of the participants were from western countries, with 54.3% (n=159) from the United States. and 14.3% (n=42) from Australia. The remaining 31.4% (n=92) were from South Korea. The most common disease conditions reported by patients were heart failure (57.7%), followed by atrial fibrillation (40.3%), and myocardial infarction (25.3%). The percentage of the patients who reported having chronic kidney disease and cancer regardless of metastasis were 13.7% and 7.5%, respectively.

Time since first ICD implantation ranged from 3 to 28 years, with an average time since first implantation of 10.1 years (SD 4.0), and since implantation, most participants had never received an ICD shock. The mean score of knowledge was 5.7 (SD 2.9). Although 59.4% (n=174) correctly answered that ICD deactivation was not the same as active euthanasia, only 33.4% (n=98) correctly knew that ICD does not always deliver shocks in the last moment of life. A total of 21.5% (n=63) participants had PHQ-9 scores of 10 or above, indicating clinically significant depressive symptoms. Approximately 23.5% (n=69) had no prior experience discussing end-of-life issues with their clinicians.

Comparison between resistant and open groups

Of the 293 participants, 57.7% (n=169) were open to discussing ICD deactivation at end of life with their clinicians (Table 1). Patients in the open group were more likely to live with someone (p=0.045), have no severe comorbidities (p=0.003), report worse experiences related to ICD treatment in general (p=0.018), and have more knowledge about the device (p=0.015). Although the open group was more likely to correctly believe that ICD deactivation is not the same as active euthanasia (p=0.020), both groups falsely believed that ICD always delivered shocks at end of life (p=0.712).

Factors associated with openness to discussing ICD deactivation

A logistic regression model with 13 variables was tested to determine the factors associated with patients' openness to discussing ICD deactivation at end of life (Table 2). Living alone (p=0.031), having severe comorbidity (p=0.004), greater ICD knowledge (p=0.003), and prior experience discussing end-of-life issues with clinicians (p=0.038) significantly contributed to the patients' openness to discussing ICD deactivation at end of life. More specifically, patients were more willing to discuss this issue if they were not living alone (OR=0.479, 95% CI=0.245-0.936), had no severe comorbidity (OR=0.382, 95% CI=0.198-0.738), had greater ICD knowledge (OR=1.172, 95% CI=1.057-1.299), and had more experience discussing end-of-life issues with their clinicians (OR=1.332, 95% CI=1.016-1.747).

Discussion

Before implanting an ICD and throughout the illness trajectory, it is recommended that clinicians discuss ICD deactivation at end of life with their patients using a shared decision-making approach.[1, 7] However, our study with a multinational sample of ICD recipients showed that roughly half of the patients across three countries were unwilling to discuss this issue, which was a higher proportion than in previous studies.[24, 34] However, studies demonstrating patients' greater desire to discuss ICD deactivation at end of life[24, 34] were published shortly after medical experts started to recommend such discussions early and throughout the illness trajectory.[35, 36] Our findings indicate that patients' openness to discussing sensitive end-of-life issues has not improved since this initial recommendation, which may imply that shared decision-making

regarding this end-of-life issue has not become a common practice in clinical settings.

A previous study using the United States and Australian subsamples demonstrated that insufficient ICD knowledge was associated with ICD recipients' unwillingness to discuss ICD deactivation at end of life.[25] Expanding on the previous study by including a Korean sample, we found that several factors were associated with recipients' openness including ICD knowledge, prior experience discussing end-of-life issues with clinicians, living arrangement, and severe comorbid conditions. Interestingly, country of origin was not a significant factor related to patients' openness.

Consistent with the findings of Hadler et al.,[37] patients who were reluctant to discuss device deactivation at end of life had poor ICD knowledge. For example, participants in the resistant group were more likely to incorrectly believe that ICD deactivation is the same as active euthanasia, suggesting that misconceptions can make patients unnecessarily fearful about ICD deactivation and thus discourage them from discussing ICD end-of-life issues with their clinician. Previous studies have also demonstrated that ICD recipients generally reported having strong faith in the device.[18, 38, 39] If a patient is overly reliant on the device without fully understanding its limitation, being reluctant to talk about ICD deactivation at end of life may be an act of denial or avoidance rather than a rational and fully informed decision. Therefore, properly addressing the benefits and risks of ICD deactivation is vital to prevent patients from making decisions they would not have preferred if they were well-informed beforehand.

