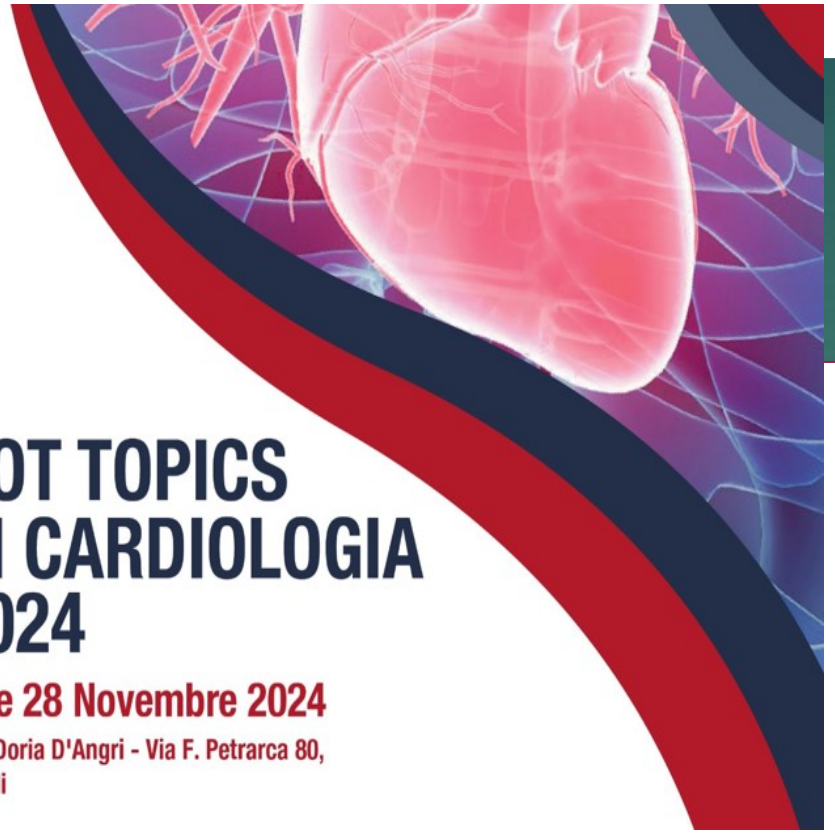


Novità in aritmologia

SALVATORE CRISPO
CARDIOLOGIA CON UTIC ED EMODINAMICA
AORN A CARDARELLI

FA

- Nuovi metodi

La FDA approva il sistema a doppia energia per l'ablazione della fibrillazione atriale

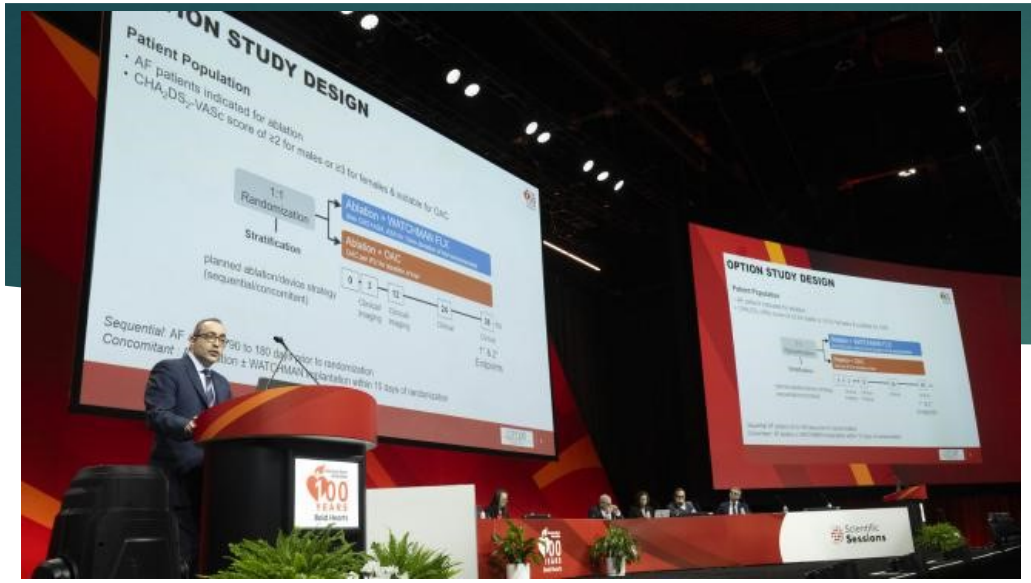
Il sistema di mappatura e ablazione Affera è il primo sul mercato in grado di erogare sia energia a campo pulsato che a radiofrequenza.

