Supplementary Table 1. Studies included in the review and select outcomes

| Study | Study design; description of study population; indications for WD use; sample size | Duration of use in days; daily use a | Mortality (all cause; VT/VF related; VT/VF specific) b | Survival | VT/VF incidence (%) c | Successful termination of arrhythmic events d | Appropriate shocks; inappropriate shocks e |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Auricchio, Klein et al., 1998  ([1](#_ENREF_1)) | WD tested in lab;  Prior cardiac arrest due to VT/VF;  NA, VT/VF induced;  N=15 | NR;  NR | NR;  NR;  NR | NR | NA | 90% (9/10) | NR;  NR |
| Bianco and Szymkiewicz, 2010  ([2](#_ENREF_2)) | Retrospective cohort;  WD users shocked for VT/VF;  NR;  N=2105 | NR;  NR | NR;  NR;  NR | NR | *NR* | 95% (240/252) | NR;  NR |
| Bianco and Szymkiewicz, 2011  ([3](#_ENREF_3)) | Retrospective cohort;  Prescribed WD post-MI and had at least one treatment for VT/VF;  NR;  N=92 | NR;  NR | NR;  NR;  NR | 30-days after resuscitation: 87%;  90-days after resuscitation: 82% | *NR* | *NR* | NR;  NR |
| Bianco and Szymkiewicz, 2011  ([4](#_ENREF_4)) | Retrospective cohort;  Heart failure patients using WD ≥365 days;  NR;  N=72 | 527 +/- 195;  NR | NR;  NR;  NR | NR | *NR* | *NR* | NR;  2.8% (2/72) |
| Bianco, Wilmer et al., 2010  ([5](#_ENREF_5)) | Case-control;  EF <35% excluding recent MI and ICD explants;  NR;  N=5134 | NR;  19.9 | 2% (91/5134), cause not reported;  NR;  NR | NR | *NR* | *NR* | 1.2% (62/5134);  NR |
| Carillo, Garisto et al., 2010  ([6](#_ENREF_6)) | Retrospective cohort;  ICD explants;  ICD explants;  N=2060 | Median: 30.5;  19.2 | 6% (111/1881), cause not reported;  0.10% (2/2060);  NR | NR | *NR* | *NR* | NR;  1.5% (29/1881) |
| Carrillo, Garisto et al., 2011  ([7](#_ENREF_7)) | Retrospective cohort;  ICD explant due to cardiac device infection;  ICD explants;  N=97 | 41.35;  18.5 | NR;  0% (0/97);  NR | NR | 2.1% (2/97) | 100% (2/2) | NR;  1.1% (1/92) |
| Chung, Szymkiewicz et al., 2010 and Zishiri, Shao et al., 2010  ([8](#_ENREF_8)) and ([9](#_ENREF_9)) | Retrospective cohort;  General WD patient population;  ICD explants (23%), LVEF ≤ 35% and non-ischemic cardiomyopathy (20%), VT/VF before ICD implantation (16%), , LVEF ≤ 35% and recent MI (13%), LVEF ≤ 35% and Post-CABG (9%), , LVEF ≤ 35% and unspecified cardiomyopathy (8%), miscellaneous or unknown (7%), LVEF >35% and recent MI (4%), and genetic predisposition (0.4%);  N=3569 | 59.8 +/- 32g;  19.9 | 0.78% (28/3569);  0.2% (8/3569);  14% (8/59) | Traditional vs. non-traditional ICD indications (90-day)f: HR (95% CI)= 4.32 (2.50-7.49), p<0.001  WD vs. ICD patients (90-day): HR (95% CI)=0.83 (0.60-1.14), p=0.26 | 1.7% (59/3569) | 86.4% (51/59) | 1.7% (59/3569);  1.9% (67/3569) |
| Deering, Curwin, et al., 2011  ([10](#_ENREF_10)) | Prospective cohort;  Post-MI who did not meet ICD implant criteria;  NR;  N=43 | 58.3;  19.8 | 0% (0/43);  0% (0/43);  0% (0/1) | NR | 2.3% (1/43) | 100% (1/1) | *NR;*  *NR* |
