

A Systematic Review of Research Studies Regarding the Applications of Wireless Cardiac Pacemaker

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Abstract- Pacemaker is a small device which is inserted into the patient's body in order to suppress the problems related to the heart rhythm, usually the slow heart rate. This is a tremendous achievement in the field of medical sciences. Over 3 million patients have a conventional pacemaker fitted inside their body but a leadless pacemaker is a new introduction to this field. A wireless pacemaker has been developed by U.S. start-up Nanostim. This is about 10% the size of conventional pacemaker which uses a built-in battery. In this paper, the applications of a wireless pacemaker, its additional features and implanting techniques are reviewed. The paper includes surveys conducted by Nanostim Inc. that show that a wireless or leadless pacemaker is working successfully in more than 100 human patients and is ready to be used on large scale. These surveys indicate that there is no issue with these pacemakers yet and they can be easily adopted for controlling the heartbeat of the patients. The paper also highlights some problems that may be faced by this advanced and sophisticated types of pacemaker and what can be the possible steps to overcome these problems. The paper also includes the predictions made by experts about the future scope of this wireless or leadless technology. The paper explains the need of a pacemaker, types of pacemakers, working of a wireless pacemaker, benefits and applications of a leadless pacemaker, comparison between wireless and conventional pacemaker. And eventually, conclusions are drawn.

Index Terms- Pacemaker, Nanostim, conventional, built-in battery, wireless

I. INTRODUCTION

A pacemaker is a small device which is inserted into the chest of the patient and is fitted with the heart in order to control heart rhythms. This device is designed to detect the slow heart rate. Whenever slow heart rate is detected, it sends small electrical signals to correct it. Not only in case of slow heart rate but even if the heartbeat is too fast, it becomes very difficult for the patient to survive. Both these situations can be averted by the use of pacemakers.

The problems that occur with the rhythm of heartbeat are known as Arrhythmias. When the heartbeat is too fast, it is called tachycardia and when it is too slow, it is called bradycardia. All these problems can be solved using a small electronic device called pacemaker.

II. NEED OF A PACEMAKER

As explained above in most of the cases, pacemakers are required to prevent the heart rate of the patient from going too slow. But it can be helpful in the reverse case also. i.e. correcting the heart rate that is going too fast. Another reason that requires the pacemaker implantation is the heart block which can also be corrected using a pacemaker. This disorder (Heart block) may occur as a result of aging or heart attack. These disorders may prove to be extremely harmful for the patient and may take the life of the patient within seconds if precautions are not taken.

Mostly these disorders happen because there is no cell in the heart that beats fast enough to maintain its proper functioning. This is because there is a block somewhere in the electrical pathway. This block doesn't allow the electrical activity to reach all the necessary portions of the heart muscles.

III. CONVENTIONAL PACEMAKER V.S. LEADLESS PACEMAKER



The conventional pacemaker is inserted in the body of the patient through surgery and is placed just below the collar bone. Its wires extend from the part where it is fitted to the heart passing through the veins. Whenever the heart rate slows down, it is detected by the pacemaker. To restore the natural heart rate, the pacemaker sends electrical pulses.



A wireless pacemaker on the other hand, is inserted into the heart without any invasive surgery. So no scarring takes place during the implantation of a wireless pacemaker.

A wireless pacemakers contains a built-in battery which provides it energy to work. Whenever the heart rate goes down, it is corrected by the pacemaker without any wires or leads. The battery lasts between 9-13 years.

IV. ADVANTAGES OF LEADLESS PACEMAKER OVER THE CONVENTIONAL ONE

1. It is about 10% the size of a conventional pacemaker.
2. It is inserted into the heart directly using catheter through the femoral vein located near the groin.
3. No invasive surgery is required. Hence, there is no such risk of infection and no scarring takes place.
4. The life-time of the built-in battery is about 9-13 years. So once the implantation is done, then the patients don't have to worry for a long time and after 9-13 years, the battery can be replaced by a fresh one.
5. The procedure of implanting a leadless pacemaker takes less than half an hour.

6. It enhances the range of activities of a patient.
7. It has been called the "future of pacemaking."

V. WORKING OF A LEADLESS PACEMAKER

A leadless pacemaker is comprised of a pulse generator which includes a battery and a steroid-eluting electrode.



This electrode sends electrical pulses to the heart when it detects a problem with the heart rate.

VI. SURVEYS CONDUCTED ON THE WIRELESS PACEMAKER TECHNOLOGY

Nanostim Inc.'s miniaturized pacemaker has proved to be promising in its first human trials. There are not many surveys conducted in this field yet as this technology has introduced just a few years back and it is still under testing in many countries. But all the surveys that have been conducted give positive results.

