Decision Aid Title

Implantable Cardioverter Defibrillator for Low Heart Function: Yes or No?

Grid Description

An implantable cardioverter defibrillator (ICD) uses electric shocks to help your heart beat correctly. This decision aid is for elderly people with low heart function from blocked arteries or a heart attack and constricted left ventricular function (<30/35%).

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Competing Interests

The editors and reviewers on this EBSCO Health Option Grid decision aid have declared no conflicts of interest, as of Jul 9, 2018. All individuals involved in editorial work are required to disclose financial conflicts of interest. Any potential conflicts of interest are reviewed and managed according to the EBSCO Health Option Grid Disclosure of Competing Interests Policy.

Supplemental Information & Evidence

About implantable cardioverter defibrillators

Implantable cardioverter defibrillators (ICDs) are battery-powered devices that can be put into the chest. When a life-threatening heart rhythm is detected, the ICD sends a shock to the heart. This shock helps to get the heart beating normally again and may prevent a sudden death. The ICD may be turned off at any time, and some people may choose to do so at the end of their life.

Description of Literature Search Process

[Please note that EBSCO Health is currently revising the description of its systematic literature surveillance process to use across multiple projects and will follow-up with an updated statement]

Evidence and Information Details

Option 1

Option 1 title (patient version): Get an ICD implant

- **FAQ 1 (What does the treatment involve?):**
  Patient content: A doctor will place a device under your skin. Wires connect it to your heart. If your pulse becomes dangerously abnormal, the ICD will shock the heart to a better rhythm. The shock might feel like a sudden kick to the chest.
  Summary of information: ICD therapy is recommended as primary prevention in patients with heart failure due to coronary artery disease or a previous heart attack. An ICD will be implanted through a small incision on the left or right side below the collarbone. A wire, called a "lead", will then be threaded through a vein and connected to the heart. The lead will be used to carry electrical charges from the device to the heart. Once the device is in its proper position and working as it should, the incision will be stitched up. The procedure will take about 1 to 1.5 hours and you will stay in the hospital for about 1 day. You may have pain and swelling for a few days in the area where the ICD was implanted. Health care providers may advise to avoid lifting objects over 10 pounds for the first month or so after surgery. ICDs will not cure the underlying cause of heart failure, and people are advised to continue taking their heart medications after ICD implantation. People with ICDs will need to be monitored throughout the year by remote monitoring or through in-person visits about every 6 months. Some people describe the electric shock as feeling like suddenly being kicked in the chest.
  Source: This question did not require systematic searching. Sources were retrieved by searching DynaMed Plus (and tracing citations), EBSCO Patient Education Reference Center, and Google ("implantable cardioverter defibrillator patient information") on Jun 22, 2018.
  Information details:

  Information summarized from the following patient information pages (note: most of these handouts are linked to DynaMed Plus [DMP])

  - EBSCOhost Patient Education Reference Center
  - American Heart Association
  - National Heart, Lung, and Blood Institute
  - Heart Rhythm Society
  - American Academy of Family Physicians
  - British Heart Foundation

  Length of stay

  - typically up to 1 day hospital stay after procedure (clinical reviewer recommendation, MedlinePlus, and British Heart Foundation)

Follow-up considerations

- careful follow-up and continuity of care required after ICD implantation
- goals of follow-up include
  - monitoring device system function
  - optimization of performance for maximal clinical effect and system lifetime
  - minimization of complications (such as inappropriate shock)
  - anticipation of replacement of system components
  - tracking devices under advisory (see recalls and warnings)
  - ensuring timely intervention for clinical problems
  - patient tracking, education, and support
  - maintenance of ICD system records
- remote device interrogation with monitoring may be useful adjunct to in-person follow-up
- frequency of follow-up
  - individualize follow-up interval based on clinical status of patients and device manufacturer
  - 6-month intervals appear safe, but more frequent monitoring may be needed
  - suggestions for minimum frequency of cardiovascular implantable electronic device (CIED) direct contact or remote monitoring

Frequency	Method
Within 72 hours of CIED implantation	In person
2-12 weeks post implantation	In person
Every 3-6 months	In person or remote
Annually until battery depletion	In person

Every 1-3 months at signs of battery depletion	In person or remote
More frequent assessment as clinically indicated	In person or remote

More frequent in-person or remote monitoring may be required as clinically indicated.

References - (1) Wilkoff BL, Auricchio A, Brugada J, et al; European Heart Rhythm Association (EHRA); American College of Cardiology (ACC); American Heart Association (AHA); European Society of Cardiology (ESC); Heart Failure Association of ESC (HFA); Heart Failure Society of America (HFSA). HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations: developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA). Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the American Heart Association. Europace. 2008 Jun;10(6):707-25. PubMed; (2) 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

- **FAQ 2 (Will it help me live longer?):**

Patient content:

An ICD may help you live longer. It will not cure your heart failure. Over the next 3 years, out of 100 people about:

- 6 (6%) will die from their heart stopping
- 25 (25%) will die from any cause

Evidence Summary: An ICD may help people live longer, but it will not cure their heart failure. In a systematic review of randomized controlled trials of patients with ischemic cardiomyopathy, ICD reduced the risk of sudden cardiac death by 61% and all-cause death by 18% compared to conventional care alone. Over the next 3 years, out of 100 people, about 6 (6%) of patients with an ICD will die of sudden cardiac death compared to about 15 (15%) of patients on conventional care. Over that same time period, about 25 (25%) of patients with an ICD will die from any cause compared to about 31 (31%) of patients on conventional care.

Search: We searched DynaMed Plus (Implantable cardioverter defibrillator (ICD)/ischemic cardiomyopathy) on May 22, 2018. We found 18 citations and included 1 in the analysis.

Database	Search string	Total number of search results	Number of included studies
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Primary Prevention of Sudden Cardiac Death (SCD) Heading ➢ Heart failure subheading ➢ Ischemic cardiomyopathy subheading	18	1

Evidence details:

- **Study conclusion (DMP level of evidence): ICD therapy appears to reduce risk of all-cause and sudden death in adults with ischemic or nonischemic cardiomyopathy (level 2 [mid-level] evidence)**
  - **Reference:** Kolodziejczak M, Andreotti F, Kowalewski M, Buffon A, Ciccone MM, Parati G, et al. Implantable Cardioverter-Defibrillators for Primary Prevention in Patients With Ischemic or Nonischemic Cardiomyopathy: A Systematic Review and Meta-analysis. *Ann Intern Med*. 2017 Jul 18;167(2):103-111. PubMed
  - **Study design:** systematic review
  - **Objective:** compare mortality with ICD therapy versus conventional care for primary prevention
  - **Population:** systematic review of 11 randomized trials comparing ICD therapy vs. conventional care in 8,716 adults with ischemic (65.7%) or nonischemic (34.3%) cardiomyopathy
    - conventional care included contemporary medical therapy, antiarrhythmic medical therapy, or placebo plus medical care
    - most patients had NYHA class II or III heart failure, 5.6% had class IV
  - **Intervention or Exposure:** ICD therapy

- **Comparison(s):** conventional care
- **Outcome(s):** All-cause mortality and sudden cardiac death
- **Duration of follow-up:** mean 3.2 years
- **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** review limited by clinical heterogeneity
        - variations in timing of ICD placement, pharmacotherapies used, and use of cardiac resynchronization therapy across trials
    - **Precision:** no other serious concerns
    - **Directness:** no other serious concerns
    - **Consistency assessment:** no other serious concerns
    - **Other considerations:** no other serious concerns
- **Results:**
    - In nonischemic and ischemic cardiomyopathy patients, ICD therapy associated with
        - 19% reduction of all-cause death compared to conventional care (hazard ratio [HR] 0.81, 95% CI 0.7-0.94) in analysis of 11 trials
        - 59% reduction of sudden death (HR 0.41, 95% CI 0.3-0.56) in analysis of 7 trials with 3,959 patients
    - in subgroup analyses for ischemic cardiomyopathy, ICD therapy associated with
        - 18% reduction of all-cause death compared to conventional care (HR 0.82, 95% CI 0.63-1.06) in subgroup analysis of 7 trials with 5,724 patients
        - 61% reduction of sudden death (HR 0.39, 95% CI 0.23-0.68) in subgroup analysis of 4 trials with 2,282 patients
    - comparing mortality in patients with ischemic cardiomyopathy on ICD vs. conventional care
        - sudden cardiac death in 6% vs 15.4% (HR 0.39, 95% CI 0.23-0.68)
        - all-cause death in 25% vs. 30.5% (HR 0.82, 95% CI 0.63-1.06)
        - Note: event rates with ICD estimated by multiplying conventional care event rate by HR
    - adverse events and complications not reported in review

- **FAQ 3 (Will it change my usual activities?):**

  Patient content:

  You can get back to usual activities in a few days. You should avoid heavy lifting for 1 month. You should not drive for 1-2 weeks after ICD implantation. You should not drive for 3 months after you get a shock. Please talk to your cardiologists and see the information in the background texts of this decision aid for further information on driving restrictions with an ICD.