Our findings also demonstrate that the more patients and clinicians discussed various end-of-life issues regarding ICD in the past, the more likely the patients were to be open to discussing device deactivation at end of life in the future. Swenson et al. also

found that patients with clinicians who acknowledged patients' importance in the decision-making process were more likely to prefer shared decision-making.[40] Although it is unknown whether our participants and their clinicians used a shared decision-making approach when discussing end-of-life issues, our findings and those of Swenson et al.[40] support the importance of empowering patients to participate in discussions regarding their treatment including end-of-life ICD deactivation. In addition, because end-of-life issues can be very challenging for both parties, forming a trusting patient-clinician relationship is extremely important. Trusting relationships require time and effort, and experience with shared discussions can act as a steppingstone for patients wanting to engage in future end-of-life discussions with their clinicians.

Severe comorbid conditions (i.e., chronic kidney disease and cancer in the current sample) were also a notable factor associated with patients' openness to discussing end-of-life issues. Patients with severe comorbidity tend to have worse health outcomes;[41] thus, they may be more likely to actively engage in end-of-life discussions. However, our results suggest otherwise, implying that these patients would rather depend on the clinicians' judgement. During regular, general practice appointments, patients with multiple chronic conditions have limited time with clinicians to address multiple topics,[41] which may create an unfriendly clinical environment for shared discussions regarding sensitive end-of-life issues. The rushed environment may discourage patients from asking questions, thus making them rely on the clinicians' professional judgement. Our counter-intuitive result may be also be related to our sample. The sample of this study reported having only chronic kidney disease or cancer among the conditions whose weights were 2 or higher in the Charlson Comorbidity Index (e.g. hemiplegia, AIDS), which indicates that our sample was likely to experience less burden from their comorbidity. Thus, our

results should be interpreted with caution and warrant further investigation.

Patients who were reluctant to discuss ICD deactivation were more likely to live alone, which is a common indicator of social isolation.[42] In contrast, people who live with someone tend to have more opportunities to discuss their illness treatment with others. Social isolation is known to be linked to a sense of existential loneliness, which can make them feel alienated and unable to communicate with others, possibly including their clinicians.[43] This alienation can be a barrier for discussing sensitive end-of-life issues.

Previous studies have shown that ICD shocks have had a mixed impact on patients' desire to discuss ICD deactivation at end of life. While some patients consider discussing deactivating the ICD at end of life due to the expected or experienced pain of ICD shocks,[18, 44] the thought of avoiding a sudden death may make others not want to engage in such discussions.[15, 18] However, in our study, previous ICD shock experience was not a significant predictor of a recipient's openness to discussion. This might be because most of our sample had not experienced ICD shocks and generally had few concerns about ICD shocks. While experiencing ICD shocks can create teachable moments to better understand the device and the nature of deactivation at end of life,[19] this finding demonstrates that not all recipients experience shocks. Hence, ICD deactivation at end of life should not be viewed as an option for only those who find the shock therapy too painful, but rather as an option for all ICD recipients who wish to pursue a more dignified death.

A key question is when patients should begin to have discussions about ICD deactivation at end of life. Unlike feeding tubes and ventilators, ICDs are often implanted before patients perceive that their health is deteriorating.[5] Thus, early discussions

regarding ICD deactivation at end of life may be difficult. In addition, while experts recommend that such discussions should begin prior to ICD implantation,[1, 7] patients' openness to discussion while waiting for ICD implantation was not explored in this study or in previous studies. Although such discussions may be difficult to initiate and patients' readiness to discuss ICD deactivation at end of life should be respected, postponing such conversations may leave patients in their last phase of life with little time to rationally contemplate their decision.[18] In a study by Petersen and colleagues,[11] after reading a vignette including a description of the pros and cons of ICD deactivation at end of life and information that turning off the device at end of life is possible, 49% of the ICD recipients expressed a desire for physicians to discuss device deactivation with them before implantation. Therefore, clinicians should encourage patients to at least think about such topics throughout their illness trajectory, as recommended.[1, 7] Exploring factors associated with openness of not only ICD recipients but also ICD candidates may help meet medical experts' recommendations.

Another key question is who will facilitate an end-of-life discussion between the patient and the clinician. Although such discussion can be challenging to initiate,[13-17] a clear solution has not been proposed. Implementing care managers may provide a potential breakthrough. Care managers in practice teams are directly involved in patient care by providing patient education and empowering patients' self-management.[45, 46] Their main role is to identify what the patients need or want regarding their treatment, and coordinate care across clinicians and clinical settings.[45, 46] By assessing the patients' needs regarding end-of-life care, care managers can communicate information across clinicians and may play a role in facilitating discussions regarding ICD deactivation at end of life. Future studies are needed to investigate the effect of care managers on

facilitating end-of-life discussions between patients and clinicians.

