IJC Heart & Vasculature 41 (2022) 101066

Contents lists available at ScienceDirect

IJC Heart & Vasculature

journal homepage: www.sciencedirect.com/journal/ijc-heart-and-vasculature

Usage of the wearable cardioverter-defibrillator during pregnancy

J.-Jacqueline Olic [a,1], Claudia Stöllberger [b], Christoph Schukro [c], Katja E. Odening [d], Edith Reuschel [e], Marcus Fischer [a], Christian Veltmann [f], David Duncker [f], Andrea Baessler [a,1,*]

[a] Department of Cardiology, University Hospital of Regensburg, Regensburg, Germany
[b] Department of Cardiology, Hospital Rudolfstiftung, Vienna, Austria
[c] Department for Cardiac Surgery, Medical University of Vienna, Vienna, Austria
[d] Translational Cardiology, Department of Cardiology and Institute of Physiology, University Hospital Bern, University of Bern, Switzerland
[e] University Department of Obstetrics and Gynecology At The Hospital St. Hedwig of The Order of St. John, University of Regensburg, 93049 Regensburg, Germany
[f] Hannover Heart Rhythm Center, Department of Cardiology and Angiology, Hannover Medical School, Hannover, Germany

ARTICLE INFO

Keywords:
Wearable cardioverter-defibrillator
Pregnancy
Sudden cardiac death
Ventricular arrhythmias
Arrhythmias during pregnancy
Cardiomyopathy

ABSTRACT

Background: Pregnancy can trigger or aggravate the risk for life-threating arrhythmias in cardiac diseases. Pregnancy is associated with reluctance for implantable cardioverter-defibrillators (ICD) due to concerns about radiation. Thus, the wearable cardioverter-defibrillator (WCD) might be an option during pregnancy. Aim of the study was to collect experiences about the use of WCD in pregnancy.

Methods and results: This study retrospectively included eight women who received a WCD during pregnancy. They suffered from ventricular tachycardia (VT) without known cardiac disease (n = 3), Brugada syndrome (n = 1), hypertrophic cardiomyopathy (n = 1), dilated cardiomyopathy (n = 1), non-compaction (n = 1), and survived sudden cardiac arrest during a preceding pregnancy (n = 1). WCD usage was started between 13 and 28 weeks of gestation. WCD wearing period ranged from 3 days to 30.9 weeks, WCD wearing time ranged from 13.0 to 23.7 h per day. Two women (25%) abandoned WCD already during pregnancy. Neither appropriate nor inappropriate WCD shocks were recorded. Antiarrhythmic management included beta-blockers (n = 5) and flecainide (n = 2). After delivery, ICD were implanted (n = 4), refused (n = 2) and estimated not necessary after successful catheter ablation (n = 2).

Conclusion: Uneventful pregnancy is possible in women at risk for sudden cardiac death by interdisciplinary monitoring and diligent pharmacotherapy protected by the WCD. Since no WCD shocks were recorded, the effectiveness of WCD during pregnancy is still unclear. However, arrhythmia detection by WCD was very good despite the changed anatomy in pregnancy. Nevertheless, further studies are necessary to assess effectiveness of WCD in pregnant women. Furthermore, efforts should be made to increase the wearing adherence of WCD during pregnancy.

1. Introduction

Pregnancy in women with inherited or acquired heart disease represents a challenge for both cardiologists and obstetricians. Limited evidence in this specific group exists as women during pregnancy and childbirth had usually been excluded from participation in clinical trials, and thus, recommendations for the treatment of pregnant women with cardiovascular diseases are based only on expert opinion [1].

Pregnancy is associated with an increased vulnerability for fatal arrhythmias [2–4]. Ventricular tachyarrhythmias in hypertrophic (HCM), dilated (DCM), restrictive (RCM) and arrhythmogenic right ventricular cardiomyopathy (ARVC) and non-compaction (NCCM), can be triggered or aggravated during pregnancy [5–9]. Implantable cardioverter-defibrillators (ICD) improve survival in patients with life-threating cardiac arrhythmias. ICD implantation, however, is associated with risks like lead-associated thrombosis, infection and ventricular perforation [10]. ICD implantation during pregnancy has been reported in several cases [11,12]. Due to the necessity for radiation and anesthesia, there are, however, concerns about the procedure during pregnancy.

The wearable cardioverter-defibrillator (WCD; LifeVest, ZOLL,

* Corresponding author at: Department of Cardiology, University Hospital of Regensburg, Franz-Josef-Strauß-Allee 11, 93053 Regensburg, Germany.
E-mail address: andrea.baessler@ukr.de (A. Baessler).
[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

https://doi.org/10.1016/j.ijcha.2022.101066
Received 1 April 2022; Received in revised form 15 May 2022; Accepted 25 May 2022

Pittsburgh, USA) was introduced for temporary prevention of sudden cardiac death (SCD). It is used in patients in whom the risk for SCD is expected to be only temporarily or if ICD implantation is unsuitable [13,14]. During pregnancy, the WCD is a therapeutic option if a cardiac disease with susceptibility to arrhythmias is diagnosed or if there is deterioration of left ventricular ejection fraction (LVEF). So far, experiences with WCD have been reported mainly from women with peripartum cardiomyopathy (PPCM) in the post-delivery period [15–18]. To our knowledge, application of a WCD during pregnancy has been reported only from 13 patients with PPCM, whose clinical details, however, are not reported and from a patient with NCCM who refused an ICD [7,18].