| Dillon, Szymkiewicz et al., 2010  ([11](#_ENREF_11)) | Retrospective cohort;  General WD patient population;  Cardiomyopathy (28%), ICD removed (21%), acute MI (21%), cardiac arrest (12%), old MI (10 %), missing (5%), and other (3%);  N=2105 | 93;  NR | NR;  0.05% (1/2105);  NR | NR | NR | NR | 2.5% (54/2145);  NR |
| Epstein, Haines et al., 2012  ([12](#_ENREF_12)) | Retrospective cohort;  Patients coded as “recent MI with EF≤35%” or ICD9410.xx, comparisons made between revascularized and non-revascularized patients;  NR;  N=9444 | Approx. 2 months;  NR | NR;  NR;  NR | NR | NR | NR | 1.4% (131/9444);  NR |
| Everitt, Verma et al., 2011  ([13](#_ENREF_13)) | Retrospective cohort;  History of cancer;  LVEF<=35%: SCA or VT (9%), ICD explant (13%), and other (78%; history of intracardiac or deep venous thrombus, active infection, radiation therapy, and lack of central venous access due to cancer location) ;  N=59 | NR;  20 | 19% (11/59), cause not reported;  NR;  NR | NR | NR | 100% (4/4) | Median: 136;  1.7% (1/59) |
| Feldman, Klein et al., 2004 and Feldman, Klein et al., 2002  ([14](#_ENREF_14)) and ([15](#_ENREF_15)) | Prospective cohort;  WEARIT and BIROAD study participants, high risk of SCD but not eligible for ICD placement;  NR;  N=289 | 93;  NR | 4% (12/289), 6 sudden 6 non-sudden;  NR;  NR | NR | NR | 67% (4/6) | NR;  2.1% (6/289) |
| Glad, Bianco et al., 2011  ([16](#_ENREF_16)) | Retrospective cohort;  Tako-tsubo patients;  NR;  N=19 | NR;  20.2 | 0% (0/19);  0% (0/19);  0% (0/2) | NR | 5.3% (1/19) | 100% (1/1) | Median: 34;  NR |
| Glad, Szymkiewicz et al., 2012  ([17](#_ENREF_17)) | Retrospective cohort;  WD users shocked for VT/VF;  NR;  N=299 | 43.2 +/- 61.3;  18.1 | NR;  NR;  NR | Single ventricular arrhythmic vs. multiple ventricular arrhythmic patients (90-day survival): 92.2% vs. 79.2%, p<0.05 | NR | NR | NR;  NR |
| Glad and Szymkiewizc, 2011  ([18](#_ENREF_18)) | Retrospective cohort;  Post shock asystol patients wearing WD;  NR;  N=not clear | NR;  NR | 60% (9/15), all died from post-shock asystole;  60% (9/15);  60% (9/15) | NR | NR | 40% (6/15) | NR;  NR |
| Glad and Szymkiewizc, 2011  ([19](#_ENREF_19)) | Retrospective cohort;  General WD patient population, urban vs. rural;  NR;  N=381 | NR;  NR | Urban: 5.5% rural: 9%  NR;  NR | NR | NR | *NR* | NR;  NR |
| Hanson, Gilette et al., 2011  ([20](#_ENREF_20)) | Retrospective cohort;  General WD patient population;  Cardiomyopathy (66%) and other (34%);  N=158 | NR;  NR | 2% (3/158), 2 end stage congestive heart failure and 1 MI associated with septic shock;  0% (0/158);  NR | NR | NR | *NR* | 2.9% (3/104);  0.63% (1/158) |
| Horstmanshof, Wan et al., 2012  ([21](#_ENREF_21)) | Retrospective cohort;  Heart transplant candidates;  NR;  N=35 | 81.6 +/- 79;  NR | 3% (1/35), cause unknown;  NR;  NR | NR | 5.7% (2/35) | 100% (2/2) | NR;  NR |