Limitations of the study

The strength of this study is that it provides insights about ICD recipients' openness to end-of-life discussions across three diverse countries, including both eastern and western countries. However, this study also has several limitations. First, a comparison between eastern and western countries was not conducted due to the small sample size of the eastern country. Interestingly, the proportion between the open group and the resistant group was not significantly different between the eastern and western countries. Second, our sample may not be representative of all ICD recipients because most patients in this study were under 65 years old and had not received shocks. In addition, about 30% of the patients who were given the questionnaires were excluded in our study due to incomplete data. Some of them may not have wanted to express their opinion or preference regarding end-of-life discussions. Third, data were collected based on patients' self-reports, which may introduce recall bias (e.g., time since ICD implantation) and social desirability (e.g., depressive symptoms). However, we provided adequate time for patients to carefully complete the questionnaire and asked patients to answer each question honestly based on their own perspective. Fourth, comorbid conditions were also measured based on self-report. This information may be different from their medical records because some patients may misunderstand their conditions (e.g., the perceptions of cure after acute treatment).[47] In addition, this study did not include items asking about patients' pharmacological backgrounds. Further studies demonstrating patients' pharmacological backgrounds and the impact on their openness

would help provide clues to address challenges related to end-of-life discussions. Finally, this study did not include patients awaiting ICD implantation.

Conclusion

Although experts have recommended that ICD deactivation at end of life be a regular topic of discussion, many patients are still unwilling to discuss this topic. We found that approximately half of the ICD recipients were not open to discussing such issues with their clinicians. Unmodifiable factors were their living arrangement and severe comorbidity, while ICD knowledge and prior experience discussing end-of-life issues with clinicians were potentially modifiable factors in the future. Addressing these factors can help promote shared decision-making regarding ICD deactivation at end of life.

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Declaration of conflict of interest

The authors declare that there is no conflict of interest.

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Table 1 Sample Characteristics (N=293)

	Total (N=293)	Resistant group (N=124)	Open group (N=169)	P-Value
Age (years)	59.0 (14.0)	59.9 (13.4)	58.4 (14.4)	0.352
Female	66 (22.5%)	26 (21.0%)	40 (23.7%)	0.585
≥High school education	217 (74.1%)	92 (74.2%)	125 (74.0%)	0.965
Living alone	51 (17.4%)	28 (22.6%)	23 (13.6%)	0.045
Country of origin				0.131
Western	201 (68.6%)	91 (73.4%)	110 (65.1%)	
Eastern	92 (31.4%)	33 (26.6%)	59 (34.9%)	
Severe comorbidity	55 (18.8%)	33 (26.6%)	22 (13.0%)	0.003
ICD-related characteristics				
Time since implantation (years)	10.1 (4.0)	10.5 (4.0)	9.9 (4.1)	0.160
ICD shock experience				0.586
No	179 (61.1%)	78 (62.9%)	101 (59.8%)	
Yes	114 (38.9%)	46 (37.1%)	68 (40.2%)	
General experience with ICD	3.3 (0.8)	3.5 (0.8)	3.2 (0.8)	0.018
Knowledge of ICD	5.7 (2.9)	5.3 (2.9)	6.1 (2.7)	0.015
Prior experience	1.4 (1.0)	1.3 (1.0)	1.5 (1.0)	0.129

discussing end-of-life				
issues with a clinician				
Psychological measures				
Depressive symptoms	5.6 (5.6)	5.7 (5.4)	5.5 (5.7)	0.831
Concerns related to ICD	7.8 (7.7)	7.1 (7.4)	8.3 (7.8)	0.160

Note. Values are mean (standard deviation) or n (%). ICD = implantable cardioverter defibrillator

Severe comorbidities include end-stage renal disease and cancer

Western = United States, Australia

Eastern = South Korea

Table 2 Predictors of openness to discussing ICD deactivation at end of life (N=293)

	Odds Ratio	P value	95% confidence interval
Age	1.020	0.069	0.998-1.042
Female	1.090	0.781	0.594-2.002
≥High school education	0.865	0.633	0.478-1.567
Living alone	0.479	0.031	0.245-0.936
Eastern vs Western	1.235	0.561	0.606-2.514
Severe comorbidity	0.382	0.004	0.198-0.738
Time since implantation	0.933	0.063	0.868-1.004
Experienced ICD shocks	0.833	0.520	0.477-1.454
General experience with ICD	0.746	0.117	0.518-1.076
ICD knowledge	1.172	0.003	1.057-1.299
Prior experience discussing end-of-life issues with a clinician	1.332	0.038	1.016-1.747
Depressive symptoms	0.998	0.924	0.950-1.047
Concerns related to ICD	1.023	0.239	0.985-1.062

Note. ICD = implantable cardioverter defibrillator

Western = United States, Australia

Eastern = South Korea

Response to reviewers

Dear reviewers of the European Journal of Cardiovascular Nursing,

We are pleased to submit an original research article (CNU-D-21-00209) entitled “Patients' openness to discussing implantable cardioverter defibrillator deactivation at end of life: A cross-sectional study” It is our pleasure to have it reviewed and receive comments from the European Journal of Cardiovascular Nursing reviewers. We have revised the manuscript according to the reviewers’ suggestions and comments. Please refer to the table below for detailed descriptions of the revision made and page numbers accordingly. All revisions are highlighted in both the revision table and revised manuscript as instructed.

