Leadless and Wireless Cardiac Devices: The Next Frontier in Remote Patient Monitoring

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Abstract: In the last decade, advances in wireless and sensor technologies, and the implementation of telemedicine, have led to innovative digital health care for cardiac patients. Continuous monitoring of patients' biomedical signals, and acute changes in these signals, may result in timely, accurate diagnoses and implementation of early interventions. In this review, we discuss commonly used wireless and leadless cardiac devices including pulmonary artery pressure sensors, implantable loop recorders, leadless pacemakers and subcutaneous implantable cardioverter-defibrillators. We discuss the concept and function of each device, indications, methods of delivery, potential complications,

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consideration for implantation, and cost-effectiveness. (Curr Probl Cardiol 2021;46:100800.)

Introduction

The rapid growth of telemedicine and the evolution of remote monitoring systems that communicate with cardiac devices have resulted in a remarkable shift in how cardiac patients are monitored. Implementation of continuous and nearly real-time hemodynamic and rhythm monitoring can allow for early detection of decompensated cardiac state and timely execution of a medical management plan.[1,2,3] (Fig 1) These advances have been embraced by various regulatory bodies, including the US Food and Drug Administration (FDA).[4] Examples of wireless cardiac devices include wireless pulmonary artery pressure (PAP) monitoring systems to guide Heart failure (HF) management;[5] implantable loop recorders (ILR) which allow for the diagnosis of unexplained syncope or palpitations when conventional monitoring systems such as Holters and 30 day cardiac event monitors have failed to do so.[6,7] Leadless pacemakers and subcutaneous implantable cardioverter-defibrillators (S-ICD) that are designed to help reduce lead or pocket related complications associated with a conventional permanent transvenous pacemaker or ICD.[6] In this comprehensive review, we discuss these various wireless and leadless implantable devices in terms of patient selection, discuss advantages and limitations when compared to conventional cardiac devices, and highlight potential barriers that may limit the widespread use of this novel technology.[8]

Wireless Implantable Pulmonary Artery Pressure Monitoring Devices

HF affects 6.2 million adults in the United States (US), with its economic burden estimated at $30.7 billion annually, including costs for health care services, medications, and missed days of work.[9] Several strategies designed to minimize the negative impact of HF on our healthcare system have been proposed. Unfortunately, in a large clinical trial, initiatives focusing on patient education and remote weight monitoring programs failed to reduce HF readmissions,[10] while other programs such as Hospital Readmission Reduction Program (HRRP) of the Affordable Care Act may have resulted in unexpected consequences including increasing mortality among HF patients.[11,12] Two wireless PAP monitoring devices are currently available in the US; the Cardiomems (Abbott)