  Studies suggest that having an ICD does not decrease overall quality of life, but fear of getting shocked may cause anxiety in some patients.

  Evidence and Information Summary: After ICD implantation, people are advised that they can return to normal activities within a few days, but should avoid strenuous activity or heavy lifting for about 1 month after implantation. In one randomized trial, a home-based aerobic exercise program in people with ICDs was found to improve cardiopulmonary function without increasing maximum heart rate or risk of death. Living with an ICD does not appear to significantly impact a person's overall quality of life; however, research is unclear whether getting shocked leads to poorer quality of life. People who experience ICD shocks may be more likely to suffer from anxiety than people who have not experienced shocks.

  People who get an ICD for primary prevention may have driving restrictions right after the procedure. In Europe, it is recommended that driving be restricted for 4 weeks post implantation and for up to 3 months post appropriate ICD therapy. People with an ICD are also restricted from driving commercially.

  Some devices may pose a small risk of interfering with ICDs. 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. Headphones may cause interference and it is advised that people keep them at least 6 inches away from their ICD. Working with power-generating equipment or welding equipment is not recommended and people are advised to stay at least 2 feet away from these devices. MRI may be safe in people with MRI-safe ICDs, but may slightly increase the risk of adverse events if done in people with non-MRI conditional ICDs. For metal detectors for security, people with ICDs are advised to not sit or stand close to a detector for a prolonged period of time. Most household appliances, such as microwaves, and equipment, such as power tools, are safe to use, but it is advised that these items stay at least 6 inches away from the ICD.

  Search: A combination of systematic literature searching and patient education resources was used to answer this question. We searched DynaMed Plus (Implantable cardioverter defibrillator (ICD)/sexual activity, Implantable cardioverter defibrillator (ICD)/physical activity, and Implantable cardioverter defibrillator (ICD)/electromagnetic interference) and PubMed ("implantable cardioverter defibrillator quality of life" and "implantable cardioverter defibrillator anxiety" with systematic reviews and English language study filters) on May 25, 2018. We found 131 citations and included 12 in the analysis. Some articles may appear in more than one search set. Additional sources retrieved by searching DynaMed Plus (and tracing citations) and Google ("ICD driving restrictions") on May 25, 2018.

Database	Search string	Total number of search results	Number of included studies
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Adverse Effects and Cautions Heading ➢ Sexual activity subheading	1	1
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Adverse Effects and Cautions Heading ➢ Physical activity subheading	2	1
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Adverse Effects and Cautions Heading ➢ Electromagnetic interference subheading	9	7
PubMed	(("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 ("quality of life"[MeSH Terms] OR ("quality"[All Fields] AND "life"[All Fields]) OR "quality of life"[All Fields])) AND (systematic[sb] AND English[lang])	90	2
PubMed	(("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 ("anxiety"[MeSH Terms] OR "anxiety"[All Fields])) AND (systematic[sb] AND English[lang])	29	1

Evidence and Information Details:

PHYSICAL ACTIVITY

Evidence

- **Study conclusion (DMP level of evidence): home-based aerobic exercise program may improve cardiopulmonary function without increasing risk of adverse events in patients with ICD for primary or secondary prevention of sudden cardiac arrest (level 2 [mid-level] evidence)**

- **Reference:** Dougherty CM, Glenny RW, Burr RL, Flo GL, Kudenchuk PJ. Prospective randomized trial of moderately strenuous aerobic exercise after an implantable cardioverter defibrillator. *Circulation*. 2015 May 26;131(21):1835-42. PubMed Full Text
- **Study design:** randomized trial
- **Objective:** evaluate effects of home exercise program
- **Population:** 160 patients (mean age 55 years, 78% male) who had ICD for primary or secondary prevention of sudden cardiac arrest were randomized to home-based aerobic exercise program vs. usual care
    - participants had ICD implanted mean 3 years before enrolling in this trial
- **Intervention or Exposure:** home based aerobic exercise program
    - aerobic exercise program consisted of walking at 60%-80% of heart rate reserve 1 hour/day 5 days/week for 8 weeks (training phase), then walking 150 minutes/week for 16 weeks (maintenance phase)
    - all patients were on beta blocker therapy
- **Comparison(s):** usual care (beta blocker therapy)
- **Outcome(s):** aerobic performance, incidence of ICD shock, hospitalization frequency
- **Duration of follow-up:** 24 weeks
- **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** low adherence
        - ≤ 76% adhered to exercise program (defined as walking for ≥ 80% of total minutes per week), only 17.5% during training phase and 8.7% during maintenance phase achieved target heart rate
        - 89% completed trial, all patients included in analyses
    - **Precision:** no other major concerns
    - **Directness:** no other major concerns
    - **Consistency assessment:** no other major concerns
    - **Other considerations:** no other major concerns
- **Results:**
    - aerobic exercise associated with significantly improved cardiopulmonary function (peak oxygen consumption, oxygen pulse, and metabolic equivalents) without increase in maximum heart rate
    - no significant differences between groups in frequency of ICD shocks, need for antitachycardia pacing therapy, or hospitalization frequency
    - no deaths or sudden cardiac arrests associated with aerobic exercise reported

Information from patient education material

- After ICD implantation, people are advised that they can return to normal activities within a few days, but should avoid strenuous activity or heavy lifting for about 1 month after implantation.
    - Reference - 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#.Ww1tAIgvyUk. Last updated September 2016. Accessed May 25, 2018.

QUALITY OF LIFE / PSYCHOLOGICAL IMPACT

- **Study conclusion (DMP level of evidence): ICD therapy for primary or secondary prevention may not be associated with adverse quality of life outcomes compared to conventional therapy in patients with heart failure (level 2 [mid-level] evidence)**
    - **Reference:** da Silva KR, Costa R, Rodrigues CG, et al. Quality of life in patients with implantable cardioverter-defibrillator: systematic review of randomized controlled trials. *Eur J Cardiovasc Nurs*. 2018 Mar;17(3):196-206. PubMed
    - **Study design:** systematic review
    - **Objective:** assess quality of life outcomes in patients on ICD therapy compared to conventional therapy
    - **Population:** systematic review of 7 randomized trials comparing ICD vs. conventional therapy for primary or secondary prevention in 5,701 patients
    - **Intervention or Exposure:** ICD therapy
    - **Comparison(s):** Conventional therapy
    - **Outcome(s):** any quality of life outcome
    - **Duration of follow-up:** range of 3 to 36 months
    - **Certainty (reasons for LOE downgrade):**
        - **Risk of bias:** analysis limited by significant heterogeneity, including inconsistent follow-up times and wide variation in quality of life questionnaires/metrics
        - **Precision:** no other serious concerns
        - **Directness:** no other serious concerns
        - **Consistency assessment:** inconsistent findings for association between receiving ICD shock and quality of life across studies, but consistent overall findings with another systematic review (Tomzik J, Koltermann KC, Zabel M, Willich SN, Reinhold T. Quality of Life in Patients with an Implantable Cardioverter Defibrillator: A Systematic Review. *Front Cardiovasc Med*. 2015 Nov 3;2:34. PubMed Full Text). The current systematic review includes the 5 trials in the 2015 systematic review, plus 2 additional trials.
        - **Other considerations:** no other serious concerns
    - **Results:**

  - No significant differences overall in quality of life outcomes between ICD and conventional therapy patients.
  - Impact of ICD shock on quality of life is unclear with inconsistent findings in 6 trials with 4,612 patients
    - AVID trial found decrease in physical component summary (PCS) and mental component summary (MCS) domains with 3 or more shocks
    - CIDS trial found lower emotional health domain scores in patients with 5 or more shocks
    - CABG-PATCH trial found lower physical and emotional functioning scores
    - AMIORVIT Trial found no difference
    - DEFINITE Trial found no difference
    - SCD-HeFT trial found lower quality of life scores I patients who had an ICD shock within 1 month

