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Rational Use of Leads in Artificial Cardiac Pacing

Uso Racional dos Cabos-Eletrodos na Estimulação Cardíaca Artificial

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ABSTRACT

Introduction: Cardiovascular implantable electronic device (CIEDs) are a proven therapy for the treatment of bradyarrhythmias, prevention of sudden death or heart failure. Since the first transvenous pacemaker implantation more than 60 years ago, technological advances in devices and improvements in surgical techniques have occurred. However, this type of therapy is still associated with significant complications, most of them related to the implantation of transvenous leads. **Objective:** To present a reflection on how to practice the rational use of lead implantation and propose strategies and alternatives to delay or avoid it, based on the current knowledge in the various fields of artificial cardiac stimulation. **Methods:** Review of literature that used articles from 1995 to 2019, from several platforms and periodicals. **Conclusion:** There is an expectation that in the coming years there will be technological and knowledge advances in the field of leadless stimulation, allowing these devices to be incorporated into clinical practice in a routine manner. Currently, if the implantation of ventricular electrodes in cases of sinus node disease with preserved atrioventricular conduction is rationalized, the implantation of atrial electrodes in implantable cardioverter-defibrillators (ICD) without the necessity of antibradicardia stimulation or ventricular electrodes in cases without the necessity of antitachycardia stimulation (ATP) considering the subcutaneous ICD implantation, this article will have fulfilled its role.

KEYWORDS: Artificial pacemaker; Sinus node syndrome; Sudden cardiac death; Heart failure.

RESUMO

Introdução: Os dispositivos cardíacos eletrônicos implantáveis (DCEIs) são terapia consagrada para o tratamento de bradiarritmias, prevenção de morte súbita ou insuficiência cardíaca. Desde o primeiro implante de marcapasso transvenoso há mais de 60 anos, ocorreram avanços tecnológicos dos dispositivos e melhorias nas técnicas cirúrgicas. No entanto esse tipo de terapia ainda está associado a complicações significativas, a maioria relacionada ao implante dos cabos-eletrodos transvenosos. **Objetivo:** apresentar uma reflexão sobre como praticar o uso racional do implante de cabos-eletrodos e propor estratégias e alternativas para postergá-lo ou evitá-lo, com base nos conhecimentos atuais nos diversos campos da estimulação cardíaca artificial. **Métodos:** Revisão da literatura que utilizou artigos de 1995 a 2019, de diversas plataformas e revistas. **Conclusão:** Há a expectativa de que nos próximos anos ocorram avanços tecnológicos e de conhecimento no campo da estimulação *leadless*, permitindo que esses dispositivos sejam incorporados na prática clínica de maneira rotineira. Atualmente, se o implante de eletrodos ventriculares nos casos de doença do nó sinusal com condução atrioventricular preservada for racionalizado, o implante de eletrodos atriais nos cardiodesfibriladores implantáveis (CDI) sem necessidade de estimulação antibradicardia ou dos eletrodos ventriculares nos casos sem a necessidade de estimulação antitaquicardia (ATP) considerando o implante de CDIs subcutâneos, este artigo terá cumprido o seu papel.

PALAVRAS-CHAVE: Marcapasso artificial; Síndrome do nó sinusal; Morte súbita cardíaca; Insuficiência cardíaca.

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INTRODUCTION

Implantable electronic cardiac devices (CIEDs) are a proven therapy for the treatment of bradyarrhythmias, prevention of sudden death or heart failure. The number of CIED implants as well as the number of leads per device has grown in recent years[1,2] and it is estimated that about 1 million devices are implanted around the world annually[3].

Since the first transvenous pacemaker implantation more than 60 years ago, technological advances in devices and improvements in surgical techniques have occurred. However, this type of therapy is still associated with significant complications, most of which are related to the implant of transvenous leads: from venous access to implant site and structural problems leading to the main industry recalls[4–7].

There are reports of up to 12% short-term complications related to surgical technique in some centers[8,9], which include pneumothorax, cardiac tamponade, store hematoma and lead displacement[10–12].

Leads are the major source of system problems, they can cause complications such as venous obstruction, tricuspid regurgitation, perforation and be a source of infectious endocarditis[13,14], the latter can have a mortality rate of 12 to 31%[15,16], causing long hospital stays and high costs to health systems[17].

In the long run, leads will certainly present structural complications such as: insulator injury, conductor fracture or prohibitive impedance increases, which may put the patient at risk or exposure to extraction interventions that may be associated with significant morbidity and mortality[18,19]. Faced with this scenario, alternatives to minimize the number of electrodes implanted per patient are necessary.

OBJECTIVE

This text aims to present a reflection on how to practice the rational use of leads implantation, as well as to propose strategies and alternatives to delay or avoid it, based on the current knowledge in the various fields of artificial cardiac stimulation.

SCENARIOS

Sinus node disease

Patients with sinus node disease (SND) can be treated with atrial (AAI), ventricular (VVI) or dual-chamber (DDD) pacemakers. Both the AAI and DDD pacemakers preserve the synchronism between atrial and ventricular contractions, causing the number of ventricular single-chamber pacemaker implants to drop dramatically over time.

Although no survival gain was observed with AAI or DDD physiological stimulation compared to the exclusive ventricular (VVI), there is a great advantage in this mode of stimulation because it presents lower rates of atrial fibrillation and pacemaker syndrome. After the discovery of the damage in ventricular function caused by unnecessary stimulation of the right ventricle, the companies invested in the development of algorithms that promoted minimal ventricular stimulation and apparently solved the issue[20–23]. Therefore, the power of the physician's decision about the type of device to be implanted decreased and the implantation of dual-chamber devices with the possibility of stimulating the ventricle only in cases of need became the standard conduct. Sophisticated dual-chamber pacemakers were used to prevent a possible evolutionary need for sinus node disease associated with atrioventricular node disease.

A historical study[24] from 2005 comparing single- and dual-chamber systems in this scenario demonstrated that DDD mode stimulation was associated with higher rates of atrial fibrillation compared to exclusive atrial pacing (AAI) and that surgical complications were more frequent in ventricular lead implants, drawing attention to the better cost-effectiveness of atrial pacing in the SND.

Atrial-based pacing modes (AAIR and DDDR) with management of ventricular pacing by algorithms with mode changes or AV hysteresis were compared in the DANPACE study, which demonstrated that both presented similar mortality rates and revealed double rate of reinterventions with AAIR pacing. The reoperations occurred, in most cases, due to the necessity of upgrade from AAIR to DDDR, consequent to the development of atrioventricular block, which may suggest some advantage in implanting the dual-chamber system. In

those with preserved atrioventricular conduction, most of those with SND, algorithms that avoid unnecessary ventricular stimulation were widely recommended as mentioned above. The message at the time was that up to 18% of patients enrolled in the AAIR arm were converted to some type of ventricular stimulation (VVI or DDD). However, under the vision of rationalizing the use of leads, 82% were unnecessarily implemented already in the first procedure[25].

In a more recent study[26], the safety and efficacy of AAIR mode pacing in the SND were evaluated in selected patients. Among the 85 patients reminiscent in the study followed for a mean period of 10.6 ± 0.6 years, 78 (91.8%) did not require ventricular lead implantation.

At the end of the follow-up, 31 patients (39.7%) were alive (mean follow-up 14.3 ± 0.7 years), while 47 patients (60.3%) died (mean follow-up 8.1 ± 0.7 years). There were no sudden cardiac deaths that could be attributed to AV block.

