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STATE OF THE ART REVIEW

A review on wearable cardioverter-defibrillators in clinical practice for sudden cardiac death prevention and heart failure management

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Abstract

Sudden cardiac death (SCD) remains a predominant mode of death in cardiovascular mortality. Despite advancements in guideline-recommended medical therapy and risk stratification, accurately identifying patients who would benefit most from implantable cardioverter-defibrillator (ICD) therapy over the long term remains a significant challenge. The wearable cardioverter-defibrillator (WCD) has emerged as a non-invasive bridge to either ICD implantation or recovery of left ventricular function.

This expert review presents a comprehensive and up-to-date summary of clinical evidence on WCD use for SCD prevention and heart failure (HF) management. Specifically, it will address: (i) the concept and mechanism of the WCD; (ii) evidence from randomized and observational studies regarding efficacy, safety, and cost-effectiveness; (iii) integration of the WCD into HF management; and (iv) knowledge gaps and priorities for future research.

Keywords Sudden cardiac death • Implantable cardioverter-defibrillator • ICD • Wearable cardioverter-defibrillator

Introduction

Sudden cardiac death (SCD) is a leading mode of death and contributes to a substantial proportion of all-cause deaths in the general population.[1,2] Each year, the European Union is estimated to experience at least 249 538 cases of SCD and 343 496 out-of-hospital cardiac arrests,[3] extrapolating to 4–5 million SCD cases globally on an annual basis. When appropriately selected, implantable cardioverter-defibrillator (ICD) therapy can significantly reduce the incidence of sudden arrhythmic death. However, patient selection for ICD therapy remains one of the main challenges,[4] as some individuals at risk of SCD remain unidentified, while others receiving an ICD never experience appropriate shocks[5] or experience inappropriate shocks only.

In patients with a history of myocardial infarction, left ventricular ejection fraction (LVEF) alone has demonstrated poor performance for SCD prediction. Even investigating numerous additional predictors has failed to significantly improve risk stratification.[6] Consequently, while LVEF remains the best predictor available, it is still a suboptimal metric.[7] In addition, LVEF is not a static parameter and likewise SCD risk can be temporarily increased.

Sudden cardiac death is responsible for 35–64% of all-cause mortality in patients with heart failure.[1–3,8–10] Early optimization of heart failure (HF) therapy is crucial to improve left ventricular function.[11,12] Over the past decade, the management of newly diagnosed heart failure has evolved significantly adopting an integrated approach that combines guideline-recommended medical therapy (GRMT), patient education, close follow-up, and the selective use of device-based interventions. Among emerging technologies aimed at reducing the risk of SCD in this vulnerable population, the wearable cardioverter-defibrillator (WCD) has gained increasing attention[13] as potential bridge to definitive therapy (*Figure 1*).[14]

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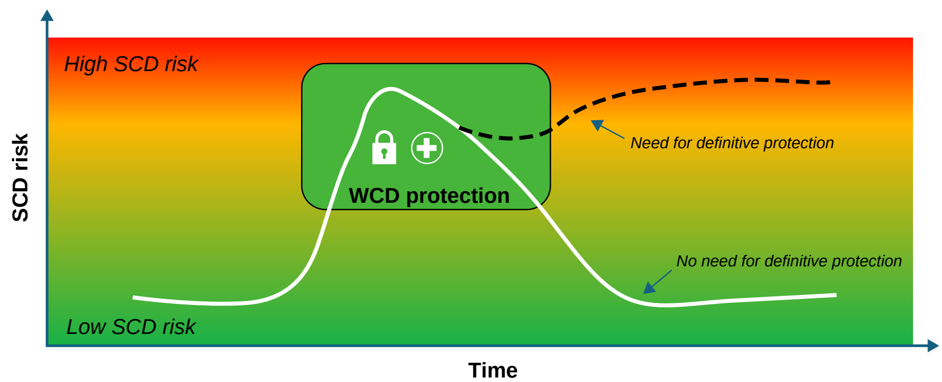

Figure 1 Temporary protection for SCD.

This expert review focuses on temporary protection against SCD through the use of a WCD during vulnerable period in clinical practice.

Wearable cardioverter-defibrillator concept

The ICD, whether transvenous or subcutaneous/extravascular, is currently the gold standard for managing patients with persistent high risk of SCD due to structural or electrical heart diseases.[15,16] However, certain clinical scenarios involve a potentially transient elevation in SCD risk, such as acute myocarditis, peripartum cardiomyopathy, HF, or myocardial infarction with reduced LVEF. Additionally, some patients may require temporary protection after ICD explantation due to infection. In these cases, a WCD may serve as a non-invasive, interim solution to prevent SCD until a permanent decision on ICD implantation can be made or the patient's condition improves to the point where protection is no longer necessary.[15,17,18]