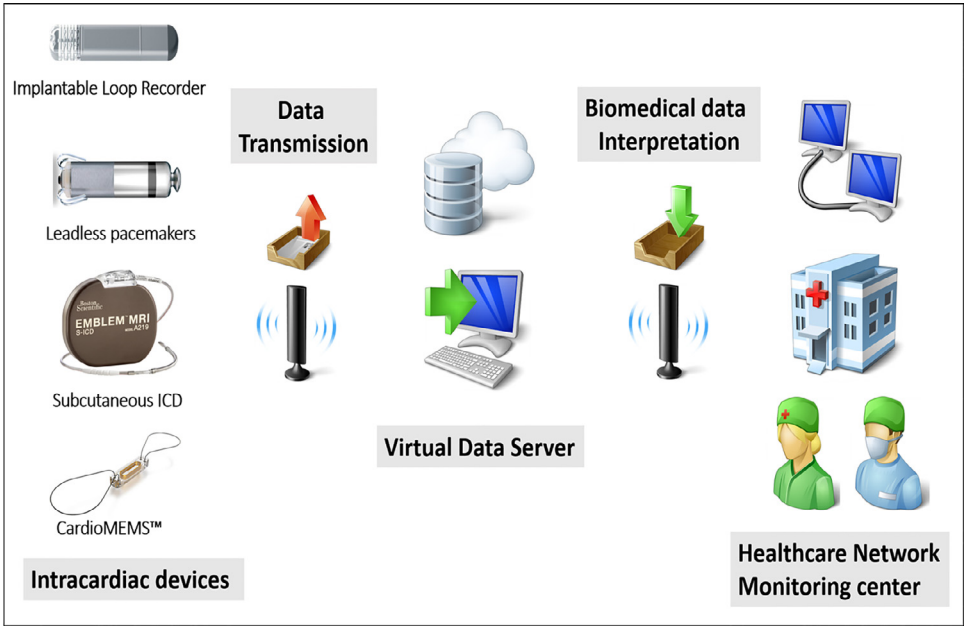


Fig 1. Various types of intracardiac monitoring devices that allow data transmission of different biomedical data to virtual data servers, which eventually will be interpreted and analyzed.

device is commercially approved (Fig 2) while the Cordella PA sensor system (Endotronix) is currently under investigation (Fig 3).[13,14]

Cardiomems is the first cardiac device that has been shown to reduce HF readmissions in a selected HF patient population.[15] This device is composed of an oil and capacitor covered by silicone, which forms a circuit that resonates at a specific frequency. The changes in PAP applied on the sensor result in changes in the frequency of resonant waves.[15] This device does not have any batteries or leads, and it is powered by radiofrequency signals. Patients initiate the reporting of their PAP data via a

Fig 2. The CardioMEMS device. Courtesy of Abbott.

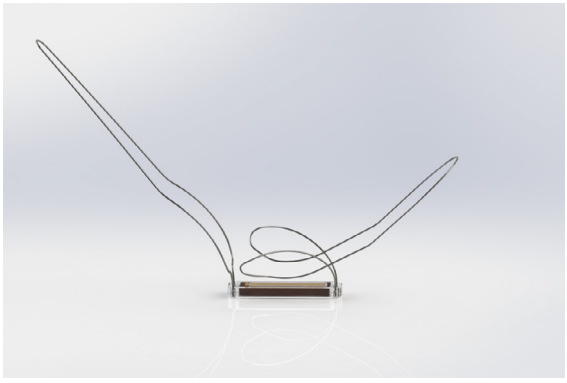


Fig 3. Cordella PA sensor system. Used with permission of Endotronix.

handheld wand near the chest, and the data are recorded on a secure online database.[16] This allows physicians and other healthcare providers to monitor patients' PAP remotely and to implement treatment changes in timely manner.

Implantation of the device is performed in the catheterization laboratory. Patients generally undergo standard right heart catheterization prior to implantation, and the device is then implanted in the distal left pulmonary artery. Implantation of this hemodynamic remote monitoring device is to be avoided in the setting of active infection, history of recurrent venous thromboembolism, or in the setting of severely reduced glomerular filtration rate, congenital heart disease, mechanical right heart valves or coagulopathy.[16]

The CHAMPION trial (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in New York Heart Association NYHA Class III HF Patients) was the first prospective, randomized, single-blinded, multicenter study that enrolled 550 HF patients with either preserved or reduced ejection fraction (HFpEF/HFrEF) and NYHA Class III symptoms and prior history of hospitalization due to HF.[17] This study showed a significant reduction in HF hospitalizations when hemodynamic monitoring and volume status was used proactively to guide diuretic therapy. HF hospitalization rates were 28% lower in the treatment arm compared to control arm (HR: 0.72; 95% CI: 0.59-0.88; P= 0.0013), and there was a strong trend toward lower mortality compared to the control arm although did not reach statistical significance (HR: 0.68; 95% CI: 0.45 to 1.02; P= 0.06).[17] Furthermore, subgroup analysis of the CHAMPION trial also revealed a decrease in HF admissions with PAP monitoring-guided therapy compared to symptomatic therapy alone.[18]

