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Implantable Device-Based Monitoring of Patients with Heart Failure: The OptiVol Users’ Summit 2006

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Introduction

W. H. Wilson Tang, MD

In November 2004, the US Food and Drug Administration (FDA) approved a novel heart failure monitoring tool, OptiVol fluid status monitoring (Medtronic, Inc., Minneapolis, MN), for use on some biventricular pacemakers. The feature is now also available on some implantable cardioverter defibrillators. OptiVol fluid status monitoring allows the measurement of intrathoracic impedance from the right ventricular lead to the can of the device. The OptiVol fluid index, a derivative of the impedance signal over time, can serve as an indicator for underlying fluid accumulation.

Although some physicians have enthusiastically embraced the concept of this new technology, many have been skeptical and are exploring how to best use the information to care for their patients. Until recently, access to OptiVol data has been limited to direct device interrogation. OptiVol was approved based on limited published data, without evidence-based algorithms on how to use the information stored in the device. Early experience has been limited largely to anecdotal case reports. Therefore, clinicians who have incorporated intrathoracic impedance data into the care of their patients have become the experts in this new technology.

Clinicians eager to share their experiences with this new device-based diagnostic tool suggested the creation of a venue to discuss the use of intrathoracic impedance assessment in clinical practice. This grassroots approach parallels the development of user groups in the computer software industry. Subsequently, >150 participants from around the country, including practicing cardiologists, electrophysiologists, advanced practice nurses, and device nurses, joined those involved in the development of the OptiVol algorithms to share their experiences and exchange ideas at the first OptiVol Users’ Summit meeting, held April 28–29, 2006, in Chicago, Illinois. The OptiVol Users’ Summit, sponsored by Medtronic, Inc., has initiated an exciting and much needed dialogue. This supplement to The American Journal of Cardiology features articles presented at this inaugural OptiVol Users’ Summit.

The first article, by Dr. Li Wang, whose work has been instrumental in the clinical development of OptiVol fluid status monitoring, begins with a description of the fundamentals of intrathoracic impedance measurements and the OptiVol fluid index. Next, Dr. Robin Germany, an electrophysiologist and heart failure cardiologist, and Dr. Christina Murray, discuss the integration of device-based diagnostics into the outpatient clinical setting. Cardiologist Dr. Roy S. Small provides further insight by focusing on the challenges of integrating device-based monitoring, and particularly intrathoracic impedance monitoring, into a high-volume private group practice. Next, Dr. John Andriulli, an electrophysiologist interested in the utility of impedance measurements in the arrhythmia practice, presents the findings of a retrospective analysis of a registry of patients with implantable devices with intrathoracic impedance monitoring capabilities. Nurse Lisa Rathman, a heart failure nurse clinician, contributes a presentation highlighting the use of intrathoracic device diagnostics as an educational tool to enhance patient adherence to medication and dietary recommendations. Dr. Wang follows with an article on a collection of cases discussing refinements in the approach used to interpret intrathoracic impedance tracings. The supplement concludes with my article on the many challenges that lie ahead for electrophysiologists, heart failure cardiologists, and nurses in the successful incorporation of device-based monitoring and a brief summary of ongoing and upcoming trials of OptiVol fluid status monitoring that should provide answers to current challenges. It is hoped these presentations will provide a “nuts and bolts” understanding of these device-based measurements and stimulate further discussions.

As we await further insights from various clinical registries and results from pivotal studies using device-based information to guide clinical management in patients with heart failure, it is very clear that this new format of peer-to-peer learning will provide insights into creative uses of intrathoracic impedance and other innovative device-based data and observations far beyond the original intended uses of this technology. This format will be vital as increasing numbers of innovative hemodynamic and remote monitoring devices become available for heart failure management.
Traditional clinical trials are unlikely to provide information on how to incorporate data from these devices into clinical practice in a timely fashion. Therefore, we will need to rely on interested clinicians and healthcare providers to evaluate the potential utility and limitations of these new data. It is hoped that further interest in the clinical application of device-based data and, in particular, intrathoracic impedance will be sparked by the discussions initiated at this inaugural users’ summit.

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The primary objective of the first-generation implantable cardiac pacemakers was to provide critical heart rate support, but these devices did not have any diagnostic capabilities. In the intervening decades, the number, type, and complexity of implantable devices has greatly expanded. Today, implantable devices not only provide heart rate support but they also provide protection from sudden cardiac death with implantable cardioverter defibrillators (ICDs) and reduce symptoms and increase survival with cardiac resynchronization therapy (CRT). Furthermore, information on physiologic variables has been collected in patients with implanted devices for the purpose of providing sophisticated closed-loop optimization of their pacing and defibrillation algorithms. Thoracic fluid status monitoring via intrathoracic impedance is the newest device-based diagnostic capability. For those patients with heart failure who are already targeted to receive an ICD or CRT with defibrillator implant, the ability to monitor fluid status can provide additional insight into the difficult problem of evaluating and managing these patients. This article reviews the basics of measuring intrathoracic impedance via OptiVol fluid status monitoring (Medtronic, Inc., Minneapolis, MN), as well as clinical results regarding the utility of evaluating OptiVol intrathoracic impedance data trends. © 2007 Elsevier Inc. All rights reserved. (Am J Cardiol 2007;99[suppl]:3G–10G)

Heart failure is a large and growing problem costing healthcare systems billions of dollars each year. The American Heart Association (AHA) estimates that approximately 5 million people in the United States have heart failure, with >500,000 new cases each year.1 Approximately $30 billion was spent in the United States on the direct and indirect costs of managing heart failure last year.1 Logically, careful monitoring of fluid status in ambulatory patients with chronic heart failure can provide an early warning of impending decompensation and help reduce the number of heart failure–related hospitalizations. Regular monitoring of body weight and clinical symptoms has been advocated for this purpose, but its reliability as a surrogate for clinical stability can be challenging. Likewise, patient characteristics may influence the interpretation of more objective diagnostic measures, such as B-type natriuretic peptide.2 Additionally, pulmonary congestion is difficult to recognize in its early stages of development because of the late appearance of symptoms before hospitalization.3,4 A mismatch may exist between the signs and symptoms of the patients and their true cardiopulmonary status, which can delay intervention.5,6

Thoracic fluid status monitoring via intrathoracic impedance is the newest device-based diagnostic capability. For those patients with heart failure who are already targeted to receive an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy/defibrillator (CRT-D) implant, the ability to monitor fluid status can provide additional insight into the difficult problem of evaluating and managing these patients. This discussion focuses on the OptiVol fluid status monitoring algorithm (Medtronic, Inc., Minneapolis, MN), which is clinically available in several ICD (Virtuoso) or CRT-D devices (InSync Sentry and Concerto).

Development and Operation of the OptiVol Fluid Status Monitoring Algorithm

The concept of using external transthoracic impedance to monitor pulmonary congestion has a long history, dating to research sponsored by the National Aeronautics and Space Administration (NASA) at the University of Minnesota in the 1960s and has been validated in animals7,8 and in humans.9,10 Over the past few decades, several device configurations and algorithms have been devel-
OptiVol fluid status monitoring represents the application of the concept of transthoracic impedance as a measure of pulmonary fluid accumulation into implantable devices. Assessment of intrathoracic impedance can be achieved by measuring impedance between the device case (typically implanted in the left pectoral region) and the lead in the right ventricle (Figure 1). This vector encompasses much of the left thoracic cavity. As the patient has worsening heart failure with increasing left atrial filling pressure caused by left ventricular dysfunction, more fluid is retained in the pulmonary circulation. Blood is among the most conductive tissues, which means it is among the least resistant tissues in the human body. Therefore, as fluid accumulates in the pulmonary circulation, a reduction in impedance is expected. The major advantage is the relatively fixed positions between the 2 implanted electrodes, which provide more consistent and reliable measurements.

Pulmonary congestion starts with vascular congestion and develops into interstitial congestion. If untreated, pulmonary edema develops in the alveoli and the interstitium, thereby putting the patient in a congestive state. Thus, any type of pulmonary congestion would be reflected in changes in intrathoracic impedance and is of interest in managing patients with congestive heart failure. Using the broad concept of Ohm’s law, the impedance (or “resistance”) can be measured by delivering a small alternating current between the lead and the device.

Application of impedance monitoring to implantable device technology requires several considerations during the initial implant surgery. Edema in the device pocket can likely lower the impedance measurements because the pocket is in the path of the measurement area. Therefore, OptiVol fluid status monitoring is not initiated until ≥34 days after implant because the earlier data may be affected by postsurgical edema and inflammation in the pocket area and may not reliably indicate worsening pulmonary congestion.

Animal data have suggested that the specific placement location of the right ventricular lead will not affect the impedance measurements. Whether the lead is placed at the septum or at the apex, the size of the right ventricular coil electrode should be of sufficient size to assess impedance across the intrathoracic region, regardless of lead position. Although it is theoretically possible that body position can affect impedance measurements, its impact is unlikely to be significant with an impedance measurement averaged over 5 hours, as implemented in current devices.

Factors Affecting Intrathoracic Impedance and OptiVol Fluid Trend Status

There are several factors that may affect the reliability and specificity of the intrathoracic impedance monitoring.
algorithm. Intrathoracic processes, such as pneumonia or pleural effusion, can affect intrathoracic impedance measurements. Any pulmonary events that occur in the lung contralateral to the implanted device should not affect the intrathoracic impedance data, although it would have to be a very isolated event to only occur in one lung and not the other. Similarly, the air volume in the lung can affect intrathoracic impedance. Air itself is an insulator, and the more air there is in the lungs, the higher the impedance. For example, in patients with chronic obstructive pulmonary disease, the functional residual volume in the lungs may change over time, so the impedance measurements can be affected over the long term. Therefore, consideration should be given for those diseases or conditions that may affect the impedance measurements. Furthermore, because intrathoracic impedance can only assess congestion within the pulmonary region, the system cannot measure and track peripheral edema or abdominal ascites that occur outside the measurement field. Nevertheless, changes from the patient’s own reference levels should theoretically be unaffected in normal circumstances.

Intrathoracic Impedance Measurements

With OptiVol fluid status monitoring, impedance is measured every 20 minutes from noon to 5 PM for a total of 64 measurements over a 5-hour period. The device records the average of those 64 measurements as the daily impedance value. By averaging many measurements over a 5-hour period, the effects of respiration and posture on impedance are minimized. The system offers a resolution of 0.25 Ω. The impedance measurements start after ventricular fibrillation detection is enabled for the first time, and it cannot be reset.

The OptiVol algorithm aims to track a patient’s fluid status over time and provides insight into whether the patient is trending toward a more wet or a more dry state. Data from the Medtronic Impedance Diagnostics in Heart Failure Patients Trial (MIDHeFT) study were used to develop the algorithm for OptiVol fluid status monitoring. The sampling period was chosen based on data from MIDHeFT, which showed that intrathoracic impedance and the patient’s fluid status were best correlated during this period. The algorithm is used to determine whether fluid buildup is occurring, and it calculates a number of values based on intrathoracic impedance measurements.

Average daily impedance: A total of 64 intrathoracic impedance measurements are made each day between noon and 5 PM and averaged to arrive at a single measurement for the day (Figure 2).