Thank you for your time and consideration.

<Revision table>

<table>
<tr><th>Reviewer</th><th>Reviewer’s comments</th><th colspan="2">Descriptions of the revisions made</th><th>Page #</th></tr>
<tr><td rowspan="4">#1</td><td rowspan="3">1)The use of a questionnaire can be considered as a limitation of the study. This should be discussed in a dedicated limitation section.</td><td colspan="2">Thank you for your comment. Previous studies demonstrating patients' openness to discussing ICD deactivation at end-of-life have been mostly qualitative studies. Although qualitative studies help us understand the phenomenon in depth, quantitative studies are needed to demonstrate results that can be generalized to the population of interest. This study is a quantitative study. To assess the participants' openness to ICD deactivation discussion in end-of-life and its related variables, we believe that using questionnaires is appropriate. The instruments used in this study have been supported in previous studies for their good psychometric properties. However, we acknowledge the limitations of using questionnaires (e.g., social desirability and recall bias) and added this information in our limitation section.</td><td rowspan="3">Page 16</td></tr>
<tr><td>Before revision</td><td>After revision</td></tr>
<tr><td>Furthermore, clinical variables (e.g., number of ICD shocks) were collected based on patients’ self-reports, which might not be accurate.</td><td>Third, data were collected based on patients’ self-reports, which may introduce recall bias (e.g., time since ICD implantation) and social desirability (e.g., depressive symptoms). However, we provided adequate time for patients to carefully complete the questionnaire and asked patients to answer each question honestly based on their own perspective.</td></tr>
<tr><td>2) The authors should better describe the comorbidities of the patients.</td><td colspan="2">We apologize for the confusion and unclear description regarding comorbidities. We have added more details in the method section regarding how we measured the participants’</td><td>[1]</td></tr>
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<td></td>
<td>Comorbidities can negatively impact on the aims of the research and should be included in the final regression model</td>
<td colspan="2">comorbidities and what they reported.

In addition, the participants' severe comorbidities were included in the original regression model. We have clearly stated which variables were included in the regression model to improve the clarity.

Before revision

[1] Patients were categorized as having serious comorbid conditions if they had at least one of the following conditions: cancer, chronic kidney disease, hemiplegia, diabetes with complications, severe liver disease, or AIDS. These diseases were selected because they score two or higher on the Charlson Comorbidity Index.

[2] A multivariable logistic regression analysis was used to explore factors associated with patients' openness to discussing ICD deactivation at end of life.

After revision

[1] Comorbid conditions were assessed by asking patients to list the diseases they had. Among the list of diseases that patients reported, conditions were considered to be severe if the weight of the conditions were two or higher in the Charlson comorbidity index, which is a common instrument to measure comorbidity burden. The patients in our sample only reported chronic kidney disease and cancer regardless of metastasis as severe comorbid conditions, based on the Charlson comorbidity index. Thus, in this study, patients with chronic kidney disease and/or cancer regardless of metastasis were defined as having severe comorbid conditions. Patients with no severe comorbid conditions were defined as patients who had conditions other than chronic kidney disease and/or cancer or those who had no chronic conditions.

[2] A multivariable logistic regression analysis was used to explore factors associated with patients' openness to discussing ICD deactivation at end of life. Factors included in the model were the participant's age, gender, education level, living arrangement, country of origin, severe</td>
<td>Page 8-9

[2]

