Cardiac Implantable Electronic Devices (CIED)

CIED is the common name for cardiac implantable electronic devices. One of the epoch-defining events in the past 10 years was the emergence of MRI-conditional devices. Conventionally, CIED covered by metal cases were contraindicated for MRI. MRI was used more frequently in Japan than in Europe or the US, and there were great expectations from healthcare professionals. Companies spent an enormous amount of time and energy to develop a device and a test method to assess the impact on CIED units and leads, and to secure and demonstrate patient safety during MRI scans. Discussion of further validation methods will be necessary in accordance with MRI advancements such as higher resolution.

The second major innovation was the development of leadless devices. The benefits of a leadless pacemaker include the elimination of infections associated with the implanting procedure of pacemakers with leads; and there is no chest protrusion from the traditional pacemaker implantation technique, where the device is placed in the heart chamber, thus freeing patients from cosmetic and lifestyle restrictions. The concept of leadless pacemakers has been present since the 1970s, but it was not technologically feasible until recently. The concept was created as a result of the integration of numerous technologies, including miniaturized electronic circuits and batteries, electrodes that stimulate the myocardium tissue lodging mechanisms, sensors that distinguish between body movements, heart movements and enabling MRI.

Additionally, a subcutaneous implantable cardioverter defibrillator (S-ICD) system was developed; it can perform shock treatment in a similar fashion to the ICD system, without placing a lead in the heart. Because the S-ICD system does not place leads into blood vessels, clinical results show a decrease in the incidence of intravascular infection, and that of heart perforation and pneumothorax during the implantation procedure that intravenously places a lead. As such, it is expected to improve patient prognoses. The S-ICD is also MRI-conditional, therefore post-implantation workup is possible.

The third innovation was the inclusion in CIED of implantable devices that are not therapeutic devices but have diagnostic functions only. They were expected to monitor cardiac rhythm and to demonstrate the ability to detect arrhythmia, particularly atrial fibrillation, and are used to investigate the cause of cryptogenic stroke and to diagnose syncope with unknown causes. As they were not treatment devices, it was imperative that CIED be particularly small in size for Japanese who are resistant to invasive implantation of foreign objects in their bodies. After much hard work, the current sized device resulted. At the end of 2018, the Basic Act on Measures against Stroke and Cardiovascular Disease came into effect, making the prevention and effective treatment of stroke and cardiovascular disease national policy. Since atrial fibrillation is a major cause of cerebral infarction and a factor of incidence and aggravation of heart failure, the role of devices that continuously diagnose and monitor heart rhythm 24/7 is expected to increase.

New fields that we expect to see in the next 10 years include telemedicine, patient monitoring, and prognostic improvements using AI and IoT. While Japan's declining birthrate and aging population squeeze the national budget and a longer healthy life-span is desired, there is a need for efficient medical care. Work-style reform of healthcare professionals is also urgent. Efficiency that does not compromise healthcare quality will be the responsibility of the entire healthcare industry. It is now deemed possible to collect biological information, including the heart rhythm of a patient, and process and analyze the data, then use it to constantly monitor the patient's condition, and give warnings or suggestions for improvement.

The collected information can then be linked to more sophisticated external AI and IoT. By connecting it to physicians and patients, we can create a world in which immediacy and convenience are enhanced, and efficiency is enabled. With increasing public awareness of health, self-management of health through wearable devices such as smart watches will increase. Heart rhythm monitoring with a wrist watch device is also becoming feasible, and this may allow patients to present data in the future, which are used by medical institutions. To that end, a number of issues need to be addressed, including: information security; establishment of a system for collaboration between clinics, hospitals, and medical institutions; challenges of healthcare economy; and data reliability. To stay up to date, the promotion of collaboration among industry, academia, hospitals, and government must be planned for the next 10 years.

Subcutaneous implantable cardioverter defibrillator (S-ICD) system

Leadless pacemaker

Implantable ECG recorder