Evidence report for implantable cardioverter defibrillator in non-ischemic cardiomyopathy

Prepared by EBSCO Information Services

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Content

Part 1 - Scoping

Methods

Using an established, structured template that delineates key elements for scoping (i.e., the population, interventions, and key outcomes to consider), we collaboratively agreed with UKSH on the scope of the present evidence report. Scoping was completed on February 4, 2019.

Results – Criteria Selection for Critical Appraisal

Population

Inclusion criteria

Patients with non-ischemic dilated cardiomyopathy

Left ventricular ejection fraction ≤ 35%

Exclusion criteria

Prior history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation

Intervention and Comparator

Implantable Cardioverter Defibrillator (ICD)

Intervention must include placement of an ICD and continued medical treatment.

Comparator must include continued medical treatment without placement of an ICD.

No ICD

Intervention must include continued medical treatment without placement of an ICD.

Comparator must include placement of an ICD and continued medical treatment.

Outcomes

FAQ 1: What does the treatment involve?

Include a description of the treatment or procedure. Include length of stay if relevant.

Descriptive responses are acceptable, and this does not involve systematic evidence searches, critical appraisal, or evidence synthesis.

FAQ 2: Will I live longer?

Outcomes of interest are all-cause mortality and sudden cardiac death.

We will identify effect estimates from randomized trials (or systematic reviews of randomized trials). Baseline risk estimates will be identified from prognostic studies if available and sufficiently valid, and if not from the randomized trial evidence.

FAQ 3: Will it change my usual activities?

Outcomes of interest are quality of life, time to return to usual activities, and time to return to work.

We will identify outcomes from randomized trial evidence. If not available in randomized trial evidence, then descriptive responses will be provided.

This FAQ consolidates “How will the treatment impact my quality of life?”, “When will I recover?” and “How will treatment impact my daily life?”

FAQ 4: Can the ICD be turned off or removed?

Descriptive responses are acceptable, and this does not involve systematic evidence searches, critical appraisal, or evidence synthesis.

FAQ 5: Will the ICD shock my heart?

Outcomes of interest are appropriate and inappropriate shocks.

In the absence of adequate sample size to assess these outcomes with randomized trial evidence, cohort studies will be considered.

This FAQ does not apply to the No ICD option.

FAQ 6: What are the risks of having the ICD put in place?

Outcomes of interest are periprocedural complications.

In the absence of adequate sample size to assess these outcomes with randomized trial evidence, cohort studies will be considered.

This FAQ does not apply to the No ICD option.

FAQ 7: What are the long-term risks?

Risks of interest – in addition to those in the literature – include repeat procedures or hospitalizations related to the ICD.

For the No ICD option, long-term risks may be reported as avoidable mortality based on the evidence review results for FAQ 2.

In the absence of adequate sample size to assess these outcomes with randomized trial evidence, cohort studies will be considered.

Part 2 - Search and Selection

Methods

First-round searching will consist of searching DynaMed Plus summaries pertinent to the topic. The search starts with DynaMed Plus because DynaMed Plus content is based on a thorough, systematic search and active literature surveillance system.

> Systematic literature surveillance (SLS) has been a cornerstone of creating DynaMed content since its inception. Currently, the SLS team works closely with members of McMaster University's Department of Health Research Methods, Evidence, and Impact to define and refine optimal search strategies, utilizing search terms for methodology and for clinical concepts (especially diagnosis and treatment) for each journal. These filters for PubMed searches are derived from PubMed Clinical Queries, McMaster University Hedges system, and DynaMed search filters and were found to capture >95% of relevant valid articles for use in DynaMed.[1]
> [1]Alper BS, Iorio A. Optimising search filters for active literature surveillance: a concordance study. Global Evidence Summit. Cape Town, South Africa; September 2017.
>
> The SLS team, in collaboration with McMaster University, continually evaluates and improves these filters to keep abreast of the ever-changing medical literature landscape. PubMed searches are performed daily. Each article is assessed by an external screener for clinical relevance, then reviewed by internal staff for both clinical relevance and validity. Any disagreements are settled by the Deputy Editor of the SLS team.
> In addition, the SLS team continually monitors the Journal source list against the list of journals catalogued in MEDLINE and existing DynaMed content to determine the set of journals that provide the highest yield for valid, clinically relevant content. As of November 2018, 507 Journals are systematically searched (see http://dynamed.com/home/content/content-sources). The journal selection threshold leads to routine adjustments to the number of journals selected.

Second-round searching will involve PubMed/MEDLINE® searches for intervention-specific systematic reviews that are more recent than those identified in first-round searching.

Third-round searching will involve original study tracing from systematic reviews, guidelines or other relevant sources. This may be done to identify additional evidence sources if the results from the first two rounds of searching are insufficient.

Fourth-round searching will involve searches for original evidence reports. Such searching will be limited to areas considered insufficiently addressed by earlier searches, such as focused concepts published after search dates in systematic reviews.

Additional selective searching, such as tracing citations from articles found or seeking related articles, may be done for additional concepts discovered.

FAQ Summary

Results

First-round searching – DynaMed Plus:

DynaMed Plus subsection	Relevant for FAQ(s)	Number of article citations	Number of unique references included
Implantable cardioverter defibrillator (ICD) topic, primary prevention of sudden cardiac death (SCD) section, heart failure subsection, nonischemic cardiomyopathy subsection (March 12, 2019)	FAQ1, FAQ2, FAQ3, FAQ5, FAQ6, FAQ7	17	1 (El Moheb 2018)
Implantable cardioverter defibrillator (ICD) topic, primary prevention of sudden cardiac death (SCD) section, heart failure subsection, nonischemic cardiomyopathy due to infectious or infiltrative diseases subsection (March 12, 2019)	FAQ1, FAQ2, FAQ3, FAQ5, FAQ6, FAQ7	1	0
Implantable cardioverter defibrillator (ICD) topic, primary prevention of sudden cardiac death (SCD) section, inherited cardiomyopathies subsection (March 12, 2019)	FAQ1, FAQ2, FAQ3, FAQ5, FAQ6, FAQ7	11	0
Implantable cardioverter defibrillator (ICD) topic, adverse effects and cautions section, procedural complications subsection (March 12, 2019)	FAQ6	9	1 (Dodson 2014)
Implantable cardioverter defibrillator (ICD) topic, adverse effects and cautions section, long-term complications subsection (March 12, 2019)	FAQ7	1	1 (Ranasinghe 2016)

Second-round searching – searches for intervention-specific systematic reviews:

Database	Search string	Relevant for FAQ(s)	Number of search results	Number of references included
March 12, 2019	(implantable OR internal) AND (cardiac defibrillator[ti] OR cardioverter defibrillator[ti] OR cardiac-defibrillator[ti] OR cardioverter-defibrillator[ti] OR cardiac defibrillators[ti] OR cardioverter defibrillators[ti] OR cardiac-defibrillators[ti] OR cardioverter-defibrillators[ti] OR ICD*[ti]) AND (shock*[tiab]) AND (systematic[sb] OR meta-analysis[tiab]) AND ("2016/01/01"[PDAT] : "3000/12/31"[PDAT])	FAQ5	24	2 (Auricchio 2017, El Moheb 2018*)

* already captured in first-round searching

Third-round searching – original study tracing from systematic reviews:

Source	Tracing	Relevant for FAQ(s)	Number of search results	Number of references included
Auricchio 2017	Tracing of a systematic review referenced by Auricchio 2017 (Gonçalves 2013) resulted in our inclusion of a brief discussion of Gonçalves 2013 within the summary for Auricchio 2017, but it did not require a full summary.			
El Moheb 2018	Tracing of two other systematic reviews published in 2018 on the same topic as El Moheb 2018 (Alba 2018, Beggs 2018) and the DANISH trial (Køber 2016), which are discussed within the context of El Moheb 2018 (therefore, these do not receive an individual summary in Part 3)			

Fourth-round searching – searches for original evidence reports:

Database	Search string	Relevant for FAQ(s)	Number of search results	Number of references included
Not applicable				

Part 3 - Critical Appraisal of Evidence Reports

Methods

For each study selected for critical appraisal, we assessed for criteria needed for Level 1 [likely reliable] evidence ratings in DynaMed's Levels of Evidence criteria in which evidence quality is labeled in 1 of 3 levels:

- **(level 1 [likely reliable] evidence)** for studies with clinical outcomes and minimal risk of bias;
- **(level 2 [mid-level] evidence)** for studies with clinical outcomes and significant methodological or statistical limitations; and
- **(level 3 [lacking direct] evidence)** for reports that do not include scientific analysis of clinical outcomes or for study types that do not include comparisons between groups.
-

The specific concepts we critically assessed are fully mapped to cover all the criteria used in GRADE. We summarized key concerns identified that reduce the certainty of evidence in categories used for GRADE methods (i.e., risks of bias, indirectness, imprecision, inconsistency, and other considerations if relevant). In the study-level summaries inconsistency assessment was applied to consistency of within-study results – this applies to consistency across related outcomes for both original studies and for systematic reviews, and also applies to consistency across studies when applied to systematic reviews.

FAQ Summary

Results - Characteristics and Results of Critically Appraised Studies/Sources

AURICCHIO 2017
Auricchio A, Hudnall JH, Schloss EJ, Sterns LD, Kurita T, Meijer A, Fagan DH, Rogers T. Inappropriate shocks in single-chamber and subcutaneous implantable cardioverter-defibrillators: a systematic review and meta-analysis. Europace. 2017 Dec 1;19(12):1973-1980. PubMed

Relevant to FAQ5

- **Study design:** systematic review of observational studies
- **Population:** adults with single-chamber or subcutaneous implantable ICD
    - single-chamber ICDs in 13 studies
    - subcutaneous implantable ICD in 3 studies
- **Intervention:** Not applicable
- **Comparison:** Not applicable

- **Study inclusion criteria:**
    - results reported inappropriate shock rates
    - ≥ 100 patients
    - ≥ 6 months follow-up

- **Number of studies:** 16
    - total of 19 cohorts from 16 studies for inappropriate shocks
        - 3 randomized trials were included each of which randomized patients to two different types of single-chamber ICDs; the two arms of these trials were each treated as a separate cohort
    - total of 8 cohorts from 7 studies for appropriate shocks
- **Number of participants:** 6,470
- **Duration of follow-up:** ranged from 11 months to 62.5 months (for all studies)
    - 11 to 45.5 for studies reporting appropriate shock rates

- **Certainty:**
    - **Certainty by outcome: Moderate for inappropriate shocks; High for appropriate shocks**
    - **Risk of bias:** No serious concern
    - **Imprecision:** No serious concern
    - **Indirectness:** No serious concern
    - **Inconsistency:**
        - Serious concern for inappropriate shocks
        - No serious concern for appropriate shocks
    - **Additional considerations:** authors used random effects Poisson regression to estimate annual rates of first shock

- **Results:**
    - 6.4% (95% CI 5.1% to 7.9%) first annual inappropriate shock rate in analysis of 19 cohorts from 16 studies (totaling 6,470 patients), results limited by significant heterogeneity

        - meta-regression analysis explored sources of heterogeneity
            - factors associated with lower rates of inappropriate shocks
                - more recent studies - reduction in annualized rate of inappropriate shock by factor of 0.93 (95% CI 0.87 to 0.98; p < 0.001) for each additional year in study's middle year of enrollment
                - studies with longer mean follow-up - trend towards reduction in annualized rate of inappropriate shock by factor of 0.78 (95% CI 0.61 to 1.01; p = 0.06) for each additional year of mean follow-up
            - factors not associated with rates of inappropriate shocks
                - device type (subcutaneous implantable ICD vs. single chamber) (rate ratio 1.81, 95% CI 0.86 to 3.80; p = 0.12)
                - VT zone programmed (yes vs. no) (rate ratio 1.13, 95% CI 0.65 to 1.97; p = 0.66)
        - A total of 926 patients received inappropriate shocks across the 16 studies
    - 5.8% (95% CI 5.3% to 6.3%) first annual appropriate shock rate in analysis of 8 cohorts from 7 studies (totaling 3,136 patients)
- **Comment**: The Introduction section of Auricchio 2017 also discusses effects of dual vs. single chamber ICDs. The authors point out that although a reason for the development of dual chamber ICD was to reduce rate of inappropriate shocks, a 2013 systematic review of 4 randomized trials comparing dual- vs. single-chamber ICD and reporting inappropriate shock as an outcome found a nonsignificant trend suggesting a possible increased risk of inappropriate shocks with dual vs. single chamber (Gonçalves 2013). We briefly examined this review as an initial part of third-round searching. For risk of inappropriate shocks with dual-chamber vs single-chamber ICD, the results with a fixed effects model were OR 1.53 (95% CI 0.91 to 2.57). However, we note the forest plot suggested inconsistency in estimates. The authors also noted this inconsistency, and as a part of exploring this inconsistency, they conducted the meta-analysis with a random effects model, which found OR 1.1 (95% CI 0.37 to 3.31). These results provide imprecise and uncertain evidence about the effects of dual- vs. single-chamber ICDs on inappropriate shocks, so we agree with Auricchio 2017's conclusion that these results reveal "no clear superiority of dual-chamber ICDs vs. single-chamber in reducing ISs [inappropriate shocks]". Considering this, and because a choice between a dual- and single-chamber ICD would not likely be determined by this outcome, we did not do a full summary of Gonçalves 2013.