di **Todd Neale** | 28 OTTOBRE 2024

FDA Approves Varipulse Pulsed-Field Ablation System for AF

The technology is integrated with company's electroanatomical mapping system, which helps guide operators during AF ablation.

by Michael O'Riordan | NOVEMBER 07, 2024



L’ occlusione dell'auricola sinistra (LAAO) sembra essere una valida alternativa all'anticoagulazione orale per la prevenzione dell'ictus in pazienti selezionati sottoposti ad ablazione transcatetere per fibrillazione atriale (FA), come dimostra lo studio OPTION.

ridotto il rischio di emorragia, garantendo al contempo un'efficacia non inferiore in termini di rischio di morte per tutte le cause, ictus o embolia sistemica in 3 anni di follow-up

Arruolando una popolazione a basso rischio con bassi tassi di eventi, "probabilmente si troverà la non inferiorità

"in una popolazione sottoposta ad ablazione con un punteggio CHA_2DS_2-VASc di almeno 2 negli uomini e di almeno 3 nelle donne, è ragionevole prendere in considerazione la chiusura dell'auricola sinistra", ha detto Wazni a TCTMD, "invece di continuare l'anticoagulazione orale".

I PM Leadless

- Bicamerali
- Nuovi accessi
- Maggiore attenzione ai sanguinamenti

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Dual-Chamber Leadless Pacemaker

Reinoud E. Knops, M.D., Ph.D., Vivek Y. Reddy, M.D., James E. Ip, M.D., Rahul Doshi, M.D., Derek V. Exner, M.D., M.P.H., Pascal Defaye, M.D., Robert Canby, M.D., Maria Grazia Bongiorni, M.D., Morio Shoda, M.D., Gerhard Hindricks, M.D., Petr Neužil, M.D., Mayer Rashtian, M.D., Karel T.N. Breeman, M.D., Jordan R. Nevo, M.S., Leonard Ganz, M.D., Chris Hubbard, M.B.A., and Daniel J. Cantillon, M.D., for the Aveir DR i2i Study Investigators*

N Engl J Med 2023;388:2360-70.

HeartRhythm

The Official Journal of the Heart Rhythm Society, The Cardiac Electrophysiology Society, and The Pediatric & Congenital Electrophysiology Society

Heart Rhythm Society

Leadless Pacing

Check for updates

Six-month electrical performance of the first dual-chamber leadless pacemaker

Gerhard Hindricks, MD, PhD, FHRS,[1] Rahul Doshi, MD, FHRS,[2] Pascal Defaye, MD,[3] Derek V. Exner, MD, PhD, FHRS,[4] Vivek Y. Reddy, MD,[5] Reinoud E. Knops, MD, PhD,[6] Robert Canby, MD, FHRS,[7] Morio Shoda, MD, PhD,[8] Maria Grazia Bongiorni, MD,[9] Petr Neužil, MD, PhD,[10] Thomas Callahan, MD, FHRS,[11] Sri Sundaram, MD, FHRS,[12] Nima Badie, PhD,[13] James E. Ip, MD, FHRS[14]

CONCLUSION This first in-human evaluation of the new dua
l-chamber leadless pacemaker
system demonstrated reliable electrical performance throughout
the initial 6-month evaluation
period.

(Heart Rhythm 2024;21:1929–1938)

HeartRhythm

The Official Journal of the Heart Rhythm Society, The Cardiac Electrophysiology Society, and The Pediatric & Congenital Electrophysiology Society

Heart Rhythm Society

Implantation techniques for a helix-fixation dual-chamber leadless pacemaker

Petr Neuzil, MD, PhD,[1] Chris Hubbard, MBA,[2] Rahul N. Doshi, MD, FHRS,[3] Vivek Y. Reddy, MD,[1,4] Robert Canby, MD, FHRS,[5] Pascal Defaye, MD,[6] Derek V. Exner, MD, FHRS,[7] Morio Shoda, MD,[8] Maria Grazia Bongiorni, MD,[9] Gerhard Hindricks, MD,[10] Thomas Callahan, MD, FHRS,[11] Sri Sundaram, MD, FHRS,[12] Kenneth P. Bruhns,[2] Daniel F. Booth, MEng,[2] Reinoud E. Knops, MD, PhD,[13] James E. Ip, MD, FHRS[14]