During the course of the study, 7 (8.2%) patients were submitted to ventricular lead implantation (primary outcome) for the following reasons: 2 patients presented pre-syncope/syncope due to AV block; 1 patient presented recurrent displacement of the atrial lead; 3 patients developed symptomatic atrial fibrillation with the necessity of ventricular lead implantation due to the low ventricular response resulting from the use of betablockers; 1 patient was submitted to elective upgrade for DDD stimulation system, at the time of generator replacement, for presenting a Wenckebach block at stimulation rates of less than 120 bpm. The implantation of these leads went uneventfully. The average time to upgrade was 5.9 years and the need to add a ventricular lead occurred at the rate of 7.8 per 1000 pacemakers/year. During the follow-up period, 30 patients (33.7%) were submitted to generator replacement maintaining the AAIR pacemaker.

The results of this study were very similar to the DANPACE study, but the authors concluded that AAIR pacing should be considered in selected patients with SND without AV block, since in 91.8% of the patients this mode of pacing is associated with lower costs, fewer electrodes and less right ventricular pacing; mainly because these pacemakers are being implanted in an increasingly older population, with a life expectancy limited due to other comorbidities[26]. In this case, more than 90% of ventricular leads could be avoided or delayed.

The ability to reflect on the subject was gradually being harvested to the point that there was no specific guidance on the type of device to be implanted in the latest Brazilian Guidelines for Implantable Electronic Heart Devices[27], which does not differ much from the European guidelines[28] that cite the single-chamber atrial pacemaker (AAI), but as a second or third option provided that the use of minimal ventricular pacing (MVP) algorithms in dual-chamber devices is considered, as illustrated in Figure 1:

In contrast, the single-chamber pacemaker is highlighted in the 2018 Guidelines of American societies[29] that study driving disorders: be it VVI in cases where it

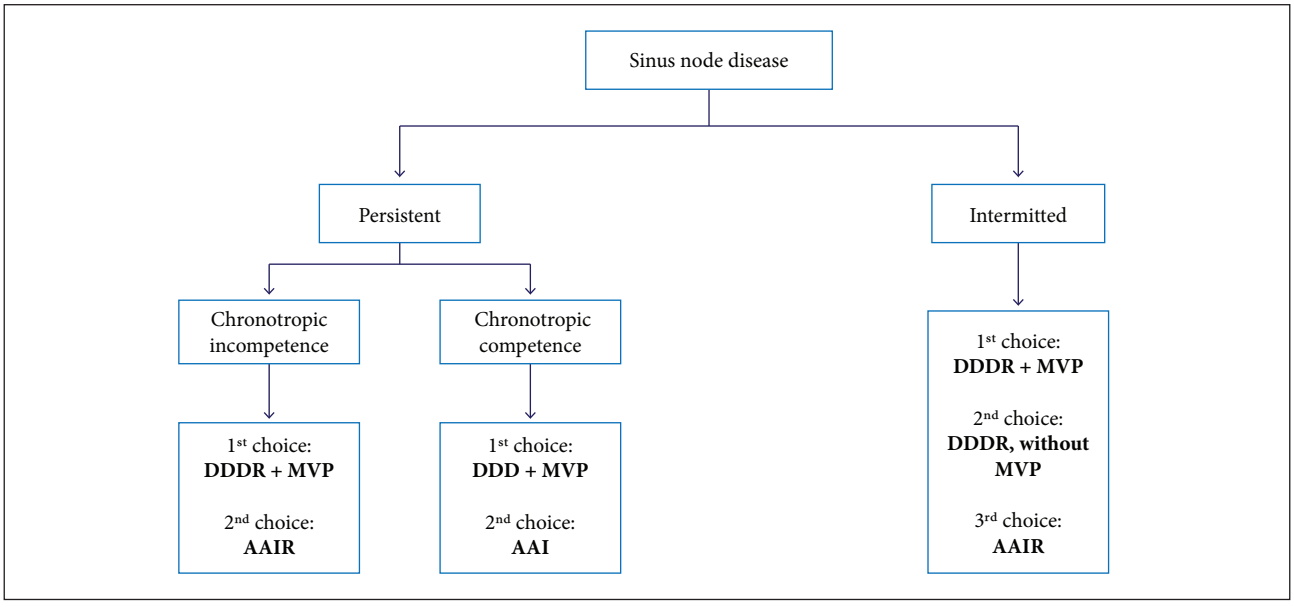

Figure 1. Flow chart with recommendations of the latest European Directives on SND stimulation mode[28].

is aimed only at safety in patients with low probability of stimulation (class IIa), or as AAI (class I) in the SND with preserved AV conduction, according to Fig. 2.

The discussion of the use of single-chamber pacemakers (mainly AAI) in the SND should be resumed. Considering the variables such as complication rate, procedure cost, exposure to vascular lesions such as thrombosis and future need for extraction, as well as the low rate of association with atrioventricular node disease, the approach to this subject is more than justified. The most worrying is the culture of automation of the thought that an extra lead "brings no consequences" especially in those more than 90% who will never need them.

Prevention of sudden death

The implantable cardioverter-defibrillator (ICD) is the device of choice for the management of ventricular arrhythmias and prevention of sudden death. Its benefit is well established, but it is subject to the same complications that can occur in the CEIDs mentioned above, with the aggravating factor of presenting higher infection rates compared to conventional transvenous pacemakers[30], besides having already been demonstrated by a study that more than 20% of the patients will present some type of dysfunction in the leads within 10 years[31]. Therefore, the discussion of unnecessary electrode implantation in this scenario becomes more important than in sinus node disease. However, the indications for ICD implantation in primary and secondary prevention are defined in Brazilian and international guidelines without any specific recommendations regarding the choice between single-chamber or dual-chamber ICD implantation.

In comparison with the single-chamber ICD (VVI-ICD), the dual-chamber ICD (DDD-ICD) is associated with a higher rate of periprocedural complications

