

## The Wearable Cardioverter/Defibrillator – Toy Or Tool?

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### Abstract

After the success story of implantable cardioverter/defibrillator systems, prevention of sudden cardiac death (SCD) remains one of the main duties in cardiology. For patients with unknown or transient risk profile for SCD, a wearable cardioverter/defibrillator (WCD) has been established for temporary and effective prevention of sudden arrhythmic death. Several studies have shown safety and efficacy of the WCD, even though randomized studies proving a mortality benefit are still lacking. This review provides an overview of actual WCD data and usage, special indications and possible risks and complications. WCD use is effective and adequate for temporary prevention of SCD in chosen populations. In particular, it provides secured time for sophisticated risk stratification to identify patients at persistent risk for SCD. Nevertheless, prospective randomized trials seem mandatory to prove a prognostic relevance and the economic value of this device.

### Introduction

Sudden cardiac arrest (SCA) due to tachyarrhythmias remains a major cause of death in western countries.<sup>1,2</sup> The implantable cardioverter/defibrillator (ICD) has been used for more than 30 years and is considered one cornerstone for primary and secondary prevention of sudden cardiac death (SCD) in high-risk patients.<sup>3</sup> Decades have passed since the milestone trials in ICD therapy. The MADIT, MADIT-II and SCD-HeFT trial enrolled patients between 1990 and 2001.<sup>4-6</sup> Since then, interventional and drug therapies for these patients have evolved tremendously and concomitantly may have affected risks for SCD. Additionally, ICD therapy may be accompanied by several device-related problems, especially lead failure.<sup>7</sup> Recently, van der Heijden et al. described an overall-incidence for device related adverse events of 20% inappropriate shocks, device infections of 6% and 18% lead failures within 12 years of follow-up.<sup>8</sup> ICD therapy has been shown to be cost-effective.<sup>9,10</sup> However, a relevant proportion of patients getting implanted do not meet evidence-based criteria for implantation.<sup>11</sup> Therefore, careful but however secured risk assessment before ICD

implantation may be even more cost-effective.

### Risk Stratification

A large number of possible risk markers like microvolt T-wave alternans, tests for autonomic dysfunction or signal averaged ECG have been proposed. Though, they did not find their way into clinical routine and are actually not supported by the guidelines.<sup>12</sup> The only evidence-based risk stratifying marker today remains left ventricular ejection fraction, thereby reading “left ventricular ejection fraction (LVEF)”.<sup>12</sup>

Having said this, in a recent study, Sjöblom et al. investigated evolution of LVEF in 91 patients after myocardial infarction (MI).<sup>13</sup> 45% of the patients met the ICD criteria of LVEF  $\leq 35\%$  40 days after MI. However, the authors found further significant improvement in LVEF in 6 more patients at 3 months follow-up ( $p=0.01$ ), meaning that these patients no longer met the criteria for ICD implantation. These findings show that there is further improvement in LVEF beyond the initial 40 days post MI. Furthermore, 10% of the patients presented with life-threatening ventricular arrhythmias within the first 9 weeks post MI, emphasizing the arrhythmic risk and the need for antiarrhythmic prophylaxis in this early phase. Accordingly, in patients with recent onset non-ischemic cardiomyopathy, the IMAC study showed no benefit from early ICD implantation.<sup>14</sup>

### Wearable Cardioverter/Defibrillator

For patients with unknown or transient risk profile for SCD, a wearable cardioverter/defibrillator (WCD) (LifeVest®, ZOLL, Pittsburgh, PA, USA) has been established for temporary but however effective prevention of sudden arrhythmic death (Figure 1). The WCD continuously analyzes the heart rhythm using 4 non-adhesive electrodes incorporated in a light garment. The ECG is registered via 2 non-standard leads (front-back and side-side). When a life-threatening arrhythmia is detected, the WCD runs an alarm cascade

### Key Words:

Sudden Cardiac Death, Ventricular Arrhythmia, Wearable Cardioverter/Defibrillator.