ABSTRACT

In a pivotal trial (NCT05252702), the AVEIR DR (Abbott) leadless pacemaker system was found to be safe and effective in delivering DDDR synchronous atrial and ventricular pacing. This dual-chamber system employs 2 leadless pacemakers with implant-to-implant communication. Although implantation of the ventricular device as a single-chamber pacemaker has been well described, there are additional considerations surrounding the dual-chamber implantation procedure. Herein, we review the dual-chamber leadless pacemaker implantation workflow while providing guidance to optimize safe and effective implantation procedures.

KEYWORDS AVEIR DR; AV synchrony; Dual-chamber leadless pacemaker; Implant technique; i2i communication

(Heart Rhythm 2024;■:1–11)

Introduction

Leadless pacemakers (LPs) are a viable, miniaturized alternative to conventional, transvenous, lead-based cardiac pacemaker systems. Following the pivotal clinical trial (AVEIR DR i2i study, NCT05252702),[1] approvals were obtained by the Food and Drug Administration and for the European Union for the AVEIR DR Dual-Chamber Leadless Pacemaker System (Abbott, Abbott Park, IL) as well as AVEIR AR for standalone AAI(R) pacing. AVEIR DR is the first implantable and retrievable dual-chamber LP system and was designed to deliver atrioventricular (AV) synchronous pacing and sensing.[2] The DR system consists of right atrial (RA) and right ventricular (RV) LPs (aLP, vLP), introducer sheath, loading tool, delivery catheter (DC), retrieval catheter (RC), link module, and programmer software application.

Features of the aLP and vLP are shown in Table 1 and Figure 1. The inner helix of the aLP serves to provide electrical performance and secondary fixation in the right atrium. The aLP length (32.2 mm) was shortened compared with the vLP (38.0 mm) to accommodate the smaller anatomy of atrial structures. The devices are capable of wireless, implant-to-implant (i2i) communication between paired LPs, enabling DDD(R) pacing. In addition, the system is upgradable—either LP can be implanted for single-chamber therapy, with the second LP later added for dual-chamber therapy. This manuscript reviews the dual-chamber LP implantation procedure, with particular focus on aLP implantation techniques and considerations for i2i communication. These techniques were drawn from experience in the aforementioned clinical trial, which

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DEVICES

WILEY PACE

Leadless pacing: Going for the jugular

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*Medtronic

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Abstract

Background: Leadless pacing is generally performed from a femoral approach. However, the femoral route is not always available. Until now, data regarding implantation using a jugular approach other than a single-case report were lacking.

Methods: The case records of all patients who underwent internal jugular venous (IJV) leadless pacemaker implantation (Micra, Medtronic, Dublin, Ireland) at our center were analyzed retrospectively.

Results: Nineteen patients underwent IJV leadless pacemaker implantation, nine females, mean age of 77.5 ± 9.6 years; permanent atrial fibrillation in all patients with normal left ventricular ejection fraction. Implant indication was atrioventricular conduction disturbance in 10, pre-AV node ablation in seven, and replacement of a conventional VVI pacemaker in two (infection in one and lead malfunction in the other). The device was positioned at the superior septum in seven patients, apicoseptal in seven patients, and midseptal in five patients. In 12 patients, a sufficient device position was obtained at the first attempt, in three at the second, in one at the third, in one at the fourth, and in two at the sixth attempt.

The mean pacing threshold was 0.56 ± 0.39V at 0.24-ms pulse width, sensed amplitude was 9.1 ± 3.2 mV, mean fluoroscopy duration was 3.1 ± 1.6 min. There were no vascular or other complications. At follow-up, electrical parameters remained stable in 18 of 19 patients.

Conclusion: Although experience is minimal, we suggest that the IJV approach is safe and may be considered in patients where the femoral approach is contraindicated.

