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Implantation of A Permanent Pacemaker without the Use of a Temporary Pacemaker: A Single-Center Experience and Review of Literature

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ABSTRACT

Introudction: *Cardiac disorder is a major cause of mortality and morbidity in Sudan, with a scarcity of cardiac centers in the country. Therefore, the purpose of this study was to investigate the experience of a single center in implanting a permanent pacemaker without the need for a temporary one.*

Methodology: *We conducted this study on consecutive patients from May 2023 to May 2024, during the Sudan armed conflict period. We received and treated the patients in North Kordofan State, an area in western Sudan that has endured extended periods of intense armed conflict. In a one-year period, we successfully placed 52 permanent pacemakers at the Cardiac Catheterization Laboratory in El-Obeid International Hospital (Aldaman), the sole facility offering cardiac intervention services in western Sudan.*

Results: *We fixed a permanent pacemaker for 52 patients without the need for a temporary one. Of the total participants, 44.2% were men, while 55.8% were women. The majority of patents were aged 70 years or older, followed by those aged 60-69 and 50-59 years, with respective proportions of 26 out of 52 (50%), 15 (28.8%), and 8 (15.3%). Of the participants, 29 out of 52 (55.7%) were rural residents, whereas 23 (44.3%) were urban residents.*

Conclusion: *It is possible to implant a permanent pacemaker without the need for a temporary one. We deem a short-duration procedure crucial for favorable outcomes when implanting a permanent pacemaker in the absence of a temporary one.*

Keywords
Permament pacemaker, Temporary pacemaker, Cardiac Catheterization, Surgery, Sudan.

Introduction

Cardiac pacemaker therapy began with successful stimulation of human hearts already in the first half of the 20th century. The complete implantation of a pacemaker by cardiac surgeon Ke Senning at the Karolinska Hospital in Stockholm on October 8, 1958, is considered the actual birth of today's pacemaker therapy. Hans-Joachim Sykosch performed the first pacemaker implantation in Germany on October 6, 1961, at the Surgical Clinic of the University of Düsseldorf. Friedrich Flemming performed the first implantation in East Germany (GDR) on September 2, 1963, at the Charité in East Berlin, two years later. West Germany launched the first pacemaker on the market in 1963, while East Germany began producing devices in 1978. In 1974, pacemaker therapy in West Germany demonstrated a 50% survival rate after 6.3 years, which was significantly higher than the 1-year survival rate associated with drug therapy. After initially using bare metal wires, pacemaker leads have significantly improved in both quality and reliability. Development culminated in the leadless pacemaker. Battery development led to a variety of inventions: rechargeable pacemakers, biogalvanic cells, bioenergy sources, nuclear generators, and lithium batteries, the latter ultimately prevailing. In the beginning, only fixed-rate ventricular pacemakers were available. Physiological requirements led to the development of systems such as on-demand pacemakers, atrial-based pacing, and rate-adaptive systems. However, it was not until the return to direct stimulation of the conduction system that truly physiological stimulation of the heart became possible [1].

Pacemakers are electronic devices that stimulate the heart with electrical impulses to maintain or restore a normal heartbeat. In 1952, Zoll described an effective method of supporting patients with intrinsic cardiac pacemaker activity and/or conducting tissue using an artificial, electric, external pacemaker. Subcutaneous electrodes accomplished the pacing of the heart, but they could only maintain it for a short period. In 1957, doctors treated complete heart block using electrodes directly attached to the heart. These early observations instilled the idea of controlling cardiac electrical failure. It ultimately led to the development of the totally implantable pacemaker by Chardack, Gage, and Greatbatch. Since then, there have been several advancements in the pacemakers, and the modern-day permanent pacemaker is a subcutaneously placed device. There are 3 types of artificial pacemakers: There are implantable pulse generators with electrodes in the endocardium or myocardium, as well as external, small, battery-powered pulse generators with exteriorized electrodes for temporary transvenous endocardial or transthoracic myocardial pacing. There are also console battery- or AC-powered cardioverters or monitors with high-current external transcutaneous or low-current endocardial or myocardial circuits for temporary pacing in asynchronous or demand modes, with manual or triggered pacing start. All cardiac pacemakers consist of 2 components: a pulse generator, which provides the electrical impulse for myocardial stimulation, and 1 or more electrodes or leads, which deliver the electrical impulse from the generator to the myocardium. This discussion focuses on the indications of pacemaker placement [2].

