Mini Review

Interventional Cardiology

Cardiovascular implantable electronic device selection based on clinical characteristics- "All devices are not the same"

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Abstract

This review is based on the premise that all available Cardiovascular Implantable Electronic Devices (CIEDs) are not the same and the selection of one over another should be based on clinical findings and requirements with particular reference to patient characteristics. Currently, the selection is driven primarily by cost and an assumption that all devices are the same. The clinical profile of the patient, and the different algorithms and technology, are disregarded. Continuation of this mode of selection will significantly impede further development of these sophisticated algorithms depriving patients of their true clinical benefit. The last five decades have seen tremendous progress in the evolution of cardiovascular implantable electronic devices.

Keywords: Cardiovascular implantable electronic devices • Device algorithms • Programmability • Device purchasing • Randomized controlled trials

Introduction

From a basic feature of delivering electrical impulses to stimulate the heart to complex algorithms designed to treat different electrical disorders, development has been possible through the collaboration of engineers and clinicians who have recognized needs and applied them to technology. Progress has been in increasing functionality, longevity, and ease of implantation. Over the last 30 years algorithms have been developed to increase device functionality and efficacy, specifically to improve hemodynamics, and management of both tachyarrhythmias and bradyarrhythmias. These algorithms allow selection by Electrophysiologists of the appropriate device for each patient based on their clinical characteristics. An Implied assumption is that devices are not equal, and each device may have a particular asset matching an individual patient's clinical requirement. The aim of the review is to draw attention and highlight that economic pressures and purchasing criteria for CIEDS will greatly impact their future development. The selection will prevent patients getting the maximal benefit from these devices.

Literature Review

Unexpectedly parallel to this progress in technology is a fundamental change in how devices are made available to clinicians and hence to patients. The driving factor as in many other aspects of current healthcare has become device cost, at the cost of clinical efficacy. This is mediated by institutions either individually or under a corporate umbrella. Sales are by contracts negotiated with the dominance of a demand for lower prices in exchange for almost exclusive use of the products of one or possibly two manufacturers. This approach is contradictory to clear evidence that all devices are

not equal. Physicians also readily accept this and even believe that these algorithms do not have a significant difference in clinical outcomes. Furthermore, this trend deflects physicians and engineers from future collaborative development adding to patient disadvantage.

This contrasts with events early in the development of CIEDS when Physicians insisted on not compromising quality because of cost issues. Early advances such as the advent of Lithium batteries and 'physiological' pacing, to name but two, were very expensive in their introduction. Physicians fought and won the expense issue for their patients. The opposite side of this coin is that recent benefits have perhaps been less dramatic than the two examples mentioned but the real penalty of dumbing down is that development stops.

The premise that all devices from different manufacturers with different algorithms and designs are the same may stem from a lack of Randomized Controlled Trials (RCTs) comparing one algorithm against another. Lead designs, and device characteristics also do not have head-to-head comparisons. It is debated that the differences, if any, are too small to be demonstrated by RCTs. The industry is reluctant to allow such comparisons often based on the huge cost of such trials. Furthermore, most industry sponsored research is in testing the safety of an algorithm against its absence rather than proving superiority over alternatives. The process in this matter could be aided by the Food and Drug Administration encouraging superiority studies of devices, something which appears to be better adopted in the pharmaceutical industry. A detailed discussion outlining the different algorithms and differences in technology between manufacturers is beyond the scope of this article. It may, however, be helpful to highlight a few examples. Rate response was extensively evaluated based on different sensor mechanisms including activity, minute ventilation, and closed loop stimulation [1]. Subtle differences may have a role in patients based on the type and levels of activity required, and respiratory status. Based on the mechanism of the rate response/sensor there could be an advantage of one sensor over another for some individuals.