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**Figure 1: Wearable Cardioverter Defibrillator (WCD)**

including audible, visual and tactile alarms. If the patient is conscious, he can withhold any therapy by pressing two response buttons on the monitor. In case of unconsciousness and consequently release of the response button, the WCD will deliver a biphasic shock after having deployed contact gel through the contact electrodes. Programming of detection rates can include a ventricular tachycardia (VT) and a ventricular fibrillation (VF) zone, programmable from 120 to 250 beats per minute. The shock energy can be chosen from 75 to 150 J. All ECG with detected arrhythmias are stored in the device and regularly transferred to a webserver where the attending physician can review all episodes as well as the patient's compliance. Since the arrhythmia detection of the WCD is performed via surface non-adhesive electrodes, there is a considerable risk for motion-related noise artifacts.

The WCD is used in patients at undefined or temporary risk for SCD as well as in patients at known persistent high risk but with transient contraindications for implantation of an ICD. Common indications for WCD wearing are shown in table 1.

WCD often gets misclassified as an alternative to permanent ICD or a "bridge to ICD". This does not give sufficient consideration to the capabilities and the concept of WCD usage. This review provides an overview of actual WCD data and usage, special indications and possible risks and complications.

### Clinical Data

In 1998, Auricchio et al. reported the first 10 patients with successful termination of ventricular arrhythmia by the WCD.<sup>15</sup> Subsequently, WCD was shown to be safe and effective in detection and termination of VF.<sup>16-18</sup>

Table 2 summarizes available data on WCD. Despite the manifest gaps in evidence, based on these registries and case reports, the actual ESC guidelines on prevention for SCD give a Class IIb level of evidence C indication for the WCD "for adult patients with poor LV

**Table 1: Common indications for wearable cardioverter/defibrillators<sup>49</sup>**

Acute myocardial infarction with/without PCI and a LVEF $\leq 35\%$
Coronary revascularization (PCI or CABG) and a LVEF $\leq 35\%$
Non-ischemic cardiomyopathy, (acute) myocarditis, stress (Takotsubo) cardiomyopathy, peripartum cardiomyopathy, LVEF $\leq 35\%$
Waiting for heart transplantation
ICD explantation until re-implantation
Post VT ablation in patients with only moderately reduced LVEF.

systolic function who are at risk for sudden arrhythmic death for a limited period, but are not candidates for an implantable defibrillator (e.g. bridge to transplant, bridge to transvenous implant, peripartum cardiomyopathy, active myocarditis and arrhythmias in the early post-myocardial infarction phase)".<sup>12</sup>

