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Patient-reported outcomes using a wearable cardioverter-defibrillator: results from a systematic review

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Abstract

Objectives: The aim of this study was to assess the effect of the wearable cardioverter-defibrillator (WCD) on patient-reported outcomes (PRO) in adult patients with high risk for sudden cardiac arrest.

Methods: We performed a systematic literature search in Medline (via PubMed) and Cochrane Library in February 2022 and included studies with a study population ≥18 years and prescribed WCD. PRO include health-related quality of life (QoL), symptoms, utilities, or satisfaction ratings. Study selection was done by two reviewers independently using predefined inclusion and exclusion criteria. Quality assessment of studies as well as data extraction was performed by one author and approved by a second author. Results of the included studies are presented quantitatively.

Results: One randomized controlled trial (RCT), one comparative non-randomized trial, and three single-arm trials were included. QoL was assessed in four studies, but with different assessment tools. One study additionally evaluated the change in depressive symptoms and anxiety and one study focused on acceptability of WCD but evaluated items that are closely related to QoL. Results of the RCT show no statistically significant difference in QoL assessed by SF-36 and EQ-5D comparing WCD and Guideline-Directed Medical Therapy (GDMT) versus GDMT alone. One comparative study reports an improvement in depressive symptoms and anxiety within groups but no significant difference between groups. Further, one single-arm study reported improvement in QoL between baseline and day 90 and day 180.

Conclusions: The available evidence demonstrates that the usage of WCD is not affecting PRO, like QoL, depressive symptoms or anxiety negatively.

Introduction

Sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) might lead to sudden cardiac arrest (SCA) and subsequently sudden cardiac death (SCD). In case of the occurrence of sustained VT or VF a prompt defibrillation is mandatory for life-saving as time to defibrillation determines the probability of survival (1). Defibrillation might be applied by bystanders or by ambulance service using external defibrillators. For primary and secondary prevention in patients with ischemic as well as non-ischemic cardiomyopathy indications (class IIa to IIb, LoE C to B-NR) a wearable cardioverter-defibrillator (WCD) is recommended to assure timely defibrillation (2). Patients with an indication for a WCD are in need for temporary protection against SCA/SCD due to sustained VT/VF until a decision of a final therapy can be made (3). In case of an SCA caused by sustained VT/VF the WCD can defibrillate automatically. The only approved and commercially available wearable defibrillator in Europe today is the LifeVest (manufactured by ZOLL Inc.). The LifeVest consists of a monitor worn on a holster around the waist, sensing electrodes, and defibrillator electrodes. An alarm system gives alarms to warn that a shock is imminent. In this case, a conscious patient might press response buttons to prevent from being shocked inappropriately (4). The WCD should be worn all-day long and only be taken off when taking a shower. Wearing the WCD might be associated with discomfort to the patient due to the weight of the defibrillator, sleep disturbance, or in sexual intercourse (5;6).

In a previously published HTA we examined the effectiveness, efficacy, and safety of WCDs in the treatment of sudden cardiac arrest (7). At that time the effects of WCD usage on some patient-reported outcomes (PRO) like health-related quality of life (QoL), utilities, or patient satisfaction had not been investigated sufficiently. Since then, further study results concerning these PRO have been published. The aim of this systematic review was to assess the effect of a wearable cardioverter defibrillator (WCD) in adult patients at increased risk of sudden cardiac death regarding patient-reported endpoints, especially QoL.

