Imperial College Healthcare NHS Trust

Fluoroless Conduction System Implant

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STUDY COORDINATION CENTRE: Dr Akriti Naraen
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Protocol authorised by:

Name & Role	Date	Signature
Prof. Zachary Whinnett Investigator	01.03.24	Prof. Zachary Whinnett

Study Management Group

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Study Management: Dr Akriti Naraen

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Study Coordination Centre

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Clinical Queries

Clinical queries should be directed to Dr Akriti Naraen who will direct the query to the appropriate person

Sponsor

Imperial College Healthcare NHS Trust is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Level 5 Sherfield building, South Kensington campus

Funder

This study will be funded by the Johnson and Johnson IIS.

This protocol describes the study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the **UK Policy Frame Work for Health and Social Care Research.** It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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Glossary of Terms

CSP: Conduction system pacing
CT: Computed tomography
ECG: Electrocardiogram
EGM: Electrogram
HBP: His-bundle pacing
ICE: Intracardiac echocardiogram
LBBB: Left bundle branch block
LBP: Left bundle pacing
LBAP: Left bundle area pacing
LV: Left ventricle
LVAT: Left ventricular activation time
MRI: Magnetic resonance imaging
RV: Right ventricle
TOE: Transoesophageal echocardiogram
TTE: Transthoracic echocardiogram

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Study Summary

TITLE	Fluoroless Conduction System Implant
DESIGN	Cohort observational study and interventional at validation phase
AIMS	1. Define a feasible fluoroless protocol for conduction system lead implantation
OUTCOME MEASURES	Primary Outcomes: 1. Success rate of conduction system lead implant Secondary Outcomes: 2. Fluoroscopy time 3. Total procedure time 4. Capture threshold 5. Number of times leads deployed 6. Complication rates: a. Lead implanted at the incorrect position: non-septal positions b. Lead displacement c. Lead injury d. Rise in threshold (late complication) e. Vascular injury f. Perforation with or without subsequent tamponade g. Device related infection h. Pneumothorax

POPULATION	Patients with any indication for a pacemaker
ELIGIBILITY	**Main Inclusion Criteria** 1. Patients with a ventricular pacing indication: high grade atrioventricular block and symptomatic trifasicular or bifasicular block. (in order to assess the level of conduction system block) 2. Adults willing to take part (ages 18 – 100 years old) 3. Able to give consent. **Main Exclusion Criteria** 1. Unable to give consent 2. Children age < 18 years and adults > 100 years old 3. Pregnant patients 4. Pacing device in situ 5. Indication for cardiac resynchronisation therapy 5.
DURATION	1 year

1. Introduction

1.1 Background

Discovering how to clinically deliver conduction system pacing efficiently could be a paradigm shift. Early work on conduction system pacing focused on the His bundle, with right atrial mapping for the His signal and deployment of a lumenless pacing lead(1). Left bundle pacing (LBP) then emerged as an alternative, approaching via the basal right ventricular septum to deploy a lead through the septum to capture the left bundle on the left side of the septum(2,3)

Current literature report improved left ventricular function, heart failure outcomes and mortality in conduction system pacing(4,5). Additionally, LBP has a larger target area, can be done with low capture thresholds, has better threshold stability and large amplitude R waves(3). Widespread roll out of conduction system pacing clinically, however, faces three major challenges.

Challenge A1: Identifying target area for lead deployment
Despite growing adoption, conduction system pacing implants remains challenging**.** Even experienced device consultants take time to learn the technique. Experienced centres achieve implant success of 95%, but centres with new conduction system implanters (but highly experienced pacemaker implanters) have rates as low as 56%(6,7).

Fluoroscopic interpretation is challenging, for several reasons. The target area is smaller than conventional right ventricular pacing, and can be even smaller when there is fibrosis in the septum. The chambers may well be dilated, which displaces not only the fluoroscopic position of the target, but also its orientation. The lead can also be difficult to advance, because of septal fibrosis, unrecognised lead entanglement and unclear trans-septal trajectory. Interpretation of surface ECG and lead data is not straightforward either: there are many levels in the conduction system at which block can occur and it is difficult to distinguish them confidently. Lead entanglement and mal-orientation may be detectable with elaborate equipment such as intracardiac echocardiography (ICE) but we do not know what fluoroscopic or electrical features might provide routine clinical operators with a timely warning. Previous approaches to address these issues have involved normal-heart cadaveric studies which do not give the electrical context of a clinical implant(8).

