ISSN: 2476-230X

Research Article

Cardiology: Open Access

Bridging Implantable Cardioverter-Defibrillator Patients Undergoing Radiotherapy with a Wearable Cardioverter-Defibrillator

Loira Leoni[1*], Matteo Sepulcri[2], Chiara Paronetto[2], Francesca Gessoni[2], Maria Silvano[1], Sara Munaron[1], Nicole Bianco[3], Sabino Iliceto[1]

[1]Cardiology, Department of Cardiac Thoracic Vascular Sciences and Public Health, Azienda Ospedale Università, Padua, Italy

[2]Radiotherapy, Veneto Institute of Oncology IOV - IRCCS, Padua, Italy

[3]ZOLL Services LLC, Pittsburgh, PA, 15238, USA

[*]Corresponding Author
Loira Leoni, Cardiology, Department of Cardiac Thoracic Vascular Sciences and Public Health, Azienda Ospedale Università, Padua, Italy.

Submitted: 28 Feb 2023; **Accepted:** 28 Mar 2023; **Published:** 03 April 2023

Citation: Leoni, L., Sepulcri, M., Paronetto, C., Gessoni, F., Silvano, M., et al. (2023). Bridging Implantable Cardioverter-Defibrillator Patients Undergoing Radiotherapy with a Wearable Cardioverter-Defibrillator. *Cardio Open, 8*(1), 24-29.

Abstract

Background: *Chest radiation therapy (RT) in patients with an implantable cardioverter defibrillator (ICD) can be problematic and cause transitory malfunction or permanent damage to the device. If the ICD cannot be properly shielded from the radiation necessary for the treatment, then it may be necessary to turn off certain aspects (i.e. tachy-therapy) of the device or to temporarily remove the device leaving the patient without protection and exposing to high risk of complications. The wearable cardioverter defibrillator (WCD) is guideline recommended as bridging therapy in patients requiring temporary removal or inactivation of an ICD.*

Objectives: *The objective of this analysis was to assess the wearable cardioverter defibrillator as a tool in high-risk implantable cardioverter defibrillator patients with cancer during the weeks to months of radiation therapy.*

Methods: *Two retrospective cohorts were analyzed from the University of Padova (Italy) and from the manufacturer's US registry. Patients undergoing RT who had their ICD removed or deactivated and were prescribed a WCD were included. Demographic, medical history and device usage data collected.*

Results: *Eighty patients were analyzed (76 US, 4 Padova). The median age was 69 years and 56% were female. The most common cancer types were breast (44%) and lung (33%). Median wear time of the WCD was 22.2 hours/day over 57 days. Strategies to protect ICDs from RT involved either removing the device (82.5%) or turning off therapy in the remaining 14 (17.5%). Ventricular arrhythmias (VA) were recorded by the wearable cardioverter defibrillator in four patients, with two sustained episodes in a patient that were successfully cardioverter by the wearable cardioverter defibrillator, and three patients with non-sustained ventricular arrhythmias that did not receive shocks. Five deaths occurred four with an asystole event and one while not wearing the device.*

Conclusions: *This study supports a role for the wearable cardioverter defibrillator in protecting implantable cardioverter defibrillator patients while undergoing radiation therapy. Back-up pacing considered for patients at risk of Brady-arrhythmias.*

Introduction

Chest radiation therapy (RT) for cancer treatment in patients with an implantable cardioverter defibrillator (ICD) can be problematic and cause transitory malfunction or permanent damage to the device. Although limited data exist, the most common reported malfunctions to ICDs are resets errors, especially during high energies that may cause secondary neutron production [1,2]. Oversensing due to electromagnetic interference could cause pacing inhibition or inappropriate detections and shocks. Manufacturer recommendations regarding safe doses vary from no safe dose (Boston Scientific and BIOTRONIK) to five Gy (Medtronic) depending on the device.

