

NASPE POSITION STATEMENT

NASPE Expert Consensus Conference: Radiofrequency Catheter Ablation in Children with and without Congenital Heart Disease. Report of the Writing Committee

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Introduction

A Consensus Conference on Pediatric Radiofrequency Catheter Ablation took place at the 21st Annual Scientific Sessions of the North American Society of Pacing and Electrophysiology (NASPE). The participants included health professionals from the pediatric and adult electrophysiological communities, and involved physicians, nurses, and other allied professionals. This statement attempts to coalesce the information presented and is directed to all health professionals who are involved in the care of pediatric patients undergoing ablation. In an attempt to write such a document, the editors must try to represent what they believed was the general consensus of opinion amongst the participants. As generally understood in the medical world, "consensus" does not indicate complete harmony within a group but a substantial degree of agreement. It is hoped that the information presented falls within that definition and will serve as a foundation on which to build toward in the future. Even as this document was being prepared, new technologies were introduced that may expand the indications and possibly the type of personnel and training necessary to perform these procedures. It will be interesting to look back on this statement of the

current state-of-the art over the next 5–10 years and see if some of the recommendations stand the test of time. As is true of many documents, only in retrospect can a judgement be made on the strength of what is stated in this statement.

The goal of the Consensus Conference was to bring together pediatric and adult practitioners in electrophysiology for an all day discussion of catheter ablation in children and in patients with congenital heart disease (CHD). The organizers believed that, in choosing topics for discussion, the development of indications for catheter ablation should flow naturally from what is known concerning the natural history of the arrhythmias in question in the pediatric population and from the latest information available concerning outcomes from these procedures. Therefore, the initial part of this statement deals with the natural history issues of specific arrhythmias in children with and without CHD. Issues of radiation exposure and animal models of toxicity due to radiofrequency (RF) application are noted followed by outcomes and complications of RF ablation for various arrhythmias. Indications for ablation are then discussed. It is important to realize that these indications as presented are not necessarily "written in stone" and do not take the place of a "Policy Statement." Rather, as mentioned above, this represents a general sense of agreement within the community of pediatric and adult electrophysiologists.

The second half of the conference then dealt with the "nuts and bolts" of performing these pro-

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cedures in these special populations. The goal of this section was not to focus on credentialing of physicians to perform these procedures, but rather on what are the agreed on special needs of children and patients with CHD, and how best to meet these needs. An area of special importance concerns the use of sedation and general anesthesia in this population. The importance of this section should not be overlooked. Pediatricians are accustomed to saying: "Children are not small adults." Thus, it is within this section that the difference in the approach to the child as compared to the adult is highlighted. The definition of "pediatric" is that of the American Academy of Pediatrics (AAP) from the Policy Statement of 1988 regarding Age Limits of Pediatrics: "The purview of pediatrics includes the physical and psychosocial growth, development, and health of the individual. This commitment begins prior to birth when conception is apparent and continues throughout infancy, childhood, adolescence, and early adulthood, when growth and developmental processes are generally completed. The responsibility of pediatrics may therefore begin with the fetus and continue through 21 years of age". Finally, the special needs of pediatric patients, as it relates to nursing care and psychological issues, are addressed.

Natural History Considerations

Structurally Normal Hearts

Some of the more important areas of interest in the natural history of supraventricular tachycardia (SVT) include the mechanism of the arrhythmia, age at presentation, the frequency, duration, and severity of symptoms, and the effects of treatment. In addition, the potential likelihood of catastrophic events and the possibility of spontaneous resolution of tachycardia episodes or the tachycardia mechanism influence treatment strategies.

