Implantable cardiac devices in geriatric patients: a primer for primary and geriatric physicians

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In the next 20 years, the percentage of people older than 65 years of age in the United States is expected to double. Heart disease is the leading cause of mortality in developed nations, including the United States. Due to the increased incidence of cardiac disease in elderly patients, the need for special treatment considerations, including cardiac devices, may be necessary to reduce morbidity and mortality in this patient population. The purpose of this review is to provide a primer of the common cardiac devices used in the management of cardiac disorders in the geriatric patient population. In order to do this, we have performed a literature review for articles related to cardiac devices published between 2000 and 2020, in addition to reviewing guidelines and recommendations from relevant professional societies. We provide readers with an overview of several cardiac devices including implantable loop recorders, pacemakers, cardiac resynchronization therapy, automated implantable cardiac defibrillators, watchman devices, and ventricular assist devices. Indications, contraindications, clinical trial data, and general considerations in the geriatric population were included. Due to the aging population and increased incidence of cardiac disease, clinicians should be aware of the indications and contraindications of cardiac device therapy in the management of various cardiac conditions that afflict the geriatric population.

Keywords

Geriatrics; Cardiology; Cardiac devices; Heart disease; Therapeutics; Primary care

1. Introduction

Due to tremendous advances in the field of medicine, life-expectancy in many developed countries has increased over the past several decades and continues to increase. The percentage of the population above the age of 65 is projected to nearly double from 12% in 2010 to 22% in 2040 [1]. Because of the fact that the population is aging, we are managing more acute and chronic conditions in the geriatric population. However, treating this patient population may not be as simple as we once believed.

As humans age, the impact of cardiologic conditions greatly increases. As humans age, ventricular hypertrophy occurs, resting heart rate decreases, total blood volume lessens, vascular resistance increases, and tachycardia responses are blunted [2]. Additionally, the elderly experience blunted renin-angiotensin systems, blunted baroreflex modulation, and variability in blood pressure which may make it difficult for elderly patients to tolerate traditional therapeutics [2]. These factors may make management of this growing patient population more challenging. Although valiant efforts have been made to create age-specific recommendations by both national and international medical associations [3, 4], treating the geriatric population is an area that requires continued attention in modern day medicine.

Cardiovascular disease is the leading cause of death in the elderly patient population. According to the American Heart Association (AHA), 69% of men and 67% of women aged 60-75 years suffer from cardiovascular disease [5]. After the age of 80 years, these numbers increase to 84% and 85% in men and women, respectively [5]. The cardiovascular diseases that afflict this population include, but are not limited to, coronary artery disease, heart failure, hypertension and arrhythmic disorders. Furthermore, interventions with cardiac devices are often implemented in the elderly. For example, 28% of Automated Implantable Cardiac Defibrillators (AICDs) placed are in patients 79 years old or older [6]. Over 40% of AICD placements occur in patients over the age of 70 [6]. With regard to pacemaker placement, the average age of patients receiving them is 75 years old [7].

The aim of this review is to provide an overview of the main indications and contraindications for several of the most common cardiac devices for primary care reference. In addition, we review published data specific to the geriatric

population while highlighting special considerations for the use of implantable cardiac devices. The most common cardiovascular condition encountered in the primary care geriatric population is heart failure, with an incidence of roughly 10 in 1000 people above the age of 65 [5]. In advanced stages, heart failure patients may require device support such as cardiac resynchronization therapy (CRT) with or without an implantable cardiac defibrillator (ICD). In very advanced stages, these patients may require even more extreme measures such as left ventricular assist devices (LVAD). Arrhythmic disorders, in particular atrial fibrillation (AF), also frequently affect the elderly population. AF is the most common arrythmia encountered in this population, and 70% of patients suffering from AF are between the ages of 65 and 80 [8]. The incidence of AF is projected to continue increasing, and as such, studying morbidity and mortality benefits of device implantation in these individuals is of the utmost importance. Other arrhythmic disorders, such as bradyarrhythmia requiring implantation of pacemaker devices, are frequently encountered in geriatric patients as well, and are reviewed in this manuscript. It is our hope that this manuscript will provide a concise and comprehensive review of cardiac devices for reference to primary care physicians.

2. Methods

A literature review in July, 2020 was performed by the lead author for articles related to different cardiac devices in the geriatric population. We searched PubMed, Google Scholar, Cochrane Library, and Ovid MEDLINE using the keywords: "geriatric" and "elderly" with "cardiac", or "devices", or "implantable loop recorder", or "pacemaker", or "cardiac resynchronization therapy", or "AICD", or "watchman", or "left ventricular assist device". We then reviewed publications in English between the years 2000-2020. In addition, we reviewed the guidelines of various professional organizations including the American Heart Association and American College of Cardiology. After the search, 54 abstracts were chosen based on relevance to the topic and the manuscripts were reviewed and agreed upon amongst all of the authors. Exclusion criteria consisted of duplicates, abstracts, non-English articles, and works that were unpublished or unrelated to the topic of interest.

3. Discussion

3.1 Implantable loop recorders

Implantable Loop Recorders (ILR) are devices placed subcutaneously for the detection of arrythmias over longer periods of time when compared to ECG or Holter Monitors. Modern ILRs range in size from 4-9 cm with an average battery life of 3 years. This allows patients with episodes of recurrent syncope to uncover the potential arrhythmic etiology. It is estimated that one third of unexplained falls in the elderly are due to cardiac causes [9]. Yet, only around 10% of those individuals receive an ILR [9].