The LifeVest (Zoll, Pittsburgh, PA) is the most widely available WCD system, approved for use in both Europe and USA. It has been the focus of several pivotal studies evaluating WCD efficacy and safety, including the Vest Prevention of Early Sudden Death (VEST) trial and large registries.[19–24] The WCD continuously monitors the patient's heart rhythm for malignant ventricular arrhythmias, such as ventricular tachycardia or fibrillation (VT/VF) and to deliver life-saving external defibrillation when necessary. The device consists of two primary components: a belt with electrodes integrated into a material vest, which is worn on the chest (available in five different sizes to cover all chest diameters between 66 and 142 cm), and a monitor that is either attached around the waist or carried on a shoulder strap. The monitor features a touchscreen, two response buttons, and a speaker for alerts and voice prompts (*Figure 2*). The WCD is programmed to detect arrhythmias within pre-set thresholds, typically between 120 and 250 beats per minute, and allows for customization of VT and VF detection zones. Default thresholds are set at 150 beats per minute for VT and 200 beats per minute for VF, with response times adjustable between 25 and 180 s, giving patients time to respond to alerts. The WCD can deliver up to five electrical shocks per episode, with shock energy programmable within a range of 75–150 J (default 150 J). The defibrillation waveform is automatically optimized to ensure precise energy delivery regardless of body impedance. For enhanced comfort, the device's electrodes remain dry and non-adhesive when inactive, while a special gel is released immediately before shock delivery to maximize therapeutic efficacy. To minimize inappropriate and unnecessary shocks, the device allows patients to delay treatment by pressing two response buttons if they are conscious and able to tolerate the arrhythmia. If the patient does not respond within the programmed response time, the WCD proceeds to deliver the shock after issuing additional alerts to the patient and nearby individuals. The entire detection-to-treatment cycle is typically completed in under 1 min. Collected data, including ECG recordings, heart rate trends, physical activity, and usage statistics, are transmitted to a secure remote patient management system. This telemonitoring platform enables healthcare providers to remotely access critical information to optimize patient management.

In addition to the LifeVest, there are two other WCD systems emerging. The ASSURE® wearable cardioverter-defibrillator system (Kestra Medical Technologies, Kirkland, WA) has been approved for use in USA by the Food and Drug Administration in 2024. [www.accessdata.fda.gov/cdrh_docs/pdf20/P200037C.pdf] The system seems to be user-friendly and effective in differentiating between true VF/VT and other non-treatable episodes.[25] Unlike the LifeVest and ASSURE, the Jewel device (Element Science, San Francisco, CA) relies on two disposable adhesive and waterproof electrode patches. It provides algorithms that decrease shock alarms with a machine learning algorithm and form fitting for females. A first human safety and effectiveness study on the Jewel patch-WCD was published in 2024.[26] In this initial study, the successful conversion rate of the first defibrillation was 89%. These data were supplemented by a clinical evaluation of 305 patients wearing the device for a median of 49 days [Q1–Q3: 23–90 days]; the median daily wear time was 23.5 h [Q1–Q3: 20.7–23.9 h/day].[27] Nine patients (3%) received 11 shocks including two inappropriate discharges.

Clinical evidence

Protection by a WCD can be beneficial in a multitude of situations with a transiently high risk of SCD. Overall, there is abundant literature on the WCD, showing consistent results in terms of safety and efficacy. European Society of Cardiology (ESC) guideline recommendations for WCD use are summarized in *Table 1*.

Efficacy of the wearable cardioverter-defibrillator

The most important task of WCD is to prevent SCD by adequately identifying sustained ventricular arrhythmia and terminating this arrhythmia via appropriate shocks.

Since its approval, WCD has been evaluated through one randomized controlled trial (VEST trial) and numerous prospective and retrospective observational studies. These studies targeted specific populations, such as patients with post-myocardial infarction LVEF $\leq$ 35%, as well as mixed populations. Several systematic reviews have

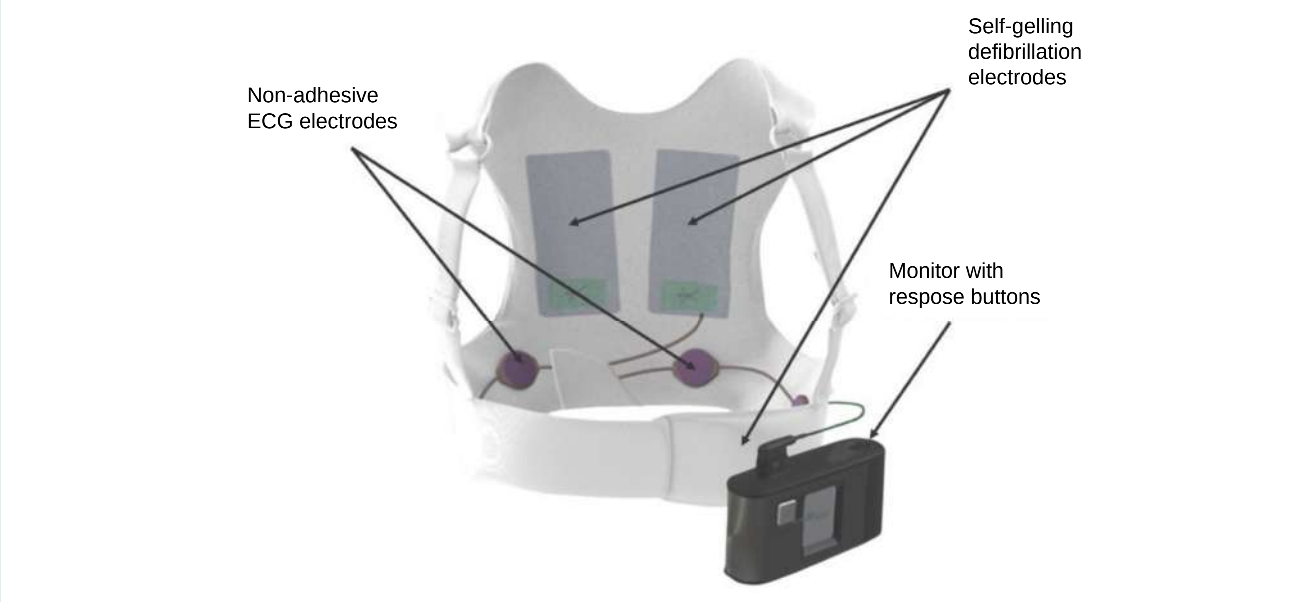

Figure 2 Explanatory figure of the LifeVest WCD (with permission).