| Karia, Bianco et al., 2010  ([22](#_ENREF_22)) | Retrospective cohort;  NICM patients;  NR;  N=not clear | 57.1 +/- 51.1g;  NR | 0.6% (1/166), cause unknown;  0% (0/166);  0% (0/0) | NR | 0% (0/166) | *NR* | NA;  1.2% (2/166) |
| Karia, Bianco et al., 2011  ([23](#_ENREF_23)) | Retrospective cohort;  ICM and NICM patients;  NR;  N=268 | NR;  NR | 0.4% (1/268), cause unknown;  NR;  NR | NR | NR | 100% (1/1) | NR;  0.75% (2/268) |
| Mirro, Richardville et al., 2011  ([24](#_ENREF_24)) | Retrospective cohort;  LV Dysfunction post-acute MI or new coronary heart failure;  NR;  N=not clear | 57.1 +/- 51.1g;  NR | NR;  NR;  NR | NR | NR | *NR* | NR;  0.74% (1/134) |
| Mitrani, McArdle et al., 2010  ([25](#_ENREF_25)) | Retrospective cohort;  Uninsured WD users;  Revascularization (4%) and ICM or NICM (96%);  N=134 | 135 +/- 127 g;  14.1 | NR;  NR;  NR | NR | 0% (0/108) | *NR* | NA;  NR |
| Mossesso, Li et al., 2011  ([26](#_ENREF_26)) | Retrospective cohort;  General WD patient population;  Most common were NICM (40.1%), MI (33.0%), and ICD pocket infection (12.1%);  N=14,475 | 59.9 +/- 59.1;  NR | NR;  NR;  NR | NR | 1.3% (185/14475) | *NR* | NR;  1.5% (223/14475) |
| Rao, Goldenberg et al., 2011 and Rao, Moss et al., 2011  ([27](#_ENREF_27)) and ([28](#_ENREF_28)) | Retrospective cohort;  Diagnosed or suspected congenital structural heart disease or inherited arrhythmias;  NR;  N=162 | Median: 27;  19 | 3% (4/162), 2 cause unknown, 1 peritonitis, and 1 chemo;  0% (0/162);  0% (0/2) | NR | 1.2% (2/162) | 100% (2/2) | *(2/162;*1.23% (2/162)  1.2% (2/162)  3% (4/162) |
| Reek, Geller et al., 2003  ([29](#_ENREF_29)) | Retrospective cohort;  ICM patients with a history of one or more MIs and undergoing an electrophysiological study;  NA;  N= 12 | WD tested in lab;  NR;  NR | NR;  NR;  NR | NR | NA | 100% (12/12) | NR;  NR |
| Saltzberg, Szymkiewicz, 2012  ([30](#_ENREF_30)) | Retrospective cohort;  Paripartum cardiomyopathy and NICM patients;  NR;  N=266 | *52.6 +/- 69.9;*  *17.7* | 5% (11/207), 7 cardiac related and 4 cause unknown;  NR;  NR | NR | NR | 100% (1/1) | NR;  0% (0/207) |
| Szymkiewicz, Dillon et al., 2009  ([31](#_ENREF_31)) | Retrospective cohort;  WD users who were shocked;  NR;  N=9,708 | 57;  NR | NR;  NR;  NR | NR | NR | NR | NR;  1.7% (167/9708) |
| Szymkiewicz and Chenarides, 2010  ([32](#_ENREF_32)) | Retrospective cohort;  WD patients for use after sudden cardiac arrest, inherited SCA risk, and prior to EP study;  NR;  N=952 | Median: 40;  20.3 | 4% (41/924), cause NR;  0.2% (2/924);  NR | NR | NR | NR | NR;  NR |
| Wan, Herzog et al., 2012  ([33](#_ENREF_33)) | Retrospective cohort;  Hemodialysis patients who experienced sudden cardiac arrest;  Previous SCA (36%), ICD removal (35%), ischemic heart disease (13%), non-ischemic heart disease (15%), and other (2%);  N=not clear | NR;  NR | NR;  NR;  NR | 63%;  NR | NR | NR | NR;  NR |