Reference impedance: Reference impedance is initialized on the 34th day of measurements by averaging the last 4 average daily impedance values. This is the only time that averaging is involved in changes to the reference impedance. After initialization, the reference impedance trend established by the OptiVol algorithm slowly adapts to fluid changes (Figure 2). The reference impedance reflects a relatively slow-moving impedance trend, and is initiated ≥34 days after implantation to allow time for pocket and lead maturation. At this time, it is expected that pocket wound swelling will have subsided and will not affect impedance measurements. The reference impedance trend is not programmable and is a reflection of each patient’s status, with each patient serving as his or her own control.

OptiVol fluid index: Any cumulative consecutive negative deviations in the average daily impedance from the reference impedance are plotted to create the OptiVol fluid index (Figure 2). The OptiVol index contains 2 pieces of information: the magnitude of impedance reduction with regard to the reference impedance (measured in ohms), and the sustainability of that reduction (measured in days). The OptiVol fluid index, therefore, has a measurement unit of ohm-days.

OptiVol threshold: The OptiVol threshold can be programmed to indicate a level that could be of potential clinical relevance for that patient (Figure 2). This threshold is nominally programmed at 60 Ω-days based on MIDHeFT data, but it can be adjusted between 30–180 Ω-days based on the fluid tolerance level that the clinician determines is best for that patient.

The case illustrated in Figure 2 shows that the average daily impedance decreased below the reference impedance line during decompensation, but it eventually crossed back over the reference impedance line. When the average daily impedance is above the reference impedance line for 2–3 days, the OptiVol fluid index resets to zero. In most cases the OptiVol fluid index will continue to rise before it is reset to zero.

The OptiVol algorithm provides some unique capabilities. For example, each patient serves as his or her own control. The clinician always compares the patient with his or her own data rather than trying to manage a specific impedance value. This approach is different from impedance measured from external impedance cardiographic technologies using population-based thresholds. Because heart failure is a dynamic condition, the ability to adjust the reference impedance level automatically is important in monitoring for changes. Additionally, the physician can determine the level (threshold) of fluid buildup that may be of clinical significance for each patient.

A more detailed understanding of OptiVol fluid status monitoring can best be seen in 2 clinical examples. In the first example, the patient was hospitalized for worsening heart failure on September 11, 2001 (Figure 3). The impedance was relatively stable 2 weeks before hospital-
Figure 2. Algorithm to track fluid accumulation. The OptiVol (Medtronic, Inc., Minneapolis, MN) algorithm calculates a number of values to aid in tracking intrathoracic fluid accumulation. (A) The average daily impedance is an average of 64 impedance measurements made between noon and 5 PM. The reference impedance is initialized 34 days after implant by averaging the last 4 average daily impedance values. The trend then adapts slowly to fluid changes and is a reflection of each patient’s fluid status. (B) Cumulative consecutive negative deviations between the average daily impedance and the reference impedance are plotted to create the OptiVol fluid index, which is a measure of the magnitude and duration of an impedance reduction. (Data on file, Medtronic, Inc.12)

Figure 3. Impedance before and during hospitalization for heart failure. As the patient experienced worsening heart failure and eventual hospitalization, intrathoracic impedance decreased. After diuresis and resolution of heart failure symptoms, intrathoracic impedance increased to the presymptomatic level. CHF = congestive heart failure; Pt = patient. (Data on file, Medtronic, Inc.13)
Wang Intra-thoracic Impedance Monitoring in Heart Failure

Figure 4. Correlation between impedance and pulmonary capillary wedge pressure (PCWP) during hospitalization for heart failure. The patient in this example was hospitalized with a fairly high PCWP. As diuresis of the patient progressed, PCWP decreased, and intrathoracic impedance increased. The inverse correlation was fairly high ($r = -0.95$, $p < 0.0001$). The curve represents the linear regression line between PCWP and impedance. (Data on file, Medtronic, Inc.12)

In summary, both examples illustrate how impedance reduction reflects worsening fluid overload before heart failure-related hospitalization. After the patients were treated and underwent diuresis, there was a good correlation ($r = -0.95$) between the increase in intrathoracic impedance and the reduction in intracardiac filling pressures.

**Clinical Studies**

Intrathoracic impedance assessment using OptiVol fluid status monitoring has been studied in the MIDHeFT study.11 The MIDHeFT study used a pacemaker modified to accept an ICD lead and special, downloaded software to automatically measure and record intrathoracic impedance in patients with severe heart failure. A total of 33 patients were enrolled, and the mean follow-up time was 20 ± 8 months. The study was divided into 2 phases. During the acute phase, patients hospitalized for acute decompensated heart failure were transferred to the CCU and received intravenous diuretics and other medications. A pulmonary artery catheter was inserted, and the PCWP values were measured every 2 hours. During this time frame, approximately 5 kg of fluid were eliminated, with a corresponding decrease in PCWP to 10 mm Hg at the time of discharge. Additionally, as PCWP was reduced, the average daily impedance levels increased correspondingly. The correlation between intracardiac filling pressures and impedance levels is highly statistically significant ($r = -0.95$, $p < 0.0001$).

In summary, both examples illustrate how impedance reduction reflects worsening fluid overload before heart failure-related hospitalization. After the patients were treated and underwent diuresis, there was a good correlation ($r = -0.95$) between the increase in intrathoracic impedance and the reduction in intracardiac filling pressures.
patients with 14 hospitalizations. Briefly, the MIDHeFT data suggest that (1) intrathoracic impedance (measured by average daily impedance) and intracardiac filling pressures (measured by a reduction in PCWP during heart failure hospitalization) were inversely correlated \( r = -0.61, p < 0.001 \), (2) intrathoracic impedance decreased before symptom onset for all heart failure–related hospitalizations, (3) symptom onset occurred 3.0 ± 2.5 days before admission, (4) the decrease in intrathoracic impedance levels preceded symptom onset by an average of 15.3 ± 10.6 days, and (5) the average decrease in average daily impedance was 12.3 ± 5.3% \( p < 0.001 \) and decreased over an average of 18.3 ± 10.1 days (range, 3–42 days) before hospitalization (Figure 5).11 Although relatively small in sample size, the MIDHeFT study demonstrated the possibility of providing an advanced warning of pulmonary congestion at a presymptomatic stage and enabling early interventions with the goal of preventing heart failure decompensation.

In considering the rate of false-positive results, it is important to keep the definition in mind. In the MIDHeFT study, there were examples of patients crossing the threshold for a number of reasons, including dietary nonadherence. The patients were not hospitalized because the physician intervened by increasing the patient’s diuretics. However, because the patients were not actually hospitalized, the threshold crossings were considered false-positive results for the purpose of the study.

Data Access: The OptiVol Example

To fully realize the clinical potential of using device-based data for heart failure monitoring purposes requires delivery of the right information to the right people at the right time in the right way. Implantable devices are now capable of generating trend data in summary reports (Figure 6).14 Up to 14 months of continuous trend information on the average daily impedance in relation to the reference impedance and on the OptiVol fluid index is available as part of the Cardiac Compass Trends report (Figure 6).14 The impedance data are temporally aligned with other parameters useful in the management of patients with heart failure, including daily atrial fibrillation...
burden and ventricular rates, patient activity, daytime and nighttime heart rates and heart rate variability, as well as the percentage of time pacing.

There are several ways of accessing these reports. During a clinic visit, the device programmer can directly extract trend reports by standard device interrogation procedures. The 90-day trend data can also be downloaded by the CardioSight Reader (Medtronic, Inc.) at the outpatient clinic for those without a device programmer. This can be achieved via transmission of interrogated data to a secure server, followed by a fax report of the Heart Failure Management Report to the clinic in <10 minutes. In the United States, the Heart Failure Management Report (including the OptiVol fluid index trends) can also be accessed through the Medtronic CareLink Network (Medtronic, Inc.) when patients remotely transmit their device information from home. The report obtained via CareLink provides the same 14 months of data but without the OptiVol threshold line.

Conclusion

Intrathoracic impedance assessment is a promising new tool in the management of patients with chronic heart failure. However, there is much to learn from practicing clinicians on how to best use its capabilities in clinical practice. It is only through a cooperative journey that we can improve intrathoracic impedance monitoring capabilities in order to better suit current clinical practice.


Implantable cardiac devices now go far beyond the functionality of early pacemakers and defibrillators. They provide us with an unprecedented amount of information about the day-to-day status of our patients with heart failure, providing insight into the complex clinical picture of these patients. More advanced technology can be seen on the horizon, and the development of strategies to incorporate this information into our clinics is needed. Traditionally, information from devices has only been accessed by the physicians implanting the device. However, heart failure physicians and their patients can benefit from the information now available and from having ways to access and use the data. This article focuses on the successful integration of device-based data into patient care in the outpatient clinical setting. © 2007 Elsevier Inc. All rights reserved. (Am J Cardiol 2007;99[suppl]:11G–16G)

Although some practices incorporate device or electrophysiology (EP) nurses into their practices, cardiologists and heart failure physicians are often removed from routine contact with these specialized nurses. Similarly, not all cardiology clinics have programmers in their office. In clinics where a programmer is available, clinicians have differing degrees of comfort and expertise in using these devices. In the past, it was necessary only to collect data from devices at routine intervals to check for appropriate device function. In this new era of data integration, device checks may be beneficial at each clinic visit and perhaps even more frequently, based on the patient’s clinical status. Reports collected at these intervals can be tailored with a focus on patient management rather than just device management.

Device Interrogation in the Non-Electrophysiologist Office

EP nurses can be recruited to develop a process to make heart failure reports accessible to the treating physician and also to provide support for the heart failure clinic. This can help ease the transition in cases in which physicians in the clinic are not accustomed to looking at the data from devices. Patients can have their devices interrogated before physician contact, and the resulting reports can be printed on full-sized paper and placed on the front of the chart. These reports focus on the heart failure–related data stored in the device and should not replace ongoing device monitoring by the implanting physician.

With the availability of an interrogation device that does not have programming capabilities, such as the CardioSight Reader (Medtronic, Inc., Minneapolis, MN), medical assistants can retrieve data from all compatible devices. The medical assistants can then record this information in the patient’s chart, just as they would vital signs and medications. If the device is not compatible, a device nurse must still interrogate the device before the physician visit. After this interrogation procedure becomes routine, it adds very little time to the patient visit, yet it provides a tremendous amount of insight. These visits do not replace routine EP visits, but the device nurse does not have to see all patients to obtain heart failure data.

Types of Data Obtained

Many different types of information can be garnered from device reports (Figure 1). These data allow patient care to be tailored for the purposes of both symptom management and safety, including titration of medications and institution of anticoagulation therapy. In addition to the usual clinical information, data patterns may emerge on these reports. In some cases, evidence of medication noncompliance may be present, and in cases where proarrhythmic drugs are being used, this should be carefully assessed.

Cardiac rhythm: Most implantable devices provide the ability to monitor episodes of nonsustained ventricular tachycardia. Daytime and nighttime heart rates are tracked. For devices with atrial and ventricular leads, hours spent in atrial fibrillation and ventricular rate during atrial fibrillation are recorded. When tracked over time, all of these parameters allow a more comprehensive approach to medication titration. Other findings, such as previously unsuspected
paroxysmal atrial fibrillation, may be present in these reports.

