The comparison of pacemaker’s automatic threshold control function and adaptability analysis

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Abstract. In the process of cardiac pacemaker automation, except for the security, power saving and convenience is also the major concern. Auto threshold capture means that the pacemaker adjusts output voltage, ensuring the safety of the patients, also extending the life of the pacemaker. In this article, by comparing the domestic three major brands of automatic threshold capture function, enable doctors to better understand the functions of their respective advantages and disadvantages, according to different patients with the optimal selection and recommendation, has great significance.

1. Introduction
With the development of biomedical engineering, cardiac pacemaker are changing to the integration of multi-function, such as diagnosis, treatment, follow-up and monitoring, these features increase the energy loss of pacemaker. Together with its wide application and increasing implant number, pacemaker’s battery life is more and more getting the attention of the people. The purpose of pacemaker design lies in increasing security, improving hemodynamics, on the other hand, it is to reduce the unnecessary loss of voltage and current, prolonging the life of the pacemaker.

Under the premise of ensuring safety, in order to reduce energy consumption, extend battery life, besides using high current density of battery electrode, and application of highly efficient hormone, there is new pacemaker function design, include the existing automatic threshold capture (auto capture), the threshold value management (threshold management), and the dynamic capture control (active capture control) function of pacemaker. If pacemaker has this function, doctors no longer need to manually test pacemaker threshold, and will be finished automatically by machines. According to statistics, the average voltage of pacemaker is greatly reduced, effectively save the electricity. This article will discuss the domestic widely used three kinds of pacemaker automatic threshold capture function, analysis of the function for pacemaker output voltage and the influence of life, and to improve the quality of life of patients with adaptability analysis.

2. The latest automated function of cardiac pacemaker
Pacemaker’s automation is defined as automatically adjusting the pace, feel or other function involves a lot of work or state parameters. Pacemaker can adjust the next phase of the working parameters and status according to the record details, including independent electrical activity. Automatic pacemaker can greatly save the pacemaker of programmable time, the electric energy, reaching better service for patients.
Pacemaker’s automation depends on a variety of functions, such as AV search mode, automatic mode conversion, independent sleep frequency and frequency response, etc. Automatic threshold control function is a high efficiency energy saving way.

The first permanent pacemaker has implanted the patient in 1958, after that, the pacemaker design and manufacturing lever have increasingly enhanced. Its clinical application got rapidly expanded. Pacemaker has become important heart disease diagnosis and treatment technology.

The development of the pacemaker roughly experienced four times (table 1).

| Phase | Type            | Time(year) | Detail Function               | Disadvantage                  |
|-------|----------------|------------|--------------------------------|--------------------------------|
| 1     | Fixed-frequency| 1958       | Rhythm pace                    | Competitive arrhythmia         |
| 2     | On Demand      | 1968       | Pace and sense                 | Pacemaker syndrome            |
| 3     | Physiological  | 1977       | Pacemake atrium-ventriculare  | AA'DD syndrome                |
| 4     | Automatic      | 1992       | Automatic adjust parameters    | expensive                      |

2.1. Automatic atrium-ventricular search function
If the patient’s atrium-ventricular conduction function work normally, usually, the doctor always hope the patient’s self-sinus excited can conduct, keeping good heart function. AV automatically search function by extending the AV interval, making it become a slow channel, can make more of the sinus rhythm along the atrium-ventricular conducting. Its fundamental purpose is to encourage more sinus downlink; Its basic method is to constantly compare the conduction duration between own atrium-ventricular node and pacemaker atrium-ventricular node. This function are applied to Dual-chamber pacemaker, it can encourage the patient’s own heart rate and save the pacemaker electric energy.

2.2. Automatic threshold capture function
This function will examine ventricles pace threshold (minimum voltage of ventricular systolic) according to the setting time, in the case of safe, with minimal energy output, extend the life of the pacemaker.