- **Study conclusion (DMP level of evidence): Symptoms of anxiety and depression reported to be common in patients with ICD (level 3 [lacking direct] evidence)**
  - **Reference:** Magyar-Russell G, Thombs BD, Cai JX, Baveja T, Kuhl EA, Singh PP, Montenegr Braga Barroso M, Arthurs E, Roseman M, Amin N, Marine JE, Ziegelstein RC. The prevalence of anxiety and depression in adults with implantable cardioverter defibrillators: a systematic review. J Psychosom Res. 2011 Oct;71(4):223-31. PubMed
  - **Study design:** systematic review
  - **Objective:** assess prevalence of anxiety and depression in adult patients with ICDs
  - **Population:** systematic review of 45 (primarily) observational studies for over 5,000 patients with ICD for primary or secondary prevention
  - **Intervention or Exposure:** ICD implantation
  - **Comparison(s):** NA
  - **Outcome(s):** prevalence of anxiety or depression
  - **Duration of follow-up:** mean time of assessment ranged from immediately after implantation to 75 months
  - **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** no control group, analysis limited by significant heterogeneity, including inconsistent follow-up times and wide variation in assessment methods; none of the instruments used to assess anxiety or depression have been validated for use in ICD patients; authors note potential for patient selection bias in included studies
    - **Precision:** no other serious concerns
    - **Directness:** significant heterogeneity in assessment methods limits generalizability
    - **Consistency assessment:** wide range of anxiety and depression is consistent with findings in literature
    - **Other considerations:** no other serious concerns
  - **Results:**
    - Prevalence of anxiety reported in

        - 27%-63% of patients prior to implantation in 7 studies
        - 13%-50% of patients 0-5.9 months post implantation in 12 studies
        - 15%-49% of patients 6-11.9 months post implantation in 6 studies
        - 5%-75% of patients 12 months or more post implantation in 30 studies
    - prevalence of depression reported in
        - 10%-36% of patients prior to implantation in 7 studies
        - 8%-38%% of patients 0-5.9 months post implantation in 10 studies
        - 10%-33% of patients 6-11.9 months post implantation in 6 studies
        - 8%-75% of patients 12 months or more post implantation in 30 studies
    - association between ICD shock and anxiety symptoms unclear with inconsistent findings in 7 studies with 672 patients
        - largest study with 116 patients reported significant increase in anxiety at 12 months follow-up in patients with shock history compared to patients with no shock history (odds ratio 2.5, 95% CI 1.1-5.7)

Information from patient education material

- ICD may cause anxiety or depression in the first few months or year after implantation
    - Reference - 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#.Ww1tAIgvyUk. Last updated September 2016. Accessed May 25, 2018.

SEXUAL ACTIVITY

Guideline recommendations

- Evidence on sexual activity in patients with ICD for primary prevention is limited. The American Heart Association (AHA) recommends
    - counseling of patient and spouse/partner useful in assisting resumption of sexual activity after ICD implant (Recommendation Grade AHA Class I, Level B)
    - sexual activity reasonable for patients with ICD implanted for primary prevention (Recommendation Grade AHA Class IIa, Level C)
    - Reference - Levine GN, Steinke EE, Bakaeen FG, Bozkurt B, Cheitlin MD, Conti JB, et al; American Heart Association Council on Clinical Cardiology; Council on Cardiovascular Nursing; Council on Cardiovascular Surgery and Anesthesia; Council on

Quality of Care and Outcomes Research. Sexual activity and cardiovascular disease: a scientific statement from the American Heart Association. *Circulation*. 2012 Feb 28;125(8):1058-72. PubMed Full Text

DRIVING

Guideline recommendations

- The German Society for Cardiology recently published a pocket guideline with driving restrictions/recommendations for patients with different forms of cardiovascular disease and treatment. This guideline is based on the German Driving License Regulations (Appendix 4) and the 2017 recommendations by the German Federal Highway Research Institute. It also takes into account the respective European recommendations. Regarding patients with ICD implanted for primary prevention, the guideline recommends that driving be restricted for 1-2 weeks in patients implanted with ICD for primary prevention (this extends to 3 months in patients that have an ICD implanted for secondary prevention). People who get an appropriate ICD shock after implantation are advised to wait up to 3 months without having shocks before driving again. After inadequate shocks, patients are advised not to drive as long as the reason for the inappropriate shock is found/treated. Patients with ICDs are in general permanently restricted from professional driving.
    - Reference - Deutsche Gesellschaft für Kardiologie, Pocket-Leitlinie Fahreignung bei kardiovaskulären Erkrankungen. Börm-Bruckmeier Verlag. https://leitlinien.dgk.org/files/2018_Pocket_Leitlinien_Fahreignung_Internetversion.pdf
    - Reference – Klein HH, Sechtem U, Trappe HJ. Fitness to drive in cardiovascular disease. *Dtsch Arztebl Int.* 2017; 114; 692-702
- In Europe, it is recommended that driving be restricted for 4 weeks in patients implanted with ICD for primary prevention. People who get an appropriate ICD shock after implantation are advised to wait up to 3 months without having shocks before driving again. People with ICDs are permanently restricted from professional driving. (Expert opinion)
    - Reference - Vijgen J, Botto G, Camm J, Hoijer CJ, Jung W, Le Heuzey JY, et al. Consensus statement of the European Heart Rhythm Association: updated recommendations for driving by patients with implantable cardioverter defibrillators. *Eur J Cardiovasc Nurs.* 2010 Mar;9(1):3-14. PubMed Full Text)

- In the United States, patients implanted with ICD for primary prevention are advised to restrict driving for at least 1 week after the procedure. People who get an ICD shock are advised to wait up to 6 months without having shocks before driving again. It is advised that people with an ICD are restricted from driving commercially in the United States. (Expert opinion)
    - References – (1) 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; (2) Epstein AE, Baessler CA, Curtis AB, Estes NA 3rd, Gersh BJ, Grubb B, Mitchell LB; American Heart Association; Heart Rhythm Society. Addendum to "Personal and public safety issues related to arrhythmias that may affect

consciousness: implications for regulation and physician recommendations: a medical/scientific statement from the American Heart Association and the North American Society of Pacing and Electrophysiology": public safety issues in patients with implantable defibrillators: a scientific statement from the American Heart Association and the Heart Rhythm Society. *Circulation*. 2007 Mar 6;115(9):1170-6. Epub 2007 Feb 7. PubMed

Policy/Law

- In the United Kingdom, it is required by law that driving be restricted for at least 6 months after implantation of ICD for primary prevention. People who get appropriate ICD therapy also must wait 6 months before driving again. Patients with ICDs have a permanent bar on Group 2 licensing (commercial driving).
    - Reference - United Kingdom Government. Cardiovascular disorders: assessing fitness to drive. GOV.UK website. https://www.gov.uk/guidance/cardiovascular-disorders-assessing-fitness-to-drive#implantable-cardioverter-defibrillator-icd. Accessed on May 25, 2018.

ELECTROMAGNETIC INTERFERENCE

Evidence

- **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

- **FAQ 4 (Will the ICD shock my heart?):**
  Patient content:
  Over the next 3 years, out of 100 people:
  - 4 (4%) to 16 (16%) will get at least 1 lifesaving shock
  - up to 12 (12%) will get at least 1 unneeded shock

  Evidence Summary: A randomized trial found that at 4 years, about 16% of patients had received at least 1 appropriate ICD shock, about 11% had received an inappropriate shock, and about 7% had received both kinds of shocks. Another trial found that at 2 years, about 14% of patients had received at least 1 appropriate ICD shock, about 12% had received an inappropriate shock, and about 4% had received both kinds of shocks. More recent research has shown that optimal ICD programming for tachyarrhythmia detection may help to reduce the number of inappropriate shocks. A recent study of patients receiving ICD for primary prevention found lower shock rates - about 17% received at least 1 ICD shock, including about 7% receiving at least 1 inappropriate shock over the course of 2 years. Additionally, secondary analysis of a randomized trial found up to an 85% risk reduction of inappropriate shocks when optimal ICD programming was used in a subset of patients without prior atrial tachyarrhythmia. To reduce the number of inappropriate shocks, it is advised that ICD programming be changed as the patient's condition changes.
  Search: We searched DynaMed Plus (Implantable cardioverter defibrillator (ICD)/effect of programming features on clinical outcomes, Implantable cardioverter defibrillator (ICD)/Primary prevention of sudden cardiac death (SCD)/Ischemic cardiomyopathy, Implantable cardioverter defibrillator (ICD)/Recommendations from professional organizations, Implantable cardioverter defibrillator (ICD)/Inappropriate therapy, including inappropriate shocks) and PubMed ("implantable cardioverter defibrillator shock outcomes primary prevention" and "inappropriate ICD therapy programming primary prevention" with Adults and English language study filters) on May 30, 2018. We found 118 citations and included 6 in the analysis. Some articles may appear in more than one search set.