If the implantable cardioverter defibrillator (ICD) cannot be safely relocated or properly shielded from the radiation therapy necessary for the treatment, then it may be necessary to turn off certain aspects (i.e. tachy-therapy) of the device or to temporarily remove the device leaving the patient without protection

and exposed to high risk of complications. How to protect the high-risk patient from sudden cardiac death (SCD) during this time is unclear. Unless the patient is pacemaker dependent, the wearable cardioverter defibrillator (WCD) may be considered as bridging therapy in patients requiring temporary removal of an infected implanted defibrillator by the American and European Guidelines [3,4]. We hypothesize that the wearable cardioverter defibrillator may be a safe and reliable tool to keep the patient temporarily protected from potentially lethal ventricular tachy-arrhythmias during the weeks/months of RT. This would allow the patient to receive the proper dose of radiation while still being protected. Once RT is finished, then the ICD can be re-implanted/ re-activated and functionality restored. We are only aware of one small case study that specifically utilized the wearable cardioverter defibrillator for this purpose [5]. The primary objective of this study was to examine a larger cohort of patients to evaluate the utility of the WCD for protecting these patients during this time.

Methods

Study Sample

The study sample was comprised of two retrospectively collected cohorts (University of Padova and the Zoll Life Vest (Pittsburgh, PA, USA) database). De-identified data from patients retrieved from a database maintained by ZOLL. All patients consented to the data collection. Only patients with complete follow-up data, having an implanted ICD, and prescribed, with a wearable cardioverter defibrillator for bridging therapy while treated with RT from November 2016- January 2021 were included.

The data collected for analysis included baseline demographics (age and sex), ICD 9/10 code indication for the WCD, length of WCD wear, malignancy type, cardiac history, reasons for wearable cardioverter defibrillator termination, ventricular arrhythmias during wearable cardioverter defibrillator use, outcomes and compliance with device use. For each patient the average daily use calculated at the end of device use. The first day, last day and days where device use was less than 15 minutes excluded from the average daily use. All-cause mortality data during wearable cardioverter defibrillator use obtained by review of records.

The Wearable Cardioverter Defibrillator (WCD)

LifeVest® (ZOLL Medical Corporation, Pittsburgh, PA) Pittsburgh, PA) has three non-adhesive defibrillator electrodes and four non-adhesive sensing electrodes. A chest garment holds the defibrillation and sensing electrodes in proper position against the skin. Sensing electrodes positioned circumferentially around the chest. Defibrillation electrodes positioned for apical-posterior defibrillation. The electrodes are connected to a monitor unit that is worn in a holster around the waist or over the shoulder. The monitor collects ECG data continuously from the sensing electrodes. If the device senses a ventricular tachycardia or ventricular fibrillation, the patient alerted first with tactile vibration, followed by an escalating audible alarm and a voice warning to bystanders of an impending shock [6]. A conscious patient can prevent a shock by simultaneously pressing two response buttons located on the monitor within 25 seconds of VT detection by the device. If there is no response, as is the case for unconscious patients, the device releases gel through the defibrillator electrodes and delivers an electrical shock (75 to 150 joules) in an attempt to restore sinus rhythm. The Wearable Cardioverter Defibrillator system transmits ECG signals and event history to the manufacturer's webserver. Shock delivery time is typically <60 seconds from the onset of tachycardia and the device can deliver up to 5 shocks per event if the arrhythmia is not terminated with the first shock [7-9]. The Wearable Cardioverter Defibrillator, including its arrhythmia detection algorithm have been described elsewhere in detail [10].

Statistical Analysis

Data analyzed using Microsoft Excel. Descriptive statistics presented as mean with one standard deviation (SD) and range for continuous variables, and frequency and percent for categorical variables. When appropriate, medians and quartiles used to describe the data. Tests of hypotheses were 2-sided, with significance declared for a p-value < 0.05. All arrhythmias occurring within 24 hours of index arrhythmia considered one episode for analysis. Device-declared arrhythmias were adjudicated and confirmed by Dr. Leoni.