2.3. Automatic frequency response functions
Frequency response pacemaker via sensing physical activity or mental emergency physiological changes, and imitate the heart to the human body metabolic needs to adjust the frequency of pacemaker, so as to meet the normal physiological needs, improve the quality of life. Implanted pacemaker in the United States, 83% of pacemaker has the frequency response function. After implanting this kind of pacemaker, the patient's heart rate will be changed based on their physical activity or mental pressure, to better cater to the patient's own needs, improve the quality of life.

3. The definition of automatic threshold capture
Among all the pacemaker automation function, automatic threshold algorithm has brought great benefits for the patient. At the beginning of the definition, we should understand the concept of threshold firstly. Pacing threshold value can be defined as, in the case of maintain a constant pulse width, the minimum output voltage that can stimulate heart efficiently.
In general, the patient’s threshold will change greatly in the two months after implanted, the 0 ~ 8 weeks after implantation is the acute phase, the threshold is very high. The threshold is relatively stable eight weeks later, then it will go into the chronic threshold period, as shown in figure 1. In order to ensure the safety of the patients, doctors usually set the pacemaker output voltage higher than the threshold about 2 ~ 3 times, but this setting for the pacemaker will unnecessarily consume large amounts of energy. Pacemakers that have the automatic threshold capture function will automatically adjust the output voltage according to the threshold after the acute phase. This function can increase the safety of the patients, but also can extend the life of the pacemaker. Automatic threshold capture function is a revolution in the field of engineering, artificial cardiac pacemaker is a new starting point of the automation mature. So far, the function can only be done in ventricular pacing.

4. The contrast of three kinds of pacemaker automatic threshold capture function
In today’s Chinese market, the use quantity of the top three cardiac pacemaker brands away with automatic threshold function. The three major brands hold of the market share of 80% or more. But the principle of the capture function and automatic threshold settings are different. The comparison and analysis on its function can help doctors to choose, can also guide the patient’s understanding of the product and reasonable use.

4.1. The Auto-Capture of the American pacesetter company—AC pacemaker
AC pacemaker’s working principle is when the pacemaker transmits stimulation signals, the sensing system will shut down last 15ms after the heart stimulation, the ER (Evoked Response ER) will appear in the detection window after 15ms, then the sensing system can sense the ER. If the sensing system haven’t detected ER, the pacemaker can conclude no capture, then the output voltage will be changed to 4.5V, the pulse width will be changed to 0.49ms, use the protective voltage to ensure effectively pacing. The pacing threshold searching process is after pacemaker stable work for 8 hours, then automatically determine the pace, based on this voltage, the pacemaker will reduce 0.3V, if succeed two times, then reduce 0.3V continually, until lost the capture. On this basis, the voltage will increase 0.3V, if the pacemaker can effectively work, this output voltage is defined as threshold. Pacemaker always work above the threshold 0.3V, a great deal of energy will be saved.

4.2. Active Capture Control of the Germany Biotronik company—ACC pacemaker
ACC pacemaker’s working principle is the pacemaker can automatically detect ER, then estimate whether the stimulus signals are effective. If the pacemaker detect the normal pulse can not capture, it will release the safety pulse width of 1.0ms. During the threshold searching process, if the ACC function is “on”, the pacemaker will start automatic threshold search as soon as no capture with three times, according to the maximum amplitude decrease the ACC voltage. When the amplitude is higher than 1.0V, the decrease step is one of 8 of the voltage. When the amplitude is below 1.0V, the
decrease step is 0.1V. While the lowest pacing voltage has been found, the pacemaker will increase
the safety margin that program in advance.