Atrioventricular Reentrant and Atrioventricular Nodal Reentrant Tachycardia

Atrioventricular reentrant tachycardia, using an accessory connection often presents in the first year of life. Subsequent peaks of presentation are reported near the end of the first decade of life and in the mid-teen years.¹ Wolff-Parkinson-White syndrome (WPW) diagnosed in infancy has been shown to have a decrease in the recurrence of tachycardia in the first several years of life and an increase in episodes at the end of the first decade. Over 90% of infants diagnosed with WPW have remission of tachycardia episodes by 18 months of age with recurrence of tachycardia later in life.²⁻⁶ The percentage of patients noted to have recurrence of SVT depends on the duration of follow-up. In the only study encompassing decades of fol-

low-up, up to 70% of infants had recurrent SVT.² In contrast, patients presenting with SVT beyond 5 years of age tend to have persistent episodes of tachycardia.¹ "Resolution" of tachycardia may, in part, be determined by lack of initiating events like atrial or ventricular ectopy, rather than resolution of the tachycardia mechanism.⁷

Although uncommon, atrioventricular nodal reentry tachycardia (AVNRT) may occur in infants.⁸ In pediatric patients, AVNRT typically presents beyond 5 years of age with a gradual increase in frequency with advancing age.⁹ Episodes presenting in infancy tend to have a lower recurrence risk compared with SVT presenting in childhood.

As a subset of the group of patients with accessory pathways (APs), children may present with incessant tachycardia due to persistent junctional reciprocating tachycardia (PJRT). The natural history of PJRT is not well described in the pediatric population, but this arrhythmia may lead to tachycardia induced cardiomyopathy if not well controlled by medication or ablative therapy.

The tendency for remission of typical SVT episodes presenting in infancy favors a pharmacological approach to therapy in this age group rather than an ablative approach, allowing the natural history to provide for a "honeymoon" period prior to the recurrence of symptomatic tachycardia in later childhood.

Sudden death in those patients with structurally normal hearts and SVT but without ventricular preexcitation is uncommon. Although deaths in those patients with WPW and structurally normal hearts occurs uncommonly, it does occur in all age groups.¹⁰ Estimates of the occurrence of sudden death with WPW range from 0.09% to 0.6% per patient year of follow-up.¹¹ The role of digoxin as a contributing factor in sudden death associated with preexcitation remains unclear, particularly in the pediatric population.

Automatic Atrial Tachycardia

A high proportion of arrhythmias in those patients with automatic atrial tachycardia can be controlled with antiarrhythmic medications. Of those achieving sinus rhythm with medications, nearly half will have spontaneous resolution of tachycardia.¹²⁻¹⁶ The minority of patients not controlled with drug therapy may represent a select population of patients with multiple foci of automaticity and are likely candidates for ablation. In addition, in children, automatic atrial tachycardia may present as in incessant tachycardia leading to dilated cardiomyopathy.

Atrial Flutter

Atrial flutter in pediatric patients with structurally normal hearts presents most commonly in

neonates and young infants; two thirds are diagnosed by the first day of life.^{17–20} Recurrence of atrial flutter in this population is exceedingly uncommon outside of the immediate newborn period.²¹

Automatic Junctional Tachycardia

Automatic junctional tachycardia is a rare rhythm disorder that is difficult to control with medications; deaths have been reported in these patients. Only 25% of reported patients had spontaneous “resolution” of arrhythmia and were no longer receiving medication, but “accelerated junctional rhythm” was still present in these patients.²² A familial occurrence is seen in 50% of cases, and an autosomal dominant mode of inheritance has been suggested. This arrhythmia may also lead to tachycardia induced cardiomyopathy, if not adequately controlled.

Ventricular Arrhythmias

In the absence of an identifiable predisposing cause (infection, electrolyte abnormalities, drug administration, mechanical irritation), sustained ventricular tachyarrhythmias tend to recur. VT associated with cardiomyopathy, either electrical (long QT syndrome [LQTS], Brugada syndrome, catecholaminergic) or due to muscle disease (dilated or hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia) are persistent and likely to progress. The time course to recurrence in idiopathic VT (right ventricular outflow tract, left ventricular) is not well defined; clinical experience suggests intermittent occurrences in childhood with increased frequency in adolescence, perhaps related to increased intensity of physical activity.^{23,24} Myocardial tumors presenting in infancy with VT may spontaneously resolve after medical control has been achieved.^{25,26}