Results

Eighty patients meeting criteria with implantable cardioverter defibrillator inactivation/removal during radiation therapy for cancer who prescribed the Wearable Cardioverter Defibrillator identified. Seventy-six patients were from the US, and four were from the site in Padova, Italy Table 1. The median age of this population was 69 years with a range of 33-88 years. Females comprised 56% of the population. Implantable Cardioverter Defibrillator (ICD) management strategy included removing the implantable cardioverter defibrillator in 66 (82.5%), or turning off therapy in the remaining 14 (17.5%). Seven of the latter group had back-up pacing for bradycardia left on.

Table 1: Description of the Patient Population Treated with Wearable Cardioverter Defibrillator (WCD) (N=80)

Variable	Frequency (%) Average (range)
Age in year: median (range)	69 (33-88)
Sex -Female	45 (56%)
WCD duration of use: median days (range)	57 (2-364)
WCD duration of use: median hours/day (range)	22.2 (8.5 to 24.0)
Cardiac history*	
-ICD implantation	80 (100%)

-CAD/ICM	43 (54%)
-CHF	47 (59%)
Cancer Type	
- Breast	35 (44%)
- Lung	26 (33%)
- Lymphoma	3 (3.8%)
- Multiple types	9 (11%)
- Other	7 (8.8%)
Medical History (non-cardiac)*	
-HTN	47 (58.8%)
-Diabetes mellitus	18 (22.5%)
-Dyslipidemia	48 (60%)
-Peripheral vascular disease	9 (11.3%)
-Chronic kidney disease	5(6.3%)
-Cerebrovascular accident	7 (8.8%)
-Obstructive sleep apnea	7 (8.8%)
-COPD	18 (22.5%)
Patients with Arrhythmia before WCD*	
-VF/VT	31 (38.8%)
-SVT	5 (6.3%)
-AF, AFL	22 (27.5%)

SD: Standard Deviation; CAD: Coronary Artery Disease; ICM: Ischemic Cardiomyopathy; CHF: Congestive Heart Failure; HTN: Hypertension; WCD: Wearable Cardioverter Defibrillator; VF: Ventricular Fibrillation; VT: Ventricular Tachycardia; NSVT: Non-Sustained Ventricular Tachycardia; AF: Atrial Fibrillation; AFL: Atrial Flutter; SVT: Supra Ventricular Tachycardia
*Not mutually exclusive

Cancer History

The most common type of cancer amongst the patient population was breast cancer (n=35, 44%), followed by lung cancer (n=26, 33%). Nine additional patients (11%) had more than one cancer documented, including breast, lung, bladder, cervical, leukemia, and prostate. All had a current cancer diagnosis and were undergoing radiation therapy at the time of wearable cardioverter defibrillator prescription.

Past Medical History (Non-Cardiac)

Serious medical co-morbidities (excluding cardiac) included: 47 patients (58.8%) had hypertension, 18 patients (22.5%) had diabetes mellitus, 48 patients (60%) had dyslipidemia, 9 patients (11.3%) had peripheral vascular disease, 5 patients (6.3%) had chronic kidney disease, 7 patients (8.8%) with obstructive sleep apnea, and 18 patients (22.5%) with chronic obstructive pulmonary disease.

Cardiac History (Before Wearable Cardioverter Defibrillator Use)

In addition to having a previously implanted defibrillator, 43 patients (53.8%) had a history of coronary artery disease (CAD) and 47 (58.8%) had a history of heart failure (HF). Arrhythmias prior to WCD use including ventricular fibrillation (VF) or ventricular tachycardia (VT) in 31 (38.8%), atrial fibrillation/flutter in 22 (27.5%), and supraventricular tachycardia in 5 (6.3%). A history of sudden cardiac arrest was present in 11 patients (13.8%).

Radiation Therapy

In the four patients from the Padova site, two of them received 2 Gy per session for a total of 30 sessions and 60 Gy, the other two underwent a more aggressive protocol with 60 Gy in 8 sessions which means 7.5 Gy per session. The type of energy used was photon beam energy of 6 MV or 10 MV with an estimated ICD dose of < 3%. Deidentified data from US patients did not include details on the type or dose of RT received.

