

Giyilebilen Defibrilatör

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TIP FAKÜLTESİ

Giyilebilen kardiyoverter-defibrilatör

- ✦ Giyilebilen kardiyoverter defibrilatör (Wearable cardioverter-defibrillator (WCD)) (**LifeVest, ZOLL, Pittsburgh, Pennsylvania**) acil ICD endikasyonu olup takılamayan fakat ani kardiyak ölüm (AKÖ) riski olan hastalar için dizayn edilmiştir
- ✦ Otomatik tedavi şansı sağlamakta
- ✦ Defibrilasyon için ikinci bir kişiye gerek yok
- ✦ Cerrahi bir işlem değil
- ✦ Kolayca çıkarılabilir
- ✦ 2002 FDA onayı

Giyilebilen kardiyoverter defibrilatör – Teknik donanım

- ✦ 2 komponent
- ✦ Giyilebilir parça
- ✦ Batarya ile çalışan monitör-defibrilatör
- ✦ Giyilebilir parça hastanın göğüs çevresi ve kilosuna göre ayarlanabilir
- ✦ Sensing ve defibrilasyon elektrotları
- ✦ 4 elektrot, 2 lead sistemi (giyilebilir parçanın bel kısmında)
- ✦ Yüzey EKG sini kaydeder ve aritmileri saptar



Giyilebilen kardiyoverter defibrilatör – Teknik donanım

- ✦ Monitör kemer üzerine ya da omuz askısına tutturulur
- ✦ Analog ve dijital filtreler kullanılır
- ✦ Aritmileri saptama sensitivitesi 90% - 100%, spesifitesi 98% - 99%
- ✦ Uygunsuz şok oranı $\approx 1\%$ to 2%



Giyilebilen kardiyoverter defibrilatör Teknik özellikler

- ✦ Aritmi tespit edildiğinde tedavi algoritması başlar
- ✦ Aritmi morfoloji ve hız kriterini karşılırsa, formal algılama başlar, cihaz hasta cevap testini başlatır
- ✦ Test: titreşim, işitme ve görsel uyarılarla yapılır
- ✦ Eğer hasta cevap butonuna basarsa, epizod sonlandırılır
- ✦ Herhangi bir cevap kaydedilmezse, defibrilasyon elektrodu deri üzerine jel boşaltır ve antero-posterior olarak uygun şok verir

Giyilebilen kardiyoverter defibrilatör

Teknik özellikler

- ★ Cevap süresi (şok tespti) : 25-60 sn
- ★ Enerji: bifazik 75-150 J, etkili şok %69-99
- ★ Cihaz 5 şoka kadar verebilir
- ★ Bir kez cihaz bir epizodu tedavi ettiğinde, giysi ve elektrotlar yenilenmeli

Rölatif Kontrendikasyonlar

- ✦ Unipolar pacemaker olan hastalar (atriyal ya da ventriküler) WCD kullanamaz
- ✦ Geniş amplitüdlü pacing aritminin tespitini zorlaştırır
- ✦ Hasta cevap testine cevap veremeyecek durumda olan hastalar

Kısıtlılıkları

- ✦ Pacing özelliği yok
- ✦ Uzun süreli kullanımlarda hasta konforu bozulur
- ✦ Obezite
- ✦ Açık ya da iyileşmekte olan göğüs duvarı yaraları
- ✦ Kutanöz yanıklar

Hasta uyumu

- ✦ Efektif WCD tedavisi için hasta uyumu önemli bir komponent
- ✦ Duş almak dışında hasta sürekli cihazı giymeli
- ✦ Tedaviyi bırakma oranları %10-22

Klinik Deneyimler

- ✦ Wearable Defibrillator Investigative Trial (WEARIT)
- ✦ Bridge to ICD in Patients at Risk of Arrhythmic Death (BIROAD)
- ✦ Results From The Prospective Registry Of Patients Using The Wearable Defibrillator (WEARIT-II Registry)
- ✦ Wearable Cardioverter-Defibrillator after Myocardial Infarction (VEST)
- ✦ Study of the wearable cardioverter defibrillator in advanced heart-failure patients (SWIFT)

WEARIT Çalışması

- ✦ Semptomatik kalp yetersizliği olan hastalar (NYHA class III–IV)
- ✦ LVEF < %30
- ✦ Yüksek riskli
- ✦ ICD takılamayan hastalar

BIROAD Çalışması

- ✦ MI ya da cerrahi revaskülarizasyon sonrası 4. aya kadar
- ✦ AKÖ açısından yüksek riskli olan hastalar
- ✦ CABG sonrası LVEF <%30
- ✦ CABG sonrası senkop
- ✦ ICD implantasyonunu reddeden hastalar

WEARIT-BIROAD Sonuçlar

- ✦ 2 prospektif çalışma, 289 hasta
- ✦ 8 defibrilasyon denemesinin 6 sı başarılı (%75), mortalite (n:12)
- ✦ %25 hasta cihazla ilişkili rahatsızlık hissi ya da advers olayalar nedeni ile çalışmadan ayrılmış (n:68)
- ✦ AKÖ açısından yüksek riskli hastalarda WCD uygunluğunu değerlendiren ilk çalışmalar

Klinik Deneyimler - USA

- ★ 2002-2006 arası US de 3569 hastada en az 1 gün olmak üzere WCD deneyimi (ortalama süre 53 ± 70 gün)
- ★ Tedaviyi erken sonlandırma %14
- ★ Daha uzun süre kullanım daha iyi uyumla ilişkili
- ★ WCD kullanım endikasyonları
 - ICD eksplantasyonu (%23)
 - Planlanmış ICD implantasyonu öncesi ventriküler aritmi (%16)
 - Yeni geçirilmiş MI (%16)
 - CABG sonrası (%9)
 - Yeni tanı kardiyomyopati LVEF < 35 (%28)

Klinik Deneyimler

- ✦ 59 hastada 80 sustained VT/VF olayı (%1.7 /yıl)
- ✦ En sık VT/VF cihaz çırakılması yapılmış hastalarda (olay sıklığı %5.2)
- ✦ İlk şokun etkililiği %99, Post VT/VF survey %90
- ✦ ICD tedavisi yapılanlar ile karşılaştırıldığında survey benzer (3.6% mortality rate versus 4.4% at 3 months; P=0.256)

Klinik Deneyimler

★ Uygunsuz şok %2

★ Nedenleri:

- Sinyal kirliliği (%68)
- Supraventriküler taşikardi (%27)
- Non-sustained VT (%6)
- Oversensing (%4)
- EKG sinyal kaybı (%4)
- Cevapsız test

Results From The Prospective Registry Of Patients Using The Wearable Defibrillator (WEARIT-II Registry)

WEARIT-II: REGISTRY DESIGN



WEARIT-II

Hasta Populasyonu

N= 2000 hasta -- ABD

Çalışma : Ağustos 2011 – Aralık 2013

Data management: University of Rochester

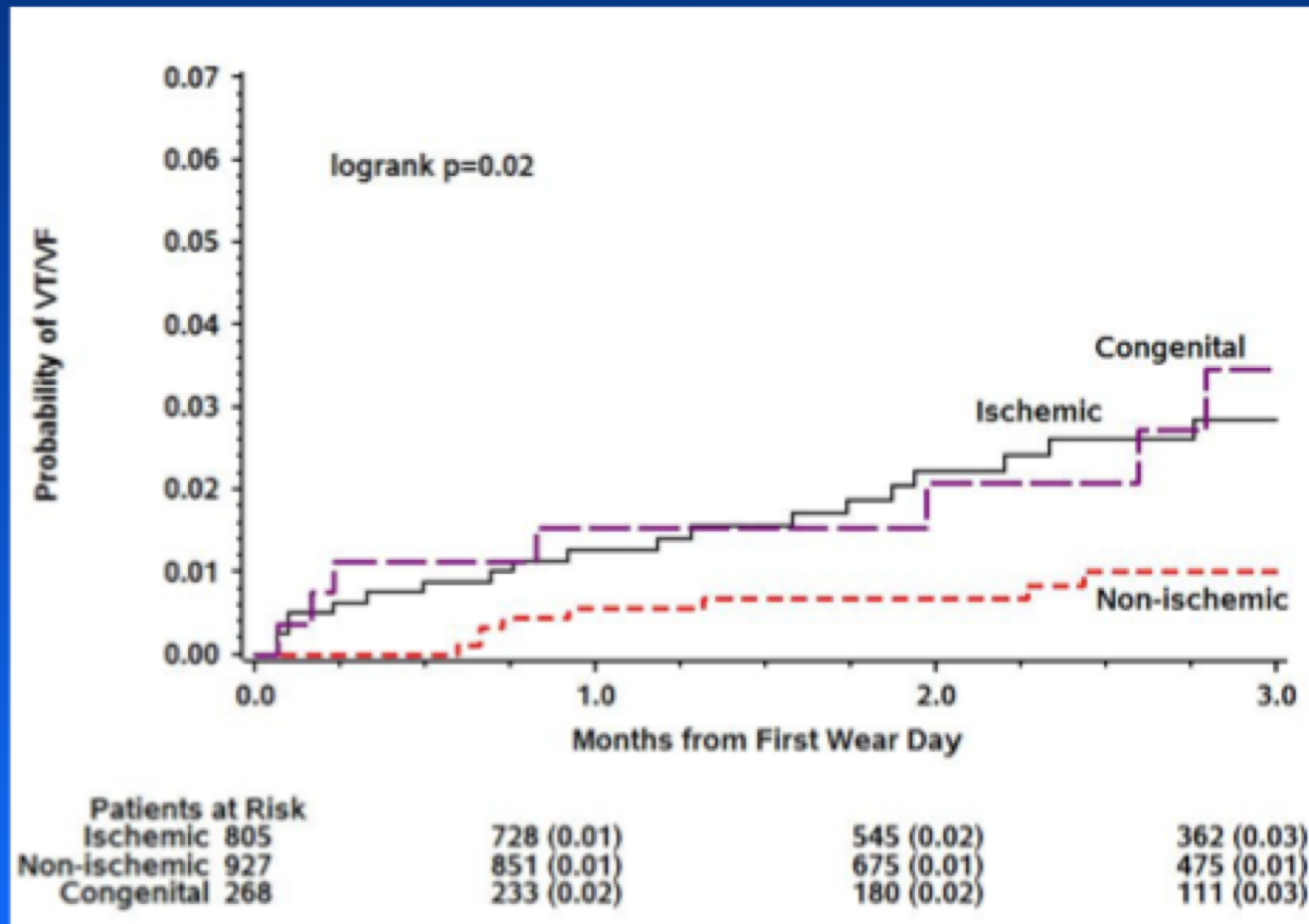
İskemik kardiyomiyopati	805 pts, 40.3%
Non-iskemik KMP	927 pts, 46.4%
Konjenital/kalıtımsal	268 pts, 13.4%

ARİTMİK OLAYLAR: TÜM POPULASYON (MEDIAN 90 GÜN)

	Patients (%)	Events (events/pt)	Event Rate Per 100 Pt- Year
Any VT/VF *	41 (2.1%)	120 (2.9)	22
NSVT	28 (1.4%)	164 (5.9)	30
Atrial arrhythmias/SVT	72 (3.6%)	561 (7.8)	121
Asystole	6 (0.3%)	9 (1.5)	2

*Treated VT/VF and those VT's that were spontaneously terminated, response button use or extended detection time.