Recently, the Cardiomems Postapproval Study, an observational single-arm trial included 1200 patients with NYHA III HF and a prior HF hospitalization in the last 12 months.[19] The primary efficacy outcome was number of HF hospitalizations in 12 months post-transplant (with PAP-guided therapy) compared to preimplant HF hospitalizations in previous 12 months (usual care). In this trial, the rate of HF hospitalization was significantly lower at 1 year postimplant compared with the 12 months prior to implantation (0.54 vs 1.25 events/patient-years; 58% reduction), and the rate of all-cause hospitalizations was also significantly lower 12 months after implantation (1.67 vs 2.28 events/patient-years; 28% reduction).[19]

Based on a recent postmarketing surveillance analysis, the complication rate during the first 3 years after FDA approval of Cardiomems was approximately 2.8%, with the most serious complications being pulmonary artery injury and hemoptysis.[16] Other rare but significant adverse effects include pulmonary embolism and/or device thrombosis, access site bleeding, infection, and death. Suboptimal device functionality, including sensor failure and/or malfunction or structural migration, can require recalibration or re-intervention.[20]

Despite the high initial cost of the device, it has been shown to reduce overall costs in the mid- to long-term. A 5-year cost-effectiveness analysis of Cardiomems revealed an increase in quality-adjusted life-years when compared to standard therapy, primarily by reducing the rate of HF hospitalizations.[19,21,22] Another study examining Medicaid patients with HF demonstrated that Cardiomems was associated with a significant reduction in HF-related hospitalizations and all-cause hospitalizations during the year after implantation, resulting in a reduction in total health care costs.[23] Similarly, in Medicare patients with HF and a Cardiomems device, there was an estimated reduction in hospital admissions, which also was related to a cost reduction of $7,433 per patient in the first 6 months following implant. The effectiveness of this device is dependent on proper patient selection, successful implantation of the device, and subsequent stewardship by health care providers by using hemodynamic information to prevent and manage HF exacerbations by titrating diuretics and vasodilators.

The Cardiomems remote hemodynamic monitoring device is commercially approved for patients with both HFpEF and HFrEF, NYHA class III symptoms, and a previous HF hospitalization in the last 12 months. The Hemodynamic-GUIDE Management of HF (GUIDE-HF) trial (NCT03387813) is an ongoing large multicenter randomized study aiming to demonstrate the effectiveness of Cardiomems in an expanded HF patient population, including patients with NYHA Class II-IV HF who

have an elevated level of N-terminal pro-brain natriuretic peptide (NT-proBNP) or an elevated brain natriuretic peptide (BNP) and/or a prior HF hospitalization.[23]

Similar to the Cardiomems, the Cordella PA sensor system includes a PAP sensor that allow for hemodynamic monitoring.[14] The potential advantage of this system is that it also includes monitoring of heart rate, pulse oximetry and weight. This device is not commercially available and is currently being investigated in a large randomized, multicenter, prospective clinical trial (PROACTIVE-HF, NCT04089059).[24]

Implantable loop recorders

ILRs were first introduced in 1990 and were designed to be used as a diagnostic tool for uncovering arrhythmic etiologies of syncope, unexplained falls, convulsive syncope, palpitations due to various brady and/or tachyarrhythmias, or unexplained (cryptogenic) embolic stroke.[7,25,26,27] In recent years, newer models of ILRs have been redesigned with advanced algorithms to detect AF, as demonstrated in the Reveal XT Performance Trial (XPECT) Study.[27-29] In XPECT trial (NCT00680927), among patients who underwent implantable cardiac monitor (Reveal XT, Medtronic Inc, Minneapolis, MN, Fig 4) and Holter monitor. Results showed that AF burden was very well correlated with extended Holter monitor (Pearson coefficient = 0.97).[29] All ILRs are designed to store recordings when automatically activated by a device-perceived arrhythmia, and recordings may also be triggered through use of an external activator signaling device. In the case of syncope, the devices are designed to record the heart's rhythm strip before, during, and after the syncopal event.[7] ILRs often are used in the research setting to follow the efficacy of catheter ablation therapy.

