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What is New in Implantable Device Technology?

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Key Points

- The leadless pacemaker is the latest breakthrough in bradycardia therapy, as it reaches phase 3 clinical trials.
- Subcutaneous ICD use is supported by early data from large international registries, showing a good safety profile and non-inferiority by comparison to standard ICD.
- Quadripolar lead and multisite LV pacing have the potential for better CRT delivery, as opposed to standard bipolar LV pacing.
- Current recommendations encourage conservative strategy when dealing with normally functioning recalled ICD leads.

Cardiovascular implantable electronic devices (CIED) have seen tremendous progress during the last 20 years, in the field of heart failure (HF) treatment, anti-bradycardia pacing and defibrillation. CIED and leads have evolved allowing easier implantation, improved long term reliability and longer battery life.

Implantable cardioverter defibrillators (ICD), initially reserved for highly selected patients, where the benefit of secondary prevention outweighed potential side effects, are now a safe and widespread therapy, and have become part of the standard of care in HF patients with severe systolic dysfunction. Cardiac resynchronisation therapy (CRT) is also coming of age. In patients with heart failure, left ventricular systolic dysfunction and wide QRS, CRT improves clinical status, leads to reverse remodelling and reduces mortality.

During the last decade, the number of complex device implantations has dramatically increased. Despite an overall low incidence (<5%), the absolute number of device-related complications has increased. The weak spot remains the endovascular lead, which can fail over time, get infected or lead to vein thrombosis.

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Several new technologies are targeting the reduction of device complication rates, such as the leadless pacemaker or the sub-cutaneous ICD. Others are attempting to improve delivery of therapy, mainly for CRT – like the multipole LV lead or the development of alternative LV lead access.

Leadless Pacemakers

Recently, a major technological breakthrough has been made in the field of bradycardia therapy with the development of the leadless pacemaker, by both St. Jude Medical (with the Nanostim) and Medtronic (with the Micra). The miniaturisation of the device allows its direct implantation into the right ventricle, where it is anchored to the inter-ventricular septum, thus eliminating the need for an endovascular lead (see Figure 1). This technology has the potential to completely eliminate pocket and endovascular lead-related complications.

The results from the LEADLESS trial have been published this year, confirming the feasibility and safety of the St. Jude device in a cohort of 33 patients (Reddy et al. 2014). While still ongoing, the post-approval European study suffered a temporary setback due to safety issues, after reports of six perforations resulting in two deaths. Those were probably related to the learning curve of the leadless pacemaker implantation technique, and the study has since resumed. While in a more incipient phase, Medtronic has recently announced, during the 2014 Cardioslim conference, the successful implantation of the Micra in the first four patients.

Future challenges include the development of a dual chamber version and possibly a bi-ventricular leadless device with wireless connection between the pacing elements. Device removal long after implantation may prove problematic, despite the fact that both manufacturers offer technical solutions in case extraction is needed.

Subcutaneous ICD

Despite undisputable benefits, ICD implantation is still associated with considerable risk, as major complication rates stand at around 1.5%. These include infection, pneumothorax, haemorrhage, perforation and death. Additionally, ICD-related risks persist after implantation such as late infection, lead endocarditis, the delivery of inappropriate therapy, vein occlusion, lead dislodgement, valvular dysfunction and lead failure due to intrinsic lead defects.

In view of these considerations, a completely subcutaneous ICD (S-ICD) system has been developed, with the first patients implanted in 2008. It has since been approved for commercial use by the European Union in 2009 and by the FDA in 2012. More than 1300 patients were implanted with S-ICD during the last 5 years.

The system comprises a pulse generator, which is introduced subcutaneously over the left thorax, in the axillary region, and a single subcutaneous lead placed along the left side of the sternum. The S-ICD can accurately detect ventricular tachy-arrhythmia, which is treated by high-energy shock (maximum 80J) (Gold et al. 2012) (see Figure 2). It can deliver temporary but not chronic pacing, so it cannot be used in patients with symptomatic bradycardia or frequently recurring ventricular tachycardia terminated with anti-tachycardia pacing.

Lambiase reported this year on early data from the multicentre EFFORTLESS S-ICD registry (Lambiase et al. 2014). He showed that in a real-life international population of S-ICD recipients, the S-ICD performed appropriately, with clinical event rates and inappropriate shock rates comparable with those reported for conventional ICDs.

Although longer follow-up data is still required for assessing lead reliability over time, the S-ICD has emerged as a valuable alternative to standard ICD in patients with no need for ventricular pacing, with the potential to prevent most of the aforementioned complications associated with intravascular ICD leads. Furthermore, it is today the preferred solution for patients in need of ICD, who suffer from vein occlusion, or who have had system extraction for infection. Future technological challenges include downsizing of the device, which is currently bulky, prevention of infections, and improvement of sensing algorithms to prevent inappropriate shocks (Gold et al. 2014).