ETYOLOJİYE GÖRE VT/VF SIKLIĞI



GÜVENLİK SONLANIM NOKTASI

TYPE	TOTAL N=2000
Inappropriate Rx, n (%)	10 (0.5%)
Death, n (%) with the WCD	3 (0.2%)*

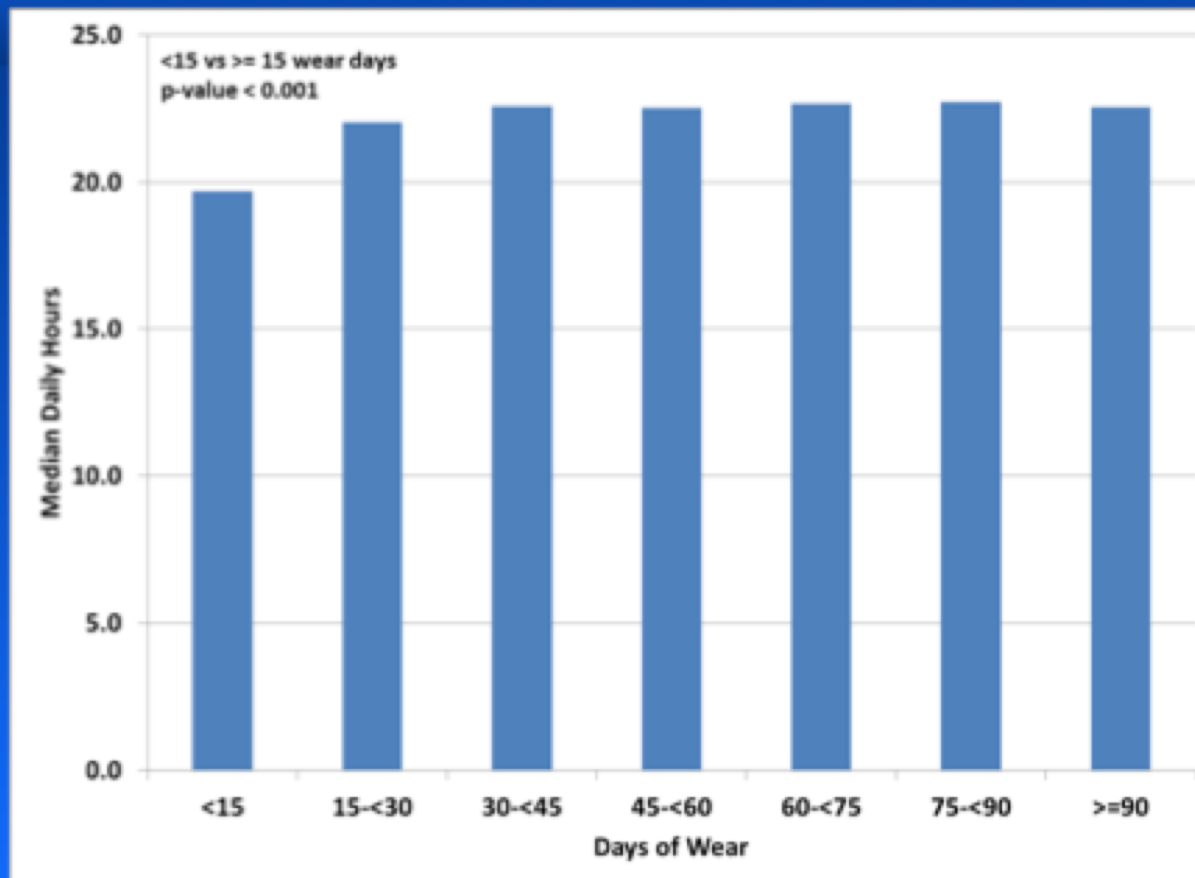
* WCD detected asystole at the time of death

No death related to unsuccessful termination of VT/VF

12-m FU data on death are still being collected

HASTA UYUMU

- Daily wear hours: median 22.5 hours



WEARIT-II

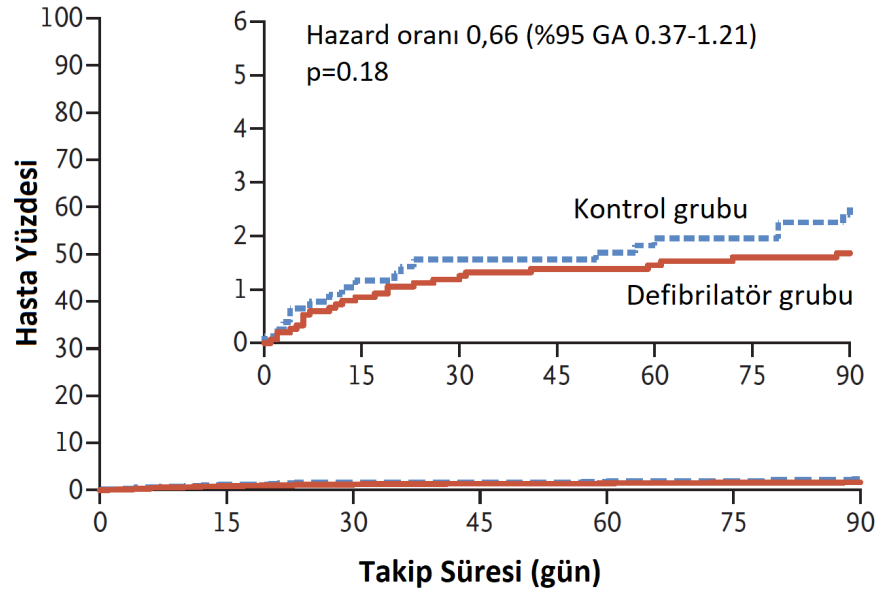
WEARIT-II kayıt çalışmasına göre WCD ile köprü tedavi olarak:

- ✦ Hayatı tehdit eden aritmik olayların önlenmesi sağlanabilir
- ✦ Uygunsuz şok oranları düşüktür
- ✦ İleride ICD implantasyon adayı olup , AKÖ riski yüksek olan hastaların belirlenmesi için risk değerlendirme skorlamalarına ihtiyaç vardır

VEST çalışması: Mİ sonrası erken dönemde giyilebilen defibrilatör

Amaç	ICD'nin henüz endike olmadığı Mİ sonrası erken dönemde giyilebilir kardiyoverter-defibrilatör ani ölüme karşı koruyucu olabilir. VEST (Vest Prevention of Early Sudden Death Trial) çalışmasında akut Mİ sonrası erken dönemde, EF'si $\leq$ %35 olan hastalarda giyilebilir defibrilatörün faydası araştırılmıştır.
Tasarımı	Randomize kontrollü çalışma
Alınma Kriterleri	Akut Mİ sonrası erken dönemde, EF'si $\leq$ %35 olan hastalar
Hasta Sayısı	Giyilebilen defibrilatör grubu=1524 Kontrol grubu=778
Primer Sonlanım	3 ay içinde ani ölüm veya ventriküler taşiaritmiye bağlı ölüm

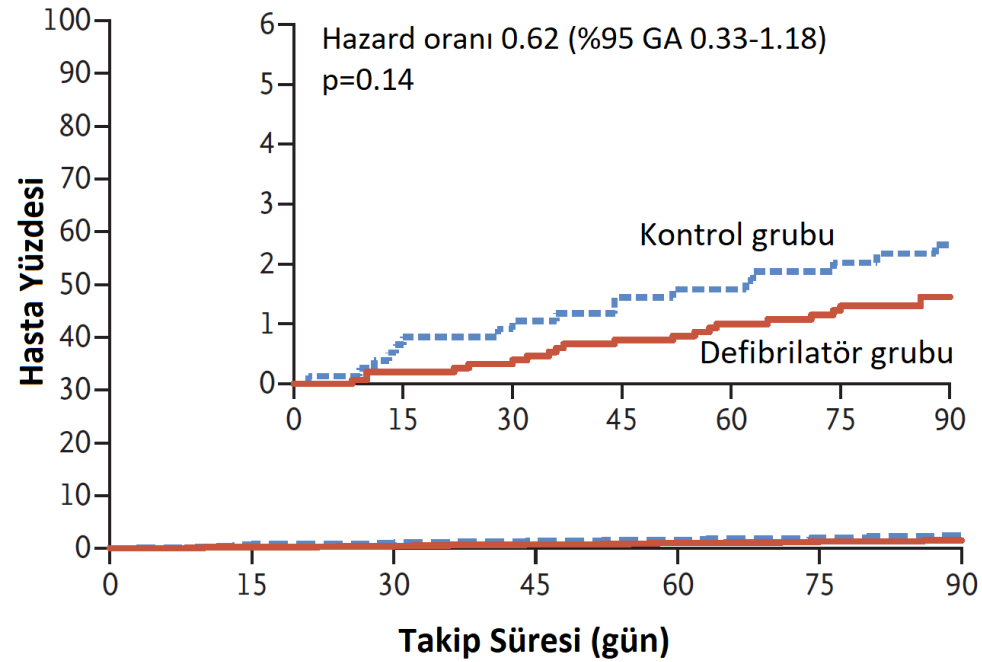
Ani ölüm veya ventriküler taşiaritmiye bağlı ölüm



Hasta Sayısı

Kontrol	778	759	754	746	742	657	650
Defibrilatör	1524	1502	1495	1486	1479	1314	1309