Atrial Fibrillation (AF) prevention and interventional pacing algorithms did not meet their commitments [2]. The efficacy of algorithms was attenuated by right ventricular pacing provoking AF [3], which followed much data showing that atrial pacing was better than ventricular pacing for AF prevention. Some algorithms remain in devices though in minimalistic and largely unused forms. Moreover, the advent of ablation for AF occurred at a time when pacing for AF was being critically examined. Certainly, device therapy cannot be recommended over ablation for AF prevention but may be considered if a patient needs permanent pacing for a standard indication. It may, also, be prudent to use a device for AF prevention together with minimizing ventricular pacing algorithms in in the context of Paroxysmal AF.

Algorithms to minimize ventricular pacing evolved after the detrimental effects of right ventricular pacing were recognized [4]. The algorithm was different between manufacturers but there was no head-to-head study comparing them. The importance of these algorithms has been reduced by the advent of the left bundle area and His bundle pacing to offset the deleterious effects of right ventricular pacing [5]. However, minimizing ventricular pacing still has an important role and the differences in these algorithms may influence the device used.

For lead and pulse generator combinations, cross-manufacturer combinations may prevent a patient from undergoing magnetic resonance imaging. The size of the leads, the engineering of the electrodes to the insulation is also not the same across all leads, additionally the size of the generators, and battery longevity, all have a bearing on device selection in patients of different ages and habitus.

Pacing for heart failure to yield improved hemodynamics has been extensively evaluated. Different algorithms have been incorporated into Cardiac Resynchronization Therapy (CRT): Adaptive pacing, multisite left ventricular pacing, and left ventricular pacing alone are just some of these different algorithms [6]. These features are different from manufacturer to manufacturer.

Pacing for syncope, neurally-mediated or other bradycardia-related syncope seems to have been left by the wayside. The initial trial results of pacing for neurally-mediated syncope were disappointing because of patient selection and their trial design [7]. Careful patient selection has been shown to have real benefits. Algorithms like closed loop stimulation and rate drop response have been shown to have benefits in a select populations [8]. There is no data comparing the two algorithms. A prospective multicenter comparing the algorithms has been suggested [9]. The population of patients with syncope and a class I or IIA indication for pacing cannot be categorized as all having the same mechanism. Patients have recurrent syncope despite permanent pacing for an apparently standard bradycardia indication. This population is under-investigated prior to pacing and may have a better outcome with ideal device and algorithm selection [10].

Leadless pacing has greatly expanded and may now be the future of pacing [11]. These devices will undoubtedly become more complex and offer more algorithms. Again, now these may not be adopted for all patients. There are select indications for their use subcutaneous defibrillators have also gained a place among defibrillator implants [12]. The efficacy has been compared with single lead defibrillators in recent trials. However, there is no comparison of a single lead defibrillator with atrial sensing detection of AF in a population where there is a risk of AF and heart failure against devices that lack this function. With the understanding the adjudicating the true mechanism of a

tachycardia event having both atrial and ventricular electrograms is useful. A single chamber defibrillator with atrial sensing would be the appropriate choice [13]. Implantable loop monitors too have their differences in detection algorithms amplitude of R waves and presence or absence of P waves. These should also be taken into account [14], presence of transthoracic impedance in a pacemaker is only available in one device and may be considered when diastolic heart failure is anticipated.

Beyond algorithms there exist differences in the design and engineering characteristics of leads and generators and devices of different manufacturers. The relationship of device selection to body habitus and demographic characteristics also has a role. Battery longevity and lead failure depend on the engineering characteristics which vary. The performance of one manufacturer's leads may not be accompanied by relevant performance from the generator. Pricing based on systems inhibits a mix and match approach which has a potential for optimal performance. There may not be randomized data from large RCTs comparing these issues. However, there is enough data illustrating the benefits offered by each of these algorithms.

Conclusion

Implantable devices have seen a phenomenal evolution in available features which have improved paced patient outcomes. However, the devices are not used with regard to those characteristics and algorithms offered. There is a clear contempt for these features of the available CIEDs offered by different manufacturers. The selection of these devices is made on issues of price, contracts, limiting vendors, and an incorrect assumption that all devices are the same.

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