| Wan, Esser et al., 2012  ([34](#_ENREF_34)) | Retrospective cohort;  ICD explant or deactivation (Germany);  ICD explant or deactivation;  N=151 | 50 +/- 38;  20.6 | NR;  NR;  NR | NR | 1.3% (2/151) | 100% (2/2) | NR;  NR |
| Wan, Glad et al., 2011  ([35](#_ENREF_35)) | Retrospective cohort;  General WD patient population;  NR;  N=15,193 | NR;  NR | NR;  NR;  NR | NR | NR | NR | NR;  1.7% (258/15193) |
| Zirishi, Cronin et al., 2011  ([36](#_ENREF_36)) | Retrospective cohort;  CABG or PCI with LVEF ≤35%;  NR;  N=4958 | NR;  NR | NR;  NR;  NR | Entire cohort,  WD vs. non-WD: HR 0.54 (43-0.68, 3-year survival)  CABG patients, WD vs. non-WD: 3% vs. 7% (90-day mortality); HR 0.42 (0.23-0.74; 3-year survival)  PCI patients, WD vs. non-WD: 2% vs. 10% (90-day mortality); HR 0.33 (0.21-0.52; 3-year survival) | NR | NR | NR;  NR |
| Mean (SD)h | **NA** | *62.7 (27.1)*  *19.6 (0.84)* | 2.6% (2.97)i  **0.33% (2.52)**  22.1% (20.9) | **NA**j | *1.4% (0.35)* | *95.6% (4.61)k* | *1.5% (0.42)*  *1.6% (0.22)* |
| CABG=coronary artery bypass grafting, ICM=ischemic cardiomyopathy, LVEF= left ventricular ejection fraction, NICM=non-ischemic cardiomyopathy, NR=not reported, NA=not applicable, PCI= percutaneous coronary intervention , VT= Ventricular tachycardia  , VF= ventricular fibrillation, WD= wearable cardioverter defibrillator  a. Days used= mean number of days the WD was used (not necessarily worn) reported as mean unless otherwise specified, daily use= mean hours of WD use per day as reported by study authors  b. All cause mortality=# of deaths from all causes/study sample; VT/VF related=# of VT/VF related deaths/study sample; VT/VF specific=# of VT/VF deaths/# of patients who experienced a VT/VF event  c. VT/VF incidence = # of patients that experienced a VT/VF event(s)/study sample  d. Successful termination of arrhythmic events = # of patients with terminated VT/VF event(s)/# of patients who experienced a VT/VF event  e. Appropriate shocks= # of patients who experienced a defibrillation for VT/VF/study sample; inappropriate shocks = # of patients who experienced a defibrillation unrelated to VT/VF/study sample  f. Traditional ICD indications included: ICD explants, VT/VF before ICD implant, genetic predisposition to SCD, LVEF ≤ 0.30 and cardiomyopathy. Non-traditional ICD indications included LVEF ≤ 0.35 and recent MI  or post-CABG or recent NICM, LVEF ≥ 35% and recent MI, and miscellaneous or unknown.  g. Authors do not indicate whether the reported estimate is a mean or median  h. Weighted by denominator  i. Glad et al., 2011a was not included in the calculation since raw numbers were not reported  j. Hazard ratios were not pooled given methodological and clinical heterogeneity (i.e., differences in study populations and time interval, 90-day vs. 3-year survival)  k. Glad et al., 2011b was not included in the calculation since raw numbers were not reported | | | | | | | | |