Quality of life in individuals with recurrent syncope has been shown to be equivalent to that of severe rheumatoid arthritis [10]. As Shen et al. pointed out, quality of life is decreased and psychosocial burden in increased due to syncope and is supported by studies that examined patients with and without recurrent syncope [10]. Thus, there appears to be great benefit in utilizing ILR to uncover sporadic arrythmias.

Most frequently, ILRs are used to detect infrequent arrhythmic episodes that may cause syncope [11]. Due to the ease of placement of these devices, ILRs are frequently being used in place of traditional monitoring strategies to detect rhythm disturbances in patients suffering from recurrent syncope, palpitations, or cryptogenic stoke [11]. Further, ILRs can be used in patients with inherited arrhythmic disorders or structural heart disease to monitor for the development of ventricular tachyarrhythmias [11].

There are several indications for the placement of ILRs. Class 1A indications include patients with recurrent, unexplained syncope who are not high-risk and who do not require hospitalization, as long as the likelihood of recurrence is within the lifetime of the device battery [12]. Additionally, if a high-risk patient had an evaluation in which the cause of syncope was not determined, an ILR is also indicated [12]. Class 2A indications include implantation for the assessment of bradycardia in patients with neurally mediated syncopal episodes to determine the need for pacemaker implantation [12]. Further, if patients suffer from severe symptoms in which routine EKG monitoring is unable to determine a cause, ILR should be utilized [12]. Lastly, implantation of an ILR is a Class 2B indication in patients with loss of consciousness who need to definitively rule out arrhythmia as a cause of syncope [12]. Considering the advancements in size and placement of ILRs, there are relatively few contraindications to placement. Situations in which placement of an ILR may be contraindicated include ongoing infection or bleeding.

Few studies have evaluated the difference in all cause mortality in groups undergoing ILR implantations compared to conventional management. A systematic review by Solbiati et al. evaluated trials comparing ILR vs conventional workup (ECG) for unexplained recurrent syncope [13]. Based on the results of the systematic review, it was determined that there is no evidence that ILR implantation reduces long-term mortality compared to conventional diagnostic assessment with electrocardiogram [13]. There were no studies examining short term mortality benefit. Finally, there was moderate evidence showing that ILR implantation increased the rate of determining a diagnosis for unexplained syncope compared to conventional assessment [13]. Other studies have also confirmed the benefit of ILR in establishing a diagnosis in cases of syncope, palpitations, and AF [14, 15].

Although there is no immediate improvement of symptoms in patients undergoing ILR placement, there is evidence that utilization of these devices improves quality of life [16]. Patients with recurrent syncope often have anxiety and fear of suffering from additional episodes. Farwell et al. found

that at 18 months post implantation patients had improved general well-being, measured using questionnaires [16]. It is thought that this improvement is multifactorial, both due to an improved confidence that their next episode will be recorded as well as implementation of appropriate therapy and resolution of symptoms when a diagnosis is captured [16].

3.2 Pacemakers

Cardiac Pacemakers are devices which are utilized to stimulate the myocardial tissue and provide an action potential leading to contraction. They consist of a pulse generator and 1 or more leads depending on the underlying electrical abnormality [17]. Traditionally, ventricular leads were placed at the right ventricular apex, however novel methods of septal pacing are being utilized. These utilize the His-Purkinje system in order to effectively transmit electrical conduction through the ventricles, termed His bundle pacing [18]. Biventricular pacing is also utilized, in which a lead is placed into the coronary sinus in order to pace the left ventricle [19].

General guidelines have been established by a joint commission of the American College of Cardiology (ACC), American Heart Association (AHA) and the Heart Rhythm Society (HRS) regarding the placement of pacemakers [19]. The broad classifications for implantation include: pacing for acquired AV block in adults, pacing for chronic Bi-fascicular and Tri-fascicular block, pacing for AV block associated with myocardial infarction, pacing in sinus nodal dysfunction, prevention and termination of tachyarrhythmias by pacing, pacing in hypersensitive carotid sinus and neurally mediated syndromes [19].

The ACC/AHA/HRS guidelines identify Class III criteria in which the risks of pacemaker implantation outweigh the benefits. Proper evaluation of the patient's symptomology secondary to SA Node dysfunction or AV block is required before consideration [20]. Additionally, as implantation requires jugular or subclavian access, local or systemic infections are contraindications [20]. Severe predisposition to bleeding or active anticoagulation are relative contraindications [20].

Complications related to pacemaker use are estimated to occur in approximately 6% of cases. The most frequent complication is lead dislodgement, with atrial lead dislodgement more common than ventricular dislodgement [21]. Pneumothorax, damage to arterial and neural structures, air embolism, thrombosis, and cardiac wall rupture are also potential complications during implantation [21]. Complications may also occur secondary to the surgical pocket in which the pacemaker is implanted. These include bleeding, erosion, and infection [21]. Lastly, patients may suffer complications related to device function [21]. As a result, careful weighing of risks and benefits, in addition to attention to quality of life, must occur to determine if an elderly patient would truly benefit from a pacemaker.

A study by Gillam *et al.* evaluated the type and frequency of

hospital readmissions and mortality after pacemaker implantation in Australia [22]. In the study, they found that approximately 9% of patients were readmitted secondary to cardiac complications, including heart failure, myocardial infarction, arrhythmias, or need for lead adjustment [22]. Further, the rate of readmission was higher in patients with single chamber pacemakers compared to dual chamber devices [22].