Methods

According to Population, Intervention, Comparator, and Outcome (PICO) criteria, study population was defined as adult patients with an indication for a WCD, thus patients with a temporarily need for protection due to a high risk for sudden cardiac arrest (2;3). The LifeVest of ZOLL Inc. version 4000 and earlier versions were assessed as it is still the only WCD in the European market. The WCD was compared to external defibrillation at home or at public places by bystanders, in-hospital monitoring, or resuscitation by an emergency ambulance. We assessed PRO that can be defined as "an outcome reported directly by patients themselves and not interpreted by an observer; PRO may include patient assessments of health status, quality of life, satisfaction with care or symptoms, or patient-reported adherence to medication"(8). Clinical symptoms as a manifestation of health status and adherence to WCD usage have been published earlier (7). Therefore, in this systematic review we focus on QoL, utilities, and patient satisfaction during WCD usage. Electronic searches were conducted on the 22nd of February 2022 in Medline (via PubMed) and Cochrane Library databases without using recognized search filters. The following search terms were used in MEDLINE, and the equivalent search was repeated on Cochrane Library databases: "WCD," "wearable defibrillator," "wearable cardiac defibrillator," "wearable cardioverter defibrillator," "Lifevest," "Life Vest," "external defibrillator jacket," "defibrillator vest," "portable cardioverter," "portable defibrillator," "mobile cardioverter," "mobile defibrillator." Search terms were entered and combined by the operator "OR." The next search step covered the search terms: "patient-related outcome," "PROs," "patient-reported outcome," "Quality of Life," "QoL," "patient-related outcome," "patient-reported outcome" and again combined by the operator "OR." Both search steps were subsequently combined with the search operator "AND." In addition to the search in literature databases, we viewed reference lists of each included study as well as the study registry ClinicalTrials.gov, in the latter case using the term "wearable cardioverter defibrillator." We applied no limitations regarding the date or type of publication. According to methodological standards two reviewers independently selected the publications in two-step approach using predefined inclusion and exclusion criteria. For each article excluded, the main reason for exclusion was recorded and is reported in the Supplemental Material. Study quality and risk of bias of RCTs and other comparative studies were assessed by means of published quality checklists (9). Study quality of non-comparative trials was assessed using the "Quality Appraisal Tool for Case Series" (10). Data of all included articles were extracted by one author and approved by another author. The reviewers utilized data extraction templates that were developed for the specific type of study. The following study characteristics and data were extracted: study design, intervention, and comparator if available, patient flow and characteristics, research period, sponsor, number of centers/countries, recruitment method, inclusion and exclusion criteria for patients, outcome measures like health-related QoL scores and conclusion.

Results

The systematic literature search yielded 304 citations (Medline n = 203 and Cochrane Library n = 99, study registry n = 2). Of these 292 were excluded during the first selection step considering title and abstract. Twelve studies were assessed in a second selection step by assessing the full text. After selection in full text one prospective, non-comparative study (11), one retrospective, non-comparative study (5), one study with a retrospective and prospective part (12), one non-randomized prospective multicenter, comparative study (13), and one multicenter, open, randomized controlled trial (RCT) (14;15) were included for final analysis (see Figure 1). The quality of the RCT was assessed as high with a low risk of bias, whereas the quality of the comparative non-randomized trial was assumed to be low with a high risk of bias. Due to the non-comparative study design the risk of bias was high for non-comparative studies. Study design, intervention, and comparator of all studies are presented in Table 1 in detail. Patient flow and patient characteristics are listed in Table 2 and study results are shown in Table 3. A detailed description of the performed quality assessment of all studies as well as further information about extracted data is given in the Supplemental Material.

The majority of study participants among the five included studies were male (range 73.5–84.2 percent of study population). Median or mean age was $\geq$ 58 years and baseline left ventricular ejection fraction (LVEF) < 35 or $\leq$ 35 percent in all studies. QoL was assessed in four included studies, but different assessment tools were used (EQ-5D-3L, SF-36, SF-12 Version 2, Kansas City Cardiomyopathy Questionnaire-12). Weiss et al. (13) additionally examined depressive and anxiety symptoms and Burch et al. (11) the sub-scores physical limitation, symptom frequency, and social limitation as part of the Kansas City Cardiomyopathy Questionnaire-12. In the latter study of Burch et al. (11) QoL Score at baseline was reported as poor to fair with 38.8 points in patients with newly diagnosed heart failure when assessed in-hospital (scale range is 1 to 100; lower scores represent more severe symptoms). Burch et al. (11) observed an improvement of QoL (one sub-scale of the Kansas City Cardiomyopathy Questionnaire-12) in 67.9 percent of patients between baseline and day 90 and in 82.8 percent of patients between baseline and day 180. All sub-scores of the Kansas City Cardiomyopathy Questionnaire-12 showed a statistically significant and clinically relevant improvement between baseline and day 90. A further statistically significant improvement between day 90 and 180 was observed for QoL only (11).

