Scheda di presentazione del Progetto P12-05

“European Pediatric Catheter Ablation Registry”

Protocol Vers. 1.0,
February 16th, 2011

Steering Committee

F. Cantu IT	Co-Principal Investigator
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Jan Janousek, CZ	Member
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INTRODUCTION

Catheter ablation has revolutionized the management of cardiac arrhythmias in patients. and has become first-line therapy for managing many pediatric patients with atrioventicular accessory pathway or atrioventricular nodal-mediated supraventricular tachycardia[1-3].
Radiofrequency catheter ablation was first used in the 1980s to treat arrhythmias in adult patients[4], and was extended to pediatric ages in the following decade[5,6], while cryoablation for arrhythmia substrates in pediatrics has been available since 2003[7].
Pediatric electrophysiologists initially had to modify existing technology and tools to serve the needs of the child with otherwise untreatable arrhythmias. Even with such modifications, smaller patients, particularly with abnormal anatomy, were challenging in terms of application of catheter-based ablation[8-10].
Over the last decade, however, with improved understanding of the differences in the risks and benefits of catheter ablation in children and the design of specific catheters and non-radiofrequency-based ablation as well as more advanced imaging and mapping systems, present ablation results in adults are not significantly different from that in children[11]. In particular, the use of point-to-point three-dimensionally rendered electroanatomic maps and cryoablation have facilitated and made ablation safer in children.
Anyway, cardiac ablation in children is not a standardized procedure as in adults as evidence gaps still have to be filled. On a European perspective, lack of a dedicated scientific society has limited so far the collection and sharing of data among the most experienced centers.
Actually there are not available data about the management of pediatric patients undergoing ablation in the clinical practice, in particular regarding the indications, the methodology and the clinical follow-up of these patients.

STUDY OBJECTIVES

The main objective of the European Pediatric Catheter Ablation Registry is to collect data on ablations procedures in the European pediatric population in order to improve the management of this subset of patients.

Secondary objectives are:

- To describe clinical indications to procedure (age, arrhythmia's type, clinical presentation, arrhythmic risk, etc.);
- To describe and compare different ablation methodologies (mapping strategy, energy source, settings, etc.);
- To evaluate safety and efficacy of ablation procedures both acutely and over long term
- To evaluate follow-up management strategies in the current clinical practice.

STUDY DESIGN

The European Pediatric Catheter Ablation Registry is an international, multicenter, prospective registry that will include pediatric patients referred to the participant centers to perform any kind of ablation procedure.

The study will start in the Steering Committee's centers. After a pilot phase of one year, up to 30 European electrophysiological centers performing pediatric ablation on a regular basis will be invited to join the registry; enrolment sites will be selected to provide a representative picture of current medical practice throughout Europe.
The enrolment is expected to last a minimum of 3 years, further extension will be decided by the steering committee. The follow-up will last 12 month after enrolment of the last patient.
All the consecutive patients undergoing ablation will be screened for inclusion/exclusion criteria. If all criteria are met, patient will be asked to sign an informed consent. Upon giving informed consent, subjects will be enrolled in the study.

Inclusion/ Exclusion criteria

The following criteria must be met for subjects to be eligible for inclusion into the study:

a. Pediatric patients candidates to any kind of ablation procedure;
b. Patients aged between 0 and 16 years;
c. Legal guardian understands the nature of the procedure, is willing to comply with study follow-up evaluations, and provide written informed consent and assent prior to the procedure.

Subjects who meet the following criteria are excluded by the present study:

d. Patient unable to commit to follow-up schedule;
e. Patient has medical conditions that preclude protocol compliance or limit study participation;
f. Patient is enrolled or intend to participate in another clinical trial during the course of this study;
g. Pregnancy.
h. Legal guardian or patient unwilling or unable to give informed consent.

Study Procedures

Clinical and procedural data will be collected at enrollment. Patients will be managed during follow-up according to local medical practice. A follow-up scheduled visit is required at 12 months after enrolment.
Additional data will be collected at unscheduled visits, secondary procedures, adverse events, study deviations and study exit/death.
Investigators must report all adverse events and their status changes.
Clinical data will be collected by means of paper Case Report Forms (CRFs) that will be later electronically converted by the central administrative office to fill the database
Data collection requirements are summarized in Table 1.

VISIT	Enrollment	Scheduled Follow-up	Unscheduled Follow-up	Study Exit/Death
Subject Screening (Inc/Exc Criteria Verified)	√			
Informed Consent	√			
Subject Demographics	√			
Medical History and biomorphometric data	√			
Ablation procedure data*	√			
Outcome and adverse events	√	√	√	√
Study deviations	√	√	√	√
Medical treatment	√	√	√	
Subject death documentation				√

* i.e.: arrhythmias treated (# and types), energy source, mapping tools, power delivered, number of spots, procedure and fluoroscopy time, LA/LV approach, etc.

