Recent Advances in Pacing and Defibrillation
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Abstract: Most current pacemaker and ICD systems involve placement of lead(s) transvenously into the heart, connected to a pulse generator. Vascular access may be difficult or limited in some patients, and intravascular leads can be associated with multiple complications such as infection, lead malfunction and vascular occlusion. Recent advances in pacing and ICDs include the development of subcutaneous ICDs and leadless pacing. Subcutaneous ICDs do not require a transvenous access or lead, and have become an important option for patients with indications for ICDs who have limited or difficult vascular access or have a significant risk with this approach. In addition, subcutaneous ICDs can be offered as an alternative to transvenous ICDs in certain patients. Leadless pacing is evolving as a new approach to pacing that can avoid or mitigate the issues associated with intravascular leads. Self-powered leadless cardiac pacemakers have been shown to be a safe and feasible option for patients requiring single chamber pacing. In addition, leadless ultrasound-based pacing has been shown to provide effective left ventricular pacing for cardiac resynchronization therapy in conjunction with a traditional transvenous device. Future advances in the technology of leadless pacing will hopefully allow multichamber pacing (and multisite pacing within a chamber) with all the sophistication of current transvenous systems. Perhaps, leadless pacing can even be combined with a subcutaneous ICD in the same patient.

Keywords: Leadless pacing, subcutaneous ICDs

Background
Cardiac Pacemakers: The heart generates its own electrical activity, and this intrinsic heart beat underlies the rhythmic contraction of the heart. When there is a problem with the origin or spread of this electrical activity, the heartbeat, and therefore the pumping function of the heart, may be impaired. In such situations, the electrical function of the heart may be restored by external electrical stimulation by devices called pacemakers. The first cardiac pacemakers were developed around 1960. They have traditionally involved 2 basic components: a generator that houses the battery and circuitry, and pacing wires (leads) that connect the generator to the heart for transmission of electrical pulses to the heart. Early pacing systems involved a large generator connected to pacing wires sutured on to the outside of the heart. These early systems were replaced by trans-venous systems, with pacing wires (leads) that pass through the blood vessels (veins) into the heart, and connect to the generator typically placed under the skin in the chest. Over time, the generators have become smaller, with a longer battery life and more sophisticated features. For instance, modern pacemakers can stimulate multiple chambers of the heart in a synchronized fashion, and can alter the pacing rate based on the perceived needs of the patient.
**Cardiac Defibrillators:** Cardiac arrest is sudden cessation of cardiac activity with collapse, that will lead to death (Sudden Cardiac Death) without prompt intervention. Cardiac arrest is most commonly due to rapid rates in the lower chambers of the heart (ventricular fibrillation); the most effective intervention for this lethal rhythm is defibrillation i.e. delivery of a high energy shock to the heart to restore normal rhythm. People who have survived a cardiac arrest or who are at high risk for developing one would benefit from placement of devices called implantable cardioverter defibrillators (ICDs), which can continuously monitor the patient’s rhythm, rapidly detect any lethal ventricular rhythm that occurs, and terminate it by prompt delivery of a high energy shock. In an analogous fashion to pacemakers, early ICDs, which were developed around 1980, required a surgical procedure (thoracotomy) to place large patches on the outside of the heart connected to large pulse generators placed within the abdomen. These have since evolved to trans-venous systems involving one or more leads that traverse the veins into the heart, connected to much smaller devices placed under the skin in the chest. Early on, patients that needed both pacing and defibrillation had 2 separate systems placed. However, current defibrillators have the capability to function as sophisticated pacemakers, and therefore only one device is required.