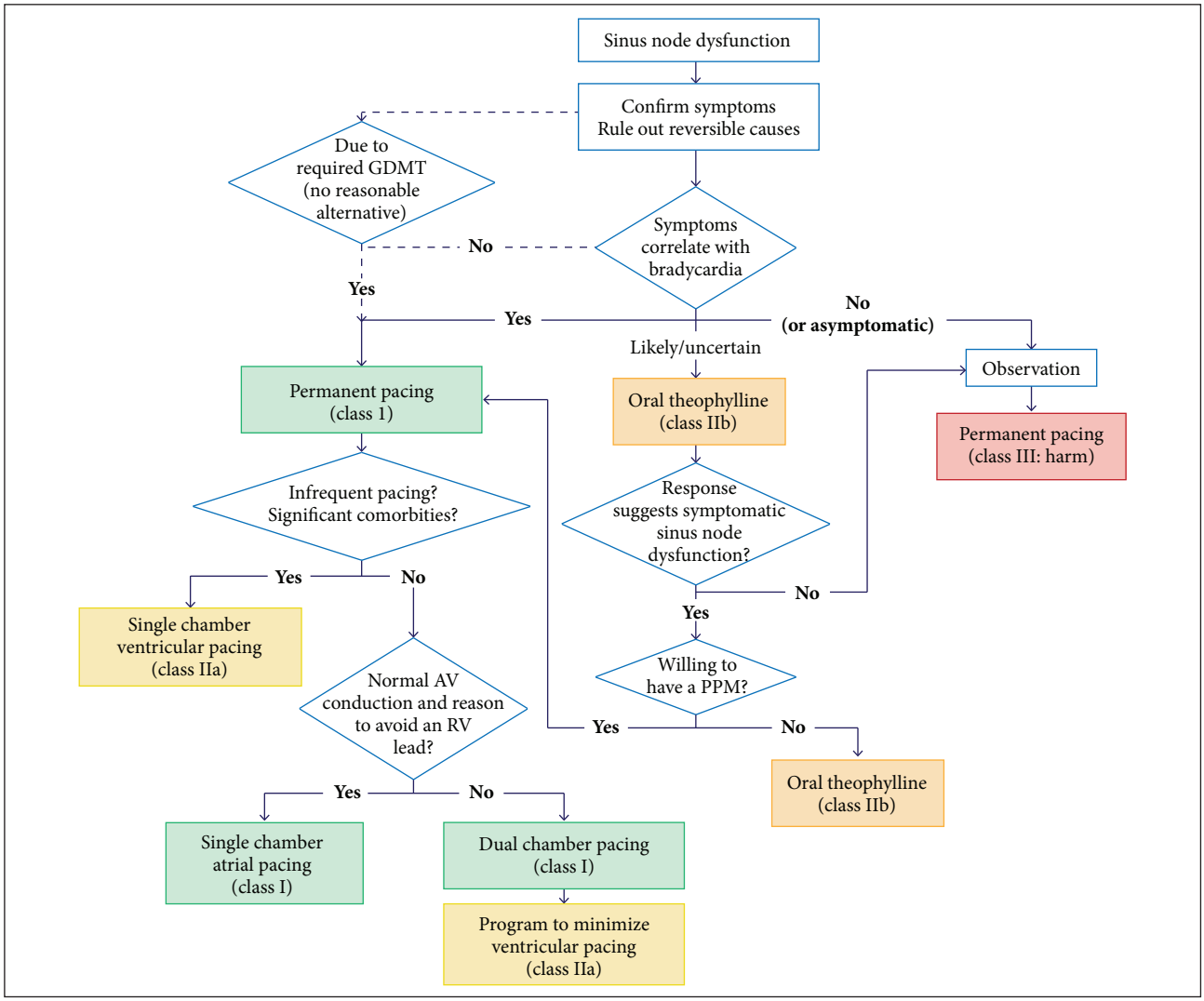

Figure 2. Flow chart with American Society recommendations for pacemaker implantation in SND[29].

and intra-hospital mortality[32], and its indication is questionable for patients who do not require cardiac pacing for bradyarrhythmias.

To avoid complications related to transvenous leads, the subcutaneous ICD is currently available. But in Brazil it is necessary to evolve in this discussion, because there are indications that on average 84–90% of dual-chamber ICDs are implanted to the detriment of single-chamber ICDs according to data provided by suppliers.

Implantable cardioverter-defibrillator (ICD) – single- or dual-chamber

Patients with indication for ICD and pacing for bradycardia and/or cardiac resynchronization therapy (CRT) will have indication for transvenous ICD implantation (DDD or VVI).

The indications for ICD implantation in primary and secondary prevention are defined in Brazilian and international guidelines. However, there are no specific recommendations on the choice between VVI-ICD or DDD-ICD implantation.

A retrospective longitudinal cohort[32] was performed to determine the rate of in-hospital complications among 104,049 patients who received DDD-ICD and VVI-ICD, between January 1, 2006 and December 31, 2007, in several centers.

The dual-chamber devices were implanted in 64,489 patients (62%). The adverse effects were more frequent in double-chamber device implants compared to single-chamber devices (3.17% vs. 2.11%, $p < 0.001$), as well as the in-hospital mortality rate (0.40% vs. 0.23%, $p < 0.001$). After adjusting for demographic data, medical comorbidities, diagnostic test data and ICD indication, the chances of any complication (odds ratio: 1.40; 95% confidence interval: 1.28 to 1.52; $p < 0.001$) and hospital mortality (odds ratio: 1.45; 95% confidence interval: 1.20 to 1.74; $p < 0.001$) were increased with DDD-ICD implantation in relation to VVI-ICD[32].

In an Israeli registry[33] published in 2016 that included a total of 1125 patients, the clinical outcomes (mortality, hospital admissions for heart failure [HF], and ICD therapy) were compared between VVI-ICD × DDD-ICD implantation for primary prevention of sudden death. Of these patients, 37% received VVI-ICD and 63% DDD-ICD, the mean follow-up time was 22 months, the mean ejection fraction was 30% and the mean QRS duration was 103 ms in both groups. There was no significant difference in mortality rate, HF admissions, appropriate or inappropriate therapy, or time to achieve any of the outcomes. Using multivariate analysis, the VVI-ICD was not associated with increased risk of death or admission by HF. In a subgroup of patients with ischemic myocardiopathy, the single-chamber device was associated with a higher rate of inappropriate therapy. The authors concluded that further prospective studies would be required to assess the benefit of DDD-ICD in reducing rates of inappropriate therapy[33].

More recently, a study was published between January 2007 and March 2011 that included a total of 2240 patients submitted to ICD implantation in 45 German centers, with an analysis of patient characteristics, procedure data, and complications over a one-year follow-up period, comparing VVI-ICD with DDD-ICD. Of these patients, 1629 were submitted to VVI-ICD and 611 DDD-ICD implantations; in the VVI group, 1358 were male, with EF = 34% ± 13%; in the DDD group, 491 were male, with EF = 35% ± 14%. The patients in the DDD group were significantly older (66 ± 12 vs. 63±13; $p< 0.001$); the history of atrial fibrillation and implant for primary prevention was lower in this group. Atrioventricular and LBBB driving disorders were more frequent in the DDD group. The number of in-hospital complications was significantly higher in the DDD group (3.0% vs. 1.2%; $p = 0.003$/n = 27 of 604 patients vs. 41 out of 1623 patients). Moreover, a higher mortality rate was observed in patients with DDD-ICD system (1.0% vs. 0.0% $p < 0.001$; n = 6 of 611 patients vs. 0 of 1629 patients). After 1 year of follow-up, the patients submitted to DDD-ICD implantation presented increased incidence of device revisions, re-hospitalization and mortality, without reaching statistical significance. This study demonstrated that, in the absence of significant sinus or atrioventricular node disease, double-chamber devices are associated with a higher rate of periprocedural complications as well as higher mortality, and the benefit of their indication is uncertain for patients who do not have such disorders. Therefore, the authors conclude that in the absence of relevant bradycardia (SND or AVB), the implantation of DDD-ICD is not justified[34].

A double-chamber ICD implant is necessary if, at the time of the procedure, the patient is also indicated

for a pacemaker implant. It is not justified to implant an additional lead simply to use it as a tachycardia discriminator. There was no reduction of inappropriate shocks in dual-chamber devices[35,36]. However, it is known that the visualization of the atrial electrograms makes the interpretation of the trace more precise (Fig. 3)[37].

One of the companies in the market (Biotronik) has DX line devices that are concerned with the maintenance of the electrograms and atrial discriminators with implantation of only one lead. Unlike traditional RVO systems (single lead with ventricular pacing and atrioventricular sensitivity), the DX ICD uses an atrial dipole with 15 mm spacing and optimized atrial signal processing system. The initial experience of this system indicates that the amplitude of the atrial signal in sinusal rhythm remains stable over time[37], which makes this device a promising alternative to the DDD-ICD.

Transvenous (TV-ICD) or subcutaneous implantable cardioverter-defibrillator (S-ICD)

The subcutaneous defibrillation lead has been used for more than 20 years in association with transvenous or epicardial leads[38–41], in specific situations (Fig. 4).

The solution currently found to the vascular problems of leads in patients who only need to prevent sudden death and without the need for cardiac stimulation was the development of an entirely subcutaneous ICD system, where the lead is placed over the sternum (Figs. 5 and 6).

