

The wearable external cardiac defibrillator for cancer patients at risk for sudden cardiac death

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The wearable external cardiac defibrillator (WCD) may be utilized for patients at risk for sudden cardiac death (SCD) for whom an implantable cardiac defibrillator (ICD) is problematic. The purpose of our study was to describe the use and limitations of the WCD in a cohort of cancer patients. Deidentified records from patients prescribed the WCD between 2005 and 2009 were reviewed, and patients with a history of cancer were included. Among 23,797 patients prescribed the WCD, 59 (0.02%) had cancer. A defibrillator was indicated in 54 of the 59 patients, based on poor ventricular function. The remaining five patients had a prior life-threatening arrhythmia. A previously implanted ICD was removed due to infection or thrombus in 6 of the 59 patients (10%). Successful shocks were delivered on 5 occasions to 4 of the 59 patients (7%) within 3 months. Among 11 deaths, none was due to noncompliance or WCD treatment failure. Limitations of the study include its retrospective nature and the minimal information available in the dataset. Nonetheless, it provides important information in that the study includes all patients with a history of cancer prescribed the WCD in a contemporary cohort. The WCD may protect cancer patients at risk for SCD until an ICD can be safely implanted or is deemed unnecessary.

Implantable cardioverter defibrillators (ICDs) are indicated for primary prevention of sudden cardiac death (SCD) in patients with reduced left ventricular function (an ejection fraction of $\leq 35\%$). ICD therapy is also recommended for secondary prevention of SCD in patients with a life-threatening cardiac arrhythmia, including aborted sudden cardiac death.

Contraindications to ICD therapy are life expectancy ≤ 1 year, incessant arrhythmia, significant psychiatric illness, syncope without evidence of inducible ventricular arrhythmia or structural heart disease, ventricular arrhythmia amenable to catheter ablation, ventricular arrhythmia due to a reversible cause, and primary prevention of SCD in patients ineligible for cardiac transplantation or cardiac resynchronization therapy.¹ In addition, relative contraindications to ICD therapy include the need for radiation therapy to the thorax, high risk for infection, and high risk for deep venous thrombosis.

A subset of patients with cancer is at risk for SCD due to a variety of cardiac causes, including chemotherapy-induced cardiomyopathy or drug-induced long QT syndrome. These patients may benefit from ICD placement. However, the aforementioned relative contraindications for permanent defibrillator implantation often coexist in patients with cancer. Moreover, an individual with acute ma-

lignancy may have other contraindications for permanent defibrillator implantation, including the potential reversibility of cardiomyopathy or arrhythmia or an unclear prognosis for 1-year survival.

For cancer patients at risk for SCD, a wearable external cardiac defibrillator (WCD) offers an alternative to ICD placement. The WCD is designed to be worn continuously to monitor for ventricular arrhythmia and to provide defibrillation therapy in less than 1 minute after a life-threatening arrhythmia is detected. However, neither antitachycardia pacing to terminate an arrhythmia nor standard pacing to treat bradycardia or asystole is possible with the WCD. The WCD can act as an event monitor by automatically recording an arrhythmia and also by patient-triggered manual recording of the ECG tracing when a patient perceives an abnormal rhythm.

Methods

Deidentified records obtained from the ZOLL Lifecor Corporation of all patients in the United

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States supplied the LifeVest WCD between 2005 and 2009 were reviewed. Exemption to review the de-identified dataset for the purpose of this retrospective study was obtained from the local institutional review board. ZOLL Medical Corporation is the sole proprietor of the WCD and prospectively maintains the clinical information of all patients prescribed the WCD, including demographics, indications for use, follow-up related to usage, and outcomes. The database was queried to identify all patients with a history of cancer or a diagnosis of chemotherapy-induced cardiomyopathy for inclusion in the study. Data on patient demographics, indication for the WCD, compliance, length of wear, and outcomes were collected. The hours of daily use were determined based on the WCD recordings of impedance (measured by delivery of a test pulse), which occurred every 7 minutes while the WCD was active. The average daily use was calculated for each patient at the end of the monitoring period.

Results

Clinical characteristics

Among 23,797 patients prescribed the WCD between 2005 and 2009, 59 patients (0.02%) had a history of cancer or a diagnosis of chemotherapy-induced cardiomyopathy. Patient demographics and clinical characteristics are shown in Table 1.

Indications for the WCD

A defibrillator was indicated for primary prevention of SCD in 54 of the 59 patients, based on the presence of reduced cardiac function with a left ventricular ejection fraction $\leq 35\%$. Five patients had a prior sudden cardiac arrest or sustained ventricular tachycardia and, thus, met criteria for a defibrillator for secondary prevention of SCD. Among seven patients with a previously implanted ICD, two (29%) underwent removal of the ICD due to thrombus, including one

TABLE 1

Patient demographics and clinical characteristics

Characteristic	Number (%)
Total patients with cancer	59
Female	46 (78%)
Age (years), mean \pm SD	50 \pm 20
Years from cancer diagnosis, median (range)	1 (0.3–24)
Prior cardiac arrest	5 (8%)
History of ventricular tachyarrhythmia	14 (24%)
Left ventricular ejection fraction $\leq 35\%$	56 (95%)
Listed for heart transplant	5 (8%)

SD = standard deviation

with persistent bacteremia due to an infected thrombus. An additional five patients with an ICD were prescribed the WCD when the ICD was removed or programmed “off” during radiation therapy to avoid ICD malfunction. For those without a prior ICD, the reasons for prescribing the WCD rather than implantation of a permanent device included a history of intracardiac or deep venous thrombus, active infection, need for radiation therapy, and lack of central venous access due to lung cancer in the area of desired ICD lead insertion. The WCD was not prescribed to treat bradycardia or prevent SCD related to asystole, as it does not have pacing capabilities.

