Introduction

In the last 40 years, great progress has been made in the development of pacemakers, such that pacemaker therapy constitutes one of the most efficient methods of treatment in cardiology today [1]. In the beginning, it contended above all with difficulties in the transmission of current to the myocardium, with the reliability and life span of the battery, and with the adaptation of the system to human physiology. In the meantime, it has reached a high standard and has blazed the trail from fixed-rate, large single-chamber pacemakers to dual-chamber systems that clearly increase the patient's quality of life. Today an average weight of less than 30 grams with an average running time of between six and eight years and a varied programmability and possibility for heart-rate adaptation are standard [2]. Implantable defibrillators have followed a path of development similar to that of pacemakers. The first devices were implanted in the 1980s and weighed around 250 grams. The weight could already be reduced to 100g by the beginning of the 1990s, and the site of implantation could be shifted from the abdomen to the thorax due to the development of endocardial shock electrodes. Expansion of therapy with antitachycardic pacing and DDD function, algorithms for the discrimination of supraventricular tachycardias, atrial cardioversion, considerable improvement of the diagnostic memory, and further reduction of the aggregate followed. The implantation of pacemakers and defibrillators proceeds today under local anesthetic and with minimal inconvenience for the patient.

The Development of Pacemaker Therapy

Since the development of electrotherapy of the heart is a dynamic process, a description of the current standard can only present a momentary picture. Many important, life-saving functions and further technological developments are already included in existing implants; however, for the most part, the complex causalities and interactions of various physiological and pathophysiological mechanisms have yet to be considered by the device. In this way, an even stronger needs-oriented therapy that treats the underlying illness can be realized; at the same time, an automation of the implant in the sense of an event-controlled therapy delivery based on expert knowledge is made possible. Several examples of current research show corresponding starting points for such an evolution, that is visualised in Figure 1.

In recent years, much attention has been directed toward the simplification of programming and the operation of devices. Automation is the catchword here. Automatic capture control can be conducted automatically by the pacemaker itself, in a number of different ways, which leads to greater security for the
patient and, at the same time, to a longer implant lifetime. The same is true for the sensing function. In many cases, an automatic follow-up program supports the physician in the care of the patient. In general, the effort is made to simplify the follow-up for the physician. This means making the technology as simple as possible for the practicing physician who does not frequently conduct pacemaker follow-up sessions. The significant expansion of diagnostic functions also helps fulfill this goal.

The search for a rate-adaptation sensor for chronotropically-incompetent patients has occupied many research groups worldwide since the end of the 1970s. The goal is to imitate the physiological behavior of the sinoatrial node as well as possible. While with this method of therapy the symptoms that occur are treated in isolation, Closed Loop Stimulation proceeds in an entirely different manner. The pathologically-limited cardiovascular system is supported in its essential task, namely to ensure a constant and stable perfusion, in that information about momentary metabolic need is obtained from the individual intrinsic neurohumoral regulation and is translated into appropriate stimulation rates. In this manner, bidirectional interaction between the pacemaker and the neurohumoral regulation system is established for the first time.

Electrotherapy is increasingly applied in areas other than acute rhythmological dysfunction. Of great scientific interest today are studies involving the use of pacemaker therapy to prevent arrhythmias or the progression of cardiac insufficiency. Daubert et al [3] have shown in numerous studies that biaxial pacing can be successfully employed in the prevention of atrial fibrillation. Saksena et al. [4] have also been able to demonstrate that bifocal right-atrial pacing can suppress paroxysmal ventricular fibrillation. A breakthrough in this field would be of enormous value to society, since atrial fibrillation occurs with an incidence of 1% in the general population and has a noticeable effect on quality of life for most of the individuals affected.

Left- or biventricular stimulation as a therapy for congestive heart failure is being pursued with even greater interest. The results from Blanc et al. [5], among others, show that left-ventricular pacing can bring about a significant regression in cardiac failure and its accompanying symptoms. In the field of lead development, a left-ventricular, transvenous lead that is easy to position has since been designed for introduction into the coronary sinus. Problems with leads including dislodgment, high sensing- and pacing thresholds, and difficult placement in the coronary venous system constituted previously the principal limitation of this therapy. There are still many open questions in this area that need to be answered.

In order to realize preventive therapies accurately and in time, the appropriate technical aids and the proper markers for prediction of arrhythmias must be found. In the USA alone, 250,000 patients die of sudden cardiac death each year. At least those patients under “clinical” observation can stratified for their individual level of risk. Schmidt et al. have provided a sensitive procedure to classify patient risk after myocardial infarction by evaluating “Heart Rate Turbulence” (HRT) [6]. By noting the “HRT Slope” and the “HRT Onset” after a ventricular extrasystole, a physician can classify the patient as being at high or low risk of sudden cardiac death and take appropriate measures.

A further technological development in this era of telecommunications is naturally the transmission of diagnostic pacemaker data to the physician over the GSM-network. This year, the principle of "Home Monitoring" was introduced in pacemaker therapy for the first time. This technology makes possible the unidirectional transmission of diagnostic data from the patient at home to the physician in the clinic. This method must be proven in practice, but it opens the door to unimagined possibilities for improving the quality of pacemaker therapy.

With all these possibilities, pacemaker therapy is presented with a number of approaches for even better patient care in the future. Some of the aspects discussed are already available in clinical practice. A consistent implementation of these and other ideas, as well as the integration of the diagnostic- and therapeutic modules into a single unit, presents a future challenge for interdisciplinary collaboration between natural scientists, physicians, and engineers.

The task ahead consists in bringing all these achievements and innovative ideas together into a self-learning, predictive, and preventive acting pacemaker. Based on automatic continuous classification of cardiovascular condition, the implant is able to analyze diagnostic data and react appropriately. Sensing and output voltage are continually adapted. If the patient is at risk of atrial fibrillation, the device provides biaxial or overdrive pacing. If the onset of atrial fibrillation has already occurred, the implant can provide car-
dioversion. Preventive overdrive stimulation is provided when there is a risk of ventricular tachycardia; anti-tachycardic pacing or shock is delivered upon onset. Also, the device can observe signs of ischemia through changes in the monophasic action potential or other predictors and evaluate the risk of sudden cardiac death. If needed, all these data can be made available to the physician through telecommunication, enabling the possibility of further intervention.

Outlook

Finally, all these characteristics will be combined into an autopilot that will be able to reach decisions based in the consistent application of expert knowledge stored in the implant memory. Obtaining this expert knowledge, refining the techniques in preventive and acute therapy, and the technical and clinical evaluation of the combination of these elements in the design of an automatic implant demands intensive collaboration between physicians, physicists, and engineers of all types, all experts in their respective fields. Only in this way can we reach the dual goal of ensuring optimal quality of life and patient prognosis while simultaneously simplifying the work to the physician.

References


