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Cardiac implantable therapeutic medical devices: A narrative review

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ABSTRACT

Heart diseases are common life-threatening acute diseases. They are leading causes of mortality worldwide, especially significant in developed countries. Other than medications for therapies and prophylaxis, special treatment considerations with implantable cardiac devices are important to reduce mortality and medical disability. This paper aims to review indications, contraindications, efficacy, complications, and generic considerations of several commonly implanted cardiac devices including pacemakers, cardiac resynchronization devices, implantable cardiac defibrillators, left atrial appendage occlusion watchman devices, and ventricular assist devices. As various implantable therapeutic cardiac devices are sometimes carried in the bodies of patients with cardiac disease, practitioners of various specialties should be familiar with different cardiac devices on the management of different cardiac conditions while providing holistic care.

KEYWORDS: Cardiology; Cardiac devices; Heart disease; Therapeutics; Implants

1. Introduction

Cardiovascular disease is the leading cause of mortality around the world[1], particularly in developed countries[2]. Coronary heart disease[3], arrhythmia[4,5], heart failure are all more prevalent with advancing age[6,7], and implantable cardiac devices are no longer new to practitioners of different subspecialties in their daily practice[8]. With the advancement of modern science, life expectancy is increasing over the past decades. Heart disease prevalence and costs are expected to increase substantially[9]. Effective prevention devices are necessary to tackle the growing burden[9]. From the American Heart Association (AHA) statistics in 2016, 69.1% and 67.9% of males and females respectively suffer from cardiovascular disease in their retirement ages of 60 to 75 years old[10]. These numbers further rise after the age of 80 years to over 80%[10].

Other than medications for treatment and prophylaxis, special therapeutic considerations with implantable cardiac devices are significant to reduce mortality and morbidity. Arrhythmic disorders are frequently seen in our growing population. Regional conduction slowing, anatomically conduction delay at the crista, and structural heart changes are all observed with aging[11]. Brady-arrhythmia requires the implantation of pacemaker devices to keep patients away from syncope. In contrast, heart failure patients require cardiac resynchronization therapy (CRT) devices, no matter or not with an implantable cardiac defibrillator (ICD) for normal daily livings. In refractory cases, ventricular assist devices (VAD) placement is a bridging therapy for the destination therapy. On the other hand, the non-electronic device of left atrial appendage (LAA) occlusion has become an alternative for anticoagulation popular in the geriatric population. Our review will go through these implantable therapeutic devices one by one.

2. Types of devices

2.1. Pacemakers

Pacemakers are pulse generators, with one or more leads according to the underlying cardiac electrical abnormality[12]. They stimulate the myocardial muscles and provide an impulse

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causing contraction[13]. Novel methods of septal pacing are advancing, yet traditionally ventricular leads were inserted into the right ventricular apex. His-Purkinje system is utilized to transmit electrical conduction effectively through the ventricles[14], whereas biventricular pacing refers to placing a lead into the coronary sinus to pace the left ventricle[12].

A joint commission of the American College of Cardiology, AHA, and the Heart Rhythm Society established guidelines in 2018-2019 regarding the placement of pacemakers[15]. They broadly classified implantation into seven categories as listed out below:

(1) Pacing for the acquired atrioventricular block in adults;

(2) Pacing for chronic bi-fascicular and tri-fascicular block;

(3) Pacing for acquired atrioventricular block associated with myocardial infarction;

(4) Pacing in sinus nodal dysfunction;

(5) Prevention and termination of tachyarrhythmias by pacing;

(6) Pacing in hypersensitive carotid sinus;

(7) Neutrally mediated syndromes.

Estimated complications relating to pacemaker was approximately 6%[16]. The commonest complication is lead dislodgement, of which atrial lead is commoner than ventricular lead dislodgement[16]. Other potential complications during implantation include pneumothorax, air embolism, damage to vascular and neural structures, vascular thrombosis, and cardiac wall rupture[16]. Complications like bleeding, erosion, and infection may also occur over the pacemaker implanted surgical pocket, whereas patients also suffer from complications related to device functioning[16]. As implantation requires jugular or subclavian access, local infections or sepsis are contraindications, while severe bleeding tendency or active anticoagulation is relatively contraindicated.