Patients with Structural Heart Disease

SVT may occur in association with CHD, or as a consequence of postoperative CHD. In general terms, SVT in association with heart disease is typically due to an accessory connection or atrioventricular nodal (AVN) reentry while postoperative arrhythmias are more commonly atrial reentry or automatic atrial mechanisms. Among pediatric patients with manifest preexcitation, structural heart disease is present in up to 20–32% of patients^{1,6,27}; this compares with structural heart disease in 7% of patients with AVN reentry.²⁷ With the exception of patients with Ebstein’s anomaly (in whom multiple accessory connections are more likely) the natural history of SVT due to accessory connections or AVN reentry is not significantly different than in patients with structurally normal hearts. However, the hemody-

namic consequences of SVT associated with structural heart disease may be more profound than in those with a normal heart.

Postoperative atrial tachycardia occurs in up to 40% of Mustard/Senning patients, 50% of Fontan patients, and up to 20% of patients with repaired atrial septal defect (ASD), or tetralogy of Fallot, and less frequently with other defects, like ventricular septal defect (VSD).^{28–36} There appears to be a consistent pattern of developing the loss of sinus rhythm and onset of atrial tachycardia with longer follow-up intervals. In those patients known to have SVT, there is a tendency for increased frequency of tachycardia episodes over years of follow-up. Risk of sudden death due to tachycardia may be as high as 20% for untreated patients³⁵ and anecdotal data suggests Senning/Mustard patients may be at higher risk for sudden death than Fontan patients. Significant morbidity from tachycardia includes congestive heart failure, thrombosis, and stroke. Medical management of atrial reentry tachycardia has met with limited success, with specific drug efficacy less than 40%.³⁷ Antitachycardia pacing may decrease the number of symptomatic arrhythmia episodes in 50–65% of patients.^{37,38} RF catheter ablation (RFCA) has acute success rates up to 70%, with high recurrence rates during short-term follow-up.³⁹

Ventricular arrhythmias typically occur following surgery involving ventriculotomies or ventricular resection, like in surgery of tetralogy of Fallot, double outlet right ventricle, aortic stenosis, and VSDs. Isolated premature ventricular contractions and nonsustained VT are seen in 65% and 8% of postoperative tetralogy of Fallot patients, respectively,^{40–42} while sustained VT is estimated to occur in 1–3% of such patients. Sudden death occurs in less than 6% of long-term survivors of tetralogy of Fallot surgery.^{43,44} Risk factors for developing sustained VT include an older age at the time of surgery, longer follow-up duration, poor hemodynamics, and marked prolongation of the QRS duration.^{45–47} Although programmed electrical stimulation may induce arrhythmias in postoperative tetralogy of Fallot patients with clinical arrhythmias,^{45,48–50} this technique has not yet been shown to identify asymptomatic patients at increased risk of sudden death.⁵⁰ Surgical therapy of residual hemodynamic defects and resection of the foci of VT has been shown to be effective.^{49,51,52}

Results of RF Ablation

In this section, the results of RF ablation procedures in children are considered. This recognizes that the success rate of the procedure and the likelihood of complications of the procedure

must be carefully considered in light of the natural history of the arrhythmias proposed for ablation.

Information Available from Studies in Animal Models

The efficacy and the risks of RF ablation reflect a balance between the creation of a lesion that is large enough to damage the tissue causing the arrhythmia, but not so large as to damage adjacent tissues unnecessarily. Extensive clinical experience suggests that RF ablation using a 4-mm tip electrode is safe and effective in adults and most children with SVTs. In children, the potential for ablative energy to create lesions that are larger than ideal, and to damage adjacent structures like the coronary arteries, is likely to be a greater problem in patients of younger age and of smaller size. There are several animal studies that have addressed these potential problems in immature myocardium.