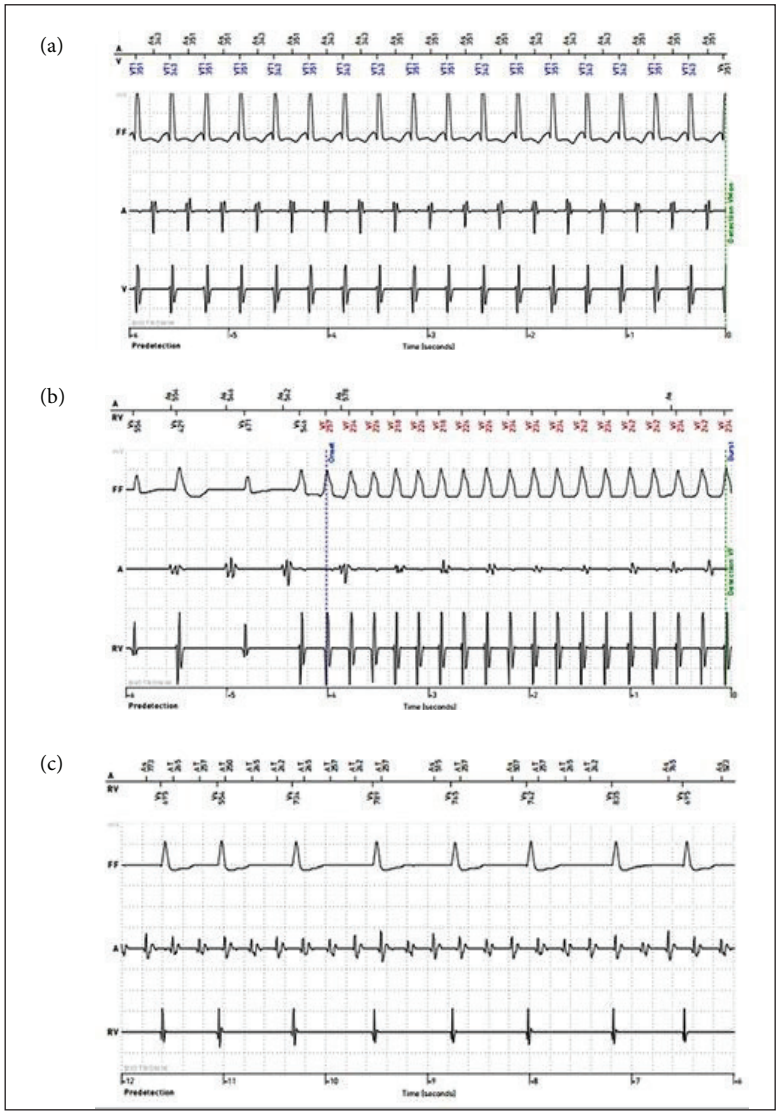

Figure 3. Example of intracavitary electrograms during (a) supraventricular tachycardia, (b) ventricular tachycardia and (c) atrial flutter.

Two major prospective studies have demonstrated the efficacy and safety of S-ICD compared to TV-ICD (IDE [S-ICD System IDE Clinical Investigation] and EFFORTLESS [Boston Scientific Post Market S-ICD Registry]), in relation to short- and long-term complications, and the incidence of inappropriate shocks.

The EFFORTLESS study[43], which had longer follow-up time (5 years), is a nonrandomized observational record with more than 800 patients enrolled in 42 clinical centers in 10 countries. The objective of the study was to demonstrate the short, medium, and long-term outcomes of the S-ICD. Patients with spontaneous, incessant or recurrent ventricular tachycardia (VT) that could be treated by antitachycardia therapy (ATP); patients with indication for cardiac resynchronization therapy (CRT) or symptomatic bradycardia, and patients with pacemakers with unipolar stimulation were excluded from the study.

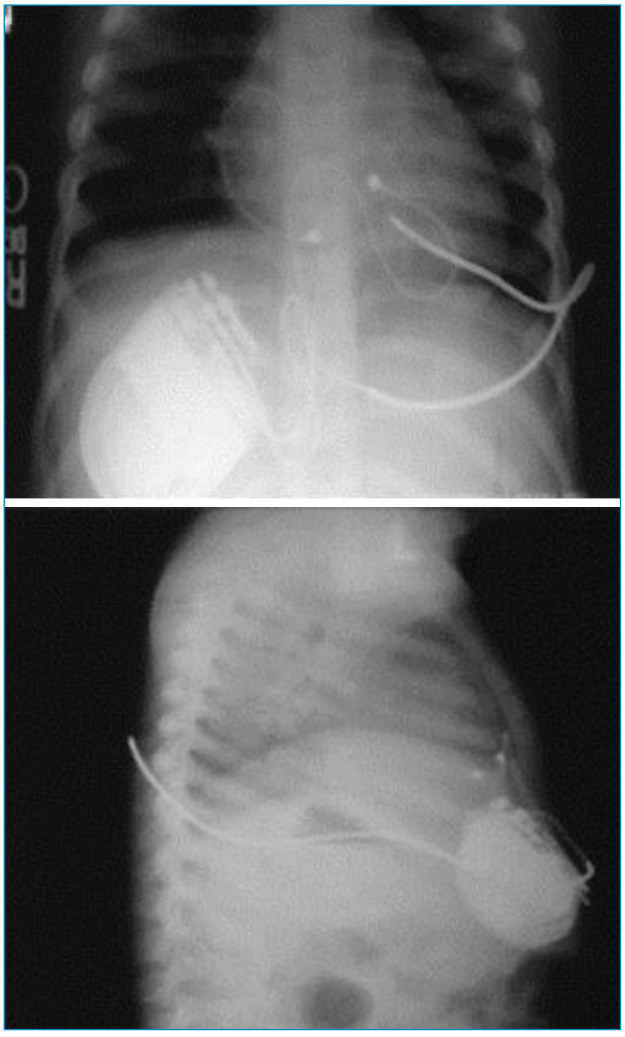

Figure 4. Chest radiography showing subcutaneous defibrillation lead implantation (Medtronic Subcutaneous Lead Model 6996SQ) associated with bipolar pacing/epicardial sensitivity lead in children[41].

This study demonstrated very high shock efficacy for spontaneous ventricular arrhythmias and reduced incidence of inappropriate shocks. The complication-free rate and low mortality rate extended beyond the first year of follow-up; as well as the rate of inappropriate shocks, risk of infection and general complications reduced as doctors performing the procedure gained more experience with the device over time[44].

Thus, it was possible to demonstrate the efficacy and safety of the S-ICD in patients with indication for implantation for primary and secondary prevention,

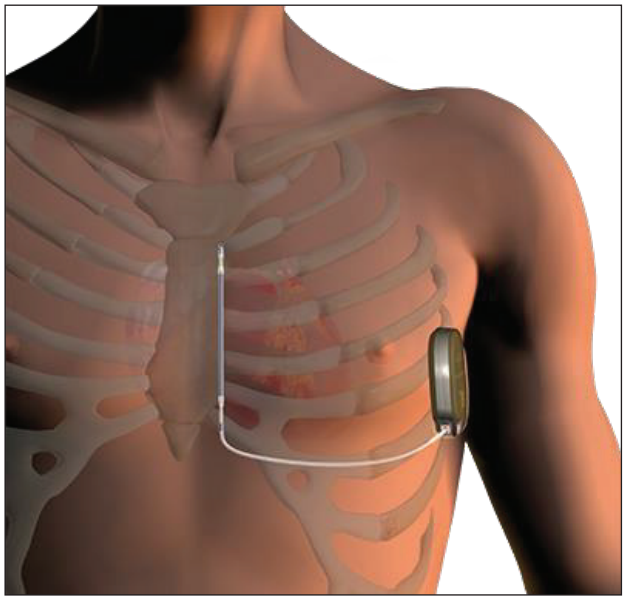

Figure 5. Graphical representation of the Boston S-ICD system Scientific – S-ICD SQRX[42].

