

**PROJECT TITLE: LONG TERM OUTCOMES OF SVT ABLATION IN CHILDREN**

**PRINCIPLE INVESTIGATOR: Leonardo Liberman**

**CO-INVESTIGATORS: Michael Fremed and Anna Joong**

**BACKGROUND AND RATIONALE:**

Supraventricular tachycardia (SVT) is a cardiac arrhythmia that originates from a focus located above the ventricles. The most common forms of SVT are atrioventricular reentrant tachycardia (AVRT) and atrioventricular nodal reentrant tachycardia (AVNRT), with the former accounting for roughly 70% of SVT cases and the latter representing between 9 and 30%. (1–3) With AVRT, an accessory pathway exists outside of the physiologic AV node pathway, as with Wolff-Parkinson-White syndrome. With AVNRT, there is an alternate pathway passing through or adjacent to the AV node that is capable of conducting in a retrograde fashion. (3) Though risk of sudden death is relatively low overall in SVT at an estimated 1%, it has been shown to be as high as 27% in patients with underlying structural heart disease. (4)

Definitive treatment of SVT involves ablation of the faulty pathway, either with radiofrequency (RF), used in the majority of cases, or cryoablation, which is sometimes used for AVNRT due to its ability to produce temporary lesions. (5) While equally effective in short term for AVNRT, there is a higher recurrence rate with CA. (6) During these procedures, attempt is made to elicit the arrhythmia with various pacing maneuvers and medical interventions. Once a suspected ectopic focus is identified, lesions are placed to break the circuit. Multiple lesions are generally required and the burn/freeze times may vary for each lesion. Once the arrhythmia has broken, similar methods are used to try and elicit the arrhythmia to ensure that the ablation was successful.

Short-term success rates of ablation are well established and have been reported as high as 95-98%, with 6-12 month follow-up recurrence rates reported at 7-10%; (3) however, longer-term recurrence rates reported in pediatric populations have varied from 6-27.7% over 2-5 year follow-up periods(7–11). Additionally, in the pediatric population, reports on success of repeat ablations and predictors of recurrence have been inconsistent, as have definitions of recurrence and methods used to quantify recurrence.(12–15) Accurate data about long term success rates and risk factors for recurrence are important for determining appropriate patient counseling and follow up, potentially sparing those patients prolonged exposure to anti-arrhythmic medications and increased need for cardiology follow up. Through this study we attempt to quantify recurrence risk after initially successful ablation and establish predictors of recurrence.

**STUDY DESIGN AND STATISTICS:**

This will be a retrospective study of patients age 0-21 who underwent initially successful ablation at MSCHONY from 2007-2011. Initial success is defined as per electrophysiology report at time of the ablation. Review of relevant data in the electronic health record (EHR) will be performed with regard to patient and procedure

characteristics and any documentation of arrhythmia recurrence as defined by ICD-9 or 10 coding, clinical documentation, EKG and/or Holter findings, and repeat ablation. Patient symptoms and subjective opinion on recurrence will be assessed via patient survey.

### **Specific Aims:**

1. Calculate 5-year success vs recurrence rates in pediatric patients who have undergone a successful ablation for SVT as defined by symptoms post-ablation or need for recurrent ablation to be determined by EHR and patient report
2. Determine predictors of recurrence following acutely successful SVT ablation based on collected follow up data.

### **Hypotheses:**

1. We predict that a significant majority of pediatric patients aged 0-21 years who had an acutely successful radiofrequency or cryoablation for AVRT or AVNRT will have remained arrhythmia-free without requiring repeat ablation over a 5 year follow up period such that fewer than 10% of patients will have recurrence.
2. We predict that for those who do experience recurrent arrhythmia, as compared to those without recurrences, predictors of recurrence can be identified among common baseline patient and procedural characteristics. More specifically, we predict that those patients with recurrent arrhythmia will have required longer time to success during initial ablation, more lesions, and longer burn/freeze times.

### **Statistical Analysis:**

All data will be entered into an excel spreadsheet and analyzed either via Excel or R. Number of recurrences will be calculated based on EHR documentation of recurrence and returned patient surveys detailing subjective post-ablation patient experiences. This will not require any in specific statistical tests. Mean time to recurrence will also be recorded.