Pacemakers are adjustable artificial electrical pulse generators that frequently emit a pulse with a duration between 0.5 and 25 ms and an output of 0.1 to 15 V at a frequency of up to 300/min. The cardiologist or pacemaker technologist will be able to interrogate and control the pacing rate, the pulse width, and the voltage, whether the device is temporary or permanent. Typically, we categorize pacemakers as either temporary or permanent. Temporarily, doctors almost always place pacemakers to stabilize the patient or facilitate a surgical procedure. Implantable pacemakers are typically permanent and often significantly more complex than temporary pacemakers. Pacemakers are one type of cardiac implantable electronic device (CIED). This broad category also includes implantable cardioverter-defibrillators (ICDs). The introduction of these devices occurred in the 1950s, shortly after the introduction of the transistor. As technology has improved, so has the pacemaker device. In 1980, researchers developed the first implantable ICD. Since then, it has become more challenging to differentiate between pacemakers and ICDs because every ICD currently implanted has an antibradycardia pacing function. The patient and any clinician should understand which device has been implanted to prevent unnecessary ICD therapy, which is most likely to occur with any electromagnetic interference and could lead to device activation with an ICD. Most CIED types implant several insulated lead wires with non-insulated tips in the heart, either through percutaneous vein insertion or directly by a cardiac surgeon. Cardiac pacemakers comprise the pulse generator and the leads or electrodes.

The North American Society of Pacing and Electrophysiology and the British Pacing and Electrophysiology Group collaborated to create a global generic pacemaker code that enables clinicians and manufacturers to describe the device's characteristics. The latest generation of pacemakers has many capabilities. The simplest settings are AAI and VVI. The AAI mode paces and senses in the atrium, and each sensed event triggers the generator to fire within the P wave. A sensed ventricular event suppresses the VVI mode, which paces and senses the ventricle [3].

All cardiac pacemakers are generally composed of a pulse generator that generates the electrical current required for stimulation of heart musculature and 1 or 2 electrodes (also referred to as leads), which are responsible for transmitting the electrical activity generated by the pulse generator to the heart musculature [4].

Perminant Pacemaker

The use of cardiac implantable electronic devices (CIEDs) has increased significantly in recent years. Consequently, more patients with CIEDs will undergo surgery during their lifetime, and thus the involvement of anesthesiologists in the perioperative management of CIEDs is increasing. Technological advancements have led to the development of various types of CIEDs, such as permanent pacemakers, leadless pacemakers, implantable cardioverter

defibrillators, cardiac resynchronization therapy-pacemakers/defibrillators, and implantable loop recorders. Electromagnetic interference, with potential sources in the operating room, can affect the functioning of CIEDs exposed to an electromagnetic field [5].

A permanent pacemaker (PPM) is a small electronic device that's implanted in the chest to help regulate the heart's rhythm. Typically, cardiologists surgically implant it, which comprises a battery-operated gadget and wires connecting to the heart. The pacemaker sends electrical signals to the heart to keep it beating at a normal rate [6]. Permanent pacemaker implantation is one of the most effective treatments for chronic arrhythmia [7].

Implantation of a permanent pacemaker is the most commonly performed surgical operation involving the heart. The modern cardiac pacemaker is a complex device that can sense and pace in both the atrium and ventricle. It also modulates the pacing rate based on sensed physiologic parameters [8].

Sinus node dysfunction (SND) and high-grade atrioventricular (AV) block are the primary indications for permanent pacemaker implantation. A task force comprising the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) has developed guidelines for cardiac pacemaker implantation. The European Society of Cardiology has developed comparable guidelines [9].