Similar to other leadless cardiac devices, ILRs are safe and can be less invasive than implantable transvenous devices. However, depending on device placement, there may be dampened signals, electrical artifact, and false positive recordings. Battery life varies per brand of ILR, with devices' longevity being between 2 and 4 years.[7] The second Eastbourne Syncope Assessment (EaSyAs II) trial was a prospective randomized control study of 226 patients in a single center in the United Kingdom that evaluated ILRs as first-line use in the diagnosis of recurrent unexplained syncope. The study found that ILR monitoring achieved a more rapid diagnosis than the "usual care" of ECG, syncope clinic, and provocative tilt testing.[30] The Cryptogenic Stroke and Underlying AF (CRYSTAL AF) trial was another randomized, controlled study of 441 patients

Fig 4. Implantable loop recorder. Reproduced with permission of Medtronic.

testing the ILR's ability to improve detection of AF in patients after cryptogenic strokes. There were 221 patients in the ILR arm and 220 patients in the conventional arm. It showed rate of detection of AF at 6 months was 8.9% in ILR arm compared to 1.4% in the conventional arm with HR 6.4 (95% CI 1.9-21.7; $P < 0.001$). At 12 months follow-up, the rate of detection of AF was 12.4% in the ILR arm compared to only 2% in the conventional arm. The study revealed superior performance of the ILRs when compared to conventional follow-up after an ischemic stroke for AF monitoring in asymptomatic patients.[31]

Implantation of an ILR entails a minimally invasive surgical procedure that can occur in a matter of minutes under local anesthesia. There is a relatively low side effect profile, with a low infection rate (including skin rash), and ILRs minimize the compliance issues that can be seen with external wearable monitors.[32] While the first generation of ILRs required patient activation following symptoms, newer generations include

enhanced, automatic AF detection algorithms, enabling diagnosis in asymptomatic patients.[33] One important drawback is that ILRs have a limited storage capacity that may result in undiagnosed arrhythmias if the memory becomes full from detection issues that lead to oversensing (and storage) of ECG data that have no clinical significance.[32]

Although the cost of an ILR is higher compared to shorter duration ECG monitoring (ie, Holter monitoring or mobile cardiac output telemetry), it provides a longer duration of continuous monitoring.[34] Ultimately, these devices may allow for fewer follow-up visits and may result in fewer hospital admissions.[30]

Leadless Pacemakers

Approximately 200,000 permanent pacemakers (PPM) are implanted in the US every year, and over one million worldwide.[35] The trends in PPM implantation in the US in the period between 1993 and 2009 showed increase of 55.6% in dual-chamber PPM.[36] With the aging of our population and increasing pacing indications, these numbers are likely to continue to increase. Although contemporary transvenous PPMs have been shown to be safe and effective, they are associated with risk for pocket infections, venous occlusion, cardiac perforation, lead dislodgement or fracture, and tricuspid regurgitation.[37,38] In this regard, leadless PPMs (Fig 5) may prevent the complications of traditional transvenous PPM.

Two leadless pacing systems have been investigated: the Micra Transcatheter Pacing system (Medtronic) and the Nanostim Leadless Cardiac Pacemaker (Abbott). These are small devices, which are implanted into the right ventricular.[35] Both of these leadless pacemakers are delivered percutaneously via the femoral vein, and using different introducing sheaths based on the device (ie, Micra has a 23 French inside compared to Nanostim which has 18 French inside). The other difference is Micra

Fig 5. Leadless pacemaker. Reproduced with permission of Medtronic.

utilizes nitonol tines to affix to the right ventricular myocardium and Nanostim uses an active fixation screw in helix.[35]