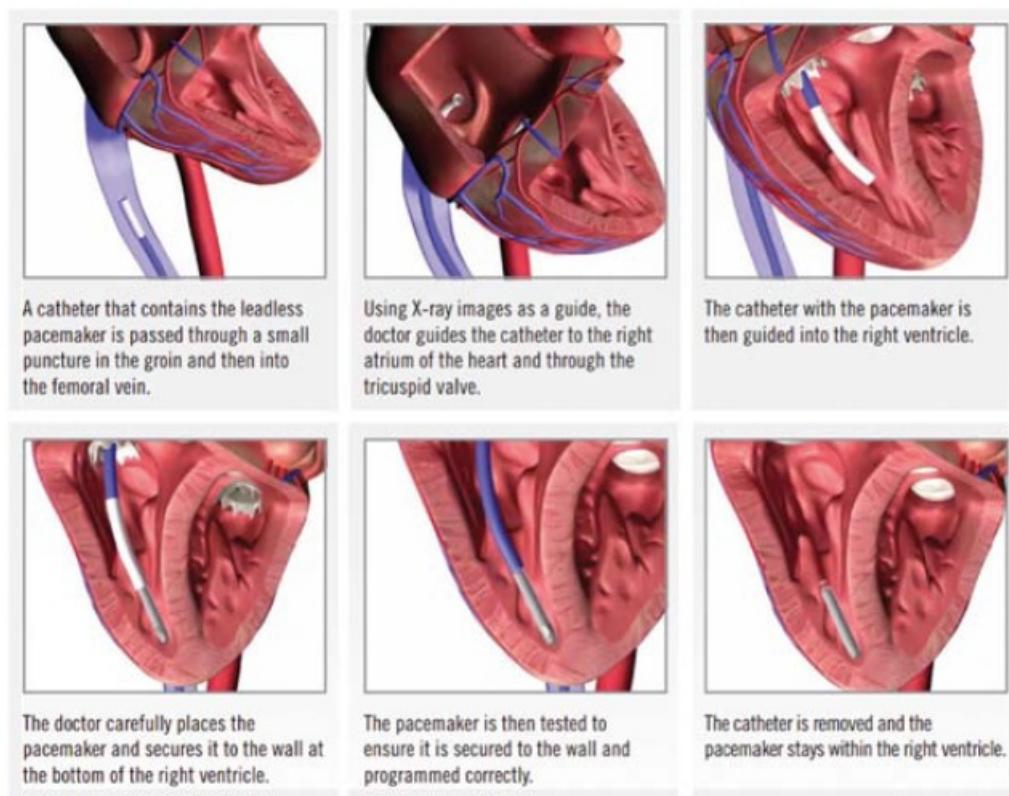


Figure 1.
Leadless pacemaker implantation technique.

Infection Prevention

Infection is the most serious complication following CIED implantation. It risk for sudden cardiac death have been implanted with Fidelis leads. Moreover, evidence suggests that the risk of Fidelis lead fracture is increasing with time (Cheung et al. 2012)

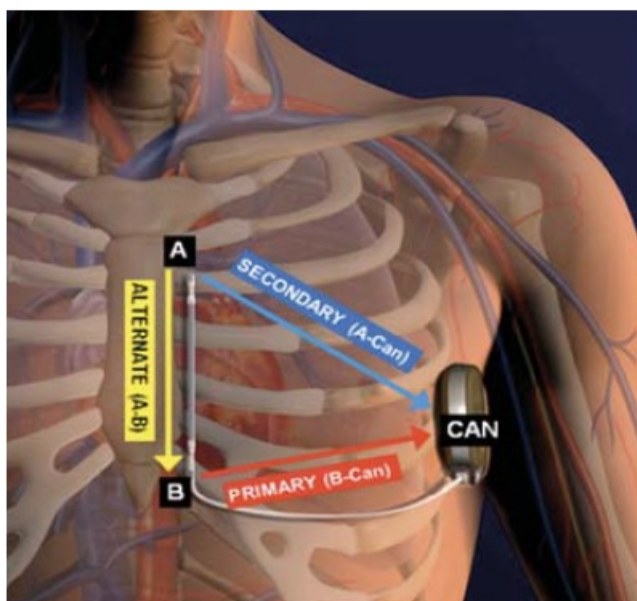


Figure 2.
The S-ICD system is completely extra-vascular and capable of delivering high-energy (up to 80J) trans-thoracic shocks, using multiple shock configurations

Subsequently, there was debate about prophylactically replacing still normally functioning Fidelis leads. Currently the FDA does not support routine removal of the lead, as it considers the risks of extraction to be higher than those associated with the potential development of lead fracture. Furthermore, Medtronic has implemented a device algorithm for early detection of lead fracture (the RV lead integrity alert – LIA). It is generally recommended to leave functioning leads in place. In which case two strategies can be adopted: either closely monitoring the lead for signs of lead fracture (complete device check-up every 3 months and also remote monitoring via Medtronic's CareLink network, including LIA check); or add a replacement lead without removing the Fidelis.