One final concern that should be considered is safety issues surrounding magnetic resonance imaging (MRI) in patients with implantable electronic devices. Due to potentially ferromagnetic materials used in the manufacturing of leads, there is a risk of interaction when exposed to the magnetic field. Potential complications include device malfunction from electromagnetic interference, lead heating, and lead dislodgment [23]. While MRI-conditional devices are now widely available, there are still concerns regarding complications, especially in older devices. However, a study by Hwang et al. evaluating the outcomes of MRI in patients with pacemakers concluded that MRI is safe under close medical supervision in both non-MRI conditional and MRI conditional devices [23].
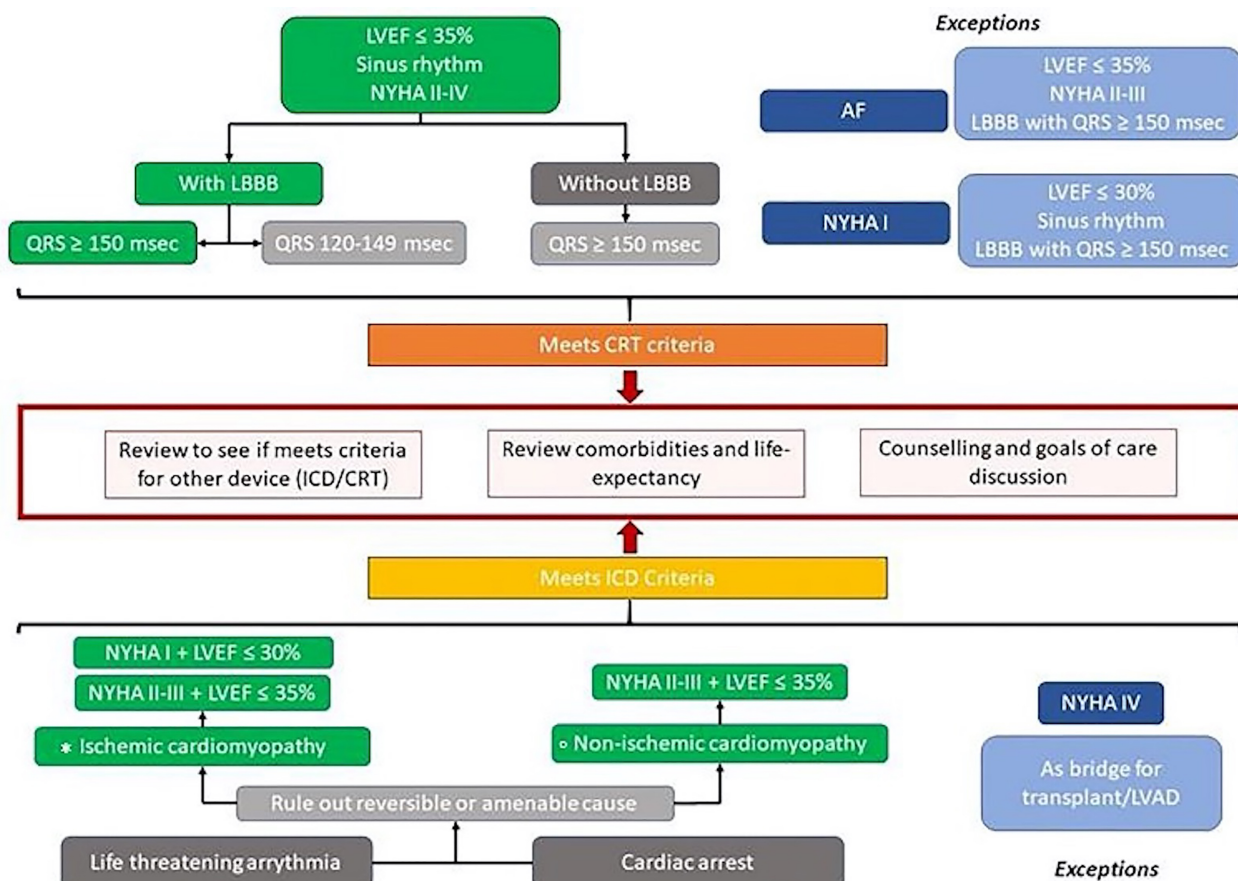
3.3 Cardiac resynchronization therapy

Cardiac resynchronization therapy (CRT) is a frequently used treatment modality to reduce all-cause mortality in heart failure patients. It can be implanted alone or in combination with defibrillator to prevent sudden cardiac death. Heart failure is one of the most common elderly presentations from a primary care standpoint, as mentioned previously. Thankfully, use of CRTs in the elderly population is quite common with 26% of patients receiving CRT being above the age of 80 [24].

Class 1 indication for CRT includes patients with significant left ventricular dysfunction (ejection fraction $< 35\%$), sinus rhythm, left bundle branch block (LBBB) with prolonged QRS (> 150 ms), and patients with advanced New York Heart Association (NYHA) functional class who are failing optimal medical therapy [25]. It may also be considered in those with LBBB and QRS 120-149 ms if they meet all other criteria [25]. Other patients who may benefit from CRT are those with atrial fibrillation (AF) if they otherwise meet CRT criteria and those with NYHA class I and an ischemic etiology of heart failure with ejection fraction 30% or less and LBBB with QRS 150 ms or greater. See Fig. 1 for an outline of the decision-making process regarding CRT.