Lackermaier et al. (5) assessed QoL once retrospectively after wearing a WCD and by means of EQ-5D-3L and additional own questions concerning fear of shock, feeling safe, sleep disturbance and impairment of usual activities in patients with symptomatic heart failure and reduced LVEF. No impairment ranged from 57 to 83 percent of patients over the five domains of the EQ-5D-3L. Report of severe impairment was uncommon (mental health issues 0 percent, self-care 1 percent, daily routine 1 percent, mobility 2 percent, pain 5 percent of patients). Mild impairment was found in all domains, most often mental health impairments like depression or anxiety (43 percent), followed by pain and mobility impairment (31 and 30 percent) as subdomains of the EQ-5D. According to the study authors' own questions, 64 percent of patients felt adequately protected by the WCD but the study also reported negative issues due to WCD like fear of shock, sleep disturbance, and restriction in daily routine in 29, 48, and 48 percent of patients respectively (5). However, 31 of 109 patients wore the WCD after ICD-explantation, which may itself be associated with infections, fear, and pain, making it difficult specifically assigning QoL effects to the patient's condition or a WCD, respectively.

Weiss et al. (13) reported statistically significant decrease in percentage of patients with at least mild depressive or anxiety symptoms as well as a statistically significant decrease in scores for depressive or anxiety symptoms as shown in Table 3. Of 85 patients with a WCD 20 patients terminated WCD wearing early because of improved LVEF function or ICD-implantation and only two patients for own will (13). Within the patient group with

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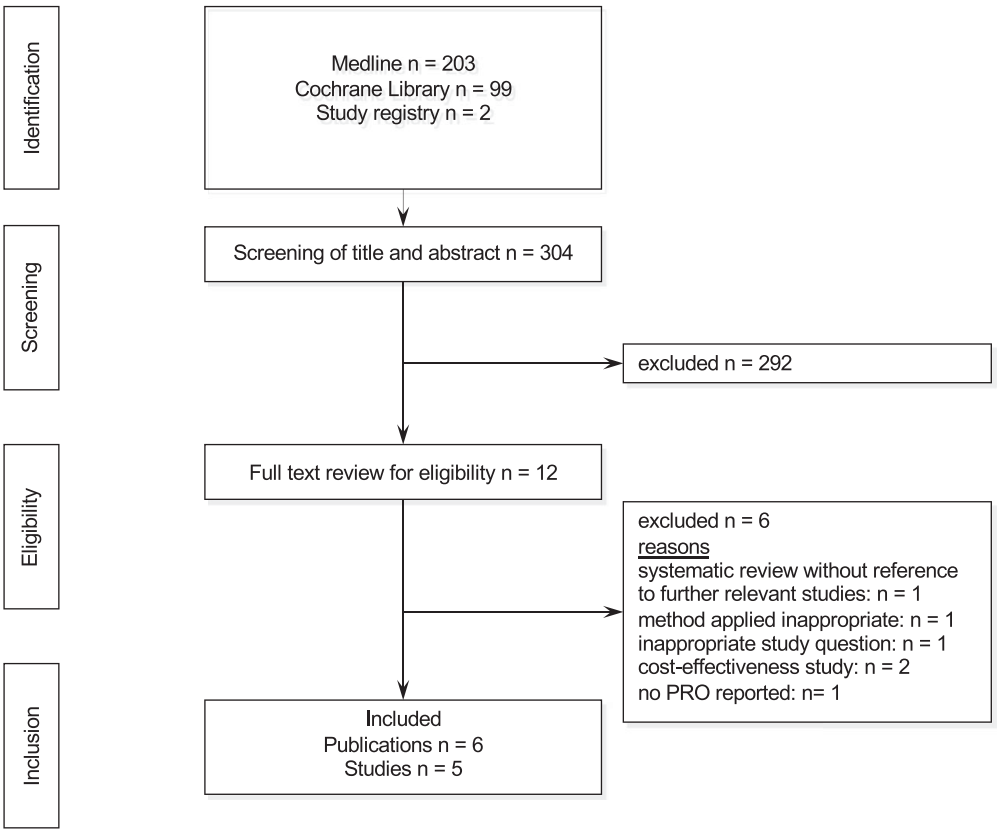