**Heart rate variability:** Heart rate variability, defined as the standard deviation of 5-minute median atrial–atrial intervals, can be calculated and recorded over time. Heart rate variability has been shown to be predictive of sudden cardiac death in patients with heart failure. A study that analyzed heart rate variability in 16-minute electrocardiographic recordings was able to stratify patients into a high-risk category using low HRV and frequent PVCs. The 3-year sudden cardiac death rate was 23% when those predictors were present, versus 3% in patients without either predictor.1

Heart rate variability in a population with heart failure has also been shown to be lower in patients with death or hospitalization, and the decrease in heart rate variability was
Cardiac resynchronization therapy has been shown to improve heart rate variability, possibly by shifting autonomic control away from sympathetic dominance. We have used these data in our clinic to help determine the frequency of follow-up.

Percentage of atrial/ventricular pacing: The percentage of atrial and ventricular pacing is important in the management of patients with heart failure. Multiple recent trials have found worsened left ventricular ejection fraction and other clinical outcomes with continuous right ventricular pacing. The Second Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) showed a trend of more frequent hospitalization in the implantable cardioverter defibrillator (ICD) group (19.9 vs 14.9, p = 0.09), but it was unclear if this effect was because of longer life spans, shock-related admissions, or right ventricular pacing. The Dual Chamber and VVI Implantable Defibrillator (DAVID) trial enrolled 506 patients with ICD indications but with no pacemaker indications. Devices were implanted and randomized to ventricular backup pacing only at a rate of 40 beats per minute (VVI-40) or dual-chamber pacing rate-responsive pacing with a low rate of 70 beats per minute.
(DDDR-70) with forced right ventricular pacing. Patients in the VVI-40 group had fewer primary end point events (death or heart failure hospitalizations) when compared with the DDR-70 group (hazard ratio [HR], 1.61; p ≤0.03). In particular, those patients with right ventricular pacing >40% had worse event-free rates (p = 0.09). Study of the Mode Selection Trial in Sinus Node Dysfunction (MOST) population evaluated complications of heart failure associated with right ventricular pacing. Pacung >40% in DDR mode was associated with an increased risk of heart failure–related hospitalizations (HR, 2.99). Furthermore, there was a linear relation between percent cumulative right ventricular pacing and the development of atrial fibrillation. Newer devices with managed ventricular pacing algorithms may be beneficial in avoiding these adverse outcomes.

**Patient activity:** Patient activity can be plotted as active hours during the day. Studies have documented that patient activity decreases as a patient approaches hospitalization (188 min/day down to 164 min/day, p = 0.028). Patient activity level is also useful in patient education. We often show the patient activity report to our patients to discuss changes in their physical activity and to encourage increased activity.

**Intrathoracic impedance:** Newer and more heart failure–specific device-based markers have been and are being developed. For example, intrathoracic impedance can be followed in some newer devices via a derived fluid index, the OptiVol fluid index (Medtronic, Inc.). Impedance is inversely proportional to pulmonary capillary wedge pressures. Pilot studies on this concept documented changes before heart failure exacerbation requiring hospitalization. Ongoing studies will determine the prospective validity of this concept.

**Other measurements and devices:** A new implantable hemodynamic monitoring system, Chronicle (Medtronic, Inc.), which provides continuous intracardiac hemodynamic data about the patient, is currently awaiting regulatory approval. The data have been shown to be reproducible, both at rest and with activity, over time. This device is specifically designed to provide information on the management of heart failure and will provide additional information on the clinical status of the patient when not in the office. This hemodynamic monitor is only the first in a number of heart failure management devices currently being developed.

Some implantable devices have been paired to external devices, such as a weight scale and blood pressure cuff that can be accessed over the Internet. An example is the Latitude patient management system (Boston Scientific, St. Paul, MN). These data along with arrhythmia and heart rate variability data can be transmitted and monitored over the Internet with physician notification via e-mail in the event of significant changes. These data can also be printed from the Internet database and placed on the patient’s chart before a clinic visit.

### Which Patients Should Be Monitored?

For physicians taking care of patients with heart failure, the use of device data is not limited to a diagnostic “spot check” of thresholds and impedance data. These data can also provide insight into what is happening with patients when they are not in the office. Ideally, reports should be collected at every patient encounter. Otherwise, the clinical utility of the information is significantly reduced. Many conditions monitored by devices are relatively asymptomatic. A patient who developed atrial fibrillation in the last 24 hours may not develop symptoms of heart failure for a few weeks. Even significant episodes of nonsustained ventricular tachycardia may not be perceptible to the patient. Thus, in our practice, we follow up all patients with compatible devices at the time of their clinic visit and at least bimonthly. Less stable patients or those with recurrent decompensation can be monitored more closely, with checks as frequently as once or twice per week.

### Remote Monitoring Using the Internet

The ability to manage device data via Internet sites is a new and growing field with great promise. Most of the implantable cardiac device companies currently offer the ability to view information over the Internet. However, only certain devices from each company are supported by Internet monitoring systems. Patients can download device data the night before a clinic visit, so the information can be accessed quickly, immediately before the visit. Another useful practice is to monitor the patient between office visits. If the download shows a problem, the patient can be contacted, and clinical treatment can be instituted. In some instances, treatment can occur without the patient having to leave the comfort of his or her home. We have found that this capability sometimes allows us to identify the need for a laboratory test or other test before the patient’s visit with us. Remote transmission has also allowed us to monitor patients who live a great distance from the clinic.

Internet access of data also provides many other potential opportunities for the prevention of heart failure hospitalization. Our clinic has asked patients who have devices with volume monitoring capability to download device data once a week to proactively identify clinical problems. Although we are awaiting the results of several upcoming trials, it is hoped that these data may allow less frequent clinic visits or more information between clinic visits. Additionally, patients have responded very favorably. They feel they are being “watched over.” The frequency of downloads may depend on both the clinic and the severity of the disease. A patient with New York Heart Association (NYHA) functional class II heart failure who has never been hospitalized may not benefit from frequent examinations of intrathoracic impedance, whereas we may request that an NYHA class IV
patient transmit information several times a week to facilitate care.

Follow-Up Evaluation

Among the best uses of technology allowing remote transmission of device data is to decrease the need for such frequent follow-up. Often, patients with heart failure are elderly, cannot drive, or live a significant distance from the managing clinic. For stable patients, the use of the technology allows the number of follow-up visits to be decreased. Other patients can then be filtered into the clinic. Follow-up frequency may be determined by specific results found in the device data. Data points, such as heart rate variability, have been proposed to help determine the frequency at which patients should be seen.9

Protocols using the data can be extremely helpful as well. We have devised protocols for the use of impedance monitoring data during a clinic visit (Figure 2) and after a scheduled download from the patient’s home (Figure 3). These protocols provide standardization and utilization for physician extenders as well as those less comfortable using the information. However, further studies are needed to determine the utility of such information to titrate drugs remotely and to reduce healthcare utilization.

Reimbursement

Although the time it takes to access these data is decreasing, this extra time may adversely affect a busy clinic. Challenges remain in determining the types of reimbursement available for this tailored medical care. A potential strategy may be to include time and/or complexity of the visit. By looking at rhythm disturbances and volume data, the visit becomes more complex and time consuming. If the data are accessed remotely as part of the routine EP evaluation of the device, this would appropriately be included in the normal interrogation charge.

Currently, the physician managing the day-to-day care is not reimbursed for the complex issues associated with HF disease management. Medicare has recently approved reim-

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*Figure 2. Use of devices in the office. BNP = B-type natriuretic peptide; exam = examination; HF = heart failure; labs = laboratory tests.*

*Figure 3. Use of device information in the outpatient setting.*
bursement for remote integration of the device, including analysis of the device functioning and thresholds. Specific billing codes, such as those now used for device interrogations by EP practices, are still needed for the isolated analysis of heart failure device data.

To add to the complexity of reimbursement in the outpatient setting, workflow patterns have to be established. As seen in the protocol, patients with abnormal volume information are contacted. If the physician calls the patient directly, this is coded as a telephone contact. However, a more practical approach is to have a nurse or physician extender contact the patient, although this is not reimbursed.

**Conclusion**

Technology has developed incredible ways to help us treat patients. Increasing numbers of patients with heart failure have implantable cardiac devices that can provide us with significant insights into their management and care. By tapping into this information, we can more effectively treat our patients. However, without creation of easy and simple ways to access and use these data, opportunities to better serve our patients may be lost. More complex and fascinating devices are on the horizon. Determining ways to incorporate this into daily clinical practice now will help ease the transition when these devices become standard of care within the next few years.

Integrating Device-Based Monitoring into Clinical Practice: Insights from a Large Heart Failure Clinic

Roy S. Small, MD

Heart failure is a difficult and costly disease to manage in part because the symptoms may be protean, the physical findings obscure, and the laboratory assessments unreliable. New implanted physiologic monitors may simplify the care of patients with heart failure, if they can be incorporated into routine clinical practice. Cardiac resynchronization therapy/defibrillators and implantable cardioverter defibrillators with continuous intrathoracic impedance monitoring capabilities (OptiVol fluid status monitoring; Medtronic, Inc., Minneapolis, MN) have recently been introduced and may provide an early warning of thoracic fluid retention. However, patients who have devices with this diagnostic capability must be identified, and the device-based information must be accessed systematically, if it is to be used in the disease management process. Ancillary information, such as the Heart Failure Management Report that is generated from data stored in Medtronic devices, may facilitate recognition of disease mechanisms associated with decompensation. The predictive value of continuous intrathoracic impedance monitoring with an implantable device is still unknown. Thus, therapeutic decisions should be made in conjunction with a clinical assessment. Physicians and other healthcare providers will need to become familiar with these devices so they can appreciate their advantages and limitations. © 2007 Elsevier Inc. All rights reserved. (Am J Cardiol 2007; 99[suppl]:17G–22G)

Heart failure–related expenditures are the single most costly US government medical expense, accounting for nearly 28 billion dollars in direct and indirect costs in 2005.1 Approximately 50% of these costs are directly related to the hospitalization of patients with acute decompensated heart failure (ADHF).2 Most patients hospitalized with ADHF have previously been diagnosed with heart failure.3 The readmission rate within 6 months after hospital discharge is 44%.4 The need for frequent rehospitalization for the treatment of ADHF reflects the difficulties in caring for these patients. Most are elderly and have many comorbidities. Management requires multiple medications, careful education, and intensive follow-up to help maintain equilibrium. It may be possible to reduce the frequency of hospitalizations by improving outpatient monitoring techniques. The potential benefits are substantial both in reducing the financial burden of this disease to society and in improving individual clinical outcomes.