Database	Search string	Total number of search results	Number of included studies/guidelines
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Technical aspects of ICD devices Heading ➢ Effect of programming features on clinical outcomes subheading	6	1
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Primary prevention of sudden cardiac death (SCD) Heading ➢ Ischemic cardiomyopathy subheading	17	1
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Technical Aspects of ICD Devices Heading	1	1

	➢ Recommendations from professional organizations subheading		
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Adverse Effects and Cautions Heading ➢ Inappropriate therapy, including inappropriate shocks subheading	1	1
PubMed	(("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 ("shock"[MeSH Terms] OR "shock"[All Fields]) AND outcomes[All Fields] AND ("primary prevention"[MeSH Terms] OR ("primary"[All Fields] AND "prevention"[All Fields]) OR "primary prevention"[All Fields])) AND ("humans"[MeSH Terms] AND English[lang] AND "adult"[MeSH Terms])	49	1
PubMed	(inappropriate[All Fields] AND ICD[All Fields] AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) AND programming[All Fields] AND ("primary prevention"[MeSH Terms] OR ("primary"[All Fields] AND "prevention"[All Fields]) OR "primary prevention"[All Fields])) AND ("humans"[MeSH Terms] AND English[lang])	44	1

Evidence details:

Studies with ICD programming

- **Study conclusion (DMP level of evidence): programmed therapy for high ventricular rates reduces mortality and inappropriate shocks compared to conventional ICD programming in patients with heart disease requiring ICD for primary prevention of sudden cardiac death (level 1 [likely reliable] evidence)**
  - **Reference:** Moss AJ, Schuger C, Beck CA, Brown MW, Cannom DS, Daubert JP, et al; MADIT-RIT Trial Investigators. Reduction in inappropriate therapy and mortality through ICD programming. *N Engl J Med*. 2012 Dec 13;367(24):2275-83. PubMed Full Text
  - **Study design:** based on randomized trial

- **Objective:** determine whether programming with high-rate ICD therapy or delayed ICD therapy was associated with lower number of first occurrence of inappropriate antitachycardia pacing or shocks compared to conventional therapy
- **Population:** 1,500 patients ≥ 21 years old with ischemic or nonischemic heart disease and requiring primary prevention of sudden cardiac death with ICD were randomized to 1 of 3 programming configurations
    - > 97% in each group were New York Heart Association class II or III at baseline
- **Intervention or Exposure:** randomized to 1 of following programming configurations
    - high-rate therapy (monitor only at heart rate [HR] 170-199 beats/minute, delay of 2.5 seconds before therapy initiation (antitachycardia pacing or shock) at HR of ≥ 200 beats/minute)
    - delayed therapy (delay of 60 seconds at HR of 170-199 beats/minute, delay of 12 seconds at HR of 200-249 beats/minute, and delay of 2.5 seconds at HR of ≥ 250 beats/minute)
    - conventional therapy (delay of 2.5 seconds at HR of 170-199 beats/minute and delay of 1 second at HR of ≥ 200 beats/minute)
- **Comparison(s):** see above
- **Outcome(s):** primary end point was first occurrence of inappropriate therapy, either antitachycardia pacing or shock; secondary endpoints included appropriate therapy and all-cause mortality
- **Duration of follow-up:** mean 1.4 years
- **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** no serious concerns
    - **Precision:** no serious concerns
    - **Directness:** no serious concerns
    - **Consistency assessment:** no serious concerns
    - **Other considerations:** no serious concerns
- **Results:**
    - all-cause mortality in
        - 3.2% with high-rate therapy (p = 0.01 vs. conventional therapy, NNT 30)
        - 4.3% with delayed therapy (p = 0.06 vs. conventional therapy)
        - 6.6% with conventional therapy
    - first occurrence of appropriate therapy (antitachycardia pacing [ATP] or shock for ventricular tachyarrhythmia) in
        - 9% with high-rate therapy (p < 0.001 vs. conventional therapy)
        - 6% with delayed therapy (p < 0.001 vs. conventional therapy)
        - 22% with conventional therapy
    - first occurrence of appropriate shock therapy only (for ventricular tachyarrhythmia) in

    - 4% with high-rate therapy (not significant vs. conventional therapy)
    - 3% with delayed therapy (not significant vs. conventional therapy)
    - 4% with conventional therapy
  - first occurrence of inappropriate therapy (antitachycardia pacing [ATP] or shock for nonventricular tachyarrhythmia) in
    - 4% with high-rate therapy ($p < 0.001$ vs. conventional therapy, NNT 7)
    - 5% with delayed therapy ($p < 0.001$ vs. conventional therapy, NNT 7)
    - 20% with conventional therapy
  - first occurrence of inappropriate shock therapy only (for nonventricular tachyarrhythmia) in
    - 2% with high-rate therapy (not significant vs. conventional therapy)
    - 3% with delayed therapy (not significant vs. conventional therapy)
    - 4% with conventional therapy
  - no significant differences among groups in first episode of syncope or procedure-related adverse events

- **Study conclusion (DMP level of evidence): compared to ICD with conventional therapy, ICD programming with a high-rate cut-off or delayed therapy may reduce inappropriate therapy in patients with no prior atrial tachyarrhythmia (level 2 [mid-level] evidence)**
  - **Reference:** Kutyifa V, Moss AJ, Schuger C, McNitt S, Polonsky B, Ruwald AH, Ruwald MH, Daubert JP, Zareba W. Reduction in Inappropriate ICD Therapy in MADIT-RIT Patients Without History of Atrial Tachyarrhythmia. *J Cardiovasc Electrophysiol*. 2015 Aug;26(8):879-884. PubMed
  - **Study design:** post-hoc analysis
  - **Objective:** evaluate how history of atrial tachyarrhythmia (AT) impacts risk for inappropriate ICD therapy and whether ICD program reduces inappropriate therapy in patients with and without history of AT
  - **Population:** post-hoc analysis of above trial of patients with and without prior history of AT;
  - **Intervention or Exposure:** ICD in patients with no prior AT
  - **Comparison(s):** ICD in patients with and without prior AT
  - **Outcome(s):** inappropriate ICD therapy (therapy delivered for arrhythmias other than ventricular arrhythmia)
  - **Duration of follow-up:** 17 months
  - **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** post-hoc analysis
    - **Precision:** no other serious concerns
    - **Directness:** no other serious concerns
    - **Consistency assessment:** no other serious concerns
    - **Other considerations:** no other serious concerns

- **Results:** compared to conventional therapy
    - 85% risk reduction in first inappropriate ICD therapy in those with no prior atrial tachyarrhythmia when programmed to high-rate cut off therapy (hazard ratio [HR] 0.15, 95% CI 0.09-0.27)
    - 76% risk reduction in first inappropriate ICD therapy in those with no prior atrial tachyarrhythmia when programmed to delayed therapy (HR 0.24, 95% CI 0.15-0.39)