Because of limited experiences with WCD during pregnancy, we report of eight pregnant women who have been temporarily equipped with a WCD.

2. Methods

In this bi-national multi-center retrospective case series, patients who received a WCD during pregnancy were included. Patients having received the WCD only after delivery were excluded. We contacted clinics in Germany and Austria with experience with the WCD by mail and telephone. If they had experience in managing pregnant women with a WCD between 01/2015 and 12/2021, these centers were invited to participate.

Data were collected retrospectively according to a preset questionnaire (Table S1, supplemental material) by the local participants and analysed in the department of cardiology at the university hospital in Regensburg.

All women remained under cardiologic, obstetric and anaesthesiologic monitoring during pregnancy and delivery, including echocardiography, ECG monitoring, assessment of pharmacotherapy, gynaecological investigations and early planning of delivery. All patients were instructed to wear the WCD continuously. The following arrhythmic events were registered with the remote monitoring system of ZOLL Patient Management Network: non-sustained ventricular tachycardia (nsVT), sustained ventricular tachycardia (VT) and ventricular fibrillation (VF). The LVEF was monitored by 2D-echocardiography.

Patients were followed up after delivery for the period of WCD therapy or for minimum two weeks.

The study was conducted in accordance with the Declaration of Helsinki and data analysis was approved by the local ethics committee of the university hospital in Regensburg.

All statistical analyses were performed using commercially available statistical software IBM SPSS Statistics Version 26.0.

3. Results

A total of 128 clinics throughout Germany and Austria were contacted. A response was received from 112 clinics (87.5%), and eight patients with WCD therapy during pregnancy from three German centers (four patients from Hannover Heart Rhythm Center, Department of Cardiology and Angiology, Hannover Medical School, Hannover, Germany, one patient form Department of Cardiology, University Hospital of Regensburg, Regensburg, Germany and one patient from Department of Cardiology, University Hospital of Freiburg, Freiburg, Germany) and one Austrian center (two patients from Department of Internal Medicine II, Division of Cardiology, Medical University of Vienna, Vienna, Austria) were included. One of the patients (patient 7) has been previously published [7]. Initiation of WCD usage was between 05/2015 and 06/2021.

3.1. Baseline characteristics

Baseline characteristics are shown in Table 1. All women became pregnant by spontaneous conception. Four patients (patients 1, 4, 6 and 7) were already suffering from known cardiac disease before pregnancy, as listed in Table 1. A further woman (patient 2) had been resuscitated because of cardiac arrest due to VF/VT in the course of a previous pregnancy five years before. In that woman, emergency cesarean section at 30 weeks of gestation (GW) had been carried out. Transthoracic echocardiography und cardiac computed tomography did not show any abnormal findings. Since the patient refused further investigations including magnetic resonance imaging of the heart, and idiopathic VF/

Table 1
Baseline characteristics and indication for WCD usage during pregnancy.

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8
Age at the beginning of pregnancy (years)	27	24	36	36	40	34	27	36
Parity (n)/Abort (n)	0/0	1/0	0/0	0/0	0/0	0/0	0/0	1/1
Pre-existing cardiac diseases	Brugada syndrome	none	none	HCM	none	DCM	NCCM	none
Arrhythmias before pregnancy	0	VF and VT	0	0	0	0	0	0
Pre-existing non-cardiac diseases:								
- *Arterial hypertension*	0	0	yes	0	0	yes	0	yes
- *Type 1 diabetes*	0	0	0	0	0	yes	0	0
- *Adiposity*	0	0	yes (BMI 35.9)	0	0	yes (BMI 33.7)	0	yes (38.3)
LVEF at beginning of pregnancy (%)	≥60	≥60	50	≥60	≥60	34	49	66
Indication for WCD	Brugada syndrome, bridging to ICD	Previous VF and VT, bridging to ICD	Sustained VTs despite therapy with flecainide and bisoprolol, bridging to VT ablation and ICD	HCM with nsVTs, bridging to ICD	Sustained VT, bridging to VT ablation	DCM with severely reduced LVEF < 35%, bridging to ICD	NCCM with decrease of LVEF and nsVTs, bridging to ICD	Sustained VT, bridging to VT ablation

BMI, body mass index; DCM, dilated cardiomyopathy; HCM, hypertrophic cardiomyopathy; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; NNCM, non-compaction; nsVT, non-sustained ventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia; WCD, wearable cardioverter/defibrillator.

VT was assumed. The further three patients (patients 3, 5 and 8) had no known pre-existing cardiac diseases with elevated risk for ventricular tachyarrhythmias but presented sustained VTs during their first months of pregnancy. In patient 3 the diagnosis of cardiac sarcoidosis was established only after delivery.

Three women had additional cardiovascular risk factors, as listed in Table 1.

3.2. WCD indication, pharmacotherapy and course of the pregnancies

Primary preventive protection by WCD was recommended in patient 1 with Brugada syndrome and increased risk for ventricular arrhythmias, patient 4 with HCM and nsVTs in Holter ECG, patient 7 with NCCM, nsVTs during Holter monitoring and decrease of LVEF from 49% to 38% during the second trimenon of pregnancy and patient 6 with DCM and severely reduced LVEF of 34% at the beginning of pregnancy (Table 1). Three further patients (patients 3, 5 and 8) presented with sustained VTs during their first months of pregnancy and were thus equipped with WCD. Patient 3 presented with scar-related VT. The other two women showed idiopathic VTs from the outflow tract. Patient 2 with cardiopulmonary resuscitation because of cardiac arrest during a preceding pregnancy received the WCD as secondary prevention (Table 1).