Page 9</td>
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			comorbidity, time since implantation, ICD shock experience, general ICD experience, ICD knowledge, prior experience discussing end-of-life issues with clinicians, depressive symptoms, and concerns related to ICD.	
	3) Same considerations are for the pharmacological background of the patients. Numbers of drugs, types, etc can really impact on the mood of the patients and their willingness. Please discuss such a point.	Thank you for your comment. We acknowledge that the pharmacological backgrounds of the patients can be associated with the patients' willingness to engage in end-of-life discussions. However, to the best of our knowledge, we have not found previous research exploring the relationship between patients' medications and their willingness to discuss end-of-life issues based on our literature research conducted before this study. As a result, items inquiring about the patients' medication background were not included in this study's questionnaires. We added this in our limitation.		Page 17
		Before revision	**After revision**	
			In addition, this study did not include items asking about patients' pharmacological backgrounds. Further studies demonstrating patients' pharmacological backgrounds and the impact on their openness would help provide clues to address challenges related to end-of-life discussions.	
	4) What about the role of care manager in such a context? The care manager might positively influence the willingness of the patients. Please discuss such a point in relation to the paper from Ciccone MM et al. Vasc Health Risk Manag. 2010 May 6;6:297-305.	Thank you for your comment and providing a reference article. We have added some discussion in the last paragraph of the discussion section regarding how care managers can be implemented to achieve patient-centered end-of-life care.		Page 15-16
		Before revision	After revision	
			Another key question is who will facilitate an end-of-life discussion between the patient and the clinician. Although such discussion can be challenging to initiate,[13-17] a clear solution has not been proposed. Implementing care managers may provide a potential breakthrough. Care managers in practice	

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<tr><td></td><td></td><td></td><td>teams are directly involved in patient care by providing patient education and empowering patients' self-management.[45, 46] Their main role is to identify what the patients need or want regarding their treatment, and coordinate care across clinicians and clinical settings.[45, 46] By assessing the patients' needs regarding end-of-life care, care managers can communicate information across clinicians and may play a role in facilitating discussions regarding ICD deactivation at end of life. Future studies are needed to investigate the effect of care managers on facilitating end-of-life discussions between patients and clinicians.</td><td></td></tr>
<tr><td># 2</td><td>1) Many thanks for submitting this interesting and well-written manuscript. It classifies the influencing factors towards patients' willingness to discuss deactivation into modifiable and non-modifiable, determining relevant implications for practice. The study was familiar, which was confirmed during the introduction & discussion sections with reference to the study published in Palliative Medicine (2018).

It would be appropriate to make clear reference within methods section in terms of data collection concurrently or sequentially.</td><td colspan="2">Thank you for your comment. We have revised the methods section based on your suggestion. Although data from the three countries were collected concurrently, the data of the South Korea cohort was later combined with the data of the United States and Australia cohorts. We have also revised the last paragraph of the introduction to clarify this point.

Before revision

[1] McEvedy et al. examined the relationship between U.S. and Australian ICD recipients' knowledge about ICD and their willingness to discuss ICD deactivation.[24] Although the study found that insufficient ICD knowledge was associated with negative attitudes about discussing ICD deactivation, other related factors were not explored. Our study expands on the previous study by adding a Korean sample and exploring patient-related factors associated with recipients' openness to end-of-life discussions in a comprehensive manner.

After revision

[1] In our previous study, ICD recipients' knowledge about ICD and their willingness to discuss ICD deactivation was examined using a sample from the United States and Australia.[25] Although the study found that insufficient ICD knowledge was associated with negative attitudes about discussing ICD deactivation, other related factors were not explored. The current study expands on our previous study by adding a Korean sample and exploring patient-related factors associated with recipients' openness to end-of-life discussions in a comprehensive manner.

[2] Data from three countries were</td><td>[1] page4

[2]

Page 5</td></tr>
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		[2] The patients' demographic and clinical information was collected by the research nurses between August 11, 2014 and September 1, 2016.	concurrently collected between August 11, 2014 and September 1, 2016.	
Additional comments	**Abstract**			
	2) Within results "Factors related to patients' openness to discussing device deactivation at end of life were greater ICD knowledge, less severe comorbid conditions"... with Conclusion being "Unmodifiable factors were their living arrangement and severe comorbidity". Please rephrase "less severe" as this is not clear... do they have something other than cancer, CKD, diabetes with complications etc.	We appreciate your careful review. We have revised the abstract to prevent confusion and further elaborated on how we defined patients with severe and less severe comorbid conditions in the method section.		Page 1
		Before revision	**After revision**	
		Factors related to patients' openness to discussing device deactivation at end of life were greater ICD knowledge, less severe comorbid conditions, more experience discussing end-of-life issues with clinicians, and living with someone (Odds ratio: 1.172, 0.382, 1.332, 0.479, respectively).	Factors related to patients' openness to discussing device deactivation at end of life were living with someone, not having severe comorbid conditions (cancer and/or chronic kidney disease), greater ICD knowledge, and more experience discussing end-of-life issues with clinicians (Odds ratio: 0.479, 0.382, 1.172, 1.332, respectively).	
	Introduction			
	3) You make the statement that "shared decision-making regarding ICD deactivation at end of life is relatively rare in clinical practice". Reference could be made to Eur J Cardiovasc Nurs. 2016 Feb;15(1):20-9 which further supports this findings .	Thank you for the comment and providing a reference article. We have revised the sentence based on your suggestion.		Page 4
		Before revision	**After revision**	
		However, in reality, shared decision-making regarding ICD deactivation at end of life is relatively rare in clinical practice.[13-16]	However, in reality, shared decision-making regarding ICD deactivation at end of life is relatively rare in clinical practice.[13-17]	
	Methods			
	4) Please provide detail of the sample population. How many patients were approached? What was the response	Thank you for your comment. We have added this information in the procedure section.		Page 5-6
		Before revision	**After revision**	