REGULATORY PROCEDURES
1. The role of the Steering Committee

The Steering Committee has the intellectual property of the protocol. It has the faculty of reviewing all data and all the events, and it's responsible for defining the publication policies.

2. MANAGEMENT OF DATA

At any time, confidentiality is maintained by all parties involved. All data are secured against unauthorized access. All patient data are kept confidential. For this purpose, a unique subject identification code (in lieu of the subject's name) will be used, which allows identification of the reported data for each subject and assures that data can always be tracked back to the source data. Patients' legal guardian provide informed consent to the treatment of their data. Data are collected from each investigator who is responsible for them. The investigators have on-line access to the data-base regarding their own cases. Data management (CRFs, clinical audit and queries) is made electronically via a web-based software.

PUBLICATION POLICIES

The first author of the main publication will be alternatively one of the two Co-Principal Investigators of the European Pediatric Catheter Ablation Registry.
Other authors of main publications will be the members of the steering committee and investigators of other participating centers selected upon qualitative (data compliance) and quantitative criteria.
All investigators not eventually listed as co-authors will be acknowledged and individually listed in an appendix (according to journal roules).
Individual centers will be allowed to publish their own data and eventual sub-analyses after the publication of the main paper.
Secondary publications (abstracts and manuscripts) will be submitted for approval to the Principal Investigators at least 15 days before submission to a scientific journal.
In case of different centers contributing to a secondary publication, co-authorship will be representative of the contribution: each contributing center will select one or more investigators as a co-author and the order of authors will be determined by the number of patients enrolled in the study, provided that quality compliant data were collected.
The Principal Investigators will review and evaluate the secondary publications and will ensure that individual requests do not present conflicts with each other.

REFERENCES

(1) Strieper M, Leong T, Bajaj T, Huckaby J, Frias P, Campbell R. Does ablation of supraventricular tachycardia in children with a structurally normal heart improve quality of life? Congenit Heart Dis. 2010 Nov;5(6):587-93

(2) Van Hare GF, Javitz H, Carmelli D, et al. Prospective assessment after pediatric cardiac ablation: demographics, medical profiles, and initial outcomes. J Cardiovasc Electrophysiol. 2004; 15: 759-770.

(3) Kugler JD, Danford DA, Houston KA, Felix G. Pediatric radiofrequency catheter ablation registry success, fluoroscopy time, and complication rate for supraventricular tachycardia: comparison of early and recent eras. J Cardiovasc Electrophysiol. 2002; 13: 336-341.

(4) Borggrefe M, Budde T, Podczeck A, Breithardt G. High frequency alternating current ablation of an accessory pathway in humans. J Am Coll Cardiol. 1987 Sep;10(3):576-82.

(5) Dick M II, O'Connor BK, Serwer GA, LeRoy S, Armstrong B. Use of radiofrequency current to ablate accessory connections in children. Circulation. 1991 Dec;84(6):2318-24.

(6) Van Hare GF, Lesh MD, Scheinman M, Langberg JJ. Percutaneous radiofrequency catheter ablation for supraventricular arrhythmias in children. J Am Coll Cardiol. 1991 Jun;17(7):1613-20.

(7) Collins KK, Schaffer MS Use of Cryoablation for Treatment of Tachyarrhythmias in 2010: Survey of Current Practices of Pediatric Electrophysiologists. Pacing Clin Electrophysiol. 2010 Nov 15.

(8) Abrams DJ. Invasive electrophysiology in pediatric and congenital heart disease. Heart. 2007;93:383–391.

(9) Joung B, Lee M, Sung JH. Pediatric radiofrequency catheter ablation: sedation methods and success, complication and recurrence rates. Circ J. 2006;70:278–284.

(10) Kirsh J, Gross G, O'Connor S, et al. Transcatheter cryoablation of tachyarrhythmias in children: initial experience from an international registry. J Am Coll Cardiol. 2005;45:133–136.

(11) Lee P, Betau H, Chen S, et al. The results of radiofrequency catheter ablation of supraventricular tachycardia in children. Pacing Clin Electrophysiol. 2007;30:655–661.

I. *Financial plan*

a. Kick-off meeting	€ 5.000
b. Registry design: form printout (n° 200)	€ 4.000
c. Registry design: website, server and back-up	€ 25.000
d. Registry website maintenance (cost per year)	€ 3.500
e. Data management: 1 part-time administrative person or 1 full time fellow (grant), hardware (notebook with ADSL)	€ 15.000
f. 2 meeting/yr paired with main EP international congresses	€ 10.000
g. 4-6/yr conference calls	€ 300
TOTAL	€ 62.800