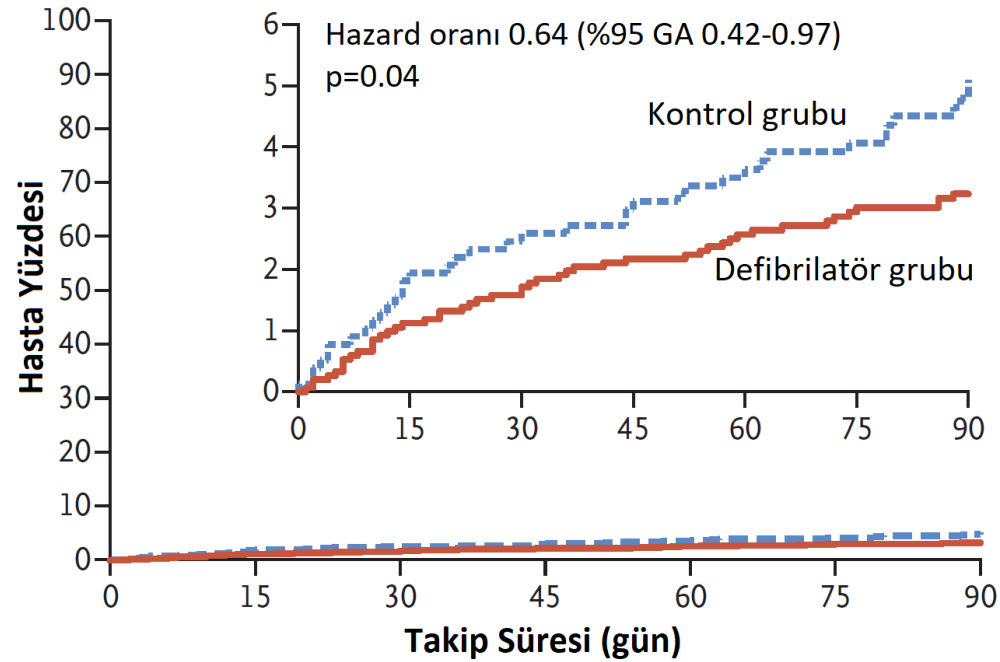
Aritmik olmayan ölüm



Hasta Sayısı

Kontrol	778	759	754	746	742	657	650
Defibrilatör	1524	1502	1495	1486	1479	1314	1309

Tüm ölümler



Hasta Sayısı

Kontrol	778	759	754	746	742	657	650
Defibrilatör	1524	1502	1495	1486	1479	1314	1309

VEST alıřması -- Sonu

MI sonrası EF'si dřk hastalarda erken dnemde giyilebilen defibrilatr takılmasıyla aritmik lmlerde anlamlı azalma olmamıřtır

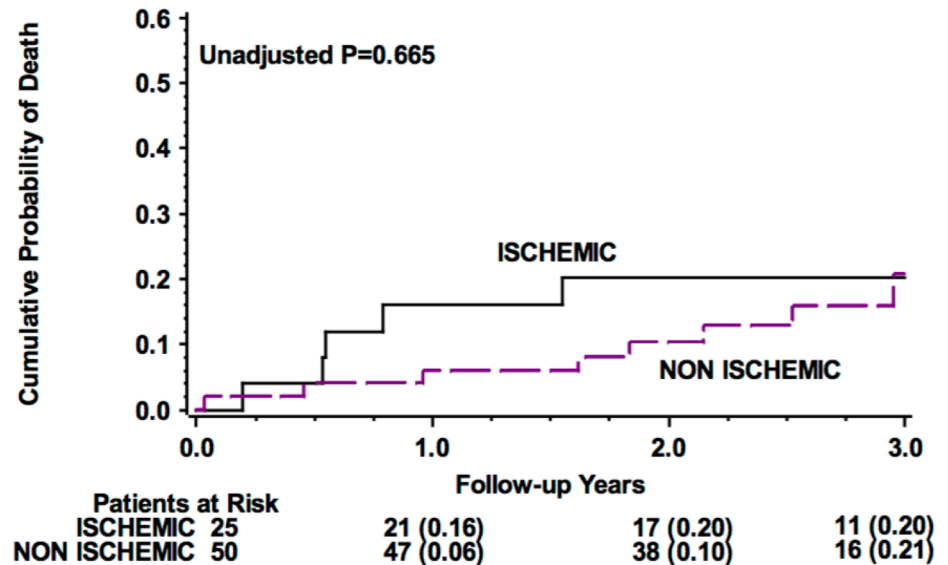
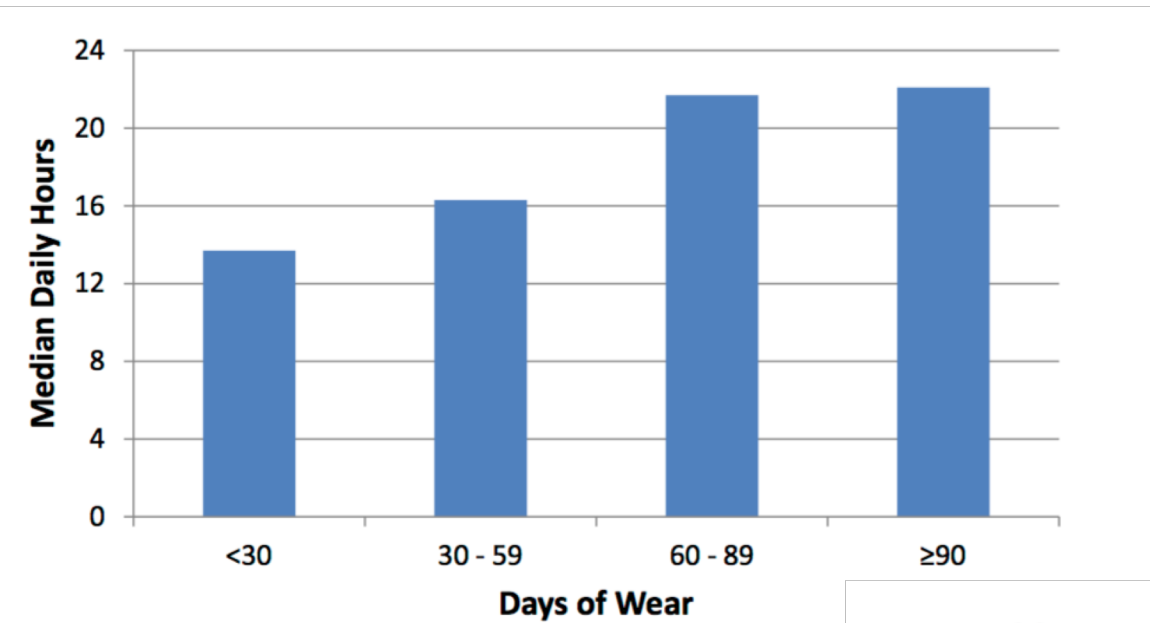
Study of the wearable cardioverter defibrillator in advanced heart-failure patients (SWIFT)

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TABLE 1 Patient characteristics

	All (n = 75)	Ischemic (n = 25)	Non- Ischemic (n = 50)	P value
Age at enrollment	51.4 ± 13.9	60.7 ± 14.4	47.0 ± 11.3	< 0.001
Female	23 (31%)	8 (32%)	15 (30%)	1.0
Diabetes	16 (21%)	8 (32%)	8 (16%)	0.139
Hypertension	34 (45%)	14 (56%)	20 (40%)	0.224
Current smoker	14 (19%)	6 (24%)	8 (16%)	0.531
Past smoker	36 (48%)	14 (56%)	22 (44%)	0.327
NYHA functional class				
III	62 (83%)	23 (92%)	39 (78%)	0.752
IV	13 (17%)	2 (8%)	11 (22%)	
Ejection fraction %	21.5 ± 10.4	25.5 ± 12.4	19.6 ± 8.7	0.043

SWIFT Çalışması



Barsheshet A, et al. Study of the wearable cardioverter failure patients (SWIFT). J Cardiovasc Electro-physiol. 2017

SWIFT Çalışması

WCD takılan hastalarda 8 aritmik olayın 5'inde ventriküler aritmi görülmüş.

3 hastada nonsustained ventriküler taşikardi veya 1 kendi sonlanan ventriküler taşikardi saptanmış.

1 polimorfik VT görülmüş olup, WCD ile başarılı bir şekilde sonlandırılmıştır.

WCD takılan hiçbir hasta ölmemiştir ve uygunsuz cihaz tedavisi almamıştır.

SWIFT Çalışması

Methods and results: The Study of the Wearable Cardioverter Defibrillator in Advanced Heart Failure Patients (SWIFT) was a prospective clinical trial carried out at two medical centers. Patients hospitalized with advanced HF symptoms and reduced left ventricular ejection function (LVEF) were enrolled and prescribed a WCD prior to discharge for a total of 3 months. Outcome measures included arrhythmic events, WCD discharge, and death. Study patients (n = 75, mean age 51 ± 14 years, 31% women) had a mean LVEF of $21.5 \pm 10.4\%$. Non-ischemic cardiomyopathy was present in 66% of patients. The median WCD wearing time was 59 (interquartile range 17–97) days, and 80% of patients wore the device >50% of daily hours. WCD interrogations showed a total of 8 arrhythmic events in 5 patients, including 3 nonsustained or self-terminating ventricular tachycardia (VT) events, and one polymorphic VT successfully terminated by the WCD. None of the patients died while wearing the device and no inappropriate device therapies occurred. Upon termination of treatment with the WCD, 21 patients (28%) received an ICD. At 3 years, the cumulative death rate was 20% in the ischemic and 21% in non-ischemic cardiomyopathy patients.

Conclusion: A management strategy incorporating the WCD can be safely used to bridge the decision regarding the need for ICD implantation in high-risk patients with advanced HF.

RESEARCH ARTICLE

Open Access



The wearable cardioverter defibrillator as a bridge to reimplantation in patients with ICD or CRT-D-related infections

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Abstract

Background: The approach to treat device infection in patients with implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) is a challenging procedure. Optimal treatment is complete extraction of the infected device. To protect these patients from sudden cardiac arrest while waiting for reimplantation and to avoid recurrent infection, a wearable cardioverter defibrillator (WCD) seems to be a valuable solution. Therefore, we investigated the management and outcome of patients with ICD or CRT-D infections using the WCD as a bridge to re-implantation after lead extraction procedures.

Methods: We conducted a retrospective study on consecutive patients who underwent ICD or CRT-D removal due to device-related local or systemic infections. All patients were prescribed a WCD at our center between 01/2012 and 10/2015. All patients returned to our outpatient clinic for regular ICD or CRT-D monitoring initially 1 and 3 months after reimplantation followed by 6-months intervals.

Results: Twenty-one patients (mean age 65.0 ± 8.0 years, male 76.2%) were included in the study. Complete lead extraction was achieved in all patients. While waiting for reimplantation one patient experienced a symptomatic episode of sustained ventricular tachycardia. This episode was converted successfully into sinus rhythm by a single 150 J shock. Mean follow-up time 392 ± 206 days, showing survival rate of 100% and freedom from reinfection in all patients.

Conclusion: The WCD seems to be a valuable bridging option for patients with ICD or CRT-D infections, showing no recurrent device infection.