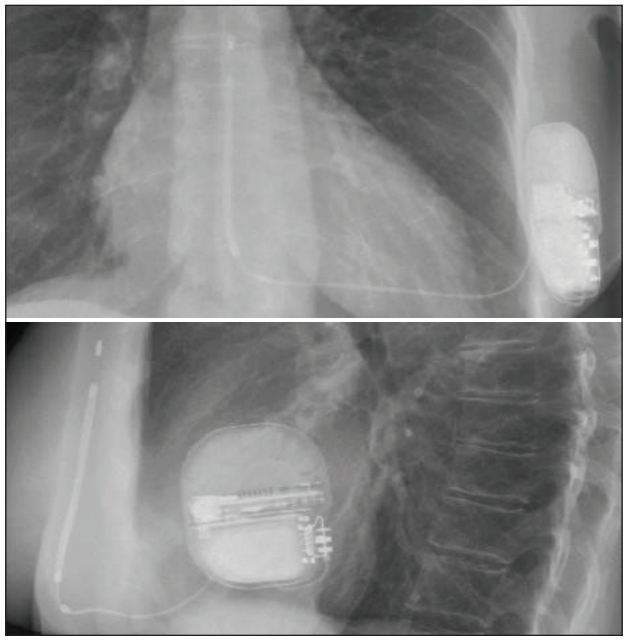

Figure 6. Post-implant radiography demonstrating optimal placement of the pulse generator and subcutaneous lead[42].

without indication for stimulation, over a follow-up period of more than three years[43,45].

The latest guidelines of the European Society of Cardiology (ESC) already contemplate the S-ICD as a therapeutic option, with recommendation class IIa, for patients with indication for ICDs who do not require stimulation for bradycardia, cardiac resynchronization or ATP[46].

The choice of TV-ICD to prioritize ATP should be based on the results of studies such as the subanalysis of the SCD-HeFT study[47], in which 7% had more than one VT episode during a 46-month follow-up, demonstrating the annual benefit of 1.8% for ATP[48] and Trial Painfree Rx II[49] which selected patients with stable monomorphic TV substrate (excluding patients in whom it is believed that this type of arrhythmia is unlikely to occur as, for example, those with hypertrophic myocardiopathy, long QT syndrome or Brugada syndrome), demonstrated a 42% reduction in shock episodes for fast TVs using ATP compared to devices programmed with shock only.

The association of leadless pacemakers in association with the S-ICD to overcome these deficiencies will mean that physicians do not have to decide between the possibility of ATP and high rates of complications of transvenous leads.

Leadless pacemaker (LLPM)

Recently the LLPM has emerged as an alternative to the use of transvenous leads in artificial cardiac pacing and, despite the short experience with these devices, they have proven to be safe.

Currently we have two leadless stimulation systems: (1) Nanostim Leadless Cardiac Pacemaker (LCP; St. Jude Medical), and (2) Micra Transcatheter Pacing System (TPS; Medtronic). Both devices are independent units (no external pulse generator required) capable of performing right ventricular pacing, detection and frequency response.

The first trial to evaluate the use of LLPM (LEADLESS Trial)[50] was a multicenter, prospective, nonrandomized, single arm study that enrolled 33 patients, who underwent LLPM implantation between December 2012 and April 2013, in three centers, in order to evaluate the safety and clinical performance of these devices. The primary safety outcome was the absence of complications at 90 days. Secondary outcomes included implant success rate, implant time and device performance measures (stimulation/sensitivity thresholds and frequency response performance).

The mean age of the patient cohort (n = 33) was 77 ± 8 years and 67% of the patients were male (n = 22/33). The most common indication for cardiac pacing was permanent atrial fibrillation with atrioventricular block (n = 22, 67%). The implant success rate was 97% (n = 32). Five patients (15%) required the use of > 1 LLPM during the procedure. One patient developed right ventricle perforation and cardiac tamponade during the implant procedure and died from a stroke. The overall complication-free rate was 94% (31/33).

After three months of follow-up, the stimulation performance measures (sensitivity, impedance and stimulation threshold) improved or were stable within the accepted limits. Therefore, in this initial experience, the single-chamber LLPM proved to be safe and viable[50].

The LEADLESS II study[51] was a prospective study conducted in 56 centers in three countries (USA, Canada and Australia), with 526 patients enrolled, with the objective of evaluating the safety and effectiveness of the LLPM system. The mean age of the patients was 75 ± 8 years and 62% were male. Of the total number of patients, 300 had the minimum follow-up time of 6 months. The implant success rate was 95.8% (504/526), the mean time of the procedure was 28.6 ± 17.8 min and 70% of the patients did not require repositioning of the device. Serious adverse events occurred in 34 patients (6.5%). Pericardial effusion occurred in 1.5% of the cases, but only 0.4% required intervention. Vascular complications occurred in 1.2% and device displacement in 1.1%. In the first two weeks after implantation, four devices moved to the pulmonary artery and two to the right femoral vein. All were percutaneously removed and new LLPMs were implanted. In addition, 0.8% of the patients required removal of the device due to high stimulation thresholds. It was then concluded that the LLPM met the pre-specified requirements for stimulation and detection in the vast majority of patients[51].

A multicenter prospective analysis published in 2016[52] was conducted to assess the efficacy and safety of Micra TPS. There were 744 patients enrolled with indications based on guidelines for ventricular pacing in 56 centers in 19 countries in North America, Europe,

Asia, Australia and Africa; 19 patients left the study because they did not consent or did not present eligibility criteria. The primary safety outcome was the absence of major complications: death, permanent device dysfunction due to electrical or mechanical problems, hospitalization, prolongation of hospitalization for at least 48 h or revision of the system. The primary endpoint of effectiveness was to maintain low and stable command thresholds at the 6-month post-implant visit.

The device was successfully implanted in 99.2% of the patients (719 in 725 individuals); of the 6 patients who were not successful in the implant, 4 presented major complications: 3 with cardiac perforation and 1 with pericardial effusion; 1 patient presented unfavorable venous anatomy, and 1 patient in whom it was not possible to obtain satisfactory command thresholds. Of the patients successfully submitted to the implant, 98.3% met the pre-established criteria of threshold capture at 6 months. The pre-specified safety criteria were also achieved and although 28 major complications occurred in 25 patients, 96% of the patients had no such complications at 6 months[52].

The first two LLPM systems demonstrated similar performance and initial promise of effectiveness and safety. There is still no long-term performance data on leadless systems to determine their technological robustness. As lead-free stimulation evolves, both in device technology and doctor experience, complications related to the procedure are likely to diminish. Randomized clinical trials comparing conventional and leadless devices are necessary to fully determine the differences between these technologies in clinical practice.

FUTURE PERSPECTIVES

To expand the benefits of lead-free pacing to more patients, efforts are being made to develop leadless systems with multicomponent communication, capable of performing dual-chamber pacing, cardiac resynchronization therapy (CRT) or serving with unit for ATP in cases of S-ICD.