KEYWORDS
jugular vein, leadless pacing, pacemaker

Pacing Clin Electrophysiol. 2019;42:395–399

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 9, NO. 8, 2023

PUBLISHED BY ELSEVIER

IMAGES AND VIGNETTES IN CLINICAL ELECTROPHYSIOLOGY

Leadless Pacemaker Implantation Using a Superior Approach When a Conventional, Femoral Implant Fails

James E. Ip, MD

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 9, NO. 8, 2023 Ip AUGUST 2023:1838 – 1839

ESC European Society of Cardiology
Europace (2024) 26, euae199
https://doi.org/10.1093/europace/euae199

CLINICAL RESEARCH

Leadless pacemaker implantation via the internal jugular vein

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ESC European Society of Cardiology
Europace (2024) 26, euae199
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CLINICAL RESEARCH

Leadless pacemaker implantation via the internal jugular vein

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Received 1 June 2024; accepted after revision 16 July 2024; online publish-ahead-of-print 25 July 2024

Aims Leadless pacemaker therapy was introduced to overcome lead- and pocket-related complications in conventional transvenous pacemaker systems. Implantation via the femoral vein, however, may not always be feasible. The aim of this study was to evaluate leadless pacemaker implantation using a jugular vein approach and compare it to the standard implantation via the femoral vein.

Methods and results The records of the first consecutive 100 patients undergoing Micra™ leadless pacemaker implantation via the right internal jugular vein from two centres were included in this study. Peri-procedural safety and efficacy of the jugular approach were compared to the first 100 patients using a femoral implantation approach at the University Hospital Zurich. One hundred patients underwent successful implantation of a leadless pacemaker via the internal jugular vein (mean age, 81.18 ± 8.29, 60% males). Mean procedure time was 35.63 ± 10.29 min with a mean fluoroscopy time of 4.66 ± 5.16 min. The device was positioned at the inferior septum in 25 patients, at the high septum in 24 patients, and mid-septum in 51 patients. The mean pacing threshold was 0.56 ± 0.35 V at 0.24 ms pulse width with a sensed amplitude of 10.0 ± 4.4 mV. At follow-up, electrical parameters remained stable in all patients. Compared with femoral implantation, patients undergoing the jugular approach were of similar age and had similar comorbidities. Mean procedure (48.9 ± 21.0 min) and fluoroscopy times (7.7 ± 7.8 min, both $P < 0.01$) were shorter compared to the femoral approach. Electrical parameters were similar between the two approaches. There were only two complications during jugular veinous implantations (1 pericardial effusion and 1 dislocation), compared to 16 complications using the femoral approach (1 pericardial effusion, 2 femoral artery injuries, and 13 major groin haematomas).

Conclusion The jugular approach may represent a safe and efficient alternative to femoral implantation of the Micra leadless pacemaker.

Europace (2024) 26, euae199 https://doi.org/10.1093/europace/euae199

REVIEW

New approaches to achieving hemostasis after venous access in cardiovascular patients

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June 20, 2022

ABSTRACT

Recent decades have seen a series of advances in percutaneous transvenous procedures for cardiac arrhythmias, including the implantation of leadless pacemakers. Many of these procedures require the insertion of large caliber sheaths in large veins, usually the femoral vein. Securing hemostasis efficiently and reliably at the access site is a key step to improving a procedure's safety profile. Traditionally, hemostasis was achieved by manual compression of venous access sites, but the trend toward larger sheaths and the increased use of uninterrupted anticoagulation has pushed the limits of this method. Achieving hemostasis by compression alone in these circumstances requires more attention and longer duration, leading to greater patient discomfort and prolonged immobility. In turn, manual compression may be more time-consuming for medical professionals and increase the number of occupied hospital beds. New approaches have been developed to facilitate early ambulation, decrease patient discomfort, and address the risk of access site complications. These approaches include vascular closure devices and subcutaneous suture techniques including figure-of-eight and purse-string sutures. This article reviews the new approaches applied to achieve venous access site hemostasis in patients undergoing transvenous procedures for cardiac arrhythmias.

Key words: catheter ablation, percutaneous cardiac catheterization procedures, leadless pacemaker, suture techniques, manual compression, vascular closure device

INTRODUCTION

Percutaneous transvenous procedures for

portion of patients who require long-term anticoagulation, and acceptance of older and

Stimolazione di branca

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 10, NO. 10, 2024

ORIGINAL RESEARCH

INNOVATIONS IN CLINICAL ELECTROPHYSIOLOGY

Standard Defibrillator Leads for Left Bundle Branch Area Pacing

First-in-Man Experience and Short-Term Follow-Up

Guram Imnadze, MD,[a] Thomas Fink, MD,[a] Thomas Eitz, MD,[b] Yuri Bocchini, MD,[a] Lilit Antonyan, MD,[a] Karen Harutyunyan, MD,[a] Valérian Valiton, MD,[c] Maxim Didenko, MD,[a] Philipp Sommer, MD,[a] Haran Burri, MD[c]