Interestingly, hospital readmissions were higher among patients with single-chamber pacemakers compared to dual-chamber devices[17]. Approximately one-tenth of patients were readmitted secondary to arrhythmias, myocardial infarction, heart failure, or need for lead adjustment[17]. Magnetic resonance imaging (MRI) compatibility is another safety concern. While MRI-compatible devices are now commonly available, older generation devices' functioning might be a problem when exposed to the magnetic field. Electromagnetic interference with the ferromagnetic materials of the leads also runs the risk of lead heating and lead dislodgment, despite the study concluded medically safe in either non-MRI conditional or MRI conditional devices[18].

2.2. CRT

CRT can be implanted alone or combine with a defibrillator to prevent sudden cardiac death and reduce heart failure patients' mortality[19]. They are indications on patients with significant left ventricular dysfunction (defined as ejection fraction <35%), left bundle branch block associated with prolonged QRS (>150 ms), and patients with advanced New York Heart Association (NYHA) functional classes who failed optimal medical therapy[20]. Atrial fibrillation patients may benefit from CRT if they got heart failure of ischemic etiology with an ejection fraction of 30% or less. However, CRTs are advised against frail elderly patients with a life expectancy of <1 year[20], based on its limited effect on patients with extreme ventricular dyssynchrony, increased myocardial scar burden, and concomitant valvular dysfunction. Heart failure usually does not stand alone in the elderly, and mortality from non-cardiac comorbidities in this population is never low.

The cardiac resynchronization heart failure trial and the comparison of medical therapy, pacing, and defibrillation in heart failure trial revealed decreased morbidity and mortality in patients aged 65 years and older with CRT defibrillators in comparison to CRT pacemakers, while CRT pacemakers, in turn, were found to be more beneficial than optimal medical therapy alone[21,22]. Multicenter automatic defibrillator implantation trial-CRT trial showed a more prominent reduced incidence of heart failure and death with CRT defibrillators in patients aged 60 and older[23]. However, there was no establish clear guideline regarding the addition of defibrillator to CRT in elderly patients[24], as fatal arrhythmias are less frequent in the elderly compared to younger patients[25,26].

Stratification of such a decision was based on clinical risk scoring systems considering factors including age, associated atrial fibrillation, comorbidities including renal or hepatic impairment, and degree of left ventricular dysfunction[27]. Frailty assessment advocated by Kubala *et al.* found less CRT response with higher frailty scores, and a higher rate of hospital admissions, due to heart failure, and increased mortality[28]. Despite all these, the patient's desires and goals of care, overall quality of life, functional status, and cognitive state should all be considered on figuring out the treatment plan.

2.3. ICD

ICDs are used for the prevention of sudden cardiac death from life-threatening arrhythmia (ventricular tachycardia and ventricular fibrillation) or cardiac arrest. It is also indicated for high-risk patients who got previous myocardial infarction and ejection fraction 30% or less, ischemic cardiomyopathy with NYHA functional class Ⅰ and ejection fraction 30% or less, or NYHA functional class Ⅱ-Ⅲ patients with ejection fraction 35% or less[29]. In contrast, life-threatening arrhythmias secondary to reversible etiologies like medications, electrolyte imbalances, or conditions amenable to surgical or catheter-ablation are not indicated for ICDs.

Although ICD use can potentially prevent arrhythmia-induced death, ICDs are not recommended to those with life expectancy of less than one year. Healey *et al.* reviewed elderly patients with a history of ventricular arrhythmias who underwent ICD placement died from non-arrhythmia-related conditions[30]. In contrast, Yung *et al.* found that the number of appropriate shocks delivered was equivalent across age groups[31]. Therefore, age alone should never be the only pivotal point in judging the potential candidate for ICD. Baseline functional status, quality of life, and frailty should also be considered as a holistic approach for implantation[32,33].