Despite the fact that current recommendations do not specify an age-limit for CRTs, they advise against the use of such devices in frail elderly patients with a life-expectancy of less than one year [25]. Some believe that CRT may not provide the same morbidity and mortality benefit in elderly patients when compared to younger patients. This theory is based on the observation that the effects of CRT are limited in patients with increased myocardial scar burden, extreme ventricular dyssynchrony, and concomitant valvular dysfunction, all of which are more prevalent in the geriatric population. Additionally, the benefit of CRT in the setting of

Exceptions

LVEF ≤ 35%
Sinus rhythm
NYHA II-IV

With LBBB

QRS ≥ 150 msec

QRS 120-149 msec

Without LBBB

QRS ≥ 150 msec

AF

NYHA I

LVEF ≤ 35%
NYHA II-III
LBBB with QRS ≥ 150 msec

LVEF ≤ 30%
Sinus rhythm
LBBB with QRS ≥ 150 msec

Meets CRT criteria

Review to see if meets criteria for other device (ICD/CRT)

Review comorbidities and life-expectancy

Counselling and goals of care discussion

Meets ICD Criteria

NYHA I + LVEF ≤ 30%

NYHA II-III + LVEF ≤ 35%

* Ischemic cardiomyopathy

NYHA II-III + LVEF ≤ 35%

◦ Non-ischemic cardiomyopathy

Rule out reversible or amenable cause

Life threatening arrythmia

Cardiac arrest

NYHA IV

As bridge for transplant/LVAD

Exceptions

Fig. 1. Suggested approach to CRT and ICD decision-making emphasizing the importance of life-expectancy evaluation, counselling and goals of care discussion. Green: Class I recommendations. **Abbreviations:** LVEF: left ventricular ejection fraction, LBBB: left bundle branch block, AF: atrial fibrillation, NYHA: new york heart association, CRT: cardiac resynchronization therapy, ICD: implantable cardiac defibrillator, LVAD: left ventricular assist device. *Provided that patients have been on optimal medical therapy for 40 days post myocardial infarction or three months after revascularization. ◦Provided that patients have been on optimal medical therapy for three months.

renal failure, commonly afflicting the elderly population, has not been determined.

The discrepancy between the age-group of patients in trials on which recommendations are based versus the age-group of actual patients requiring CRT in the clinical setting have led to the publication of studies focusing on the benefit of CRT in the elderly. Sub-group analysis of patients aged 65 and older from the Cardiac Resynchronization Heart Failure (CARE-HF) and Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure (COMPANION) trials revealed decreased morbidity and mortality in patients with CRT defibrillators (CRT-D) in comparison to CRT pacemakers (CRT-P), while CRT-P in turn was found to be more beneficial than optimal medical therapy alone [26, 27]. Similarly, results from the Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy (MADITCRT) showed reduced incidence of heart failure and death with CRT-D in patients 60 years and older, however this reduction was less prominent in those younger than 60 years [28]. Killu *et al.* reviewed CRT cases to asses mortality benefits specifically in the elderly population [29]. Of 728

patients, 12% (90 patients) were above the age of 80 years. It was noted that despite overall survival rates being lower in the elderly, both octogenarians and younger groups showed similar clinical improvement in NYHA functional class and EF, suggesting that there is indeed improvement in morbidity and quality of life. Similarly, Martens *et al.* studied the clinical response to CRT and outcomes in those aged 80-89 years [24]. The octogenarians (178 patients) and the younger group (508 patients) showed similar improvement in symptoms and EF [24]. Although mortality rates were still higher in the elderly group, the survival rates and life expectancy of the elderly with heart failure with reduced ejection fraction (HFrEF) receiving CRT were comparable to an age-matched population without heart failure [24]. This finding leads us to believe that there may indeed be some mortality benefit for CRT in the elderly after all.

In regards to the addition of defibrillator (CRT-D) in elderly patients, there is not enough data to establish clear guidelines [30]. There are reports suggesting that fatal arrythmias are less frequent in the elderly compared to younger patients, raising question regarding the true benefit of CRT-

D in geriatric patients [31]. Further, in contrast to the CARE-HF and COMPANION trials, a 2018 study by Doring et al. revealed a lack of survival benefit in patients above the age of 75 who received CRT-D versus CRT-P alone [32].

There are special considerations that must be taken into account when treating the elderly with CRT devices. One must know that heart failure is rarely an isolated disease in the elderly, and the risk of death from noncardiac comorbidities in this population is higher than in their younger counterparts. Recently, authors have suggested performing frailty assessment in elderly patients being considered for such interventions [33]. Kubala et al. found that those with higher frailty scores showed less response to CRT, had higher rates of hospital admissions due to HF, and increased mortality [33]. Other clinical risk scoring systems have recently been created to help aid in the decision between CRT-P versus CRT-D in the elderly; factors that are considered include age, associated atrial fibrillation, comorbidities including renal or hepatic impairment and degree of left ventricular dysfunction [34]. These scoring systems help select patients with lower risk of early noncardiac death who are more likely to benefit from CRT-D [34]. Independent of these clinical risk scores, one must consider the patient's desires and goals of care, overall quality of life, functional status and cognitive state before deciding on a treatment plan. These additional factors are what render the decision-making process in the geriatric population complex and a true clinical challenge.