The LEADLESS trial (NCT01700244) studied the safety and clinical performance of a completely self-contained leadless cardiac pacemaker (the Nanostim device) in 33 patients at 3 centers.[39] Successful implantation occurred in 97% of patients, and 94% were complication-free at 90 days. One patient died following major complications including cardiac tamponade during implantation. This patient underwent emergent surgery and later suffered an ischemic stroke during a nontherapeutic international normalized ratio (INR) in the setting of atrial fibrillation (AF). The LEADLESS II trial (NCT02030418) included 56 centers across 3 countries and enrolled 526 patients with the intent of assessing the safety and efficacy of leadless PPMs. The primary efficacy endpoint was an acceptable pacing threshold and sensing amplitude, and the primary safety endpoint was device-related serious adverse events. Primary endpoints were analyzed in the first 300 patients who completed follow-up at 6 months, with the results showing that 90% of patients met the primary efficacy endpoint, and 6.7% of patients suffering device-related serious adverse events.[40] Of note, implantations of Nanostim leadless cardiac pacemakers worldwide remain halted, and further production has been suspended, due to multiple reported incidents of docking button detachment.[41] Other complications included pericardial effusion, vascular complications, and device dislodgement.[42]

Two major studies were conducted on the Micra device, the Micra Investigational Device Exemption (IDE) study and the Micra Post Approval Registry (PAR), both with early results exhibiting excellent safety and efficacy.[43,44] In Micra PAR (NCT02004873), the performance of the Micra was consistent with published data and Micra PAR has 63% less major complication compared to transvenous PPM.[30] Another study examined Micra transcatheter pacing system in a cohort of 725 patients (NCT02004873) and showed freedom of major complication related to the device or procedure in 96% of patients. Additionally, adequate pacing capture threshold was obtained in 98.3% of patients. Among patients who have had major complications, 3 of them required system revision, 1 patient had loss of device function and 1 patient died of consequences of metabolic acidosis.[44]

Leadless PPM should be considered in patients deemed to be at risk for pocket-site or lead infection. The Leadless PPM has proven to be an option for AF patients requiring atrioventricular nodal ablation for AF with an uncontrolled ventricular rate.[35] Leadless pacemakers are also an option in patients with a standard VVI (ventricular-only demand pacing)

pacemaker indication, prior device infections, or inadequate vascular access.[45] Though a great leap forward in technology, these devices are limited to patients with an indication for a single-chamber device therefore future research should focus on expansion of this technology to dual chamber pacing and cardiac resynchronization therapy.[46] More recently, Micra Atrial Tracking Using a Ventricular Accelerometer 2 (MARVEL 2, NCT03752151) trial studied the dual-chamber sensing using enhanced accelerometer-based algorithms among patients with sinus rhythm and complete heart block. Among 75 patients, using accelerometer-based algorithms showed a mean percentage increase of AV synchrony from 26.8% during ventricular demand pacing, to 89.2% during VDD pacing with no pauses or oversensing episodes.[47]

Although the initial cost of implantation of a transvenous PPM is approximately $2500-$8000 -this cost for the pulse generator-compared to $10,000 for Micra, long term cost-effectiveness might favor of the leadless pacemaker, due to lower longer-term complication rates with the Micra.[48,49] In a propensity score-matched analysis that included 440 patients, the complication rate at 800 days of follow-up was 0.9% for leadless pacemakers vs 4.7% among transvenous PPMs ($P = 0.02$). The TV-PPM complications were either related to the transvenous lead (ie, lead dislocation, lead fracture, tricuspid valve damage by lead), or related to subcutaneous pocket (ie, pneumothorax in attempting to obtain vascular access or pocket revision).[42] In another report of over 72,000 transvenous PPMs, acute (within 1 month) complications ranged 7.7%-9.1%, and long-term complications (1-36 months) ranged between 6.4% and 5.9%. The prevalence and cost of acute complications such as thoracic trauma and infections were 3.71%/$70,114 and 1.15%/$80,247, respectively.[50]