Table 1 European guideline recommendations for indications of the WCD

Guideline	Recommendation	Class of recommendation	Level of evidence
2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure[11]	A wearable ICD may be considered for patients with HF who are at risk of SCD for a limited period or as a bridge to an implanted device.	IIb	B
2022 ESC guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death[15]	The WCD should be considered for adult patients with a secondary prevention ICD indication, who are temporarily not candidates for ICD implantation.	IIa	C
	The WCD may be considered in the early phase after MI in selected patients.	IIb	B
2023 ESC guidelines for the management of cardiomyopathies[28]	The WCD should be considered for adult patients with a secondary prevention ICD indication who are temporarily not candidates for ICD implantation.	IIa	C

summarized the available evidence on WCD. However, the inclusion and exclusion criteria used across these reviews vary, leading to differences in the number of studies included.[29–33]

Appropriate shocks and rate of successful shocks

In the VEST trial, appropriate shocks occurred in 1.3% of patients with LVEF $\leq$ 35% post-MI (20 of 1524 patients).[24]

In the three key registries, WEARIT-II registry (prospective, 2000 patients, USA), the German registry (retrospective, 6043 patients, Germany), and the WEARIT-France cohort study (prospective, 1157 patients, France), appropriate shock occurred in 3.25%, 1.56%, and 1.56% of patients, respectively, with a median WCD wear duration of 90 days, 59 days, and 62 days.[19,21,34] Across all prospective registries, the range of appropriate shocks during WCD wear time was 1.1–8.3%.[29]

Successful shock ranges from 94% (German registry) to 100% (WEARIT-II registry, WEARIT-France cohort study). In the WEARIT-II registry, all patients who required shock delivery had their VT/VF episodes successfully terminated with the first shock.[19] In the WEARIT-France cohort study, only one patient (5%) required two shocks to terminate the arrhythmia episode.[21] The number of shocks is not specified in the German registry.[34] Regarding patch-WCD, eight of the nine shocks were successful with a single shock.[27]

Mortality

In the VEST trial, all-cause mortality at 3 months was 3.1%, including arrhythmic mortality of ~1.6% in the WCD group (4.9%; $P = 0.04$ and 2.4%; $P = 0.18$ in the control group, respectively).[24] A meta-analysis estimated that mortality while wearing WCD was 0.7% over 3 months (95% CI: 0.3–1.7).[32]

It is important to emphasize that the arrhythmic mortality rate is very low, ranging from 0 to 1%,[30] and that in the VEST trial, most arrhythmic deaths in the WCD group occurred while patients were not wearing the WCD (=16 patients out of the 25 SCD in the WCD group). In prospective observational studies, all-cause mortality in patients with WCD was between 0 and 5.2%. In the WEARIT-II registry, three out of 2000 (0.2%) patients died. All three patients had an asystole event.[19] In the WEARIT-France cohort study, 24 of 1157 (2.1%) patients died.[21] Among these patients, in nine who wore the WCD at the time of death, non-arrhythmic death was the cause of death in seven and electrical storm in two. In this context, it is important to note that while the majority of shocks delivered by a WCD can be effective, electromechanical dissociation can still occur in the aftermath of the shock, and the patient death cannot be avoided by the system.[33]

Quality of life and impact on perceived health status

Wearable cardioverter-defibrillator is considered a non-invasive therapy with potential lifestyle benefits. Nevertheless, wearing a WCD might be uncomfortable owing to physical strain, alarms, and battery handling.[35] Therefore, quality of life has been assessed in several studies. While wearing the WCD, severe impairment was rarely mentioned, and most often, mild impairment of mobility, daily routine, mental health, and sleep were noted.[36] In the WEARIT-France cohort study, the use of WCD was generally positively associated with health and lifestyle benefits.[21] The two main patient perceptions were the following: 'Wearing the LifeVest makes me take my condition seriously' and 'I follow lifestyle modification recommendations from my physician'. It translates additional benefits of the WCD beyond the simple function of a 'shock box'. This is potentiated by the education session delivered to the patient, which encompasses the nature of the disease, indication, and functioning of the WCD. Furthermore, an improvement in the QoL dimensions of pain, mental health, and restrictions in daily routine was shown in patients who received a standardized training and adherence surveillance programme.[36]

Unlike an ICD, the WCD empowers patients to take an active role in their own care by allowing them to respond to alerts and either activate or deactivate the device as necessary. This unique feature not only enhances safety by reducing inappropriate and unnecessary shocks but also underscores the importance of patient engagement in their treatment.[21]

Inappropriate shocks

Although its discrimination is based on a surface ECG, the WCD offers a high level of safety because of the possibility for the patient to abort shock delivery in case of consciousness, avoiding inappropriate shocks. According to the Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy (PRAETORIAN) trial, inappropriate shocks with transvenous or subcutaneous ICD occurred in 2.5% of participants after 3 months of follow-up.[37] In comparison, in the VEST trial, 0.6% of patients with WCD received inappropriate shock after 3 months.[24] Nevertheless, the rate of inappropriate shocks in observational studies was between 0 and 4.3%[29] and was estimated to be 2% according to a pooled analysis.[32]

The Jewel IDE study reported two inappropriate shocks out of 11 shocks.[27]

Other adverse events

Further itching and rash were reported in patients with the WCD.[24,38] False alarms are frequent. A total of 369 alarms occurred in the WEARIT-France cohort study. Among them, 11% were related to ventricular arrhythmias, 82% to artefacts, and 7% to atrial or supraventricular arrhythmias.[21] The rate of false alarms was also assessed in the Swiss WCD registry.[39] Approximately 72% of the registered alarms were clinically irrelevant, and a higher rate of alarms did not lead to a higher rate of WCD discontinuation.