**Complications associated with intra-vascular leads:** As noted above, most current pacemaker and ICD systems involve placement of lead(s) transvenously into the heart, connected to a pulse generator. Potential acute complications associated with vascular access and transvenous placement of leads include pneumothorax (collapse of the lung due to accumulation of air around it), hemothorax (blood collection around the lung), cardiac tamponade (blood collection around the heart impeding its normal function) and lead dislodgement. In addition, vascular access may be difficult or limited in some patients. In the long term, intravascular leads can be associated with multiple complications such as vascular occlusion, lead malfunction (conductor fracture or insulation breach), infection and valvular regurgitation. Most of these issues necessitate lead extraction, which can be associated with significant morbidity and mortality. In fact, intravascular leads are considered the weakest link of the pacing or ICD system. Recent advances in pacing and ICDs include the development of subcutaneous ICDs and leadless pacing which eliminate the need for intravascular leads and their associated complications.

**Cardiac resynchronization therapy (CRT)** is a form of pacing designed to synchronize activation of the ventricles in certain patients with heart failure. CRT typically involves pacing the left ventricle through a lead that is delivered transvenously to a branch of the coronary venous system (the venous system of the heart) to pace the left ventricle from the epicardium (outer aspect of the heart). Ideally, the pacing lead should be placed close to the area of the left ventricle that has maximal dys-synchrony; however, with the transvenous coronary vein approach, where the lead can be placed is limited by the anatomy of the coronary venous system. To avoid this limitation, studies have tested leads delivered to the endocardium (inner aspect) of the left ventricle. However, embolic complications (that can cause strokes) are a potential risk with this approach. Recent advances in leadless pacing offer promise for endocardial left ventricular pacing for CRT at the desired site, while minimizing the embolic risks associated with indwelling leads in the arterial system.

**Subcutaneous ICDs**
An entirely subcutaneous defibrillator (S-ICD system, Cameron Health, Inc., San Clemente, California) has been developed and tested in humans. The S-ICD system includes a single lead implanted subcutaneously in the chest parallel to the breast bone, which is connected to the pulse generator
implanted subcutaneously in the left side of the chest. The system can deliver a defibrillating pulse of up to 80J (transvenous ICDs typically can deliver up to 35-40J). Subcutaneous ICDs are particularly useful in patients with difficult or absent venous access. They should also be considered in patients at high risk for blood stream infection, such as those with indwelling intravascular catheters. In addition, they should also be considered in young patients who require defibrillators, since they eliminate the physical stress on leads associated with cardiac motion. The lack of demand pacing in these systems contraindicates their use in patients who require consistent pacing support. In addition, certain fast ventricular arrhythmias may be terminated by rapid pacing without the need for a high energy shock, and in such patients traditional transvenous ICD systems which have this capability would be preferred.

**Leadless cardiac pacemakers**

There are two types of leadless pacemakers. The first are self-powered devices implanted in the heart. The second type involves receiver electrodes implanted within the heart that are powered by a power source implanted outside the heart.

The leadless cardiac pacemaker (Nanostim Inc, Sunnyvale CA) is a self-powered cylindrical device, about 4 cm long with a diameter of <6mm, that is implanted in the heart. The device includes the pacemaker electronics, battery and electrodes and is delivered to the heart using a delivery catheter. The device functions as a basic single chamber pacemaker that can alter the pacing rate based on the perceived needs of the patient.

As discussed above, traditional pacemakers involve leads that traverse the veins to connect the generator to the heart. Implanted leads may sometimes need to be removed, due to infection of the pacing system, lead failure or vascular complications. Removal of pacing wires that have been in place for a long time can be quite challenging and risky, and can result in life-threatening bleeding. Leadless pacemakers would eliminate these problems since they do not require leads that traverse the vascular system.

Initial short term studies have demonstrated the acute safety and feasibility of this approach in humans. Obviously, long term reliability and safety have to be demonstrated in larger numbers of patients before this technology is ready for prime time. The current version of the leadless pacemaker has only the most basic functions whereas modern traditional pacemakers have more sophisticated features. There are technical challenges associated with implantation that must be carefully handled. Dislodgement and migration of the implanted pacemaker to other sites (embolization) is a potential concern. When the battery of the implanted leadless pacemaker is exhausted, a new implant is necessary, with all the potential risks associated with this. Though retrievability of the device has been demonstrated in the short term, it is not known if it will be feasible to safely retrieve the old device after it has been in place for years. If the old device is left in place, it is not known what the long term effects of this will be.