In a study performed in infant sheep, Saul et al.⁵³ made endocardial atrial and ventricular RF lesions, and lesions on the atrioventricular (AV) annulus in young lambs (average weight 11 kg) at 4 and 8 weeks of age. Necropsy examination of the lesions that were generated were assessed immediately after ablation, after 1 month, and after 8 months. Atrial lesions were larger at 1 month than immediately after ablation and showed no further increase in size at 8 months. Ventricular lesions increased in size from a width of 5.9 ± 2.5 mm acutely to 7.4 ± 2.5 mm at 1 month and 10.1 ± 3.3 mm at 8 months. Lesions placed on the annulus were essentially the same size at all periods of assessment, but fibrous invasion of normal ventricular myocardium was observed.

In another study performed in 6-week-old pigs (average weight 12.5 kg) Paul et al.⁵⁴ applied RF current to achieve a temperature of 70°C for 30 seconds at the atrial aspect of the tricuspid valve annulus, the mitral valve annulus, and at the left ventricular apex. Histological examination revealed damage to the right coronary artery with thickening and fibrosis of the adventitia, media, and intima in two of five animals examined at 6 months and in three of eight animals evaluated after 12 months. Coronary artery diameter was reduced by 10% to 60%. The circumflex coronary artery was free of injury. Serial coronary angiography failed to show lesions during follow-up. However, intracoronary ultrasound showed that intimal plaque formation was apparent by 6 months.⁵⁵ Thus, coronary artery injury in animal models can be produced by RF energy applied from the endocardial surface and is likely to be a greater risk in small hearts with close proximity of the artery to the ablation site. This may be of par-

ticular concern during ablation at the inferior aspect of the coronary sinus ostium, and along the tricuspid annulus in those patients with Ebstein's anomaly of the tricuspid valve.

While there may be questions concerning the applicability of these animal models to the immature human heart, these observations support the notion that a cautious approach is warranted, including the avoidance of catheter ablation when possible in infants, and minimization of the total number of RF applications.

Radiation Safety Considerations

Most adverse consequences of the RF ablation are readily apparent to the patient and physician on completion of the procedure or soon thereafter. However, the possibility of injury related to radiation injury is of concern, despite the fact that some manifestations of radiation injury may take years to become evident. In this respect, the possibility of radiation induced injury is of potentially greater concern in children, given the longer time period subsequent to the ablation procedure in which to develop such injuries.

Acute effects of radiation toxicity, of course, may rarely be seen, like acute dermatitis or pneumonitis associated with excessive acute exposure. Less apparent are the potential for late morbidity associated with radiation exposure, including malignancy, retarded bone growth, teratogenic effects, or cataract formation. As these effects may not manifest for many years, they are particularly important in young patients who are undergoing somatic growth, have a long life expectancy, and whose reproductive years lie ahead.

Radiation exposure may result in a variety of risks, to the exposed individual (somatic risks) and to their progeny (hereditary effects). In the case of malignancies, any exposure is presumed to pose a risk. For other tissue effects like dermatitis and cataract formation, a "safe" level of exposure can be incurred without development of injury. For dermatitis, in particular, the risk of transient erythema begins with a threshold dose of 2 Gy, an effect that may become evident hours after exposure. At higher doses, more severe effects develop, like dry desquamation (10 Gy), moist desquamation (15 Gy), dermal necrosis (18 Gy), and secondary ulceration (20 Gy). The most severe effects appear weeks to months after the exposure, but are likely only with inconceivably long exposures or malfunctioning equipment.

Malignancies are more difficult to calculate. However, the risks are greatest for tissues receiving the highest doses, like lung, more so than breast or bone marrow (leukemia).

Malignancy risks for 60-minute fluoroscopy exposure in adults have been estimated at

0.01%–0.1%, though a variety of factors other than fluoroscopy time contribute to the actual absorbed dose for a given individual. These exposures and resultant risks are quite small in comparison to the 10–20% lifetime likelihood of developing a malignancy. In comparison to radiation exposure during ablation or other medical procedures, it should be kept in mind that natural background radiation in the environment results in 100–300 mrem (10–30 Gy) per year.