These challenges can be overcome with visualising the cardiac anatomy that can be achieved with electroanatomical mapping. These 3D mapping systems are also being used to develop fluoroless implant strategies. Cumulative radiation exposure is a well-documented operator risk that has been minimised through various approaches that include personal lead protection, lead shields, image intensifier position, reduced frame rate and short acquisitions (9,10). With the reduction in fluoroscopy time in this study, cumulative radiation exposure to implanters is further reduced through a novel method.

Advances in electroanatomical mapping have allowed fluoroless techniques to have similar procedure times to conventional conduction system implant methods. Fluoroless His-bundle implants have been described in small observational studies, using Abbott's Ensite Precision mapping systems. (11–15)

1.2 Original Hypothesis

1. Conduction system leads can be implanted with almost no fluoroscopy using electro-anatomical mapping
2. Using electro-anatomical mapping will increase safety of conduction system lead implantation
3. The procedure times with electro-anatomical mapping will be less than that of conventional methods using fluoroscopy

1.3 Rational for Current Study

Currently conductions system pacing can have long fluoroscopy times when compared to conventional right ventricular pacing. This may be due to difficult cardiac anatomy, altered lead trajectory and obstacles such as entanglement, that is not readily visualised with fluoroscopy. As a result operators experience additional cumulative fluoroscopy times. Our study will devise a standardised implantation protocol using 3D electroanatomical mapping systems to reduce both fluoroscopy and procedure times.

2. Study Objectives

Primary Objective
The primary objective of this study is develop a fluoroless implant protocol of conduction system leads using 3D electroanatomical mapping.

Secondary Objective
The secondary objectives will be
1. To reduce the overall procedure and fluoroscopy time with utilisation of targeted lead deployment.
2. Improve complication rates

3. Recruitment

A total of 75 patients will be recruited for the study

50 patients with a ventricular pacing indication (high grade atrioventricular block and symptomatic trifasicular or bifasicular block) for pacing will be recruited prospectively. The patients will be divided into two groups; 25 patients in the derivation cohort and 25 patients in the validation cohort. The derivation cohort will undergo a detailed research protocol to determine the optimised work flow and this will be applied prospectively to the validation cohort.

The success rates, procedure times, complication rates and fluoroscopy times will be assessed. The 25 patients undergoing conventional methods of conduction system pacing will be recruited as a control arm to compare these outcomes.

In summary, the 75 patients will be grouped as following; 25 patients in the derivation cohort, 25 patients in the validation cohort and 25 patients in the control arm.

4. Methodology

4.1 Derivation

The derivation cohort will comprise of 25 prospectively recruited patients. These patients will undergo the research protocol. In these patients, we will attempt to implant a permanent conduction system pacing lead, in lieu of the RV or LV lead. The lead will be implanted by operators who have implanted more than 40 leads to overcome the learning curve.

Pre-implant

Prior to the procedure, patients will undergo a clinically indicated Cardiac MRI. We will use these scans to retrospectively assess for the presence of potential mechanisms which could prevent successful lead implantation, such as the presence of septal fibrosis and chamber dimensions, so that we can assess how these can contribute to challenges at the time of implant. We will also be able to review mechanisms for *successful* implants. This information will be corroborated with data collected from the electro-anatomical maps.

The MRI scans will also be used to merge the anatomical information using CartoMerge to reduce procedure times by building the anatomical geometry prior to the mapping-catheter collecting this information invasively.

During Implant

The participants will undergo the following procedural steps after written informed consent is gained:

1. A left infraclavicular incision and axillary access for the lead will be gain as per standard clinical protocol.

2. Access from the femoral vein will be sought where a sheath will be placed in the femoral vein to introduce the mapping catheter.

3. Fast anatomical mapping (FAM) of the right atrial and right ventricular anatomy will be made where CartoMerge has not already created this anatomy. This will include the right ventricle, the tricuspid valve and the right ventricular outflow tract. Activation and voltage maps will be then be made of the His-bundle area (including the His cloud), right ventricle, right ventricular outflow tract and right ventricular septum.