Keywords: Wearable cardioverter defibrillator, CIED-infection, ICD infection, Sudden cardiac arrest, Lead/ device extraction, Ventricular tachycardia

Table 1 Baseline and clinical characteristics

Patients	(n = 21)
Demographics	
Age, years	65 ± 8
Male gender, n (%)	16 (76.2)
Medical history	
Renal failure, n (%)	7 (33.3)
Diabetes mellitus, n (%)	9 (42.85)
Coronary artery disease, n (%)	11 (52.4)
Symptoms	
Pocket infection, n (%)	14 (66.7)
Systemic infection, n (%)	7 (33.3)
Laboratory	
Leucocytes billion/l	8.7 ± 2.2
C-reactive protein mg/l	66.0 ± 61

Continuous variables are expressed as mean ± standard deviation and categorical are expressed by values and percentages

Table 2 Device characteristics

Devices	(n = 21)
Indication for implantation	
Ischemic cardiomyopathy, n (%)	7 (33.3)
Non-ischemic cardiomyopathy, n (%)	14 (66.7)
Long QT syndrome, n (%)	1 (4.8)
ARVC, n (%)	2 (9.5)
Secondary prophylaxis, n (%)	11 (52.4)
Explanted	
WI-ICD, n (%)	5 (23.8)
DDD-ICD, n (%)	6 (28.6)
CRT-D, n (%)	10 (47.6)
Reimplanted	
WI-ICD, n (%)	6 (28.6)
DDD-ICD, n (%)	3 (14.3)
CRT-D, n (%)	9 (42.8)
S-ICD, n (%)	3 (14.3)
Time to re-implantation, days	51.6 ± 16.9

ARVC Arrhythmogenic right ventricular cardiomyopathy

Continuous variables are expressed as mean ± standard deviation and categorical are expressed by values and percentages

Ortalama tekrar implantasyon zamanı 51,6 + 16,9 (29-108) gün

Hastaların CRP ve lökosit sayıları normal aralıkta ve 3 kan kültürü negatif ise tekrar cihaz implantasyonu planlanmıştır.

Giyilebilen defibrilatör tedavisi altında bir hastada cihaz çıkarıldıktan 6 hafta sonra sustained ventriküler taşikardi başarılı bir şekilde tedavi edilmiştir.

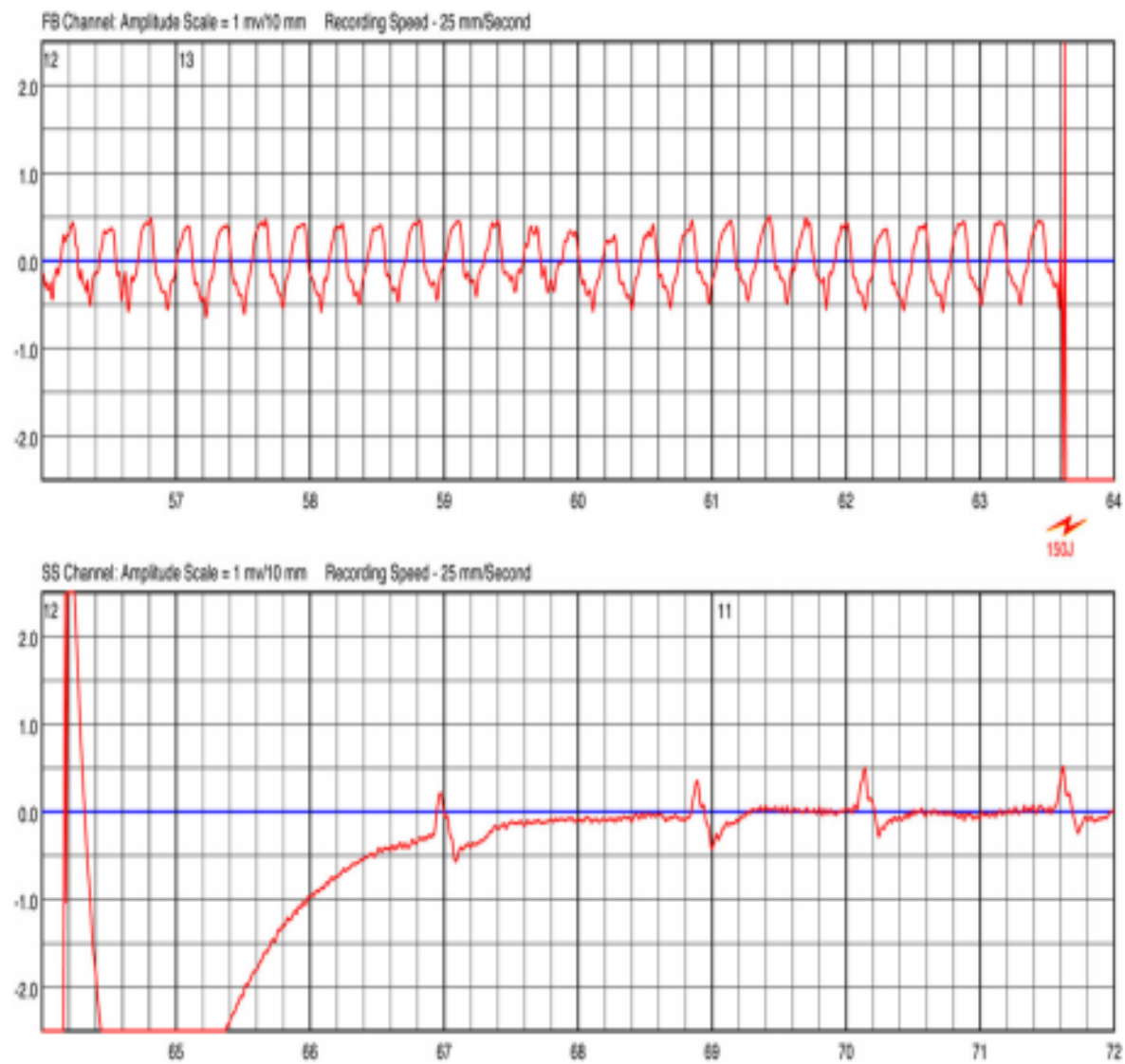


Fig. 1 Successful wearable cardioverter defibrillator shock (150 J)

Avoiding Untimely Implantable Cardioverter/Defibrillator Implantation by Intensified Heart Failure Therapy Optimization Supported by the Wearable Cardioverter/Defibrillator—The PROLONG Study

David Duncker, MD; Thorben König, MD; Stephan Hohmann, MD; Johann Bauersachs, MD; Christian Veltmann, MD

Background—Optimal timing of implantation of an implantable cardioverter/defibrillator (ICD) after newly diagnosed heart failure is unclear given that late reverse remodelling may occur. We aimed to analyze left ventricular ejection fraction (LVEF) after diagnosis of an LVEF $\leq 35\%$ during optimization of heart failure drug therapy.

Methods and Results—One hundred fifty-six patients with newly diagnosed LVEF $\leq 35\%$ receiving a wearable cardioverter/defibrillator (WCD) were analyzed. WCD was prescribed for 3 months until first re-evaluation. Indications for prolongation of WCD wearing period instead of ICD implantation were: (1) LVEF at 3-month visit 30% to 35%; (2) increase in LVEF of $\geq 5\%$ compared to the last visit; and (3) nonoptimized heart failure medication. Mean LVEF was $24 \pm 7\%$ at diagnosis and $39 \pm 11\%$ at last follow-up (mean, 12 ± 10 months). Whereas 88 patients presented a primary preventive ICD indication (LVEF $\leq 35\%$) at 3-month follow-up, only 58 showed a persistent primary preventive ICD indication at last follow-up. This delayed improvement in LVEF was related to nonischemic origin of cardiomyopathy, New York Heart Association functional class at baseline, heart rate, better LVEF after 3 months, and higher dosages of mineralocorticoid receptor antagonist. Twelve appropriate WCD shocks for ventricular tachycardia/ventricular fibrillation occurred in 11 patients. Two patients suffered from ventricular tachycardia/ventricular fibrillation beyond 3 months after diagnosis.

Conclusions—A relevant proportion of patients with newly diagnosed heart failure shows recovery of LVEF $> 35\%$ beyond 3 months after initiation of heart failure therapy. To avoid untimely ICD implantation, prolongation of WCD period should be considered in these patients to prevent sudden cardiac death while allowing left ventricular reverse remodeling during intensified drug therapy. (*J Am Heart Assoc.* 2017;6:e004512. DOI: 10.1161/JAHA.116.004512.)

Key Words: heart failure • sudden cardiac death • ventricular remodelling • wearable cardioverter/defibrillator