3.4 Automated implantable cardiac defibrillator (AICD)

Implantable cardiac defibrillators are used for primary prevention of sudden cardiac death (SCD) in high risk patients and secondary prevention in those who previously suffered from life-threatening arrythmia (ventricular tachycardia, ventricular fibrillation) or cardiac arrest. High risk patients include those with previous myocardial infarction (MI) and EF 30% or less, NYHA functional class II-III with EF 35% or less, or those with ischemic cardiomyopathy with NYHA functional class I and EF 30% or less [35]. Patients with ischemic cardiomyopathy should be assessed 40 days after MI or at least three months after revascularization. For those with nonischemic cardiomyopathy, they should be on optimal medical therapy for at least three months prior to evaluation for ICD [35]. Some patients with NYHA functional class IV may be considered for ICD placement as bridging therapy to cardiac transplantation or LVAD [35]. Fig. 1 provides an outline of the decision-making process regarding ICD placement in the elderly.

ICD, however, is not recommended in those with life-threatening arrythmias secondary to reversible causes such as drugs, electrolyte imbalances or conditions amenable to surgical or catheter-ablation. Additionally, patients in NYHA functional class IV should not receive ICDs unless they are candidates for LVAD or cardiac transplantation due to higher rates of death from advanced HF as opposed to fatal arrythmias in this group. In addition, it is not recommended to use ICDs in those with a life-expectancy less than one year.

In the elderly population in particular, confounding factors such as having multiple comorbidities and polypharmacy increases the risk of noncardiac death, greatly impacting life-expectancy. In fact, Healey et al. reviewed 1866 patients with a history of ventricular arrythmias undergoing ICD placement divided into two groups; those younger than 75 years and those 75 years and older [36]. They concluded that most elderly patients with a history of ventricular arrythmias died from non-arrythmia related conditions [36]. Therefore, the benefit of ICD in this patient population is brought to question as it may not provide the same mortality benefit it provides younger patients. In contrast, Yung et al. found that despite the fact that elderly patients receiving ICDs did indeed have higher mortality rates, the number of appropriate shocks delivered were equivalent to those of the younger group, thus emphasizing that age alone should not be the pivotal point in deciding who is a candidate for ICD [37].

Although ICD use can potentially prevent arrhythmia-induced death, it is imperative that we take a multifaceted approach when deciding whether to utilize these devices in elderly patients. Similar to CRT, it is important to consider baseline functional status, quality of life and frailty when making such a decision [38, 39]. Additionally, the presence of co-morbidities that are expected to reduce life-expectancy alongside management goals identified through extensive discussion with the patient should contribute significantly to the decision-making process. In fact, recommendations from the ACC/AHA/HRS state that in older patients (> 75 years) with significant comorbidities an ICD should only be considered if meaningful survival of greater than 1 year is expected (Class 2A recommendation) [35].

3.5 Watchman device/left atrial appendage closure

Atrial fibrillation is the most common arrythmia affecting the elderly population. As atrial fibrillation predisposes patients to the development of embolic complications, including stroke, anticoagulation is often necessary in patients with sufficient risk. The elderly population is particularly susceptible to developing these thromboembolic events. A study by Wang et al. evaluated the effect of age on outcomes at 1 and 3 years after stroke in patients with AFIB [40]. They found that patients above the age of 75 had significantly increased rates of mortality at 1 and 3 years post-stroke when compared to younger patients [40]. However, long-term anticoagulation is associated with an increased risk of bleeding, and this risk is amplified as patients age, especially due to the fact that advancing age is a major risk factor for having multiple comorbidities and elevated fall risk. Additionally, other concomitant factors including renal dysfunction and drug interactions due to polypharmacy limit the use of oral anticoagulation in this group. Because of this, left atrial appendage occlusion has become a popular alternative for anticoagulation in the geriatric population.

LAA occlusion is indicated in patients at high risk of thromboembolism with contraindications to oral anticoagulation such as those with history of significant hemorrhage

or an elevated HASBLED-score (hypertension, abnormal renal/liver function, stroke, bleeding history, labile international normalized ratio, elderly age > 75, drug/alcohol use) [41]. This recommendation was only recently added to the AHA/ACC guidelines for treating atrial fibrillation in 2019 (Grade IIb recommendation) [41]. Other clinical scenarios where LAA occlusion may be considered include patients with renal failure or those requiring a prolonged course of triple anticoagulation and antiplatelet therapy due to significant coronary artery disease due to the elevated risk of bleeding in these populations. In addition, patients who develop thromboembolic events despite being on oral anticoagulation may also be candidates for LAA occlusion. In patients undergoing cardiac surgery, a large meta-analysis performed demonstrated that surgical closure or amputation of the LAA is associated with lower rates of embolic events and stroke postoperatively, and also confers better mortality rates postoperatively [42]. Therefore, in some patients, surgical closure may play a role as well as percutaneous closure.

Although there are no clear contraindications to LAA occlusion, it should be noted that there are limitations regarding eligibility for this procedure. Patients undergoing LAA occlusion require 45 days of anticoagulation post-procedure to prevent device-related thromboembolic events until complete epithelization has taken place. Therefore, patients who are unable to tolerate anticoagulative therapies are excluded from most trials. This contraindication remains controversial, as data from the ASAP trial demonstrated that patients with non-valvular AFIB can undergo LAA closure safely without a warfarin transition [43]. Further research is needed to develop firm recommendations.