While the concerns regarding late effects of radiation exposure are somewhat hypothetical, acute radiation injury is a real, albeit rare, complication. As described in a 38-year-old patient by Rosenthal et al.,⁵⁶ acute dermatitis developed over a 4×4 cm region on the mid-back. Symptoms (pruritis) first appeared 3 weeks after the procedure, and progressed to painful blistering, erythema, and eventual sloughing and necrosis. The patient received only 65 minutes of fluoroscopy exposure, but excessive exposure was attributed to a malfunction in the autobrightness circuit, resulting in output 10–20 times normal operating levels and patient exposure estimated between 15–26 Gy. Protracted healing of primary and secondary erosions occurred over the next several months.

Whereas most studies have examined fluoroscopy time and skin exposure measured at the skin, an estimation of absorbed tissue exposure is much more important in ascribing long-term risk. Such estimates can only be derived using careful assessment of actual radiation output with anthropomorphic patient factors. Geise et al.⁵⁷ conducted a small but careful study in nine patients between 2 and 20 years of age and 13 and 72 kg in weight. Using continuous measurements of the fluoroscopy equipment, the exposure was then modeled as a function of peak kilovoltage, x-ray tube current, gantry angle, x-ray field size, source-skin distance, and exposure time. Anthropomorphic dimensions of each patient's chest were measured and included in the calculations and a computer simulation technique was used to account for overlapping fields.

Maximum skin dose estimated in these patients ranged from 0.01 to 2.33 Gy (1–233 rad) during exposure times ranging from 7 to 105 minutes. Fluoroscopy time and chest size did not completely account for exposure rates, even when examining procedures performed with the same equipment. The high variation was attributed to differences in the radiation path length and different gantry angles. Likewise, the site of maximum skin exposure varied widely between patients, particularly when overlapping fields were included in the estimates. It was noted that the dose rate, normalized for time, increases exponentially

with body size, doubling for every 2–4 cm increase in chest thickness. The maximum skin dose was 2.35 Gy in a 20-year-old patient who received a 105-minute exposure.

Several studies examined radiation exposure early in the RF ablation experience. Initial estimates of radiation exposure were reported by Calkins et al.⁵⁸ and Lindsay et al.⁵⁹ Calkins et al.⁵⁸ used thermoluminescence dosimeter (TLD) crystals applied to patient and physician to measure skin dosimetry. In contrast, Lindsay et al.⁵⁹ estimated exposure using a commercial electrometer/ion chamber x-ray monitor in conjunction with single phantom model. The measured output and the total fluoroscopy time were used to derive an estimate "entrance exposure." From these studies, initial estimates of lifetime increased malignancy risk were similar (Calkins: 1/1000 per 1 hour of exposure; Lindsay: 1/745 cases for mean 50-minute exposure). Likewise, both investigators derived similarly low risk of genetic defects (0.001–0.002%).

Kovoor et al.⁶⁰ measured exposure in nine young adult women with TLD crystals placed over 41 body sites. Fluoroscopy times were 33–157 minutes, including 13–80 minutes of exposure for diagnostic study. The absorbed doses and risks were estimated. Total malignancy risk was approximately 300 excess fatal malignancies per 1 million cases (0.03% excessive risk), with lung cancers (0.03%) representing the highest risk, followed by hematological (0.002%), breast (0.001%), and thyroid malignancies (0.0002%). Of note, ovarian exposure was estimated rather than measured, but estimated ovarian exposure was below the threshold for increased ovarian malignancy. Hereditary defects were estimated to be < 1 defect per 1 million cases for 60 minutes of fluoroscopy. This study was significant in establishing a risk estimated roughly one third of previous reports.