	rate? Where the hospitals tertiary (implanting centres) or local hospitals.	In this cross-sectional study, ICD recipients were recruited from outpatient clinics affiliated with academic medical centers in the United States, South Korea, and Australia. Patients were eligible for this study if they had an ICD implanted for at least one year and had not been diagnosed with psychiatric diseases other than mood disorders. Patients were excluded if they were referred for heart transplantation, diagnosed with cognitive impairment, were institutionalized, or had a ventricular assist device (VAD). **Procedures** This study was approved by the Institutional Review Board in Australia (215/15; 42-2015; 2015-165R), the United States (61699; 13.0666) and South Korea (2-1046881-A-N-01-201412-HR-054). Eligible patients were referred to the investigators by their clinicians. Patients provided signed, written, informed consent if they agreed to participate in this study after the research nurses explained the purpose and the detailed procedures of the study. Patients were also fully informed about their anonymity and given enough time to answer the questionnaire. The investigation conforms with the principles outlined in the Declaration of Helsinki. The patients' demographic and clinical information was collected by the research nurses between August 11, 2014 and September 1, 2016. A total of 293 patients completed the questionnaire packet during their clinic visits or mailed it to the investigator after completing it at home.	In this cross-sectional study, ICD recipients were recruited from cardiology clinics in tertiary hospitals including academic medical centers in the United States, Australia, and South Korea. Patients were eligible for this study if they had an ICD implanted for at least one year and had not been diagnosed with psychiatric diseases other than mood disorders. Patients were excluded if they were referred for heart transplantation, diagnosed with cognitive impairment, were institutionalized, or had a ventricular assist device (VAD). **Procedures** This study was approved by the Institutional Review Board in the United States (61699; 13.0666), Australia (215/15; 42-2015; 2015-165R), and South Korea (2-1046881-A-N-01-201412-HR-054). The investigation conforms with the principles outlined in the Declaration of Helsinki. Data from three countries were concurrently collected between August 11, 2014 and September 1, 2016. Eligible patients were referred to the investigators by their clinicians. Patients provided signed, written, informed consent if they agreed to participate in this study after the research nurses explained the purpose and the detailed procedures of the study. Patients were also fully informed about their anonymity and given enough time to answer the questionnaire. After giving informed consent,	

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Another limitation is that most patients in this study were under 65 years old, which is young for an ICD cohort and may not be representative of all ICD recipients.</td><td>the participants were given the option to take a copy of the questionnaire home to mail in after completing it at their leisure or to complete it during their clinical visit.

Over 90% of the participants agreed to take the questionnaire home and return by post; the response rate was 82.7%. Of 401 patients, 108 were excluded due to incomplete data on the questionnaires, leaving a sample size of 293. When comparing the demographic characteristics between patients who were included and excluded in this study, there were no significant differences regarding gender. However, the patients included in this study were younger than the excluded patients.</td><td></td></tr>
<tr><td></td><td rowspan="3">5) In addition please confirm if the questionnaires were translated for the Korean cohort and how was this completed? Please refer to Equator network for reporting guidance</td><td colspan="2">All measures except the PHQ-9 used for the Korean cohort were translated with the standard method for cross-cultural translation using the Brislin’s team approach (doi:10.1177/135910457000100301). Regarding PHQ-9, the Korean version were previously developed, and the reliability and validity were supported.</td><td rowspan="3">[1]

p. 6

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Page 7-8</td></tr>
<tr><td>Before revision</td><td>After revision</td></tr>
<tr><td>[2]

ICD knowledge. The patients’ knowledge regarding ICD treatment was evaluated using the knowledge subscale of the EOL-ICDQ.[25] This subscale has 11 statements about the functions of ICD, practical consequences and ethical aspects of ICD related to end of life. Patients answered each statement with ‘True, False, or Don’t know’. Each correct response received a score of 1 and each incorrect response, along with a ‘Don’t know’ response, received a score of 0. The total</td><td>[1]