Most patients admitted with ADHF have adequate cardiac output and elevated left ventricular filling pressures.5 The clinical and laboratory assessment of patients with heart failure frequently fails to detect the insidious onset of fluid retention, which may then progress to overt vascular congestion prompting hospitalization. Rales and edema may be present in only a few patients with elevated filling pressures, and an accurate assessment of jugular venous pressure is inconsistent.6 Up to 40% of patients admitted with ADHF and severely elevated left ventricular filling pressures may have chest x-ray findings of no or minimal congestion.7 The correlation of plasma B-type natriuretic peptide levels and pulmonary capillary wedge pressure is weak and particularly unreliable in patients with impaired left ventricular systolic function.8 Although diagnostic models using trans-thoracic impedance measurements (impedance cardiography) have recently been described and may help predict subsequent decompensation,9 their utility has yet to be validated in prospective clinical trials. Daily weight measurements are helpful and readily obtained but are not a reliable indicator of heart failure status.10 Thus, the high frequency of ADHF hospitalizations is, in part, because of the lack of an accurate barometer for monitoring patients with a propensity for fluid retention. Intrathoracic impedance monitoring may be such a tool.

Intrathoracic impedance is inversely correlated with left ventricular filling pressure.11 This principle has been used to design the OptiVol fluid status monitoring algorithm,12 which has been incorporated into the InSync Sentry cardiac resynchronization therapy/defibrillator (CRT-D) device (Medtronic, Inc., Minneapolis, MN) with standard interrogation capabilities. The newer Virtuoso implantable cardioverter defibrillator and Concerto CRT-D (Medtronic, Inc.) have additional wireless capa-
abilities, which can be programmed to automatically transmit device diagnostics at prespecified routine intervals. These novel devices require the implementation of clinical procedures to deal with programmed device alerts as well as unsolicited data obtained during routine interrogations. If device-derived diagnostic information is not used, then the additional expense associated with these devices is not justified. Furthermore, the opportunity to use remote physiologic monitoring to reduce hospital costs and improve patient outcomes will have been squandered. Clinics that have advanced practice nurses with training in heart failure are ideally suited to incorporate device-based diagnostics into routine practice. The integration of heart failure and electrophysiology (EP) device follow-up facilitates the use of device-based diagnostic information.

Incorporation of Intrathoracic Monitoring in the Heart Failure Clinic

Routine monitoring of intrathoracic impedance may be a useful tool for monitoring patients with chronic heart failure by providing an early warning concerning fluid retention and impending decompensation. The Heart Group (Lancaster, PA) implanted its first CRT-D device with intrathoracic impedance monitoring at Lancaster General Hospital in December 2004 and currently monitors >500 patients with a CRT-D implant in the heart failure clinic, including >200 with devices featuring intrathoracic impedance–monitoring capabilities.

The practice model in The Heart Group (a large private heart failure clinic) is a physician-directed and nurse practitioner–implemented model. The heart failure clinic coordinates its services with the EP clinic for device follow-up. Information derived from device diagnostics is shared with both the heart failure and EP services to ensure that the data are analyzed and used appropriately. For example, if impedance data indicating a potential decompensation are discovered during device interrogation in EP, the information is forwarded to the heart failure group for analysis and therapeutic intervention. Similarly, heart failure clinicians and members of the EP group meet regularly to discuss the management of CRT nonresponders.

Simple and seamless access to device-based diagnostic data is a key to optimizing clinical utility. Although it may seem self-evident, if a patient is not identified as having a device with monitoring capabilities, or if the device is not interrogated, then the opportunity to integrate the device-based information into the clinical decision-making process will be lost. Therefore, we label each patient’s medical record in our heart failure clinic with an identifying sticker indicating the presence of an impedance-monitoring device. When the patient arrives in the heart failure clinic, the device is interrogated using a data access tool—the CardioSight Reader (Medtronic, Inc.)—as shown in Figure 1. This data reader facilitates access to diagnostic information and can be used safely by trained technical staff. It has read-only capabilities and cannot be used to alter the programmed settings of the device. The telemetry antenna of the reader is positioned over the device, which then transmits the data over a standard phone line to a secure server. A detailed report, the Heart Failure Management Report, is faxed back to the clinic for use during the patient’s visit in <10 minutes. This report includes 90-day trend data for the following variables: intrathoracic impedance data (average daily impedance and the OptiVol fluid index), atrial arrhythmia profile, ventricular response during atrial arrhythmias, patient activity index, nighttime heart rate, heart rate variability, and percent atrial and ventricular pacing. These trends are aligned across time, which facilitates recognition of their interrelations. Device interro-

Figure 1. Downloading the device diagnostics using the CardioSight Reader. (Courtesy of Medtronic, Inc., Minneapolis, MN)
gation using this service is quick and easy and is associated with minimal, if any, cost. The printed report is included in the patient record so that it is available to the clinician for review during the clinic visit. We put the Heart Failure Management Report in the same category as a vital sign, and as such, it is a requisite part of a follow-up visit.

Insights in Data Interpretation in Daily Clinical Practice

Figure 2 summarizes a case in which a patient was hospitalized and treated for anemia and gastrointestinal bleeding. Had his device been interrogated earlier, the hospitalization may have been aborted because the intrathoracic impedance had been decreasing 2 weeks before the patient’s eventual admission.

The Heart Failure Management Report provides additional information that is often beneficial in treating these complex cases. The therapeutic benefit derived from CRT is because of the coordination of right and left ventricular systole. Clearly, the loss of consistent ventricular pacing negates the benefits of the therapy. Figure 3 outlines a case in which inappropriate programming resulted in the loss of consistent biventricular pacing and eventual decompensation. The etiology of this episode of ADHF is readily apparent from analysis of the Heart Failure Management Report.

In addition to atrial arrhythmia detection and percent atrial and ventricular pacing, the Heart Failure Management Report provides a graphic display of patient activity. This can be used as an objective measurement of the patient’s sense of well-being. Heart rate variability is a marker of neurohormonal activation in patients with heart failure. Impaired heart rate variability in patients with chronic heart failure using continuous measurements from a CRT-D is associated with high mortality and risk for hospitalization. Nighttime heart rate and patient activity index also correlate with prognosis but may be less sensitive.

When interpreting OptiVol fluid status data, it is important to consider factors regarding operation of the algorithm. It is a common misconception that the severity of fluid retention is proportional to the amplitude of the OptiVol fluid index after a threshold crossing. It is not. Rather, the OptiVol fluid index only indicates that the average daily impedance values have deviated significantly from the established baseline for an extended period. In essence, an “event” has occurred that may correlate with the development of vascular congestion. The degree of fluid retention can be assessed by analysis of the raw impedance data. An increased negative average daily impedance deflection from the established baseline indicates a more significant episode of fluid retention. After the OptiVol fluid threshold has been crossed, the raw daily impedance data may continue to provide useful information and can be monitored to track im-

Figure 2. Patient case 1. CHF = congestive heart failure; EF = left ventricular ejection fraction.
provement, even while the OptiVol fluid index is above the physician-established threshold (Figure 4).

The impedance data should be interpreted within the context of the patient history and physical examination. Although each patient serves as his or her own control, the sensitivity and specificity of continuously monitored intrathoracic impedance data from an implantable device in the general heart failure population is still unknown. The default OptiVol fluid threshold is set at a nominal value of 60 $\Omega$-days. However, it may be reprogrammed to an alternative level. Whether a different threshold setting will affect the predictive value of the data is unknown. Preliminary analysis of our own treatment population indicates a false-positive rate (ie, an OptiVol fluid threshold crossing that occurs without the development of signs or symptoms of congestion) of approximately 0.5 episodes per year per patient when set at the default threshold. Therefore, clinical evaluation of the patient should be performed before therapeutic adjustments based on impedance data. False-positive findings may occur for clinically obvious reasons (pouch hematoma, pneumonia, or pocket revisions) or for unapparent causes (Figure 5).

Patients who respond to CRT-D as evidenced by an improvement in their New York Heart Association (NYHA) functional class will often require less diuretic therapy to maintain homeostasis. Figure 6 depicts the course of a woman who crossed the OptiVol threshold when her diuretic dose was appropriately decreased after CRT-D implantation. The intrathoracic impedance feature initialized 34 days after implant while the patient was dehydrated because of excessive diuretics. (Note that the impedance reference value is not established until approximately 1 month after implant to allow wound healing.) As the patient returned to normal volume status after adjustment of the diuretic dose, the change in her thoracic fluid volume was reflected by a decrease in intrathoracic impedance and subsequent threshold crossing. Thus, this case illustrates why a reflex response to an OptiVol threshold crossing is not appropriate.

**Conclusion**

Device-based intrathoracic impedance monitoring should not be considered an “easy button” for the management of patients with heart failure. Identification of patients with devices with diagnostic capabilities coupled with implementation of efficient systems to capture the available information remains a challenge. The predictive value of intrathoracic impedance data derived during continuous monitoring via an implanted device is still unknown. Thus, intrathoracic impedance data should be interpreted in conjunction with clinical assessment of the patient. Although the derived OptiVol fluid index may simplify interpretation of the impedance data, the raw thoracic impedance data are a more useful measure of the patient’s fluid volume status. Analysis of the entire Heart Failure Management Report provides additional information that can be incorporated into the clinical assessment of patients and facilitate their management. The report should be available for review.
during the patient visit. Appropriate interventions require experience with using the specific device diagnostics. A heart failure clinic is ideally suited to this task. However, methods must be developed to analyze and react to device-based data, which may be monitored remotely with routine transmission to the clinic.

Figure 4. Impedance change after device revision. Improved clinical status is reflected in rising impedance despite persistent index crossing. The OptiVol fluid index helps quantify the change in impedance but is not a measure of absolute impedance. P = program.

Figure 5. Patient case 3. BNP = B-type natriuretic peptide; CHF = congestive heart failure; exam = examination; NYHA = New York Heart Association; P = program.
With the proper recognition of their limitations, implanted physiologic monitors can become important tools in disease management. The individual clinical benefits for routine heart failure management are substantial. Whether or not these devices may help abort an episode of ADHF requires prospective study. However, if these devices can be successfully incorporated into disease management algorithms, then the financial savings to a distressed medical system could be enormous.

Device Monitoring of Intrathoracic Impedance: Clinical Observations from a Patient Registry

John Andriulli, DO

A distinct advantage of implantable device diagnostics is that the data may be made available on a continuous basis, rather than at sporadic intervals associated with clinical testing. Recently, intrathoracic impedance monitoring has also become available in some implantable devices as an index of congestion and thoracic fluid accumulation secondary to decompensated heart failure. Despite the potential advantages, new advances in implantable device diagnostic technology also pose important questions regarding their clinical application. To examine these questions and to generate hypotheses, the relation between daily intrathoracic impedance measurements and other physical measurements or comorbidities was studied. A retrospective review was performed of 25 patients who previously underwent implantation of a cardiac resynchronization therapy/defibrillator device with the capability to continuously monitor intrathoracic impedance. This limited scope analysis demonstrated that daily measurement of intrathoracic impedances might reveal the intrinsic relations between heart failure decompensation and the onset of atrial and ventricular arrhythmias. Abnormal patterns of intrathoracic impedance that has increased and plateaued after implant may indicate worsening heart failure. The severity of congestive heart failure at the time of interrogation may correlate with device-based impedance measurements. Weight, sex, and body index may have a limited impact on impedance, and the lowest impedances may be seen in older patients. Patients with severe pulmonary disease may present with unique daily impedance profiles. Finally, daily impedance may have unpredictable relations with other clinical markers of heart failure. In summary, intrathoracic impedance represents a clinically useful diagnostic tool that can increase our understanding of a dynamic disease state on an individual patient basis. © 2007 Elsevier Inc. All rights reserved. (Am J Cardiol 2007;99[suppl]:23G–28G)
on the relation between daily intrathoracic impedance measurements and other physical measurements or comorbidities, my colleagues and I performed a retrospective review of 25 patients from our center who previously underwent implantation with a CRT/defibrillator (CRT-D) device with the capability to continuously monitor intrathoracic impedance (InSync Sentry; Medtronic, Inc., Minneapolis, MN). This registry protocol was approved by the local institutional review board and adhered to published guidelines for clinical research. Each subject provided written informed consent before participation. The registry consisted of a single clinic visit during which patients were physically assessed. Each subject completed a short interview regarding their heart failure symptoms and medical history. Subsequently, New York Heart Association (NYHA) functional class was documented, the medical chart since the time of implantation was reviewed, and device diagnostic data were downloaded. The average implant duration for the population was 283 ± 124 days.