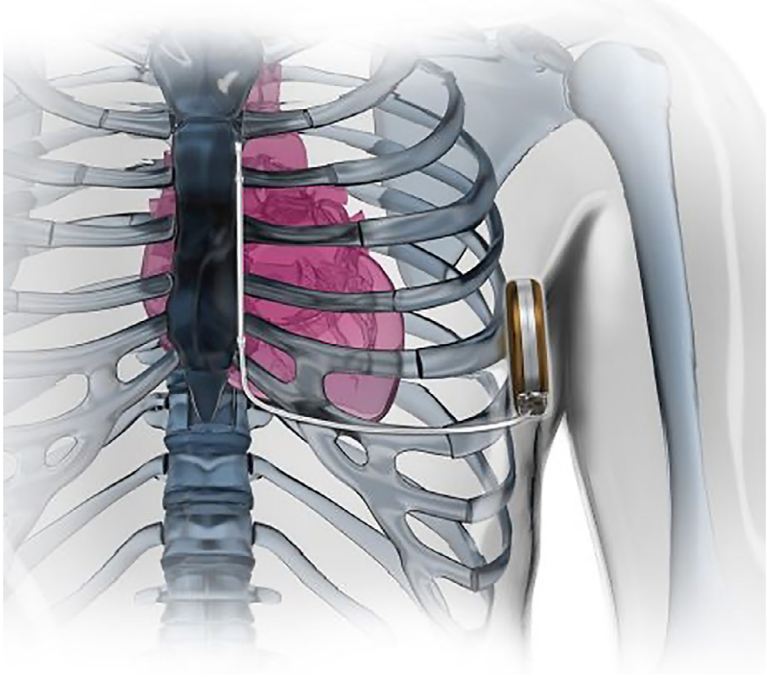
Subcutaneous implantable cardioverter-defibrillators

Because sudden cardiac death (SCD) is the leading cause of death among patients with HF, and the internal cardioverter-defibrillator (ICD) is very effective at aborting sudden cardiac arrest, the ICD has become the primary prevention of death among patients with a decreased ejection fraction.[51,52] The US has the highest implantation rate of ICDs, with 185 ICD implants per million inhabitants, compared with other parts of worlds such as Western Europe, which has only 31 ICD implants per million inhabitants.[53] A recent systematic review and meta-analysis showed that among HFrEF patients, the rate of SCD decreased to 4.39% with ICD therapy compared to 12.5% in those receiving only conventional

guideline directed medical therapy without an ICD. The magnitude of the decrease in sudden death was similar for patients with ischemic cardiomyopathy (HR, 0.39 [CI, 0.23 to 0.68]) and nonischemic cardiomyopathy (HR, 0.44 [CI, 0.17-1.12]).[54] Similar to the pattern seen with the transvenous PPM, device- and lead-related complications, including systemic infection and vascular thrombosis, are the Achilles heel of conventional transvenous ICDs. With its completely extra-thoracic and extra-vascular localization, the S-ICD in this context seems to be an attractive alternative technology (Fig 6A). The S-ICD (Fig 6B) became available in 2009 and has since undergone additional improvement in the size, the ability to store >40 arrhythmic events as well as remaining battery lifespan.[52] Furthermore, the newer generation of S-ICD has better detection of arrhythmias and preventing of inappropriate shocks based on the morphology and utilizing special high-pass-filter, this algorithm called "SMART-PASS."[52] The system of S-ICD was build based on the conventional ICD system, consisting of 2 major components, the device generator and a defibrillation lead. This defibrillation lead has distal and a proximal sensing ring electrode and with the generator this serve as 3 poles for sensing configurations to detect ventricular arrhythmias. A major difference between S-ICD and the conventional ICD system is S-ICD can only deliver a shock therapy and it lacks "anti-tachycardia pacing" functionality of conventional ICD system.[52] This device was FDA approved in 2012 following completion of the Investigational Device Exemption (IDE) study.[52]

The S-ICD IDE enrolled 314 patients and was completed in 2011. The complication-free rate at 180 days was 99%. The primary efficacy endpoint was the rate of successful conversion of induced VF, defined as 2 consecutive VF conversions of 4 attempts and compared with a prespecified goal of 88% success. The acute VF conversion rate was >90%.[55] Subsequently, Evaluation oF FactORs ImpacTing CLinical Outcome and Cost EffectiveneSS of the S-ICD (EFFORTLESS S-ICD), a global multicenter registry of 985 participants, followed patients for a mean of 3.1 years. The primary endpoints were inappropriate shocks and device-related complications. The rate of inappropriate shocks was 11.7% during the mean 3.1 years follow-up, with complications at 30 and 360 days being 4.1% and 8.4%, respectively.[25] The Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy (PRAETORIAN) trial[56] enrolled 849 patients (426 in the S-ICD group and 423 in the transvenous ICD group) with any Class I or Class IIa indication for ICD implantation. The primary endpoint was a composite of device-related complications and inappropriate shocks,