In addition to WCD usage, patients 3–7 received antiarrhythmic medication, as listed in Table 2A.

WCD usage was started between GW 13 and 28. Median cumulative WCD wearing time was 19.5 weeks (range 3 days to 30.9 weeks). Median daily WCD wearing time was 21.1 h (range 13.0–23.7 h). Three patients had a wearing adherence of <20 h/day, and two of them eventually refused the WCD because of personal reasons. In spite of intensive patient education, one woman (patient 6) was not aware of the possible consequences of their decision or rather she did not want to admit the possible consequences. Despite repeated enquiries, no detailed information about the reasons for discontinuation of the other patients were retrospectively obtained.

Neither appropriate nor inappropriate WCD shocks occurred. Patient 8 showed VTs from the right ventricular outflow tract (RVOT) which were haemodynamically tolerated, therefore no WCD shock was necessary. The patient stopped the shock-delivery with the response button and the detected VT terminated spontaneously. Because of haemodynamically well tolerated VTs and the patient's preference there was no clinical consequence of this event during pregnancy. Patient 3 had a scar-related VT (most likely due to the cardiac sarcoidosis diagnosed after delivery) which was haemodynamically tolerated, therefore no WCD shock was necessary. The patient stopped the shock-delivery with the response button and the VT terminated spontaneously. As consequence of this event, the dosage of flecainide was increased and the shock-delivery threshold of the WCD was changed from >180 to 200 beats per minute.

Additionally, in patients 4 and 7 nsVTs were recorded by the WCD. Especially, patient 7 showed recurrent nsVTs with maximum 22 consecutive ventricular beats.

All these VTs and nsVTs were correctly detected by the WCD. In patient 8 artefacts led to a warning signal prior to administration of a shock. Shock-delivery was stopped with the response button. All other artefacts or supraventricular tachycardias were properly detected by the WCD and did neither result in a warning signal nor in an inappropriate shock.

No patient developed any pregnancy complication, like gestosis, coagulation abnormalities and infections. Only patient 1 developed a gestational diabetes.

3.3. Delivery and follow-up

All women gave birth by cesarean section at a time when the medical staff of all involved departments was present (Table 2B). No arrhythmia occurred during delivery.

Postpartum echocardiography showed no deterioration of systolic function in women with previously normal or just slightly reduced LVEF. LVEF of the patient with DCM (patient 6) decreased further, as shown in Table 3 and remained severely reduced. LVEF of a woman with NCCM (patient 7) improved to pre-pregnancy conditions during the first month after delivery.

One woman (patient 2) suffered from an infection (a pilonidal cyst abscess with the need for surgical therapy) in childbed.

Median WCD wearing after delivery was 4.5 weeks (range 2.0–11.9 weeks). Four of the eight women (patients 1–4) consented with implantation of an ICD after delivery. In patients 5 and 8, ICD implantation

Table 2
Pregnancy and delivery in patients with WCD usage during pregnancy.

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8
(A) Pregnancy								
LVEF at initiation of WCD use (%)	≥60	≥60	50	≥60	≥60	34	38	66
GW at WCD initiation	28	13	16	14	28	15	25	19
Cumulative WCD wearing (weeks)	15.1	21.3	24.9	17.7 (refused further wearing)	22.9	0.4 (refused further wearing)	15.6	30.9
WCD wearing per day (hours)	13 0.0	22.0	data missing	17.8	23.7	14.0	21.1	23.1
Cardiac medication during pregnancy	0	0	yes	yes	yes	yes	yes	yes
- *Beta-blockers*	0	0	bisoprolol 5 mg/d	bisoprolol 10 mg/d	metoprolol 190 mg/d	metoprolol 190 mg/d	bisoprolol 5 mg/d	0
- *Other antiarrhythmic drugs*	0	0	flecainide 300 mg/d	0	flecainide 200 mg/d	0	0	0
- *Other antihypertensive drugs*	0	0	0	0	0	methyldopa 1500 mg/d	0	methyldopa 500 mg/d
Other medication during pregnancy	0	0	0	0	potassium 80 mmol/d	insulin	enoxaparin 4000 IE/d	levothyroxine
(B) Delivery								
GW at delivery	38	32	39	39	39	34	37	39
Complications during delivery	0	0	0	0	0	0	0	0

GW gestational week; LVEF, left ventricular ejection fraction; WCD, wearable cardioverter/defibrillator.

Table 3
Postpartum period in patients with WCD usage during pregnancy.

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8
LVEF after delivery (%)	≥60	≥60	50	≥60	≥60	26	46	66
WCD wearing time after delivery (weeks)	4.9	2.0	2.6	refused (already during pregnancy)	11.9	refused (already during pregnancy)	4.0	10.7
Significant arrhythmias after delivery	0	0	VTs	0	0	0	0	VTs
ICD implantation	4.9 weeks after delivery	2.0 weeks after delivery	2.6 weeks after delivery	14.9 weeks after delivery	0	0, refused	0, refused	0
Catheter ablation	0	0	2.0 weeks after delivery	0	7.9 weeks after delivery	0	0	10.7 weeks after delivery

ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; WCD, wearable cardioverter/defibrillator.

was no longer necessary after a successful catheter ablation of VTs. Implantation of an ICD was recommended but declined in the patient with NCCM and recurrent nsVTs (patient 7) and the patient with DCM and severely reduced LVEF (patient 6). No patient died during a follow-up period of 2.0–11.9 weeks postpartum.