Regarding the patch-WCD, 31.5% reported rash, 4.3% reported skin injury, and 7.5% reported discomfort.[27]

Compliance

Wearing the WCD almost continuously is cornerstone to guarantee protection against SCD by the device.[40] Nevertheless, the reported compliance was lowest in the VEST trial, with a median wear time of 18 h per day.[24] This contrasts with the higher median wear time reported in observational or register studies, ranging from 20 to 23.5 h per day.[31] Due to the controlled study setting, no follow-up training, remote monitoring of wearing time, or contacting patients to improve wearing time was allowed, which can explain the short wearing time in the VEST trial. Compliance can be improved by a standardized training and adherence surveillance programme, as shown in a study by Kellnar *et al.*[36] in 2023, in which a cohort of patients with a prescription for a WCD was trained by a standardized WCD training programme and compared with a historical cohort.

Specific aetiology

Patients with specific considerations, which are less common than ischaemic cardiomyopathy but often affect younger individuals, may benefit from WCD to protect against potential SCD during the optimization of drug therapy.[41] These conditions include non-ischaemic dilated cardiomyopathy, myocarditis, peripartum cardiomyopathy, and congenital heart disease.

For **non-ischaemic dilated cardiomyopathy** with LVEF ≤ 35%, the incidence of ventricular arrhythmias ranged from 1 to 2.4% during the first 3 months of follow-up in the WEARIT-II and WEARIT-II European registries.[19,20] The 2023 ESC guidelines for the management of cardiomyopathies specifically provide a Class IIa recommendation for use in adults with a secondary prevention ICD indication, who are temporarily ineligible for ICD implantation.[28]

Myocarditis, a condition often affecting younger individuals, represents a transient high-risk period for ventricular arrhythmia during the acute phase, during which WCD use may offer protection. The rate of cardiac arrhythmia in patients with myocarditis is in the range from to 5 to 10%.[42] In a registry published in 2023, 2.4% of patients with myocarditis and reduced ejection fraction experienced appropriate WCD shock.[43]

Women with **peripartum cardiomyopathy** are at significant risk of sudden cardiac arrest in the early months after diagnosis.[44] A recent analysis of patients diagnosed with peripartum cardiomyopathy revealed ventricular tachycardia in 4.2%, ventricular fibrillation in 1%, and cardiac arrest in 2.2%.[45] In a multicentre German registry, 12% of the patients presented with ventricular tachyarrhythmias during the WCD period.[46]

Patients with **congenital or inherited heart disease** may also benefit from the WCD. In the WEARIT-II registry, the rate of ventricular arrhythmias was 3% at 3 months of follow-up.[19]

Randomized trial

One must be cautious regarding bias in reporting evidence with regard to WCD.[47] To date, only one randomized controlled trial has been conducted and published, leaving a gap in robust evidence. Furthermore, a multitude of observational studies involving heterogeneous populations exist.

The VEST trial examined the effectiveness of WCD in reducing SCD and overall mortality in patients with left ventricular dysfunction following myocardial infarction.[24] The trial included 2302 patients who were randomized to receive either WCD plus optimal medical therapy or optimal medical therapy alone with a follow-up period of 90 days.

The primary outcome, a composite of SCD and death due to ventricular tachyarrhythmia, did not show a statistically significant

Table 2 Relative risk for mortality in intention-to-treat, as-treated, and per-protocol analyses

	Arrhythmic mortality	All-cause mortality
Intention-to-treat analysis	RR 0.67 (95% CI: 0.37–1.21), $P = 0.18$	RR 0.64 (95% CI: 0.43–0.98), $P = 0.04$
As-treated	RR 0.43 (95% CI: 0.21–0.91), $P = 0.03$	RR 0.26 (95% CI: 0.14–0.48), $P < 0.001$
Per-protocol	RR 0.38 (95% CI: 0.17–0.86), $P = 0.02$	RR 0.25 (95% CI: 0.13–0.48), $P < 0.001$

reduction in the WCD group compared with the control group (1.6% vs. 2.4%; $P = 0.18$). It was hypothesized that this may be due to a lack of power and low compliance. Nevertheless, there was a significant reduction in all-cause mortality in the WCD group (3.1% vs. 4.9%; $P = 0.04$), suggesting that while WCD may not significantly lower the risk of SCD, it may contribute to overall survival benefits. The reasons for this effect are not fully clear, but may involve earlier medical intervention, stronger awareness for the disease, and a behavioral 'sentinel effect', which means that wearing a visible medical device can remind patients and relatives to adhere to guideline-directed therapy, fluid restriction, and other regimens such as cardiac rehabilitation.

In terms of compliance, patients in the WCD group wore the device for an average of 14.1 h per day. The device delivered appropriate shocks in 1.4% of cases and inappropriate shocks in 0.6% of cases.