DODSON 2014

Dodson JA, Reynolds MR, Bao H, Al-Khatib SM, Peterson ED, Kremers MS, Mirro MJ, Curtis JP; NCDR. Developing a risk model for in-hospital adverse events following implantable cardioverter-defibrillator implantation: a report from the NCDR (National Cardiovascular Data Registry). J Am Coll Cardiol. 2014 Mar 4;63(8):788-96. Epub 2013 Dec 11. PubMed

Relevant to FAQ6

- **Study design:** observational study
    - data analyzed from ICD Registry, which collects data on > 90% of ICDs placed in United States
- **Population:** patients having new ICD implantation or ICD replacement
- **Intervention:** ICD implantation or ICD replacement

- **Comparison:** not applicable
- **Study inclusion criteria:**
  - procedures conducted from April 1, 2010 to December 31, 2011
- **Number of studies:** Not applicable
- **Number of participants:** 240,632
  - number above is for ICD implantation procedures
- **Duration of follow-up:** only peri-procedural complications analyzed (while patients were still at hospital)

- **Certainty: High**
  - **Certainty by outcome:** Same for all outcomes
  - **Risk of bias:** No serious concern
  - **Imprecision:** No serious concern
  - **Indirectness:** No serious concern
  - **Inconsistency:** No serious concern

- **Results:**

Risk of Complications and Mortality Among Study Sample (n = 240,632)	N (%)
Complication (any)	3,751 (1.56)
Lead dislodgement	1,580 (0.66)
Hematoma	723 (0.30)
Pneumothorax	573 (0.24)
Cardiac arrest	482 (0.20)
Coronary venous dissection	230 (0.10)
Device-related infection	194 (0.08)
Pericardial tamponade	147 (0.06)
Cardiac perforation	107 (0.04)
Stroke or transient ischemic attack	106 (0.04)
Hemothorax	60 (0.02)
Set screw problem	67 (0.03)
Urgent cardiac procedure	38 (0.02)
Myocardial infarction	41 (0.02)
Mortality	637 (0.26)
Complications or mortality	4,388 (1.82)

EL MOHEB 2018

El Moheb M, Nicolas J, Khamis AM, Iskandarani G, Akl EA, Refaat M. Implantable cardiac defibrillators for people with non-ischaemic cardiomyopathy. Cochrane Database Syst Rev. 2018 Dec 8;12:CD012738. PubMed

Relevant to FAQ2, FAQ3

- **Study design:** systematic review of randomized trials
- **Population:** adults with chronic non-ischemic cardiomyopathy due to left ventricular systolic dysfunction with ejection fraction $\leq$ 35%

- **Intervention:** implantable cardioverter-defibrillator plus optimal medical therapy
- **Comparison:** optimal medical therapy alone

- **Study inclusion criteria:** follow-up > 12 months
    - Because some studies (e.g., ScD-HeFT) included patients with ischemic and non-ischemic cardiomyopathy, the authors contacted the study authors for the data for the patients with non-ischemic cardiomyopathy. If they could not obtain that information, they planned to extract data for adverse events and health-related quality of life from both ischemic and non-ischemic participants when the percentage with ischemic cardiomyopathy was less than 25%; however, they did not encounter any such trials.

- **Number of studies:** 6
- **Number of participants:** 3,128
- **Duration of follow-up:** 16.5 to 67.6 months
    - COMPANION (total n = 1,520, but n = 682 had non-ischemic cardiomyopathy), median follow-up durations were 14.8, 16.5, and 16.0 months in the optimal medical therapy group (n = 127), optimal medical therapy + cardiac resynchronization with pacemaker group (n = 285), and optimal medical therapy + cardiac resynchronization with pacemaker-defibrillator group (n = 270), respectively
        - Cochrane review does not report follow-up duration for optimal medical therapy group (obtained via full-text of the COMPANION trial), because the Cochrane review uses the optimal medical therapy + cardiac resynchronization therapy with pacemaker group as the control group in attempt to control for the use of cardiac resynchronization therapy in the group that received optimal medical therapy + cardiac resynchronization with pacemaker-defibrillator.
    - AMIOVIRT (n = 103), mean follow-up duration of 24 months
    - DEFINITE (n = 458), mean follow-up duration of 29 months
    - ScD-HeFT (total n = 2,521, but n = 1,211 had non-ischemic cardiomyopathy, with n = 419 in group receiving amiodarone in addition to optimal medical therapy, n = 398 in group receiving ICD in addition to optimal medical therapy, and n = 394 in group receiving optimal medical therapy alone), mean follow-up duration of 45.5 months
    - CAT (n = 104), mean follow-up duration of 5.5 years (66 months)
    - DANISH (n = 1,116), median follow-up duration of 67.6 months

- **Certainty and Results:**

Efficacy outcomes

Outcome	Follow-up duration (range)	Number of patients (studies)	Relative effect	Control group event rate % (n/N)	Certainty (downgrade reason)
All-cause mortality*†‡§¶	16.5 to 67.6 months**	3,128 (6)	HR 0.78 (95% CI 0.66 to 0.92)	21.8% (195/895)	High
Cardiovascular mortality††	22.8 to 67.6 months**	1,781 (4)	RR 0.75 (0.46 to 1.21)	14.2% (127/895)	Moderate (downgraded

					due to imprecision)
Sudden cardiac death‡‡	24 to 67.6 months**	1,677 (3)	RR 0.47, 95% CI 0.30 to 0.73	7.4% (62/841)	High
Noncardiovascular mortality§§	22.8 to 67.6 months**	1,781 (4)	RR 1.17 (0.81 to 1.68)	5.7% (51/895)	Moderate (downgraded due to imprecision)

* Control group event rates extracted from RR analyses (1.2), as these data are not available in the HR analyses (1.1)
† Both HR and RR were calculated and reported by systematic review authors. However, 2 trials with large numbers of patients (SCD-HeFT and COMPANION) could not be pooled in RR analysis because the number of events in non-ischemic subgroup from these trials could not be extracted. Because number of patients pooled was greater for HR than RR, the authors based their conclusion on the HR analysis. The RR analysis showed similar results but was not significant (RR 0.87, 95% CI 0.72 to 1.05).
‡ Consistent results in sensitivity analysis that excluded the COMPANION trial in which all patients had concomitant cardiac resynchronization therapy.
§ Test of subgroup effect showed no difference in effect between patients with and without cardiac resynchronization therapy (for the former, the comparison evaluated was cardiac resynchronization therapy-defibrillator [CRT-D] vs. cardiac resynchronization therapy-pacemaker [CRT-P])
¶ El Moheb 2018 includes a subgroup analysis by age (based on the DANISH trial): <65 years old (HR 0.51, 95% CI 0.29 to 0.91) vs >65 years old (HR 0.98, 95% CI 0.73 to 1.31); further exploration of this finding appears below (see 'Other considerations'), but age *per se* is considered unlikely to be a genuine effect modifier, and therefore it is not considered appropriate for evidence synthesis statements/conclusions regarding age-stratified or age-dependent results.
** The study contributing the most data to these analyses is the DANISH trial, which had a median follow-up duration of 67.6 months (about 5.6 years).
†† Consistent results with meta-analysis of 2 trials with 1,219 patients using the HR as measure of effect (HR 0.78, 95% CI 0.58 to 1.05). Because number of patients pooled was greater for RR than HR, the authors based their conclusion on the RR analysis.
‡‡ Consistent results with meta-analysis of same 3 trials with same number of patients using HR as measure of effect (HR 0.45, 0.29 to 0.70).
§§ Consistent results with meta-analysis of 2 trials with 1,219 patients using the HR as measure of effect (HR 1.11, 95% CI 0.72 to 1.71). Because number of patients pooled was greater for RR than HR, the authors based their conclusion on the RR analysis.

- first ICD-related hospitalization not reported in any trial
- health-related quality of life
    - 4 trials reported data on quality of life
        - COMPANION and SCD-HeFT trial quality of life data not extracted for review because > 25% of patients had ischemic cardiomyopathy (55% and 52% respectively)
        - 2 trials with total of 561 patients (AMIOVIRT and DEFINITE trials) evaluated health-related quality of life using four different scales; because the trials reported data in different ways and at different time points, they were not pooled
            - no significant differences between ICD and control groups in either trial
            - outcome was judged Moderate certainty by review authors, downgraded due to lack of blinding (this was the only outcome the authors downgraded for lack of blinding, because it is subjective and the other outcomes are objective)
            - only DEFINITE trial assessed impact of shocks on quality of life
                - no significant difference in health-related quality of life scores between shocked and non-shocked patients

        - among shocked patients, decline in mental and emotional components of quality of life scores comparing pre-shock and post-shock values

Adverse events

- only 2 trial included data for adverse events
    - COMPANION trial data not extracted for review because 55% of patients had ischemic cardiomyopathy
    - DANISH trial (n = 1,116) reported increase in following 4 adverse events, with Moderate certainty evidence downgraded due to imprecision
        - device infection (RR 1.36, 95% CI 0.77 to 2.40)
            - subgroup analysis suggested risk may be clearer in patients with no previous CRT (RR 6.08; 95% CI 1.38 to 26.86) than in patients with previous CRT (RR 0.84; 95% CI 0.43 to 1.63), but CI for patients without previous CRT is very wide
        - pneumothorax (RR 1.85, 95% CI 0.69 to 4.96)
        - serious device infection (RR 1.16, 95% CI 0.56 to 2.42)
        - bleeding requiring intervention (RR 3.02, 95% CI 0.12 to 74.01)

Other considerations:

- review included table that displays comparison with 20 other systematic reviews published on this topic since 2016
    - all but 1 reported significant decrease in all-cause mortality
    - included studies
        - 9 excluded COMPANION trial because of concomitant CRT in all patients
        - other 5 trials included in all 20 systematic reviews
- DANISH trial and suggestions from other systematic reviews
    - El Moheb 2018 suggests possible effect modification of age based on their subgroup analysis (Analysis 1.11) stating "Our results suggest that ICD, when added to optimal medical therapy, may decrease the rate of death from any cause in patients who are younger than 65 years of age … but probably has little or no effect on patients who are 65 years of age or older … (possibility of both plausible benefit and no effect)." and later "ICD therapy decreases mortality rate in patients who are younger than 65 years of age, but probably has little or no effect on patients who are 65 years old or more".
        - This is 1 of 8 subgroup analyses reported on by El Moheb 2018 (in addition to 2 sensitivity analyses based on risk of bias and use of amiodarone). The subgroup analysis for age is also based on data from a single trial (the DANISH trial). We note this should generally be viewed as hypothesis-generating rather than a conclusive demonstration, many subgroup analyses that show possible effect modification are not supported by further study, and subgroup analyses also sacrifice the benefits of randomization/by definition become observational in nature. Although in some cases subgroup analyses are accompanied by details about the characteristics of patients in the subgroups, this information is not available here, so we do not know whether the "ICD vs no ICD" groups within the age strata are prognostically similar. We also note a key potential confounder that is not addressed: any effect modification that might exist may be less about age *per se* and more about competing risk for death (versus sudden cardiac death), with older people generally having more competing risks

than younger people. In other words, there is a high prior probability that the "driver" of that finding is more related to the patient's overall clinical picture (i.e., comorbidities, functional status, competing risks, life expectancy) rather than age *per se*. For instance, a 68-year-old patient with NICM and EF ≤35% along with severe multimorbidity and frailty may not be as good a candidate for an ICD based on his/her overall clinical picture, but a 68-year-old patient with NICM and EF ≤35% and less prominent comorbidities and no frailty might still conceivably benefit. Additionally, even if one were to accept the age-based subgroup analysis as likely reflecting an underlying truth about age *per se* (we again emphasize the cautionary statements laid out thus far), this would still leave important uncertainty for those ≥65 years old. Rather than El Moheb 2018's suggestion that their findings suggest an ICD "probably has little or no effect on patients who are 65 years of age or older", we note the confidence interval shows the data are reasonably compatible with anything from about a 22% relative reduction to a 31% relative increase. Both are likely meaningful for this outcome, so this too would call for further study rather than concluding there is "probably … little or no effect".