Although it is not an exclusively autonomous LLPM system, another stimulation system has been clinically investigated. This system consists of two separate components: (1) a cableless pacing lead fixed to the left ventricle free wall and (2) a subcutaneous ultrasonic transmitter with a battery, which are synchronized with

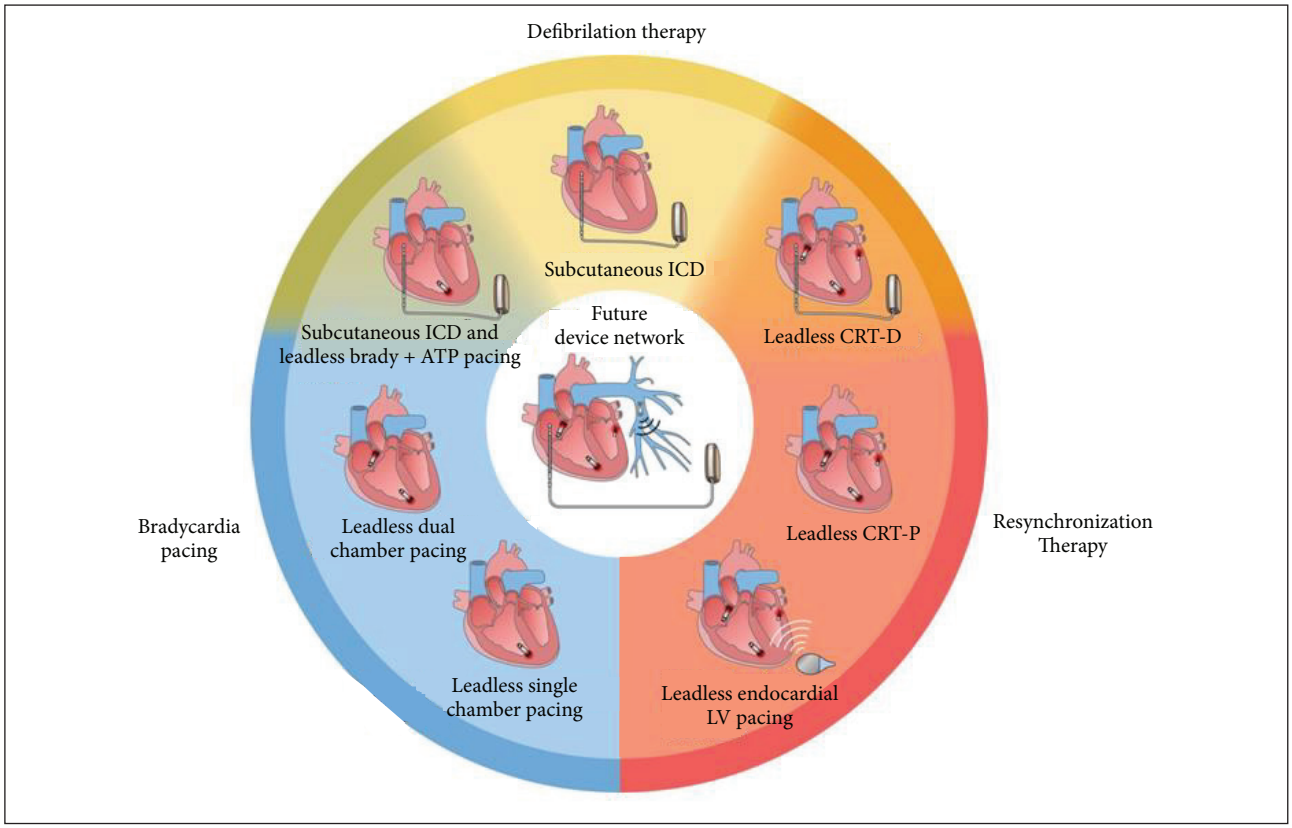

Figure 7. Future perspectives for artificial cardiac pacing[56].

the right side of the pacing system and emits ultrasonic pulses. The stimulation lead converts the ultrasound energy into electrical stimuli, resulting in left ventricle stimulation for cardiac resynchronization. A large multicenter FDA clinical trial is planned to begin in the near future[53].

It is also expected that leadless stimulation can be combined with defibrillation therapy. Although there is no vast clinical experience with this combination, there are reports of concomitant but noncommunicative implants of S-ICD and LLPM[54,55].

In addition, a third LLPM system that can provide antitachycardia stimulation (ATP) when associated with an S-ICD has been successfully tested in a pre-clinical study. It is expected that clinical trials of this combination therapy will begin soon[56](Fig. 7).

CONCLUSION

Artificial heart pacing has been in constant evolution since the initial experiences in the area, however, there is still great concern in relation to complications related to implants, especially those related to leads that are still responsible for significant morbidity. For this reason, the possibility of implanting as few transvenous electrodes as possible should always be considered.

It is expected that in the coming years technological and knowledge advances will occur in the field of leadless stimulation, allowing these devices to be incorporated into clinical practice on a routine basis.

Today, if ventricular electrode implantation in cases of SND with preserved AV conduction is rationalized, atrial electrode implantation in the ICDs without the need for antibradicardia stimulation or ventricular electrodes in cases without the need for ATP considering the subcutaneous ICDs implant, this article will have fulfilled its role.

REFERENCES

1. Raatikainen MJP, Arnar DO, Merkely B, Camm AJ, Hindricks G. Access to and clinical use of cardiac implantable electronic devices and interventional electrophysiological procedures in the European Society of Cardiology Countries: 2016 Report from the European Heart Rhythm Association. EP Eur. 2016; 18(IS 3):iii1–79. https://doi.org/10.1093/europace/euw244

2. Greenspon AJ, Patel JD, Lau E, Ochoa JA, Frisch DR, Ho RT et al. Trends in permanent pacemaker implantation in the United States from 1993 to 2009: increasing complexity of patients and procedures. J Am Coll Cardiol. 2012; 60(16):1540–5. https://doi.org/10.1016/j.jacc.2012.07.017

3. Mond HG, Proclemer A. The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009 – a World Society of Arrhythmia's Project. Pacing Clin Electrophysiol. 2011; 34(8):1013–27. https://doi.org/10.1111/j.1540-8159.2011.03150.x

4. Cohen TJ, Asheld WJ, Germano J, Islam S, Patel D. A comparative study of defibrillator leads at a large-volume implanting hospital: results from the Pacemaker and Implantable Defibrillator Leads Survival Study ("PAIDLESS"). J Invasive Cardiol. 2015; 27(6):292–300.

5. U.S. Food and Drug Administration. Safety: Medtronic Sprint Fidelis defibrillator leads. 2007. [citado em 31 Jul 2016]. Disponível em: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=65383

6. U.S. Food and Drug Administration. Safety: St. Jude Medical, Riata and Riata ST silicone endocardial defibrillation leads: class 1 recall – failures with lead insulation. 2016. [citado em 31 Jul 2016]. Disponível em: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=105847

7. Kersten DJ, Yi J, Feldman AM, Brahmbhatt K, Asheld WJ, Germano J, et al. The number of recalled leads is highly predictive of lead failure: results from the Pacemaker and Implantable Defibrillator Leads Survival Study ("PAIDLESS"). J Invasive Cardiol. 2016; 17(4):E198–202.