4.3. Ventricular Capture Management of the American Medtronic company—VCM pacemaker
VCM pacemaker’s working principle is the pacemaker base on the slope of the ER, the ER value is
high and the sensing circuit is sensitive to the change, it can accurate judge whether the pulse is
effective. The automatic detection process of Pacing threshold is divided into two steps, the first step
is determining the voltage intensity, voltage base strength can be as a voltage threshold, namely when
the pulse width of 1.0 ms pacemaker voltage threshold; The second step for the determination of value,
the pacemaker output voltage is 2 times as the threshold value, gradually shorten the pacemaker pulse
width, stable took the most narrow pulse width value of ventricular duration, also known as pulse
width threshold. When the safety coefficient of voltage and pulse width is determined, the actual
voltage is equal to the duration of the wrestle multiply pacemaker safety coefficient and pulse width
safety coefficient. Because the value are changing, so the actual output voltage values also change
accordingly.

4.4. The compare of three kinds of automatic threshold pacemaker

Table 2. The comparison of pacemaker’s automatic threshold control function

| Items                  | AC (Pacesetter)                                                                 | ACC (Biotronik)                                                                 | VCM (Medtronic)                                                                 |
|------------------------|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Advantage              | 1. Beat-by-beat verify; 2. No capture alternate pulse                          | 1. Beat-by-beat verify; 2. Single/double pacemaker compatible wire; 3. The programmable safety margin, selectivity, save electric energy; 4. The minimum ACC amplitude can be optimized. | 1. No manual measuring heart R wave; 2. The threshold search interval can be programmed; 3. Programmable multiple security; 4. Low polarization electrode wires. |
|                        | 3. Two stimulate failure can activate a threshold search; 4. Fusion wave avoid algorithm. |                                                                                |                                                                                |
| Disadvantage           | 1. Bipolar electrode wire--unipolar pacing, bipolar perception; 2. Security pulse 4.5V, high energy consumption; 3. Manually test ER; 4. Safety allowance fixed value of 0.25V/0.3V, not SPC; | 1. When the minimum ACC amplitude set is 3.6V, power consumption is higher; 2. The pulse width is 1.0ms, it will increase power consumption. | 1. No every beat confirmation; 2. No alternate pulse; 3. The safety margin using multiple; 4. Need bipolar electrode wire 5. Slow and complex threshold test; |
|                        | High security, automation function, measurement precision and intelligence tests is normal. | Safety first, save electricity, intelligent degree is high, easy to use.          | Security is low, the intelligent degree is normal.                               |

5. Three types automatic pacemaker adaptability analysis
Based on the detailed comparison, as a whole, the automatic capture pacemaker has brought great
benefits to the patients. Because pacemaker threshold is not a static value, with the change of the
patient’s daily activity, the threshold changed dynamically. Latest algorithm can automatically
response to the real time threshold, largely improve the patient’s safety, save battery power, it is
meaningful to reduce the size of the whole device. Give the doctor’s diagnosis and treatment convenience, improve the work efficiency greatly. According to clinical data, this function has extended the pacemaker life by about 60% on average, extended the pacemaker replacement time. In clinic occasionally will happen no capture and alternate pulse, at the same time because of the individual differences, after implantation, some patients due to high threshold, the doctors have to shut down the automatic threshold function, but these are just a few phenomenon.

According to the above AC, ACC, VCM function, and their respective advantages and disadvantages, AC series pacemaker must match special low polarization bipolar electrode, in order to reduce the polarization potential, and require programming the pacemaker into unipolar pace and bipolar sense. ACC, VCM function do not need special electrode, matching with the international standard wire, so the clinical operation is simple, also suitable for the pacemaker replacement.

In addition, AC focused on energy conservation, high security, program control is relatively complicated, need to strengthen the training of clinical doctors, and give the patient good follow-up education. VCM function focused on convenience, program control is simple, more suitable for the inconvenience follow-up patients. Due to the ACC function pacemaker appear on the market later than the front two, considering the advantages and disadvantages, and on the overall design, not only pay attention to the safety of products, and through the intelligent parameter setting provides convenience, and the special threshold search interval can relieve the patient’s discomfort, the function is suitable for all kinds of patients, with higher applicability.

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