- **Study conclusion (DMP level of evidence): Dual-chamber ICD devices may not be associated with lower risk of inappropriate shocks compared to single-chamber ICD devices in patients with heart failure due to ischemic or nonischemic heart disease (level 2 [mid-level] evidence)**
    - **Reference:** Peterson PN, Greenlee RT, Go AS, Magid DJ, Cassidy-Bushrow A, Garcia-Montilla R, et al. Comparison of Inappropriate Shocks and Other Health Outcomes Between Single- and Dual-Chamber Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death: Results From the Cardiovascular Research Network Longitudinal Study of Implantable Cardioverter-Defibrillators. J Am Heart Assoc. 2017 Nov 9;6(11). PubMed Full Text
    - **Study design:** retrospective cohort (National Cardiovascular Data Registry)
    - **Objective:** compare risk of adverse outcomes between single and dual chamber ICDs for primary prevention
    - **Population:** 1,042 patients > 18 years old with ischemic or nonischemic heart disease and requiring primary prevention of sudden cardiac death with ICD and followed for median 2 years
        - 54% implanted with single-chamber devices
        - 46% implanted with dual-chamber devices
        - 64.6% had ischemic heart disease
        - programming not standardized across patients, but lowest programmed rate threshold, regardless of arrhythmia detection zone, was categorized as <180, 180 to 199, and >200 beats per minute
    - **Intervention or Exposure:** single-chamber ICD devices
    - **Comparison(s):** dual-chamber ICD devices
    - **Outcome(s):** type of ICD shocks, time to first inappropriate shock
    - **Certainty (reasons for LOE downgrade):**
        - **Risk of bias:** retrospective analysis
        - **Precision:** no other serious concerns
        - **Directness:** lack of subgroup analysis may limit generalizability to specific disease groups
        - **Consistency assessment:** inappropriate shock rates lower than what has been found in well-known RCTs, but may be related to integration of optimal ICD programming in today's clinical practice

    - **Other considerations:** no other serious concerns
- **Results:**
    - overall 17.3% received at least 1 shock, including 6.6% receiving at least 1 inappropriate shock
    - comparing single vs. dual chamber ICDs, shocks (at least 1 episode) were
        - inappropriate in 6.9% vs. 6.3% (not significant)
        - uncertain appropriateness in 4.3% vs. 2.7% (p = 0.18)

Studies without specific ICD programming

- **Study conclusion (DMP level of evidence): appropriate or inappropriate ICD shocks associated with higher mortality compared to no ICD shocks in patients with heart failure (level 2 [mid-level] evidence)**
    - **Reference:** Poole JE, Johnson GW, Hellkamp AS, Anderson J, Callans DJ, Raitt MH, Reddy RK, Marchlinski FE, Yee R, Guarnieri T, Talajic M, Wilber DJ, Fishbein DP, Packer DL, Mark DB, Lee KL, Bardy GH. Prognostic importance of defibrillator shocks in patients with heart failure. *N Engl J Med*. 2008 Sep 4;359(10):1009-17. PubMed Full Text
    - **Study design:** cohort analysis of data from SCD-HeFT trial
    - **Objective:**
    - **Population:** 811 patients with LVEF ≤ 35% and NYHA Class II or III heart failure were randomized to ICD
        - single zone of therapy was used and an episode of tachycardia was defined as at least 18 of 24 beats at a rate of 188 beats per minute or more (≤320 msec)
        - antitachycardia pacing and second zone of therapy was not allowed as patients with known sustained ventricular tachycardia were excluded from the study
    - **Intervention or Exposure:** ICD shocks
    - **Comparison(s):** no ICD shocks
    - **Outcome(s):** mortality
    - **Duration of follow-up:** followed for median 45.5 months
    - **Certainty (reasons for LOE downgrade):**
        - **Risk of bias:** post hoc analysis
        - **Precision:** no other serious concerns
        - **Directness:** no other serious concerns
        - **Consistency assessment:** no other serious concerns
        - **Other considerations:** no other serious concerns
    - **Results:** ICD shocks (at least 1 episode) were

    - appropriate in 128 patients (15.8%)
    - inappropriate in 87 patients (10.7%)
    - both appropriate and inappropriate in 54 patients (6.7%)
  - compared to receiving no shocks appropriate or inappropriate shocks associated with increased risk of mortality (hazard ratio 5.68, 95% CI 3.97-8.12)

- **Study conclusion (DMP level of evidence): inappropriate ICD shocks may be associated with higher mortality compared to receiving no shocks in patients with history of myocardial infarction and reduced LVEF (level 2 [mid-level] evidence)**
  - **Reference:** Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P, et al.; MADIT II Investigators. Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. *J Am Coll Cardiol*. 2008 Apr 8;51(14):1357-65. PubMed Full Text
  - **Study design:** post hoc analysis of interventional arm of MADIT-II trial
  - **Objective:** evaluate incidence and outcomes of inappropriate ICD shocks
  - **Population:** 742 patients with history of MI and LVEF < 30% were implanted with ICD
  - **Intervention or Exposure:** investigators suggested 2 monitoring algorithms to minimize inappropriate shocks, but programming left to the discretion of practicing physician
    - stability algorithm, monitoring the regularity of the tachyarrhythmia
    - sudden onset algorithm, the monitoring degree to which the arrhythmia began suddenly versus gradually
  - **Comparison(s):** NA
  - **Duration of** follow-up: 2 years
  - **Outcome(s):** incidence and types of ICD shocks
    - therapy deemed inappropriate if delivered for any reason other than ventricular tachycardia or ventricular fibrillation
  - **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** no control group in analysis
    - **Precision:** No other serious concerns
    - **Directness:** specific ICD programming protocol not described limiting replication; stability programming was not commonly used, likely reflecting clinical practice at time of study and thus limiting generalizability to today's practice
    - **Consistency assessment:** shock rates similar to SCD-HeFT trial, but may be higher than what is seen in today's practice

    - **Other considerations:** No other serious concerns
- **Results:** ICD shocks (at least 1 episode) were
    - appropriate in 14.1%
    - inappropriate in 11.5%
    - both inappropriate and appropriate in 3.8%
  - patients receiving inappropriate shocks were less likely to have been programmed with a stability detection algorithm compared to those with programming (36% vs. 17%, p = 0.03)
  - compared to receiving no shocks inappropriate shocks associated with increased risk of mortality (hazard ratio 2.29, 95% CI 1.11-4.71)

- **Guideline Recommendations**
  - Heart Rhythm Society/European Heart Rhythm Association/Asia Pacific Heart Rhythm Society/Sociedad Latinoamericana de Estimulacion Cardiaca y Electrofisiologia (HRS/EHRA/APHRS/SOLAECE) recommendations for optimal ICD programming advise that the programming of the ICD be changed as a patient's condition changes and as additional clinical considerations become apparent
    - for primary prevention of sudden cardiac death (SCD)
      - program tachyarrhythmia detection duration criteria to require tachycardia to continue 6-12 seconds or for 30 intervals before completing detection to reduce total therapies (Recommendation Grade HRS/EHRA/APHRS/SOLAECE Class I, Level A)
      - program slowest tachycardia therapy zone limit between 185 and 200 beats per minute to reduce total therapies (Recommendation Grade HRS/EHRA/APHRS/SOLAECE Class I, Level A)
    - Reference - Wilkoff BL, Fauchier L, Stiles MK, Morillo CA, Al-Khatib SM, Almendral J, et al. 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. *Heart Rhythm*. 2016 Feb;13(2):e50-86. PubMed

  - inappropriate ICD therapy reported in 10%-24% during 20-45 months of follow-up (pooled rate provided in guideline; no recommendation grade provided)
    - 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

- **FAQ 5 (What are the risks of having an ICD put in place?):**
  Patient content:
  Soon after getting an ICD, out of 100 people about:
  - 2 (2%) need to replace the device or move the wires
  - Up to 1 or 2 (1% or 2%) have serious bleeding or get an infection
  - 1 (1%) have a collapsed lung

  Fewer than 1 out of 100 people (less than 1%) get a blood clot, heart attack, stroke, or die.
  Evidence Summary: Shortly after surgery, about 2% need to have a lead replaced or repositioned, up to 1% have a collapsed lung, up to 1% get infection. Fewer than 1% die, get excess fluid around their heart or lung, get a blood clot, or have a heart attack or stroke. Some studies suggest that women may have higher risks than men; however, women in these studies may have also had more baseline heart problems compared to men. Bleeding complications may be higher in patients on certain anticoagulant or antiplatelet medications.
  Search: We searched DynaMed Plus (Implantable cardioverter defibrillator (ICD)/procedural complications and Implantable cardioverter defibrillator (ICD)/For patients on anticoagulation) on May 22, 2018. We found 13 citations and included 5 in the analysis.