8. Kirkfeldt RE, Johansen JB, Nohr EA, Jørgensen OD, Nielsen JC. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. Eur Heart J. 2014; 35(18):1186–94. https://doi.org/10.1093/eurheartj/eht511

9. Udo EO, Zuithoff NP, van Hemel NM, de Cock CC, Hendriks T, Doevendans PA, Moons KG. Incidence and predictors of short and long-term complications in pacemaker therapy: The FOLLOWPACE study. Heart Rhythm. 2012; 9(5):728–35. https://doi.org/10.1093/europace/eus054

10. Kirkfeldt RE, Johansen JB, Nohr EA, Moller M, Arnsbo P, Nielsen JC. Pneumothorax in cardiac pacing: a population-based cohort study of 28 860 Danish patients. EP Eur.2012; 14(8):1132–8. https://doi.org/10.1093/europace/eus054

11. Kiviniemi MS, Pirnes MA, Eränen HJK, Kettunen RVJ, Hartikainen JEK. Complications related to permanent pacemaker therapy. Pacing Clin Electrophysiol. 1999; 22(5):711–20. https://doi.org/10.1111/j.1540-8159.1999.tb00534.x

12. Ellenbogen KA, Hellkamp AS, Wilkoff BL, Camunãs JL, Love JC, Hadjis TA, et al. Complications arising after implantation of DDD pacemakers: the MOST experience. Am J Cardiol.

2003; 92(6):740–1. https://doi.org/10.1016/S0002-9149(03)00844-0

13. Haghjoo M, Nikoo MH, Fazelifar AF, Alizadeh A, Emkanjoo Z, Sadr-Ameli MA. Predictors of venous obstruction following pacemaker or implantable cardioverter-defibrillator implantation: a contrast venographic study on 100 patients admitted for generator change, lead revision, or device upgrade. EP Eur. 2007; 9(5):328–32. https://doi.org/10.1093/europace/eum019

14. Harcombe AA, Newell SA, Ludman PF, Wistow TE, Sharples LD, Schofield PM, et al. Late complications following permanent pacemaker implantation or elective unit replacement. Heart. 1998; 80(3):240–4. https://doi.org/10.1136/hrt.80.3.240

15. Brunner MP, Cronin EM, Wazni O, Baranowski B, Saliba WI, Sabik JF, et al. Outcomes of patients requiring emergent surgical or endovascular intervention for catastrophic complications during transvenous lead extraction. Heart Rhythm. 2014; 11(3):419–25. https://doi.org/10.1016/j.hrthm.2013.12.004

16. Tarakji KG, Wazni OM, Harb S, Hsu A, Saliba W, Wilkoff BL. Risk factors for 1-year mortality among patients with cardiac implantable electronic device infection undergoing transvenous lead extraction: the impact of the infection type and the presence of vegetation on survival. EP Eur. 2014; 16(10):1490–5. https://doi.org/10.1093/europace/euu147

17. Ahmed FZ, Fullwood C, Zaman M, Qamruddin A, Cunnington C, Mamas MA, et al. Cardiac implantable electronic device (CIED) infections are expensive and associated with prolonged hospitalisation: UK retrospective observational study. PLOS ONE. 2019; 14(3):1–13. https://doi.org/10.1371/journal.pone.0213682

18. Hauser RG, Hayes DL, Kallinen LM, Cannom DS, Epstein AE, Almquist AK, et al. Clinical experience with pacemaker pulse generators and transvenous leads: An 8-year prospective multicenter study. Heart Rhythm. 2007; 4(2):154–60. https://doi.org/10.1016/j.hrthm.2006.10.00919

19. Maisel WH, Hauser RG, Hammill SC, Hauser RG, Ellenbogen KA, Epstein AE, et al. Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines. Heart Rhythm. 2009; 6(6):869–85. https://doi.org/10.1016/j.hrthm.2009.04.02420

20. Connolly SJ, Kerr CR, Gent M, Roberts RS, Yusuf S, Gillis AM, et al. Effects of Physiologic Pacing versus Ventricular Pacing on the Risk of Stroke and Death Due to Cardiovascular Causes. N Engl J Med. 2000; 342(19):1385–91. https://doi.org/10.1056/NEJM20000511342190221

21. Kerr CR, Connolly SJ, Abdollah H, Roberts RS, Gent M, Yusuf S, et al. Canadian trial of physiological pacing: effects of physiological pacing during long-term follow-up. Circulation. 2004; 109(3):357–62. https://doi.org/10.1161/01.CIR.0000109490.72104.EE22

22. Lamas GA, Lee KL, Sweeney MO, Silverman R, Leon A, Yee R. Ventricular pacing or dual-chamber pacing for sinus-node dysfunction. N Engl J Med. 2002; 346(24):1854–62. https://doi.org/10.1056/NEJMoa01304023

23. Healey JS, Toff WD, Lamas GA, Andersen HR, Thorpe KE, Ellenbogen KA, et al. Cardiovascular outcomes with atrial-based pacing compared with ventricular pacing meta-analysis of randomized trials, using individual patient data. Circulation. 2006; 114(1):11–7. https://doi.org/10.1161/CIRCULATIONAHA.105.610303

24. Castelnuovo E, Stein K, Pitt M, Garside R, Payne L. The effectiveness and cost-effectiveness of dual-chamber pacemakers compared with single-chamber pacemakers for bradycardia due to atrioventricular block or sick sinus syndrome: systematic review and economic evaluation. Health Technol Assess. 2005; 9(43):1–269. https://doi.org/10.3310/hta943025

25. Nielsen JC, Thomsen PEB, Højberg S, Møller M, Vesterlund T, Dalsgaard D, et al. A comparison of single-lead atrial pacing with dual-chamber pacing in sick sinus syndrome. Eur Heart J.2011; 32(6):686–96. https://doi.org/10.1093/eurheartj/ehr02226

26. Senaratne J, Herath T, Beaudette D, Irwin M, Gulamhusein S, Senaratne M. Safety and efficacy of AAIR pacing in selected patients with sick sinus syndrome. Medicine. 2018; 97(42):1–6. https://doi.org/10.1097/MD.0000000000001283327

27. Fuganti CJ, Melo CS, Moraes Junior AV, Pachon-Mateos JC, Pereira WL, Galvão Filho SS, et al. Diretrizes Brasileiras de Dispositivos Cardíacos Eletrônicos Implantáveis do Departamento de Estimulação Cardíaca Artificial (DECA) da Sociedade Brasileira de Cirurgia Cardiovascular (SBCCV). J Cardiac Arrythmias. 2015; 28(2 Supl):S1–6228.

28. Brignole M, Auricchio A, Baron-Esquivias, G, Bordachar, P, Boriani G, Breithardt O-A, et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). Eur Heart J. 2013; 34(29):2281–329. https://doi.org/10.1093/eurheartj/eht15029

29. Kusumoto FM, Schoenfeld MH, Barrett C, Edgerton JR, Ellenbogen KA, Gold MR, et al. 2018 ACC/AHA/HRS Guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2018; 140(8):e382–482. https://doi.org/10.1161/CIR.0000000000000062830

30. Rattanawong P, Kewcharoen J, Mekraksakit P, Mekritthikrai R, Prasitlumkum N, Vutthikraivit W, et al. Device infections in implantable cardioverter defibrillators versus permanent pacemakers: A systematic review and meta-analysis. J Cardiovasc Electrophysiol. 2019; 30(7):1053–65. https://doi.org/10.1111/jce.13932

31. Kleemann T, Becker T, Doenges K, Vater M, Senges J, Schneider S, et al. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. Circulation. 2007; 115(19):2474–80. https://doi.org/10.1161/CIRCULATIONAHA.106.663807

32. Dewland TA, Pellegrini CN, Wang Y, Marcus GM, Keung E, Varosy PD. Dual-chamber implantable cardioverter-defibrillator selection is associated with increased complication rates and mortality among patients enrolled in the NCDR implantable cardioverter-defibrillator registry. J Am Coll Cardiol. 2011; 58(10):1007–13. https://doi.org/10.1016/j.jacc.2011.04.03933