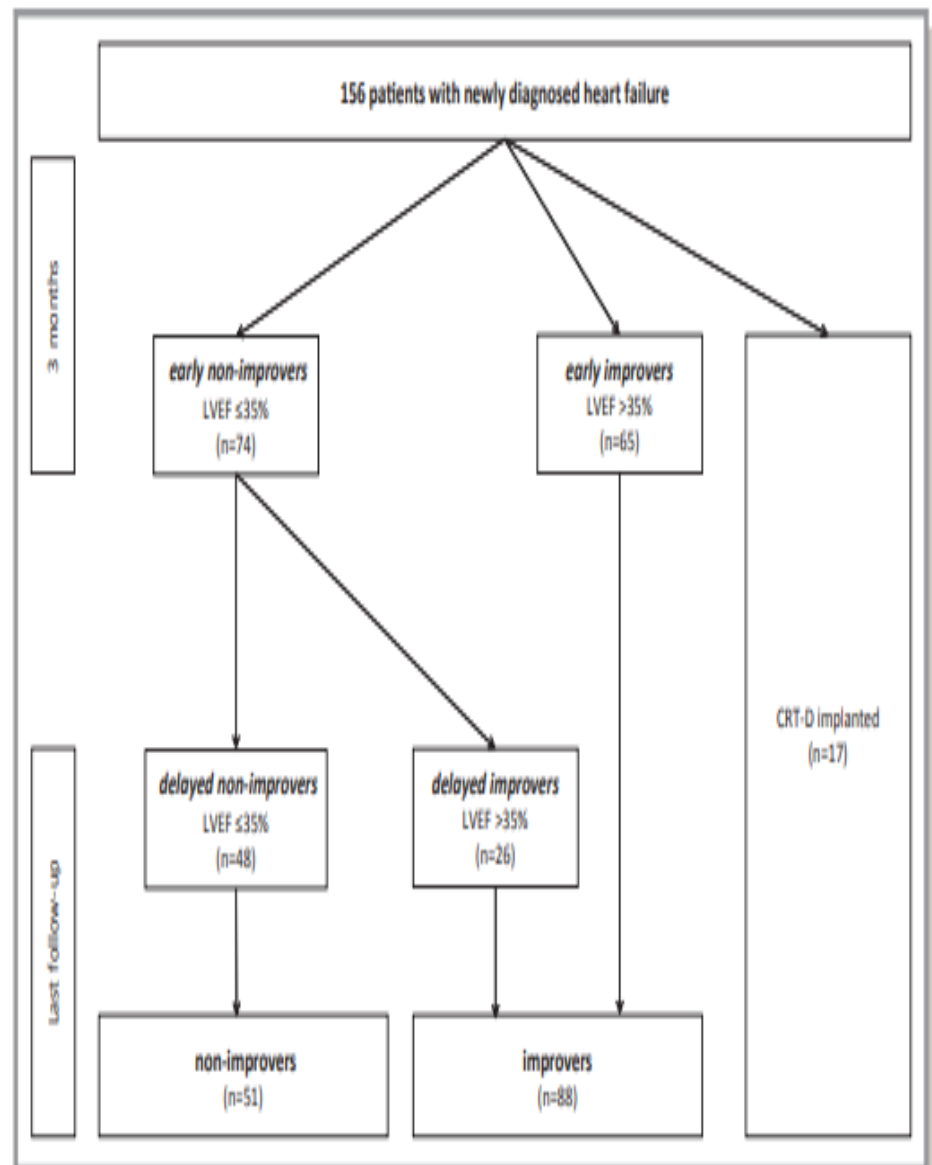
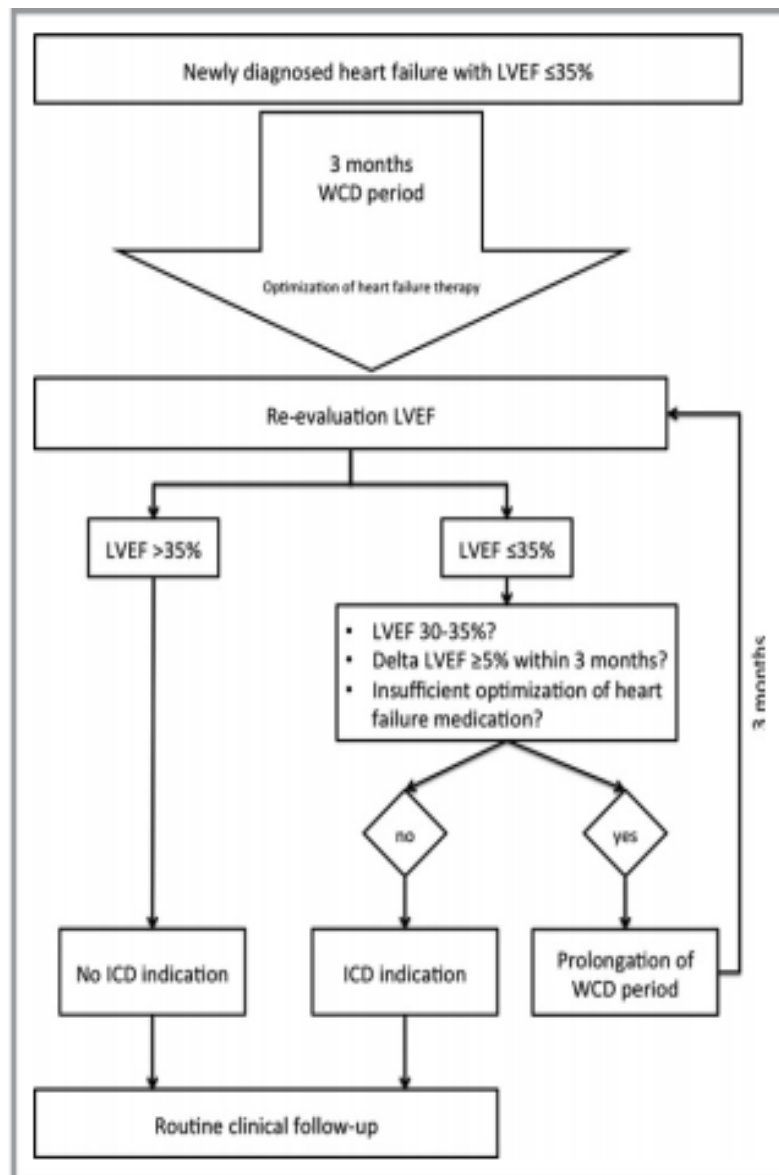


Table 1. Baseline Characteristics and 3 Months Follow-up Data of the Study Cohort

	Baseline (n=156)	3 Months Follow-up (n=153)	P Value
NYHA	2.8±0.7	2.0±0.5	<0.001
LVEF, %	24±7	35±10	<0.001
LVEF ≤35%, n (%)	167 (100)	89 (58)	
Δ LVEF from baseline, %	—	11±11	
Rhythm, n (%)			0.486
Sinus	136 (87)	138 (90)	
AF	19 (13)	13 (8)	
Other	1 (1)	2 (1)	
Heart rate, bpm	80±18	69±14	<0.001
QRS, ms	112±26	115±27	0.081
Beta-blocker			
N (%)	149 (96)	145 (95)	1.000
Dosage (% from target dose)	47±26	63±30	<0.001
RAS antagonist			
N (%)	151 (97)	152 (99)	0.250
Dosage (% from target dose)	45±25	65±29	<0.001
MRA			
N (%)	140 (90)	136 (89)	0.791
Dosage (% from target dose)	49±21	55±27	0.001
Diuretics, n (%)	130 (83)	123 (80)	0.388
Ivabradine			
N (%)	37 (24)	31 (20)	0.146
Dosage (% from target dose)	78±12	76±14	0.274
Digitalis, n (%)	19 (12)	14 (9)	0.227

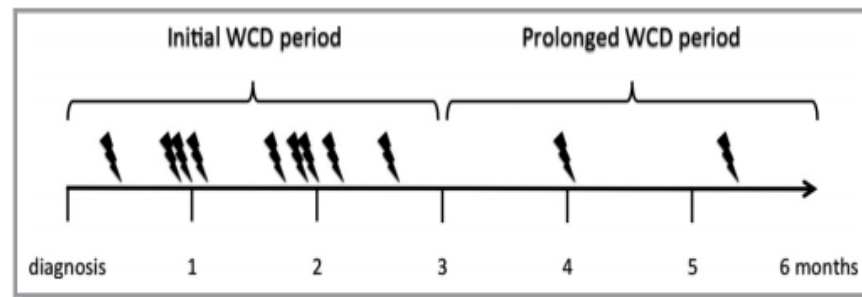
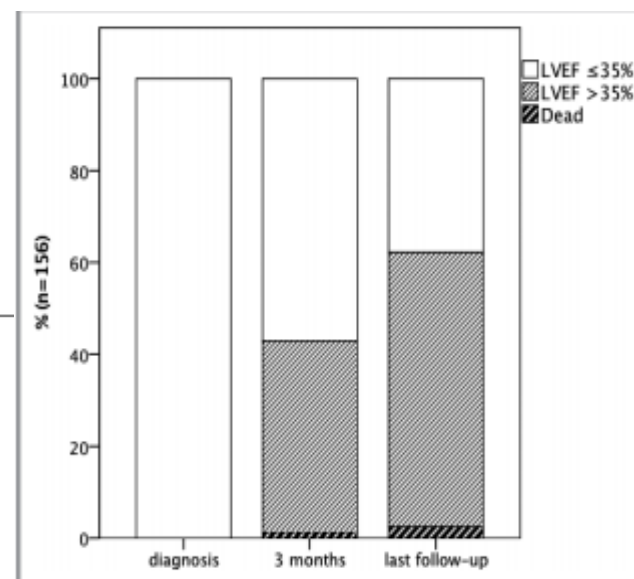


Figure 6. Occurrence of ventricular tachyarrhythmia episodes during early and prolonged WCD period in 11 patients. Note that patients showed life-threatening arrhythmias in both periods.

Prolong çalışması ile;

Yeni tanı konulmuş kalp yetersizliği hastalarında uzamış 6 ay giyilebilir defibrilatör tedavisi yapılarak, optimal ilaç tedavisi alan hastalarda sol ventrikül remodelingine izin vererek, ani ölüme karşı önlem alınabileceği gösterilmiştir. Çünkü hastalar erken ve geç remodeling döneminde hala risk altındadırlar.



Extended use of the wearable cardioverter-defibrillator in patients at risk for sudden cardiac death

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Aims

Data on outcomes in patients using the wearable cardioverter-defibrillator (WCD) > 90 days are limited. We aimed to analyse the clinical course of patients with WCD use ≤ 90 days vs. WCD use > 90 days.

Methods and results

We assessed arrhythmia events during WCD use, and ejection fraction (EF) improvement/implantable cardioverter-defibrillator (ICD) implantation at the end of WCD use in patients with WCD use ≤ 90 days vs. WCD use > 90 days enrolled in the WEARIT-II registry, further assessed by disease aetiology (ischaemic vs. non-ischaemic vs. congenital/inherited heart disease). There were 981 (49%) patients with WCD use > 90 days, and 1019 patients with WCD use ≤ 90 days (median 120 vs. 55 days). There was a lower incidence of sustained ventricular tachycardia/ventricular fibrillation (VT/VF) events (11 vs. 50 events per 100 patient-years, $P < 0.001$), WCD treated VT/VF events (1 vs. 8 events per 100 patient-years, $P < 0.001$), and non-sustained VT events (21 vs. 51 events per 100 patient-years, $P = 0.008$) with WCD use > 90 vs. WCD use ≤ 90 days. Non-ischaemic cardiomyopathy patients presented with similar rates of sustained VT/VF events during WCD use > 90 vs. ≤ 90 days (13.4 vs. 13.7 events per 100 patient-years, $P = 0.314$), while most of these events terminated spontaneously. One-third of the patients with extended WCD use further improved their EF and they were not implanted with an ICD, with similar rates among ischaemic and non-ischaemic patients.

Conclusions

In WEARIT-II, patients with extended WCD use > 90 days remain at risk for ventricular arrhythmia events. One-third of the patients with WCD use > 90 days further improved their EF, avoiding the need to consider ICD implantation.

Keywords

Wearable cardioverter-defibrillator • Extended use • Sudden cardiac death • Outcomes

Table 1 Baseline clinical characteristics by WCD use ≤ 90 days

Demographics	WCD ≤ 90 days	WCD > 90 days	P-value
Number of patients	1019	981	
Aetiology: ischaemic (ICM)	434 (43)	371 (38)	0.03
Non-ischaemic (NICM)	434 (43)	493 (50)	<0.001
Congenital/inherited (C/I)	151 (15)	117 (12)	0.057
Age	63 (16)	61 (17)	0.011
Female gender	302 (30)	296 (30)	0.79
White race	901 (88)	790 (81)	<0.001
Ejection fraction	30 (15)	25 (15)	0.015
Hispanic	31 (3)	41 (4)	0.39
Daily use (h)	22.2 (2.6)	22.5 (3.3)	0.001
Heart failure at baseline	481 (47)	559 (57)	<0.001
Atrial fibrillation	316 (31)	241 (25)	0.001
Hypertension	635 (62)	573 (58)	0.07
Hyperlipidaemia	539 (53)	456 (46)	0.004
Diabetes	296 (29)	255 (26)	0.12
Renal disease	79 (8)	83 (8)	0.56
Myocardial infarction	479 (47)	406 (41)	0.011
Percutaneous coronary angioplasty	335 (33)	275 (28)	0.019
CABG	183 (18)	139 (14)	0.021
Cardiomyopathy	434 (43)	465 (47)	0.031
Aldosterone antagonist	243 (24)	318 (32)	<0.001
ACE-I/ARB	714 (70)	768 (78)	<0.001
Beta-blockers	871 (85)	859 (88)	0.17
Amiodarone	142 (14)	117 (12)	0.18

Data are expressed as number and percentages and median and interquartile ranges. P-values <0.05 are highlighted in bold.