Database	Search string	Total number of search results	Number of included studies
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Adverse Effects and Cautions Heading ➢ Procedural complications subheading	8	4
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Adverse Effects and Cautions Heading ➢ For patients on anticoagulation subheading	5	1

Evidence details:

- **Study conclusion (DMP level of evidence): risk scores predict in-hospital complications or in-hospital mortality after ICD implantation (level 1 [likely reliable] evidence)**
  - **Reference:** Haines DE, Wang Y, Curtis J. Implantable cardioverter-defibrillator registry risk score models for acute procedural complications or death after implantable cardioverter-defibrillator implantation. Circulation. 2011 May 17;123(19):2069-76. PubMed Full Text
  - **Study design:** cohort study with independent derivation and validation cohorts
  - **Objective:** develop risk stratification to identify patients and low and high risk of in-hospital adverse events after ICD implantation and to report in-hospital complications
  - **Population:** 268,701 patients who had ICD implantation from 1,300 hospitals in 2006-2008 were randomly divided into

    - derivation cohort of 134,069 patients
    - validation cohort of 134,632 patients
- **Intervention or Exposure:** risk variables, including admission patient characteristics, history and risk factors, indications for ICD implantation, diagnostic studies, and device type
- **Comparison(s):**
- **Outcome(s):** procedure related complications or death
- **Duration of follow-up:** hospital stay
- **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** No serious concerns
    - **Precision:** No serious concerns
    - **Directness:** No serious concerns
    - **Consistency assessment:** No serious concerns
    - **Other considerations:** No serious concerns
- **Results:** overall in-hospital complications, incidence of
    - in-hospital complication rate was 3.2%
    - in-hospital mortality rate was 0.38%
    - any complication in 3.05%
    - cardiac arrest in 0.3%
    - hematoma (not defined) in 0.93%
    - lead dislodgement in 0.93%
    - pneumothorax in 0.42%
    - deep phlebitis in 0.02%
    - TIA in 0.02%
    - stroke in 0.06%
    - myocardial infarction in 0.02%
    - infection in 0.03%
    - death in 0.38%

- **Study conclusion (DMP level of evidence): Procedural-related adverse events may be similar for patients implanted with ICD and CRT defibrillator (level 2 [mid-level] evidence)**

- **Reference:** Reynolds MR, Cohen DJ, Kugelmass AD, Brown PP, Becker ER, Culler SD, Simon AW. The frequency and incremental cost of major complications among medicare beneficiaries receiving implantable cardioverter-defibrillators. J Am Coll Cardiol. 2006 Jun 20;47(12):2493-7. PubMed Full Text
- **Study design:** retrospective cohort study
- **Objective:** evaluate early complications after ICD implantation in the Medicare population and risk factors associated with it
- **Population:** 30,984 Medicare patients having ICD (75%) or CRT defibrillator (25%) implantation in 2003 included
- **Intervention or Exposure:** ICD
- **Comparison(s):** CRT-D
- **Outcome(s):** procedural related adverse event and death
- **Duration of follow-up:** hospital stay (median length of stay 2 days)
- **Certainty (reasons for LOE downgrade):**
  - **Risk of bias:** retrospective analysis
  - **Precision:** No other serious concerns
  - **Directness:** No other serious concerns
  - **Consistency assessment:** No other serious concerns
  - **Other considerations:** No other serious concerns
- **Results:** comparing ICD vs. CRT defibrillator for in-hospital major complications, incidence of
  - any major complication in 11% vs. 10.5% (not significant)
  - mechanical complication of ICD system in 4.8% vs. 3.8% ($p < 0.001$)
  - mechanical complication of ICD system with lead or pocket revision in 1.2% vs. 1.8% ($p < 0.001$)
  - hematoma/hemorrhage (not defined, but classified as major) in 2.5% vs. 3.4% ($p < 0.0001$)
  - infection associated with implant in 1.4% vs. 0.7% ($p < 0.0001$)
  - pneumothorax in 1% vs. 1.2% (not significant)
  - death 0.9% vs. 1.1% ($p = 0.07$)
  - other cardiac complications in 0.8% vs. 0.7% (not significant)
  - pericardial effusion/tamponade in 0.3% vs. 0.3% (not significant)
  - acute renal failure with new hemodialysis in 0.3% vs. 0.3% (not significant)

- **Study conclusion (DMP level of evidence): Women may have higher rates of procedural related in-hospital adverse events after ICD implantation for primary prevention (level 2 [mid-level] evidence)**

- **Reference:** Peterson PN, Daugherty SL, Wang Y, Vidaillet HJ, Heidenreich PA, Curtis JP, et al; National Cardiovascular Data Registry. Gender differences in procedure-related adverse events in patients receiving implantable cardioverter-defibrillator therapy. *Circulation*. 2009 Mar 3;119(8):1078-84. PubMed Full Text
- **Study design:** retrospective cohort
- **Objective:** compare procedural related in-hospital adverse events in men and women after receiving ICD implantation
    - ICD indicated for primary prevention in 72%
- **Population:** 161,470 patients (mean age 67 years, 27% women) having first-time ICD implantation included
    - at baseline, women more likely to have
        - history of heart failure
        - worse New York Heart Association (NYHA) functional class
        - nonischemic cardiomyopathy
    - biventricular ICD in 39% of women vs. 34% of men ($p < 0.01$)
- **Intervention or Exposure:** ICD implantation in women
- **Comparison(s):** ICD implantation in men
- **Outcome(s):** procedural related adverse events and mortality
- **Duration of follow-up:** in-hospital stay (mean overall stay not reported)
- **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** retrospective analysis
    - **Precision:** no other serious concerns
    - **Directness:** no other serious concerns
    - **Consistency assessment:** no other serious concerns
    - **Other considerations:** significant differences in some baseline characteristics between men and women
- **Results:** comparing in-hospital adverse events in women vs. men
        - any adverse event in 4.4% vs. 3.3% ($p < 0.001$)
        - major adverse events in 2% vs. 1.1% ($p < 0.001$)
        - in-hospital mortality 0.44% vs. 0.41% (not significant)
        - overall in-hospital complications
            - Major adverse event in 1.35%
            - Stroke in 0.07%
            - TIA in 0.03%
            - Deep phlebitis in 0.03%
            - Coronary venous dissection in 0.15%

    - Hemothorax in 0.1%
    - Pericardial tamponade in 0.09%
    - Cardiac perforation in 0.08%
    - Myocardial infarction in 0.03%
    - Cardiac arrest in 0.34%
    - Pneumothorax in 0.51%
    - Infection related to device in 0.3%
  - *Study commentary:* Women may have a greater risk for adverse events than men; however, this risk could be attributed to higher incidence of heart problems at baseline. More women had higher percentage of patients with history of heart failure and NYHA Class III or IV compared to men.

- **Study conclusion (DMP level of evidence): Women may have higher rates of procedural related adverse events after ICD implantation for primary or secondary prevention (level 2 [mid-level] evidence)**
  - **Reference:** MacFadden DR, Crystal E, Krahn AD, Mangat I, Healey JS, Dorian P, Birnie D, Simpson CS, Khaykin Y, Pinter A, Nanthakumar K, Calzavara AJ, Austin PC, Tu JV, Lee DS. Sex differences in implantable cardioverter-defibrillator outcomes: findings from a prospective defibrillator database. *Ann Intern Med*. 2012 Feb 7;156(3):195-203. PubMed
  - **Study design:** retrospective cohort
  - **Objective:** evaluate differences in procedural related outcomes between men and women undergoing ICD implantation
  - **Population:** 6,021 patients (78.6% male) referred for ICD implantation for primary or secondary prevention evaluated
  - **Intervention or Exposure:** ICD implantation in women
  - **Comparison(s):** ICD implantation in men
  - **Outcome(s):** major complications included electrical storm, lead dislodgement (repositioned), lead replacement, any lead repositioning, myocardial perforation, pneumothorax or hemothorax, pocket infection, and pulmonary edema
  - **Duration of follow-up:** up to 45 days after procedure
  - **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** retrospective analysis; study did not evaluate the effect of gender on events before referral
    - **Precision:** no other serious concerns
    - **Directness:** no other serious concerns
    - **Consistency assessment:** no other serious concerns
    - **Other considerations:** no other serious concerns
  - **Results:** comparing complications in females vs. males within 45 days of ICD implantation (overall rates not reported)
      - Major complications in 5.4% vs. 3.3% (p = 0.002)