The findings highlight that while the WCD did not significantly reduce the rate of SCD, it did contribute to a reduction in overall mortality.

Following the completion of the trial, the influence of compliance on the results was examined, leading to an additional analysis.[48] An 'as-treated' analysis revealed a relative risk of 0.43 for arrhythmic death (95% CI: 0.21–0.91, uncorrected $P = 0.03$, Bonferroni corrected $P = 0.32$) and 0.26 for the endpoint death of any cause (95% CI: 0.14–0.48; $P < 0.001$). Per-protocol analysis demonstrated a benefit of the WCD in reducing arrhythmic death (RR = 0.38; 95% CI: 0.17–0.86; $P = 0.02$) and death from any cause (RR = 0.25; 95%CI: 0.13–0.48; $P < 0.001$), *Table 2*.[24,48]

These additional analyses suggest that the effectiveness of the WCD is closely related to patient compliance.

In the VEST trial, 20 of 1524 (1.3%) patients received appropriate shocks delivered by the WCD, and all shocks successfully terminated ventricular arrhythmias. This demonstrates that when the WCD is worn, it reliably detects ventricular arrhythmias and terminates them successfully.[24,48]

These findings highlight the importance of considering both the statistical outcomes and practical clinical benefits when evaluating medical devices.

Cost-effectiveness

To date, cost-effectiveness studies have been conducted on the use of the WCD either in patients post-myocardial infarction or in patients after ICD explantation.

A Markov model compared the WCD with standard of care in patients with myocardial infarction with an LVEF ≤ 35% from the Italian National Health System perspective.[49] Standard of care was defined as discharge from hospital with medical therapy only. Effectiveness data from the VEST trial were used for the calculations. The costs per live year saved was estimated at 38.276 Euro and costs per quality adjusted life year (QALY) gained at 47.709 Euro.[49]

One additional US study evaluated the cost-effectiveness of WCD in post-MI patients. Medicare Claims Data were used in the study by Clark *et al.*[50] to assess incremental cost-effectiveness ratio (ICER) in hospitalized patients after myocardial infarction. The 1-year ICER for patients with WCD was calculated to be 12.373 USD per life-year gained.

In patients undergoing ICD explantation, a cost-minimization analysis using a Markov model evaluated the WCD compared to the standard care, defined as in-hospital stays until ICD implantation, from the Italian National Health System perspective.[51] The base case scenario indicated a cost reduction of 1.782 Euro (range 0–3.500 Euro in sensitivity analyses) per patient using the WCD.

Healy and Carrillo examined the cost-effectiveness of the WCD in patients waiting for ICD reimplantation after ICD removal. Patients discharged to home with a WCD were compared to patients discharged home with no protection, discharged to a skilled nursing facility, or inpatient monitoring.[52] Compared to discharge home with no protection, the incremental cost-effectiveness of the WCD was 20 300 USD per life-year gained or 26 436 USD per QALY. Comparing the WCD to discharge to a skilled nursing facility or inpatient monitoring demonstrated better outcomes of the WCD at lower costs.[52]

In summary, the WCD appears to be a cost-effective treatment option in selected high-risk patients, including those post-MI and, perhaps even more so, those with device explantation awaiting ICD reimplantation.

Usage in different European countries

The WCD has been in clinical use in several countries across Europe since 2001. While WCD adoption is rising, there are European regions where the WCD is not available yet. This includes Denmark, Norway, Finland, Portugal, the Czech Republic, and Hungary, among others. The availability of WCD in Europe is currently variable depending on national regulatory policies (*Figure 3*). As with any medical technology, adoption rates vary between regions, particularly for therapies with a predominantly ESC IIb recommendation, such as the WCD.[11]

The WCD was first introduced in Germany, where its utilization has grown significantly. France has the second-highest adoption rate, with over >15% of post-MI and ischaemic HF patients utilizing the therapy (non-ischaemic HF is not reimbursed in France).

Consistent adoption is also reported in Switzerland, Austria, and Italy. However, in countries such as the Netherlands, Spain, Poland, and the UK, the WCD is considered an emerging therapy. In many countries, the lack of comprehensive reimbursement systems creates financial barriers that limit the widespread adoption of the WCD. In countries such as Italy and Spain, adoption rates vary significantly between autonomous regions due to differences in healthcare policies. Despite these challenges, the WCD has seen a consistent growth across Europe, with an annual prescription rates increasing by more than 20% over the past 5 years. Therapy adoption in different countries is influenced by several variables such as reimbursement, national and international guidelines, inpatient–outpatient resources, responsible disciplines, availability of services, and more.

Reimbursement

Reimbursement plays a critical role in therapy adoption. In countries such as Germany, Switzerland, and the Netherlands, ESC indications