2.4. LAA closure device

LAA occlusion is a popular alternative for anticoagulation use to atrial fibrillation, the commonest arrhythmia affecting the elderly population. It refers to the Watchman device (Boston Scientific, Natick, Massachusetts) on literature, and this device entity is the only non-electronic cardiac implantable device discussed over this whole review. Atrial fibrillation predisposes patients to embolic complications, such as stroke and visual loss[34,35], and anticoagulation is indicated on those with sufficient risk. However, titration is often disturbing due to comorbidities of renal failure and polypharmacy-related drug interactions, limiting the compliance use of oral anticoagulation. Long-term anticoagulation usage is also associated with an increased risk of bleeding, particularly in elderlies with multiple comorbidities and elevated fall risk.

Supported by the AHA/American College of Cardiology guidelines for treating atrial fibrillation in 2019, LAA occlusion shines a light on patients at high thromboembolism risk but contraindicated to oral anticoagulation, including the history of significant hemorrhage, or an elevated HAS-BLED score (hypertension, abnormal renal/liver function, stroke, bleeding history, labile international normalized ratio, elderly aged>75 years old, drug/alcohol use)[36]. Being an alternative to anticoagulation, LAA is also useful on those significant coronary artery disease patients requiring a prolonged course of triple anticoagulation and antiplatelet therapy. Besides, oral anticoagulation patients who still suffered from thromboembolic events are also candidates for LAA occlusion[37].

In theory, patients who received LAA occlusion surgery require post-procedure 45-day of anticoagulation to prevent device-related thromboembolic events, when it takes ~1.5 months for complete epithelization to take place. Although patients incapable of tolerating anti-coagulative therapies were excluded from most trials, this remains controversial to be a contraindication. Data from the ASA Plavix feasibility study with the Watchman LAA closure technology trial demonstrated that patients with non-valvular atrial fibrillation could undergo LAA closure safely without a warfarin transition[37]. A higher level of evidence is needed to support future recommendations.

Randomized trial and retrospective studies were published in the past few years studying the safety and efficacy of LAA occlusion, particularly on the elderly population[38-42]. They cannot show significant mortality differences in both the elderly and younger groups of patients. Gafoor *et al.* concluded that LAA occlusion is not just safe, but also effective in lowering the risk of atrial fibrillation-associated stroke[39]. Freixa *et al.* published the largest multicenter LAA occlusion retrospective study in 2016, evaluating peri-procedural complications across the age of 75 years old[40]. They demonstrated both procedural success rates, rate of stroke, and major bleeding were comparable regardless of age groups[40]. Therefore, LAA occlusion despite being an invasive procedure is considered a safe and viable alternative for anticoagulation in the geriatric population[42].

2.5. VAD

VADs are circulatory supportive devices for heart failure patients[43]. The pump has an inflow cannula connected to the heart apex; it works by drawing blood from the left ventricle and returning blood to the systemic circulation *via* an outflow graft, typically sewn to the ascending aorta[44]. It establishes a parallel blood flow path similar to physiologic circulation to assist the heart functioning[44]. VADs are used for the management of treatment-refractory, severe, acute, and chronic heart failure[43].

Heart failure is prevalent in elderly patients, with more than half of the cases suffering from heart failure exacerbations and subsequent hospital admission[45]. VAD placement is indicated as a bridge to transplant, a bridge to recovery, a bridge to candidacy, or by itself as destination therapy[43,46]. Bridge to recovery refers to the temporary usage of VADs on those who are suffering from reversible causes of heart failure. Bridge to candidacy refers to the temporary placement of VAD on those who do not meet the criteria for a heart transplant at present, but who are likely to become candidates eligible on the transplant queue in the near future. For example, patients with heart failure and secondary pulmonary hypertension may improve after VAD placement, as VAD helps reducing left ventricular pressure. With cardiac rehabilitation by diverging flow, these cases may eventually improve and be eligible for a heart transplant[43]. Multiple factors were adopted across different authorities on excluding heart failure patients from being the heart transplant candidate. They include but are not limited to, advanced age, frailty, severe pulmonary hypertension, malignancy, liver disease, or kidney disease[43]. VADs utilization on patients who do not meet the strict criteria for a heart transplant is termed as destination therapy.