        - Electrical storm in small cell size (SC) vs. 0.3% (not significant)
        - Lead replacement in 1.9% vs. 0.7% ($p < 0.001$)
        - Any lead repositioning in 1.4% vs. 1.2% (not significant)
        - Myocardial perforation in SC vs. 0.2% (not significant)
        - Pneumothorax or hemothorax in 0.6% vs. 0.3% (not significant)
        - Pocket infection in SC vs. 0.4% (not significant)
        - Pulmonary edema in 0.6% vs. 0.2% ($p = 0.02$)
        - Pocket hematoma (classified as minor) in 0.6% vs. 0.8% ($p = 0.41$)
    - no significant difference between women and men in ICD implantation rate following referral or total mortality
    - overall complications within 45 days of ICD implantation
        - Lead replacement in 0.95%
        - Any lead repositioning in 1.28%
        - Pneumothorax or hemothorax in 0.37%
        - Pulmonary edema in 0.25%
        - Pocket hematoma (classified as minor) in 0.79%
    - unable to determine overall complication rate for electrical storm, myocardial perforation, and pocket infection

- **Study conclusion (DMP level of evidence): Heparin bridging therapy and dual antiplatelet therapy associated with higher risk of bleeding complications during cardiac rhythm device implantation compared to no antiplatelet or anticoagulation therapy (level 2 [mid-level] evidence)**
    - **Reference:** Bernard ML, Shotwell M, Nietert PJ, Gold MR. Meta-analysis of bleeding complications associated with cardiac rhythm device implantation. *Circ Arrhythm Electrophysiol*. 2012 Jun 1;5(3):468-74. PubMed Full Text
    - **Study design:** systematic review of primarily observational studies
    - **Objective:** to determine rate of bleeding events after cardiac rhythm device implantation with and without antiplatelet and anticoagulation therapy
    - **Population:** systematic review of 13 studies (2 randomized trials, 11 observational studies) evaluating bleeding complications during implantation of cardiac rhythm device (pacemaker or implantable cardioverter defibrillator) in 5,978 patients
    - **Intervention or Exposure:** ICD implantation while: without antiplatelet or anticoagulation therapy, with single antiplatelet therapy, with dual antiplatelet therapy, or with heparin-bridging therapy
    - **Comparison(s):** see above
    - **Outcome(s):** peri-procedural bleeding complication (all major or minor bleeding events)

  - major bleeding defined as bleeding: requiring transfusion or surgical intervention, pericardial effusion, hemothorax, or that is life-threatening
  - minor bleeding defined as any hematoma requiring: conservative management only, not requiring transfusion, or discontinuation of medication
- **Duration of follow-up:** exact timeframe unclear; all "periprocedural" complications documented
- **Certainty (reasons for LOE downgrade):**
  - **Risk of bias:** definition of bleeding complication varied across studies, follow-up times unclear
  - **Precision:** no other major concerns
  - **Directness:** no other major concerns
  - **Consistency assessment:** no other major concerns
  - **Other considerations:** no other major concerns
- **Results:**
  - pooled incidence of total bleeding complications (major and minor) in all 13 studies
    - 4.6% overall
    - 2.2% of 1,500 patients not taking antiplatelet or anticoagulation therapy
    - 2.5% of 1,044 patients with anticoagulants stopped
    - 2.8% of 1,200 patients with anticoagulants continued
    - 3.9% of 1,165 patients with single antiplatelet therapy
    - 9.4% of 392 patients with dual antiplatelet therapy
    - 14.6% of 667 patients with heparin-bridging therapy
  - compared to no anticoagulation therapy, increased risk of bleeding complications in patients on
    - heparin bridging therapy (adjusted odds ratio [OR] 8.3, 95% CI 5.5-12.9)
    - dual antiplatelet therapy (adjusted OR 5, 95% CI 3-8.3)
    - withheld anticoagulants (adjusted OR 1.7, 95% CI 1-31)
    - continued anticoagulants (adjusted OR 1.6, 95% CI 0.9-2.6)
    - aspirin only (adjusted OR 1.5, 95% CI 0.9-2.3)
  - no severe or life-threatening bleeding events reported
  - pooled incidence of minor and major bleeding in secondary analysis of 11 studies
    - 1.5% and 0.2% of 961 patients not taking antiplatelet or anticoagulation therapy
    - 2.1% and 0.2% of 1,044 patients with anticoagulants stopped
    - 2.2% and 0.5% of 1,079 patients with anticoagulants continued

- 1.6% and 0.2% of 618 patients with single antiplatelet therapy
- 3% and 1.9% of 263 patients with dual antiplatelet therapy
- 9.1% and 2% of 551 patients with heparin-bridging therapy

- **FAQ 6 (What are the long-term risks?):**

  Patient content:

  The ICD battery will need to be replaced every 5 to 8 years or so. Over the next 3 years, out of 100 people about:

  - 3 (3%) need hospital care for a problem with the ICD
  - 2 (2%) need to replace their ICD due to malfunction

  Evidence and Information Summary: Within about 3 years of ICD implantation for primary prevention, about 3% total experienced a complication that required another operation, about 2% had a device malfunction requiring reoperation, about 3% had a mechanical complication that required a hospital visit, about 1% had an infection that required either hospitalization or reoperation. About 2% developed blot clots over a period of about 5 years, but it is unlikely that this risk is directly associated with ICD use. The risk for blood clots is more likely associated with the number and severity of comorbidities in the individual patient. Safety advisories or device recalls for ICDs may be issued, and a small number of people may need to have ICD parts replaced. ICD batteries may need to be replaced about every 5 to 8 years or so.

  Search: We searched DynaMed Plus (Implantable cardioverter defibrillator (ICD)/long-term complications) and PubMed ("implantable cardioverter defibrillator venous thromboembolism" and "implantable cardioverter defibrillator battery longevity" with Humans and English language study filters) on May 29, 2018. We found 62 citations and included 4 in the analysis. Additional sources retrieved by searching DynaMed Plus (and tracing citations), EBSCO Health Patient Education Reference Center, and Google ("ICD recalls patient implications") on May 29, 2018.

Database	Search string	Total number of search results	Number of included studies
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Adverse Effects and Cautions Heading ➢ Long-term complications subheading	1	1
PubMed	(("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 ("venous thromboembolism"[MeSH Terms] OR ("venous"[All Fields] AND "thromboembolism"[All Fields]) OR "venous thromboembolism"[All Fields])) AND ("humans"[MeSH Terms] AND English[lang])	13	1
PubMed	(("defibrillators, implantable"[MeSH Terms] OR ("defibrillators"[All Fields] AND "implantable"[All Fields]) OR "implantable defibrillators"[All Fields] OR ("implantable"[All Fields] AND	48	2

	"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])		

Evidence and Information Details:

LONG-TERM COMPLICATIONS

Study conclusion (DMP level of evidence): device related complications rate about 6 per 100 patient-years in patients ≥ 65 years old receiving first ICD (level 2 [mid-level] evidence)

- **Reference:** 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 May 3. PubMed
  - **Study design:** retrospective cohort study
  - **Objective:** evaluate long-term complications associated with ICD implantation
  - **Population:** 95,545 patients with ICD for primary prevention and 18,939 patients with ICD for secondary prevention
  - **Intervention or Exposure:** ICD implantation for primary or secondary prevention and with single-chamber, dual chamber, or CRT-D
  - **Comparison(s):** see above
  - **Outcome(s):** ICD-related complications requiring reoperation or hospitalization and reoperations
  - **Duration of follow-up:** median 2.7 years
  - **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** retrospective analysis
    - **Precision:** no serious concerns
    - **Directness:** no serious concerns
    - **Consistency assessment:** no serious concerns
    - **Other considerations:** no serious concerns
  - **Results:**
    - mortality 35% at median follow-up 2.7 years, and 55% at 6-year follow-up
    - long term complications after ICD implantation for primary prevention vs. secondary prevention (p values not reported)
      - Any device complication in 6.01% vs. 6.52%
      - complication requiring reoperation in 2.65% vs. 2.39%
      - device malfunction requiring reoperation in 2.12% vs. 1.9%

        - infection requiring reoperation in 0.46% vs. 0.42%
        - pocket related complications requiring reoperation in 0.04% vs. 0.04%
        - mechanical complication requiring hospitalization (but not reoperation) in 2.58% vs. 3.28%
        - infection requiring hospitalization (but not reoperation) in 0.79% vs. 0.86%
    - complication rates were significantly higher with cardiac resynchronization therapy with defibrillator and with dual-chamber ICD compared to single-chamber ICD