- Additionally, El Moheb's cut-point of 65 years of age is also ultimately arbitrary. For instance, the DANISH trial authors (Køber 2016) considered different cut-points, and their subgroup analysis of those <68 years of age yielded HR 0.64 (95% CI 0.45 to 0.90); in their discussion, the DANISH trial authors also focus not on age, but frailty: "the subgroup data … might be used as an argument for not implanting ICDs in frail patients". So, even if one wanted to consider age as a deciding factor of some sort, the cut-point remains unclear, but more importantly, using age *per se* seems too questionable/uncertain.
    - We note focusing on frailty rather than age is consistent with both our comments above and the recommendations from the 2017 guidelines from the American Heart Association, American College of Cardiology, and Heart Rhythm Society (Al-Khatib 2018), which include consideration of the DANISH trial (see Recommendations Table 7.2.2, which makes no differentiation by age, but rather, frailty, and and Figure 6, which does not consider age, but rather, functional status, life expectancy, and patient preference).

- We add that El Moheb 2018 also notes (in the "Authors' Conclusions" section of their review, subsection "Implications for research") the following statement: "[t]he large majority of these patients … will not have their lives saved by the device. Age may be an important variable to be used for this purpose, but the interesting results observed in the DANISH trial need to be confirmed in further trials." This is a more appropriate concluding remark than what they say earlier in the review.

- Beggs 2018 is a systematic review and meta-analysis investigating the same issue as El Moheb 2018 (also included in El Moheb 2018's comparative table of 20 systematic reviews). Beggs 2018 also found a benefit for all-cause mortality in their analysis. Although not addressed by El Moheb 2018 explicitly, Beggs 2018 goes on to suggest "careful interpretation of these data suggest that the neutral result of the DANISH trial may more accurately reflect the utility—or relative lack therein—of ICDs in the modern

era. In part, this is because contemporary heart failure therapy reduces both sudden cardiac death and death from worsening heart failure, thus making an additional beneficial effect of defibrillator therapy on overall mortality harder to demonstrate".

- El Moheb 2018 also explored the potential for the era in which the trial was conducted/published to serve as an effect modifier. They used a publication date cut-point of 2003/2004 based on discovery/institution of beta-blockers as a cornerstone therapy, and they found no evidence of heterogeneity of treatment effect (Analysis 1.11, I^2 =0.0%, p = 0.84). Beggs 2018's statement about the "relative lack therein" for benefit in the DANISH trial overemphasizes statistical significance and underappreciates analysis of the totality of the data. There is general consistency in the data across the body of trials. This can be seen in the forest plot for all-cause mortality from El Moheb 2018 (without conducting any subgroup analysis; Analysis 1.1), which also has an I^2 = 0% (p = 0.8). The subgroup analysis noted above by El Moheb 2018 further corroborates this notion. We also conducted two additional subgroup analyses on the data from El Moheb 2018: (1) comparing trials with publication dates of 2005 or later versus trials with publication dates of 2004 or earlier, and (2) comparing the DANISH trial to all trials before the DANISH trial (data available on request). Neither of these subgroup analyses demonstrated heterogeneity of treatment effect ([1] had I^2 of 0%, p = 0.35; [2] had I^2 of 32%, p = 0.23). Alba 2018 also conducted a systematic review and meta-analysis considering the same question as El Moheb 2018 and Beggs 2018. It too is included in El Moheb 2018's comparative table of 20 systematic reviews, and although not explicitly considered by El Moheb 2018, Alba 2018 also conducted a subgroup analysis looking at trials where use of ACE-Is/ARBs and beta-blockers was <80% or >80%; here too there was no evidence of heterogeneity of treatment effect, either by inspection of the forest plot or formal testing (I^2 = 0%, p = 0.88).

RANASINGHE 2016

Ranasinghe I, Parzynski CS, Freeman JV, Dreyer RP, Ross JS, Akar JG, Krumholz HM, Curtis JP. Long-Term Risk for Device-Related Complications and Reoperations After Implantable Cardioverter-Defibrillator Implantation: An Observational Cohort Study. Ann Intern Med. 2016;165:20-29. PubMed

Relevant to FAQ7

- **Study design:** observational study
  - ICD implantations from ICD Registry linked with fee-for-service claims data from Medicare
  - data from 1,437 hospitals in United States
- **Population:** patients aged ≥ 65 receiving ICD for first time from 2006 to 2010
  - 79.3% had prior diagnosis of heart failure
  - 79.1% had a left ventricular ejection fraction of less than 35%
  - Mean age 74.8 years
- **Intervention:** ICD implantation
  - 83.5% were implanted for primary prevention
  - single-chamber, 19.8%
  - dual-chamber, 41.3%

    - cardiac resynchronization therapy with defibrillator (CRT-D), 38.9%
- **Comparison:** Not applicable

- **Study inclusion criteria:**

- **Number of studies:** Not applicable
- **Number of participants:** 114,484
- **Duration of follow-up:** median 2.7 years

- **Certainty: Moderate for mortality outcome; High for all other outcomes**
    - **Certainty by outcome:** Not applicable
    - **Risk of bias:** No serious concern
    - **Imprecision:** No serious concern
    - **Indirectness:** Serious concern for mortality outcome
        - Included only patients > 65 years old (with mean age of 74.8 years), and rate of mortality may be higher in this group compared to younger patients
    - **Inconsistency:** No serious concern

- **Results:**

Outcome	**Cumulative incidence***		
	1-year follow-up	3-year follow-up	5-year follow-up
Mortality†‡	11%	30%	46%
Any ICD-related complication‡§¶	7%	11%	14%
Complication requiring reoperation	4%	6%	8%
Generator change or removal **	1%	2%	3.5%
Lead procedure ††	3%	4%	4.5%
Complication requiring hospitalization only	4%	6.5%	8%
ICD reoperations for reasons other than complications‡ § ‡‡	1.5%	5%	19%

ICD, implantable cardioverter-defibrillator
* estimates were extracted from survival curves, using the primary prevention curves when available (mortality, any ICD-related complication, and ICD reoperations for reasons other than complications)
† cumulative incidence of mortality increased linearly over time
‡cumulative incidence of mortality, ICD-related complications, and reoperations for reasons other than complications were significantly higher among patients receiving CRT-D or dual-chamber device versus single-chamber device
§ accounting for competing risk of death
¶ cumulative incidence of ICD-related complications increased rapidly to 5.4% in early post-implantation period, with highest rate at 0 to 90 day period
** with or without lead- or pocket-related complications
†† with or without pocket-related complications
‡‡ reoperations for reasons other than complications typically include device upgrades or generator replacements for battery depletion; these events occurred throughout follow-up, but highest rates were observed after third year

- pocket-related complications occurred primarily during 0-90 day period post-implantation, with a rate of 0.36 events (95% CI 0.29 to 0.43 events) per 100 patient-years at risk after ICD implantation. This amounts to a 0.089% (95% CI 0.072% to 0.106%) absolute risk within 90 days (regardless of whether one uses a linear or exponential method to calculate absolute risk)

Part 4 - Evidence Review

Methods

For each FAQ, the key concepts (results and factors affecting certainty of the results) from the included studies that are most relevant to evidence synthesis will be summarized in Evidence Review Tables. Where evidence is very limited, or the FAQ is for descriptive summary, summary text will be provided.

Results

FAQ 1: What does the treatment involve?

FAQ1a: ICD

Descriptive Summary

Types of implantable cardioverter-defibrillators (ICDs)

An implantable cardioverter-defibrillator (ICD) is a small device – smaller and thinner than a deck of cards, or about the size of a pager – that delivers electric shocks when the device detects the heart is in a dangerous rhythm. The ICD is made of a generator (the biggest part) and leads (wires that extend from the generator to specified areas of the heart). The "traditional" or transvenous ICD is the most commonly used ICD (a newer kind, the subcutaneous ICD, will be discussed later). Depending on a person's specific needs, a traditional ICD can be single-chamber (lead goes to the right ventricle), dual-chamber (leads go to right atrium and right ventricle), or biventricular (leads go to right atrium, right ventricle, and the left ventricle). A biventricular ICD is also often referred to as cardiac resynchronization therapy (CRT) or cardiac resynchronization therapy-defibrillator (CRT-D), because it helps the heart beat more in sync. A traditional ICD is typically implanted under the skin just below the collarbone on the left side of the chest. Therefore, an incision is required to place it, but the incision is typically not very large (about 2 inches). The ICD leads are then passed through a large vein under the collarbone to reach the chamber(s) of the heart where the lead(s) should go (inside the chamber for right-sided leads, and on the surface of the heart for the left side). Traditional ICDs can also help the heart beat correctly with low levels of electrical stimulation (called pacing) when a bad rhythm is detected, and this may be able to stop at least some rhythms from escalating to the point where an electric shock is needed to restore a normal rhythm. Pacing is not typically associated with discomfort. People may feel nothing at all, or a slight fluttering in the chest.

There is also a newer type of ICD, called a subcutaneous ICD. This type of ICD is typically implanted under the skin along the left side of the chest in the underarm area. It is bigger than a traditional ICD; therefore, it requires a bigger incision (about 4 to 5 inches), but some patients appreciate the incision (and the device) being more hidden compared to a traditional ICD. One potential benefit of a subcutaneous ICD is that the single lead for a subcutaneous ICD does not have to go through the vein like a traditional ICD. Instead, the lead is placed in the tissue to the left of the breastbone rather than in the heart. However, it cannot help with pacing, so people are only eligible for a subcutaneous ICD if they do not also need pacing (whether antibradycardic, antitachycardic, or as part of CRT). As discussed above, pacing may be able to stop at least some rhythms from ever getting to the point where an electrical shock is needed. There are other considerations that determine a person's eligibility for a subcutaneous ICD (e.g., people who are too thin may not be good candidates, and sometimes a person's electrocardiogram may suggest they are not a good candidate), and for someone being considered for a subcutaneous ICD, these will be assessed at that time.

An ICD battery typically lasts about 5 to 8 years or so.

Having an ICD placed
Having an ICD implanted may generally take about 2 to 5 hours (the actual time will depend on the specifics of the patient's situation). You can be awake while the ICD is inserted, but a sedative will be given, and local anesthesia will be applied to the area where the ICD is being inserted. An ICD is sometimes implanted as an outpatient procedure, but it is common to spend one night in the hospital after implantation for monitoring.

Recovery after having an ICD placed
You will receive instructions specific to you from your health care professional, but in general:

The area where the ICD is implanted may be tender or swollen for a few days or weeks, but medicines can help with this pain.

Full recovery from the procedure may take about 4 to 6 weeks, but most people return quickly to their normal activity level, including activities such as exercise, work, and sex. The American Heart Association recommends people not drive for 1 week following implantation of an ICD when they have never before had a cardiac arrest or ventricular dysrhythmia; however, an earlier guideline from the European Society of Cardiology recommends 4 weeks. If a person receives a shock from the ICD, s/he is often discouraged from driving or not allowed to drive for up to 6 months. However, this may vary somewhat from state to state. People are often not able to get a commercial driver's license if they have an ICD. For 4 weeks after the procedure, you may be advised to avoid lifting anything more than 5 to 15 pounds, playing contact sports, strenuous exercises, or certain other activities, many of which involve activity or exercise that can affect the arm on the side of your body where the ICD was placed (e.g., golf, tennis, swimming, bicycling, bowling, or vacuuming).

ICD shocks
Although people's exact experiences may vary, when an ICD of any kind delivers a shock, it is painful. The pain should only last for a second or so. Depending on the rhythm the ICD detects, cardioversion or defibrillation may be administered by the ICD. Cardioversion is often perceived as being less painful, but it still hurts quite a bit (it may feel like being "thumped" in the chest). Defibrillation is often much more painful. People often liken it to being hit with a baseball bat or being kicked by a horse, and it knocks some people off their feet. Nevertheless, although having an ICD does not have to impact a person's day-to-day life, receiving a shock and/or the fear of possibly receiving a shock can be considerably distressing/anxiety-provoking for some people. If your ICD shocks you, you should notify your health care professional.

Deactivation of an ICD
An ICD can be deactivated at any time if the person desires. If an ICD is deactivated, it will no longer monitor a person's heart rhythm, and it will not deliver shocks.