3.4. Newborns

Clinical data were available from six of the eight newborns. Among them, only the neonate of the woman with DCM (patient 6) showed a reduced Apgar score with 7/8/8. More detailed characteristics of the newborns are listed in Table S2 (supplemental material).

4. Discussion

This retrospective study of WCD usage during pregnancy of women with an increased arrhythmic risk shows that all eight women had an uneventful pregnancy and delivery under close monitoring. In none of the patients an appropriate or inappropriate WCD shock occurred during pregnancy, delivery or after delivery. In two of the eight patients haemodynamically well tolerated VTs were recorded during pregnancy, but in both cases shock-delivery was stopped by the response button and VTs terminated spontaneously. Only in one case artefacts led to a warning signal prior to administration of a shock. Fortunately, shock-delivery was stopped with the response button. All other artefacts, supraventricular tachycardias and nsVTs were properly detected by the WCD and did not cause any inappropriate warning alarm. No ventricular arrhythmias were recorded during delivery. Daily WCD wearing time was between 13.0 and 23.7 h (median daily WCD wear time 21.1 h).

The use of the WCD during pregnancy has numerous advantages over ICD implantation.

In seven of the eight women, this was the first pregnancy with an initial diagnosis of a cardiac disease or aggravation of pre-existing cardiac disease during pregnancy. Therefore, bridging by a WCD until ICD implantation or catheter ablation of VTs scheduled soon after delivery was considered as necessary. Thus, WCD is useful to protect pregnant women in whom ICD implantation or catheter ablation needs to be postponed to avoid exposure to radiation and anesthesia during pregnancy.

WCD can also be used to protect women with only temporary increased risk for malignant arrhythmias, e. g. by a temporary decrease of LVEF occurring during pregnancy or changes in ECG during PPCM [19]. The physiological haemodynamic changes during pregnancy and cessation of heart failure medication may lead to a worsening of LVEF during pregnancy in women with preexisting cardiomyopathy. After delivery LVEF may recover under improved heart failure medication. Thus, WCD prescription can avoid untimely ICD implantation if LVEF improvement can be expected.

WCD usage in non-pregnant patients with newly diagnosed heart failure is already popular to avoid untimely ICD implantation [13,14,20–24]. A relevant proportion of patients with newly diagnosed heart failure shows improvement of LVEF after initiation and optimization of heart failure therapy [21,24] and also during long-term follow-up [20] according to underlying etiology [25]. Such a LVEF improvement can be expected in young women after delivery as well.

By the WCD-based remote rhythm monitoring, an interdisciplinary medical care could be facilitated. Furthermore, the WCD allows calculation of the heart rate variability (HRV). Although not addressed in our study, the HRV has been identified as an independent predictor for LVEF improvement [26]. Especially postpartum this could be a clinically relevant information to obviate untimely ICD implantation.

There are also relevant limitations of WCD usage in pregnancy.

One drawback of WCD usage is the dependence of protection against SCD from wearing adherence. Daily WCD wearing time of the eight women was similar or somewhat less than reported in the literature from non-pregnant patients [18,27–31]. The daily WCD wearing time varies depending on the patient group and decreases over time [30,31]. In our study three of eight women had a reduced wearing adherence of <20 h/day and two of them (25%) eventually refused the WCD already during pregnancy despite intensive patient education regarding possible medical consequences. Due to the retrospective character of the study, unfortunately, no detailed information about the reasons for discontinuation was obtainable. In studies with non-pregnant participants 8 – 14% stopped wearing the WCD prematurely due to issues with comfort or adverse reactions [30]. Additionally, in a study of women with heart failure, the proportion of patients with discontinuation of WCD usage because of nonadherence or device discomfort was high: 14% among the women with PPCM and 8% among women with dilated cardiomyopathy [18]. In further studies with non-pregnant patients it was shown that WCD use can negatively affect various quality of life measures (e. g. mental health, usual activities and mobility) [30,32]. However, in another study, an improvement in depression scores was found during WCD usage [30,33]. Whether the high WCD-refusal rate in pregnancy may be due to the increase of abdominal girth is uncertain because six of our patients (75%) wore the WCD until delivery. Hence, in the majority of the patients the physical body changes during pregnancy did not seem to be an obstacle. When using the WCD in pregnancy, efforts should be made to increase the wearing adherence.

The effectiveness of the WCD was already shown in numerous studies, including patients with newly diagnosed heart failure with severely reduced LVEF [13,20,23], and women with PCCM [14,15,22].

Application of WCD in pregnancy has, so far, only been reported in few cases [7,18]. In none of them, neither appropriate nor inappropriate WCD shocks have been reported. In our study all women had an incidence-free pregnancy and delivery without an appropriate or inappropriate WCD shock. This may be due to close interdisciplinary monitoring and additional diligent pharmacotherapy in five of eight women. Pharmacotherapy makes a decisive contribution to reducing ventricular tachyarrhythmias [1]. Thus, the safety and effectiveness of WCD during pregnancy remains unknown, and the results of our study

cannot resolve these concerns. We can only report that almost all arrhythmias were correctly detected despite the changed anatomy in pregnancy. Especially, all VTs were detected and resulted in a warning signal prior to shock-delivery. Since the VTs were hemodynamically well tolerated, shock-delivery was prohibited by response button. Artefacts were misinterpreted by the WCD only in one case. In this case the women stopped the shock-delivery. Any other artefacts, supraventricular arrhythmias or nsVTs led to inappropriate warning signals or WCD shocks.