VENOUS THROMBOEMBOLISM

- **risk of venous thromboembolism may not be directly associated with use of implantable cardioverter-defibrillators (level 2 [mid-level] evidence)**
    - **Reference:** Pedersen SB, Hjortshøj SP, Bøtker HE, Farkas DK, Schmidt M, Sørensen HT, Nielsen JC. Venous thromboembolism in patients with implantable cardioverter-defibrillators. *Europace*. 2017 Jun 1;19(6):991-1001**.** PubMed
    - **Study design:** retrospective cohort (Danish National Patient Registry)
    - **Objective:** assess incidence of venous thromboembolism (VTE) and associated risk factors in patients with implantable cardioverter defibrillators (ICDs)
    - **Population:** 8,132 patients (median age at implantation 65 years) with ICDs
    - **Exposures:** variables evaluated included gender, age, ICD type, prior device implantation, comorbidity level, individual comorbidities, and use of antithrombotic therapy
    - **Outcome(s):** risk of VTE (deep vein thrombosis or pulmonary embolism) within 3 months and 5 years of implantation
    - **Duration of Follow-up:** median 3 years
    - **Certainty:**
        - **Risk of bias:** retrospective analysis
        - **Precision:** no serious concerns
        - **Directness:** subgroup analysis of VTE outcomes in ischemic cardiopathy patients is unavailable; however, data from this large, nationwide cohort of Danish National Patient Registry allows for generalization to broad audience
        - **Consistency:** the authors discuss that the VTE rates may be lower than a US study with similar patients, but point out that the US study included patients with VTE diagnosed prior to ICD implantation whereas this study did not
        - **Other considerations:** No other serious concerns
    - **Results:** overall risk of VTE, 0.3% within 3 months and 1.9% within 5 years
        - At 5 years, VTE found in 1.3% in patients with no-comorbidity vs. 3.2% in patients with severe comorbidity

    - no association found between number of leads or ICD type and the risk of VTE
- **Note:** Venous thromboembolism was identified as a potential long-term risk by clinical reviewer in initial scoping session. This large cohort suggests that there is no association between the number of leads or ICD type and the risk for VTE. The risk for VTE may be more dependent on comorbidity severity level. Therefore, this outcome is not listed as a device related adverse-event in the patient content.

BATTERY LIFE

- **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 of 3 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

- 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

- **FAQ 7 (Can the ICD be turned off or removed?):**
  Patient content: Yes, an ICD can be turned off. It is usually not removed unless there is an infection or a need to change the battery. In your communication with your physician, you should address the possibility to deactivate the ICD in an emergency or end-of life situation.
  Summary of Information: Removal of an ICD is typically not recommended unless there is a need to remove it, such as battery replacement or infection or chronic pain related to the device. Instead, if a person would like to stop ICD treatment, the device can easily be deactivated by altering settings on the device without surgical procedure. It is the patient's right to choose to stop having treatment and may do so because their quality of life has changed or they are at the end of their life and do not want to be burdened with shocks. ICD shocks in the end stage of life may be distressing to patients, caregivers, and relatives, and deactivation can allow for a more peaceful final stage of life. Providers and patients should discuss deactivation considerations before ICD implantation and if there is any significant decline in health.
  Source: This question did not require systematic searching. Sources were retrieved by searching DynaMed Plus (and tracing citations), 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.
  Information details:

  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

Option 2

Option 2 title (patient version): Do not get an ICD implant

- **FAQ 1 (What does the treatment involve?):**
  Patient content: You will not get an ICD.
  Information Summary: You will not get an ICD, but you may still take medicines for your heart problems.

- **FAQ 2 (Will it help me live longer?):**
  Patient content:
  Over the next 3 years, out of 100 people about:
  - 15 (15%) will die from their heart stopping
  - 31 (31%) will die from any cause

  Evidence Summary: In a systematic review of randomized controlled trials of patients with ischemic cardiomyopathy, ICD reduced the risk of sudden cardiac death by 61% and all-cause death by 18% compared to conventional care alone. Over the next 3 years, out of 100 people, about 6 (6%) of patients with an ICD will die of sudden cardiac death compared to about 15 (15%) of patients on conventional care. Over that same period, in total about 25 (25%) of patients with an ICD will die from any cause compared to about 31 (31%) of patients on conventional care.
  Search: We searched DynaMed Plus (Implantable cardioverter defibrillator (ICD)/ischemic cardiomyopathy) on May 22, 2018. We found 18 citations and included 1 in the analysis.

Database	Search string	Total number of search results	Number of included studies
DynaMed Plus	Implantable cardioverter defibrillator (ICD) Topic ➢ Primary Prevention of Sudden Cardiac Death (SCD) Heading ➢ Heart failure subheading ➢ Ischemic cardiomyopathy subheading	18	1

- **Study conclusion (DMP level of evidence): ICD therapy appears to reduce risk of all-cause and sudden death in adults with ischemic or nonischemic cardiomyopathy (level 2 [mid-level] evidence)**
  - **Reference:** Kolodziejczak M, Andreotti F, Kowalewski M, Buffon A, Ciccone MM, Parati G, et al. Implantable Cardioverter-Defibrillators for Primary Prevention in Patients With Ischemic or Nonischemic Cardiomyopathy: A Systematic Review and Meta-analysis. *Ann Intern Med*. 2017 Jul 18;167(2):103-111. PubMed

- **Study design:** systematic review
- **Objective:** compare mortality with ICD therapy versus conventional care for primary prevention
- **Population:** systematic review of 11 randomized trials comparing ICD therapy vs. conventional care in 8,716 adults with ischemic (65.7%) or nonischemic (34.3%) cardiomyopathy
    - conventional care included contemporary medical therapy, antiarrhythmic medical therapy, or placebo plus medical care
    - most patients had NYHA class II or III heart failure, 5.6% had class IV
- **Intervention or Exposure:** ICD therapy
- **Comparison(s):** conventional care
- **Outcome(s):** All-cause mortality and sudden cardiac death
- **Duration of follow-up:** mean 3.2 years
- **Certainty (reasons for LOE downgrade):**
    - **Risk of bias:** review limited by clinical heterogeneity
        - variations in timing of ICD placement, pharmacotherapies used, and use of cardiac resynchronization therapy across trials
    - **Precision:** no other serious concerns
    - **Directness:** no other serious concerns
    - **Consistency assessment:** no other serious concerns
    - **Other considerations:** no other serious concerns
- **Results:**
    - In nonischemic and ischemic cardiomyopathy patients, ICD therapy associated with
        - 19% reduction of all-cause death compared to conventional care (hazard ratio [HR] 0.81, 95% CI 0.7-0.94) in analysis of 11 trials
        - 59% reduction of sudden death (HR 0.41, 95% CI 0.3-0.56) in analysis of 7 trials with 3,959 patients
    - in subgroup analyses for ischemic cardiomyopathy, ICD therapy associated with
        - 18% reduction of all-cause death compared to conventional care (HR 0.82, 95% CI 0.63-1.06) in subgroup analysis of 7 trials with 5,724 patients
        - 61% reduction of sudden death (HR 0.39, 95% CI 0.23-0.68) in subgroup analysis of 4 trials with 2,282 patients
    - comparing mortality in patients with ischemic cardiomyopathy on ICD vs. conventional care
        - sudden cardiac death in 6% vs 15.4% (HR 0.39, 95% CI 0.23-0.68)
        - all-cause death in 25% vs. 30.5% (HR 0.82, 95% CI 0.63-1.06)
        - Note: event rates with ICD estimated by multiplying conventional care event rate by HR
    - adverse events and complications not reported in review

- **FAQ 3 (Will it change my usual activities?):**
  Patient content: No
  Information Summary: Without an ICD, you do not have to change your usual activities.

- **FAQ 4 (Will the ICD shock my heart?):**
  Patient content: Does not apply
  Information Summary: Does not apply

- **FAQ 5 (What are the risks of having an ICD put in place?):**
  Patient content: Does not apply
  Information Summary: You will avoid the risks of ICD surgery.

- **FAQ 6 (What are the long-term risks?):**
  Patient content: Does not apply
  Information Summary: You will avoid the long-term risks of ICD surgery.
- **FAQ 7 (Can the ICD be turned off or removed?):**
  Patient content: Does not apply
  Information Summary: Does not apply

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