(AHA 2016; Al-Khatib 2018; Cleveland Clinic 2015, 2018; EBSCO Health Patient Education Reference Center 2016; El Moheb 2018; Epstein 2012; Johns Hopkins nd; HRS nd; Klein 2017; Levine 2012; Mayo Clinic 2017; NIH 2018; Turakhia 2010; Turnage 2018; Vijgen 2009)

FAQ1b: No ICD

Descriptive Summary
You will not receive an ICD. You will continue taking medications.

FAQ 2: Will I live longer?

FAQ2a: ICD

Evidence Review Table

Comparing implantable cardioverter-defibrillator plus optimal medical therapy vs. optimal medical therapy alone on all-cause mortality and sudden cardiac death (El Moheb 2018; systematic review of randomized trials)

Outcome	Follow-up duration (range)	Number of patients (studies)	Relative effect	Control group event rate (n/N)	Intervention group event rate estimate*	Certainty (downgrade reason)
All-cause mortality†‡§¶**	16.5 to 67.6 months††	3,128 (6)	HR 0.78 (95% CI 0.66 to 0.92)	21.79% (195/895) ‡‡	17.44%	High
Sudden cardiac death§§	24 to 67.6 months††	1,677 (3)	RR 0.47 (95% CI 0.30 to 0.73)	7.37% (62/841)	3.46%	High

* These rates are estimated in the standard fashion with the control group event rate and the relative effect estimate. Of note, the calculation for a hazard ratio is different than the calculation for a relative risk.

† Both HR and RR mortality estimates were calculated and reported by systematic review authors. However, 2 trials with large numbers of patients (SCD-HeFT and COMPANION) could not be pooled in RR analysis because the number of events in non-ischemic subgroup from these trials could not be extracted. Because number of patients pooled was greater for HR than RR, the authors based their conclusion on the HR analysis. The RR analysis showed similar results but was not significant (RR 0.87, 95% CI 0.72 to 1.05).

‡ Consistent results in sensitivity analysis that excluded the COMPANION trial in which all patients had concomitant cardiac resynchronization therapy.

§ Test of subgroup effect showed no difference in effect between patients with and without cardiac resynchronization therapy (for the former, the comparison evaluated was cardiac resynchronization therapy-defibrillator [CRT-D] vs. cardiac resynchronization therapy-pacemaker [CRT-P])

¶ El Moheb 2018 includes a subgroup analysis by age (based on the DANISH trial): <65 years old (HR 0.51, 95% CI 0.29 to 0.91) vs >65 years old (HR 0.98, 95% CI 0.73 to 1.31). Age *per se* is considered unlikely to be a genuine effect modifier, and therefore it is not considered appropriate for evidence synthesis statements/conclusions regarding age-stratified or age-dependent results. Instead, we emphasize the importance of assessing the patient's overall clinical picture (i.e., comorbidities, functional status, competing risks, life expectancy) to help determine appropriateness/candidacy for ICD therapy, which is consistent with suggestions from both the DANISH trial authors (Køber 2016) and 2017 guidelines from the American Heart Association, American College of Cardiology, and Heart Rhythm Society (Al-Khatib 2018). Further details are in Part 3.

** Cochrane review includes table that displays comparison with 20 other systematic reviews published on this topic since 2016 and all but 1 reported significant decrease in all-cause mortality

†† The study contributing the most data to both these analyses is the DANISH trial, which had a median follow-up duration of 67.6 months (about 5.6 years).

‡‡ Control group event rates extracted from RR analyses (1.2), as these data are not available in the HR analyses (1.1)

§§ Consistent results with meta-analysis of same 3 trials with same number of patients using HR as measure of effect (HR 0.45, 0.29 to 0.70).

FAQ2b: No ICD

Descriptive Evidence Review

Estimates for risk of death and sudden cardiac death are based on the control group event rates provided in the Evidence Review Table for FAQ2a: ICD.

FAQ 3: Will it change my usual activities?

FAQ3a: ICD

Evidence Review Table: Health-related quality of life

Comparing implantable cardioverter-defibrillator plus optimal medical therapy vs. optimal medical therapy alone on health-related quality of life (El Moheb 2018; systematic review of randomized trials)

Outcome	Follow-up duration (range)	Number of patients (studies)	Key findings	Certainty (downgrade reason)
Health-related quality of life	24 to 29 months	561 (2)	Health-related quality of life was evaluated in 2 trials (AMIOVIRT and DEFINITE) using a total of 4 different scales (2 scales for each trial). Neither trial showed statistically significant difference in score between the ICD and control groups, on either scale. Because the trials reported data in different ways and at different time points, their results were not pooled. Only DEFINITE trial assessed impact of shocks on quality of life. It found no significant difference in health-related quality of life scores between shocked and non-shocked patients; however, among shocked patients, there was a significant decrease in mental and emotional components of quality of life scores comparing pre-shock and post-shock values.	Moderate (downgraded due to lack of blinding)*

*Cochrane authors downgraded for serious risk of bias because they judged (and we agree) that the lack of blinding may have influenced the ratings of this subjective outcome measure.

Descriptive Summary: ICD shocks and recovery after having an ICD placed

As noted in FAQ1:

ICD shocks

Although people's exact experiences may vary, when an ICD of any kind delivers a shock, it is painful. The pain should only last for a second or so. Depending on the rhythm the ICD detects, cardioversion or defibrillation may be administered by the ICD. Cardioversion is often perceived as being less painful, but it still hurts quite a bit (it may feel like being "thumped" in the chest). Defibrillation is often much more painful. People often liken it to being hit with a baseball bat or being kicked by a horse, and it knocks some people off their feet. Nevertheless, although having an ICD does not have to impact a person's day-to-day life, receiving a shock and/or the fear of possibly receiving a shock can be considerably distressing/anxiety-provoking for some people. If your ICD shocks you, you should notify your health care professional.

Recovery after having an ICD placed
You will receive instructions specific to you from your health care professional, but in general:

The area where the ICD is implanted may be tender or swollen for a few days or weeks, but medicines can help with this pain.

Full recovery from the procedure may take about 4 to 6 weeks, but most people return quickly to their normal activity level, including activities such as exercise, work, and sex. The American Heart Association recommends people not drive for 1 week following implantation of an ICD when they have never before had a cardiac arrest or ventricular dysrhythmia; however, an earlier guideline from the European Society of Cardiology recommends 4 weeks. If a person receives a shock from the ICD, s/he is often discouraged from driving or not allowed to drive for up to 6 months. However, this may vary somewhat from state to state. People are often not able to get a commercial driver's license if they have an ICD. For 4 weeks after the procedure, you may be advised to avoid lifting anything more than 5 to 15 pounds, playing contact sports, strenuous exercises, or certain other activities, many of which involve activity or exercise that can affect the arm on the side of your body where the ICD was placed (e.g., golf, tennis, swimming, bicycling, bowling, or vacuuming).

FAQ3b: No ICD

Descriptive Summary

No

FAQ 4: Can the ICD be turned off or removed?

FAQ4a: ICD

Descriptive Summary

As noted in FAQ1, an ICD can be deactivated at any time if the person desires. If the ICD is deactivated, it will no longer monitor your heart rhythm, and it will not shock you.

An ICD can also be removed, but this will require another procedure.

FAQ4b: No ICD

Does not apply

FAQ 5: Will the ICD shock my heart?

FAQ5a: ICD

Evidence Review Table

Rates of appropriate and inappropriate shock (Auricchio 2017; systematic review of observational studies)

Outcome	Follow-up duration (range in months)	Number of patients (studies)	Annual shock rate (95% CI)	Certainty (downgrade reason)
appropriate shocks	11 to 45.5	6,470 (16)	5.8% (95% CI 5.3% to 6.3%)	High
inappropriate shocks	11 to 62.5	3,136 (7)	6.4% (95% CI 5.1% to 7.9%)	Moderate (downgraded due to heterogeneity*)

*Meta-regression identified study recency was associated with lower rates of inappropriate shocks, with reduction in annualized rate of inappropriate shock by factor of 0.93 (95% CI 0.87 to 0.98; $p < 0.001$) for each additional year in study's middle year of enrollment. Studies with longer mean follow-up also tended to have a lower annualized rate of inappropriate shock by factor of 0.78 (95% CI 0.61 to 1.01; $p = 0.06$) for each additional year of mean follow-up.

FAQ5b: No ICD

Does not apply

FAQ 6: What are the risks of having the ICD put in place?

FAQ6a: ICD

Evidence Review Table

Risk of periprocedural complications and mortality during hospital stay among 240,632 ICD implantation procedures conducted in United States from April 2010 to December 2011 (Dodson 2014)

Risk of Complications and Mortality Among Study Sample (n = 240,632)*	N (%)
Complication (any)	3,751 (1.56)
Lead dislodgement	1,580 (0.66)
Hematoma	723 (0.30)
Pneumothorax	573 (0.24)
Cardiac arrest	482 (0.20)
Coronary venous dissection	230 (0.10)
Device-related infection	194 (0.08)
Pericardial tamponade	147 (0.06)
Cardiac perforation	107 (0.04)
Stroke or transient ischemic attack	106 (0.04)
Hemothorax	60 (0.02)
Set screw problem	67 (0.03)
Urgent cardiac procedure	38 (0.02)
Myocardial infarction	41 (0.02)
Mortality	637 (0.26)
Complications or mortality	4,388 (1.82)

*Certainty was judged High for all outcomes

Ranasinghe 2016 was an analysis of the ICD Registry data with an intent to assess the risks of device-related complications and reoperations after ICD implantation procedures in 114,484 patients in United States from April 2006 to 2010. There main goal was to assess longer-term complications, which are captured in FAQ7. However, they also reported on pocket-related complications, which occurred primarily during the 0-90 day period post-implantation, with a rate of 0.36 events (95% CI 0.29 to 0.43 events) per 100 patient-years at risk after ICD implantation. This amounts to a 0.089% (95% CI 0.072% to 0.106%) absolute risk within 90 days (regardless of whether one uses a linear or exponential method to calculate absolute risk). (High certainty)

FAQ6b: No ICD

Does not apply

FAQ 7: What are the long-term risks?

FAQ7a: ICD

Evidence Review Table

Long-term risk for device-related complications and reoperations after ICD implantation procedures conducted in 114,484 patients in United States from April 2006 to 2010 (Ranasinghe 2016)

Outcome	**Cumulative incidence***			**Certainty**
	1-year follow-up	3-year follow-up	5-year follow-up	
Mortality†‡	11%	30%	46%	Moderate (downgraded due to indirectness)
Any ICD-related complication‡§¶	7%	11%	14%	High
Complication requiring reoperation	4%	6%	8%	High
Generator change or removal **	1%	2%	3.5%	High
Lead procedure ††	3%	4%	4.5%	High
Complication requiring hospitalization only	4%	6.5%	8%	High
ICD reoperations for reasons other than complications‡ § ‡‡	1.5%	5%	19%	High

ICD, implantable cardioverter-defibrillator

* estimates were extracted from survival curves, using the primary prevention curves when available (mortality, any ICD-related complication, and ICD reoperations for reasons other than complications)

† cumulative incidence of mortality increased linearly over time

‡cumulative incidence of mortality, ICD-related complications, and reoperations for reasons other than complications were significantly higher among patients receiving CRT-D or dual-chamber device versus single-chamber device

§ accounting for competing risk of death

¶ cumulative incidence of ICD-related complications increased rapidly to 5.4% in early post-implantation period, with highest rate at 0 to 90 day period

** with or without lead- or pocket-related complications

†† with or without pocket-related complications

‡‡ reoperations for reasons other than complications typically include device upgrades or generator replacements for battery depletion; these events occurred throughout follow-up, but highest rates were observed after third year

FAQ7b: No ICD

Descriptive Summary

Some people will die from a dangerous rhythm that an ICD could have stopped. See ‘Will I live longer?’.

Non-scoped supplemental content
The following content is included for reference due to its potential relevance, despite it not being included in scoping. The content below is a result of searching for (including citation tracing where relevant/applicable) and critically appraising content from: DynaMed Plus (sections noted), PubMed (search strings noted), and/or patient education materials (e.g., EBSCO Health Patient Education Reference Center), guidelines, and consensus statements. This was completed by Brian Alper, MD, MSPH, FAAFP and Karie Rosolowski, MPH. The information is organized by general topic.

Electromagnetic interference

Evidence

DynaMed Plus (Implantable cardioverter defibrillator (ICD)/adverse effects and cautions/electromagnetic interference), May 25, 2018.