Wearable Cardioverter Defibrillator Use and Events

The wearable cardioverter defibrillator prescribed for protection against life-threatening ventricular arrhythmias (VA) in these patients while undergoing RT for cancer, during which time their ICDs were not active. Days of Wearable Cardioverter Defibrillator use analyzed for all patients resulting in a median of 57 days worn with a range of 2 to 364 days. The median daily use time was 22.2 hours with a range of 8.5 to 24 hours per day.

During wearable cardioverter defibrillator use, 3 appropriate shocks were delivered to one patient (Male, 66 years old, lung cancer, history of coronary artery disease and VT/VF) during sustained ventricular tachy- arrhythmias. Successful defibrillation shocks were delivered on two separate days, both for VF. The second VF episode required two shocks to convert to sinus rhythm. The patient survived and was re-implanted with an ICD. There were also 20 inappropriate shocks delivered to one patient due to ECG artifact caused by cardiopulmonary resusci-

tation (CPR) given during asystole. The patient did not survive. Other non-shocked arrhythmias that were recorded by the wearable cardioverter defibrillator included non-sustained VT (9, 15 and 16 seconds duration, of 33, 42 and 42, beats, respectively) in three patients, episodes of fast supra-ventricular tachyarrhythmia's/atrial fibrillation in 14 patients that were recorded by the wearable cardioverter defibrillator, and four patients with asystole, none of whom survived. None of the patients with asystole had back-up pacing left in place. Arrhythmic events during wearable cardioverter defibrillator use were not correlated with any specific cancer type as shown in Table 2.

Table 2: Arrhythmic Events during Wearable Cardioverter Defibrillator Use by Cancer Location

Variable	VT/VF n(% of type)	NSVT n(% of type)	Asystole n(% of type)	SVT/AF/AFL n(% of type)
Cancer Type				
Breast	0	2 (5.7)	2 (5.7)	6 (17.1)
Lung	1 (2.8)	0	2 (7.7)	4 (15.4)
Lymphoma	0	0	0	1 (33.3)
Multiple types	0	0	0	1 (11.1)
Other	0	1 (14.3)	0	2 (28.6)

VF: Ventricular Fibrillation; VT: Ventricular Tachycardia; NSVT: Non-Sustained Ventricular Tachycardia; SVT: Supra Ventricular Tachycardia; AF: Atrial Fibrillation; AFL: Atrial Flutter

Outcomes

The majority of patients (n = 57, 71%) ended wearable cardioverter defibrillator use as planned or with the implantable cardioverter defibrillator replaced. Eleven patients (14%) ended wearable cardioverter defibrillator use for unknown/other reasons, and seven patients (9%) ended use for non-compliance or comfort reasons. During the study period 5 deaths were reported (mortality rate of 6.3%) in patients with lung (3) and breast cancer (2), including the patient that was shocked due to CPR artifact. Deaths occurred 3, 28, 33, 116, and 134 days from the start of wearable cardioverter defibrillator use. Four of five (80%) had asystole as the terminal ECG rhythm recorded by the WCD. The fifth reportedly died from heart failure while not wearing the wearable cardioverter defibrillator.

Discussion

With heart disease and cancer being the top two causes of death in the Unites States, it is not surprising that these two conditions often overlap. Radiation therapy (RT) is used in approximately fifty percent of adults with cancer [11]. While improved RT technology and techniques have improved the safety and reduced off-target effects to vital organs such as the heart and lungs, the cardiac devices themselves may be at risk of damage, especially ICDs and in the presence of higher beam energies [12,13]. Many variables will dictate what types of precautions should be taken to protect the device and the patient, and several expert consensus statements and society guidelines have been written on the topic [1,2,13]. Occasionally, depending on the risk to the device, the best decision may be to deactivate or remove the defibrillator to prevent damage and potential harm to the patient, but there is little guidance on how to protect the patient during this high-risk time [14].