Figure 1. Flow chart of the selection process.

Table 1. Description of included studies: study design, intervention, and comparator

Author, Year	Study design	Intervention	Comparator
Burch et al., 2021[1]	Prospective, non-comparative study	WCD "LifeVest", Version: n.r. Wearing time: up to 180 days	n.r.
Garcia et al., 2021	Non-comparative study with prospective and retrospective parts	WCD "LifeVest", Version: n.r. Wearing time overall population: 62.0 (37-97) days	n.r.
Lackermaier et al., 2018	Retrospective, non-comparative study	WCD "LifeVest 4000" Wearing time: 56.2 ± 42.4 days	n.r.
Weiss et al., 2019	Prospective multicenter, comparative study, non-randomized	WCD, name/version not explicitly specified Decision for WCD was made by the treating physician based on his subjective risk-benefit judgement prior to discharge of the patient. Wearing time: 6 weeks	No WCD
VEST Trial, 2020[2]	Multicenter, open, randomized controlled trial	WCD "LifeVest" plus GDMT, for three months	GDMT alone for three months

Note: GDMT = Guideline-Directed Medical Therapy, n.r. = not relevant, WCD = wearable cardioverter defibrillator.
[1]Plus additional information from study registry (NCT03016754).
[2]Olgin et al. (15) and Cheung et al. (14).

WCD prescription a higher rate of patients had reported anxiety at baseline, before a decision concerning WCD prescription was made. Accordingly, a lower rate of patients reported anxiety at baseline in the group of patients without a WCD prescription (58.9 percent versus 29.2 percent, $p = 0.02$). The baseline state anxiety score however did not differ significantly between groups (Score (SD): 41 (13) versus 39 (13)); $p = 0.22$). Patients equipped with a WCD showed higher, but not statistically significant reduction in depression and anxiety scores (13).

The randomized controlled Vest Trial compared effectiveness and safety in patients after a myocardial infarction and an LVEF ≤35 percent with or without a WCD. Both groups received guideline-directed therapy. Results from the Vest Trial showed no significant differences between both groups in the assessed endpoints SF-36, EQ-5D, CES-D 10, and State-Trail Anxiety Inventory (14).

The WEARIT-France cohort study was the only trial that focused on WCD therapy acceptability rather than on QoL.

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Table 2. Description of included studies: patient flow and patient characteristics