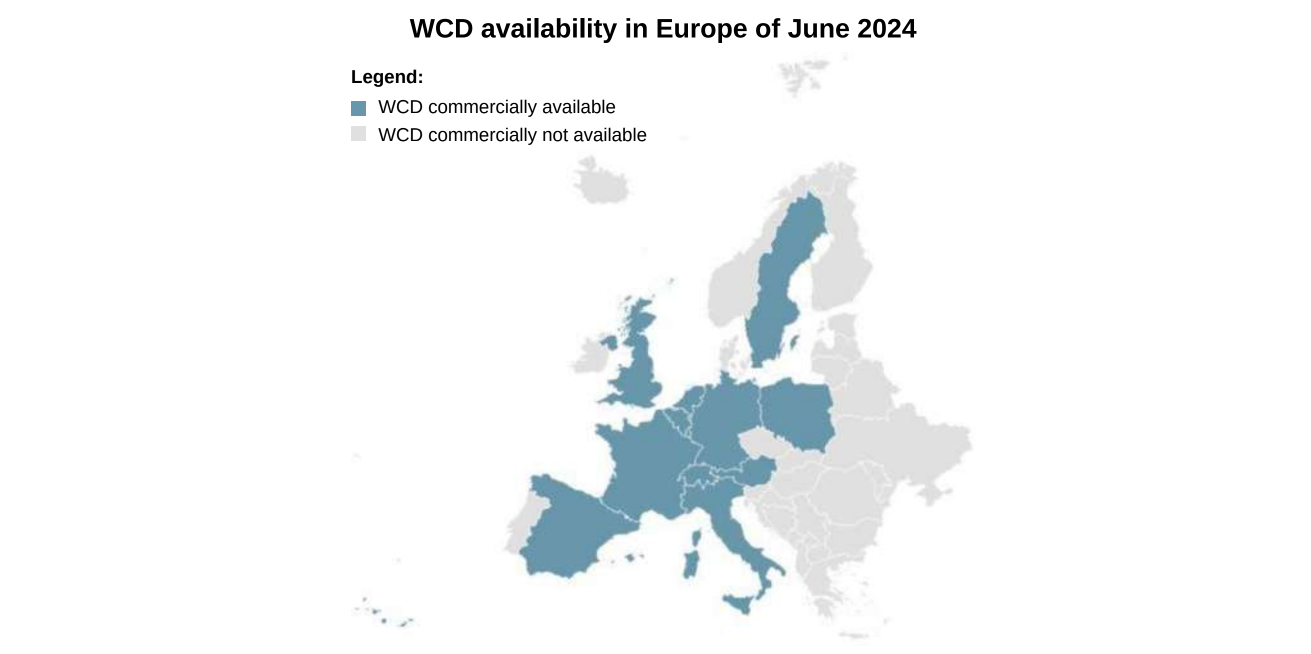

Figure 3 WCD availability in Europe (June 2024).

for WCD can be fully reimbursed by the national health systems. Other countries, such as France, currently reimburse only certain ESC indications, such as post-MI, ischaemic HF, ICD explant, ICD delay, and waiting for heart transplant. Other indications are still pending approval.

In countries where reimbursement is not yet comprehensive, such as Italy and Poland, therapy adoption has grown steadily, supported by ongoing efforts at the national and regional levels to secure funding.[53]

Detailed health economic models have been developed to justify WCD reimbursement across several European geographies. Health economic models of WCD utility were developed for reimbursement, with several being publicly available[49,51] demonstrating cost-effectiveness or even cost-savings for the respective healthcare system. Additionally, shorter hospital stays associated with WCD use represent another significant economic advantage. A 2023 study by Cardelli et al.[54] highlighted this benefit, further supporting the economic value of the WCD.

National and international guidelines

National and international clinical guidelines play a crucial role in raising awareness, improving understanding, and influencing the adoption of medical therapies, including the WCD. The ESC guidelines, widely regarded as the standard of care across Europe, have significantly impacted clinical practice in the region.[11,15] An international consensus document by the European Heart Rhythm Association (EHRA), aligned with the ESC guidelines, also highlights the use of the WCD for treatment of ventricular arrhythmias.[55]

In countries where the WCD is an established tool, additional guidelines or position papers exist. The Italian WCD position paper published in 2023 is a good example of such a document, covering clinical information and practical tools for patient screening and risk stratification[56] while still being aligned with the international ESC guidelines.

Several countries have developed their own position papers to complement the ESC guidelines. These national documents often provide more specific recommendations tailored to local healthcare systems, addressing topics such as patient compliance, reimbursement, and clinical indications. Notably, countries with extensive experience using the WCD frequently advocate for its application in broader clinical scenarios than those outlined in international guidelines.

Further national guidelines include the German Cardiac Society (DGK) position paper from 2019,[57] the position paper of the German Society for Thoracic and Cardiovascular Surgery (DGTHG),[58] the Polish Cardiac Society's position paper,[59] and the consensus document of the Spanish SEC-working group on myocarditis.[60]

Here more specific recommendations for different indications are given, as well as information on patient compliance and reimbursement. The DGK position paper, for instance, suggests considering WCD use in some paediatric patients a recommendation not covered by ESC guidelines and currently approved only by the US FDA. This remains an off-label use in Europe but highlights the potential for more flexible and innovative applications in certain countries.[57]

Other factors

The recent focused update to the ESC Heart Failure guidelines in 2023[12] indicates that intensive up-titration of HF medication is a I-B indication, emphasizing the effectiveness of drug therapy on recovery, when individual optimal dosage is achieved timely.

In parallel, current ESC guidelines on ventricular arrhythmia and prevention of SCD recommend optimal medical therapy for 90 days prior to consideration of ICD implantation.[15]

Telemonitoring modalities in telecardiology for patients equipped with a wearable cardioverter-defibrillator

The advent of telemonitoring in cardiology has revolutionized patient management, particularly for those at risk of life-threatening arrhythmias. This is particularly true in the setting of WCD, which allows beyond defibrillation a real benefit that should be recognized.

The WCD features integrated telemetry, which enables real-time transmission of cardiac data to healthcare providers. These data includes ECG recordings, heart rate, and event triggers. Telemonitoring platforms allow healthcare teams to assess patient status remotely and respond promptly to any abnormalities. The ability to monitor patients from their homes enhances convenience and reduces the need for frequent hospital visits.