Outcomes

The WCD was worn for a mean of 20 ± 5 hours per day over a range of 1 to 442 days (median, 136 days). Appropriate and successful shocks were delivered on five occasions to four patients (7%), all within 3 months of use. The life-threatening arrhythmia was sustained ventricular tachycardia in two patients and ventricular fibrillation in two others. A single inappropriate shock occurred for atrial fibrillation at a conducted ventricular rate of 184 beats per minute in one patient. The discharge successfully converted this patient to sinus rhythm. There were no inappropriate discharges and no documented failure of ventricular arrhythmia detection. Among

11 deaths, none was due to noncompliance with the use of the WCD or malfunction of the WCD, such as failure to detect a lethal arrhythmia or unsuccessful defibrillation.

The WCD was discontinued in 20 patients (34%) when an ICD was placed, 8 patients (14%) when the cardiac condition improved, and 3 patients (5%) when a heart transplant was performed. There were 10 patients (17%) who were unable to comply with wear, 5 of whom reported discomfort due to the weight of the WCD and related breast cancer, bone cancer, or arthritis. The WCD was discontinued for unknown reasons in an additional 15 patients (25%).

Discussion

The WCD is an alternative to the ICD in select patients at risk for SCD. The WCD has been approved by the US Food and Drug Administration for use in adults since 2002, with studies showing few inappropriate shock episodes and successful detection and treatment of ventricular arrhythmia.^{2–4}

In this study, the WCD successfully aborted SCD in 7% of patients prescribed the device within 3 months of use. The temporary nature of the WCD also allowed for discontinuation of the WCD in 14% of patients whose cardiac condition improved. Moreover, there were no deaths related to failure of the WCD to detect a lethal arrhythmia or to deliver

successful defibrillation. The ability of the WCD to record patient compliance through continuous impedance monitoring, document alarm history, and review tracings enabled physicians not only to monitor usage but also to document the occurrence of life-threatening arrhythmia within the threshold of detection.

In addition to the impact on mortality in this series, the WCD likely reduced morbidity by avoiding an invasive implant in these cancer patients at increased risk for thrombosis and infection. It is well known that patients with cancer have an increased risk of venous thrombosis, reported in 4%–15% of patients undergoing chemotherapy.^{5–8} Moreover, cancer patients who experience a thrombotic episode have a greater probability of death. The transvenous insertion of an ICD system predisposes to thrombus formation and complications similar to those associated with indwelling central venous catheters.^{9,10} Among seven patients with a previously placed ICD in this series, two required removal of the ICD system because of thrombus formation with or without endocarditis. Thus, the WCD may be an alternative to an implanted device, especially in cancer patients who are in the acute treatment phase with hypercoagulability related to the tumor cells, chemotherapeutic agents, indwelling central catheters, and/or immobilization due to the disease process or surgery.

Another contraindication to device implantation that is not uncommon in cancer patients is an active bloodstream infection. Chemotherapeutic agents used to treat cancer, certain forms of active malignancy, and malnutrition related to cancer and its treatment all contribute to a reduction in cellular or humoral immunity and a greater susceptibility to infection.^{11,12} Surgery for implantation of a defibrillator generator as well as the placement of an intravascular defibrillator lead to a further increase in

the risk of infection in the immunocompromised patient.^{13,14} Use of the WCD circumvents the infectious risks related to device implantation until the patient's malignancy is in remission, the immune system has recovered from chemotherapy, or an active infection has resolved. In patients with a previously implanted defibrillator that requires removal due to infection, intravenous antibiotic therapy can be administered at home using the WCD for SCD prevention until therapy is complete and implantation of a new permanent device can be performed safely.

Lastly, the WCD is advantageous for this patient subset because of its temporary nature. The American Heart Association guidelines list life expectancy of ≤ 1 year as a contraindication to an implantable defibrillator.¹ It can be difficult to estimate the life expectancy of patients with cancer until a response to therapy is seen. The WCD can be a temporary bridge until a decision about the appropriateness of an implantable device can be made.

For patients receiving chest radiation, the WCD can be easily removed to avoid interference with the function of the defibrillator or the radiation dosing to the targeted tumor area. Although data are limited as to the effect of radiation therapy on ICDs, reported problems have included sensing threshold changes such that inappropriate delivery of a shock may result, shock energy deviations, shock coil failure, transient reprogramming of the device, or permanent device failure.^{15–17} These malfunctions have varied both between models and within the same model depending upon the radiation dose and position of the device in the radiation field. Moreover, the components of contemporary ICDs are more sensitive to radiation than are earlier-generation models.¹⁵

The ease of removal of the WCD is also of benefit when MRI is needed

for cancer staging. Depending upon the type of defibrillator, lead, scanner, and MR sequence used, the presence of an ICD is a contraindication to MRI; when MRI has been performed in this setting, the presence of an ICD has resulted in scatter artifact, which can affect its interpretation.^{18,19}

The permanent WCD may also be of benefit in patients with potentially reversible causes of arrhythmia or cardiomyopathy. They include patients with an immediate but temporary need for QT-prolonging medications or those with a newly diagnosed cardiomyopathy, which may improve with optimal heart failure therapy.^{20–25} Other patients may choose to delay ICD implantation until the prognosis of their cancer and the side effects of treatment are clearer, allowing them to make a more informed decision regarding palliative or end-of-life care.

Conclusion

Patients with cancer who are at risk for SCD but who have contraindications to an ICD, relative or absolute, may benefit from the WCD. Although the mean daily wear time is good for those who can comply, careful patient selection and ongoing assessment of use are imperative. The WCD protects the compliant patient from SCD until an ICD can be safely implanted or the ICD is deemed unnecessary.

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