Although the systemic illness was once considered as a contraindication to VADs previously, certain conditions such as human immunodeficiency virus infection, or advanced organ dysfunction are no longer precluding patients from VAD placement[47]. However, few contraindications to VAD implantation remain despite the evolving evidence. These include systematically ill with a life expectancy of fewer than two years, active disease of malignancy in the past five years, irreversible kidney or liver dysfunction, severe chronic obstructive pulmonary disease, and multiple organs involved systemic illness[47].

Two landmarking clinical trials evaluated the efficacy of VADs, with the greatest impact on the geriatric patient population, were the randomized evaluation of mechanical assistance for the treatment of congestive heart failure (REMATCH) trial published in 2001[48] and the HeartMate Ⅱ destination therapy trial published in 2009[49]. REMATCH trial compared end-stage heart failure patients who were not eligible for cardiac transplant on receiving VAD or medical management[48]. The VAD used in this trial was a Thermo cardiosystem; the HeartMate vented electric (HeartMate VE) left ventricular assist system (Thoratec Corp.), which is a pulsatile flow device. Patients receiving left VAD showed a statistically significant reduction in all-cause mortality compared to the medical therapy group[48]. Besides, survival rates at one and two years were both

statistically significantly higher in the left VAD group[48]. Although significant mortality benefits exist, there was a price to pay on a much higher rate of serious adverse events in the VAD group, including infection, bleeding, and device malfunction[48]. Despite this; the REMATCH trial demonstrated a substantial survival benefit with VAD as a destination therapy for patients with advanced heart failure.

HeartMate Ⅱ destination therapy trial compared between the continuous flow device HeartMate ® Ⅱ (Thoratec Corp., Pleasanton, California) against the traditional pulsatile flow device (HeartMate VE)[49]. The conclusion is outstanding on treatment with continuous flow VAD with an increased two-year stroke-free survival, and significantly less frequent device failure[49]. In terms of quality of life and functional capacity, both the REMATCH trial and the HeartMate Ⅱ destination therapy trial demonstrated significant improvement in both VAD groups[49]. These results are particularly important for the geriatric patient population, as they often suffered from multiple co-morbidities that bar them away from getting on the heart transplant list, such as advanced age, frailty, multi-systems chronic illnesses, and concomitant malignancy. VADs could safely be utilized as destination therapy or palliative care on these elderly, as proven and supported by major clinical trials.

Despite all these promising results, complications do exist for the invasive intervention as with any other cardiology procedures, which is particularly susceptible over the geriatric population. Complications of VAD and causes of 90-day hospital readmission in patients after left VAD implantation was evaluated by a multicenter study[50]. The commonest reasons for readmission were worsening heart failure, arrhythmias, and complications related to the implanted device including bleeding and infections[50]. Therefore, the risks and benefits of VAD implantation should be thoroughly discussed prior to the persuasion of the procedure.

3. Conclusions

With the advancement of implantable cardiology therapeutic heart devices and an incline in implantation rate accompanied with lengthening of life expectancy worldwide, physicians should be familiar with the evolving devices. These devices, no matter electronic or not, provide lifesaving therapies, improve cardiology patients' quality of life, and reduce mortality on many occasions. Despite the beneficent and therapeutic efficacy these interventions offered, attending physicians should be aware of their associated complexities and challenges in providing holistic care to their heart disease patients, particularly the older geriatric group.

Conflict of interest statement

The authors report no conflict of interest.

Authors' contributions

C.P.S.H.: Acquisition of data; drafting the article; S.C.L.A.: Concept and design of the study; acquisition of data; revising the article critically for important intellectual content.

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