   This will help determine a few key aspects
   1. Level of conduction system block and therefore guide site of lead deployment
   2. Anatomy of the right heart and overcome challenges this may propose
   3. Evidence of septal fibrosis and/or scar that need to be overcome
   4. Activation pattern of the septum in conduction system block

4. Anatomical FAM maps, voltage maps and activation patterns will be compared against the data collected from the cardiac MRI to assess
   1. Accuracy of anatomy
   2. Fibrosis and scar patterns

The CartoMerge module will be used to expedite anatomical mapping using the MRI data collected.

5. The mapping catheter will be removed and an intracardiac echo (ICE) catheter, will be inserted through the femoral vein.

6. The conduction system pacing lead will be inserted through the axillary vein. A right atrial lead will be inserted into the right ventricular apex for back up pacing in the instance the conduction system is bumped. The basal-septum, mid-septum, high-septum and anterior walls will be paced to identify electrical markers for optimal implant sites.

7. The lead will be visualised on the Carto maps created.

8. The lead will be deployed at the predetermined target site under direct visualisation using the ICE catheter. Through direct visualisation, three key determinants can be assessed:
    1. Lead trajectory through the septum with the goal of achieving perpendicularity
    2. Lead septum interaction and whether there is evidence of entanglement preventing lead progression.
    3. Relationship between the sheath and lead that can lead to or prevent failure of lead deployment.

9. Once the conduction lead is secured the right atrial lead will be pulled back and secured in the right atrium.

10. The procedure will be completed as per standard clinical implant protocol with routine clinical follow-up thereafter:

The information from echocardiography will be corroborated with the lead-septum interaction visualised on electro-anatomical maps created on CARTO.

In this cohort of patients, the conduction system lead will initially pace the His-bundle then the left bundle in order to collect data for both methods of physiological pacing. The information collected from ICE and electro-anatomical mapping will be used to develop a streamlined workflow that will map targeted areas, where challenging implant sites will be rapidly identified (such as areas of scar), reducing the number of attempted lead deployments and visualise lead-septum interaction, apposition and progression, improving safety parameters.

At the end of the procedure, the lead position will be documented with a very short, *single fluoroscopic acquisition.* This remains integral for future comparison in the instances of lead complications and in particular lead displacement.

4.2 Validation

25 patients will be recruited to the validation cohort.

An optimised work flow will be derived using the information collected from the derivation cohort. Namely, the target areas for FAM and electro-anatomical maps will be determined, and the successful pattern of lead septum interaction on CARTO will be defined.

The streamlined workflow will then be applied to 25 prospective patients. The success rates, procedure time, fluoroscopy time, capture threshold, number of attempted lead deployments and complication rates will be assessed.

4.3 Control Arm

The control arm will consist of 25 patients undergoing a conduction system pacemaker using conventional pacing methods, with the same pacing indications as the study arm.

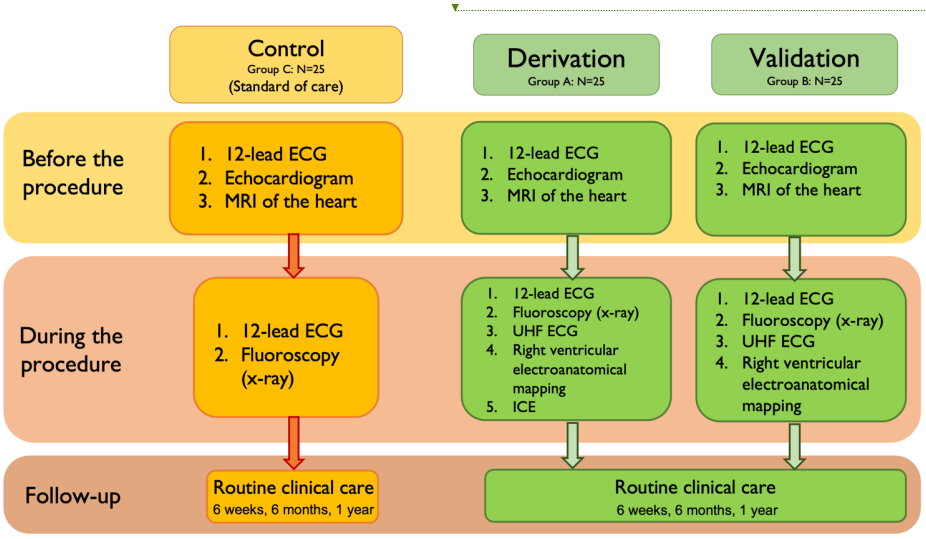

Figure 1: Recruitment workflow

4.4 Follow-up

All 75 patients will have standard clinical follow-up at 6 weeks, 6 months and 1 year. The clinical information at these visits will be used to identify complications rates that will include lead displacement, rise in capture threshold and lead injury, device related infections.