Is Intrathoracic Impedance Associated with Arrhythmias or Vice Versa?

Intrathoracic impedance and VT: The increased risk of VT in the CHF population has been well described. In addition, the concept of mechanical—electrical feedback has been demonstrated in multiple animal and computer models and represents a potential mechanism for the observed clinical relation between CHF and VT. Despite this previous work, the dynamic relation between pulmonary congestion/decompensated heart failure and VT in the clinical environment is not well understood. It could be hypothesized that pulmonary congestion secondary to increased atrial or ventricular loading or “stretching” may be associated with an increased incidence of arrhythmias. Alternatively, AT or VT may also alter loading conditions leading to increased pulmonary congestion. Together, these mechanisms could initiate a vicious circle of intermittent or continuous arrhythmias and symptomatic pulmonary congestion. Monitoring both fluid status and arrhythmias in patients with heart failure may enable better management of arrhythmias in this population.

Figure 1 shows device-recorded intrathoracic impedance data recorded from an 80-year-old man with NYHA functional class III CHF and a history of ischemic cardiomyopathy and VT. The subject underwent several unsuccessful VT ablations and was subsequently implanted with an InSync Sentry device. The device logged a total of 80 episodes of VT in the 320 days after implant. Daily
intrathoracic impedance, ventricular tachycardia/ventricular fibrillation episodes, and device-mediated VT shocks are presented in Figure 1. Note that each discrete decrease in the daily impedance (or increase in the fluid index) corresponded with storms of VT and ≥1 VT shock. The daily impedance was statistically compared between days with and without VT shock and between days with and without VT episodes, using data derived from the stored device logs (rank sum test). In this patient, the daily impedance was significantly lower on days in which a VT shock was delivered versus no shock (54.1 ± 3.4 Ω vs 60.2 ± 4.1 Ω; p < 0.05). There was a significant negative correlation between the average VT cycle length and daily impedance (r = 0.62, p < 0.05). Thus, an association between potentially life-threatening VT and decreased intrathoracic impedance was observed. Further investigation is required to determine whether the management of pulmonary congestion can diminish the incidence of VT.

Intrathoracic impedance and AT: The “chicken or the egg” relation between AT and CHF has been well described. Just as CHF may lead to AT, atrial fibrillation and associated high ventricular rates can induce ventricular cardiomyopathies.14 My colleagues and I stratified subjects based on the presence or absence of any device-documented AT in the 90 days before interrogation. The data in Figure 2 indicate that 7 of 8 patients with a prior documented AT episode had 7-day median daily impedances <70 Ω. Furthermore, after pooling the data, the mean impedance from patients with AT was significantly lower than those without an AT episode 90 days before interrogation. Based on these data, it is reasonable to hypothesize that a recent history of AT could result in lower daily impedance measurements. Thus, routine assessment of intrathoracic impedance in patients with a history of AT may help to better understand individual patterns of AT recurrence.

Can Changes in Impedance over Time from Device Implant Be Characterized?

Reported data from the MIDHeFT trial suggested a consistent nonlinear increase in the mean daily impedance that began at implantation and plateaued several months from the time of implantation.4 A similar time-dependent increase in impedance was seen in our registry study patients (Figure 3). When each patient’s 7-day median daily impedance measurement was plotted against the number of days since implant, a positive correlation (p = 0.06) was noted up to approximately 250 days after implant. Subsequent to this time point, no relation between impedance and time from implant was observed. The clinical experience of my colleagues and I has shown generally lower daily impedance values in patients with more advanced heart failure. For example, Figure 4 shows data from a patient with very low daily impedance values immediately after implant. The patient was readmitted to the hospital for worsening CHF symptoms approximately 60 days after implant. During hospitalization, CRT therapy settings were adjusted and diuretic therapy increased. After 5 months of continuous CRT therapy, the basal impedance increased significantly. Thus, the raw intrathoracic impedance data may be indicative of the patient having been quite hypervolemic at the time of implant, despite standard CHF care. This case points to the key clinical utility of the raw daily impedance because the fluid index was not helpful for this patient. The clinical utility of raw basal impedance values represents an interesting topic for future clinical investigations.

Do Breathing Disorders Affect Daily Impedance Values?

Intrathoracic impedance measurements taken at the time of atrial fibrillation cardioversion were recently reported to be significantly lower in patients with a past history of smoking, and there was also a trend for higher impedance values in those patients diagnosed with chronic obstructive pulmonary disease (COPD).15 Because device measurements of intrathoracic impedance include a significant pulmonary component, it was hypothesized that patients with breathing disorders secondary to COPD with larger residual lung volumes and, hence, less fluid between the right ventricular coil and CRT-D device might have higher daily impedance values.

A total of 7 patients included in the registry had previously been diagnosed with COPD. Interestingly, these patients encompassed the lowest and the highest 7-day median daily impedance measurements at the time of interrogation (Figure 5). However, a distinct relation between daily impedance values and history of COPD was not found in this limited data set. Of note, the 2 patients with COPD presenting with the lowest daily impedance values also had a history of AT within the 90 days before interrogation. Thus, it may be hypothesized that patients with COPD have dramatic “swings” in impedance when other comorbidities are present. Additionally, a previous report on the use of impedance cardiography for the measurement of cardiac output in COPD patients suggested that the estimation of cardiac output via impedance was less accurate in patients with greater disease severity.16

Do Body Mass, Weight, Sex, or Age Alter Baseline Impedance Values?

Weight has previously been shown to have a relatively high specificity, but low sensitivity, to worsening heart failure.17
This may be, in part, because patients gain or lose weight for reasons other than decompensation, and that decompensation is occasionally unaccompanied by weight gain. Thus, the relation between body weight and intrathoracic impedance may not be expected to behave uniformly throughout the CHF population. Accordingly, the registry data demonstrated no clear relation between weight and raw daily impedance.

In addition, the effects of age on basal impedance are not well understood. My colleagues and I observed a marginally significant inverse correlation between age and impedance (p = 0.07) in this patient population. However, because age also may be correlated with CHF severity, the impact of age on intrathoracic impedance measurements is uncertain and may be better elucidated from analyses of forthcoming larger clinical databases.

What Is the Association Between Impedance and Biologic or Clinical Markers of Congestive Heart Failure?

The association between impedance and biologic clinical markers of CHF has not yet been clinically evaluated. Recently, Vollman and colleagues reported a significant negative correlation between changes in intrathoracic impedance and changes in plasma levels of amino-terminal segment of B-type natriuretic peptide during approximately 12 weeks in a series of 52 patients implanted with the InSync Sentry device. However, other data suggest that absolute plasma B-type natriuretic peptide levels may not be accurate predictors of variations in heart failure decompensation status.

Currently, my colleagues and I are performing a prospec-
tive multicenter clinical evaluation of the relations among thoracic impedance, weight, 6-minute hall walk, plasma B-type natriuretic peptide levels, and other secondary clinical parameters. The hypothesis is that an increase in thoracic impedance will also correlate with improvement in exercise capacity and other clinical markers of heart failure. The trial will enroll 100 patients and monitor them for a period of 12 months.

Conclusion

Observations obtained through daily intrathoracic impedance monitoring have led to multiple novel hypotheses on the nature of decompensated heart failure. Daily measurement of intrathoracic impedance may reveal intrinsic relations between heart failure decompensation and the onset of AT and ventricular arrhythmias. Abnormal patterns of thoracic impedance that has increased and plateaued after implant may indicate worsening heart failure. The severity of CHF at the time of interrogation may correlate with device-based impedance measurements. Weight, sex, and body index may have a limited impact on impedance, and the lowest impedances may be seen in older patients. In addition, patients with severe pulmonary disease may present with unique daily impedance profiles. Finally, daily impedance may have unpredictable relations with other clinical markers of heart failure. Each of these observations should be the subject of future prospective evaluation. However, intrathoracic impedance represents a clinically useful diagnostic tool that can increase our understanding of a dynamic disease state on an individual patient basis.

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Figure 5. Association between daily intrathoracic impedance and chronic obstructive pulmonary disease (COPD). (A) Raw impedance values for patients with (circles) and without (triangles) COPD. (B) Box and whiskers representation of data in A. Patients with COPD (+COPD) tended to have either very high or very low intrathoracic impedance independent of time since implant. Thus, the relation between lung disease and intrathoracic impedance may be complex and warrants additional study.

Use of Device Diagnostics as an Educational Tool to Improve Patient Adherence

Lisa Rathman, MSN, CRNP

Implantable cardiac devices are increasingly being used to treat heart failure and may provide an opportunity to more effectively monitor a patient’s clinical status and prevent hospitalization by detecting subclinical congestion before progression to acute decompensated heart failure. This article reviews the use of device diagnostics in clinical practice and discusses their utility as tools in heart failure disease management, with a focus on the use of a new intrathoracic impedance diagnostic as an educational tool to improve patient adherence. © 2007 Elsevier Inc. All rights reserved. (Am J Cardiol 2007;99[suppl]:29G–33G)

Heart failure is a common disorder associated with significant morbidity and mortality. It affects nearly 5 million people in the United States, with 550,000 new cases each year. Heart failure is the primary or contributing cause of death in 286,700 patients per year and accounts for >1 million hospitalizations annually. Despite advances in treatment, patients with heart failure remain at high risk for frequent hospitalization, most commonly because of exacerbation of chronic heart failure. Within 6 months of hospital discharge, ≥50% of patients are readmitted.

Most heart failure–related hospital readmissions are from preventable causes, such as excess dietary sodium intake and/or medication nonadherence. Vinson et al found that nearly 50% of readmissions for heart failure were caused by medication or dietary nonadherence. In a study of 585 heart failure admissions, Bennett et al demonstrated that excess sodium intake leading to volume overload was the precipitant in 59% of admissions. Additionally, as many as 20% of patients fail to notify their healthcare provider when heart failure symptoms reoccur, until the symptoms are so severe that they require hospitalization. Other reasons cited for early readmission for acute decompensated heart failure (ADHF) include inadequate discharge planning or follow-up and a failed social support system.