Despite the overall low risk incurred by patients during these procedures, a variety of approaches to minimize exposure should be followed compulsively. First, physicians and institutional radiation safety personnel should work closely together to ensure optimal operation of the equipment. Physicians should be familiar with the specific equipment being used and appraised of any special operational features. While pulsed fluoroscopy should be used at the lowest frame rate providing adequate images, it should be recognized that some units operate at a higher current during pulsed operation compared to continuous mode. Whenever possible, an image freeze should be used to capture an image for inspection rather than watching or assessing catheter positions in "real time." If permanent images are de-

sired, direct capture of fluoroscopy images should be used rather than cineangiography, which adds considerable additional exposure. Stability of catheter position during RF lesions can often be assessed without direct visualization by monitoring impedance during the lesion and periodically using a brief burst of fluoroscopy. To limit the output of the operational equipment, it is important to place the x-ray source (typically beneath the table) as far away from the patient as possible and the image intensifier (typically above the patient) as close as possible. The x-ray beam should be directed away from the operator to minimize their exposure. The size of the field of view should be minimized by adjusting the gantry, but "magnified modes" may increase output and should be used judiciously. For prolonged procedures, variation between two or more viewing projections helps minimize maximal exposure at any give site. However, simultaneous views of two projections in biplane mode should be used only as necessary.

In summary, some small degree of fluoroscopy exposure remains a largely inescapable risk of catheter ablation. Yet, this risk appears acceptably low, considering the benefits to be derived from the procedure. Efforts to minimize exposure, while important, should not compromise the primary goal of the procedure, which is success.

Results and Complications in Patients Without CHD

In 1991, a voluntary registry of pediatric ablation procedures was started and has been maintained by the Pediatric Electrophysiological Society. The Pediatric Radiofrequency Ablation Registry has collected data on 7,524 procedures in patients with or without associated structural heart disease, of which 6,578 procedures performed in 6,004 patients were without structural heart disease. Procedures were reported from January 1991 to April 1999 from 49 centers. All data below are from the group without structural heart disease.

The median age of patients undergoing ablation was 13.2 years and the median weight was 50.5 Kg. Patients underwent ablation because of preference rather than drug treatment or no treatment in 54%, medically refractory tachycardia in 32%, and life-threatening symptoms in 7% of cases.

Tachycardia due to an accessory connection was the most common arrhythmia for which ablation was attempted (4,838 pathways in 4,462 patients). Ablation was acutely successful for 92.2% of all pathways. The success rate was highest for left free-wall pathways (96.5%) and lowest for anteroseptal APs (81.1%). For left-sided accessory

connections, a transseptal approach was used in 1,867 cases with a 96% acute success rate and 3.3% incidence of major complications. A retrograde aortic approach was used in 769 cases with a 94% success rate and 2.6% incidence of major complications.

AVNRT was the second most common diagnosis (1,706 patients). Ablation was acutely successful in 97.4% of patients. Complete AV block (AVB) occurred in 20 patients (1.17%), 19 during slow pathway ablation and 1 during attempted fast pathway ablation.

Ablation of atrial ectopic tachycardia was acutely successful in 86.7% of patients. The success rate was slightly higher for left atrial ectopic tachycardias (89.9%) compared to right atrial ectopic tachycardias (84.2%). Ablation of atrial flutter was successful in 84.8%. Ablation of idiopathic right VT was acutely successful in 79.7%.

Multivariate analysis revealed the following variables were associated with greater success: procedural experience (> 20 and > 100 cases), left free-wall AP, AVNRT, and posteroseptal APs. Failure was associated with attempted ablation of right VT.

Complications occurred in 7.2% (473/6,578) procedures. Major complications (defined as those that required immediate treatment and/or follow-up) occurred in 2.6% (177/6,578) procedures. Over the period of the Registry, the incidence of major complications decreased from 4.8% in 1991 to 1.4% in 1997.

The most common major complications reported in the group of patients with structurally normal hearts included second- and third-degree AVB, perforation, pericardial effusion, embolization, brachial plexus injury, and pneumothorax. Seven patients died related to complications of ablation for a death rate of 0.106% for the 6,578 procedures and 0.117% for the 6,004 patients as compared to the previously mentioned risk of sudden death with a diagnosis of WPW of 0.09%–0.6% per patient year of follow-up.