Supplementary Table 2. Synthesis and Quality of Evidence for Question 3

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Research Question 3:** Are wearable defibrillators efficacious and/or effective for the following patient groups?  1a. ≤ 40 days post-MI and a measured LVEF ≤ 0.35  1b. >40 days post-MI and a measured LVEF ≤ 0.35 | | | | | | | | | | | | | |
|  | **Quality assessment** | | | | |  | **Summary of findings** | | | | | | |
| **No of studies** | **Design** | **Quality, average NOS risk of bias rating** | **Consistency** | **Directness** | **Other modifying factors** |  | **Group A** | **Group B** |  | **Relative (95% CI)** | **Absolute risk** | **Quality** | **Importance** |
| **All-cause mortality (# of deaths from all causes/study sample)** | | | | | | | | | | | | | |
| 1 | Observational design | Serious, NOS=5 | -- | Not serious | Publication bias suspected |  | Entire cohort= 43 | -- |  | -- | 0% (0/43) | Very low quality a | Important |
| **VT/VF specific mortality (# of VT/VF deaths/# of patients who experienced a VT/VF event)** | | | | | | | | | | | | | |
| 2 | Observational design | Serious,  NOS=4.5 | No serious inconsistency | Not serious | Publication bias suspected |  | Entire cohort= 2774 | -- |  | -- | 18.2% (2/22) | Very low quality b | Critical |
| **Survival** | | | | | | | | | | | | | |
| 1 | Observational design | Serious,  NOS=4 | -- | Not serious | Publication bias suspected |  | Entire cohort= 92 | -- |  | -- | 30-days after resuscitation: 87% (raw numbers not reported);  90-days after resuscitation: 82% (raw numbers not reported) | Very low quality c | Critical |
| **Successful termination of arrhythmic events (# of WD terminated VT/VF events/# of VT/VF events)** | | | | | | | | | | | | | |
| 2 | Observational design | Serious,  NOS=5.5 | -- | Not serious | Publication bias suspected |  | Entire cohort= 2774 | -- |  | -- | 81.8% (9/11) | Very low quality b | Critical |
| **Appropriate shocks (# of defibrillations for VT/VF/study sample)** | | | | | | | | | | | | | |
| 2 | Observational design | Serious,  NOS=5 | -- | Not serious | Publication bias suspected |  | Entire cohort= 9785 | -- |  | -- | 1.5% (141/9785) | Very low quality b | Important |
| **Research question 3:**  2a. ≤ 90 days post CABG or PCI (PTCA) and LVEF ≤ 0.35  2b. > 90 days post CABG or PCI (PTCA) and LVEF ≤ 0.35 | | | | | | | | | | | | | |
|  | **Quality assessment** | | | | |  | **Summary of findings** | | | | | | |
| **No of studies** | **Design** | **Quality, average NOS risk of bias rating** | **Consistency** | **Directness** | **Other modifying factors** |  | **Group A** | **Group B** |  | **Relative (95% CI)** | **Absolute risk** | **Quality** | **Importance** |
| **VT/VF specific mortality (# of VT/VF deaths/# of patients who experienced a VT/VF event)** | | | | | | | | | | | | | |
| 1 | Observational design | Serious,  NOS=6 | -- | Not serious | Publication bias suspected |  | Entire cohort= 2731 | -- |  |  | 50% (1/2) | Very low quality d | Critical |
| **Survival** | | | | | | | | | | | | | |
| 1 | Observational design | Serious,  NOS=5 | -- | Not serious | Publication bias suspected |  | Entire cohort= 4958 | -- |  | CABG patients, WD vs. non-WD: HR 0.42 (0.23-0.74; 3-year survival)  PCI patients, WD vs. non-WD: HR 0.33 (0.21-0.52; 3-year survival) | -- | Very low quality e | Critical |
| **Successful termination of arrhythmic events (# of WD terminated VT/VF events/# of VT/VF events)** | | | | | | | | | | | | | |
| 1 | Observational design | Serious,  NOS=6 | -- | Not serious | Publication bias suspected |  | Entire cohort= 2731 | -- |  | **--** | 50% (1/2) | Very low quality d | Critical |
| **Appropriate shocks (# of defibrillations for VT/VF/study sample)** | | | | | | | | | | | | | |
| 1 | Observational design | Serious,  NOS=6 | -- | Not serious | Publication bias suspected |  | Entire cohort= 2731 | -- |  | **--** | 0.82% (2/243) | Very low quality d | Important |
| **Research question 3:**  3a. ≤ 3 months non-ischemic cardiomyopathy (NICM) and LVEF ≤ 0.35  3b. > 3 months non-ischemic cardiomyopathy (NICM) and LVEF ≤ 0.35 | | | | | | | | | | | | | |
|  | **Quality assessment** | | | | |  | **Summary of findings** | | | | | | |
| **No of studies** | **Design** | **Quality, average NOS risk of bias rating** | **Consistency** | **Directness** | **Other modifying factors** |  | **Group A** | **Group B** |  | **Relative (95% CI)** | **Absolute risk** | **Quality** | **Importance** |
| **All-cause mortality (# of deaths from all causes/study sample)** | | | | | | | | | | | | | |
| 2 | Observational design | Serious, NOS=4.5 | No serious inconsistency | Not serious | Publication bias suspected |  | Entire cohort= 325 | -- |  | **--** | 3.7% (12/325) | Very low quality f | Important |
| **VT/VF specific mortality (# of VT/VF deaths/# of patients who experienced a VT/VF event)** | | | | | | | | | | | | | |