The following conditions are included in the ACC/AHA/HRS guidelines for pacemaker insertion: Sinus node dysfunction. Both acquired atrioventricular (AV) block and chronic bifascicular block are present. The acute phase of myocardial infarction is followed by neurocardiogenic syncope, hypersensitive carotid sinus syndrome, post-cardiac transplantation, and hypertrophic cardiomyopathy. Pacing is used to detect and remove tachycardia. Patients with severe systolic heart failure and those with congenital heart disease utilize cardiac resynchronization therapy.

The ACC/AHA/HRS categorizes the indications for pacemaker implantation into three distinct classes. **Class I:** These conditions warrant the implantation of a pacemaker due to the significant benefits outweighing the associated risks. There is documented evidence of symptomatic sinus bradycardia, which is characterized by frequent sinus pauses inducing symptoms, as well as symptomatic sinus bradycardia resulting from necessary pharmacological treatment. If a person cannot raise their heart rate to 85% of its maximum level during formal or informal stress tests, or if they cannot raise their heart rate to the appropriate level for their age during normal activities, this condition is known as symptomatic chronotropic incompetence.

Class II: These conditions indicate placement, yet there exists conflicting evidence or divergence of opinion. In Class IIa, the weight of evidence supports efficacy, indicating that benefits outweigh risks. In contrast, Class IIb presents a less established efficacy, suggesting that benefits are greater than or equal to the risks. Sinus bradycardia is characterized by a heart rate of less than 60 beats per minute; however, there is no evident correlation between the symptoms and the bradycardia. Electrophysiological studies identify or induce clinically significant abnormalities in sinus node function, leading to unexplained syncope. Patients with minimal symptoms and a chronic heart rate below 40 while awake are considered to have unexplained syncope.

Class III: These conditions suggest that permanent pacing is inadvisable and may, in some cases, present greater hazards than advantages. There are circumstances in which pacemaker implantation is not advantageous or lacks sufficient evidence to justify its application. The ACC/AHA/HRS guidelines or the European Society of Cardiology guidelines occasionally refer to these as class III indications, which include sinus bradycardia without substantial symptoms and asymptomatic first-degree AV block [10,11].

Temporary Pacemaker

Temporary pacemakers (TPs) are used in the emergency treatment of patients with severe bradyarrhythmia. Emergency situations often utilize them, as do older patients in poor general condition who are hemodynamically unstable and uncooperative. Temporary pacemakers are used in older patients with extreme bradyarrhythmia and occasionally with acute myocardial infarction. Serious complications are not uncommon (22% of all patients) and can range from femoral hematoma to cardiac tamponade and even death (6%). Repositioning the electrode was necessary in 9% of the patients due to sensing failure or loss of ventricular capture. Patients with a permanent pacemaker can use temporary pacing as a bridge when replacing the generator [12].

In extreme emergency situations, we use temporary pacing, frequently implanting these devices in older, uncooperative patients. Hemodynamic and/or electric instability typically accompany implantation, sometimes preventing perfect placement and leading to increased morbidity and mortality. Furthermore, during on-duty hours, when cardiology staff supervision may be limited, medical residents often perform implantations. Due to the progressive aging of the population, the incidence of atrioventricular block (AVB) is higher, and this fact may explain the higher number of permanent pacemakers and, by extension, temporary pacemakers that are required [13]. The presence of temporary leads does not significantly impact clinical outcomes, irrespective of bacterial growth on the lead. However, the timing and duration of sheath placement play a crucial role in contamination incidence. Therefore, it is crucial to place temporary leads/sheaths shortly before the procedure and remove them promptly to minimize the risk of contamination or infection [14].

As a consequence of the war, resources are limited, and many things are unaffordable; therefore, our aim was to highlight the merit of fixing a permanent pacemaker without a need for the aid of a temporary one, which reduces the subsequent complications.

Patients and Methods

This study was performed in consecutive patients during the Sudan armed conflict 2023-2024. The patients were received and treated in North Kordofan State, which is still one of the western Sudan states that witnessed prolonged hot armed conflict. During a one-year period (May 2023 to May 2024), we placed 52 permanent pacemakers at the Cardiac Catheterization Laboratory in El-Obeid International Hospital (Aldaman), the only hospital providing cardiac intervention services in western Sudan.