ACE-I, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; CABG, coronary artery bypass grafting; C/I, congenital or inherited condition; ICM, ischaemic cardiomyopathy; NICM, non-ischaemic cardiomyopathy; WCD, wearable cardioverter-defibrillator.

Table 2 Arrhythmia events during WCD use by ≤ 90 days vs. >90 days

Event	Patients, n (%)	Events (mean events/ patient)	Event rate per 100 patient-years	P-value for ≤ 90 days vs. >90 days
WCD use ≤ 90 days				
All sustained VT/VF	28 (2.7)	76 (2.7)	50	<0.001
Sustained VT no treatment	12 (1.2)	49 (4.1)	32	0.008
Sustained VT treated	19 (1.9)	27 (1.4)	18	<0.001
NSVT	12 (1.2)	78 (6.5)	51	0.030
WCD use >90 days				
All sustained VT/VF	13 (1.3)	44 (3.4)	11	<0.001
Sustained VT no treatment	10 (1.0)	41 (4.1)	10	0.008
Sustained VT treated	3 (0.3)	3 (1)	1	<0.001
NSVT	16 (1.6)	86 (5.4)	21	0.030

P-values <0.05 are highlighted in bold.

NSVT, non-sustained ventricular tachycardia; VT/VF, ventricular tachycardia/ventricular fibrillation; WCD, wearable cardioverter-defibrillator.

Table 3 Ventricular arrhythmia events during WCD use ≤90 days by aetiology

	Patients, n (%)	Events (mean events/ patient)	Event rate per 100 patient-years	P-value for ≤90 days vs. >90 days
Ischaemic cardiomyopathy				
All sustained VT/VF	17 (4.6)	37 (2.2)	56.8	0.001
Sustained VT no treatment	6 (1.6)	23 (3.8)	35.3	0.074
Sustained VT treated	13 (3.5)	14 (1.1)	21.5	<0.001
NSVT	3 (0.8)	39 (13)	59.8	0.063
Non-ischaemic cardiomyopathy				
All sustained VT/VF	5 (1.2)	9 (1.8)	13.7	0.314
Sustained VT no treatment	2 (0.5)	6 (3.0)	9.1	0.543
Sustained VT treated	3 (0.7)	3 (1.0)	4.6	0.055
NSVT	5 (1.2)	22 (4.4)	33.5	0.541
Congenital/inherited heart disease patients				
All sustained VT/VF	6 (4)	30 (5.0)	135.9	0.003
Sustained VT no treatment	4 (2.7)	20 (5.0)	90.6	0.013
Sustained VT treated	3 (2)	10 (3.3)	45.3	n.a.
NSVT	4 (2.6)	17 (4.3)	77.0	0.043

P-values < 0.05 are highlighted in bold.
NSVT, non-sustained ventricular tachycardia; VT/VF, ventricular tachycardia/ventricular fibrillation; WCD, wearable cardioverter-defibrillator.

Table 4 Ventricular arrhythmia events during WCD use >90 days by aetiology

	Patients, n (%)	Events (mean events/ patient)	Event rate per 100 patient-years	P-value for ≤90 days vs. >90 days
Ischaemic cardiomyopathy				
All sustained VT/VF	7 (1.9)	16 (2.3)	10.6	0.001
Sustained VT no treatment	5 (1.3)	2 (0.4)	1.3	0.074
Sustained VT treated	2 (0.5)	14 (7)	9.3	<0.001
NSVT	5 (1.3)	12 (2.4)	7.9	0.063
Non-ischaemic cardiomyopathy				
All sustained VT/VF	5 (1)	27 (5.4)	13.4	0.314
Sustained VT no treatment	4 (0.8)	26 (6.5)	12.9	0.543
Sustained VT treated	1 (0.2)	1 (1.0)	0.5	0.055
NSVT	7 (1.4)	69 (9.9)	34.3	0.541
Congenital/inherited heart disease patients				
All sustained VT/VF	1 (0.9)	1 (1)	2.0	0.003
Sustained VT no treatment	1 (0.9)	1 (1)	2.0	0.013
Sustained VT treated	0 (0)	0 (0.0)	0.0	n.a.
NSVT	4 (3.4)	5 (1.3)	10.1	0.043

P-values < 0.05 are highlighted in bold.

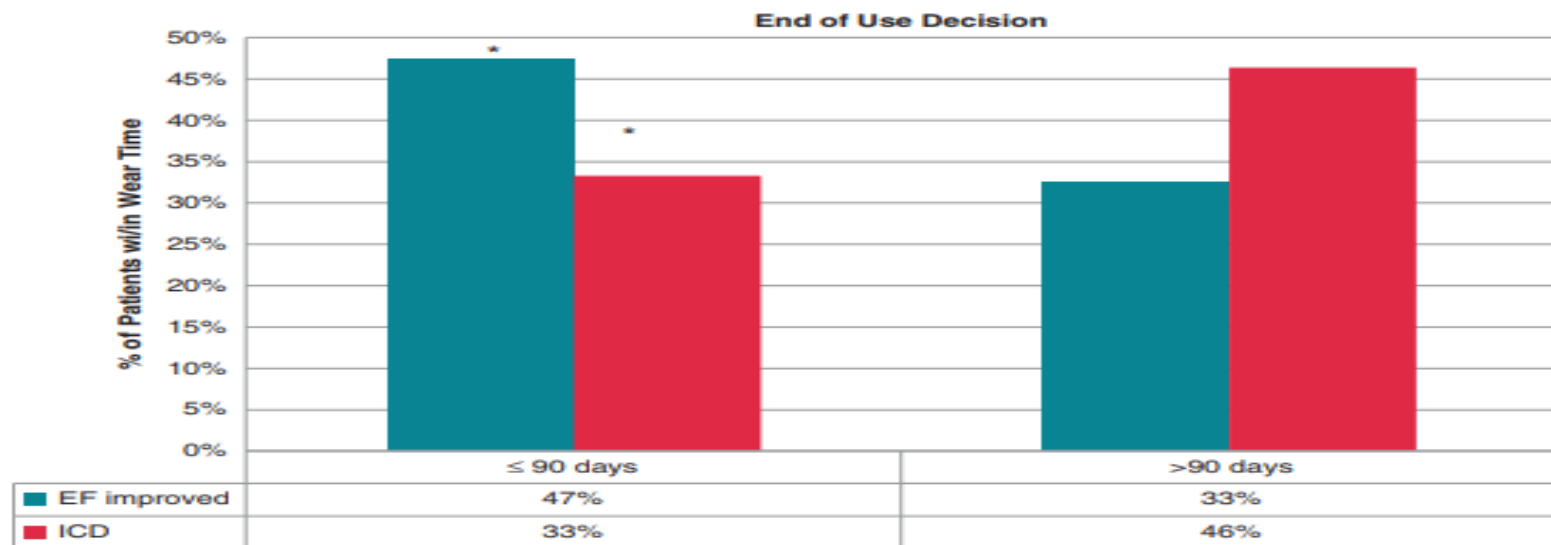


Figure 2 Clinical outcomes at the end of WCD use by duration of WCD use. * $P < 0.001$ for end of use category for patients with ≤ 90 days of total wear vs. > 90 days of total wear. EF, ejection fraction; ICD, received implantable cardioverter-defibrillator; WCD, wearable cardioverter-defibrillator.

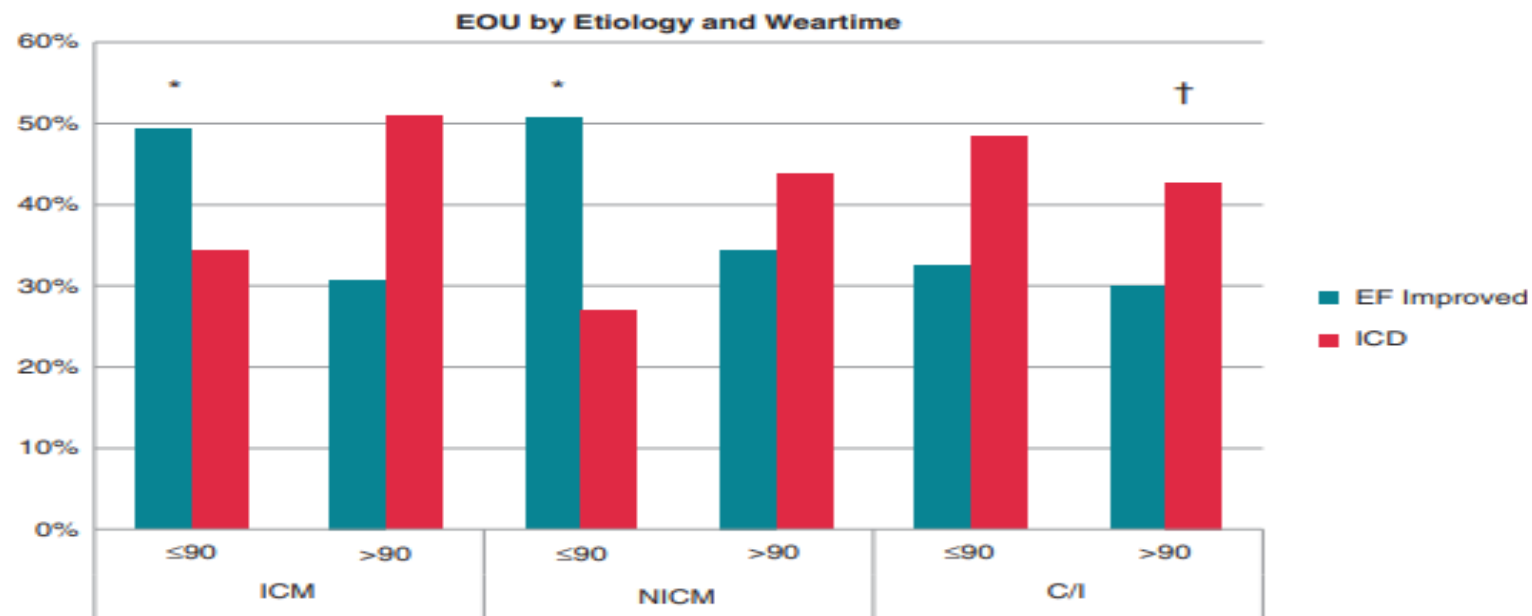


Figure 3 Clinical outcomes at the end of WCD use by the duration of WCD use and by disease aetiology. * P -value < 0.001 for ≤ 90 vs. > 90 total days wear time. † P -value < 0.001 in the ≤ 90 days wear time group for EOU by disease aetiology. C/I, congenital or inherited heart disease; EF, ejection fraction; EOU, end of use; ICD, implantable cardioverter-defibrillator; ICM, ischaemic cardiomyopathy; NICM, non-ischaemic cardiomyopathy; WCD, wearable cardioverter-defibrillator.