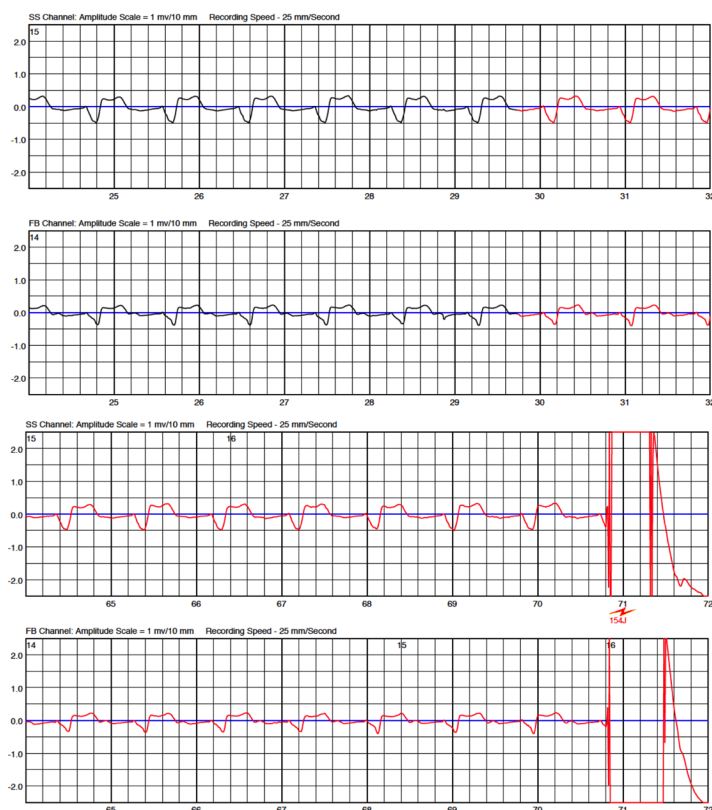
Epstein et al. analyzed 8453 patients wearing the WCD early post MI<sup>19</sup> and found 133 patients (1.6%) receiving 309 appropriate shocks. Beyond that, 114 inappropriate shocks occurred in 99 patients. Mean time from MI to WCD prescription was  $9 \pm 9$  days and mean time from prescription to first shock delivery was  $22 \pm 32$  days. This shows that commonly accepted waiting time between MI and ICD implantation of 40 days and 3 months respectively nevertheless may remain a period at risk for life-threatening arrhythmias. These findings are consistent with those of the VALIANT study which found the highest mortality in the first 30 days after MI.<sup>20</sup> The DINAMIT<sup>21</sup> and IRIS<sup>22</sup> study suggested no survival benefit from ICD implantation early post MI, even though in both studies, the rate of SCD was halved in the ICD group. Unfortunately, this reduction of SCD was negated by an increased number of non-sudden cardiovascular deaths.<sup>23</sup> The reason for this difference has not been clarified sufficiently. Furthermore, relevant differences are obvious comparing the populations of these two studies with a population of a recent heart failure trial, e.g. in terms of optimized heart failure medication. Given the great improvement in heart failure therapy and interventional development for the treatment of acute MI in the last years, the amount of non-sudden cardiac deaths may therefore be relevantly reduced, leaving the amount of preventable arrhythmic death at the disposal of antiarrhythmic devices.

Despite the great amount of descriptive or cohort studies on WCD and the presumed self-evident benefit of the WCD, most of these studies lack a control group, not to mention a randomization. Therefore, the net benefit of the WCD still remains to be proven. The only randomized controlled trial on patients after MI is the multicenter VEST trial with a total of 1900 randomized patients ([www.clinicaltrials.gov](http://www.clinicaltrials.gov), NCT01446965), which is about to complete enrollment. The primary endpoint is sudden death mortality.

The recently published WEARIT-II prospective registry<sup>24</sup> enrolled 2000 patients receiving WCD for a median of 90 days. 40% of the patients had ischemic cardiomyopathy, 46% had non-ischemic cardiomyopathy and 14% had congenital heart disease. Authors reported 120 ventricular tachyarrhythmias in 41 patients (2%) and only 10 patients (0.5%) receiving an inappropriate shock. Even though the WEARIT-II registry represents the greatest prospective database on WCD published to date, it still does not answer the relevant unsettled questions on hard endpoints in WCD use.

### Special Indications

Especially for possibly transient circumstances which may temporarily elevate the risk for life-threatening arrhythmias,



**Figure 2:** ECG shows normal sinus rhythm with T wave oversensing. The patient did not press the response buttons and therefore received an inappropriate therapy. Fortunately, the shock was triggered to the true R-wave

the WCD offers protected time for any further diagnostics, risk stratification, re-evaluation or simply letting any sort of therapy work without letting the patient at risk during this period.

### Rare Cardiomyopathies

Successful use of the WCD has been described in acute or suspected myocarditis,<sup>25, 26</sup> stress cardiomyopathy,<sup>27, 28</sup> noncompaction cardiomyopathy,<sup>29</sup> alcohol toxic cardiomyopathy,<sup>30</sup> congenital heart disease<sup>24, 31, 32</sup> as well as in children.<sup>33</sup> Candidates for cardiac transplantation can likewise be provided a WCD until transplantation.<sup>34</sup> However, since these days waiting for a donor organ may take several years, implanting an ICD has to be seriously considered.