- **Study conclusion (DMP level of evidence): portable headphones in close proximity to skin surface may interfere with pacemaker or implantable cardioverter defibrillator function; patients with ICD using headphones may be more likely to experience temporary magnetic interference compared to patients with pacemaker using headphones (level 2 [mid-level] evidence)**
  - **Reference:** Lee S, Fu K, Kohno T, Ransford B, Maisel WH. Clinically significant magnetic interference of implanted cardiac devices by portable headphones. *Heart Rhythm*. 2009 Oct;6(10):1432-6. PubMed
  - **Conclusion relevant to OG (note: if different from study conclusion):**
  - **Study design:** prospective cohort study
  - **Objective:** determine if portable headphones cause clinically relevant magnetic interference in patients with pacemaker or implantable cardioverter defibrillator (ICD)
  - **Population:** 100 patients with pacemaker or ICD assessed for clinically relevant magnetic interference from portable headphones
    - 45 with pacemaker
    - 55 with ICD
  - **Intervention or Exposure:** portable headphones (8 headphone models)
  - **Comparison(s):** NA
  - **Outcome(s):** device interference (defined as asynchronous pacing or inhibition of tachyarrhythmia detection)
  - **Duration of follow-up:** immediate evaluation
  - **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** no serious concerns
    - **Precision:** no serious concerns
    - **Directness:** 8 headphone models tested; applicability to other models uncertain
    - **Consistency assessment:** no serious concerns
    - **Other considerations:** no serious concerns
  - **Results:**
    - device interference in
      - 30% with headphones with magnetic field strength (MFS) ≥ 10 gauss at 2 cm from skin surface vs. 0% with headphones with MFS < 10 gauss at 2 cm from skin surface ($p < 0.0001$)
      - 20% with pacemaker vs. 38.2% with ICD ($p = 0.048$)

        - no device interference observed when headphones placed ≥ 3 cm from skin surface
        - in all but 1 patient, removal of headphones immediately restored normal device function

- **Study conclusion (DMP level of evidence): hand-held metal detectors do not appear to interfere with pacemaker or implantable cardioverter defibrillator function (level 3 [lacking direct] evidence)**
    - **Reference:** Jilek C, Tzeis S, Vrazic H, Semmler V, Andrikopoulos G, Reents T, et al. Safety of screening procedures with hand-held metal detectors among patients with implanted cardiac rhythm devices: a cross-sectional analysis. Ann Intern Med. 2011 Nov 1;155(9):587-92. PubMed
    - **Study design:** cross-sectional study
    - **Objective:** determine whether exposure to hand-held metal detectors changes functioning of pacemakers and ICDs
    - **Population:** 388 patients presenting for routine follow-up of pacemaker or ICD function had 30-second exposure to 2 commercially available hand-held metal detectors with maximum electromagnetic flux density of 6.3 microtesla
        - 209 with pacemaker
        - 179 with ICD
    - **Intervention or Exposure:** hand-held metal detectors with maximum electromagnetic flux of 6.3 μT
    - **Comparison(s):** NA
    - **Outcome(s):** rhythm device malfunction (defined as pacing inhibition, loss of capture, inappropriate mode switch, ventricular oversensing, and spontaneous reprogramming after 30 seconds of exposure)
    - **Duration of follow-up:** immediate evaluation
    - **Certainty (reasons for LOE downgrade):**
        - **Risk of bias:** convenience sample population
        - **Precision:** no serious concerns
        - **Directness:** evaluated only 2 different kinds of hand-held metal detectors used in Europe**;** evaluated risk of interference in isolated room, not in other settings where many electric devices emit electromagnetic radiation at the same time
        - **Consistency assessment:** no serious concerns
        - **Other considerations:** no serious concerns
    - **Results:** no change in device function (including pacing or sensing abnormalities or device reprogramming) observed in any patient

- **Study conclusion (DMP level of evidence): In patients with ICD, quickly walking through an electronic surveillance system does not appear to induce interactions, but clinically important interference of ICD reported to occur after standing close to electronic surveillance system gate transmitter for 2 minutes or more (level 3 [lacking direct] evidence)**
    - **Reference:** Groh WJ, Boschee SA, Engelstein ED, Miles WM, Burton ME, Foster PR, Crevey BJ, Zipes DP. Interactions between electronic article surveillance systems and

implantable cardioverter-defibrillators. *Circulation*. 1999 Jul 27;100(4):387-92. PubMed Full Text

- **Study design:** case series
- **Objective:** evaluate ICD function in patients exposed to 3 common electronic surveillance systems
- **Population:** 170 patients with ICD
- **Intervention or Exposure:** 3 electronic surveillance systems manufactured by Sensormatic Electronics Corporation
- **Comparison(s):** NA
- **Outcome(s):** ICD events or defibrillator reprogramming
- **Duration of follow-up:** immediate
- **Certainty (reasons for LOE downgrade):**
  - **Risk of bias:** single arm study
  - **Precision:** no other serious concerns
  - **Directness:** evaluated systems from only 1 manufacturer
  - **Consistency assessment:** no other serious concerns
  - **Other considerations:** no other serious concerns
- **Results:** quickly walking through electronic surveillance systems reported to induce interactions in 0%, but clinically important interference reported in 4.1% of volunteers standing close to gate transmitter for 2 minutes in cohort study of 170 patients with ICD

- **Study conclusion (DMP level of evidence): 1.5 Tesla magnetic resonance imaging (MRI) scan appears to have low risk of adverse events in patients with non-MRI conditional implantable cardioverter-defibrillators or pacemakers (level 2 [mid-level] evidence)**
  - **Reference:** Nazarian S, Hansford R, Rahsepar AA, Weltin V, McVeigh D, Gucuk Ipek E, et al. Safety of Magnetic Resonance Imaging in Patients with Cardiac Devices. *N Engl J Med*. 2017 Dec 28;377(26):2555-2564. PubMed Full Text
  - **Study design:** prospective cohort study
  - **Objective:** evaluate safety of using MRI at magnetic field strength at 1.5 Telsa in patients with pacemakers or ICD
  - **Population:** 1,509 adults (median age 69 years, 64% men) with non-MRI conditional implantable cardioverter-defibrillator (ICD) (42%) or pacemaker (58%) having 2,103 clinically indicated 1.5 Tesla MRI scans were assessed
    - exclusion criteria included lead implantation ≤ 4 weeks prior, permanent surgical epicardial or nonfunctional leads, subcutaneous ICD, dependence on pacing with ICD without asynchronous pacing mode, and ICD model before year 2000 or pacemaker model before year 1996
    - changes to cardiac device settings prior to MRI scan
      - if heart rate < 40 beats/minute, then set to asynchronous pacing mode
      - if heart rate ≥ 40 beats/minute, then set to no pacing mode
      - deactivation of functions to treat tachyarrhythmia
  - **Intervention or Exposure:** MRI exposure
    - after MRI, baseline settings were restored and device interrogation performed
    - MRI scan region was head or neck in 52% of scans, abdomen or pelvis in 27%, thorax in 12%, and arm or leg in 9%
    - 96% of all MRI scans performed without power-on reset, need for early termination, or notable change in lead setting immediately after MRI

- **Comparison(s):** NA
- **Outcome(s):** patient-reported outcomes (pain or discomfort) and generator failure, power-on reset, changes in pacing threshold, or sensing for system revision or programming, battery depletion, cardiac arrhythmia, inhibition of pacing, and inappropriate delivery of antitachycardia pacing or shock
- **Duration of follow-up:** during and immediately following MRI for all patients; data for long term follow-up (median 1 year) available for 63% of patients
- **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** no serious concerns
    - **Precision:** no serious concerns
    - **Directness:** single center data; may not be generalizable to all facilities**;** may not be generalizable to interactions with higher MRI field strengths
    - **Consistency assessment:** no serious concerns
    - **Other considerations:** no serious concerns
- **Results:** adverse events during or immediately after MRI included
    - power-on reset in 9 scans (0.4%)
        - device replacement in 1 instance in which device had < 1 month of expected battery life
        - transient in 8 instances
    - premature MRI termination in 7 scans (0.3%) due to image artifacts (3), arrhythmia (2), pulling sensation in chest (1), or reversion to inhibited pacing mode in a pacing-dependent patient (without clinical sequelae) (1)
    - device parameter changes of > 50% from baseline included
        - decrease in P-wave amplitude in 1% of patients immediately after MRI
        - decrease in P-wave amplitude (4%), increase in atrial capture threshold (4%), increase in right ventricular capture threshold (4%), or increase in left ventricular capture threshold (3%) at median 1-year follow-up of 958 patients
    - no parameter changes resulted in device revision or reprogramming

- **Study conclusion (DMP level of evidence): nonthoracic magnetic resonance imaging (MRI) does not appear to cause device or lead failure in patients with non-MRI-conditional implanted cardiac devices (level 2 [mid-level] evidence)**
    - **Reference:** Russo RJ, Costa HS, Silva PD, Anderson JL, Arshad A, Biederman RW, et al. Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator. *N Engl J Med*. 2017 Feb 23;376(8):755-764. PubMed
    - **Study design:** prospective cohort study
    - **Objective:** evaluate safety of using MRI at magnetic field strength at 1.5 Telsa in patients with pacemakers or ICD
    - **Population:** 1,246 adults with non-MRI-conditional ICD (34%) or pacemaker (66%) implanted after 2001 had 1,500 nonthoracic 1.5 Tesla MRI scans
        - changes to cardiac device settings prior to MRI scan
            - patients with pacemakers
                - not dependent on pacing had pacing and sensing functions and magnet response disabled
                - dependent on pacing had pacemakers set to asynchronous pacing mode and magnet response disabled

        - patients with ICDs not dependent on pacing had antitachycardia, sensing, and pacing functions disabled (patients with ICDs who were dependent on pacing were not eligible for study entry)
        - baseline settings were restored and full device interrogation completed following MRI
    - **Intervention or Exposure:** MRI
        - MRI scan region was spine in 46% of scans, brain in 39%, extremity or joint in 11%, abdomen or pelvis in 5%, and other in 11%
    - **Comparison(s):** NA
    - **Outcome(s):** death, generator or lead failure, loss of capture, cardiac arrhythmia, loss of capture, electrical reset, reprogramming
    - **Duration of follow-up:** during and immediately following MRI
    - **Certainty (reasons for LOE downgrade):**
        - **Risk of bias:** study supported by industry funded grants; however, authors state that funders did not have a role in design of study protocol, data collection or analysis, or writing of manuscript
        - **Precision:** no serious concerns
        - **Directness:** may not be generalizable to interactions with higher MRI field strengths
        - **Consistency assessment:** no serious concerns
        - **Other considerations:** no serious concerns
    - **Results:**
        - during or immediately after MRI
            - self-terminating atrial arrhythmia in 0.5% of scans in patients with pacemakers and 0.2% of scans in patients with ICDs (0.4% overall)
            - partial electrical reset in 0.6% of scans in patients with pacemakers and 0% of scans in patients with ICDs
            - no deaths, ventricular arrhythmia, lead failures requiring immediate replacement, or loss of capture reported
        - repeat MRI not associated with increase in device setting changes

- **Study conclusion (DMP level of evidence): magnetic resonance imaging does not appear to cause device malfunctions in most patients with select standard implanted cardiac devices (level 2 [mid-level] evidence)**
    - **Reference:** Nazarian S, Hansford R, Roguin A, Goldsher D, Zviman MM, Lardo AC, et al. A prospective evaluation of a protocol for magnetic resonance imaging of patients with implanted cardiac devices. *Ann Intern Med*. 2011 Oct 4;155(7):415-24. PubMed
    - **Study design:** prospective cohort study
    - **Objective:** evaluate safety of using MRI at magnetic field strength at 1.5 Telsa in patients with pacemakers or ICD
    - **Population:** 438 patients with non-MRI conditional ICD (46%) had 555 clinically indicated 1.5 Tesla MRI scans and were monitored for blood pressure, electrocardiography, oximetry, and symptoms
        - changes to cardiac devices prior to MRI scan
            - if patient dependent on pacemaking, then set to asynchronous pacing mode
            - if patient not dependent on pacemaking, then set to demand

        - deactivation of functions to treat tachyarrhythmia
    - **Intervention or Exposure:** MRI
        - MRI scan region was brain in 40% of scans, spine in 22%, heart in 16%, abdomen or pelvis in 13%, and arm or leg in 9%
    - **Comparison(s):** NA
    - **Outcome(s):** appropriate device function (sensing, lead impedance, appropriate capture), activation or inhibition of pacing, patient symptoms
    - **Duration of follow-up:** immediately after MRI and long-term data (median 214 days) available for 61%
    - **Certainty (reasons for LOE downgrade):**
        - **Risk of bias:** low long-term follow up rate
        - **Precision:** no serious concerns
        - **Directness:** may not be generalizable to interactions with higher MRI field strengths
        - **Consistency assessment:** no serious concerns
        - **Other considerations:** no serious concerns
    - **Results:**
        - 0.7% of patients had cardiac device revert back to transient back-up programming mode during MRI but not associated with long-term effects
        - no device revision or reprogramming required during follow-up for any devices