| 2 | Observational design | Serious, NOS=5 | No serious inconsistency | Not serious | Publication bias suspected |  | Entire cohort= 712 | -- |  | **--** | 25% (1/4) | Very low quality f | Critical |
| **Successful termination of arrhythmic events (# of WD terminated VT/VF events/# of VT/VF events)** | | | | | | | | | | | | | |
| 2 | Observational design | Serious, NOS=5.5 | No serious inconsistency | Not serious | Publication bias suspected |  | Entire cohort= 705 | -- |  | **--** | 80% (4/5) | Very low quality f | Critical |
| **Appropriate shocks (# of defibrillations for VT/VF/study sample)** | | | | | | | | | | | | | |
| 2 | Observational design | Serious, NOS=5.5 | No serious inconsistency | Not serious | Publication bias suspected |  | Entire cohort= 705 | -- |  | **--** | 0.71% (5/705) | Very low quality f | Important |
| **Inappropriate shocks (# of defibrillations unrelated to VT/VF/n)** | | | | | | | | | | | | | |
| 2 | Observational design | Serious, NOS=4.5 | No serious inconsistency | Not serious | Publication bias suspected |  | Entire cohort= 325 | -- |  | **--** | 0.61% (2/325) | Very low quality f | Important |
| **Research question 3:**  4. Ischemic cardiomyopathy | | | | | | | | | | | | | |
|  | **Quality assessment** | | | | |  | **Summary of findings** | | | | | | |
| **No of studies** | **Design** | **Quality, average NOS risk of bias rating** | **Consistency** | **Directness** | **Other modifying factors** |  | **Group**  **A** | **Group**  **B** |  | **Relative (95% CI)** | **Absolute risk** | **Quality** | **Importance** |
| **All-cause mortality (# of deaths from all causes/study sample)** | | | | | | | | | | | | | |
| 1 | Observational design | Serious, NOS=4 | -- | Not serious | Publication bias suspected |  | ICM patients= 53 | -- |  | **--** | 0% (0/53) | Low quality g | Important |
| **Successful termination of arrhythmic events (# of WD terminated VT/VF events/# of VT/VF events)** | | | | | | | | | | | | | |
| 1 | Observational design | Serious, NOS=6 | -- | Not serious | Publication bias suspected |  | ICM patients= 12 | -- |  | **--** | 100% (12/12) | Low quality h | Critical |
| HR=hazard ratio, ICM= ischemic cardiomyopathy, NICM= non-ischemic cardiomyopathy, LVEF=left ventricular ejection fraction, NOS=Newcastle-Ottawa Scale (rating out of a possible 9 stars where 9=minimal threats to internal validity), VT/VF=ventricular tachycardia/ventricular fibrillation, WD=wearable cardioverter defibrillator  a. No comparison group, 30% of patients were lost to follow up, and no statement on how missing data was handled.  b. Includes studies using retrospective design, no comparison group, and no statement on how missing data was handled.  c. Retrospective design, no comparison group, no statement on how missing data was handled, no statement on patients lost to follow up, in all studies at least 1 author was employed by the device manufacturer, and data for the exposed cohort came from a database maintained by the device manufacturer (indication of possible publication bias).  d. Retrospective design, non-exposed cohort drawn from a different source than exposed cohort, no statement on how missing data was handled, and no statement on the proportion of patients lost to follow up. In all studies, at least 1 author was employed by the device manufacturer and data for the exposed cohort came from a database maintained by the device manufacturer (indication of possible publication bias).  e. Retrospective design, non-exposed cohort drawn from a different source than exposed cohort, no statement on how missing data was handled, and no statement on the proportion of patients lost to follow up. Authors report use of an adjusted model but variables not reported. Propensity score matching was used but not clear on which variables matching occurred and how similar groups were after matching. In all studies, at least 1 author was employed by the device manufacturer (indication of possible publication bias). Although the estimate was large (<0.5) the overall quality score could not be upgraded since threats to validity were detected. Upgrading scores only applies to studies when no threats to validity are detected.  f. Retrospective design, no statement on how missing data was handled, and no statement on the proportion of patients lost to follow up. In all studies, at least 1 author was employed by the device manufacturer and data for the exposed cohort came from a database maintained by the device manufacturer (indication of possible publication bias).  g. Retrospective design, no statement on how missing data was handled, and 35% of study participants lost to follow up.  h. Small sample and all studies included at least 1 author employed by the device manufacturer (indication of possible publication bias). | | | | | | | | | | | | | |
| GRADE Working Group grades of evidence High quality: Further research is very unlikely to change our confidence in the estimate of effect.  Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate. | | | | | | | | | | | | | |