A



B

Fig 6. (A and B) Subcutaneous ICD images provided courtesy of Boston Scientific. 2021 Boston Scientific Corporation or its affiliates. All rights reserved.

which occurred in 15.1% of the S-ICD group and 15.7% of the transvenous ICD group (HR 0.99; 95% CI 0.71-1.39; $P = 0.01$ for noninferiority). Secondary end points included death and appropriate shocks. There was no significant difference between the groups in terms of mortality (HR 1.23; 95% CI, 0.89-1.70) or appropriate shocks (HR, 1.52; 95% CI, 1.08-2.12).[56]

As with transvenous PPMs, ICDs have a higher rate of lead-related complications, including systemic infections and device extraction, when compared to S-ICD.[38,57] The S-ICD is a great alternative not only for patients with high infection risk (including those requiring hemodialysis, or those with previous endocarditis or device infections), but also for patients whose transvenous leads have failed, or those who lack vascular access.[45,46,57,58] The lateral placement of the generator often is more esthetically pleasing than the typical prepectoral location of the transvenous-ICD can. Because of lower risk of lead-related complications, the S-ICD allows for a more active lifestyle without jeopardizing lead integrity. The S-ICD should be strongly considered in patients who are young, have a life expectancy >10 years, have prosthetic valves, and women.[57,59] Because current iterations are not capable of cardiac pacing, the S-ICD is not ideal for patients with systolic HF and left bundle branch block with QRS equal or greater than 150 milliseconds (as implantation of a CRT-capable device would be more appropriate), symptomatic bradycardia requiring pacemaker, or recurrent sustained monomorphic VT indicated for anti-tachycardia pacing (ATP).[57]

Although the cost of S-ICD remains significantly higher when compared to a single chamber ICD (approximately $21,000 vs $8,000),[60] a cost-benefit analysis should be considered given the high costs of readmissions and procedures in patients with transvenous devices due to the higher rates of infection and lead failure that may ultimately require extraction.

Future Implications

The increasing shift toward virtual healthcare allows clinical providers to have digitally access to their patients' biomedical data without the need to arrange in-person visit. Remote monitoring offers potential for delivering faster, better, less expensive, and more convenient care.[61] Though reimbursement continues to be the greatest challenge, we believe these new wireless and leadless devices may play an important role in a selected patient population and may lead to improved outcomes and reduced overall health care costs. For instance, with its significant

Table. Summary of trials of currently approved leadless and wireless cardiac devices

Device	Trial name	Study details	Primary endpoint	Results	Trial number
CardioMEMS	CHAMPION	Multicenter, randomized, single blinded inclusion: NYHA III, HFrEF	1. Reduction in HFH- 6 months 2. Devices related problems	reduction in morbidity and mortality in patients on GDMT.	NCT00531661
CardioMEMS	CardioMEMS HF System Post Approval Study	Prospective, multicenter, open-label, observational, single-arm trial. Involved 1200 patients with NYHA III and prior HF hospitalization	1. Freedom from device/system related complication 2. All-cause mortality 3. Heart failure hospitalization	lower PA pressures, lower rates of HF hospitalization and all-cause hospitalization.	NCT02279888
CardioMEMS	GUIDE HF	Prospective, single blinded, randomized, multicenter Inclusion: NYHA II, III, HFrEF, HFpEF, elevated BNP, prior HFH	Recurrence in heart failure hospitalization.	Ongoing trial	NCT03387813
Cordella PA Sensor System	PROACTIVE-HF	Prospective, multicenter, randomized, controlled, single blind clinical trial	Mortality and HFH or Emergency Department or Hospital. Outpatient intravenous diuretic visits.	Ongoing trial	NCT04089059
Implantable loop recorders (ILR)	EaSyAS II	Randomized; factorial assignment; open label	Time to electrocardiogram diagnosis of syncope (how soon the ILR detects abnormal heart rhythms or normal ones).	ILR monitoring achieved a more rapid diagnosis in unexplained syncope than usual care.	NCT00517023
Leadless pacemaker	LEADLESS I	Prospective nonrandomized study	The primary safety end point was freedom from complications at 90 days.	The implant success rate was 97%. One patient developed right ventricular perforation and cardiac tamponade.	NCT01700244