**Leadless pacemaker for cardiac resynchronization therapy**

Leadless pacing is being explored as an option for endocardial left ventricular pacing for cardiac resynchronization in heart failure patients. The traditional approach of placement of a lead in a branch of the venous system of the heart has inherently limited options. Leadless pacing could potentially target the optimal area of the left ventricle for pacing.

As mentioned above, in addition to self-powered devices, leadless pacing can also involve receiver electrodes implanted within the heart that are powered by a power source implanted outside the heart.
in the chest. An ultrasound-based cardiac stimulation pacing system (wireless cardiac stimulation\textreg; LV system, EBR Systems Inc.) has been developed to deliver left ventricular pacing in conjunction with a traditional transvenous system. The system includes a transmitter implanted subcutaneously in the chest that transfers energy to a small receiver electrode(s) implanted in the endocardium of the left ventricle. The transmitter is connected to a pulse generator (battery) that can be placed in the side of the chest or in the abdomen. The system relies on RV pacing pulses from the transvenous implant to trigger LV pacing. The advantage with this approach is the ability to deliver the electrode(s) to the optimal site in the LV and the potential option for multisite LV pacing.

**Conclusion**

Most current pacemaker and ICD systems involve placement of lead(s) transvenously into the heart, connected to a pulse generator. Vascular access may be difficult or limited in some patients, and intravascular leads can be associated with multiple complications such as infection, lead malfunction and vascular occlusion. Recent advances in pacing and ICDs include the development of subcutaneous ICDs and leadless pacing. Subcutaneous ICDs do not require a transvenous access or lead, and have become an important option for patients with indications for ICDs who have limited or difficult vascular access or have a significant risk of infection with this approach. In addition, subcutaneous ICDs can be offered as an alternative to transvenous ICDs in young patients. Leadless pacing is evolving as a new approach to pacing that can avoid or mitigate the issues associated with intravascular leads. Self-powered leadless cardiac pacemakers have been shown to be a safe and feasible option for patients requiring single chamber pacing. In addition, leadless ultrasound-based pacing has been shown to provide effective left ventricular pacing for cardiac resynchronization therapy in conjunction with a traditional transvenous device. Future advances in the technology of leadless pacing will hopefully allow multichamber pacing (and multisite pacing within a chamber) with all the sophistication of current transvenous systems. Perhaps, leadless pacing can even be combined with a subcutaneous ICD in the same patient.
**Bibliography:**

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Dr. Harish Doppalapudi is an Assistant Professor of Medicine at the University of Alabama at Birmingham (UAB) in Birmingham, Alabama, USA. After graduating in medicine from Guntur Medical College in Guntur (AP, India) in 1997 as the best outgoing student of the college and the university, he completed residency training in internal medicine at UAB, where he went on to complete fellowships in cardiovascular disease and clinical cardiac electrophysiology. He has been on faculty in the electrophysiology section of the cardiovascular division at UAB since 2007, and is the Director of the Fellowship Training Program in clinical cardiac electrophysiology. His clinical practice encompasses all aspects of electrophysiology such as complex ablation, lead extraction, pericardial interventions, and device placement and troubleshooting. He is actively involved in medical student teaching as the co-director of the cardiovascular module. He has been recognized with numerous awards for his teaching contributions to medical students, residents and fellows. He is a member of the core clinical faculty for internal medicine and cardiovascular disease. He has several publications in electrophysiology including the first description of two idiopathic VT syndromes (posterior papillary muscle VT and VT from the crux of the heart) and has coauthored multiple book chapters. He lives in Birmingham with his wife, Harini Ganga, who practices internal medicine at the Bessemer Clinic, and two sons, Siddharth and Nishanth.