This study observed whether the wearable cardioverter defibrillator (WCD) might be useful in managing SCD risk during radiotherapy when the existing implantable defibrillator has been deactivated or removed. There is little guidance on how to manage these high-risk patients. The WCD is capable of continuous ECG monitoring and treatment until the decision regarding the ICD can be made. Although the wearable cardioverter defibrillator has not been tested on a patient during a RT session, it can be removed prior to the RT and then put back on immediately afterwards. A patient with previous ventricular arrhythmias (VA) or having high anxiety and stress may be at even higher risk of having an event during the RT session. Such high-risk patients should have continuous heart rate and/or rhythm monitoring and access to an external defibrillator in case of emergency during the live RT session [11]. In patients that are pacemaker dependent, we recommend use of an external or temporary pacemaker.

Several unique observations from this retrospective cohort study are worth noting, including:

1. Patients with active cancer undergoing RT were compliant with WCD use (median 22 hrs/day over 57 days),
2. The WCD bridged the time until the ICD could be safely replaced in a majority of patients,
3. The WCD successfully aborted SCD during VF in a patient on two separate days,
4. Worsening disease and Brady-asystole rhythms, led to death in 6.4%, and
5. Patients had a high prevalence of atrial arrhythmias (17.5%) that were fast enough to be captured by the WCD algorithm. Heart rate alerts from the ZOLL Patient Management Network could be used to alert the healthcare provider to such tachyarrhythmia.

In our clinic, implantable cardioverter-defibrillator patients are, by definition, at high risk of sudden cardiac death and thus we follow a protocol to assure the best possible protection for the patient. In the cases presented here, it was necessary to deactivate the device in order to ensure adequate RT while avoiding risk of implantable cardioverter-defibrillator malfunction.

In particular, we followed this protocol:

- Verified the non-pacing-dependence
- Verified the integrity of the implanted ICD system before starting RT
- Assessed the arrhythmic burden

- Inactivated the ventricular anti-tachycardia therapy, maintaining back up pacing at 40 bpm
- Programmed, or provided if not already active, the telemedicine function of the ICD with daily transmissions to verify system integrity
- At the same time, activated the WCD with its telemedicine function, and performed training for the patient and his or her family
- The patient continued to be monitored remotely through both devices for two weeks after the end of RT, then an in-clinic follow-up was performed to verify the integrity of the implanted system and, if confirmed, the ICD was reactivated and the WCD removed.

This approach seems to be in line with the most recent indications that also emerged from the EHRA consensus on prevention and management of interference due to medical procedures in patients with cardiac implantable electronic devices [2].

Abbreviations

CAD: Coronary Artery Disease
CPR: Cardiopulmonary Resuscitation
HF: Heart Failure
ICD: Implantable Cardioverter-Defibrillator
ICM: Ischemic Cardiomyopathy
SVT: Supra Ventricular Tachycardia
RT: Radiation Therapy
SCD: Sudden Cardiac Death
CHF: Congestive Heart Failure
VA: Ventricular Arrhythmias
VF: Ventricular Fibrillation
WCD: Wearable Cardioverter-Defibrillator

Conclusions

Many patients will undergo cancer remission or recovery after appropriate treatment, and the WCD may be a reasonable option to protect ICD explanted or deactivated patients during radiotherapy. The WCD can bridge until the ICD replaced, if desired, or re-activated in most patients. Under these circumstances, patients that are pacemaker dependent should have back-up pacing in place. Considering our positive experience and other recent literature data in which modern cardiac implantable electronic devices very rarely need to be preventively explanted or re-located to a contralateral pectoral position, we consider a safe approach the temporary deactivation of ICD combined with the use of WCD.

Study Limitations

This study has the established limitations of a retrospective analysis derived from a registry database. Several data of particular interest were not recorded or recorded inconsistently, including ICD data such as device specifics, pacemaker dependency and the primary reason for implantation. Evidence of pacing was not available in patients with pacing function left on. Finally, as the registry does not include data following the end of WCD use, long-term data is unavailable.

Conflict of Interest: Nicole Bianco is an employee of ZOLL.