Are patients really to blame for nonadherence to their prescribed heart failure treatment regimen? Perhaps they do not clearly understand why it is imperative that they follow their medication, dietary, and symptom management regimens. In a study of 113 patients with heart failure referred to an outpatient heart failure clinic, Ni et al found that although all of the patients had a lengthy history of heart failure and were observed by a cardiologist, nearly 40% of patients reported that they knew little or nothing about their heart failure. In addition, 40% of patients did not recognize that weighing themselves daily was important. Only one third of the patients in the study reported that they always avoided salty foods, and 36% of the patients thought they should drink a lot of fluids. Perhaps patients are not being properly instructed on how to monitor their heart failure symptoms. Data from the Acute Decompensated Heart Failure National Registry (ADHERE) suggest that only 35% of patients discharged after a heart failure hospitalization receive appropriate discharge instructions. The lack of understanding on the part of patients with heart failure of their disease is associated with symptom exacerbation and repeat hospitalizations. Improved patient education and monitoring may be a way to improve current outcomes.

Role of the Heart Failure Nurse in an Integrated Approach to Heart Failure Management

Patient education is key to decreasing repeat hospitalizations and encouraging patients to make appropriate lifestyle changes. Heart failure nurses play a pivotal role in teaching patients the importance of following their heart failure treatment regimens and in making lifestyle changes. In a study that examined the effects of a 1-hour, one-on-one teaching session with a nurse educator at discharge compared with the standard discharge process, Koelling and colleagues found that a patient-focused heart failure education program delivered at hospital discharge led to a 35% reduction in death or repeat hospitalization at 180 days compared with standard discharge teaching. Furthermore, there was a 51% reduction in the need for repeat hospitalization in the group that received the directed patient education. In the study, the nurse reviewed the causes of heart failure and treatment regimens, including medications, lifestyle changes, and other self-care behaviors with the patient.

In addition to discharge education for the prevention of heart failure readmission, patients also require appropriate outpatient follow-up and support. Without it, the likelihood of readmission with heart failure increases. Outpatient disease management programs have been shown to reduce...
hospitalization rates and associated costs.\textsuperscript{13} Initiation of a multidisciplinary heart failure program that includes patient education and close patient follow-up in combination with the use of appropriate heart failure medications can reduce hospitalizations for ADHF by as much as 85% and improve the functional status of patients.\textsuperscript{14–16}

The goals of outpatient heart failure management programs are not only to reduce the dependence on hospital services but also to offer disease management by monitoring the patient across the continuum of care. Outpatient heart failure disease management programs can range from basic interventions, such as telephone follow-up, to the use of comprehensive multidisciplinary teams. Although these programs are diverse, patient education provided by nurses is a common thread and key element of all of these programs.

**Using Devices to Improve Connections with Patients**

Another common thread in heart failure disease management programs is the goal of increasing the provider’s connection with patients. Devices can play a role in achieving this goal. Devices have been increasingly used in the management of patients with heart failure. For example, cardiac resynchronization therapy (CRT) has been recognized as the standard of care for patients with medically refractory heart failure and ventricular conduction disorders. CRT devices are available either with or without an implantable cardioverter defibrillator (CRT-D). In addition to providing therapies, these heart failure devices can also provide diagnostic information that allows clinicians to monitor patients more closely and effectively. Device diagnostics can provide useful clinical information about arrhythmias. The diagnostic data can also provide insight into the clinical status of patients with heart failure. For example, a downward trend in heart rate variability or patient activity or an increase in nighttime heart rate may correlate with worsening heart failure status.\textsuperscript{17}

More recently, intrathoracic impedance monitoring has been incorporated into certain devices and can be monitored to assess volume status. A recently completed study by Yu et al\textsuperscript{18} demonstrated that intrathoracic impedance is inversely related to pulmonary capillary wedge pressure. As intrathoracic impedance decreases, pulmonary capillary wedge pressure increases. OptiVol fluid status monitoring (Medtronic, Inc., Minneapolis, MN), which has been incorporated into selected CRT-D and implantable cardioverter defibrillator devices, uses this concept and may provide an early warning of an impending ADHF. Information on intrathoracic impedance, the OptiVol fluid index, and other diagnostic measures available on the Heart Failure Management Report can be useful not only in the treatment process but can also figure prominently in patient education efforts.

**Using Device Diagnostics to Improve Patient Adherence**

Device diagnostics provide another objective data point that can be used in a clinical evaluation. Device diagnostic information can be obtained easily through an in-office or remote reader, which downloads a report from the device in <10 minutes. The CardioSight Reader (Medtronic, Inc.), for example, has no programming capability and can be used by ancillary personnel to download device diagnostic information. With the remote reader, patients can download diagnostic information while at home or on vacation. Device data should be obtained at every visit and used in the context of the patient’s subjective complaints and clinical findings.

Device diagnostics can be used as a tool to improve patient adherence to treatment recommendations. Many times, patients will forget or deny lapses in diet or medication regimens. Device diagnostic data, when shown to a patient, can facilitate more in-depth conversations about lifestyle changes and how they relate to their disease process. In our clinic we regularly share this information with patients and use it as a patient education tool. For example, trends in the patient’s intrathoracic impedance, OptiVol fluid index, and patient activity level can provide potential insight into patient nonadherence with self-care recommendations. This information can be used as a teaching tool to potentially affect patient behavior. The utility of device-based information can be seen in 3 cases from The Heart Group.

**Case Studies**

**Case 1:** The first case involves a 75-year-old man with worsening heart failure symptoms who was evaluated in our heart failure clinic (Figure 1). Device diagnostics provided additional objective information to confirm the diagnosis of worsening congestion and also served as a teaching tool for the patient. After the patient was shown his intrathoracic impedance report, he admitted that he had stopped weighing himself daily and was not adhering to his sodium restriction. He also reported that his wife had been having some medical problems and that, as a result, he was using canned soups and vegetables for convenience. Examination of the OptiVol fluid trends report showed that his daily impedance values were decreasing and that he was approaching the OptiVol threshold. His diuretic dose was increased, and the device information allowed us to have a discussion about the importance of daily weight measurements and the resumption of his sodium restriction. In addition, we discussed alternatives to canned products as well as other low-sodium meal possibilities. When the patient was seen at a subsequent visit, his symptoms were much improved, and he reported following the recommended lifestyle changes. His daily impedance values were increasing, and the OptiVol fluid index decreased.

**Case 2:** An 82-year-old man reported that he was taking all of his medications faithfully and was not skipping any doses (Figure 2). Review of his thoracic impedance and OptiVol fluid index data revealed that the patient had...
Patient: 75-year-old man

Medical History: Ischemic cardiomyopathy, EF = 0.28, CRT-D implanted 7/05, paroxysmal AF, severe COPD, hyperlipidemia. **Medications:** Lisinopril, carvedilol, spironolactone, bumetanide, warfarin

3/14/06 Routine CHF clinic visit
- Complaints of increased dyspnea
- Not taking daily weights; weight in clinic up 10 lb
- No angina, dyspnea on exertion and edema
- Exam: + volume overloaded
- HF Management Report: No arrhythmias, 100% CRT pacing, decline in intrathrocacic impedance

Treatment
- Increased diuretics
- Daily weights, sodium restriction
- Telephone follow-up for 3 days, CHF office visit in 1 week

3/21/06 CHF clinic follow-up visit
- Symptoms much improved
- Exam still with mild volume overload
- Continue increased diuretics/follow-up 1 week
- Continue 2,000 mg/day sodium restriction

3/27/06 CHF clinic follow-up visit
- Dyspnea resolved
- Exam: No evidence of congestion
- Diuretics to previous dosage
- Continue sodium restriction

Patient: 82-year-old man

Medical History: Nonischemic cardiomyopathy; EF = 0.27; paroxysmal AF; hyperlipidemia; CRT-D.

**Medications:** Bumetanide, enalapril, warfarin, carvedilol, spironolactone

31G Rathman/Device Diagnostics as an Educational Tool

Figure 1. Device diagnostics as a recall and teaching tool. AF = atrial fibrillation; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CRT = cardiac resynchronization therapy; CRT-D = cardiac resynchronization therapy/defibrillator; EF = left ventricular ejection fraction; HF = heart failure. 1 lb = 0.45 kg.

Figure 2. Device diagnostics to improve patient adherence to medications. A The dotted line indicates the physician programmed OptiVol threshold; B The solid line indicates the daily impedance value. The dotted line indicates the reference impedance. AF = atrial fibrillation; CRT-D = cardiac resynchronization therapy/defibrillator; EF = left ventricular ejection fraction.
threshold crossings indicative of worsening heart failure every 4–6 weeks. These data were reviewed with the patient who subsequently admitted that he ran out of his medications at the end of each month and did not refill them until he felt poorly. Consultation with his pharmacy confirmed this refill pattern, and the patient noted he could not afford his monthly medication expenses. This additional data allowed us to intervene with medication assistance and provided a teaching point on the importance of his medication adherence.

Case 3: In another application of device-based diagnostic information, a patient’s activity level can be used to monitor patient adherence with exercise recommendations. If a patient is encouraged to start a walking program, it is beneficial to show the patient his or her report to give them visual confirmation of their activity and subsequent progress. A 73-year-old man was seen for a routine appointment in the heart failure clinic. The Heart Failure Management Report demonstrated that he clearly had been more active. Discussion with the patient determined that the period in question correlated with his winter vacation to Palm Springs, Florida, and that he had been playing golf and going for walks daily (Figure 3). The report served as a teaching tool for the patient to reinforce recommendations about increasing his exercise.

Using Device Diagnostics as a Disease Management Tool

Device diagnostics can also be used as a disease management tool because the data are objective (similar to the patient’s vital signs). The data can be used to follow the patient’s response to treatment or to alert the provider to worsening congestion before the patient becomes symptomatic, both of which could potentially prevent future hospitalizations. However, the clinician must recognize the utility of the available information and download the data. As was previously mentioned, accessing the data is easy and can be done efficiently, either in the office or remotely from home. This allows a greater connection between the patient and provider. Newly released devices will allow the automated wireless download of information from the device, further reducing the need for patient compliance in transmitting information. For example, the Concerto CRT-D device (Medtronic, Inc.) can be programmed to remotely alert the patient’s healthcare provider via phone, fax, or pager about parameters, such as episodes of atrial fibrillation, delivered.
device therapies, and battery/lead issues, among others, without intervention from the patient. However, currently, a remote alert for OptiVol fluid status monitoring is not approved by the US Food and Drug Administration (FDA) and cannot be programmed.

Although device diagnostics provide a great deal of potentially beneficial information, they can also result in data “overload,” with information from remote alerts being sent at varying times during the day. Thus, providers must develop systems to deal with these issues. Heart failure disease management programs that involve a team of physicians, nurse practitioners, and nurses are ideally suited to develop systems to handle these issues and provide greater monitoring of patients. Electrophysiology and heart failure clinics should collaborate to share device diagnostic information about patients, especially if there are noteworthy changes. In many cases, both clinics are interested in the data generated, and changes in patient treatment may require input from both groups. To develop collaborative relationships, both groups should meet and discuss how they will integrate the data and what types of diagnostic data should be shared.