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 10, NO. 10, 2024
Standard Defibrillator Leads for LBBAP OCTOBER 2024:2263 – 2268

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 10, NO. 2, 2024

PUBLISHED BY ELSEVIER

ORIGINAL RESEARCH

CIED - PHYSIOLOGICAL PACING

Left Bundle Branch Pacing vs Left Ventricular Septal Pacing vs Biventricular Pacing for Cardiac Resynchronization Therapy

Juan C. Díaz, MD,[a,b] Usha B. Tedrow, MD, MS,[b,c] Mauricio Duque, MD,[d] Julian Aristizabal, MD,[e] Eric D. Braunstein, MD,[f] Jorge Marin, MD,[g] Cesar Nillo, MD,[g] Oriana Bastidas, MD,[f] Nestor Lopez Cabanillas,[g] Bruce A. Koplan, MD, MPH,[h] Carolina Hoyos, MD,[h] Carlos D. Matos, MD,[h] Daniela Hincapie, MD,[h] Alejandro Velasco, MD,[h] Nathaniel A. Steiger, MD,[h] Sunil Kapur, MD,[h] Thomas M. Tedrow, MD,[h] Paul C. Zei, MD, PhD,[h] William H. Sauer, MD,[c] Jorge E. Romero, MD[a]

ABSTRACT

BACKGROUND Left bundle branch pacing (LBBP) and left ventricular septal pacing (LVSP) are considered to be acceptable as LBBAP strategies. Differences in clinical outcomes between LBBP and LVSP are yet to be determined.

OBJECTIVES The purpose of this study was to compare the outcomes of LBBP vs LVSP vs BiVP for CRT.

METHODS In this prospective multicenter observational study, LBBP was compared with LVSP and BiVP in patients undergoing CRT. The primary composite outcome was freedom from heart failure (HF)-related hospitalization and all-cause mortality. Secondary outcomes included individual components of the primary outcome, postprocedural NYHA functional class, and electrocardiographic and echocardiographic parameters.

RESULTS A total of 415 patients were included (LBBP: n = 141; LVSP: n = 31; BiVP: n = 243), with a median follow-up of 399 days (Q1-Q3: 249.5-554.8 days). Freedom from the primary composite outcome was 76.6% in the LBBP group and 48.4% in the LVSP group (HR: 1.37; 95% CI: 1.143-1.649; $P = 0.001$), driven by a 31.4% absolute increase in freedom from HF-related hospitalizations (69% vs 51.6%; HR: 3.55; 95% CI: 1.856-6.791; $P < 0.001$) without difference in all-cause mortality. LBBP was also associated with a higher freedom from the primary composite outcome compared with BiVP (HR: 1.43; 95% CI: 1.175-1.730; $P < 0.001$), with no difference between LVSP and BiVP.

CONCLUSIONS In patients undergoing CRT, LBBP was associated with improved outcomes compared with LVSP and BiVP, while outcomes between BiVP and LVSP are similar. (J Am Coll Cardiol EP 2024;10:295–305) © 2024 by the American College of Cardiology Foundation.

Le aritmie Ventricolari

L'ablazione transcatetere di prima linea funziona per la soppressione della TV post-infarto miocardico: VANISH2

Entrambi gli studi VANISH hanno arruolato esclusivamente pazienti che avevano già un ICD in atto ma che avrebbero potuto trarre beneficio dalla soppressione della TV.

Altri studi (PAUSE-SCD , PREVENTIVE-VT , SMASH-VT e VTACH) hanno supportato il vantaggio dell'ablazione precoce nella TV anche prima dell'impianto dell'ICD.

Review > J Innov Card Rhythm Manag. 2024 Nov 15;15(11):6088-6094.
doi: 10.19102/icrm.2024.15115. eCollection 2024 Nov.