4.5 Burden/Risk

The main burdens for the patient include:

1. The extra time taken to perform the experiments and experimental procedures during their scheduled clinical procedure due to the additional diagnostic investigations. The right heart electro-anatomical mapping will add 10 minutes. The echocardiography will add an additional 5 minutes.
2. The extra access in the groin for the mapping catheter and ICE catheter.
3. Patients receiving unconventional therapy with conduction system lead implantation

The burden will be mitigated by the minimum extra time being used to complete the experiments, the use of local anaesthetic and the immediate removal of extra research related sheaths as soon as they are not needed

The main risks for the patient are:
A conduction system pacing wire is not known to have a higher complication rate compared to a conventional pacing wire. Conduction system pacing wires have been shown to be as effective as conventional pacing wires at preventing slow heart rates and improving heart pumping. If a complication occurs and the conduction system pacing wire cannot be implanted or does not perform as expected during follow-up a procedure will be performed to convert your pacing system to a conventional pacing system.

The additional risks of vascular tube placement include:
- 1% risk of bruising around the area
- 1 in 1000 risk of damage to the blood vessels requiring surgery
- Less than 1 in 500 risk of stroke

The additional risks of intracardiac echocardiogram include
- 1% risk of bruising around the access area in the leg
- Less than 1 in 1000 risk of heart perforation

The additional risks of electro-anatomical mapping include
- Less than 1 in 1000 risk of heart perforation

Therefore, the overall risk of serious complications arising from taking part in the research study are less than 4 in 1000 (0.4%)

Pacemaker implantation involves exposure to ionising radiation to visualise lead implantation. Taking part in this study involves exposure to additional exposure to radiation above the standard clinical procedure due to the additional measurements that will be taken.

Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will increase the chances of this happening to you from 0.01% to 0.1% (13Gy.cm² (2.1mSv) per patient per procedure).

4.6 Study Outcome Measures

Primary Outcome Measures

1. Success rates of conduction system lead implant (fluoroless workflow vs conventional methods)

Secondary Outcome Measures

1. Procedure and fluoroscopy times of the fluoroless workflow vs current conventional methods *of His-bundle and Left-bundle pacing*
2. Procedure and fluoroscopy times of the fluoroless workflow vs conduction system implant to current *right ventricular pacing*
3. Assess capture threshold of His-bundle and Left-bundle pacing from the fluoroless workflow vs that of *conventional methods of conduction system implantation*
4. Number of times leads deployed in the fluoroless protocol vs *conventional methods of conduction system implantation*
5. Complication rates in the fluoroless protocol vs *conventional methods of conduction system implantation:*

a. Lead implanted at the incorrect position: non-septal positions
b. Lead displacement
c. Lead injury
d. Rise in threshold (late complication)
e. Vascular injury
f. Perforation with or without subsequent tamponade
g. Device related infection
h. Pneumothorax

5 Participant Entry

5.1 Pre-registration Evaluations

5.2 Inclusion Criteria

1. Patients with a ventricular pacing indication: high grade atrioventricular block and symptomatic trifasicular, bifasicular block or left bundle branch block LBBB for cardiac resynchronisation therapy
2. Adults willing to take part (ages 18 – 100 years old)
3. Able to give consent.

5.3 Exclusion Criteria

1. Unable to give consent
2. Children age < 18 years and adults > 100 years old
3. Pregnant patients
   - As per standard of care, female patients of child-bearing age will have a urine pregnancy test prior to their procedure.