Conclusion

Devices have improved the connection between patients and their healthcare providers. Furthermore, device-based diagnostics can provide an additional source of objective data, which can be reviewed with the patient during an office visit or remotely while the patient is at home. This information can be used to assess patient adherence to the treatment plan in addition to serving as a patient teaching tool. Incorporation of devices into a heart failure disease management program allows closer monitoring of patients, with the potential to further decrease hospitalizations and improve patient outcomes.

Key Lessons from Cases Worldwide

Li Wang, PhD

Since OptiVol fluid status monitoring (Medtronic, Inc., Minneapolis, MN) was released to the market in 2004, the manufacturer has been working together with clinicians to better understand the operation and utility of OptiVol in a clinical setting. This has been done through completed and ongoing clinical studies and through evaluation of case studies submitted by clinicians. In the process, much has been learned about some interesting aspects of OptiVol fluid status monitoring and its use with patients with heart failure. © 2007 Elsevier Inc. All rights reserved. (Am J Cardiol 2007;99[suppl]:34G–40G)

This article presents 6 cases, each of which illustrates an interesting aspect of OptiVol fluid status monitoring (Medtronic, Inc., Minneapolis, MN). It is hoped that in understanding these cases, clinicians will be better equipped to use OptiVol fluid status monitoring in managing their patients with heart failure.

Case 1: Impedance Reduction Patterns Before Heart Failure–Related Hospitalization

Case 1 is from a collection of patients. The OptiVol trends reports show the impedance reduction before heart failure–related hospitalization in 4 different patients (Figure 1). In each case, impedance decreased, and the patient crossed the OptiVol fluid threshold before admission to the hospital. However, the magnitude of impedance reduction varied. Impedance reductions in relation to the OptiVol threshold come in different sizes and forms. Patient 1 had a left ventricular lead dislodgement and experienced a huge impedance reduction before admission. The impedance reduction for patient 4 was very small but sustained for a relatively long period.

Key lesson: Impedance reduction before hospitalization varies with the particular patient and the reason for decompensation, and it involves both the magnitude of reduction and the duration of the reduction.

Case 2: Impedance Measurements Using an Epicardial Patch

In this case, intrathoracic impedance measurements were made between an epicardial defibrillation patch electrode and the device case rather than between the right ventricular (RV) coil on a transvenous implantable cardioverter defibrillator lead and the device case, which is typically the norm. As seen in Figure 2, the average daily impedance values on the OptiVol fluid trends report are very low—around 30 Ω—rather than the 60–70 Ω typically seen in most patients. The impedances are very low because the epicardial patch has a much larger surface area than the RV coil. The bigger the surface area of the measuring electrode, the lower the expected impedance.

Key lesson: Absolute intrathoracic impedance values are affected by the sizes and locations of the electrodes used to measure intrathoracic impedance.

Case 3: Rapid Impedance Changes

A review of the definition and function of the reference impedance trend may be helpful in better understanding a case involving rapid impedance change. The reference impedance is initialized on the 34th day of measurements by averaging the last 4 daily impedance values. This is the only time that averaging is involved in changes to the reference impedance. The patient’s volume state when the reference impedance is initialized—euvolemic or hyper- or hypovolemic—will be the starting point for quantifying subsequent deviations in impedance. After initialization, the reference impedance will go up and down over time in the same direction as the daily impedance. But the reference impedance is only allowed to change slightly from day to day. The fluid index will only increase when the daily impedance is below the reference line, and will be reset to zero if the daily impedance is above the reference line for 2–3 days. The reference impedance is not programmable. If, for example, the reference impedance is initialized while the patient is hypovolemic, the OptiVol fluid index may go up as the patient is improving and approaching a euolemic state. This may be interpreted as fluid buildup and a worsening of the patient’s condition, unless the patient’s history is taken into account during review of the data. The OptiVol fluid index can be used to quantify a sustained reduction in daily impedance, but it is not a measure of a specific fluid level. Eventually, however, the reference impedance will catch up and reflect the patient’s stable pulmonary and clinical state.
Figure 1. (A and B). OptiVol fluid (Medtronic, Inc., Minneapolis, MN) data trends before and after a heart failure–related hospitalization in 4 different patients. The vertical solid line in B represents the time of heart failure–related hospitalization.
Keeping this information in mind, consider the case of a patient who committed a number of dietary indiscretions while on a cruise vacation. The patient’s OptiVol fluid index crossed the nominal threshold of 60 Ω-days on November 3, 2004 and was admitted to the hospital on November 12, 2004, with severe symptoms of heart failure. He underwent
diuresis and lost 10 kg in a very short period. He then showed clinical improvement and the daily impedance increased dramatically—approximately 25 Ω (Figure 3). The reference impedance lags behind but increases at a relatively slow rate per the design of the algorithm.

On January 4, 2005, the patient was once again hospitalized because of severe heart failure symptoms. He underwent diuresis and lost approximately 3 kg before being discharged on January 25, 2005. There was an associated increase in the daily impedance during this period. After discharge, the daily impedance remained relatively stable. At the next follow-up, in mid-April 2005, the patient reported feeling better than he had in a long time, and his physicians and nurses believed he had finally stabilized. The reference impedance had also been increasing during this time and has now “caught up” with the daily impedance (Figure 4).

The OptiVol fluid index was flat after the initial hospitalization in November 2004, because the reference impedance was below the daily impedance for the most part. Therefore, the fluid index remained at zero, even though the daily impedance was decreasing significantly after the initial hospital discharge and before the second admission in early January 2005. In the weeks before the second hospitalization, the reference impedance was incremented slowly as per the algorithm. Therefore, there is no OptiVol fluid index because the patient’s daily impedance is higher than the reference impedance. It is only when the daily impedance is below the reference impedance because of progressive decompensation that the OptiVol fluid index starts to increase. After the patient was admitted and underwent diuresis in the hospital, the daily impedance increased. Subsequently, the daily impedance remained stable for approximately 1 month after hospital discharge, and the reference impedance finally caught up with the daily impedance (Figure 4).

The reference impedance has been designed to capture or follow the slow changes in impedance, not the rapid changes, which is why the reference impedance lags behind the dramatic change in the patient’s daily impedance. As such, there have been other examples of a dramatic decrease in the patient’s daily impedance without changes in the OptiVol fluid index. We are actively researching potential improvement in this area.
Key lesson: Daily impedance reflects the patient’s status. It may take some time for the reference impedance to catch up when there are rapid changes in daily impedance associated with significant changes in patient status, e.g., as a result of in-hospital intravenous diuretic treatment.

Case 4: Pleural Effusion

Pleural effusion may or may not be related to heart failure; however, worsening heart failure can lead to pleural effusion. In either case, pleural effusion is another example in which one may see a reduction in daily impedance. In this particular case, the patient reported fatigue and had weight gain and limited capacity at a regular follow-up visit. The patient was hospitalized, and after some analysis, a diagnosis of pleural effusion on the left side was made. The patient was treated with a pleural tap, and the fluids drained very quickly. The patient lost 2.8 kg, had better capacity, and had less dyspnea. Impedance is affected by rapid fluid removal from the chest, so a corresponding rapid increase in daily impedance can be seen on the OptiVol fluid trends report (Figure 5).

Key lesson: If fluid in the chest is removed quickly, impedance will increase rapidly. Fluid outside the pulmonary circulation will also affect impedance measurement, as long as it is in the measurement pathway.

Case 5: Pneumothorax

A similar concept is involved when a patient has pneumothorax. The patient in this case had a late occurrence of pneumothorax and was hospitalized. An endocostal drain was performed, and the air was removed. A rapid reduction in daily impedance was seen, and the patient crossed the OptiVol threshold (Figure 6). This does not mean that the patient had fluid overload. It only means that the daily impedance was reduced because the extra air in the chest, which is an electrical insulator, was removed. The impedance measurements were accurate, and OptiVol fluid status monitoring was operating properly.1

Key lesson: As discussed in case 4, impedance will be affected by changes within its measurement pathway. In this case, the impedance value is affected by the air volume in the chest. Additionally, it is very important to know the patient and his or her medical history before any judgment can be made regarding a patient’s fluid status based on OptiVol data.

Case 6: Pocket Revision

Fluid will accumulate in the pocket after the initial implant or a revision because of the surgery. This fluid accumulation is reflected in the impedance measurements, as seen in the case of a patient who had a pocket revision, because the...
Figure 6. Pneumothorax. A rapid reduction in intrathoracic impedance was observed after the patient’s pneumothorax was treated with an endocostal drain. The reduction in impedance was not caused by fluid overload but rather by removal of the extra air in the chest. Air is an electrical insulator, and its removal results in decreased intrathoracic impedance. P = program. (Reprinted from Pacing Clin Electrophysiol.1)

Figure 7. Pocket revision will affect the daily impedance and the reference impedance and may be viewed as a false positive. The amount of time it takes for impedance values to recover depends on the specific patient. OptiVol fluid (Medtronic Inc., Minneapolis, MN) is an accumulation of the difference between the daily and reference impedance. Patient history is important in determining whether the patient has crossed the OptiVol threshold for decompensated heart failure or for another reason. P = program.
pocket fluid is within the measurement pathway (Figure 7). Daily impedance values were relatively stable until they decreased precipitously, and the patient crossed the OptiVol threshold after the pocket was revised. Is this really a false-positive finding? The OptiVol fluid index reacted correctly to the pocket edema. Again, if the patient’s history is known, this should not be an issue.

What is the expected length of time for edema to resolve and for impedance measurements to stabilize after the pocket is revised? There is no definitive answer to this question. In our clinical experience, my colleagues and I have seen the impedance stabilize as early as 4–5 weeks and as late as 3 months.

**Key lesson:** Revising the pocket for any reason will affect impedance measurements, and the amount of time it takes for impedance values to recover and stabilize may vary by patient. Determining whether an OptiVol threshold crossing is owing to the pocket revision or other causes requires evaluation of the patient’s history.

**Conclusion**

As real-life experiences with intrathoracic impedance measurements accumulate, we are also learning how to interpret and better use the data in clinical practice. The daily impedance reflects the patient’s status and may be affected by multiple factors, some of which are owing to heart failure and others which are not. A decrease in impedance may not always mean a clinical decompensation caused by increased pulmonary volume overload. To reach a clinical conclusion, it is necessary to review the OptiVol data, and more importantly, the patient data, including the history, signs/symptoms, and medications.

The reference impedance and OptiVol fluid index are tools to quantify impedance changes but are not a direct measure of fluid status. The reference impedance is designed to capture and follow the slow changes in impedance and is used to quantify the impedance reduction. It does not reflect the patient’s ideal fluid status. The fluid index is a measure of impedance reduction (measured in ohms) and the sustainability of the reduction (measured in days), and is reported in ohm-days.

In some cases, the reference impedance will lag behind the daily impedance, especially when there has been a rapid change in daily impedance. When the daily impedance is above the reference impedance, reductions in the daily impedance will not be reflected in the fluid index, although the daily impedance reduction is a result of pulmonary volume overload caused by worsening heart failure. Therefore, it is more important to review the daily impedance trend when looking at the OptiVol fluid status trend report.