References

1. Indik, J. H., Gimbel, J. R., Abe, H., Alkmim-Teixeira, R., Birgersdotter-Green, U., Clarke, G. D., ... & Woodard, P. K. (2017). 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. Heart Rhythm, 14(7), e97-e153.
2. Stühlinger, M., Burri, H., Vernooy, K., Garcia, R., Lenarczyk, R., Sultan, A., ... & Nitta, T. (2022). EHRA consensus on prevention and management of interference due to medical procedures in patients with cardiac implantable electronic devices: For the European Heart Rhythm Association (EHRA), Heart Rhythm Society (HRS), Latin America Heart Rhythm Society (LAHRS), Asian Pacific Heart Rhythm Society (APHRS). Europace, 24(9), 1512-1537.
3. Al-Khatib, S. M., Stevenson, W. G., Ackerman, M. J., Bryant, W. J., Callans, D. J., Curtis, A. B., ... & Page, R. L. (2018). 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation, 138(13), e210-e271.
4. Authors/Task Force Members, Priori, S. G., Blomström-Lundqvist, C., Mazzanti, A., Blom, N., Borggrefe, M., ... & Zannad, F. (2015). 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC) Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). Ep Europace, 17(11), 1601-1687.
5. Bowers, R. W., Scott, P. A., & Roberts, P. R. (2014). Use of external defibrillator jacket to facilitate safe delivery of radiotherapy for lung cancer–a report of two cases. indian heart journal, 66(1), 111-114.
6. Feldman, A. M., Klein, H., Tchou, P., Murali, S., Hall, W. J., Mancini, D., ... & wearit and biroad investigators and coordinators. (2004). Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of WEARIT/BIROAD. Pacing and clinical electrophysiology, 27(1), 4-9.
7. Klein, H. U., Meltendorf, U. L. F., Reek, S., Smid, J. A. N., Kuss, S., Cygankiewicz, I., ... & Moss, A. J. (2010). Bridging a temporary high risk of sudden arrhythmic death. Experience with the wearable cardioverter defibrillator (WCD). Pacing and clinical electrophysiology, 33(3), 353-367.
8. Adler, A., Halkin, A., & Viskin, S. (2013). Wearable cardioverter-defibrillators. Circulation, 127(7), 854-860.
9. Chung, M. K., Szymkiewicz, S. J., Shao, M., Zishiri, E., Niebauer, M. J., Lindsay, B. D., & Tchou, P. J. (2010). Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. Journal of the American College of Cardiology, 56(3), 194-203.
10. Reek, S., Burri, H., Roberts, P. R., Perings, C., Epstein, A. E., Klein, H. U., ... & Savelieva, I. (2017). The wearable cardioverter-defibrillator: current technology and evolving

indications. Europace, 19(3), 335-345.
11. Fradley, M. G., Lefebvre, B., Carver, J., Cheung, J. W., Feigenberg, S. J., Lampert, R., ... & Lenihan, D. J. (2021). How to manage patients with cardiac implantable electronic devices undergoing radiation therapy. Cardio Oncology, 3(3), 447-451.
12. Grant, J. D., Jensen, G. L., Tang, C., Pollard, J. M., Kry, S. F., Krishnan, S., ... & Rozner, M. A. (2015). Radiotherapy-induced malfunction in contemporary cardiovascular implantable electronic devices: clinical incidence and predictors. JAMA oncology, 1(5), 624-632.
13. Zecchin, M., Severgnini, M., Fiorentino, A., Malavasi, V. L., Menegotti, L., Alongi, F., ... & Boriani, G. (2018). Management of patients with cardiac implantable electronic devices (CIED) undergoing radiotherapy: a consensus document from Associazione Italiana Aritmologia e Cardiostimolazione (AIAC), Associazione Italiana Radioterapia Oncologica (AIRO), Associazione Italiana Fisica Medica (AIFM). International journal of cardiology, 255, 175-183.
14. Miften, M., Mihailidis, D., Kry, S. F., Reft, C., Esquivel, C., Farr, J., ... & Wilkinson, J. (2019). Management of radiotherapy patients with implanted cardiac pacemakers and defibrillators: a report of the AAPM TG-203. Medical physics, 46(12), e757-e788.