ICD therapy in inherited arrhythmia syndromes like long QT syndrome, Brugada syndrome or arrhythmogenic right ventricular dysplasia is challenging due to the rather young patient age, limited available data and elevated complication rate.<sup>35</sup> WCD can facilitate and cover time to diagnosis and risk stratification in these patients. In the study by Rao et al., among 119 patients with inherited arrhythmias receiving a WCD, the predominant indication was pending genetic testing.<sup>32</sup> Again, the WCD should not be considered as a bridge to ICD in these patients, but rather as a tool for serving protected time to exclude a diagnosis or to stratify the patient as low-risk and thus omitting ICD implantation.

### Peripartum Cardiomyopathy

The concept of temporary prophylaxis for SCD of the WCD is particularly attractive for transient pathologies leading to a temporarily elevated risk for SCD. Peripartum cardiomyopathy

(PPCM) represents a rare idiopathic cardiomyopathy leading to heart failure LV dysfunction towards the end of pregnancy or in the months following delivery.<sup>36</sup> Even if initial LVEF often is severely affected at the time of diagnosis, there is a high potential for LVEF recovery after starting an optimal heart failure medication regimen.<sup>37</sup> In a large cohort of 107 patients with PPCM wearing a WCD, Saltzberg et al. did not report any arrhythmic event (though 3 patients died after WCD use).<sup>38</sup> This may eventually be due to the retrospective character of their analysis. On the contrary, we recently reported 12 consecutively admitted patients with first diagnosis of PPCM.<sup>39</sup> 7 patients presented with a LVEF of  $\leq 35\%$  and received a WCD for 3 to 6 months. Among these 7 patients, we observed 4 events of VF in 3 of the patients. Patients significantly recovered in LVEF during follow-up. Our data strongly suggest an elevated risk for life-threatening arrhythmias in these young mothers early after diagnosis of PPCM and warrant an uninterrupted use of the WCD in all patients in the early phase of PPCM during recovery.

### ICD Explantation Due To Infection

Due to increasing numbers of ICD implantations and subsequent generator exchanges, numbers of device infections with need of system explantation are increasing, too. Especially for patients with secondary prophylactic indications for an ICD, continuous monitoring after explantation seems mandatory. Besides inpatient monitoring for the period of antibiotic therapy, outpatient management using a WCD for this period seems reasonable. Tannawuttiwat et al. presented a retrospective analysis of 97 patients wearing a WCD after ICD removal.<sup>40</sup> 2 patients received 4 shocks, 1 patient received 2 unnecessary shocks. 8 patients (8.2%) died (5 patients in hospital, 3 patients at home), no one was wearing the WCD at the time of death. In a cost-effectiveness model, the WCD was shown to be cost-effective in comparison to inpatient strategy until re-implantation.<sup>41</sup>

### Malignancies

WCD can successfully be used in cancer patients who often present a contraindication for ICD implantation.<sup>42</sup> Special considerations can be raised on patients with planned radiotherapy adjacent to an implanted ICD. Depending on the local findings and the planned radiation protocol, an explantation of the ICD with temporary use of a WCD for the radiation period and subsequent re-implantation may be a favorable strategy, as reported by Bowers et al.<sup>43</sup>

### Renal Disease

Patients who are in end-stage renal disease are known to have a high risk for ventricular arrhythmias, but are as well known to show reduced benefit from primary prophylactic ICD therapy due to competing risks.<sup>44</sup> Nevertheless, Wan et al. reported 84 SCA episodes in 75 patients on hemodialysis showing the important arrhythmic burden in these patients.<sup>45</sup> Not all of these episodes were tachyarrhythmias, but 18 episodes were described as asystoles not treated by the WCD.

The actually enrolling WED-HED study (www.clinicaltrials.gov, NCT02481206) is a multi-center, prospective, randomized controlled clinical trial with 1:1 assignment of treatment and control. It will evaluate the impact of WCD use on sudden cardiac death in incident hemodialysis patients.