Advanced algorithms analyse the data collected from the WCD, providing healthcare professionals with actionable insights. Telemonitoring systems can automatically flag significant arrhythmic events, allowing immediate clinical intervention. Regular reports generated from the WCD data facilitate ongoing assessment of the patient's condition, enabling healthcare providers to adjust treatment plans as needed.

Telemonitoring also emphasizes patient engagement. Patients equipped with a WCD receive education about their condition, the importance of monitoring, and what to expect from the device. This knowledge empowers patients to be proactive in managing their health and enhances adherence to monitoring protocols.

The significance of telemonitoring, particularly in the context of WCDs, extends beyond mere defibrillation. While the primary function of the WCD is to provide immediate cardioversion in the event of a critical arrhythmia, the comprehensive nature of telemonitoring offers numerous benefits.

(1) Timely interventions
Real-time monitoring allows for timely identification of arrhythmic events or haemodynamic changes, leading to immediate intervention.[61] Quick responses to life-threatening arrhythmias can prevent progression to more severe outcomes, such as cardiac arrest. The ability to initiate treatment promptly can significantly improve survival rates.

(2) Reduction of hospital readmissions
Telemonitoring has the potential to reduce hospital readmissions by allowing for effective outpatient management of patients. Continuous monitoring and timely interventions can help to identify patients at risk,[61] stabilize patients, and prevent exacerbations of their condition, leading to fewer hospital visits.

(3) Enhanced communication and informed decision-making
Telemonitoring fosters enhanced communication between patients and healthcare providers. This collaborative approach promotes a patient-centred model of care.

(4) Psychosocial support
The constant connection facilitated by telemonitoring can provide patients with a sense of security, reducing anxiety about their condition.[21] Knowing that their heart health is continuously monitored can empower patients and promote adherence to prescribed treatment plans.

In a large observational study, the WCD was associated with a 39% relative risk reduction in overall mortality in post-revascularization patients with severe LV systolic dysfunction, despite the fact that only 1.3% of WCD patients had an appropriate therapy for ventricular arrhythmia. In this study, mortality differences between WCD and non-WCD propensity-score matched groups could not be solely attributed to the termination of life-threatening ventricular arrhythmias by the WCD. Although the WCD is highly effective in terminating potentially life-threatening arrhythmias, the incidence of such arrhythmias in WCD patients included in large-scale registries is very low.[62] While a treatment selection bias could account for some of the mortality reduction in observational studies (even with propensity score matching), it is important to consider that the WCD provides patients with other benefits such as a sense of security, an alarm system with response buttons allowing the option to withhold unnecessary therapy,[63] the ability to sit or lie down to avoid injury in case of impending loss of consciousness (warned by the WCD), and monitoring of heart rate (HR control alert).

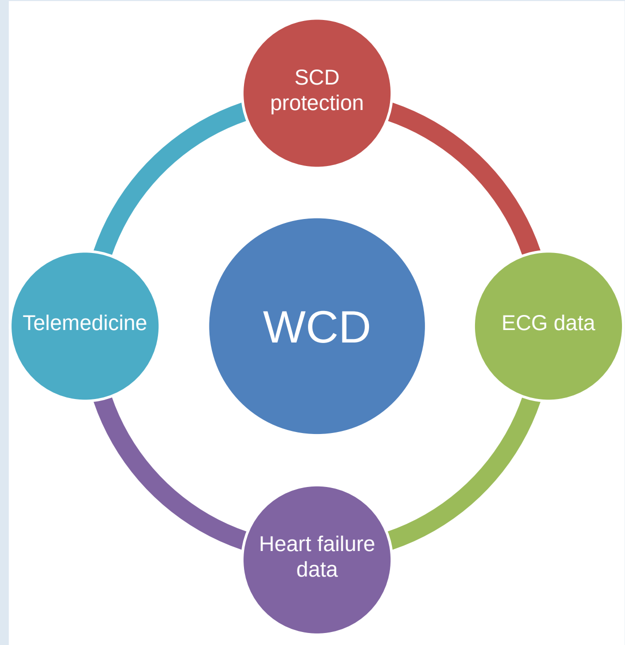

Figure 4 The WCD provides SCD protection, but also ECG data, HF, and telemedicine.

Additionally, caregivers are better aware/trained, and non-compliance is detected early by remote monitoring reminding patients to wear the WCD and also acting to reinforce other positive health behaviours overall. These multiple benefits, which are not directly related to WCD therapy, might contribute to improved outcomes, although innovatively designed studies are needed to definitively prove this.

In conclusion, telemonitoring modalities in telecardiology, particularly for patients equipped with a WCD, play a crucial role in managing high-risk patients. The ability to continuously monitor cardiac health, coupled with advanced data analytics and real-time communication with healthcare providers, enhances patient safety and supports timely interventions. As the healthcare landscape continues to evolve, the integration of telemonitoring into routine cardiology practice will be vital in improving outcomes for patients at risk of SCD. This approach not only focuses on the immediate provision of defibrillation but also emphasizes comprehensive patient management and the potential to save lives through proactive monitoring and engagement.