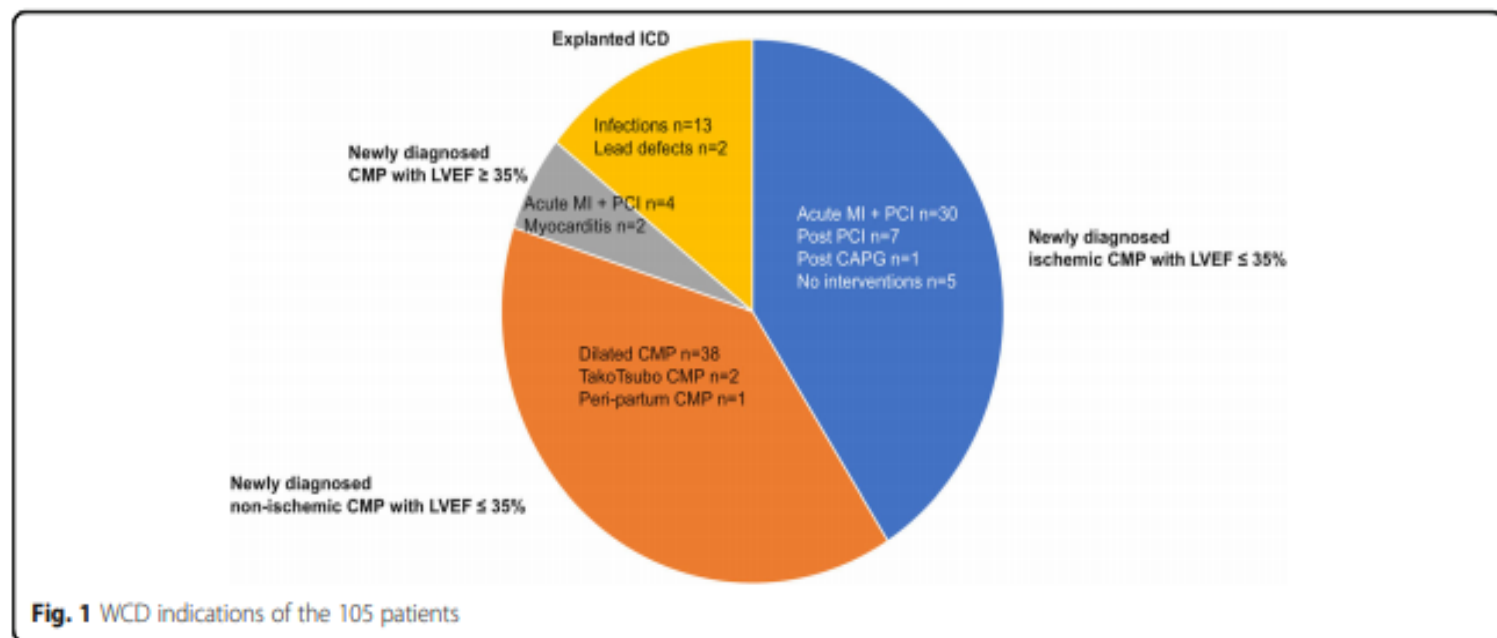
RESEARCH ARTICLE

Open Access



Therapy optimization in patients with heart failure: the role of the wearable cardioverter-defibrillator in a real-world setting

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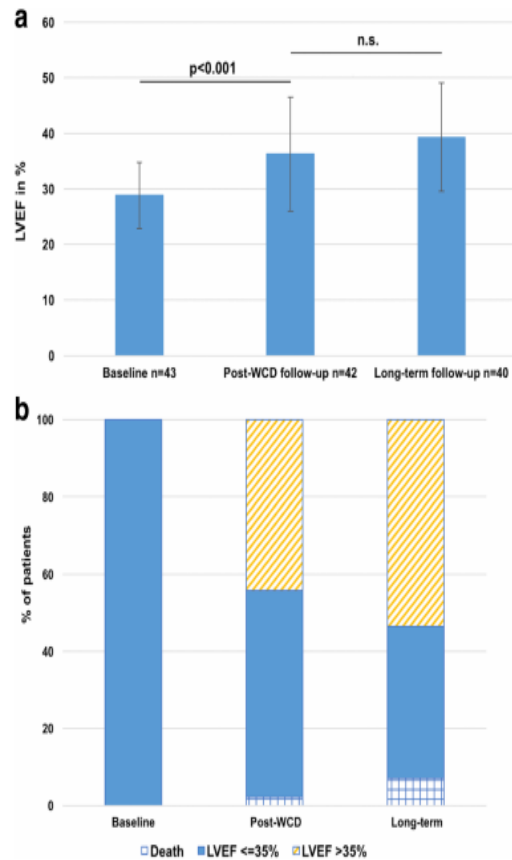


Fig. 2 a Evolution of LVEF during follow-up in patients with newly diagnosed ICM with LVEF $\leq 35\%$ (mean $\pm$ SD). b Evolution of LVEF/ICD indication in patients with newly diagnosed ICM with LVEF $\leq 35\%$

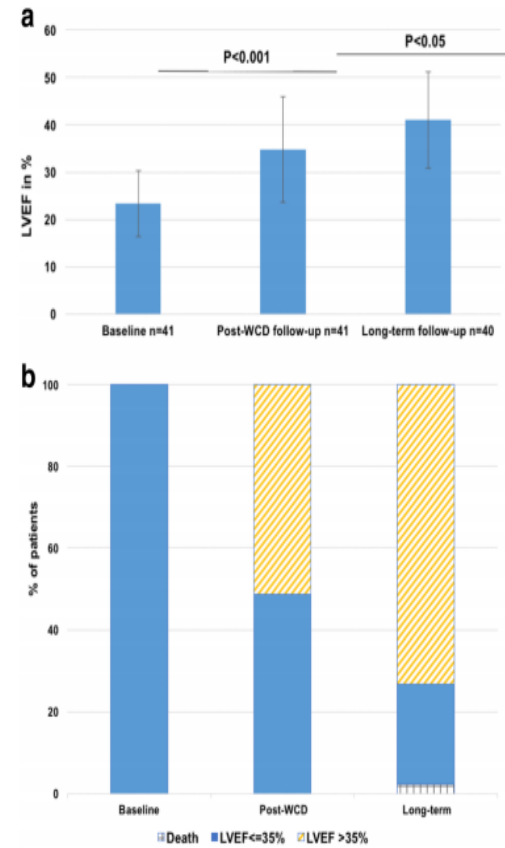
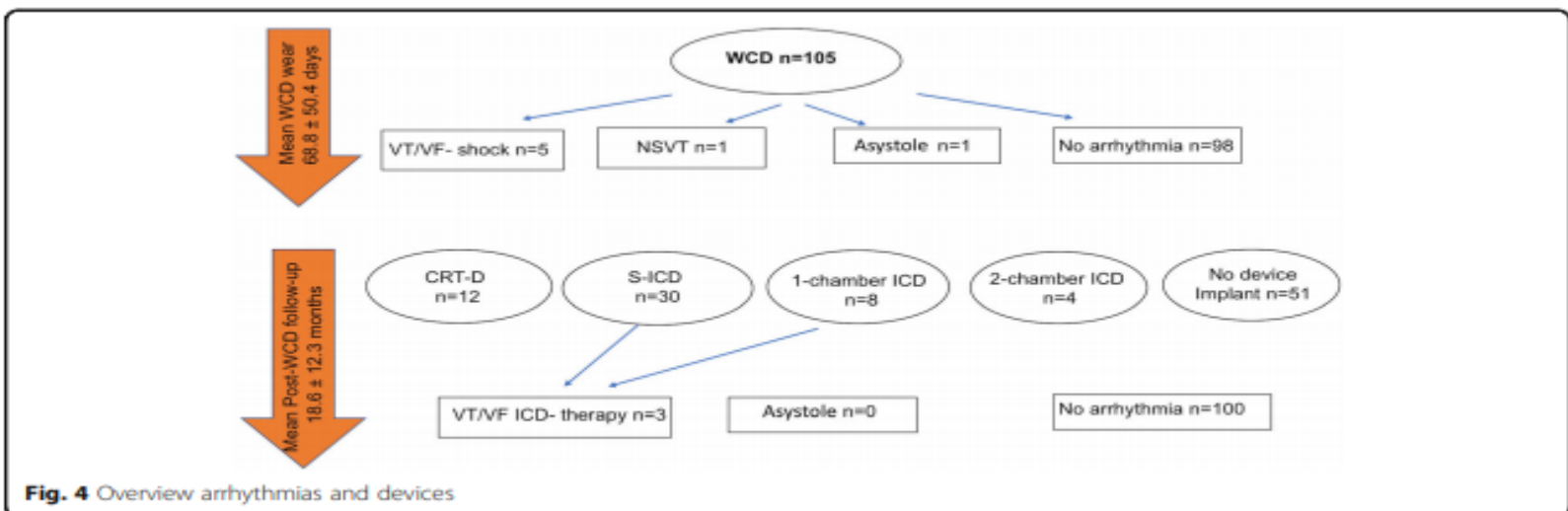


Fig. 3 a Evolution of LVEF during follow-up in patients with newly diagnosed NICM with LVEF $\leq 35\%$ (mean $\pm$ SD). b Evolution of LVEF/ICD indication in patients with newly diagnosed NICM with LVEF $\leq 35\%$

Table 3 Characteristics of patients with appropriate WCD shocks

Patient, Age	Indication for WCD	Baseline LVEF	Shock days from start of WCD	Type of arrhythmia	1.Shock successful	Time to shock
Male, 64	ICM STEMI, PCI RCA	35%	72	VF	yes	54 s
Male, 50	ICM STEMI, PCI LAD	25%	3	VF	yes	46 s
Male, 45	Dilated CMP Previous explant of primary preventive trans-venous ICD	30%	67	VF	yes	49 s
Male, 71	ICM WCD because of systemic infection that precluded ICD implant	20%	154	VT with heart rate 180/min	yes	69 s
Female, 26	Myocarditis	53%	38	VF	yes	63 s

WCD = wearable cardioverter-defibrillator, PCI = percutaneous coronary intervention, VT = ventricular tachycardia, VF = ventricular fibrillation, LVEF = left ventricular ejection fraction, ICM = ischemic cardiomyopathy, sec = seconds





Role of the Wearable Defibrillator in Newly Diagnosed Heart Failure

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Abstract

Purpose of Review The wearable defibrillator (WCD) was shown to be safe and effective in detecting and terminating ventricular tachyarrhythmias and therefore allows temporary protection from sudden cardiac death. This review gives an overview of the current data on WCD in newly diagnosed cardiomyopathy.

Recent Findings Patients with newly diagnosed heart failure and reduced LVEF appear to have an increased risk of ventricular tachyarrhythmias, which may decrease over time when heart failure medication is optimized and left ventricular function improves. This was shown to apply for patients with ischemic and non-ischemic cardiomyopathy, including peripartum cardiomyopathy. Prolongation of the WCD period may support to further optimization of heart failure medication, by protecting the patient from sudden cardiac death during this time and to avoid untimely ICD implantation.