In addition, the influence of WCD shocks on the fetal outcome is unclear. In contrast, effectiveness and safety of ICD shocks in pregnancy were already shown in several studies [34–36]. These reports, found no increased risk for adverse fetal outcomes following the occurrence of ICD shocks [35–40]. Similar results can be expected for WCD shocks, but further studies are necessary.

Our study has several limitations. First, the study design and data collection were retrospective. Second, the number of patients was low and only six of the eight patients completed pregnancy with the WCD. Third, our cohort was heterogenous. Women were supplied with a WCD because of different diagnoses. Fourth, we cannot provide data on the effectiveness of WCD shocks during pregnancy since neither appropriate nor inappropriate shocks occurred. Fifthly, WCD recording data of one woman are incomplete. Sixthly, detailed reasons for discontinuation in 25% of the patients were not obtainable.

5. Conclusion

Uneventful pregnancy and delivery are possible in women at risk for life-threatening arrhythmias by early diagnosis, interdisciplinary monitoring and pharmacotherapy protected by the WCD.

Almost all arrhythmias (including VTs, nsVTs and supraventricular tachycardias) were correctly detected by the WCD. Only in case of one artefact it was necessary to stop the shock-delivery by response button. No inappropriate WCD shocks occurred. This indicates an adequate WCD monitoring function in pregnancy despite the changed anatomy. Our data, however, provide no information about the effectiveness of the WCD. Efforts should be made to increase the wearing adherence of WCD in pregnancy.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgement

The authors thank Ute Hubauer at the Department of Cardiology of the University Hospital of Regensburg for her contribution in developing and designing the questionnaire for retrospective data collection.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2022.101066.

References

[1] V. Regitz-Zagrosek, J.W. Roos-Hesselink, J. Bauersachs, C. Blomström-Lundqvist, R. Cífková, M. De Bonis, B. Iung, M.R. Johnson, U. Kintscher, P. Kranke, I.M. Lang, J. Morais, P.G. Pieper, P. Presbitero, S. Price, G.M.C. Rosano, U. Seeland, T. Simoncini, L. Swan, C.A. Warnes, C. Deaton, I.A. Simpson, V. Aboyans, S. Agewall, E. Barbato, P. Calda, A. Coca, I.M. Coman, J. De Backer, V. Delgado, G. Di Salvo, S. Fitzsimmons, D. Fitzsimons, M. Garbi, S. Gevaert, G. Hindricks, G. Jondeau, J. Kluin, C. Lionis, T.A. McDonagh, P. Meier, P. Moons, A. Pantazis, M. F. Piepoli, B. Rocca, M. Roffi, S. Rosenkranz, A. Sarkozy, E. Shlyakhto, C. K. Silversides, K. Sliwa, M. Sousa-Uva, J. Tamargo, S. Thorne, M. Van de Velde, B. Williams, J.L. Zamorano, S. Windecker, V. Aboyans, S. Agewall, E. Barbato, H. Bueno, A. Coca, J.-P. Collet, I.M. Coman, V. Dean, V. Delgado, D. Fitzsimons, O. Gaemperli, G. Hindricks, B. Iung, P. Jüni, H.A. Katus, J. Knuuti, P. Lancellotti, C. Leclercq, T.A. McDonagh, M.F. Piepoli, P. Ponikowski, D.J. Richter, M. Roffi, E. Shlyakhto, I.A. Simpson, M. Sousa-Uva, J.L. Zamorano, N. Hammoudi, A. Piruzyan, J. Mascherbauer, F. Samadov, A. Prystrom, A. Pasquet, J. Caluk, N. Gotcheva, B. Skoric, H. Heracleous, N. Vejlstrup, M. Maser, R.J. Kaaja, E. Srbinovska-Kostovska, C. Mounier-Vehier, T. Vakhtangadze, K. Rybak, G. Giannakoulas, R.G. Kiss, I.S. Thrainsdottir, R.J. Erwin, A. Porter, G. Geraci, P. Ibrahimi, O. Lunegova, I. Mintale, Z. Kadri, H. Benlamin, J. Barysiene, C. A. Banu, M. Caruana, C. Gratii, L. Haddour, B.J. Bouma, M.-E. Estensen, P. Hoffman, A.O. Petris, O. Moiseeva, L. Bertelli, B.V. Tesic, J. Dubrava, M. Koželj, R. Prieto-Arévalo, E. Furenäs, M. Schwerzmann, M.S. Mourali, N. Ozer, O. Mitchenko, C. Nelson-Piercy, 2018 ESC Guidelines for the management of cardiovascular diseases during pregnancy, Eur. Heart J. 39 (34) (2018) 3165–3241.

[2] A. Shotan, E. Ostrzega, A. Mehra, J.V. Johnson, U. Elkayam, Incidence of arrhythmias in normal pregnancy and relation to palpitations, dizziness, and syncope, Am. J. Cardiol. 79 (1997) 1061–1064, https://doi.org/10.1016/s0002-9149(97)00047-7.