Device Therapy in Cardiac Sarcoidosis: Current Review, Challenges, and Future Prospects

Mohamed ElRefai [1], Christina Menexi [2], Paul R Roberts [3 4]

Affiliations + expand

PMID: 39563989 PMCID: PMC11573303 DOI: 10.19102/icrm.2024.15115

Abstract

Sarcoidosis is a complex disease characterized by inflammatory granulomas that can affect various organs, including the heart. The diagnosis of cardiac sarcoidosis poses challenges, and current criteria involve the use of advanced imaging techniques and histological confirmation. Clinical manifestations of cardiac sarcoidosis vary widely, ranging from heart block to ventricular tachycardia and heart failure. Sudden cardiac death (SCD) is a significant concern, and implantable cardioverter-defibrillators (ICDs) are recommended for preventing SCD in high-risk cases. However, some patients with cardiac sarcoidosis do not meet the current guidelines for ICD implantation, leaving them at risk. Traditional transvenous ICDs are associated with complications, especially in immunosuppressed patients. The subcutaneous implantable cardioverter-defibrillator (S-ICD) offers a potential solution, as it avoids vascular complications and reduces the risk of infections. However, concerns regarding inappropriate shocks and the lack of pacing therapy limit its widespread use. Leadless pacing combined with S-ICD represents a potential novel approach to managing cardiac sarcoidosis patients. Ongoing human clinical trials are expected to shed light on the safety and efficacy of this combined therapy. Cardiac sarcoidosis patients, who have been underserved by traditional device therapies, may benefit from this personalized approach. Further research is needed to guide the management of SCD risk in this population.

Keywords: Cardiac sarcoidosis; leadless pacemaker; subcutaneous ICD; sudden cardiac death.

Review > Europace. 2024 Nov 1;26(11):euae272. doi: 10.1093/europace/euae272.

Drug therapy and catheter ablation for management of arrhythmias in continuous flow left ventricular assist device's patients: a Clinical Consensus Statement of the European Heart Rhythm Association and the Heart Failure Association of the ESC

Petr Peichl [1], Antoni Bayes-Genis [2], Thomas Deneke [3], Ovidiu Chioncel [4 5], Marta deRiva [6], Maria Generosa Crespo-Leiro [7], Antonio Frontera [8], Finn Gustafsson [9], Raphaël P Martins [10], Matteo Pagnesi [11], Philippe Maury [12], Mark C Petrie [13], Frederic Sacher [14], Offer Amir [15], Luigi Di Biase [16], Isabel Deisenhofer [17], Alessio Gasparetti [18], Mélèze Hocini [19], Francisco Moscoso Costa [20], Brenda Moura [21 22], Hadi Skouri [23 24], Carlo Gabriele Tocchetti [25], Maurizio Volterrani [26], Reza Wakili [27]

Affiliations + expand

PMID: 39478667 PMCID: PMC11580222 DOI: 10.1093/europace/euae272

Abstract

Left ventricular assist devices (LVADs) are an increasingly used strategy for the management of patients with advanced heart failure. Although these devices effectively improve survival, atrial and ventricular arrhythmias are common with a prevalence of 20-50% at one year after LVAD implantation. Arrhythmias predispose these patients to additional risk and are associated with considerable morbidity from recurrent implantable cardioverter-defibrillator shocks, progressive failure of the unsupported right ventricle, and herald an increased risk of mortality. Management of patients with arrhythmias and LVAD differs in many aspects from the general population heart failure patients. These include ruling out the reversible causes of arrhythmias that in LVAD patients may include mechanical irritation from the inflow cannula and suction events. For patients with symptomatic arrhythmias refractory to medical treatment, catheter ablation might be relevant. There are specific technical and procedural challenges perceived to be unique to LVAD-related ventricular tachycardia (VT) ablation such as vascular and LV access, signal filtering, catheter manoeuvrability within decompressed chambers, and electroanatomic mapping system interference. In some patients, the arrhythmogenic substrate might not be readily accessible by catheter ablation after LVAD implantation. In this regard, the peri-implantation period offers a unique opportunity to surgically address arrhythmogenic substrate and suppress future VT recurrences. This document aims to address specific aspects of the management of arrhythmias in LVAD patients focusing on anti-arrhythmic drug therapy and ablations.

Keywords: Atrial fibrillation; Catheter ablation; Heart failure; Left ventricular assist device; Ventricular arrhythmia.

June 19, 2023 / Heart, Vascular and Thoracic / Electrophysiology

INTEGRA-D Trial Launch Raises Prospect of Cardiac Contractility Modulation and Defibrillation in a Single Device

First-in-world implantation performed at Cleveland Clinic

Durante la sessione sponsorizzata al THT 2024, il Dr. Niraj Varma presenta la progettazione e i criteri di inclusione dello studio Integra D. CCM-D è un dispositivo sperimentale in studi clinici che ha sia funzionalità CCM che defibrillatore.


BREAKING NEWS
BREAKING
NEWS