Few randomized trials studying the safety and efficacy of LAA occlusion versus oral anticoagulation have included patients over the age of 75 [43]. Four main retrospective studies have been done in the past six years regarding LAA occlusion in this patient population [44–46]. Gafoor *et al.* reviewed 75 cases of patients above the age of 80 who underwent LAA occlusion [44]. Among those studied, only one patient suffered a stroke in the early post-operative phase while one suffered from serious hemorrhage [44]. They concluded that LAA appendage occlusion is both safe and effective in reducing risk of AF-associated stroke in the elderly [44]. In 2016, Freixa *et al.* performed the largest multicenter retrospective study of LAA occlusion in the elderly, evaluating procedural success and peri-procedural complications between those younger than 75 years (377 patients) and those above 75 years of age (452 patients) [45]. Both procedural success rates and rate of stroke and major bleeding were comparable between the two groups [45]. In 2017, a similar comparison was performed by Davtyan et al. evaluating 18 patients above 75 years of age and 54 patients younger than 75 years [46]. Similar to Freixa et al., they found no significant difference in mortality between the elderly population and younger group of patients [46]. Finally, Taurez *et al.* performed a retrospective study of 116 patients who underwent watchman procedure, of whom 54%

were aged 80-89 years and 13% were aged 90-99 years [47]. No significant difference in major complications was noted between the two patient categories and their younger counterparts, thus confirming once again that LAA occlusion is a safe and viable alternative for anticoagulation in the geriatric population [47].

3.6 Ventricular Assist Devices

Ventricular Assist Devices (VAD) are circulatory support devices that are used for the management of treatment refractory, severe, acute and chronic heart failure [48]. These are devices designed to assist the heart via establishment of a parallel blood flow path similar to that of physiologic circulation [49]. The pump works by drawing blood from the left ventricle via an inflow cannula connected to the apex, and returning blood to systemic circulation via an outflow graft, typically sewn to the ascending aorta [49]. The incidence of heart failure in the United States is projected to increase over the next ten years, due mostly in part to an aging population [50]. Heart failure is much more common in elderly patients, with over half of the patients needing hospital admission for heart failure exacerbations being older than 75 years of age [50]. Further, the prevalence of heart failure is greater than 10% in patients older than 80 years [50]. Based on these prevalence statistics, it is likely that the development of end-stage heart failure and subsequent need for VAD placement is an important consideration in the elderly population.

The indications for VAD placement are as a bridge to transplant, bridge to recovery, bridge to candidacy, or destination therapy [48]. VAD utilization as a bridge to transplant is beneficial in patients with stage D heart failure in whom cardiac transplant is anticipated or planned (Class 2a recommendation) [25]. Bridge to recovery refers to the utilization of VADs in patients whom are suffering from reversible causes of heart failure. Bridge to candidacy refers to the utilization of VAD placement in patients who do not currently meet the criteria for heart transplant, but whom may become eligible in the future. An example of this includes patients with secondary pulmonary hypertension who may have improvement in their condition after VAD placement to reduce left ventricular pressure, eventually allowing them to become eligible for transplant [48]. Finally, destination therapy refers to the use of VADs in patients who do not meet criteria for heart transplant. Conditions that may exclude a patient from transplant candidacy include advanced age, frailty, severe pulmonary hypertension, malignancy, liver disease, or kidney disease [48].

There are several absolute contraindications to implantation of VADs. These include presence of a systemic illness with life expectancy of less than 2 years, presence of malignancy within the past 5 years, irreversible kidney or liver dysfunction, severe chronic obstructive pulmonary disease, and systemic disease with multiple organ involvement [51]. Although systemic illness can be a contraindication as described previously, certain conditions such as HIV or advanced organ dysfunction (ex. profoundly elevated creatinine) may not

necessarily preclude patients from VAD placement [51]. One important consideration is that age, while not a contraindication to VAD placement, may preclude patients from heart transplant eligibility [51].

There have been two landmark clinical trials evaluating the efficacy of ventricular assist devices that likely have the greatest impact on the geriatric patient population. In 2001, the REMATCH trial evaluated 129 patients with end stage heart failure who were ineligible for cardiac transplant in two groups, either receiving LVAD (n = 68) or medical management (n = 61) [52]. The LVAD used in this trial was the HeartMate VE, which is a pulsatile flow device. Patients receiving LVAD showed a reduction in all cause mortality by 48% compared to the group receiving medical therapy ($P = 0.001$) [52]. Further, survival rates at one and two years were both significantly higher in the LVAD group [52]. Despite the fact that patients receiving devices had significant mortality benefits, there was also a much higher rate of serious adverse events in the device group, including infection, bleeding, and device malfunction [52]. Overall, the results of this study demonstrated that patients with advanced heart failure may have substantial survival benefit from receipt of a VAD when cardiac transplant is not an option (destination therapy). In 2009, the HeartMate II trial evaluated the benefit of continuous flow devices (HeartMate II) vs the traditional pulsatile flow device (HeartMate VE) [53]. During the course of the study, it was found that treatment with continuous flow devices significantly increased 2 year survival free from stroke and device failure [47]. Similar to the REMATCH trial, the HeartMate II trial demonstrated significantly improved quality of life and functional capacity in both device groups [53]. These trials are important, especially for the geriatric patient population, as these patients often possess many of the qualities that could exclude them from transplant, including advanced age, frailty, multiple chronic conditions, and increased risk of malignancy. Therefore, VADs in these patients may be used more frequently in the context of destination therapy and palliative care, as is the case in these clinical trials.

As with any procedure, it is important to consider the complications of the intervention, especially in the geriatric population. A 2018 multicenter study by Tripathi et al. examined the complications and causes of 90-day readmission in patients after LVAD implantation [54]. The most common complications were cardiac causes, including worsening heart failure, complications related to the implanted device, arrythmias, bleeding complications, and infections [54]. It is important to recognize that one of the most significant predictors for increased complications included older age ($P < 0.01$), however, it is also important to note that this study could not significantly conclude that age was a predictor for readmissions ($P = 0.08$) [54]. While the use of these devices may provide survival benefit and improve quality of life in geriatric patients, they are also at elevated risk of post-implant complications. A thorough discussion of the risks and benefits should take place between patient and provider prior to pursuing VAD implantation.