- **Study conclusion (DMP level of evidence): MRI does not appear to increase risk of device-related complications or decrease device performance in patients with MRI-safe ICDs (level 2 [mid-level] evidence)**
    - **Reference:** Gold MR, Sommer T, Schwitter J, Al Fagih A, Albert T, Merkely B, et al.; Evera MRI Study Investigators.Full-Body MRI in Patients With an Implantable Cardioverter-Defibrillator: Primary Results of a Randomized Study. *J Am Coll Cardiol*. 2015 Jun 23;65(24):2581-2588. PubMed Full Text
    - **Study design:** randomized trial
    - **Objective:** evaluate safety of full-body MRI in patients with MRI-safe ICDs
    - **Population:** 263 patients (mean age 60 years, 76% men) with MRI-safe single- or dual-chamber ICD were randomized 9-12 weeks after implantation to full-body 1.5-Tesla MRI vs. no MRI
        - MRI-safe ICDs (Evera MRI ICD) are specifically designed to reduce interaction with MRI environment during full-body MRI
    - **Intervention or Exposure:** 175 patients allocated to undergo MRI
    - **Comparison(s):** 88 patients allocated to control group (1 hour waiting period)
    - **Outcome(s):** sustained ventricular tachyarrhythmia, complication related to MRI within 30 days, and loss of capture within 30 days of MRI
    - **Duration of follow-up:** within 30 days post MRI
    - **Certainty (reasons for LOE downgrade):**
        - **Risk of bias:** no intention-to-treat analysis
        - **Precision:** no serious concerns
        - **Directness:** may not be generalizable to interactions with higher MRI field strengths
        - **Consistency assessment:** no serious concerns
        - **Other considerations:** no serious concerns

- **Results:**
  - 91% received intervention and were included in safety analyses
  - no device-related complications including sustained ventricular tachyarrhythmia during MRI, MRI-related complications within 30 days, or loss of capture within 30 days were reported
  - no significant differences in ventricular pacing or sensing between groups

Information from patient education materials

- **Devices that can interfere with an ICD include:**
  - Cell phones and MP3 players: Cell phones and MP3 plays may still be used, but patients are advised to avoid putting these devices in shirt pockets near the ICD and are recommended to hold their cell phone to the ear opposite of the implant.
  - Some household appliances, like microwave ovens: Appliances can still be used, but patients are advised to keep some distance
  - Metal detectors: Patients are advised to notify security before going through a metal detector and to not sit or stand close to a detector for a prolonged period of time
  - Industrial welders and electrical generators: Patients are advised to stay at least 2 feet away from industrial welders or electrical generators
  - High-tension wires
  - Reference: National Heart, Lung, and Blood Institute. Implantable cardioverter defibrillators. National Heart, Lung, and Blood Institute website. https://www.nhlbi.nih.gov/health-topics/implantable-cardioverter-defibrillators#. Accessed May 25, 2018.
- **Most household equipment, including power tools and electronic devices, pose little risk, but patients are advised to keep equipment at least 6 inches away from their ICD**
  - Reference - American Heart Association. Devices that may interfere with implantable cardioverter defibrillators (ICD). American Heart Association website. http://www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/Devices-that-may-Interfere-with-Implantable-Cardioverter-Defibrillators-ICDs_UCM_448464_Article.jsp#.Ww15VIgvyUl. Last updated September 2016. Accessed May 25, 2018.
- **Patients are advised to keep headphones at least 6 inches away from their ICD**
  - Reference - American Heart Association. Devices that may interfere with implantable cardioverter defibrillators (ICD). American Heart Association website. http://www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/Devices-that-may-Interfere-with-Implantable-Cardioverter-Defibrillators-ICDs_UCM_448464_Article.jsp#.Ww15VIgvyUl. Last updated September 2016. Accessed May 25, 2018.
- **small number of reports of x-rays used during computed tomography (CT) examinations causing some implanted and external electronic medical devices to malfunction, but most patients with electronic medical devices have no adverse events with CT scans**
  - Reference – Public Health Notification from FDA MedWatch 2008 Jul 16

Battery life
Evidence

PubMed search string

(("defibrillators, implantable"[MeSH Terms] OR ("defibrillators"[All Fields] AND "implantable"[All Fields]) OR "implantable defibrillators"[All Fields] OR ("implantable"[All Fields] AND "cardioverter"[All Fields] AND "defibrillator"[All Fields]) OR "implantable cardioverter defibrillator"[All Fields]) AND battery[All Fields] AND ("longevity"[MeSH Terms] OR "longevity"[All Fields])) AND ("humans"[MeSH Terms] AND English[lang])

returned 48 citations on May 29, 2018, of which 2 were included.

- **Study conclusion (DMP level of evidence): Median battery life for single- or dual-chamber implantable cardioverter defibrillator reported to be 5.9 years (level 3 [lacking direct] evidence)**
  - **Reference:** Zanon F, Martignani C, Ammendola E, Menardi E, Narducci ML, DE Filippo P, Santamaria M, Campana A, Stabile G, Potenza DR, Pastore G, Iori M, LA Rosa C, Biffi M. Device Longevity in a Contemporary Cohort of ICD/CRT-D Patients Undergoing Device Replacement. *J Cardiovasc Electrophysiol*. 2016 Jul;27(7):840-5. PubMed
  - **Study design:** case-series study
  - **Objective:** report on time and reason for ICD and CRT-D replacement
  - **Population:** 1,012 consecutive patients underwent replacement or upgrade for ICD or CRT-D from March 2013 to May 2015
  - **Intervention or Exposure:**
  - **Comparison(s):** NA
  - **Outcome(s):** time and reason for replacement
  - **Duration of follow-up:** NA
  - **Results:**
    - overall median battery life of 5.9 years in single and dual chamber ICD implants
    - reported median time to replacement for battery depletion
      - 5.3 years for Biotronik devices
      - 6.3 years for Boston Scientific devices
      - 6.4 years for Medtronic devices
      - 6.7 years for St. Jude Medical devices
      - 6.4 years for Sorin devices

- **Study conclusion (DMP level of evidence): in industry funded study, longevity for implantable cardioverter defibrillator battery reported to be up to 13 years using remote monitoring system (level 3 [lacking direct] evidence)**
  - **Reference:** Boriani G, Ritter P, Biffi M, Ziacchi M, Diemberger I, Martignani C, Valzania C, Valsecchi S, Padeletti L, Gadler F. Battery drain in daily practice and medium-term projections on longevity of cardioverter-defibrillators: an analysis from a remote monitoring database. Europace. 2016 Sep;18(9):1366-73. PubMed Full Text
  - **Study design:** cohort analysis of industry funded database
  - **Objective:** evaluate device measured residual battery capacity and battery longevity projections

- **Population:** 4,851 patients with ICD or CRT-D implants followed for a minimum of3 years using remote monitoring system
    - 58% of patients had single or dual chamber ICD
- **Intervention or Exposure:** evaluate risk factors for battery drain, including age, sex, low left ventricular ejection fraction (LVEF), New York Heart Association (NYHA) class, atrial fibrillation, atrioventricular junction ablation, coronary artery disease, diabetes, and implantation of CRT-D
- **Comparison(s):** NA
- **Outcome(s):** battery longevity, battery drain
- **Duration of follow-up:** followed for minimum 3 years
- **Results:** multi-linear regression analysis used to identify variables associated with year-to-year decrease in battery function
    - Using risk stratification model, ICD battery longevity projection estimates
        - 13 years for patients with single-chamber ICDs
        - 12 years for patients with dual-chamber ICDs

Information from patient education material

- **ICD batteries typically last**
    - between 5 and 7 years
        - References – (1) EBSCO Health Patient Education Reference Center. Discharge instructions for automatic cardioverter/defibrillator implantation. EBSCO Health Patient Education Reference Center website. http://web.b.ebscohost.com/perc/detail?vid=3&sid=4be670a7-deb9-4c72-aea2-eedfe427e6aa%40sessionmgr101&bdata=JnNpdGU9cGVyYy1saXZl#AN=2009869581&db=perc. Accessed Jun 22, 2018.; (2) American Heart Association. Living with your implantable cardioverter defibrillator (ICD). American Heart Association website. http://www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/Living-With-Your-Implantable-Cardioverter-Defibrillator-ICD_UCM_448462_Article.jsp#.Wy0W_6dKiUk. Accessed Jun 22, 2018.
    - between 4 to 8 years
        - Reference - MedLine Plus. Implantable cardioverter defibrillator - discharge. Medline Plus website. https://medlineplus.gov/ency/patientinstructions/000108.htm. Reviewed Aug 2, 2016. Accessed Jun 22, 2018.
    - between 5 and 8 years
        - Reference - Heart Rhythm Society. Implantable cardioverter defibrillators. Heat Rhythm Society website. https://www.hrsonline.org/Patient-Resources/Treatment/Implantable-Cardioverter-Defibrillator#axzz3GE42fmXb Accessed Jun 22, 2018.
    - between 7 and 10 years (Expert Opinion from content clinical reviewer)

Device recalls

In addition to searching DynaMed Plus and EBSCO Health Patient Education Reference Center, a generic search of "ICD recalls patient implications" was done on the search engine Google on May 29, 2018.

- Tracking devices under advisory is advised as part of routine follow-up (Expert Opinion)
  - Reference - Epstein AE, DiMarco JP, Ellenbogen KA, Estes NA 3rd, Freedman RA, Gettes LS, et al; American College of Cardiology Foundation; American Heart Association Task Force on Practice Guidelines; Heart Rhythm Society. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Circulation. 2013 Jan 22;127(3):e283-352. PubMed Full Text
- Safety advisories or device recalls for ICDs may be issued. In a cohort of 1,051 patients with ICD, about 26% of ICD devices underwent a recall over a period of about 8 years. As a result, about 6% of generators needed to be replaced and about 11% of leads needed to be replaced.
  - Reference - Schwartz J, Blangy H, Zinzius PY, Freysz L, Aliot E, Sadoul N. Recall alerts in implantable cardioverter-defibrillator recipients: implications for patients and physicians. *Pacing Clin Electrophysiol*. 2011 Jan;34(1):96-103. PubMed

Deactivation, including end-of-life considerations

Sources were retrieved by searching DynaMed Plus (and tracing citations) and Google ("ICD deactivation" and "ICD extraction guidelines") on May 29, 2018. PubMed ("Implantable cardioverter defibrillator end-of-life care") was also searched on Aug 23, 2018 for reviews on ICD deactivation awareness and considerations.

Deactivation considerations

- Patients have the option of deactivating their ICD. Deactivation can be done by electronically altering the settings on the device without surgical procedure.
  - Reference - British Heart Foundation. ICD deactivation: your questions answered. British Heart Foundation website. https://www.bhf.org.uk/heart-matters-magazine/medical/icds-and-end-of-life/icd-deactivation-faqs. Accessed May 29, 2018.
- A patient with decision-making capacity has the legal right to refuse or request the withdrawal of any medical treatment. If the patient lacks capacity, a surrogate decision-maker may refuse/request withdrawal on their behalf.
  - Reference - Lampert R, Hayes DL, Annas GJ, Farley MA, Goldstein NE, Hamilton RM, et al; American College of Cardiology; American Geriatrics Society; American Academy of Hospice and Palliative Medicine; American Heart Association; European Heart Rhythm Association; Hospice and Palliative Nurses Association. HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. *Heart Rhythm*. 2010 Jul;7(7):1008-26. PubMed

Extraction considerations

- Due to the potential for adverse events, it is recommended that ICDs are not removed unless there is an appropriate indication for extraction, including battery replacement, infection, or chronic pain related to the device.