33. Konstantino Y, Haim M, Boxer J, Goldenberg I, Feldman A, Michowitz Y, et al. Clinical outcomes of single- versus dual-chamber implantable cardioverter defibrillators: lessons from the Israeli ICD registry. J Cardiovasc Electrophysiol.2016; 27(6):718–23. https://doi.org/10.1007/s00392-019-01584-x34

34. 34. Bogossian H, Frommeyer G, Hochadel M, Ince H, Spitzer SG, Eckardt L, et al. Single chamber implantable cardioverter defibrillator compared to dual chamber implantable cardioverter defibrillator: less is more! Data from the German Device Registry. Clin Res Cardiol. 2019. https://doi.org/10.1007/s00392-019-01584-x35

35. Defaye P, Boveda S, Klug D, Beganton F, Piot O, Narayanan K, et al. (2017). Dual- vs. single-chamber defibrillators for primary prevention of sudden cardiac death: long-term follow-up of the Défibrillateur Automatique Implantable — Prévention primaire registry. EP Eur.2017; 19(9):1478–84. https://doi.org/10.1093/europace/euw23036

36. Auricchio A, Hudnall JH, Schloss EJ, Sterns LD, Kurita T, Meijer A, et al. Inappropriate shocks in single-chamber and subcutaneous implantable cardioverter-defibrillators: a systematic review and meta-analysis. EP Eur. 2017;19(12):1973–80. https://doi.org/10.1093/europace/euw41537

37. Worden NE, Alqasrawi M, Krothapalli SM, Mazur A. "Two for the price of one": A single-lead implantable cardioverter-defibrillator system with a floating atrial dipole. J Atr Fibrillation. 2016; 8(6):1396.38.

38. Higgins SL, Alexander DC, Kuypers CJ, Brewster SA. The subcutaneous array: a new lead adjunct for the transvenous ICD to lower defibrillation thresholds. Pacing Clin Electrophysiol. 1995; 18(8):1540–8. https://doi.org/10.1111/j.1540-8159.1995.tb06740.x

39. Kühlkamp V, Dörnberger V, Khalighi K, Suchalla CMR, Ziemer G, Seipel L. Effect of a single element subcutaneous array electrode added to a transvenous electrode configuration on the defibrillation field and the defibrillation threshold. Pacing Clin Electrophysiol. 1998; 21(12):2596–605. https://doi.org/10.1111/j.1540-8159.1998.tb00036.x

40. Gradaus R, Block M, Seidl K, Brunn J, Isgro F, Hammel D, et al. Defibrillation efficacy comparing a subcutaneous array electrode versus an "active can" implantable cardioverter defibrillator and a subcutaneous array electrode in addition to an "active can" implantable cardioverter defibrillator: results from active can versus array trials I and II. J Cardiovasc Electrophysiol. 2001; 12(8):921–7. https://doi.org/10.1046/j.1540-8167.2001.00921.x

41. Madan N, Gaynor JW, Tanel R, Cohen, M, Nicholson S, Vetter V, Rhodes L. Single-finger subcutaneous defibrillation lead and "active can": a novel minimally invasive defibrillation configuration for implantable cardioverter-defibrillator implantation in a young child. J Thorac Cardiovasc Surg. 2003; 126(5):1657–9. https://doi.org/10.1016/S0022-5223(03)01032-8

42. Boston Scientific. Produtos - Desfibriladores (CDI) - Sistema S-ICD™. c2020. [citado em: 3 Abr 2020]. Disponível em: https://www.bostonscientific.com/pt-BR/products/defibrillators/s-icd1.html

43. Lambiase PD, Barr C, Theuns DAMJ, Knops R, Neuzil P, Johansen JB, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. Eur Heart J. 2014; 35(25):1657–65. https://doi.org/10.1093/eurheartj/ehu112

44. Knops RE, Nordkamp LRAO, Groot JR, Wilde AAM. Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator. Heart Rhythm. 2013; 10(8):1240–43. https://doi.org/10.1016/j.hrthm.2013.05.01645

45. Weiss R, Knight BP, Gold MR, Leon AR, Herre JM, Hood M, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation. 2013; 128(9):944-53. https://doi.org/10.1161/CIRCULATIONAHA.113.003042

46. Priori SG, Blomström-Lundqvist C, Mazzanti A, Blom N, Borggrefe M, Camm J, et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. Rev Esp Cardiol (English Edition). 2016; 69(2):176. https://doi.org/10.1016/j.rec.2016.01.001

47. Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med. 2005; 352(3):225–37. http://doi.org/10.1056/nejmoa043399

48. Poole JE, Gold MR. Who should receive the subcutaneous implanted defibrillator? The subcutaneous implantable cardioverter defibrillator (ICD) should be considered in all ICD patients who do not require pacing. Circulation. 2013; 6(6):1236–45. https://doi.org/10.1161/CIRCEP.113.000481

49. Wathen MS, DeGroot PJ, Sweeney MO, Stark AJ, Otterness MF, Adkisson WO, et al. Prospective randomized multicenter trial of empirical antitachycardia pacing versus shocks for spontaneous rapid ventricular tachycardia in patients with implantable cardioverter-defibrillators: Pacing Fast Ventricular Tachycardia Reduces Shock Therapies (PainFREE Rx II) trial results. Circulation. 2004; 110(17):2591–6. https://doi.org/10.1161/01.CIR.0000145610.64014.E4

50. 50. Reddy VY, Knops RE, Sperzel J, Miller MA, Petru J, Simon J, et al. Permanent leadless cardiac pacing: results of the LEADLESS trial. Circulation. 2014; 129(14):1466–71. https://doi.org/10.1161/CIRCULATIONAHA.113.006987

51. 51. Reddy VY, Exner DV, Cantillon DJ, Doshi R, Bunch TJ, Tomassoni GF, et al. Percutaneous implantation of an entirely intracardiac leadless pacemaker. N Engl J Med. 2015; 373:1125–35. https://doi.org/10.1056/NEJMoa1507192

52. 52. Reynolds D, Duray GZ, Omar R, Soejima K, Neuzil P, Zhang S, et al. A leadless intracardiac transcatheter pacing system. N Engl J Med. 2016; 374(6):533–41. https://doi.org/10.1056/NEJMoa151164353

53. 53. Auricchio A, Delnoy P-P, Butter C, Brachmann J, Van Erven L, Spitzer S, et al. Feasibility, safety, and short-term outcome of leadless ultrasound-based endocardial left ventricular resynchronization in heart failure patients: results of the Wireless Stimulation Endocardially for CRT (WiSE-CRT) study. EP Eur. 2014; 16(5):681–8. https://doi.org/10.1093/europace/eut43554

54. 54. Tjong FVY, Brouwer TF, Smeding L, Kooiman KM, Groot JR, Ligon D, et al. Combined leadless pacemaker and subcutaneous implantable defibrillator therapy: feasibility, safety, and performance. EP Eur. 2016; 18(11):1740–7. https://doi.org/10.1093/europace/euv45755

55. 55. Mondésert B, Dubuc M, Khairy P, Guerra PG, Gosselin G, Thibault B. Combination of a leadless pacemaker and subcutaneous defibrillator: first in-human report. Heart Rhythm Case Rep. 2015; 1(6):469–71. https://doi.org/10.1016/j.hrcr.2015.07.00956

56. 56. Tjong FVY, Brouwer TF, Kooiman KM, Smeding L, Koop B, Soltis B, et al. Communicating antitachycardia pacing-enabled leadless pacemaker and subcutaneous implantable defibrillator. J Am Coll Cardiol. 2016; 67(15):1865–66. https://doi.org/10.1016/j.jacc.2016.02.039