[3] M. Brodsky, R. Doria, B. Allen, D. Sato, G. Thomas, M. Sada, New-onset ventricular tachycardia during pregnancy, Am. Heart J. 123 (1992) 933–941, https://doi.org/10.1016/0002-8703(92)90699-v.

[4] P. Szekely, L. Snaith, Paroxysmal tachycardia in pregnancy, Br Heart J. 15 (1953) 195–198, https://doi.org/10.1136/hrt.15.2.195.

[5] S.C. Siu, M. Sermer, J.M. Colman, A.N. Alvarez, L.-A. Mercier, B.C. Morton, C. M. Kells, M.L. Bergin, M.C. Kiess, F. Marcotte, D.A. Taylor, E.P. Gordon, J. C. Spears, J.W. Tam, K.S. Amankwah, J.F. Smallhorn, D. Farine, S. Sorensen, Prospective multicenter study of pregnancy outcomes in women with heart disease, Circulation 104 (5) (2001) 515–521.

[6] J. Grewal, S.C. Siu, H.J. Ross, J. Mason, O.H. Balint, M. Sermer, J.M. Colman, C. K. Silversides, Pregnancy outcomes in women with dilated cardiomyopathy, J. Am. Coll. Cardiol. 55 (1) (2009) 45–52.

[7] E. Reuschel, A. Baessler, C. Stöllberger, J. Finsterer, L. Maier, M. Fischer, F. Poschenrieder, F. Heissenhuber, K. Kurzidim, C.P. Schepp, G. Badelt, B. Seelbach-Göbel, Interdisciplinary management of left ventricular hypertrabeculation/noncompaction during pregnancy with a wearable defibrillator, Int. J. Cardiol. 223 (2016) 154–158.

[8] C. Autore, M.R. Conte, M. Piccininno, P. Bernabò, G. Bonfiglio, P. Bruzzi, P. Spirito, Risk associated with pregnancy in hypertrophic cardiomyopathy, J. Am. Coll. Cardiol. 40 (2002) 1864–1869, https://doi.org/10.1016/s0735-1097(02)02495-6.

[9] S. Goland, I.M. van Hagen, G. Elbaz-Greener, U. Elkayam, A. Shotan, W.M. Merz, S. C. Enar, I.R. Gaisin, P.G. Pieper, M.R. Johnson, R. Hall, A. Blatt, J.W. Roos-Hesselink, Pregnancy in women with hypertrophic cardiomyopathy: data from the European Society of Cardiology initiated Registry of Pregnancy and Cardiac disease (ROPAC), Eur. Heart J. 38 (35) (2017) 2683–2690.

[10] L. Su, J. Guo, Y. Hao, H. Tan, Comparing the safety of subcutaneous versus transvenous ICDs: a meta-analysis, J Interv Card Electrophysiol. 60 (2021) 355–363, https://doi.org/10.1007/s10840-020-00929-1.

[11] M. Yano, Y. Nishida, K. Kai, T. Ishii, N. Takahashi, H. Narahara, Long QT syndrome in pregnancy: a successful case of ICD implantation during the prenatal period, J. Obstet. Gynaecol. 37 (2017) 531–532, https://doi.org/10.1080/01443615.2017.1284771.

[12] E. Gherbesi, C. Bonanomi, V. Bottari, G.B. Danzi, Ventricular tachycardia triggered by pregnancy in left-ventricular non-compaction cardiomyopathy: a controversial indication to automated defibrillator implantation, Monaldi Arch. Chest Dis. (2020), https://doi.org/10.4081/monaldi.2020.1280.

[13] T.A. McDonagh, M. Metra, M. Adamo, R.S. Gardner, A. Baumbach, M. Böhm, H. Burri, J. Butler, J. Čelutkienė, O. Chioncel, J.G.F. Cleland, A.J.S. Coats, M. G. Crespo-Leiro, D. Farmakis, M. Gilard, S. Heymans, A.W. Hoes, T. Jaarsma, E. A. Jankowska, M. Lainscak, C.S.P. Lam, A.R. Lyon, J.J.V. McMurray, A. Mebazaa, R. Mindham, C. Muneretto, M. Francesco Piepoli, S. Price, G.M.C. Rosano, F. Ruschitzka, A. Kathrine Skibelund, R.A. de Boer, P. Christian Schulze, M. Abdelhamid, V. Aboyans, S. Adamopoulos, S.D. Anker, E. Arbelo, R. Asteggiano, J. Bauersachs, A. Bayes-Genis, M.A. Borger, W. Budts, M. Cikes, K. Damman, V. Delgado, P. Dendale, P. Dilaveris, H. Drexel, J. Ezekowitz, V. Falk, L. Fauchier, G. Filippatos, A. Fraser, N. Frey, C.P. Gale, F. Gustafsson, J. Harris, B. Iung, S. Janssens, M. Jessup, A. Konradi, D. Kotecha, E. Lambrinou, P. Lancellotti, U. Landmesser, C. Leclercq, B.S. Lewis, F. Leyva, A. Linhart, M.-L. Løchen, L. H. Lund, D. Mancini, J. Masip, D. Milicic, C. Mueller, H. Nef, J.-C. Nielsen, L. Neubeck, M. Noutsias, S.E. Petersen, A. Sonia Petronio, P. Ponikowski, E. Prescott, A. Rakisheva, D.J. Richter, E. Schlyakhto, P. Seferovic, M. Senni, M. Sitges, M. Sousa-Uva, C.G. Tocchetti, R.M. Touyz, C. Tschoepe, J. Waltenberger, M. Adamo, A. Baumbach, M. Böhm, H. Burri, J. Čelutkienė, O. Chioncel, J.G. F. Cleland, A.J.S. Coats, M.G. Crespo-Leiro, D. Farmakis, R.S. Gardner, M. Gilard, S. Heymans, A.W. Hoes, T. Jaarsma, E.A. Jankowska, M. Lainscak, C.S.P. Lam, A. R. Lyon, J.J.V. McMurray, A. Mebazaa, R. Mindham, C. Muneretto, M.F. Piepoli, S. Price, G.M.C. Rosano, F. Ruschitzka, A.K. Skibelund, 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: developed by the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) With the special contribution of the Heart Failure Association (HFA) of the ESC, Eur. Heart J. 42 (36) (2021) 3599–3726.