- Reference - Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul CI, Birgersdotter-Green UM, Carrillo R, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. *Heart Rhythm*. 2017 Dec;14(12):e503-e551. PubMed Full Text

ICD deactivation awareness and patient preferences in end stage of life

- ICD shocks in the end stage of life may be distressing to the patient, caregivers, and relatives; deactivation may allow for a more peaceful final stage of life
  - based on systematic review of 15 observational studies with 1,362 patients with ICD in final stage of life
  - incidence of shocks in the final hour of life in 22%-66% in analysis of 7 studies
  - 3 studies evaluated impact of shocks on patients
    - 76% of physicians reported that patients are distressed by shocks in final stage of life
    - hospice caregivers reported distress in 74% of patients receiving shocks in final stage of life
    - hospice caregivers reported distress in 92% of (witnessing) family members of patients receiving shocks in final stage of life
  - Reference - Stoevelaar R, Brinkman-Stoppelenburg A, Bhagwandien RE, et al. The incidence and impact of implantable cardioverter defibrillator shocks in the last phase of life: An integrated review. *Eur J Cardiovasc Nurs*. 2018 Aug;17(6):477-485. PubMed
- Discussion between the provider and patient on ICD deactivation considerations is needed to determine desired end of life care
  - based on systematic review of 9 observational studies, including 5 quantitative and 4 qualitative studies, with 25,132 patients with ICDs and 362 providers
  - patients may be uniformed about ICD deactivation options
    - only 7% of patients discussed end of life deactivation with their provider and 46% never considered deactivation in 1 study with 109 patients
    - 36% of providers reported that initiating discussion on ICD deactivation is dependent on circumstances and only 15% of providers rated ICD deactivation discussions as “important” in 1 study with 177 providers
  - recommendations on when ICD deactivation should be discussed based on structured interview of 25 patients
    - before implantation
    - with indication of health decline
    - at end of life
  - Herman M, Horner K, Ly J, Vayl Y. Deactivation of Implantable Cardioverter-Defibrillators in Heart Failure: A Systematic Review. *J Hosp Palliat Nurs*. 2018 Feb;20(1):63-71. PubMed
- A person may choose to have their ICD deactivated because they are terminally ill, their quality life has changed and they do not want treatment from the ICD, or they are at the end of their life.
  - Reference - Heart Rhythm Society. End of life and heart rhythm devices. https://www.hrsonline.org/content/download/21396/940307/file/End%20of%20Life%20and%20Heart%20Rhythm%20Devices.pdf. Accessed on May 29, 2018
- Majority of patients may desire ICD deactivation in the context of significant functional and cognitive disabilities

- based on survey
- 95 patients ≥ 50 years old (72% male) with ICD completed 20-minute telephone survey about potential benefits and harms of ICD and deactivation preferences regarding the following scenarios
    - permanently unable to get out of bed
    - permanent memory problems
    - burden to family members
    - prolonged (> 1 month) mechanical ventilation
    - advanced incurable disease
- 71% "possibly" or "definitely" desired ICD deactivation in ≥ 1 scenario
- Reference - Dodson JA, Fried TR, Van Ness PH, Goldstein NE, Lampert R. Patient preferences for deactivation of implantable cardioverter-defibrillators. *JAMA Intern Med*. 2013 Mar 11;173(5):377-9. PubMed Full Text

- Germany: Position paper by the German Society for Cardiology and sister organizations on "Responsible handling of the ICD" was published in August 2017, with the following content:
    - Address that the deactivation of ICD device at the end-of-life is an important, patient-relevant aspect of ICD treatment
    - Ethical questions surrounding deactivation at the end-of-life need to be addressed. Non-deactivated ICDS may prolong the process of dying and cause unnecessary suffering and pain by repeatedly shocking the patients heart. The experts in this context talk about "palliative ICD deactivation"
    - Shared decision making including comprehensive information of the patient on the pros and cons of ICD implants are considered a must in these situations.
    - The recommendations suggest that
        1. Patients should talk to their physicians and physicians should talk to their patients about the potential palliative ICD deactivation early in the treatment process and discuss as specific as possible about when and how to deactivate the device.
        2. Patients should talk to their family members or other important relatives / friends / caregivers about this difficult topic early in the treatment process.
        3. The decision on how to proceed in these situations should be taken and written down, e.g. in a patient consent or patient decree form. This should be done early in the treatment process when the patient is still able and willing to take such an important decision.
    - Reference - Waltenberger J, Schöne-Seifert B, Friedrich DR, Alt-Epping B, Bestehorn M, Dutzmann J, Ertl G, Fateh-Moghadam B, Israel CW, Maase A. Verantwortlicher Umgang mit dem ICD ("Responsible Handling of the ICD", Stellungnahme der Deutschen Gesellschaft für Kardiologie und Ihrer Schwestergesellschaften, Kardiologe 2017. 11: 383-397

Part 5 - Evidence Synthesis

Methods

Evidence synthesis process

Synthesis methods will be based on the most appropriate methods matching the available evidence. We will systematically consider synthesis methods with the following questions:

Is it useful and appropriate to present the synthesis of evidence results as a combined, single result as the best representation of the body of evidence?

State "Yes" or "No". Provide justification if "No".

If "Yes", what method is the best approach?

Pick one of the following and justify:

(1) meta-analysis already done

(2) meta-analysis created from the evidence results

(3) median of sufficiently-valid results, stating cutoff for validity

(4) median of all results

If "No", what method is best to represent the evidence synthesis?

Pick one of the following and justify:

(1) range of all results

(2) range of sufficiently valid results

(3) descriptive summary without quantitative representation (e.g., consistency in direction, but inconsistency in magnitude)

(4) statement of inconsistency too limiting for single synthesized conclusion

Where evidence is very limited, or the FAQ is for descriptive summary, such that summary text was provided instead of Evidence Review Tables, the Descriptive Evidence Summary will be noted.

Results

FAQ 1: What does the treatment involve?

FAQ1a: ICD

Pre-Synthesis Efforts: Not applicable

Descriptive Summary

Types of implantable cardioverter-defibrillators (ICDs) and having an ICD placed

An implantable cardioverter-defibrillator (ICD) is a small device – smaller and thinner than a deck of cards, or about the size of a pager – that delivers electric shocks when the device senses the heart is in a dangerous rhythm. The "traditional" or transvenous ICD is the most commonly used ICD. A traditional ICD is typically placed under the skin just below the collarbone on the left side of the chest. The incision required to do this is typically not very large (about 2 inches). Wires from the ICD are then passed through a large vein under the collarbone to reach the chamber(s) of the heart where the wires need to go (inside the chamber for the right side of the heart, and on the surface of the heart for the left side).

A subcutaneous ICD is a newer type of ICD that is typically placed under the skin along the left side of the chest in the underarm area. It is bigger than a traditional ICD, so a bigger incision is needed (about 4 to 5 inches), but some patients appreciate the incision (and the device) being more hidden compared to a traditional ICD. One potential benefit of a subcutaneous ICD is that the wire for a subcutaneous ICD does not have to go through the vein like a traditional ICD. Instead, the wire is placed in the tissue to the left of the breastbone rather than in the heart. However, unlike a traditional ICD, a subcutaneous ICD cannot help with pacing, so only people who don't also need pacing can have a subcutaneous ICD. Even if a person does not otherwise need pacing, pacing may also be able to stop at least some rhythms from ever getting to the point where an electrical shock is needed. There are other considerations that determine whether a subcutaneous ICD is an option. For example, it may not be good for people who are very thin, and sometimes a person's electrocardiogram may suggest it is not a good option.

Having an ICD placed may generally take about 2 to 5 hours (the actual time will depend on the specifics of the patient). You can be awake while the ICD is placed, but you will be given medicine to make you sleepy and to numb the area where the ICD is being placed. An ICD is sometimes placed as an outpatient procedure, but it is common to spend one night in the hospital for monitoring.

See FAQ3 for discussion of recovery after having an ICD placed and ICD shocks.

Deactivation of an ICD

An ICD can be deactivated at any time if the person desires. If an ICD is deactivated, it will no longer monitor a person's heart rhythm, and it will not deliver shocks.

(AHA 2016; Al-Khatib 2018; Cleveland Clinic 2015, 2018; EBSCO Health Patient Education Reference Center 2016; El Moheb 2018; Epstein 2012; Johns Hopkins nd; HRS nd; Klein 2017; Levine 2012; Mayo Clinic 2017; NIH 2018; Turakhia 2010; Turnage 2018; Vijgen 2009)

A device will be placed under your skin. Wires will connect it to your heart. Having an ICD placed may take 2 to 5 hours depending on the patient and the type of ICD. It is common to stay overnight in the hospital after you have an ICD placed. If your heart rhythm becomes dangerously abnormal, the ICD will shock the heart to a better rhythm. The shock might feel like a sudden kick to the chest. You will continue taking medications.

FAQ1b: No ICD

Pre-Synthesis Efforts: Not applicable

Descriptive Summary

You will not receive an ICD. You will continue taking medications.

FAQ 2: Will I live longer?

FAQ2a/b: ICD vs no ICD

Pre-Synthesis Efforts:

Part 2 Search:

	Number of articles evaluated	Number of unique articles selected for evaluation
First-round (DynaMed Plus)	29	1 (El Moheb 2018)
Second-round (Systematic review searches)	Not applicable	
Third-round (Original study tracing)	Tracing of two other systematic reviews published in 2018 on the same topic as El Moheb 2018 (Alba 2018, Beggs 2018) and the DANISH trial (Køber 2016), which are discussed within the context of El Moheb 2018 (therefore, these do not receive an individual summary in Part 3)	
Fourth-round (Original article searches)	Not applicable	

Part 3 Critical Appraisal (evidence evaluated for FAQ2):

Certainty	**Systematic reviews**	**Randomized trials**	**Other article types**
High	El Moheb 2018 (for both all-cause mortality and sudden cardiac death)		
Moderate			
Low			
Very low			
Unusable			
Not applicable			

Evidence Synthesis Process for FAQ2
Is it useful and appropriate to present the synthesis of evidence results as a combined, single result as the best representation of the body of evidence?

Yes

If "Yes", what method is the best approach?

Pick one of the following and justify:

(1) meta-analysis already done

Results from a 2018 Cochrane review provide relative risk estimates representing the best estimates of effect from the body of evidence.

The most valid evidence for effect estimates for all-cause mortality and sudden cardiac death are found in 2018 Cochrane review with High certainty for both outcomes (El Moheb 2018, which includes the DANISH trial).

Part 4 Results for FAQ2:

Comparing implantable cardioverter-defibrillator plus optimal medical therapy vs. optimal medical therapy alone on all-cause mortality and sudden cardiac death (El Moheb 2018)

Outcome	Follow-up duration (range)	Number of patients (studies)	Relative effect	Control group event rate (n/N)	Intervention group event rate estimate*	Certainty (downgrade reason)
All-cause mortality†	16.5 to 67.6 months‡	3,128 (6)	HR 0.78 (95% CI 0.66 to 0.92)	21.79% (195/895)	17.44%	High
Sudden cardiac death	24 to 67.6 months‡	1,677 (3)	RR 0.47 (95% CI 0.30 to 0.73)	7.37% (62/841)	3.46%	High

* These rates are estimated in the standard fashion with the control group event rate and the relative effect estimate. Of note, the calculation for a hazard ratio is different than the calculation for a relative risk.
† Cochrane review includes table that displays comparison with 20 other systematic reviews published on this topic since 2016 and all but 1 reported significant decrease in all-cause mortality
‡ The study contributing the most data to both these analyses is the DANISH trial, which had a median follow-up duration of 67.6 months (about 5.6 years). Therefore, we use the follow-up period from DANISH for summary statements.

El Moheb 2018 includes a subgroup analysis for age (using a cut-point of 65 years of age) based on results from a single trial (the DANISH trial). This is considered in detail in Part 3, but briefly: Age *per se* is considered unlikely to be a genuine effect modifier, and therefore it is not considered appropriate for evidence synthesis statements/conclusions regarding age-stratified or age-dependent results. Instead, we emphasize the importance of assessing a patient's overall clinical picture (i.e., comorbidities, functional status, competing risks, life expectancy) to help determine appropriateness/candidacy for ICD therapy. This is also consistent with suggestions from both the DANISH trial authors (Køber 2016) and

2017 guidelines from the American Heart Association, American College of Cardiology, and Heart Rhythm Society (Al-Khatib 2018).

Out of 100 people with non-ischemic cardiomyopathy with left ventricular ejection fraction ≤35%:

17 (17%) may die of any cause with ICD implantation within 5 to 6 years
22 (22%) may die of any cause with no ICD implantation within 5 to 6 years

3 (3%) may die of sudden cardiac death with ICD implantation within 5 to 6 years
7 (7%) may die of sudden cardiac death with no ICD implantation within 5 to 6 years

FAQ 3: Will it change my usual activities?