Results and Complications in Patient's with CHD Undergoing Ablation of SVT, Including Atrial Flutter

Patients with most types of CHD appear to have a similar risk as the general population for occurrence of typical forms of accessory connection mediated SVT. Additionally, certain congenital diseases are associated with an increased incidence of common and uncommon forms of SVT. Ebstein's anomaly of the tricuspid valve is associated with WPW syndrome, Mahaim fibers, and the occurrence of multiple accessory connections. Complex heterotaxy is associated with AV discordance with "twin AV nodes" and conduction

slings. Patients who have undergone atrial surgery frequently develop atypical intraatrial reentrant tachycardias (IART). Several features common among patients with CHD have the potential to complicate RFCA of SVT, and might be expected to reduce acute and long-term efficacy, and increase the risk of procedural complications. The anatomic landmarks commonly used to ascertain the location of the AVN and annular rings are often absent or abnormal, and may be further distorted or rendered inaccessible by surgical intervention. Systemic venous anomalies and acquired venous occlusion may render vascular access problematic. In addition, hemodynamic and pulmonary impairments increase the risks of procedures and require careful management during catheterization.

Initial small series established feasibility of RF ablation in patients with CHD.^{61–63} Initial experience suggested an increased incidence of multiple APs, antidromic tachycardia, and syncope. Outcomes data drawn from the Pediatric Radiofrequency Ablation Registry have been reviewed (J. Perry, personal communication). Between the years 1990 and 1994, 291 patients with CHD were enrolled. The success rate for ablation of ectopic atrial tachycardias was 86%, for accessory connection mediated tachycardias 76–80% (accessory connection/WPW, 76%; Mahaim fiber, 80%; PJRT, 76%), for AVNRTs 59% and for IART 55%. Combining these numbers yields an estimated overall acute success rate for SVT of 71%. It was concluded that acute success rates for CHD were lower than for ablation in a normal heart for the reasons noted above.

A recent query of the Registry over the period 8/89–10/99 revealed that of 7,524 patients enrolled in the Registry, 786 (10.4%) were coded as having concomitant CHD. Acute success rate among these 786 patients was 80.0%. This represents all anatomic and arrhythmia diagnoses. Among the 473 (6.3% of total) patients who had a SVT other than IART, the acute success rate was 86.7%, which suggests an overall improvement compared to the period from 1990 to 1994 described above.

Among 786 patients with CHD, a total of 63 complications were reported in 61 patients, yielding a per patient complication rate of 7.8% (confidence interval 6.0–9.9%). Complications were considered “serious” if they resulted in permanent injury and/or required significant additional therapy and/or monitoring. A total of 33 “serious” complications (estimated per patient rate of 4.2%, confidence interval 2.9–5.8%) were reported, including third-degree AVB, brachial plexus stretch injury, cardiac arrest, Horner’s syndrome, and superior vena cava (SVC) thrombus. Two deaths

were reported for a mortality of 0.3% (confidence interval 0.03–0.9%), slightly higher than complication and mortality rates for patients without CHD observed in this registry.

There are several situations in patients with congenital heart defects and arrhythmias that warrant special mention. First, Ebstein’s anomaly of the tricuspid valve is associated with an increased prevalence of preexcitation and possibly with atrial tachycardia as well. The difficulty of RF ablation is often increased due to the frequent presence of multiple accessory connections, the ambiguous location of the right AV annulus, and markedly abnormal, long, fractionated atrial electrograms recorded along the tricuspid annulus. Cappato et al.⁶⁴ reported a series of 21 patients with 34 right-sided APs. Acute success was achieved in 16 (76%) patients; arrhythmias recurred in 4 (25%) of 16 patients. Similarly, Reich et al.⁶⁵ summarized data on 65 patients with Ebstein’s anomaly from the Pediatric RF Registry in 1998. These patients constitute approximately 16% of the registry population with CHD. Approximately half of the patients had a single accessory connection, 29% had multiple connections, 9% had other arrhythmia mechanisms, and 9% had an accessory connection and other arrhythmia mechanisms. The acute success rate at first RF ablation attempt was 83% and the specific location of the accessory connection did not appear to affect the acute success rate or the recurrence rate.