[14] T. Deneke, R. Bosch, L. Eckardt, B. Nowak, J.O. Schwab, P. Sommer, C. Veltmann, T.M. Helms, Der tragbare Kardioverter/Defibrillator (WCD) – Indikationen und EinsatzWearable cardioverter defibrillator (WCD)—Indications and use: Empfehlung der AG1 der Deutschen Gesellschaft für Kardiologie – Herz- und Kreislaufforschung eWearable cardioverter defibrillator (WCD)—Indications and

use: Recommendations of the working group 1 of the German Cardiac Society (DGK), Kardiologe 13 (5) (2019) 292–304.
[15] D. Duncker, A. Haghikia, T. König, S. Hohmann, K.-J. Gutleben, R. Westenfeld, H. Oswald, H. Klein, J. Bauersachs, D. Hilfiker-Kleiner, C. Veltmann, Risk for ventricular fibrillation in peripartum cardiomyopathy with severely reduced left ventricular function-value of the wearable cardioverter/defibrillator, Eur. J. Heart Fail. 16 (12) (2014) 1331–1336.
[16] D. Duncker, R. Westenfeld, T. Konrad, T. Pfeffer, C.A. Correia de Freitas, R. Pfister, D. Thomas, A. Fürnkranz, R.P. Andrié, A. Napp, J. Schmitt, L. Karolyi, R. Wakili, D. Hilfiker-Kleiner, J. Bauersachs, C. Veltmann, Risk for life-threatening arrhythmia in newly diagnosed peripartum cardiomyopathy with low ejection fraction: a German multi-centre analysis, Clin. Res. Cardiol. 106 (8) (2017) 582–589.
[17] M.C. Honigberg, M.M. Givertz, Arrhythmias in peripartum cardiomyopathy, Card Electrophysiol Clin. 7 (2015) 309–317, https://doi.org/10.1016/j.ccep.2015.03.010.
[18] M.T. Saltzberg, S. Szymkiewicz, N.R. Bianco, Characteristics and outcomes of peripartum versus nonperipartum cardiomyopathy in women using a wearable cardiac defibrillator, J Card Fail. 18 (2012) 21–27, https://doi.org/10.1016/j.cardfail.2011.09.004.
[19] D. Duncker, T.J. Pfeffer, J. Bauersachs, C. Veltmann, ECG and arrhythmias in peripartum cardiomyopathy. [EKG und Arrhythmien bei Peripartumkardiomyopathie]EKG und Arrhythmien bei Peripartumkardiomyopathie, Herzschrittmacherther. Elektrophysiol. 32 (2) (2021) 207–213.
[20] J. Mueller-Leisse, J. Brunn, C. Zormpas, S. Hohmann, H.A.K. Hillmann, J. Eiringhaus, J. Bauersachs, C. Veltmann, D. Duncker, Extended follow-up after wearable cardioverter-defibrillator period: the PROLONG-II study, ESC Heart Fail. 8 (6) (2021) 5142–5148.
[21] C. Veltmann, S. Winter, D. Duncker, C.G. Jungbauer, N.K. Wäßnig, J.C. Geller, J. W. Erath, O. Goeing, C. Perings, M. Ulbrich, M. Roser, D. Husser, L.S. Gansera, K. Soezener, F.M. Malur, M. Block, T. Fetsch, V. Kutyifa, H.U. Klein, Protected risk stratification with the wearable cardioverter-defibrillator: results from the WEARIT-II-EUROPE registry, Clin Res Cardiol. 110 (1) (2021) 102–113.
[22] D. Duncker, C. Veltmann, Role of the Wearable Defibrillator in Newly Diagnosed Heart Failure, Curr Heart Fail Rep. 15 (2018) 368–375, https://doi.org/10.1007/s11897-018-0415-7.
[23] D. Duncker, T. König, S. Hohmann, J. Bauersachs, C. Veltmann, Ventricular arrhythmias in patients with newly diagnosed nonischemic cardiomyopathy: Insights from the PROLONG study, Clin. Cardiol. 40 (2017) 586–590, https://doi.org/10.1002/clc.22706.
[24] D. Duncker, T. König, S. Hohmann, J. Bauersachs, C. Veltmann, Avoiding untimely implantable cardioverter/defibrillator implantation by intensified heart failure therapy optimization supported by the wearable cardioverter/defibrillator-the PROLONG study, J. Am. Heart Assoc. 6 (1) (2017), https://doi.org/10.1161/JAHA.116.004512.
[25] J. Mueller-Leisse, J. Brunn, C. Zormpas, S. Hohmann, H.A.K. Hillmann, J. Eiringhaus, J. Bauersachs, C. Veltmann, D. Duncker, Delayed improvement of left ventricular function in newly diagnosed heart failure depends on etiology-A PROLONG-II substudy, Sensors (Basel) 22 (5) (2022) 2037.