FAQ3a: ICD

Pre-Synthesis Efforts:

Part 2 Search:

	Number of articles evaluated	Number of unique articles selected for evaluation
First-round (DynaMed Plus)	29	1 (El Moheb 2018)
Second-round (Systematic review searches)	Not applicable	
Third-round (Original study tracing)	Not applicable	
Fourth-round (Original article searches)	Not applicable	

Part 3 Critical Appraisal (evidence evaluated for FAQ3a):

Certainty	**Systematic reviews**	**Randomized trials**	**Other article types**
High			
Moderate	El Moheb 2018 (for health-related quality of life)		
Low			
Very low			
Unusable			
Not applicable			

Evidence Synthesis Process for FAQ3a
Is it useful and appropriate to present the synthesis of evidence results as a combined, single result as the best representation of the body of evidence?

No

If "No", what method is best to represent the evidence synthesis?
Pick one of the following and justify:

(3) descriptive summary without quantitative representation (e.g., consistency in direction, but inconsistency in magnitude)

Only 2 of the randomized trials included in the Cochrane review (El Moheb 2018) reported on quality of life, and because they each reported data in different ways and at different time points, their results were not pooled (see table below). Other outcomes pertinent to FAQ3 were not reported in randomized trials.

Part 4 Results for FAQ3a: Health-related quality of life

Outcome	Follow-up duration (range)	Number of patients (studies)	Key findings	Certainty (downgrade reason)
Health-related quality of life	24 to 29 months	561 (2)	Health-related quality of life was evaluated in 2 trials (AMIOVIRT and DEFINITE) using a total of 4 different scales (2 scales for each trial). Neither trial showed statistically significant difference in score between the ICD and control groups, on either scale. Because the trials reported data in different ways and at different time points, their results were not pooled.	Moderate (downgraded due to lack of blinding)

In people with non-ischemic cardiomyopathy with left ventricular ejection fraction ≤35%, we have Moderate certainty evidence of no important difference in health-related quality of life comparing patients with ICD implantation vs. patients with no ICD implantation. However, as noted below, some people feel stress or fear about the idea of having a shock.

Descriptive Summary for FAQ3a: ICD shocks and recovery after having an ICD placed

ICD shocks

When an ICD delivers a shock, it is painful. The pain should only last for a second or so, but people often describe the strongest kind of shock as feeling like they were hit with a baseball bat or kicked by a horse. It may also knock some people off their feet.

Having an ICD does not have to impact a person's day-to-day life, but receiving a shock and/or the fear of possibly receiving a shock causes stress or anxiety for some people.

Recovery after having an ICD placed

You will receive instructions specific to you from your health care professional, but in general:

Full recovery from having an ICD placed may take about 4 to 6 weeks. However, most people return quickly to their normal activity level, including things like exercise, work, and sex.

For 4 weeks after the procedure, you may be advised to avoid:

- lifting anything more than 5 to 15 pounds
- playing contact sports
- strenuous exercises
- certain other activities, many of which involve activity or exercise that can affect the arm on the side of your body where the ICD was placed (e.g., golf, tennis, swimming, bicycling, bowling, or vacuuming)

For people who have never had their heart stop or a dangerous rhythm from the bottom of their heart, the American Heart Association recommends not driving for 1 week after they have an ICD placed. This is generally consistent with German guidelines, which suggest people can drive 1 to 2 weeks after they have an ICD placed. However, an earlier recommendation from the European Society of Cardiology recommends not driving for 4 weeks. If the ICD shocks you, you should notify your health care professional. After having an appropriate shock from the ICD, people are often discouraged from driving or not allowed to drive for up to 3 to 6 months. After an inappropriate shock, people may be discouraged from driving or not allowed to drive until a health care professional verifies appropriate steps have been taken to reduce the chance of additional inappropriate shocks. However, the specifics of driving restrictions may vary somewhat from country to country and even state to state. People are often not able to get a commercial driver's license if they have an ICD.

(see FAQ1 for references)

You may be advised to avoid some heavy activity or activity using your left arm for 4 weeks or so as you heal from the surgery. You may be advised to not drive for 4 weeks or longer. For most of your activity you will not feel a change. Some people feel stress or fear about the idea of having a shock.

FAQ3b: No ICD

Pre-Synthesis Efforts: Not applicable

Descriptive Summary

No

FAQ 4: Can the ICD be turned off or removed?

Pre-Synthesis Efforts: Not applicable

Descriptive Summary

You can have your ICD turned off at any time. If your ICD is turned off, it will no longer monitor your heart, and it will not shock you.

An ICD can also be removed, but this will require another procedure.

(See FAQ1 for references)

FAQ 5: Will the ICD shock my heart?

Pre-Synthesis Efforts:

Part 2 Search:

	Number of articles evaluated	Number of unique articles selected for evaluation
First-round (DynaMed Plus)	29	0
Second-round (Systematic review searches)	24	1 (Auricchio 2017)
Third-round (Original study tracing)	Tracing of a systematic review referenced by Auricchio 2017 (Gonçalves 2013) resulted in our inclusion of a brief discussion of Gonçalves 2013 within the summary for Auricchio 2017 in Part 3, but it did not require a full summary (see Part 3 for details).	
Fourth-round (Original article searches)		

Part 3 Critical Appraisal (evidence evaluated for FAQ5):

Certainty	Systematic reviews	Randomized trials	Other article types
High	Auricchio 2017 (for appropriate shocks)		
Moderate	Auricchio 2017 (for inappropriate shocks)		
Low			
Very low			
Unusable			
Not applicable			

Evidence Synthesis Process for FAQ5
Is it useful and appropriate to present the synthesis of evidence results as a combined, single result as the best representation of the body of evidence?

Yes

If "Yes", what method is the best approach?

Pick one of the following and justify:

(1) meta-analysis already done

Meta-analytic estimates for annual rates of appropriate and inappropriate first shock extracted from a systematic review of observational studies (Auricchio 2017).

Part 4 Results for FAQ5:

Annual rates of appropriate and inappropriate first shock (Auricchio 2017; systematic review of observational studies)

Outcome	Follow-up duration (range in months)	Number of patients (studies)	Shock rate, %/year (95% CI)	Certainty (downgrade reason)
appropriate shocks	11 to 45.5	6,470 (16)	5.8% (95% CI 5.3% to 6.3%)	High
inappropriate shocks	11 to 62.5	3,136 (7)	6.4% (95% CI 5.1% to 7.9%)	Moderate (downgraded due to heterogeneity)

Each year, out of 100 people with an ICD:

- **About 6 (6%) may experience an appropriate shock**
- **About 6 (6%) may experience an inappropriate shock**

When an ICD delivers a shock, often only one shock is delivered. However, some people may receive more than one shock.

FAQ 6: What are the risks of having the ICD put in place?

Pre-Synthesis Efforts:

Part 2 Search:

	Number of articles evaluated	Number of unique articles selected for evaluation
First-round (DynaMed Plus)	39	2 (Dodson 2014, Ranasinghe 2016)
Second-round (Systematic review searches)	Not applicable	
Third-round (Original study tracing)	Not applicable	
Fourth-round (Original article searches)	Not applicable	

Part 3 Critical Appraisal (evidence evaluated for periprocedural risks for FAQ6):

Certainty	Systematic reviews	Randomized trials	Other article types
High			Dodson 2014, Ranasinghe 2016
Moderate			
Low			
Very low			
Unusable			
Not applicable			

Evidence Synthesis Process for FAQ6, periprocedural risks and Summarization of Part 4 Results

To estimate the risks of having the ICD implanted, we used as our evidence source a report that analyzed the proportion of patients with a range of periprocedural complications during hospital stay among 240,632 ICD implantation procedures conducted in United States from April 2010 to December 2011 (Dodson 2014). However, this report did not include pocket-related complications; therefore, data for this complication was extracted from another evidence source which primarily assessed long-term risks for device-related complications after ICD implantation procedures conducted in 114,484 patients in United States from April 2006 to 2010 and found that pocket-related complications occurred primarily during first 90 days (Ranasinghe 2016).

Risk of periprocedural complications and mortality during hospital stay among 240,632 ICD implantation procedures conducted in United States from April 2010 to December 2011 (Dodson 2014)

Risk of complications and mortality among study sample*	N (%)
Complication (any)	3,751 (1.56)
Lead dislodgement	1,580 (0.66)
Hematoma	723 (0.30)
Pneumothorax	573 (0.24)
Cardiac arrest	482 (0.20)
Coronary venous dissection	230 (0.10)
Device-related infection	194 (0.08)
Pericardial tamponade	147 (0.06)
Cardiac perforation	107 (0.04)
Stroke or transient ischemic attack	106 (0.04)
Hemothorax	60 (0.02)
Set screw problem	67 (0.03)
Urgent cardiac procedure	38 (0.02)
Myocardial infarction	41 (0.02)
Mortality	637 (0.26)
Complications or mortality	4,388 (1.82)

*Certainty was judged High for all outcomes

Absolute risk estimate for pocket-related complications within 90 days, based on data from Ranasinghe 2016, was 0.089% (95% CI 0.072% to 0.106%).

Evidence Synthesis Result for FAQ6: periprocedural risks

In-hospital complications following ICD implantations are uncommon. Out of 1000 patients at the hospital following their ICD implantation:

- fewer than 3 (< 0.3%) will die
- fewer than 16 (< 2%) will have any complication
    - considering specific complications, complications with rates > 0.2% include
        - lead dislodgement – 0.66%
        - hematoma – 0.3%
        - pneumothorax – 0.24%
        - cardiac arrest 0.2%

Complications that immediately follow an ICD being placed (while the patient is still in the hospital) are uncommon. The risk of any complication is less than 2 out of 100 (2%).

- **Serious complications, such as death, having a lung collapse, having the heart stop all happen in less than 1 out of 100 (<1%).**
- **Of the less serious complications, having the wires move out of place or having a pocket of blood at the place where the ICD is inserted are the most common. These also happen in less than 1 out of 100 (<1%).**

FAQ 7: What are the long-term risks?

FAQ7a: ICD

Pre-Synthesis Efforts:

Part 2 Search:

	Number of articles evaluated	Number of unique articles selected for evaluation
First-round (DynaMed Plus)	30	1 (Ranasinghe 2016)
Second-round (Systematic review searches)		
Third-round (Original study tracing)		
Fourth-round (Original article searches)		

Part 3 Critical Appraisal (evidence evaluated for FAQ7a):

Certainty	Systematic reviews	Randomized trials	Other article types
High			Ranasinghe 2016
Moderate			
Low			
Very low			
Unusable			
Not applicable			

Evidence Synthesis Process for FAQ7a, risks and Summarization of Part 4 Results

Long-term risk for device-related complications and reoperations after ICD implantation procedures conducted in 114,484 patients in United States from April 2006 to 2010 (Ranasinghe 2016)

Outcome	Cumulative incidence			Certainty
	1-year follow-up	3-year follow-up	5-year follow-up	
Any ICD-related complication	7%	11%	14%	High
Complication requiring reoperation	4%	6%	8%	High
Complication requiring hospitalization only	4%	6.5%	8%	High
ICD reoperations for reasons other than complications*	1.5%	5%	19%	High

* reoperations for reasons other than complications typically include device upgrades or generator replacements for battery depletion; these events occurred throughout follow-up, but highest rates were observed after third year

An ICD battery typically last about 5 to 8 years or so (see FAQ1 for references).

Evidence Synthesis Result for FAQ7a: risks

Long-term risks (1, 3 and 5 years after implantation) for device-related complications and reoperations out of 100 people having ICD implantation:

- Any ICD-related complication:
  - 7 (7%) at 1 year
  - 11 (11%) at 3 years
  - 14 (14%) at 5 years
- Complication requiring reoperation:
  - 4 (4%) at 1 year
  - 6 (6%) at 3 years
  - 8 (8%) at 5 years
- Complication requiring hospitalization only:
  - 4 (4%) at 1 year
  - 7 (7%) at 3 years
  - 8 (8%) at 5 years
- ICD reoperations for reasons other than complications (like having the ICD upgraded or having the battery changed):
  - 2 (2%) at 1 year
  - 5 (5%) at 3 years
  - 19 (19%) at 5 years

An ICD battery typically lasts about 5 to 8 years or so.

Out of 100 people followed for 5 years after an ICD is placed:

- **14 (14%) may have a complication of any kind related to the ICD**
  - **8 (8%) may need a repeat surgery due to the complication**
  - **8 (8%) may need to stay in the hospital due to the complication**
- **19 (19%) may have a repeat surgery for a reason other than a complication, like having the ICD upgraded or having the battery changed. An ICD battery usually lasts about 5 to 8 years or so.**

FAQ7b: No ICD

Pre-Synthesis Efforts: Not applicable

Descriptive Summary

Some people will die from a dangerous rhythm that an ICD could have stopped. See 'Will I live longer?'.

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