5.4 Withdrawal criteria

The research protocol will be terminated early if

1. Patients lose their capacity to consent or become clinically unstable
2. The patient chooses to withdraw from the study
3. The sponsor, the chief investigator or the research team review the data and decide to stop the study

5.5 Consent

Patients will be identified by members of their direct care team when they attend clinic appointments or are admitted as an inpatient to the hospital. Patient records may be reviewed to assess suitability and this will be performed by members of the direct care team. Participation in the study will be discussed with the patients by their direct care team and information will only be passed on to the research team with the patients consent. Verbal consent will be gained by the direct care team for personal contact information to be shared with the research team. This will be documented in the patient notes.

The direct care team will make patients aware that participation is voluntary and that if they do not wish to participate it will not affect their usual care.

Consent for the study of the prospectively recruited patients will be obtained by a member of the research team, this will be a physician who is experienced in performing conduction system implantation. Patients will have details of the study discussed with them and any family members or friends the patients wish to be present. They will also be provided with written information (patient information sheets). Patients will be given as much time as they wish, with a minimum of at least 24 hours, to decide whether they wish to participate in the study and will be offered additional visits to further discuss the study if they wish. Patients are able to withdraw their consent from the study at any time. Patients will be made aware that their participation is voluntary and that if they do not want to take part it will not affect their usual care. Patients who agree to take part in the study will sign a consent form, a copy of the form will be given to the patients and a second copy will be kept in their study record file. A copy will also be kept in the site file.

6 Adverse events

6.1 Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

6.2 Reporting Procedures

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

6.3 Non serious AEs

All such events, whether expected or not, should be recorded.

6.4 Serious AEs

An SAE form should be completed and faxed to the Chief Investigator within 24 hours. However, hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the "name of REC when allocated" where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and

- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all related and unexpected SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
RGIT@imperial.ac.uk
Prof. Zachary Whinnett email: z.whinnett@imperial.ac.uk
Please send SAE forms to: Hammersmith Hospital, Du Cane road, London W12 0HS.
Tel: 020 8383 4967 (Mon to Fri 09.00 – 17.00)

7 Assessment and Follow-up

Patients will be followed up for a 1 year period. During this time they will undergo the device interrogation and wound check at 6 weeks as part of standard clinical care. One year after device implantation, patients will undergo a device interrogation follow-up appointment. Any incidental findings that we identify during the study will be reviewed by the research team and reported to the GP and also the cardiology team normally looking after the patient.

Definition of end of Study
The end of the study will be defined as completion of the 1 year follow-up of the 75 prospectively recruited patients for the invasive aspect of the study. This will be the date of the final visit of the last participant at 1 year.

8 Statistics and data analysis

The following statistical analysis has been reviewed and approved by our statistician, Prof. Darrel Francis.

Power Calculations:
25 patients would provide the ability to determine the mean time of lead implantation of 120 minutes with a precision of (as a standard error) approximately ± 10 minutes (assuming standard deviation of 47min)[7]

25 patients will provide the ability to determine the percentage of a successful implant with a precision of a SE (± 8%) of a success rate of approximately 80%
SD of implant time = SD of total procedure time / √2 = 67 / √2 =47.37
SE = SD/ √sample size = 47.37/√25 = 9.47

Data and all appropriate documentation will be stored for a minimum of *5 years after* the completion of the study, including the follow-up period.

To assess the primary outcome of the success rates of the conduction system lead implant using the fluoroless workflow developed during our study, ECG information will be collected and capture will be determined by experts.

Fluoroscopy and procedural times will be analysed with one-way ANOVA. Success rates, capture thresholds and battery life will be analysed with t-test.

9 Regulatory issues

9.1 Ethics approval

The Study Coordination Centre has obtained approval from the "Name of REC when allocated" and Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

9.2 Consent

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

9.3 Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.
Data will be pseudonymised.

9.4 Indemnity

Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Resolution for NHS Trusts in England, which apply to this study

9.5 Sponsor

Imperial College Healthcare NHS Trust will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

9.6 Funding

Johnson and Johnson

Patients' transport in the form of a taxi will be provided as well as refreshments during the additional appointments for purposes of the research study. We have costed £50 for transport and £10 for refreshments per visit.

Researchers will not receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research.

9.7 Audits

The study may be subject to inspection and audit by Imperial College Healthcare NHS Trust under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research

10 Study Management

The day-to-day management of the study will be co-ordinated by Dr Akriti Naraen.