[26] H.A.K. Hillmann, S. Hohmann, J. Mueller-Leisse, C. Zormpas, J. Eiringhaus, J. Bauersachs, C. Veltmann, D. Duncker, Feasibility and first results of heart failure monitoring using the wearable cardioverter-defibrillator in newly diagnosed heart failure with reduced ejection fraction, Sensors (Basel) 21 (23) (2021) 7798.
[27] M.M. Zylla, H.A.K. Hillmann, T. Proctor, M. Kieser, E. Scholz, E. Zitron, H.A. Katus, D. Thomas, Use of the wearable cardioverter-defibrillator (WCD) and WCD-based remote rhythm monitoring in a real-life patient cohort, Heart Vess. 33 (11) (2018) 1390–1402.
[28] S.L. Rosenkaimer, I. El-Battrawy, T.C. Dreher, S. Gerhards, S. Röger, J. Kuschyk, M. Borggrefe, I. Akin, The wearable cardioverter-defibrillator: experience in 153 patients and a long-term follow-up, J. Clin. Med. 9 (3) (2020) 893.
[29] V. Kutyifa, A.J. Moss, H. Klein, Y. Biton, S. McNitt, B. MacKecknie, W. Zareba, I. Goldenberg, Use of the wearable cardioverter defibrillator in high-risk cardiac patients: data from the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry), Circulation 132 (17) (2015) 1613–1619.
[30] C.C. Cheung, J.E. Olgin, B.K. Lee, Wearable cardioverter-defibrillators: a review of evidence and indications, Trends Cardiovasc. Med. 31 (2021) 196–201, https://doi.org/10.1016/j.tcm.2020.03.002.
[31] J.E. Olgin, M.J. Pletcher, E. Vittinghoff, J. Wranicz, R. Malik, D.P. Morin, S. Zweibel, A.E. Buxton, C.S. Elayi, E.H. Chung, E. Rashba, M. Borggrefe, T.F. Hue, C. Maguire, F. Lin, J.A. Simon, S. Hulley, B.K. Lee, Wearable cardioverter-defibrillator after myocardial infarction, N. Engl. J. Med. 379 (13) (2018) 1205–1215.
[32] K. Lackermair, C.G. Schuhmann, M. Kubieniec, L.M. Riesinger, I. Klier, T. J. Stocker, S. Kääb, H.L. Estner, S. Fichtner, Impairment of quality of life among patients with wearable cardioverter defibrillator therapy (LifeVest®): a preliminary study, Biomed. Res. Int. 2018 (2018) 1–6.
[33] M. Weiss, G. Michels, F. Eberhardt, W. Fehske, S. Winter, F. Baer, Y.-H. Choi, C. Albus, D. Steven, S. Baldus, R. Pfister, G. Andò, Anxiety, depression and quality of life in acute high risk cardiac disease patients eligible for wearable cardioverter defibrillator: results from the prospective multicenter CRED-registry, PLoS ONE 14 (3) (2019) e0213261.
[34] T. Miyoshi, C.A. Kamiya, S. Katsuragi, H. Ueda, Y. Kobayashi, C. Horiuchi, K. Yamanaka, R. Neki, J. Yoshimatsu, T. Ikeda, Y. Yamada, H. Okamura, T. Noda, W. Shimizu, Safety and efficacy of implantable cardioverter-defibrillator during pregnancy and after delivery, Circ. J. 77 (5) (2013) 1166–1170.
[35] A. Natale, T. Davidson, M.J. Geiger, K. Newby, Implantable cardioverter-defibrillators and pregnancy: a safe combination? Circulation 96 (1997) 2808–2812, https://doi.org/10.1161/01.cir.96.9.2808.
[36] A. Topf, N. Bacher, K. Kopp, M. Mirna, R. Larbig, M.C. Brandt, J. Kraus, U. C. Hoppe, L.J. Motloch, M. Lichtenauer, Management of implantable cardioverter-defibrillators during pregnancy-a systematic review, J. Clin. Med. 10 (8) (2021) 1675.
[37] S. Boule, L. Ovart, C. Marquie, E. Botcherby, D. Klug, C. Kouakam, F. Brigadeau, L. Guedon-Moreau, L. Wissocque, J. Meurice, D. Lacroix, S. Kacet, Pregnancy in women with an implantable cardioverter-defibrillator: is it safe? Europace. 16 (11) (2014) 1587–1594.
[38] P.K. Schuler, A. Herrey, A. Wade, R. Brooks, D. Peebles, P. Lambiase, F. Walker, Pregnancy outcome and management of women with an implantable cardioverter defibrillator: a single centre experience, Europace. 14 (2012) 1740–1745, https://doi.org/10.1093/europace/eus172.
[39] W. Bonini, G.L. Botto, T. Broffoni, C. Dondina, Pregnancy with an ICD and a documented ICD discharge, Europace. 2 (2000) 87–90, https://doi.org/10.1053/eupc.1999.0063.
[40] A. Ahmed, J.R. Phillips, Teenage pregnancy with catecholaminergic polymorphic ventricular tachycardia and documented ICD discharges, Clin. Case Rep. 4 (2016) 361–365, https://doi.org/10.1002/ccr3.366.