4. Limitations

While a literature review, this manuscript is not without limitations. The inherent reliance on existing literature left a subjective aspect to the literature review when deciding if manuscripts were relative to the topic discussed. Furthermore, when performing the literature search, some less-commonly used nouns to describe the geriatric population were not searched, such as "octogenarian". Lastly, the content, indications, and contraindications were approved and directed by the senior authors of this manuscript. Though supported by literature sources, the primary care physician and geriatrician should recognize there are always patients with special considerations, institutional guidelines, and specialist preferences that may result in interventions different from the indicated treatment described here. Therefore, it is impossible to be entirely comprehensive. Lastly, when reviewing international guidelines, we found that there was little mention of specific recommendations for geriatric/elderly patients. This could be either due to the fact that indications for elderly patients are the same as for the general population, or that there is insufficient focus on this population. We believe that this lack of specific recommendations is due to insufficient focus on the elderly population. In fact, the 2013 ACC/AHA Guideline for the Management of Heart Failure explicitly states that "It is of major concern that the majority of randomized controlled trials failed to randomize a sufficient number of the elderly, women, and underrepresented minorities, thus limiting our insight into these important patient cohorts" [25]. However, when specific recommendations were made with regards to elderly patients in the professional society guidelines, we have included it in this manuscript.

5. Conclusions

As the aging population in the United States continues to grow, physicians should be aware of the complexities and challenges of managing the medical conditions that affect the geriatric population. Cardiac disease is the leading cause of death in the United States, and its incidence increases with age. Because of this, geriatric patients are more likely to require special treatment strategies, including the use of a multitude of cardiac devices. Primary care physicians should be familiar with these devices and their appropriate use criteria in order to effectively manage this patient population (summarized in Table 1). As medical technologies continue to advance, there remains a need for continued research to evaluate the benefits of new devices and technologies in the treatment of the geriatric population. We also ask clinical researchers to look hard at how the geriatric population is affected in future studies compared to non-geriatric patients as the United States population continues to age and require special attention.

Table 1. Cardiac Device Summary. A consolidated primary care reference for the indications of each cardiac device discussed in the manuscript with references.

Device	Indication	Treatment Effect	Class of Recommendation
Implantable Loop Recorders	Recurrent, unexplained syncope if patient is not high risk and does not require hospitalization [12]	No immediate improvement of symptoms, however there is evidence that utilization of these devices improves quality of life [16]	Class 1 Recommendation [3] - Recurrent syncope of unknown origin who have absence of high risk criteria requiring hospitalization/intensive evaluation or when likely recurrence is within longevity of the battery life (LOE: A) Class 2A Recommendation - assessment of bradycardia in patients with neurally mediated syncopal episodes to determine the need for pacemaker implantation (LOE: B) Class 2B Recommendation - loss of consciousness who need to definitively rule out arrhythmia as a cause of syncope (LOE: C)
Pacemaker	Pacing for acquired AV block in adults, pacing for chronic Bi-fascicular and Tri-fascicular block, pacing for AV block associated with myocardial infarction, pacing in sinus nodal dysfunction, prevention and termination of tachyarrhythmias by pacing, pacing in hypersensitive carotid sinus and neutrally mediated syndromes [19]	- Observational studies have demonstrated that pacing prevents recurrence of syncope and improves survival in adults and children with AV block. - There is no evidence that cardiac pacing prolongs survival in patients with sinus node dysfunction, however, it has been shown to reduce the risk of systemic thromboembolism in patients suffering from sick sinus syndrome. - Finally, for patients with functional bradycardia, the only reason for cardiac pacing is to prevent recurrent syncope [4]	Class 1 recommendations [3] - Sinus node disease when symptoms are clearly attributed to bradycardia, or for reducing the risk of AFIB and stroke (LOE: B) - Acquired third or second degree type 2 AV block - Permanent AFIB and AV block (LOE: C) - Bundle branch block with syncope and a positive electrophysiology study (LOE: B) - Alternating bundle branch block with or without symptoms (LOE: C) - Carotid sinus syncope and recurrent unpredictable syncope (LOE: B) Class 2 recommendations - Sinus node disease when symptoms are likely due to bradycardia, even if evidence is not conclusive (LOE: C) - Acquired second degree type 1 AV block which causes symptoms (LOE: C) - Reflex asystolic syncope in patients > 40 years old - Patients with a history of syncope and documentation of asymptomatic pauses > 6 seconds due to sinus arrest, sinus-atrial block or AV block (LOE: B) - Bundle branch block and unexplained syncope without diagnostic investigations (LOE: B) - Tilt-induced cardioinhibitory syncope with recurrent, frequent unpredictable syncope after alternate therapy has failed (LOE: B) - Unexplained syncope and positive adenosine triphosphate test (LOE: B) Class 3 Recommendations - Sinus node disease when sinus bradycardia is asymptomatic or reversible (LOE: C) - AV block due to reversible cause (LOE: C) - Asymptomatic bundle branch block (LOE: B) - Tilt-induced non-cardioinhibitory syncope (LOE: B) - Unexplained syncope without evidence of bradycardia or conduction disturbance (LOE: C) - Unexplained falls (LOE: B)

