

His Bundle Pacing for Congenitally Corrected Transposition of the Great Arteries

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1.0 Background

Congenitally corrected transposition of the great arteries (CCTGA) is a rare cardiac anomaly that is characterized by ventricular inversion with a resultant sub-systemic morphologic right ventricle, co-existing congenital abnormalities, and a significant risk for progressive AV block. Many patients with CCTGA develop progressive RV failure in adult life, due to the inability of the morphologic RV to perform under systemic vascular resistance. Patients at particular risk are those who undergo transvenous pacemaker placement for AV block, where indices of RV failure may develop rapidly.[1] To aggravate this problem, up to 20-30% of patients with CCTGA have significant abnormalities of the coronary sinus drainage, so that CRT may even require a surgical approach.[2, 3] Recent data has demonstrated His bundle pacing to be superior to conventional pacing in the general population,[4] and this approach may be applicable to the CCTGA population.

The present study intends to evaluate the procedural aspects and outcomes of patients with CCTGA who have undergone His bundle pacing at a group of international centers experienced with the treatment of complex congenital heart disease. It is hypothesized that His bundle pacing is not only feasible, but will be associated with stable pacing characteristics as well as favorable clinical outcomes in this population.

2.0 Rationale and Specific Aims

The present investigation aims to characterize the procedural approach and clinical outcomes of patients with CCTGA undergoing His bundle pacing at multiple academic centers recruited through PACES.

Hypothesis #1: His bundle pacing is feasible for patients with CCTGA and pacing characteristics will be reliable during follow up.

Hypothesis #2: CCTGA patients undergoing His bundle pacing will demonstrate stable RV systolic function following device implantation.

Primary Aim: To describe the procedural aspects and outcomes of a small population of CCTGA patients undergoing His bundle pacing.

3.0 Prior Studies

There is a single case report describing His bundle pacing for CCTGA.[5] Given the extreme paucity of clinical data in this situation, a pilot study to demonstrate the safety and efficacy of this approach is herein proposed.

4.0 Inclusion / Exclusion Criteria

Inclusion: All patients with CCTGA with a systemic right ventricle who have undergone transvenous pacemaker placement utilizing either selective or non-selective His bundle pacing will be eligible.

Exclusion:

- Patients with anatomic repair of CCTGA (i.e. systemic LV)
- Patients with co-existing CRT systems will be excluded

5.0 Study Procedures

All participating institutions will be asked to search their databases and identify all patients with CCTGA who have undergone His bundle pacing. A data sheet in REDCap will be then completed for each patient. Only anonymized data will be requested and received at the coordinating center at UCLA. No center will share patient identifiers such as name, medical record number, date of birth, or specific dates of procedures with another center. Each patient will be assigned

a unique code which will only be known to the primary investigator at each site and will not be available to the investigators at UCLA.

Study data will be collected according to appendix A (below).

6.0 Statistical Considerations

Data will be presented as mean \pm standard deviation or median (interquartile range; IQR) for continuous variables as appropriate, and as frequencies and percentages for dichotomous variables. The study will be descriptive, with no inferential statistics performed. Descriptive analyses will be performed with JMP software (SAS Inc., Cary, NC).

7.0 Risks

There is a risk of loss of patient confidentiality that is expected to pose minimal risk to study participants.

8.0 Privacy / Confidentiality Issues

Only individuals directly involved with the study will have access to data. Information is for research only and will be used for publication purposes. Access to identified patient information will be limited to the investigators listed within this IRB application. De-identified information with HIPPA identifiers removed will be available to other investigators following appropriate IRB approval. Confidentiality and security will be maintained for the database. The database is stored behind a firewall (in addition to the institutional firewall) with the highest level of protection, i.e. the same level of protection as the on-line hospital information system at UCLA. This means that users must logon to a web server that sits between the institutional firewall and the firewall to the database, and only this application server is allowed to query the database. Only users approved through our institutional review board will be allowed access to

patient identifiers. Other levels of authorization may exist for future approved users following IRB approval, e.g. access to de-identified data.

Data is initially collected in the medical record for each individual study participant. The information will be extracted from the patient's medical record and then transferred into the CRF.

The CRFs will not include personal identifiers for participant. All data will be transmitted to the coordinating institution via the CRF. A master list with patient demographics will be accessible to the local principle investigator and his senior co-investigator. This data will not be available to others.

9.0 Follow-up and Record Retention

The study will continue for 1 year. The data will be maintained for 1 year after completion of the study.

10.0 Reference List

1. Yeo, W.T., et al., *Adverse impact of chronic subpulmonary left ventricular pacing on systemic right ventricular function in patients with congenitally corrected transposition of the great arteries*. Int J Cardiol, 2014. **171**(2): p. 184-91.
2. Bottega, N.A., et al., *The cardiac veins in congenitally corrected transposition of the great arteries: delivery options for cardiac devices*. Heart Rhythm, 2009. **6**(10): p. 1450-6.
3. Moore, J.P., et al., *Implantation techniques and outcomes after cardiac resynchronization therapy for congenitally corrected transposition of the great arteries*. Heart Rhythm, 2018. **15**(12): p. 1808-1815.
4. Vijayaraman, P., et al., *Permanent His-bundle pacing: Long-term lead performance and clinical outcomes*. Heart Rhythm, 2018. **15**(5): p. 696-702.
5. Kean, A.C., et al., *Permanent nonselective His bundle pacing in an adult with L-transposition of the great arteries and complete AV block*. Pacing Clin Electrophysiol, 2017. **40**(11): p. 1313-1317.

Appendix A – Data Collection

- Baseline
 - Month of birth, year of birth
 - Gender
 - Congenital diagnosis
 - Surgical history
 - Cardiac implantable device history
 - Arrhythmia history (date AV block developed, if present)
 - ECG data (rhythm, QRS duration)
 - Copy of baseline ECG
 - Echocardiographic data (RV dP/dT, TASPE, FAC, EF, tricuspid valve regurgitation)
 - Advanced imaging data (CT/MRI)
 - New York Heart Association class
 - Cardiopulmonary exercise data, if available
 - Reason for His bundle pacing
- Procedural data
 - Month of procedure, year of procedure
 - Management of pre-existing leads
 - Use of 3D mapping system/type
 - Concomitant procedures, if any
 - Location of His bundle target
 - Catheters/sheaths used for His bundle placement
 - Acute R wave sensing and pacing threshold
 - Type of His bundle capture (selective/non-selective)
 - Procedure/fluoroscopy duration
 - Device programming (mode, rates)
 - Hospital length of stay
 - Copy of initial post-implant ECG
 - Procedural complication
- Follow up data
 - Month last follow-up, year last follow-up
 - Echocardiographic data (RV dP/dT, TASPE, FAC, EF, tricuspid valve regurgitation)

- Advanced imaging data (CT/MRI)
- Most recent New York Heart Association class
- Most recent cardiopulmonary exercise data, if available
- Pacemaker lead characteristics (sensing/pacing) at last follow up
- Copy of chest x ray at last follow up
- Copy of ECG at last follow up
- Other outcome (death/transplant)
- Surgery during follow up