Before conducting the study in South Korea, measurements with no Korean-translated version with sound psychometric properties were translated using Brislin’s standard for cross-cultural translation method (i.e., forward and backward translations, and expert panel review for conceptual and semantic equivalence).[26]</td></tr>
</table>

		scores ranged from 0 to 11. *Depressive symptoms.* Depressive symptoms were measured with the 9-item Patient Health Questionnaire-9 (PHQ-9).[28] Patients were asked how often they experienced a particular depressive symptom over the past 2 weeks. The symptoms in the questionnaire were consistent with the symptoms of major depressive disorders according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition.[28] Each item was rated on a 4-point Likert scale (0=not at all, 3=nearly every day). The total scores, ranging from 0 to 27, were the sum the items. A score of 10 is used as a clinical cut-off score for clinically significant depressive symptoms.[29] *Concerns related to ICD.* The 8-item version of the ICD-related Concerns Questionnaire (ICDC) was used to measure concerns related to ICD.[30] The ICDC asked patients how much they worried about the ICD firing. Each item was rated on a 5-point Likert scale (0=not at all, 4= very much) and the total scores were the sum of the items, ranging from 0 to 32. Higher scores indicated greater concerns related to ICD.	[2] ***ICD knowledge.*** The patients' knowledge regarding ICD treatment was evaluated using the knowledge subscale of the EOL-ICDQ.[27] This subscale has 11 statements about the functions of ICD, practical consequences and ethical aspects of ICD related to end of life. Patients answered each statement with "True, False, or Don't know." Each correct response received a score of 1 and each incorrect response, along with a "Don't know" response, received a score of 0. The total scores ranged from 0 to 11. The Korean version was translated for this study, and the internal consistency of the Korean version in this study was 0.69. ***Depressive symptoms***. Depressive symptoms were measured with the 9-item Patient Health Questionnaire-9 (PHQ-9).[30] Patients were asked how often they experienced a particular depressive symptom over the past 2 weeks. The symptoms in the questionnaire were consistent with the symptoms of major depressive disorders according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition.[30] Each item was rated on a 4-point Likert scale (0=not at all, 3=nearly every day). The total scores, ranging from 0 to 27, were the sum the items. A score of 10 is used as a clinical cut-off score for clinically significant depressive symptoms.[31] For Korean patients, the Korean version of the PHQ-9 was used. The Korean version was translated and validated in a previous study.[32] ***Concerns related to ICD.*** The 8-item version	

			of the ICD-related Concerns Questionnaire (ICDC) was used to measure concerns related to ICD.[33] The ICDC asked patients how much they worried about the ICD firing. Each item was rated on a 5-point Likert scale (0=not at all, 4= very much) and the total scores were the sum of the items, ranging from 0 to 32. Higher scores indicated greater concerns related to ICD. The Korean version was translated for this study, and Cronbach's alpha of the Korean version in this study was 0.94.	
	6) Page 6, it is noted "Several factors related to patients' desire to discuss ICD deactivation at end of life were identified from previous studies"- which factors and were they used to inform your data analysis? Please clarify	We are sorry for the confusion. All of the main variables (i.e., depressive symptoms, concerns related to ICD, ICD knowledge, general ICD experience, prior experience of discussing end-of-life issues with clinicians) were identified from previous studies. We have revised the manuscript to clarify this point.		Page 6-7
		Before revision	**After revision**	
		Several factors related to patients' desire to discuss ICD deactivation at end of life were identified referring to previous studies.[5, 15, 23, 26, 27]	Factors related to patients' desire to discuss ICD deactivation at end of life (i.e., General experience related to ICD, ICD knowledge, prior experience of discussing end-of-life issues with clinicians, depressive symptoms, concerns related to ICD) were identified in accordance with previous studies.[15, 18, 19, 24, 25, 28, 29]	
	7) Please update references as a number are outdated, such as reference 3, 5, 27, 29	Thank you for your thorough review. We have updated the references and deleted references that were outdated. However, a few early references were still considered due to their ongoing signficance. First, considering that the study conducted by Goldstein and colleagues (2008) was one of the early studies exploring ICD recipients' resistance to discussing ICD deactivation at end of life in depth, we did not delete this reference. In addition, a study conducted by Swenson et al. (2004) was also a signficant study providing insights regarding whether patients really prefered patient-centered care and shared decision-making. Finally, we did not delete references of studies that developed measurements used in this study (i.e., the development of PHQ-9 (DOI: 10.1046/j.1525-1497.2001.016009606.x.) and ICDC (DOI: 10.1348/135910705x52264).		Page 19-25