Table 1. Continued

Device	Indication	Treatment Effect	Class of Recommendation
Cardiac Resynchronization Therapy	Patients with significant left ventricular dysfunction (ejection fraction < 35%), sinus rhythm, left bundle branch block (LBBB) with prolonged QRS (> 150 ms), patients with advanced New York Heart Association (NYHA) functional class who are failing optimal medical therapy [25]	- CRT helps to restore cardiac synchrony, improve LV function, reduce functional mitral regurgitation, and reverse remodeling. The mechanism of benefit of CRT varies from patient to patient, and within an individual patient over time. Because of this, there is no measure to accurately predict a patients response to CRT [3]	Class 1 Recommendations [4] - Chronic HF patients, NYHA Class 2-4 with LVEF $\leq$ 35% who develop LBBB with QRS duration > 150 ms - Chronic HF patients, NYHA Class 2-4 with LVEF $\leq$ 35% who develop LBBB with QRS duration 120 – 150 ms Class 2 recommendations - Chronic HF patients, NYHA Class 2-4 with LVEF $\leq$ 35% without LBBB and QRS duration > 150 ms - Chronic HF patients, NYHA Class 2-4 with LVEF $\leq$ 35% without LBBB and QRS duration 120-150 ms - Patients with chronic HF, LVEF $\leq$ 35%, NYHA class 3-4 with permanent AFIB provided that Biventricular pacing as close to 100% can be achieved. - Patients with reduced LVEF who are candidates for AV junction ablation for rate control Class 3 recommendations [25] - CRT is not recommended for patients with NYHA Class 1 or 2 symptoms and non-LBBB pattern with WRS < 150 ms - CRT is not indicated for patients whose comorbidities and/or frailty limit survival to < 1 year
Automated Implantable Cardiac Defibrillator (AICD)	High risk patients and secondary prevention in those who previously suffered from life-threatening arrythmia (ventricular tachycardia, ventricular fibrillation) or cardiac arrest. High risk patients include those with previous myocardial infarction (MI) and EF 30% or less, NYHA functional class II-III with EF 35% or less, or those with ischemic cardiomyopathy with NYHA functional class I and EF 30% or less [35]	- Randomized controlled trials have demonstrated that AICDs are highly effective in terminating life-threatening ventricular arrythmias in patients with LV dysfunction, structural heart disease, ventricular tachycardia, and survivors of cardiac arrest [35]	Class 1 Recommendations [35] - Patients with ischemic heart disease who survive sudden cardiac arrest due to ventricular arrythmia or who experience hemodynamically unstable ventricular tachycardia (LOE: B) or who experience stable sustained ventricular tachycardia not due to reversible causes (LOE: B) - For secondary prevention of sudden cardiac death when patients risk of death due to ventricular arrythmia is deemed high and the risk of non-arrhythmic death is low based on comorbidities and functional status (LOE: B) - Patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic ventricular tachycardia (LOE: B) Class 2 Recommendations - For patients older than 75 years and with significant comorbidities who meet indications for a primary prevention ICD, ICD is reasonable if survival of greater than 1 year is expected. (LOE: B)

Table 1. Continued

Device	Indication	Treatment Effect	Class of Recommendation
Left Atrial Appendage Closure/Amputation	Patients at high risk of thromboembolism with contraindications to oral anticoagulation such as those with history of significant hemorrhage or an elevated HASBLED-score (hypertension, abnormal renal/liver function, stroke, bleeding history, labile international normalized ratio, elderly age > 75, drug/alcohol use) [41]	- Left atrial appendage device closure was shown to decrease the risk of hemorrhagic stroke, while the difference in ischemic stroke incidence was not significant between left atrial appendage closure and in patients on warfarin in two RCTs [41]	Class 2 Recommendation [41] - Percutaneous Left atrial appendage closure may be considered in patients with atrial fibrillation at increased risk of stroke who have contraindications to anticoagulation (LOE: B) - Surgical occlusion of the left atrial appendage may be considered in patients with atrial fibrillation undergoing cardiac surgery (LOE: B)
Ventricular Assist Devices	Patients with need of management of treatment refractory, severe, acute and chronic heart failure as a bridge to transplant, bridge to recovery, bridge to candidacy, or destination therapy [48]	- 1-year survival in patients after implantation of the continuous flow LVAD is 80%, which is close to the 1-year survival for patients after heart transplant (86%) [48]	Class 2 Recommendations [25] - Mechanical circulatory support (such as LVAD) is beneficial in patient with Stage D Heart failure with reduced ejection fraction in whom cardiac transplant or cardiac recovery is anticipated or planned (LOE: B) - The use of percutaneous and extracorporeal ventricular assist devices is reasonable as bridge to recovery or bridge to decision in patients suffering from heart failure with reduced ejection fraction and acute hemodynamic compromise (LOE: B) - Durable mechanical circulatory support is reasonable to prolong survival in carefully selected patients with stage D heart failure with reduced ejection fraction (LOE: B)

Recommendations: Class 1 - Evidence that a treatment is beneficial, useful, or effective

Class 2 - Conflicting evidence surrounding the usefulness/efficacy of the treatment

Class 3 - Evidence that a treatment is not useful/effective, and may even be harmful

LOE (Level of Evidence)

A = Data derived from multiple randomized clinical trials or meta-analyses

B = Data derived from a single randomized clinical trial or large non-randomized studies

C = Consensus of opinion of the experts and/or small studies, retrospective studies, registries

Author contributions

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