We carried out the permanent pacemaker fixation, adhering to the recommended procedure outlined elsewhere [15], with a mean time of 48 minutes. We completed all cases without the use of a temporary pacemaker.

Results

A permanent pacemaker was fixed for 52 patients without the aid of a temporary pacemaker. Of the total participants, 23 out of 52 (44.2%) were men, while 29 out of 52 (55.8%) were women. The majority of patents were aged 70 years or older, followed by those aged 60-69 and 50-59 years, with respective proportions of 26 out of 52 (50%), 15 (28.8%), and 8 (15.3%). Of the participants, 29 out of 52 (55.7%) were rural residents, whereas 23 (44.3%) were urban residents.

Discussion

The results of the current study demonstrated remarkable outcomes, as all patients successfully overcame their conditions, and to date, no complications have been reported. This experience may prompt an inquiry into the appropriateness of recommending the implantation of a permanent pacemaker, potentially obviating the necessity for a temporary one. This concept will mitigate the anticipated subsequent complications, such as infections and hematoma. The implantation of a temporary cardiac pacemaker through the femoral and subclavian veins is a prevalent clinical intervention for patients experiencing severe bradycardia or tachycardia. However, this procedure presents significant technical challenges and carries a risk of complications that may reach as high as 30% [16,17]. Individuals necessitating a temporary pacemaker experienced an extended duration of hospitalization. An extended duration of hospitalization correlates with increased incidences of general complications and overall mortality rates [18].

The diagnosis and management of infections associated with cardiac implantable electronic devices (CIEDs) present considerable complexity, significantly influencing both mortality rates and healthcare expenditures. In light of these considerations, recent evaluations have been conducted regarding the risk factors associated with CIED infections and the strategies for their prevention. This review encapsulates the prevailing understanding of the topic at hand [19]. The occurrence of infection in pacemakers represents a significant complication that necessitates a comprehensive, multidisciplinary strategy for effective management [20]. Pocket hematoma represents a prevalent complication subsequent to device implantation, constituting 14–17% of all reoperations [21]. The presence of a pocket hematoma poses a considerable risk for various forms of infection, with wound infection being the most commonly encountered type. Nevertheless, the potential for wound infections linked to a pocket hematoma remains ambiguous [22].

Certain domains exist where the criteria for pacemaker implementation are unequivocal; however, there are also instances where clinical acumen and specialized knowledge are paramount. While the guidelines strive to delineate practices that cater to the majority of patients, the final determination for the patient ought to be grounded in the specific circumstances presented, the clinician's expertise, and a thorough dialogue with the patient regarding the associated risks and benefits of the procedure. Specific pacemaker generators are utilized for patients exhibiting AV block and sinus node dysfunction, tailored to their particular presentations. Generators can be categorized into several types, including single-chamber, dual-chamber, and biventricular configurations. A consultation with a cardiologist is strongly advised before proceeding with the insertion of a pacemaker [10].

A significant factor contributing to our success in this endeavor was the brevity of the operational period. The procedure typically requires a duration of one to three hours; however, it may extend beyond this timeframe if concurrent heart surgeries are being performed. In the domain of radiofrequency ablation for atrial fibrillation, the innovative approach of very high-power short-duration protocols demonstrates promising outcomes and has the potential to decrease procedural duration [23]. Nevertheless, there exists a paucity of data concerning the factor of operation time, as a diminished operation duration can mitigate patients' risks associated with surgery, such as hematoma and infection. While the current study introduces a novel approach to executing permanent procedures universally, without necessitating a temporary alternative, it is not without its limitations, particularly concerning its observational framework.

Conclusion

A permanent pacemaker may be implanted directly, eliminating the necessity for a temporary device. The brief duration of the procedure is considered crucial for achieving favorable outcomes when implanting a permanent pacemaker in the absence of a temporary device.

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