Author, Year	Patient flow	Patient characteristics
Burch et al., 2021[1]	Baseline: 210 patients 90 days Follow-up: no information 180 days Follow-up: 134 patients	Mean age (SD): 58 years (13.6) Female: 26% (54 patients) Primary indication for WCD: nonischemic cardiomyopathy (54%) LVEF at baseline (% ± SD): 23 ± 6.9
Garcia et al., 2021	Baseline: 1157 patients Follow-up: n.r. Subsample of patients with questionnaire: $n = 202$	Mean age (SD): 60 years (12) Female: 16% (183 patients) Primary indication for WCD: ischemic cardiomyopathy (82.1%) LVEF at baseline (% ± SD): 27 ± 9
Lackermaier et al., 2018	Baseline: 109 patients Complete data on QoL: 87 patients Follow-up: n.r.	Mean age (SD): 58 (±16) years Female: 22% LVEF at baseline (% ± SD): 32±14
Weiss et al., 2019	Baseline: 123 patients (100%) WCD: 85 (69%) Comparator: 38 (31%)	Mean age (SD): 59 (±14) years Female: 25%
	Follow-up after 6 weeks: 97 patients (79%) WCD: 73 (86% of WCD patients) Comparator: 24 (63% of patients in comparator arm)	LVEF (% ± SD): Total population: 26 ± 8 WCD: 26 ± 8 Comparator: 25 ± 7
	Reasons for discontinuation: 2 patients lost to follow-up 6 patients deceased within 6 weeks 15 patients rejecting follow-up examination 3 patients with incomplete follow-up questionnaire data	
VEST Trial, 2020[2]	Baseline: 2.302 patients WCD plus GDMT: 1.524 (66%) GDMT only: 778 (34%)	Mean age WCD plus GDMT: 60.9 ± 12.6 years GDMT only: 61.4 ± 12.3 years
	Mean follow-up after 84.3 ± 15.6 days: 1.340 patients with completed health questionnaires WCD plus GDMT: 898 (59% of WCD patients) GDMT only: 442 (57% of GDMT only patients)	Female: 26.5% LVEF (% ± SD): WCD plus GDMT: 28.2 ± 6.1 GDMT only: 28.2 ± 5.8
	Loss to follow-up after 90 days: WCD plus GDMT: 10 participants (0.7%) GDMT only: 12 participants (1.5%)	

Note: GDMT = Guideline-Directed Medical Therapy, LVEF = left ventricular ejection fraction, n.r. = not reported, QoL = quality of life, SD = standard deviation, WCD = wearable cardioverter defibrillator
[1]Plus additional information from study registry (NCT03016754).
[2]Olgin et al. (15) and Cheung et al. (14).

Patients were asked for their agreements, assessed in a 5-point Likert agreement scale. Mostly agreed were the claims, "I follow lifestyle modification recommendations from my physician" (>90 percent) and "Wearing the LifeVest makes me take my condition seriously" (>85 percent), followed by "I would recommend LifeVest to family or friends with a similar medical condition" (80 percent). Mostly disagreed was, "I sleep significantly better, knowing I am protected by the LifeVest" (ca. 20 percent), followed by "LifeVest has given me the confidence to perform exercise and or cardiac rehabilitation (ca. 10 percent) (12).

Discussion

In our previously published health technology assessment, we stated that QoL during WCD usage has not been investigated sufficiently (7). Since then, further study results concerning PRO have been published that justify the conduction of this systematic review.

The results of the comprehensive literature search revealed a limited number of trials. The Vest Trial provides results of high quality of evidence. Due to the design of an RCT of high quality, it assures comparability of patient characteristics in both groups. Even though the results on QoL are presented as a poster presentation (14) further information from an additional publication (15) can be used to judge the overall study quality. One limitation of the Vest Trial is the missing information concerning improvement or deterioration of PRO between baseline and follow-up within groups. The study by Weiss et al. (13) used a comparative study design but did not randomize study participants. The authors hypothesized that psychological distress is high in acute high-risk cardiac patients eligible for a WCD and is associated with low QoL. They furthermore assumed that distress is aggravated by a WCD. Patients were recruited consecutively to the Colone Registry of External Defibrillator in case of an indication for a WCD. It was up to the decision of the treating physician if a WCD was prescribed. This led to a imbalance in group size (WCD: $n = 85$ versus no WCD: $n = 38$) and potential bias in study results. At baseline, patients with a later prescription of a WCD reported higher scores for depression and anxiety symptoms compared to patients without WCD prescription. In both groups improvement in symptoms was observed. The authors conclude that a WCD clearly is not associated with an increase of anxiety or depression. Forty-three percent of study participants in the trial of Lackermaier et al. (5) report mild mental health impairment. Because of the lack of a comparator arm, it is uncertain if the high rate of mild mental health impairment is caused by the disease or by using the WCD. This is especially true for