### Risks and Complications of WCD Wearing

The WEARIT/BIROAD registry reported two patients with unsuccessful defibrillation due to incorrectly placed therapy

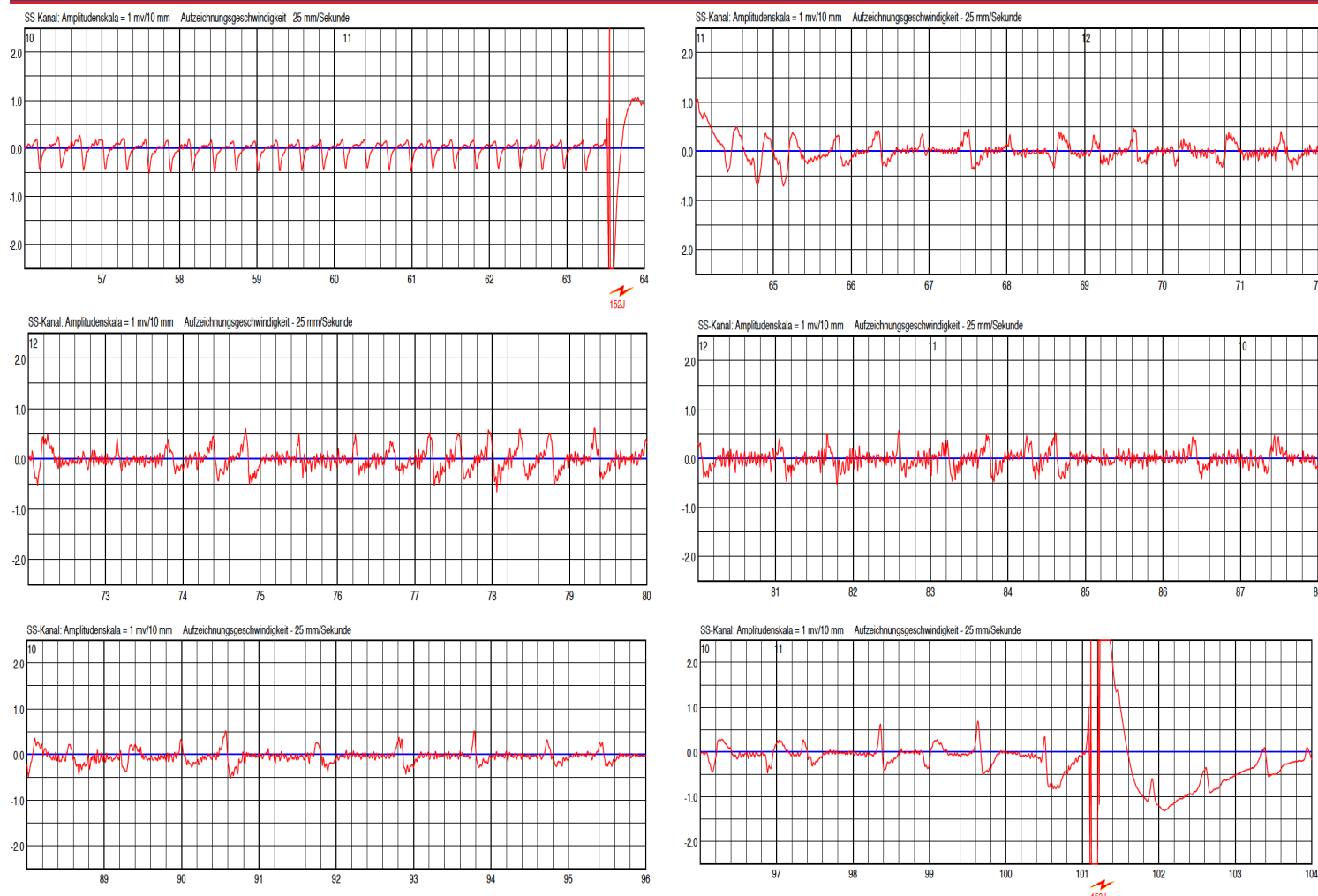


Figure 3:

**Episode of a patient with dilative cardiomyopathy. Patient fell on the floor and remained unconscious. ECG shows ventricular tachycardia that was adequately detected and WCD shock was delivered. After WCD shock, the patient remained unconscious and developed irregular ventricular rhythm going along with some noising leading to oversensing and delivery of another – inappropriate – WCD shock**

electrodes.<sup>18</sup> Accurate and thorough training and instruction of the patients therefore seems mandatory. The effectiveness and reliability of the WCD mainly depends on the patient's compliance.