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Table. (*continued*)

Device	Trial name	Study details	Primary endpoint	Results	Trial number
Leadless pacemaker	LEADLESS II	Multicenter study, we implanted an active-fixation leadless cardiac pacemaker	Acceptable pacing threshold and an acceptable sensing amplitude. The primary safety end point was freedom from device-related serious adverse events.	The leadless pacemaker was successfully implanted in 95.8%. Device-related serious adverse events were observed in 6.7%.	NCT02030418
Subcutaneous implantable cardioverter-defibrillators (S-ICD)	PRAETORIAN	Noninferiority, randomized, parallel assignment trial	Number of participants with implantable cardioverter defibrillator related adverse events (ie, inappropriate shocks and/or device related complications.	Device-related complications were higher in transvenous ICD. Inappropriate shocks and death occurred higher in S-ICD group.	NCT01296022
CRT	SELECT-LV	Prospective, multicenter, evaluation of safety and performance of the WiCS-LV system in patients indicated for cardiac resynchronization therapy	Procedure-related adverse events as a measure of safety, and Bi-ventricular pacing capture.	Device-related events occurred in 3 patients (8.6%) within 24 hours. Biventricular pacing occurred in 33 out of 34 patients. Among 28 patients (84.8%) had improvement in the clinical composite score at 6 months.	NCT01905670

CHAMPION, CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients; EaSyAS II, Eastbourne Syncope Assessment Study II; EF, ejection fraction; GUIDE-HF, Hemodynamic-GUIDEd Management of Heart Failure; HFH, Heart failure hospitalizations; HFrEF, heart failure with reduced EF; HFpEF, heart failure with preserved EF; ILR, implantable loop recorders; LEADLESS II, The LEADLESS Pacemaker IDE Study; MEMS, microelectromechanical systems; PA, pulmonary artery; PRAETORIAN, PRospective, rAndomizEd Comparison of subcuTaneOous and tRansvenous ImplANtable Cardioverter Defibrillator Therapy; S-ICD, subcutaneous implantable cardioverter-defibrillators; WiCS-LV system, Wireless cardiac stimulator implant to pace the left ventricle for CRT Transvascular endocardial implantation of wireless pacing Electrode and subcutaneous implantation of Implantable Pulse Generator.

reduction in HF readmissions, increased use of PAP monitoring devices may improve care in HFpEF patients, who remain at high risk for readmissions and in whom no guideline directed medical therapy has shown survival benefit. With regards to the S-ICD and leadless PPMs, current evidence shows that these devices are clinically useful among patients who are at high risk for infection, vascular, or lead related complications. Research focusing on the combination of S-ICD and leadless PPM into a single device is underway.[62] Another current limitation of these devices is the lack of CRT capability. In this regard, a newer approach for biventricular pacing was recently explored in the Safety and Performance of Electrodes implanted in the Left Ventricle (SELECT-LV) study, in which a wireless pacing electrode was implanted in the left ventricle and powered by a subcutaneous pulse generator. This breakthrough technology showed an improvement in clinical composite score at 6 months and a positive echocardiographic CRT response (Table).[63]

Conclusion

Leadless and wireless cardiac devices offer a novel approach to remote monitoring of cardiac patients. Patient selection and the cost of these devices will be essential determinants in their widespread adoption. Considering the limitations of current strategies, particularly lead-related vascular complications, we believe this wireless and leadless technology will bring sustaining benefits while preventing other devices' common complications.

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