Wearable cardioverter-defibrillator as a component of integrated management in newly diagnosed heart failure

While LVEF relevantly improves from optimal medical therapy in newly diagnosed cardiomyopathy patients,[64–66] clear predictors for recovery remain elusive. During this early phase, it may be premature to implant an ICD—especially if there is a reasonable likelihood of partial or full recovery of systolic function. Still, this early phase remains a phase of elevated arrhythmic risk.[67]

The majority of newly diagnosed HF patients qualify for a quadruple therapy regimen. However, real-world adherence to these

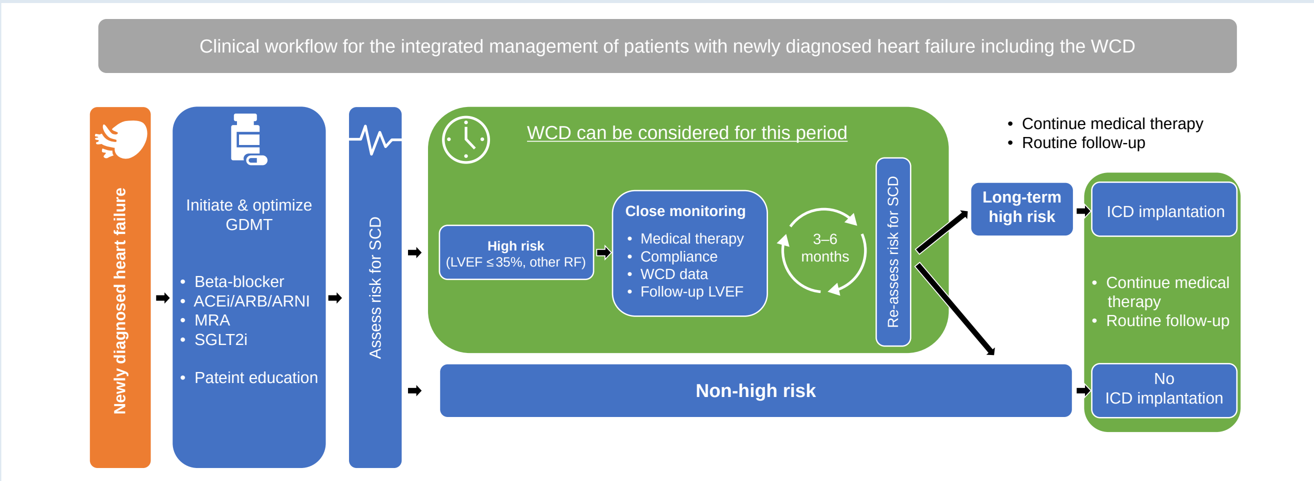

Figure 5 Clinical workflow for the integrated management of patients with newly diagnosed HF including the WCD.

comprehensive guidelines remains suboptimal. Among eligible patients, only 15.3% actually receive all four medications at discharge, while 41.5% receive a triple therapy approach.[68]

Recent data have further emphasized the importance of timely and comprehensive HF management in this setting. Notably, the HF-OPT study[69] underscores how early and thorough optimization of medical therapy can influence LVEF recovery in newly diagnosed HF patients even beyond the first 3 months after diagnosis.[70]

Clinical trials and registries indicate that while WCDs may reduce the short-term risk of SCD in carefully selected patients, their efficacy in the broader HF population is still an area of ongoing investigation.[24,48] Nevertheless, real-world experience and evidence from contemporary studies support the idea that a WCD may be beneficial for patients with newly diagnosed cardiomyopathy awaiting re-evaluation of their ejection fraction.[20,22,23,41,46,71,72]

An integrated management plan that combines a WCD for selected patients also involves concerted efforts to optimize medical therapy and address modifiable risk factors. In this context, the WCD offers temporary protection from SCD, but also provides additional ECG and HF data and offers remote monitoring (*Figure 4*).

The identification and treatment of comorbidities—such as atrial fibrillation, Type 2 diabetes, or chronic kidney disease—play a critical role in the overall management of HF. Ultimately, the decision to prescribe a WCD should be individualized, taking into account clinical status, the likelihood of improvement in left ventricular function, patient adherence, and the presence of other comorbidities that might influence device tolerability or benefit.

The WCD can be viewed as a valuable component of integrated management for newly diagnosed HF patients. It combines real-time arrhythmia detection and treatment with rigorous medical therapy optimization (*Figure 5*).

Gaps in evidence

The evidence supporting the use of the WCD and its potential to save lives primarily comes from observational non-randomized and retrospective studies, with the addition of a single randomized trial.[24] However, during the VEST trial, the primary endpoint was changed from all-cause to arrhythmic mortality, and the intention-to-treat analysis shows the opposite result as the on-treatment analysis. Additionally, the primary endpoint 'sudden death or death from ventricular tachyarrhythmia' does not seem very relevant since the DINAMIT and IRIS trials suggest that many patients who are saved from arrhythmic death by cardioversion/defibrillation subsequently die from progressive HF.[73,74] A new prospective randomized trial (WCD or no WCD on top of optimal medical treatment) with the primary endpoint all-cause mortality would be desirable.[75]

Conclusions

The use of the WCD provides a non-invasive yet potentially life-saving strategy for patients at temporary increased or unclear risk of SCD. This is of particular importance during the early phase of newly diagnosed HF while GRMT optimization is still in progress. While high-quality randomized evidence is limited, substantial observational and registry data support the concept of WCD efficacy in detecting and terminating life-threatening arrhythmias showing potential to avoid unnecessary ICD implantations. However, significant gaps remain. More robust prospective data including well-powered RCTs are needed to fully determine which patient subgroups are most likely to derive net benefit and to clarify optimal duration of WCD use.

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