In the WEARIT/BIROAD registry 65 out of 289 patients discontinued WCD use before prematurely, 30% did so due to comfort or lifestyle issues.<sup>18</sup>

LaPage et al. reported one case of missing a fatal ventricular arrhythmia in a patient with unipolar pacemaker stimulation.<sup>46</sup> Unipolar stimulation should be avoided in patients wearing the WCD.

Sudden cardiac arrest may be due to asystole in some patients. Chung et al. reported 23 patients showing asystole events, 17 of which died.<sup>47</sup> Asystole is a relevant cause of SCD in patients with reduced LV function<sup>48</sup> and to date, there are no data about the relevance of backup pacing on mortality benefit in ICD patients.

Since the WCD is not able to provide pacing for bradyarrhythmia, asystole may lead to SCD even though the patient is wearing the WCD. Nevertheless, an asystole event will trigger the alarm cascade and may call possible bystander's attention to the patient.

Inappropriate therapies are another concern during WCD use. They are reported occurring in 0.5-3% of the patients.<sup>24, 32</sup> Like in implanted devices, there is the possibility of T wave oversensing. If the patient fails to press the response buttons, inadequate shock will

be delivered (Figure 2). Since the WCD is programmed to deliver a "synchronized" shock in case of regular VT, a "synchronized" shock triggered by an oversensed T wave may happen with a high risk of induction of VF. This underlines again the need for a dedicated training of the patient in handling the WCD.

One of our patients presented a hemodynamic unstable VT and fell unconscious. VT was detected and shocked by the WCD. Immediately after WCD shock, the patient developed irregular ventricular rhythm. This rhythm was inappropriately classified as a ventricular tachyarrhythmia by the WCD. Since the patient was still not fully conscious, he failed to press the response buttons and therefore received a second shock, which was inappropriate (Figure 3). Besides the psychic and painful consequences, inadequate therapies bear the risk for proarrhythmogenicity by triggering malignant arrhythmias. The concept of pressing the response buttons gives relevant safety, but however there are possible scenarios in which the patient may not be capable to withhold therapies, as shown in our case.

Undersensing due to low amplitudes during VF is a major concern in ICD. Low amplitudes in VF may even more occur in surface ECG. In one patient, we noticed VF undersensing due to very low amplitudes during VF (Figure 4).

### Workflow

The LifeVest Network® (Zoll, Pittsburgh, PA, USA) permits



Figure 4:

**Spontaneous ventricular fibrillation (VF) occurred in this patient with peripartum cardiomyopathy. Amplitude of VF rapidly decreased followed by myopotentials (black arrow) which were possibly linked to hypoxia-related seizures. Due to this high-frequency low-amplitude signals, VF criteria were no longer satisfied and detection was cancelled (white arrows). VF was redetected several more times. Probably due to some increase in VF amplitude, VF was finally redetected and the life-saving shock was successfully applied 80 seconds after onset of the tachycardia**

surveillance of WCD patients via remote monitoring. As a result of increasing patient numbers being considered for WCD wearing, the process of screening, prescription, training and remote monitoring of the patients becomes more and more time consuming. Increasing patient numbers require structured and optimized patient management strategies to assure both, reliable logistics and adequate handling of critical events. In our department, we have established a workflow determining responsibilities and sequences in the course of a WCD wearing (Figure 5). Screening possible patients for WCD wearing is performed by a trained nurse using a screening protocol considering the indications listed in table 1. The decision for WCD wearing is then taken by a physician taking into account device-related issues (efficacy and safety), patient-related factors (compliance, aptitude, acceptance), and disease-related aspects (indications and survival benefit). Cautious instruction of the patient (and, if feasible, family members) is performed by the manufacturer when supplying the device. WCD data (arrhythmia

events, compliance, etc.) is available through the telemonitoring system. Any event reported in LifeVest-Network® is verified by the responsible nurse and submitted for further review to the physician, if classified as “critical event”. “Critical events” were defined as: (1) any therapy delivery, (2) any sustained or non-sustained tachycardia, (3) any abnormality in the ECG not convincingly attributed to noise. In order to identify patients at nontransient, enduring risk for SCD, a careful follow-up for re-evaluation of LVEF is scheduled after 3 months. We use this standardized workflow to facilitate and optimize patient management in clinical routine.