The wireless pacemaker was implanted in three patients at Homolka Hospital in Prague last year. The process went smoothly in two patients and the device worked properly. While in the third patient, the doctors had to reposition the device three times until it was at the optimal position. The device is now working properly.

Dr. Vivek Reddy, director of electrophysiology at Mount Sinai Hospital in New York who has been practicing on heart patients for a very long time, presented the findings with the first three patients at the meeting of Heart Rhythm Society in Denver. He said, "the absence of wires removes a source of complications as they can become infected, dislodged or damaged."

Also, in a telephone interview, he said “this is a shift in how we think about pacing, but a lot of the technology, the way it touches the heart and the way we deliver it, has been worked out already.”

Larry Biegelsen, an analyst at Wells Fargo in New York said, “Nanostim appears to be ahead of Medtronic Inc. (MDT) {the world’s biggest maker of heart rhythm devices} and Boston Scientific Corp.(BSX) in developing a wireless pacemaker.

John Day, the director of heart-rhythm services at Intermountain Medical Center in Murray, Utah said, “ a wireless device may be particularly important for younger patients and athletes, whose activity can stress the leads.” He said in a telephone interview, “ for the most part, these devices are incredibly reliable. For the wired device, everytime you move your arm, you are putting some strain on the lead. But with this device, there won’t be such problem.” About the future scope of this technology, Day said, “We need to make sure not only can it be implanted safely but what really need to know is how long this holds up. You trade the leads for a new set of problems. Now we are talking about the wireless communication. It’s not a fool proof either. But I believe, this is the future.” He said.

Dr. Johannes Sperzel said, “For the past 40 years the therapeutic promise of wireless pacing has been discussed, but until now, no one has been able to overcome the technical challenges. This revolutionary technology offers my patients a safe, minimally invasive option for pacemaker delivery that eliminates the leads. This is the future of cardiac pacing.” he said.⁹

Dr. Mark D. Carlson, St. Jude Medical chief medical officer and vice president of global clinical affairs said in an interview, “Since the introduction of the first implantable pacemaker in 1958, pacemaker technology has continued to evolve into smaller, more efficient devices.”

The trial process being conducted in Europe, US and Canada is called Leadless II. These trials are being conducted to evaluate the safety and effectiveness of the Nanostim leadless pacemaker. The trials are being conducted under Investigational Device Exemption (IDE) and approximately 670 patients at

50 centers in US, Europe and Canada will be enrolled for the trials.

VII. RISKS WITH THE IMPLANTATION OF LEADLESS PACEMAKER

The possible risks with the implantation procedure include severe bleeding, bruising, infections including infections of heart or surrounding tissues, infections or other complications of blood or wounds. Then there are risks like allergies and intolerance reactions, dizziness, shortness of breath. Problems like chest pain or heart problems like heart attack, irritability or heart damage may occur. There maybe heart rhythm changes, rupture of blood vessel, formation of blood clots, air or debris traveling in the blood to the brain, heart or lungs. The excess of fluid in your vessels or lungs can affect your kidneys. This may arise problems like kidney failure, complications from anesthesia or other medication. Then the problems like blood pressure problems, pain, minor or major stroke may arise. It can also cause skin damage, damage to blood vessels, soft tissues or nerves, excessive scar formation and compressive damage to nerves and soft tissues.¹¹

Prof. Jeremy Pearson, associate medical director at British Heart Foundation warned against embracing the technology too early in an interview with BCC News.

Prof. Pearson said, “This is potentially exciting development but it’s early days. Before this leadless pacemaker becomes widely available, we need a better understanding of how long it will last, as well as how easy it is to replace if necessary. As our knowledge of this new pacemaker widens, so too will the expertise needed to fit this potentially exciting device.”¹²

And he is right in some manner as we are not yet aware of the lifetime of this device. We don’t know how long will it last. This is one of the reasons why the availability of this device is limited to Europe. But as per the speculations, it will soon be available in US also.

VIII. CONCLUSION & FUTURE SCOPE OF THE LEADLESS PACEMAKER

We have already understood the benefits of using a leadless pacemaker and its advantages over the conventional pacemaker. Eventually, it would be

relevant to say that this technology is going to be the future of artificial pacing. Currently, this technology is available only in Europe but once it clears all the test and goes through all the trials, this will be available in other countries also. This technology is going to be launched in US soon and if everything goes well, it will reach other countries also.

Dr. John Day, director of heart-rhythm services at Intermountain Medical Center in Murray, Utah has said, "We need to make sure not only can it be implanted safely but what really need to know is how long this holds up. You trade the leads for a new set of problems. Now we are talking about the wireless communication. It's not a fool proof either. But I believe, this is the future."

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So the future scope of leadless pacemaker is very bright and with time, the conventional pacemakers will completely be replaced by the leadless ones.

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