Summary The WCD should be considered in structured patient management for newly diagnosed heart failure during the early phase of the disease. Careful patient selection, structured patient management, and patient's compliance is crucial for a successful WCD strategy.

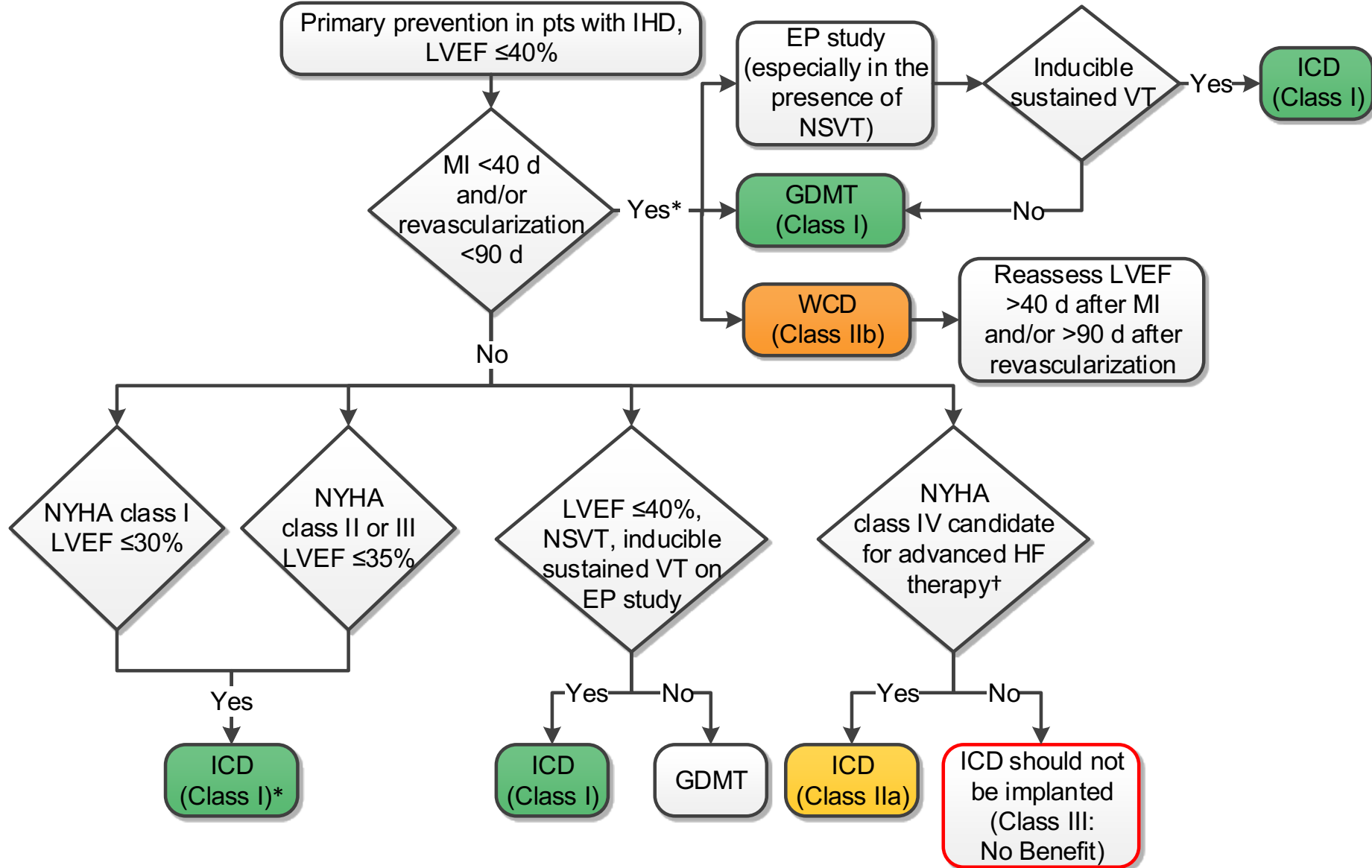
Keywords Wearable defibrillator · Newly diagnosed cardiomyopathy · Heart failure · Sudden cardiac death

Güncel Kılavuzlar Ne Öneriyor?

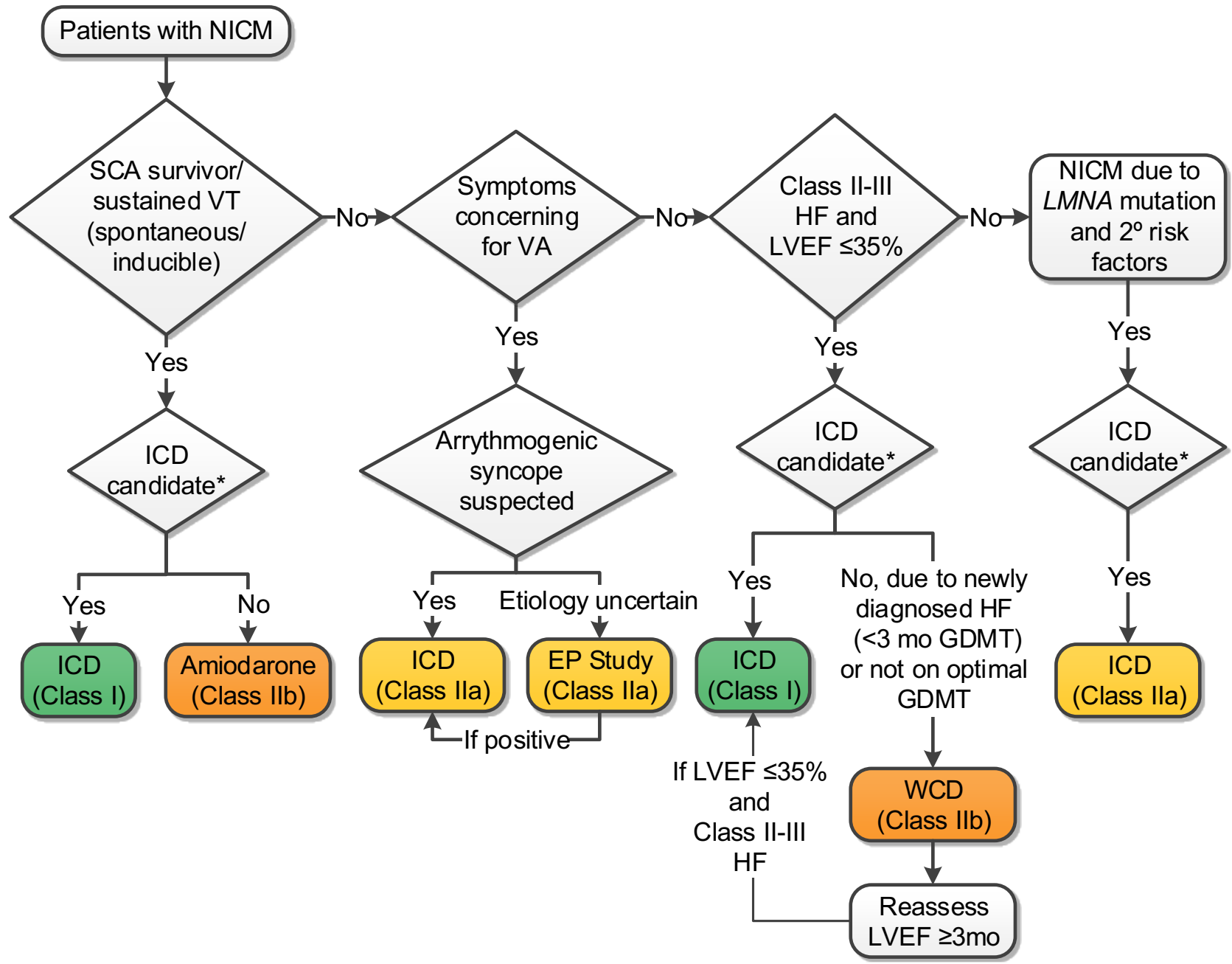
2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death



İskemik Kalp Hastalığında AKÖ – Primer Koruma



Non-iskemik KMP AKÖ – Primer ve Sekonder Koruma



WCD İçin Potansiyel Endikasyonlar

Enfeksiyon ve Ekstraksiyon

- ✦ ICD implantasyonu –enfeksiyon $\approx 1\%$ ve $> 2\%$ jeneratör replasmanı
- ✦ Enfeksiyonu elimine etmek için tüm sistemin çıkarılması gerekiyor
- ✦ Çıkarım- yeniden implantasyon sırasındaki gecikme !
- ✦ Eğer gecikme uzayacak ise ya da hasta AKÖ açısından yüksek riskli ise
WCD düşünülebilir -- Sınıf IIa

WCD İçin Potansiyel Endikasyonlar

Bilinmeyen Kardiyak Prognoz

- ✦ Peripartum Kardiyomiyopati
- ✦ Miyokarditler
- ✦ Katekolaminlerin indüklediği miyokardiyal hasar
- ✦ Taşikardiyomyopati
- ✦ Tiroid ile ilişkili kardiyomyopati
- ✦ Kemoterapi ile ilişkili kardiyomyopati

Köprü tedavi olarak AKÖ riski yüksek ise düşünülebilir

Table I Current recommendations on the use of wearable cardioverter defibrillators (WCDs)

Indication	Class	Level of evidence
AHA advisory: endorsed by the Heart Rhythm Society (2016)		
Use of WCDs is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection	IIa	C
Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation	IIa	C
Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or with treatment of left ventricular dysfunction; for example, in ischemic heart disease with recent revascularization, newly diagnosed non-ischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc.) in which the underlying cause is potentially treatable	IIb	C
WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 days of MI	IIb	C
WCDs should not be used when non-arrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 months	III	C
ESC guidelines (2015)		
The WCD may be considered for adult patients with poor LV systolic function who are at risk of 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)	IIb	C

Giyilebilen kardiyoverter-defibrilatör

Hangi durumlarda köprü olarak kullanılmakta??

- Post-MI hastalar
- Koroner revaskülarizasyon sonrası
- Yeni tanı dilate non-iskemik KMP
- Peripartum kardiyomiyopati
- Kalıtsal aritmik ya da konjenital hastalıklar

Sonuç olarak...

- ✦ AKÖ potansiyel olarak önlenabilir ölüm nedenlerindendir
- ✦ Mevcut defibrilatör tedavilerin kısıtlılıkları ve riskleri mevcuttur
- ✦ Geçici AKÖ riski olan hastalarda giyilebilen defibrilatörler aritmik ölümleri önlemede geçici bir çözüm sunar
- ✦ Giyilebilen defibrilatörler tedavisinde hasta seçimi ve bilgilendirilmesi önemlidir

TEŞEKKÜRLER