# Supplementary

**Systematic Literature Review Protocol**

# Main research question:

* 1. How efficacious and/or effective are wearable defibrillators (WD) compared to no WD use among adult patients (≥ 18 years old) at high risk of sudden cardiac death?
  2. How efficacious and/or effective are wearable defibrillators (WD) compared to other resuscitation methods (i.e., ICD and external defibrillators) among adult patients (≥ 18 years old) at high risk of sudden cardiac death?

**P**opulation: Adult patients (≥ 18 years old) at high risk of sudden cardiac death

**I**ntervention: Wearable defibrillators

**C**omparison: No WD use and other resuscitation methods (i.e., ICD and external defibrillators)

**O**utcomes: Measures of efficacy and effectiveness (see list below)

**S**tudy Designs: Randomized control trials, quasi experimental studies, and observational studies

* 1. Is WD efficacious and/or effective for the following 7 patient groups?

1. ≤ 40 days post-MI and a measured LVEF ≤ 0.35
2. >40 days post-MI and a measured LVEF ≤ 0.35
3. ≤ 90 days post CABG or PCI (PTCA) and LVEF ≤ 0.35
4. > 90 days post CABG or PCI (PTCA) and LVEF ≤ 0.35
5. ≤ 3 months non-ischemic dilated cardiomyopathy (NIDCM) and LVEF ≤ 0.35
6. > 3 months non-ischemic dilated cardiomyopathy (NIDCM) and LVEF ≤ 0.35
7. Ischemic cardiomyopathy
   1. What risks/harms do WDs pose to the patient?
8. **Measures (data extracted)**
   1. Efficacy and effectiveness

* All-cause mortality (# died/# at risk in a given time)
* Sudden cardiac death
  + VT/VF related
  + Other causes non-VT/VF related
* Short term survival (e.g., 3-30 day)
* Long term survival (e.g., 1+ years, usually post-WD)
* Mortality from sudden cardiac death
* Accurate detection of VT/VF by the WD
* Sensitivity/specificity of WD: shock by VT/VF occurrence
* Successful termination of arrhythmic events
  1. Compliance and harms
     + Mean duration of use (# of days)
     + Mean patient compliance (# of hours used/day)
     + Reported harms and risks
  2. Study characteristics
     + Manuscript type (peer-reviewed journal, juried conference abstract, non-juried conference abstract)
     + Funding, device manufacturer, and author affiliation
     + Study design and data sources (years of data analyzed)
     + Sampling method, power calculation, sample size, and loss to follow up
     + Location: US (regional), international, and urban/rural
     + Inclusion/exclusion criteria
     + Use of a comparison group
     + Analytic model and adjustments
     + Limitations
  3. Patient characteristics
     + Demographics: age, sex, race, income
     + Baseline medical characteristics and indications of use
     + Results reported on sub-groups of interest