		Before revision	After revision	
		3. Goldberger Z and Lampert R. Implantable cardioverter-defibrillators: expanding indications and technologies. *Jama* 2006; 295: 809-818. 2006/02/16. DOI: 10.1001/jama.295.7.809. 29. Manea L, Gilbody S and McMillan D. Optimal cut-off score for diagnosing depression with the Patient Health Questionnaire (PHQ-9): a meta-analysis. *Cmaj* 2012; 184: E191-E196. DOI: 10.1503/cmaj.110829. 37. Keles H, Ekici A, Ekici M, et al. Effect of chronic diseases and associated psychological distress on health- related quality of life. Internal medicine journal 2007; 37: 6-11. DOI: 10.1111/j.1445-5994.2006.01215.x. 39. Fung CH, Setodji CM, Kung F-Y, et al. The relationship between multimorbidity and patients' ratings of communication. Journal of general internal medicine 2008; 23: 788-793. DOI: 10.1007/s11606-008-0602-4. 41. Sand L and Strang P. Existential loneliness in a palliative home care setting. J Palliat Med 2006; 9: 1376-1387. 2006/12/26. DOI: 10.1089/jpm.2006.9.1376.	3. Gadler F, Valzania C and Linde C. Current use of implantable electrical devices in Sweden: data from the Swedish pacemaker and implantable cardioverter-defibrillator registry. Europace 2015; 17: 69-77. 2014/10/23. DOI: 10.1093/europace/euu233. 5. MacIver J, Tibbles A, Billia F, et al. Patient perceptions of implantable cardioverter-defibrillator deactivation discussions: A qualitative study. SAGE Open Med 2016; 4: 2050312116642693. 2016/04/26. DOI: 10.1177/2050312116642693. 31. Moriarty AS, Gilbody S, McMillan D, et al. Screening and case finding for major depressive disorder using the Patient Health Questionnaire (PHQ-9): a meta-analysis. Gen Hosp Psychiatry 2015; 37: 567-576. 2015/07/22. DOI: 10.1016/j.genhosppsych.2015.06.012. 41. Sullivan MK, Rankin AJ, Jani BD, et al. Associations between multimorbidity and adverse clinical outcomes in patients with chronic kidney disease: a systematic review and meta-analysis. BMJ Open 2020; 10: e038401. 2020/07/02. DOI: 10.1136/bmjopen-2020-038401.	

<table>
<tr><td></td><td></td><td></td><td>43. Bolmsjö I, Tengland PA and Rämgård M. Existential loneliness: An attempt at an analysis of the concept and the phenomenon. Nurs Ethics 2019; 26: 1310-1325. 2018/02/24. DOI: 10.1177/0969733017748480.</td><td></td></tr>
<tr><td></td><td colspan="4">Results:</td></tr>
<tr><td></td><td>8) page 9- please clarify what is meant by "worse general ICD experience"

Also I am unsure what is meant by "had fewer severe comorbidity (OR=0.382, 95% CI=0.198-0.738)"? Does this mean cancer, compared to cancer and CKD? How many is fewer- 1 compared to 2 or 5 compared to 6... please provide details to improve understanding.</td><td colspan="2">We apologize for the confusion. First, regarding the participants' general ICD experience, we measured their general ICD experience using a 4-point Likert scale (1=very bad, 4=very good) and interpreted it as a continuous variable. Therefore, a higher score indicated having a better ICD experience in general. We revised the manuscript to avoid further confusion.

Second, regarding the participants' comorbidity, we provided more detail on how we defined patients with and without severe comorbid conditions in the method section (page 8-9). In short, patients with chronic kidney disease and/or cancer were considered to have severe comorbid conditions. (see our response to review #1's second comments)

Before revision | After revision

Patients in the open group were more likely to be living with someone (p=0.045), not having severe comorbidities (p=0.003), a worse general ICD experience (p=0.018), and more knowledge about the device (p=0.015). | Patients in the open group were more likely to live with someone (p=0.045), have no severe comorbidities (p=0.003), report worse experiences related to ICD treatment in general (p=0.018), and have more knowledge about the device (p=0.015).</td><td>Page 10</td></tr>
<tr><td></td><td>9) Acknowledgement place after conclusion</td><td colspan="2">Thank you for your comment. We have placed the acknowledgement after the conclusion based on your suggestion.</td><td>Page 18</td></tr>
</table>

Implication of practice

- We found that about half of the patients were open to discussing ICD deactivation at end-of-life.
- We found that patients' ICD understanding and prior experience with end-of-life discussions were significantly associated with their willingness to discuss ICD deactivation at end-of-life. Patients' living arrangement and severe comorbid conditions were also associated with their openness to discussing ICD deactivation at end-of-life.
- The results of the study affirm that analyzing these factors will provide guidance to promote end-of-life discussions.

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1-2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported3	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5-9
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-9
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	N/A
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	6
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9-10
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	8-10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-11

		(*b*) Report category boundaries when continuous variables were categorized	8-10
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11
Discussion			
Key results	18	Summarise key results with reference to study objectives	11-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.