Collaboration Among General Cardiologists, Heart Failure Specialists, and Electrophysiologists: What Are the Barriers?

W. H. Wilson Tang, MD

Although ongoing research has focused on the reliability and accuracy of data derived from implanted devices, important challenges remain, among which is the development of a framework for handling the data, including delineation of responsibility for interpretation and management of the data. The barriers to a successful device-monitoring program include difficulties in data access, unfamiliarity with a new treatment approach, lack of sufficient knowledge and experience in data interpretation, and difficulty incorporating the program into the existing workflow. The dynamics of collaboration between heart failure and electrophysiology (EP) specialists may differ locally and regionally, but a common set of barriers resulting from traditional models of care constrains incorporation of device-based data into clinical practice. Active dialogue between EP and heart failure specialists that involves the sharing of experiences and practice models is an important first step to overcoming these barriers. In the future, a “virtual clinic” model of patient care can only be realized with the successful incorporation of remotely accessed device data. © 2007 Elsevier Inc. All rights reserved. (Am J Cardiol 2007;99[suppl]:41G–44G)

Data obtained from implantable devices have several unique advantages. These devices have the ability to provide objective and individualized data using existing interrogation techniques with less reliance on patient compliance. However, the successful implementation of any clinical monitoring strategy for heart failure requires scientific validation of the accuracy and reliability of diagnostic algorithms, evidence of clinical benefit, and cost-effectiveness.

As technology continues to evolve, an important but seldom-discussed challenge is how to handle the data and who should be responsible for its interpretation and management. Interestingly, patients often welcome remote monitoring of their clinical status, although payers are often reluctant to recognize such efforts as patient encounters. This article broadly discusses some of the barriers involved in the incorporation of device-based data into clinical practice, potential solutions, future clinical studies, and future directions for this mode of treatment.

Barriers to Collaboration Between Heart Failure and Electrophysiology Specialists

The data access barrier: Specialization in medicine has created isolated “silos” of care with little or poor communication among physicians treating patients with heart failure. This is a complex problem that varies widely according to the nature and location of practice and is perhaps the biggest challenge to the future development of device-based clinical monitoring for patients with heart failure. In the early days of cardiac pacing, practicing cardiologists performed most of the device interrogations and follow-up. This is still true in many countries. However, as implantable devices have become more sophisticated, many of these tasks have become the responsibility of electrophysiology (EP) specialists or their nurse extenders. Device interrogation itself has become increasingly complicated, particularly with the optimization of biventricular pacemakers. Simply obtaining data from the device, either at the bedside or remotely, can be daunting to nonspecialists. Indeed, most non-EP healthcare providers are unfamiliar with sophisticated devices and may have limited experience with device-based monitoring. Fewer and fewer nonspecialists hold the primary responsibility of interrogating and managing implanted devices. As a result, EP specialists are faced with the prospect of establishing systems to meet the increased need for device interrogation and maintenance.

The treatment approach barrier: Despite advances in medical and device therapy, the approach we use when treating patients with heart failure has not changed dramatically. Patients are routinely observed in the clinic. When worsening signs and symptoms occur, patients can be seen either in the urgent setting or after they have been admitted to the hospital. This reactive approach stems from a fundamental lack of understanding in how stable patients with heart failure deteriorate and decompensate. Data, such as intrathoracic pressures or impedance deriv-
atives, can provide new insight into the hemodynamic manifestations of disease progression. These data allow the documentation of physiologic fluctuations in advance of the inciting hospitalization event rather than relying on subjective complaints or alterations in weight or edema to assess patient stability. The availability of such data forces us to rethink our approach to heart failure and to develop an entirely different proactive treatment model. However, there are a number of major barriers that must be addressed before this new approach can be implemented.

**The knowledge barrier:** The threshold of 60 $\Omega$-days that is used to predict heart failure hospitalization with OptiVol fluid status monitoring (Medtronic, Inc., Minneapolis, MN) is an arbitrarily defined limit based on a single patient series. It is a first-pass attempt to establish a triage point that balances sensitivity and specificity. As with any other physiologic processes, intrathoracic impedance information requires interpretation as part of a spectrum of manifestations that may vary from individual to individual. Therefore, a large knowledge gap still exists in understanding the consistency and reliability of the derived intrathoracic impedance data (Figure 1). Thus, we are still far away from reaching a consensus on the frequency with which OptiVol data should be checked, the optimum threshold that should be used, and the appropriate clinical responses to such data.

**The workflow barrier:** New technologies, such as intrathoracic impedance, can be intimidating for both heart failure and EP specialists because of the potential for increased workload and responsibility, and to some degree, liability. EP specialists may be reluctant to implant these devices if they are the primary recipients of the downloaded data, especially in the case of remote device interrogations, because of the added responsibilities involved in acting on the results. These actions may include adjustment of diuretics or clinical evaluation beyond the scope of main areas of expertise of the EP specialist. In contrast, cardiologists, heart failure specialists, and nurses who have been trying very hard to find a reliable objective assessment of fluid status and an index of clinical stability may find themselves facing many hurdles in actually obtaining such device information for use in the clinical evaluation of patients. Additionally, they may have difficulty in interpreting the results of a device interrogation. This labor-intensive process does not easily fit into current workflow patterns and has yet to be reimbursed, making effective implementation even more challenging.

**Recommendations for Successful Collaboration**

The ideal collaboration resembles the concept of a “virtual clinic” that EP physicians have successfully incorporated into their device clinics. This can involve asking patients with heart failure to track their blood pressure, heart rate, and body weight as part of their self-monitoring tasks and...
periodically reviewing their device data as part of the regular clinical assessment.

Start a dialogue: The first and foremost priority is for healthcare providers to meet with each other and discuss available options. This dialogue can center on individual patient cases and discussion of the choice of devices, or in some cases, how to best evaluate and manage patients with devices that provide potential diagnostic monitoring capabilities. This discussion need not be limited to a particular practice or institution; it can also involve a regional collaboration on use of heart failure disease management clinics.

Learn device interrogation procedures and share experiences: Among the most important requirements of the proactive use of device-based monitoring is to become familiar with device interrogation procedures and establish collaborative relationships among the different caregivers involved in the task of clinical monitoring. The educational process should not be limited to learning how to measure intrathoracic impedance. It should also involve device parameters available from almost any standard pacemaker or implantable cardioverter defibrillator (ICD), such as heart rate, arrhythmic episodes and characteristics (especially atrial fibrillation), and pacing frequencies. Before a reliable algorithm for the use of data obtained from devices can be established, ongoing discussions and potential questions for research projects should be considered.

Incorporate shared responsibilities into the workflow: Teamwork is the key to successful collaboration. EP specialists must be reassured that the data obtained from implantable devices will be used well and that the management responsibilities will be shared. Organizing heart failure and EP clinics to meet the demands of the workflow can be among the most challenging aspects of collaboration.

Some clinics make arrangements so that a patient can visit both clinics on the same day. Others ask their patients to download device data before clinic visits so that it is available for use at the time of their clinic visit. Germany and Murray1 and Small2 share their insight on how to incorporate device data into the clinic in articles elsewhere in this supplement. However, their arrangements may not be replicated easily in other practices because of expertise and required equipment, and because of the comfort level required on the part of both heart failure and EP specialists.

### Future Directions

The use of device-based data in the proactive monitoring of patients with heart failure will require adequate confidence in the data so that “well-care visits” can be conducted online. It will also require the development of local or regional networks to interpret and distribute device data and heart failure disease management programs that can operate in a scalable fashion. Additionally, it requires that remote monitoring be reimbursed in much the same manner as clinic-based interrogation of ICDs or pacemakers. Remote monitoring allows more frequent and convenient follow-up and may reduce the overall workload, if algorithms can be developed to flag abnormal data for the early detection of problems. After establishing these tools, we will then need to determine what treatment strategies can alter the natural course of the disease process.

Regulatory agencies are also very sensitive to these issues and have expressed different concerns in different countries. At present, the current indications for the use of intrathoracic impedance measurements or, for that matter, any device-based hemodynamic monitoring are limited to aiding in the assessment of a patient’s heart failure status.

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**Table 1**

Current and ongoing clinical research studies contributing to the knowledge of intrathoracic impedance assessment

<table>
<thead>
<tr>
<th>Study</th>
<th>Purpose</th>
<th>Status</th>
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<tbody>
<tr>
<td>MIDHeFT</td>
<td>Proof of concept study that showed inverse correlation between intrathoracic impedance and pulmonary capillary wedge pressure; sensitivity of 76.9% in detecting heart failure hospitalizations</td>
<td>Published</td>
</tr>
<tr>
<td>FAST</td>
<td>IDE trial that characterized impedance data in relation to patients’ clinical status, including hospitalizations and diuretic use</td>
<td>Completed, ongoing extension phase</td>
</tr>
<tr>
<td>SENSE-HF OUS EU Registry</td>
<td>Postmarket trials to provide sensitivity and false alert rates from blinded data; utility with alert enabled</td>
<td>Ongoing</td>
</tr>
<tr>
<td>PARTNERS-HF and OFISSER</td>
<td>Postmarket trials to characterize the relation between monitoring data and heart failure–related events</td>
<td>Ongoing</td>
</tr>
<tr>
<td>PRECEDE-HF</td>
<td>IDE trial to compare the composite of heart failure hospitalization and all-cause mortality in the Cardiac Compass with OptiVol* guided-care treatment arm versus the control arm blinded to Cardiac Compass with OptiVol in North America</td>
<td>Planning</td>
</tr>
<tr>
<td>External research studies</td>
<td>Multiple physician-initiated trials to investigate various aspects of OptiVol</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>

EU Registry = European Observational InSync Sentry Study; FAST = Fluid Accumulation Status Trial; IDE = investigational device exemption; MIDHeFT = Medtronic Impedance Diagnostics in Heart Failure Trial; OFISSER = OptiVol Fluid-Index InSync Sentry Registry; PARTNERS-HF = Program to Access and Review Trending Information and Evaluate Correlation to Symptoms in Patients with Heart Failure; PRECEDE-HF = Prospective, Randomized, Evaluation Using Cardiac Compass with OptiVol in Early Detection of Decompensation Events for Heart Failure; SENSE-HF OUS = Sensitivity of the InSync Sentry OptiVol Feature for the Prediction of Heart Failure Outside of the US.

* OptiVol; Medtronic, Inc., Minneapolis, MN.
Several registries and outcomes research trials that are currently ongoing or in the planning stages may help demonstrate the potential benefits of treatment strategies guided by such device-based data (Table 1).³

Conclusion

OptiVol fluid monitoring has started a new era in patient care by facilitating effective remote monitoring of physiologic data. However, a framework must be developed to incorporate the use of these data into clinical practice. A one-size-fits-all solution will not work for this problem. Local and regional dynamics between heart failure and EP specialists may vary, but traditional models of care pose constraints. Active dialogue between EP and heart failure specialists is an important first step in developing successful arrangements for the use of device-based data.

Acknowledgment: I thank Nancy Johnson for providing the summary table of upcoming clinical trials.