# Phase I: Identification

* 1. Eligibility criteria:
     1. Types of articles
        1. Included: published in peer-reviewed journals and conference abstracts
        2. Excluded: gray literature and commissioned reports
     2. Study types
        1. Included: Randomized control trials, quasi-experimental studies, and observational studies
        2. Excluded: Case reports and qualitative studies
     3. Other: English language, no date restriction, no country restriction

## Information sources:

## Databases: PubMed, Embase, Scopus

* + 1. Bibliographies of identified articles
    2. Consultation with experts in the field
  1. Search strategy:
     1. Search #1: broad, all encompassing
     2. Search #2: specific terms
     3. Search #3: additional search to be conducted after the eligibility phase

**Table 1. Search strategy**

|  |  |
| --- | --- |
| **Search #1** | |
|  | Terms |
| 1 | (wearable AND defibrillator\*) |
| **Search #2** | |
| 1 | lifecor OR lifevest OR wearit OR biroad |
| **Search #3 (**New terms to be selected during the identification, screening, and eligibility phase) | |
| 1 | (Asahi Kasei AND defib\*) |
| 2 |  |
| 3 |  |

## Organizing and storing searches:

### Keep a record of the exact searches performed in each database and the date (such that they can be replicated and yield the exact results): Search\_v1.exl

### Download and store all electronic searches into folder

### Create an EndNote library and import searches into EndNote:

### Use My Groups to sort citations by database searches (folders for PubMed, Scopus, and Embase)

## Identify records from other sources

* + 1. Enter records into EndNote and use My Groups to create a folder “Other Sources Pre Screening”

## Remove duplicates

### Create a clone of Search1\_AllRecords.enl that contains the results of ALL searches plus records from other sources

### References>Remove Duplicates

* + 1. Save this library, indicating removal of duplicates in the name **Search1\_NoDups.enl**

# Phase 2: Screening

* 1. Develop screening codebook to document which records are excluded and why
  2. Generate a clone of and save as a separate library
  3. From EndNote print out all titles and abstracts (export-annotated) of all records
  4. Screen titles and/or abstracts and exclude those that are clearly not relevant in topic or do not meet eligibility criteria (e.g., letters to the editor)
     1. Mark print out with appropriate code
     2. Keep a running list of new search terms
     3. Enter into excel
  5. Generate an EndNote library and remove excluded records

# Phase 3: Eligibility

* 1. Retrieve full texts for all records, save PDFs in 1 folder, and print a copy
  2. Review full texts.
     1. Use screening codebook to record reasons for exclusion
     2. Keep a running list of new search terms
  3. Removes excluded records from EndNote and rename
  4. Tally # of records excluded and record reasons for exclusion in Excel doc

# Phase 4: Perform 2rd Search

* 1. Based on the running list of search terms identified in the screening and eligibility phases, perform another database search
  2. Create a separate EndNote library to store all of the search following similar protocol outlined in the Identification phase
  3. Cross-reference against the library that contains the results from the initial search. Exclude all records that were identified in the initial search.
  4. For the remaining records, screen and assess for eligibility, keeping record of excluded records
  5. Generate an EndNote library

# Phase 5: Included

* 1. Combine libraries to create a file of all included titles
  2. This library should reflect all articles that will be included in the synthesis of the literature review

1. **Data extraction**

# Create and pilot paper data extraction form

* 1. Pilot: randomly select 10% articles and pilot form
  2. JU to extract data, in this process also aim to identify articles from the same study.
  3. Data items (information extracted)
     1. Study characteristics
     2. Patient characteristics
     3. Results
     4. Level of evidence
     5. Risk of bias
     6. Conflict of Interest

1. **Meta-analysis**

If data are adequate and there is no evidence of heterogeneity, we will consider quantitative pooling using a random effects method.

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