### Perspective

The WCD also offers new diagnostic options that may be used in future versions. The exceptional chance of this device consists in a continuous ECG monitor for 3 to 6 months. It already detects asystole events (without giving any therapeutic options), but it could just as well detect other arrhythmias. By detecting asymptomatic atrial fibrillation, the WCD could enable stroke prevention at an

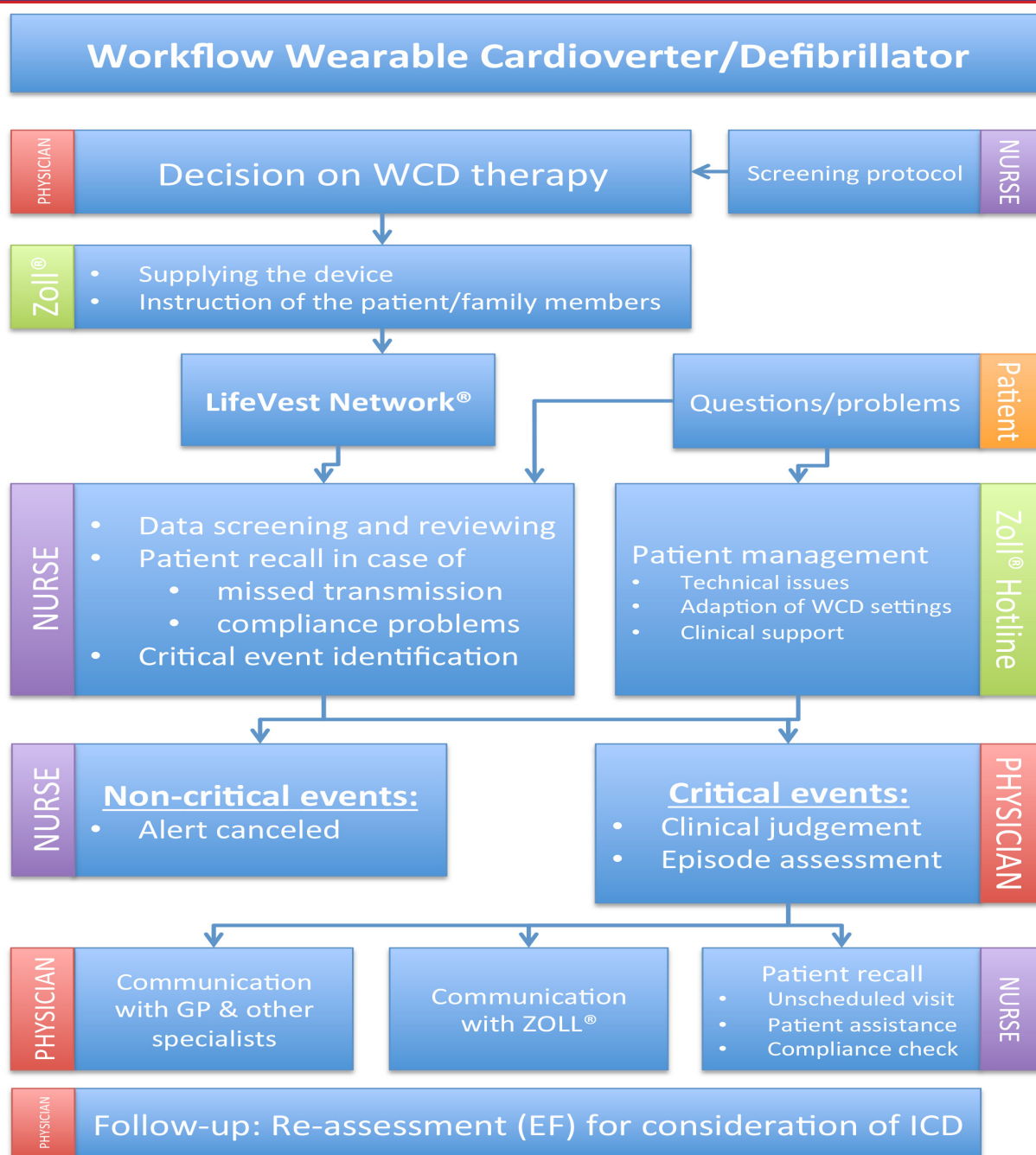


Figure 5:

**Workflow of the Wearable Cardioverter/Defibrillator (WCD) program at Hannover Medical School (GP: general practitioner, EF: left ventricular ejection fraction)**

early stage. Continuous analysis of the ECG during this long period in high-risk or assumingly high-risk patients has never been done before. Additionally, the device can offer supplemental parameters, such as heart failure indices or tests, which may be relevant in some patients. Technicians and developer of the manufacturer should yield this hoard to discover new unprecedented insights in rhythmic and arrhythmic evolution in these patients. This tool offers completely new options for future ECG risk stratification.

### Conclusions

WCD use is effective and adequate for temporary prevention of sudden arrhythmic death in chosen populations. In particular, it provides secured time for sophisticated risk stratification to identify patients at persistent risk for SCD. Nevertheless, prospective

randomized trials seem mandatory to prove a prognostic effect/relevance and the economic value of this device.

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Table 2:

**Registries on WCD (MI: myocardial infarction, PPCM: Peripartum cardiomyopathy, NICM: non-ischemic cardiomyopathy, CHD: congenital heart disease, IA: inherited arrhythmias)**

Publication	Year	Patients (n)	Etiology	Prospective/retrospective	Appropriate shocks	Compliance (h/d)	Cumulative wearing time	Unnecessary shocks
WEARIT/ BROAD <sup>18</sup>	2004	289	Miscellaneous	Prospective	6	n/a	Mean 3.1 months	6 (2%)
Klein <sup>90</sup>	2009	354	Miscellaneous	Retrospective	27 (27.6%)	Mean 21.3	Mean 106 days	0
Saltzberg <sup>38</sup>	2009	258	PPCM/ NICM	Retrospective	0/2	18.3/17.0	Mean 75±81/56±54 days	0/0
Dillon <sup>17</sup>	2010	2105	Miscellaneous	Retrospective	54	Median 21.3	Median 36 days (3-365)	34
Chung <sup>47</sup>	2010	3569	Miscellaneous	Retrospective	76 (2.1%)	Mean 19.9±4.7	Mean 52.6±69.9 days	67 (1.9%)
Rao <sup>32</sup>	2011	162	CHD, IA	Retrospective	0/2%	Mean 19	Mean 27/29 days	0/3%
Epstein <sup>19</sup>	2013	8453	Post MI	Retrospective	146 shocks in 133 (1.6%) patients	Median 21.8	Mean 69±61 (median 57) days	114 in 99 patients
Zishiri <sup>51</sup>	2013	4958	Miscellaneous	Retrospective observational cohort study	18 shocks in 11 patients	n/a	n/a	n/a
Tanawuttiwat <sup>40</sup>	2014	97	Explantation of ICD	Retrospective	4	Median 20	Median 21 days	2
Sasaki <sup>52</sup>	2014	9		Retrospective	1	Mean 23.7	Mean 21 days	0
Duncker <sup>39</sup>	2014	9	PPCM	Prospective	4	Mean 22.0±2.4	Mean 133±103 days	0
Opresanu <sup>34</sup>	2015	122	Candidates for cardiac transplant	Retrospective	7	Mean 17±7 (median 20)	Mean 127±392 (median 39) days	2
WEARIT-II <sup>24</sup>	2015	2000	ICM, NICM, CHD,	Prospective	120 in 41 patients	Median 22.5	Median 90 days	10 patients

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