In order to analyze predictors of recurrence power analysis was performed in anticipation of paired t-test. For an alpha of 0.5 and beta of 0.8, assuming a 10% recurrence rate and a standard deviation of 1, we will have the power to detect differences in continuous risk factors rates of 0.78 standard deviations.

Because there are multiple continuous variables that will likely not be normally distributed and time to recurrence is being determined with censored data, Wilcoxon analysis will be performed on primary risk factors being studied as mentioned above.

Other baseline characteristics will be collected in order to suggest differences between those with recurrence and those without as listed above. For these, Cox proportional hazard modeling can be performed given categorical variables with time to recurrence.

### **Baseline Data to be Collected:**

- Patient variables
  - Age at diagnosis, ablation
  - Sex
  - Weight
  - Anti-arrhythmic medications
  
- Procedure variables
  - Type of SVT
  - Type of ablation procedure
    - RF ablation
      - Cumulative RF time
      - Number of RF applications
      - Maximum temperature achieved
    - Cryoablation
      - Cumulative cryoablation time
      - Number of cryoablation applications
      - Minimum temperature achieved
      - Temporary lesions placed prior to permanent lesions?
    - Both RF and cryoablation performed?
  - Length of time to success (in accessory pathway)
  - Rhythm during ablation (SVT, a pacing, v pacing, sinus rhythm, etc.)
  - Catheter tip size
  - Location of ablation
  - Duration of observation after last RF/cryoablation
  - Use of isoproterenol in post-ablation testing
  - Insurance lesion performed?
  - Presence of more than 1 pathway
  - Anesthesia type

### **STUDY PROCEDURES:**

1. Electronic health record (EHR) review of initial ablation note, cardiology follow-up encounters including events found on EKG, Holter/event monitors, subsequent EP studies, and any records of repeat ablation.
2. Additional data including subjective patient experience (symptoms, medical interventions, further care from physician outside our institution, patient opinion of success of ablation(s)) will be collected via patient survey (see attached). Survey will be mailed to all patients in the study. If no response is received within 4 weeks, attempts will be made to contact patient/guardian by phone and/or email.

### **STUDY QUESTIONNAIRE:**

The study questionnaire (see attached) will include questions related to the following:

1. Pre/Post ablation SVT symptoms
2. Pre/Post ablation anti-arrhythmic medications

3. Pre/Post ablation frequency and duration of SVT symptoms/events
4. Emergency room/hospital admissions for arrhythmia pre/post-ablation
5. Medical monitoring or interventions required pre/post ablation
6. Patient view regarding success of initial and any repeat ablations.

### **STUDY SUBJECTS**

282 patients between 2007-2011 with accessory pathways or AVNRT were successfully ablated at CHONY.

Inclusion criteria: All pediatric patients aged 0 to 21 with AVRT or AVNRT who underwent a successful cryoablation or radiofrequency ablation at CHONY as defined by the electrophysiology report between the years 2007-2011.

Exclusion criteria: Patients with congenital heart disease (exceptions: ASD, PDA)

### **SUBJECT SELECTION**

As this is a retrospective study mainly relying on chart review, no active recruitment will be done with the exception of patient surveys, which will be sent to all included patients or legal guardians. Data regarding subjective patient experience can only be included if the patient or guardian returns the survey.

Consent and assent forms including description of the study will be mailed to patients along with the patient survey. Patients over the age of 14 will be considered able to provide assent and complete the survey independently.

### **CONFIDENTIALITY OF STUDY DATA:**

Data will be entered into and stored in Excel spreadsheet on password protected laptops that are compliant with institution privacy protection policies. Hardcopy data including surveys will be stored in a locked office and will be accessible only to study investigators.

### **POTENTIAL RISKS/BENEFITS:**

There is not more than minimal risk to the study subjects as this is a retrospective study. Potential risks include breach of confidentiality.

Minimal benefit exists for study participants. Potential benefits for society include better understanding of ablation success rates, enhanced clinical judgement of risk factors in treatment decisions, and decreased need for post-ablation monitoring, medication, and follow up.

### **ALTERNATIVES:**

The alternative is not participating in this study (i.e. not returning the mailed patient survey).

### **MINORS AS SUBJECTS:**

All study investigators have completed appropriate Minors as Subjects Research training as per IRB requirement.

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