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Table 3. Results of included studies

Author, Year	Results
Burch et al., 2021[1]	*Baseline* Patient-reported QoL (SD) measured by Kansas City Cardiomyopathy Questionnaire-12 (questionnaire completed in-hospital vs. after discharge), 38.8 (28.8) and 35.8 (22.8), respectively; $p = 0.434$
	Day 90 and 180 Subscale scores: physical limitation, symptom frequency, QoL and social limitation: significant improvement baseline to day 90 in all subscores (all *p*-values <0.001) Subscore QoL improvement day 90 to day 180 ($p < 0.001$)
	QoL development: Day 90: 67.9% ($n = 91$) patients improved Day 180: 82.8% ($n = 111$) patients reported an improvement, 3.7% ($n = 5$) reported a net decrease, 13.4% ($n = 18$) had no net change
Garcia et al., 2021	Results of the questionnaire are solely shown in a figure of the publication. Thus, the reported percentages are inprecise. Percentages are the sum of answers "strongly agree" and "agree". The LifeVest gives me peace of mind: 77% I don't worry as much because I know the LifeVest is protecting me: 69% I sleep significantly better knowing I am protected by the LifeVest: 52% I feel more confident returning to my normal daily activities when wearing the LifeVest: 70% LifeVest has given me the confidence to perform exercise or cardiac rehabilitation: 49% Wearing the LifeVest makes me take my condition seriously: 88% I take significantly better care of myself since being prescribed the LifeVest: 65% I follow lifestyle modification recommendations from my physician: 92% I would recommend LifeVest to family or friends with a similar medical condition: 80%
Lackermaier et al., 2018	Results of QoL measured by the 5 different items of EQ-5D-3L:
	Mobility impairment Severe: 2%; mild: 30%; none: 68%
	Self-care impairment Severe: 1%; mild: 16%; none: 83%
	Daily routine impairment Severe: 1%; mild: 24%; none: 75%
	Mental health impairment Severe: 0%; mild: 43%; none: 57%
	Pain Severe: 5%; mild: 31%; none: 64%
	Average QoL on a visual analogue scale: 70/100 point
Weiss et al., 2019	***Depression (BDI Score)***
	Baseline: Patients with at least mild depressive symptoms: 21% mean BDI score (SD): 10 (± 5)
	6 weeks: Patients with at least mild depressive symptoms: 7%; compared to baseline: 21% vs. 7% (p=0.004) mean BDI score (SD): 6 (± 6); compared to baseline: 10 vs. 6 (p<0.001)
	Between groups: WCD vs. without WCD: mean change (SD): -4.1 (±6.1) vs -1.8 (±3.9); p = 0.09
	Anxiety (State Anxiety Score)
	Baseline: Patients with anxiety symptoms: 52% mean state anxiety score (SD): 41 (±12) 17% of patients showed concomitant depressive and anxiety symptoms
	6 weeks: Patients with clinically significant anxiousness: 25%, compared to baseline: 52% vs. 25% ($p < 0.001$) Mean anxiety score (SD): 36 (± 10); compared to baseline: 41 vs. 36 ($p < 0.001$)
	Between groups: WCD vs. without WCD: mean change (SD): −4.6 (9.5) vs −3.7 (9.1), $p = 0.68$
	QoL (SF-12, Version 2, german): Results have not been reported
VEST Trial, 2020[2]	***QoL (SF-36) – physical component score (score ± SD)*** WCD plus GDMT: 40.2 ± 10.8 GDMT only: 40.9 ± 10.7 ***QoL (SF-36) – mental component score (score ± SD)*** WCD plus GDMT: 45.6 ± 13.6 GDMT only: 45.8 ± 13.5 ***QoL (EQ-5D) (score (%))*** *Poor mobility* WCD plus GDMT: 259 (38.8) GDMT only: 127 (39.4) *Poor self-care* WCD plus GDMT: 71 (10.7) GDMT only: 37 (11.4) *Problems with usual activities* WCD plus GDMT: 356 (53.4) GDMT only: 163 (50.3) *Pain / discomfort* WCD plus GDMT: 335 (50.2) GDMT only: 175 (54.0) *Anxiety / depression* WCD plus GDMT: 272 (40.8) GDMT only: 123 (40.0) *Health scale (self-reported out of 100)* WCD plus GDMT (SD): 65.0 ± 22.3 GDMT only (SD): 66.1 ± 21.9 *Depression (CES-D 10 score)* WCD plus GDMT (SD): 7.73 ± 6.42 GDMT only (SD): 7.49 ± 6.58 *Anxiety (State-Trait Anxiety Inventory Score)* WCD plus GDMT (SD): 37.3 ± 12.9 GDMT only (SD): 36.9 ± 13.1