In November 2011, the St. Jude Riata and Riata ST were recalled due to documented premature erosion of the insulation around the electrical conductor wires, resulting in insulation failure. The insulation failure may cause some conductors inside Riata to migrate entirely outside the outer lead insulation – a phenomenon defined as externalisation, which can be documented by x-ray or fluoroscopy. As opposed to predominant pace-sense channel failure in the Fidelis, the main mechanism for electrical dysfunction in Riata is high-voltage failure, caused by short-circuits between high-voltage components and potentially resulting in the death of the patient (Hauser et al. 2012).

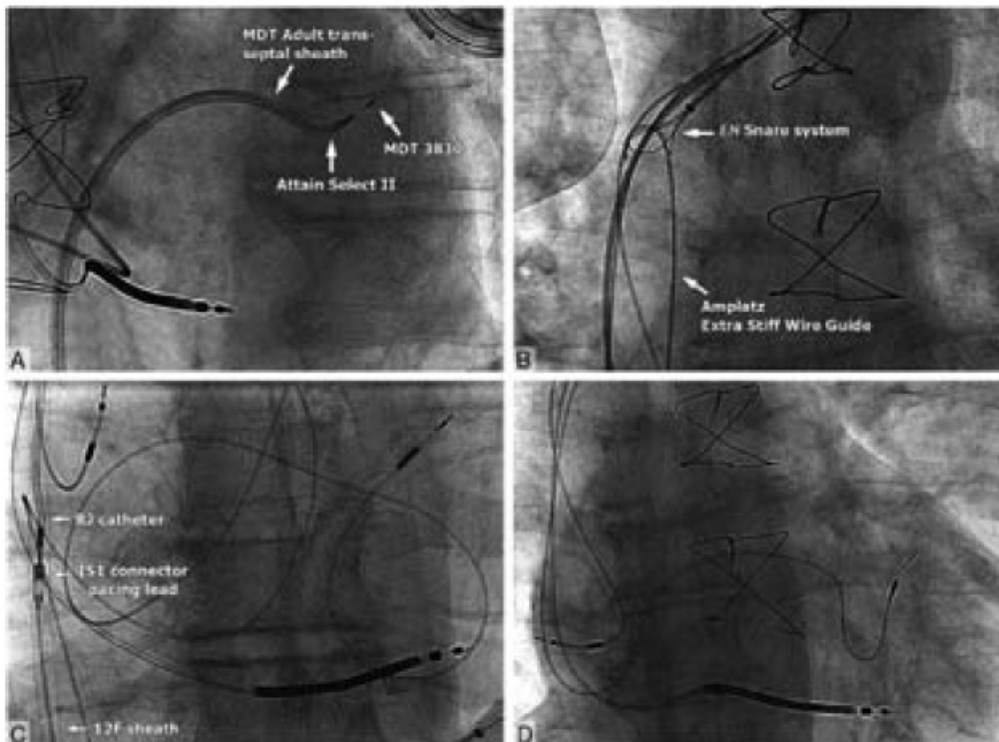


Figure 3.

Trans-septal endocardial LV lead implantation is a particularly challenging technique; the classical trans-septal atrial puncture is performed from below, allowing active LV lead implantation (A), which is then pulled endovascularly into the left prepectoral region using a complex technique involving snaring (B,C) (Gelder et al., 2011)

Currently the FDA recommends close device monitoring and periodic fluoroscopic imaging of previously normal Riata leads. For leads with normal electrical function, removal is not recommended, regardless of the presence of externalisation. For those with abnormal electrical function, replacing or adding a new lead is mandatory. The new St. Jude DurataICD lead has seen the addition of an Optim coating, resulting in an increase of the distance between the conducting wires and lead edge. Furthermore the new generation of St. Jude ICDs are equipped with an automatic high-voltage lead integrity check (HVLIC), enabling early detection of ICD lead failure.

A recent real-life registry analysis has shown that the new generation ICD leads perform better than the recalled models (Liu et al. 2014).

Conclusion

The field of CIED has seen exciting new developments during the last decade. Progress and improvements have been made in pacemaker, ICD and CRT technologies, consolidating the role of device-based therapy and preparing the transition towards the next generation of devices.

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