11 Publication Policy

Our aim to publish in a major international cardiology journal and present at international cardiology conferences. Findings will also be published in internal reports and presented in local meetings.

12 References

1. Arnold AD, Whinnett ZI, Vijayaraman P. His-Purkinje conduction system pacing: State of the art in 2020. Arrhythm Electrophysiol Rev. 2020;9(3).
2. Arnold AD, Shun-Shin MJ, Keene D, Howard JP, Chow JJ, Lim E, et al. Electrocardiographic predictors of successful resynchronization of left bundle branch block by His bundle pacing. J Cardiovasc Electrophysiol. 2021;32(2).
3. Huang W, Chen X, Su L, Wu S, Xia X, Vijayaraman P. A beginner's guide to permanent left bundle branch pacing. Heart Rhythm. 2019;16(12).
4. Ali N, Shin MS, Whinnett Z. The Emerging Role of Cardiac Conduction System Pacing as a Treatment for Heart Failure. Vol. 17, Current Heart Failure Reports. 2020.
5. Upadhyay GA, Vijayaraman P, Nayak HM, Verma N, Dandamudi G, Sharma PS, et al. On-treatment comparison between corrective His bundle pacing and biventricular pacing for cardiac resynchronization: A secondary analysis of the His-SYNC Pilot Trial. Heart Rhythm. 2019;16(12).
6. Bhatt AG, Musat DL, Milstein N, Pimienta J, Flynn L, Sichrovsky T, et al. The Efficacy of His Bundle Pacing: Lessons Learned From Implementation for the First Time at an Experienced Electrophysiology Center. JACC Clin Electrophysiol. 2018;4(11).
7. Sharma PS, Naperkowski A, Bauch TD, Chan JYS, Arnold AD, Whinnett ZI, et al. Permanent his bundle pacing for cardiac resynchronization therapy in patients with heart failure and right bundle branch block. Circ Arrhythm Electrophysiol. 2018;11(9).
8. Jastrzębski M, Moskal P, Hołda MK, Strona M, Bednarek A, Kiełbasa G, et al. Deep septal deployment of a thin, lumenless pacing lead: A translational cadaver simulation study. Europace. 2020;22(1).
9. Vano E. Radiation exposure to cardiologists: How it could be reduced. Vol. 89, Heart. 2003.
10. Bru P, Dompnier A, Amara W, Haddad G, Galuscan G, Sagnol P, et al. Radiation exposure during cardiac device implantation: Lessons learned from a multicenter registry. PACE - Pacing and Clinical Electrophysiology. 2020;43(1).
11. Patel H, Hiner E, Naqvi A, Wrobel J, Machado C. The safety and efficacy of electroanatomical mapping (EAM)-guided device implantation. PACE - Pacing and Clinical Electrophysiology. 2019;
12. Richter S, Ebert M, Bertagnolli L, Gebauer R, Lucas J, Scheller D, et al. Impact of electroanatomical mapping-guided lead implantation on procedural outcome of His bundle pacing. Europace. 2021;23(3).
13. Sharma PS, Huang HD, Trohman RG, Naperkowski A, Ellenbogen KA, Vijayaraman P. Low Fluoroscopy Permanent His Bundle Pacing Using Electroanatomic Mapping: A Feasibility Study. Circ Arrhythm Electrophysiol. 2019;12(2).
14. Orlov M V., Koulouridis I, Monin A, Casavant D, Maslov M, Erez A, et al. Direct Visualization of the His Bundle Pacing Lead Placement by 3-Dimensional Electroanatomic Mapping. Circ Arrhythm Electrophysiol. 2019;12(2).
15. Zanon F, Marcantoni L, Centioni M, Pastore G, Baracca E. His Bundle Pacing. Card Electrophysiol Clin. 2022 Jun;14(2):141–9.
16. Deshmukh A, Deshmukh P. His bundle pacing: Initial experience and lessons learned. Vol. 49, Journal of Electrocardiology. 2016.

17. Vijayaraman P, Dandamudi G, Zanon F, Sharma PS, Tung R, Huang W, et al. Permanent His bundle pacing: Recommendations from a Multicenter His Bundle Pacing Collaborative Working Group for standardization of definitions, implant measurements, and follow-up. Heart Rhythm. 2018;15(3).