Note: BDI = becks depression inventory; GDMT = Guideline-Directed Medical Therapy; QoL = quality of life; SD = standard deviation; WCD = wearable cardioverter defibrillator.
[1]Plus additional information from study registry (NCT03016754).
[2]Olgin et al. (15) and Cheung et al. (14).

the 28.4 percent (31/109) of patients that had previously undergone ICD-explantation. In their single-arm study, Burch et al. report a statistically significant improvement in all domains of the Kansas City Cardiomyopathy Questionnaire between baseline and day 90. Due to the study design, no group comparison was applicable.

For the assessment of PRO adequate and validated assessment tools were used in the included studies. The additional own questions of Lackermaier et al. (5) do not represent a validated assessment tool and statements based on these questions should therefore be interpreted with care due to potential bias.

Two statements of the questionnaire applied in the study of Garcia et al. (12) can be used for a comparison to the results of the study of Lackermaier et al. (5). About 68 percent of patients with WCD report not worrying as much because they know that the

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WCD is protecting them (12). This is in line with 64 percent of patients feeling safe in the study of Lackermaier et al. (5). In contrast, only about 20 percent of patients disagree with the statement that they sleep significantly better (12), compared to 48 percent of patients with sleep disturbances as reported in the study of Lackermaier et al. (5).

We excluded one Health Technology Assessment that reported the results of a focus-group interview assessing the patient´s perspective (16). Methodological recommendations suggest the assessment of PRO by asking affected patients directly (8). However, interviewed persons had no experiences with using the WCD or knowledge about the WCD (16). Therefore, we estimate the results of the focus group interview as not appropriate for an evaluation of PRO.

Our literature search was limited to the electronic databases Medline and Cochrane Library and the recall (sensitivity) of this literature search might be limited. But as the search in the Cochrane Library was not limited to Cochrane reviews solely, information about clinical trials listed in Embase was screened, too. The search in a study registry (clinicaltrials.gov) revealed two registry entries of trials that assess PRO as secondary endpoints (12;17). The publication of Garcia et al. (12) was included into this systematic review. The study of the second registry entry (NCT01326624) was published but without reporting data concerning QoL (17).

No Information specialist or medical librarian was involved in the development of the literature search. Further, we did not use recognized search filters. Potential impact might be an inadequate search strategy and missed studies.

Due to the limited number of studies, the generalization of the results of this review might be limited.

Conclusion

While patients eligible for a WCD seem to have an impaired QoL, the present evidence supports the conclusion that the usage of a WCD does not negatively affect patients regarding QoL or depression or anxiety. Furthermore, we found evidence that PRO might improve during WCD use.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/S0266462322003300.

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