Second, macroreentrant or IART encompass a variety of reentry circuit types including common atrial flutter and complex reentry circuits defined by regions of block created by scarring, surgical incisions, patches, and baffles. Multiple reentry circuits in a single patient are common. Van Hare et al.⁶⁶ and Kanter et al.⁶⁷ reported 21 patients with transposition of the great vessels who had IART after a Mustard or Senning procedure. Ablation was acutely successful in 17 (81%) patients. Kalman et al.⁶⁸ and Baker et al.⁶⁹ each reported series with mixed anatomic diagnoses in 1996 with acute success rates of 15 (89%) of 18 patients and 13 (93%) of 14 patients, respectively. Collins et al.⁷⁰ presented a series of 88 patients undergoing a first ablation attempt. Acute success was observed in 29 (73%) of 40 Fontan patients, 17 of 24 patients who had undergone biventricular repair of a congenital heart defect (71%) and 12 of 15 patients with a prior Mustard or Senning procedure. The remaining nine patients had normal hearts or unclassified congenital defects. Combining the results of these case series, RF ablation was acutely successful in 103 (78%) of 132 patients.

In their report of acute outcomes of IART ablation published in 1996, Baker et al.⁶⁹ reported

arrhythmia recurrence in 6 (46%) of 13 patients; after a second ablation procedure in those patients, overall freedom from arrhythmia was 86% at a mean of 7.5 months. In 1997, Triedman et al.³⁹ reported a more focused follow-up study of arrhythmia recurrence in a population of 33 patients with mixed congenital defects who had acutely successful RF ablations of IART. Recurrence was observed in 17 (53%) of 33 patients at an average interval of about 4 months with an actuarial estimate of freedom from recurrence of 40% at 2 years. Measures of arrhythmia activity including frequency of documented IART and cardioversion demonstrated a significant reduction after RF ablation.

From 1989 to 1999, 748 (9.9% of total) patients have been enrolled in the Pediatric Radiofrequency Registry with an arrhythmia diagnosis of IART or atrial flutter. Acute success rate reported for these patients has been 82.2%. Of these patients, 271 (3.6% of total) are also coded as having CHD, and may be more representative of the complex patients discussed above. Acute success rate for ablation among these 271 patients has been 73.3%, which is improved from the early acute success rates of 55% reported by Perry from the Registry. Possible explanations for this may include center-specific strategies for management of this arrhythmia. Of the 59 centers contributing data to the Registry from 1989 to 1999, 6 centers have performed more than half of the recorded IART ablations in patients with CHD. It is possible that effects of the learning curve phenomenon⁷¹ and/or the focused introduction of new technologies for mapping and ablation specific to high volume centers may explain the apparent global improvement in acute outcomes for this procedure among Registry patients.

In summary, patients with CHD and SVT who undergo RF ablation have diverse anatomic and arrhythmia substrates. Compared to patients with anatomically normal hearts, this special population has a lower acute success rate. They also may have a slightly higher risk of major procedural complication and procedural mortality. Two major subgroups predominate: Ebstein's anomaly and IART after atrial surgery. In each of these groups, the lower acute success rates as compared to patients without CHD are likely due to the complex arrhythmia substrate. Recurrence rates in these groups are also significantly higher than that seen in those patients without CHD. Acute success rates in those patients with CHD appear to have improved over time. In the case of IART, application of RF ablation at present is concentrated in a small number of centers, which may contribute to gradual improvement in acute success rates for this entity.

Results and Complications in Patients with CHD Undergoing Ablation of VT

VT, and its relationship to the occurrence of sudden death, is one of the most difficult management issues in patients who have previously undergone surgical repair of significant congenital heart defects. Sudden death in this patient population is even more devastating when one considers that in most patients, the congenital heart defect had been successfully repaired. Initially, attention had been focused on the possibility that the development of complete AVB might be a possible explanation for sudden death in such patients. However, while AVB is certainly the explanation in a few patients, AVB has not been implicated in most instances of sudden death.⁷² In patients who have undergone major atrial surgery, like the Mustard or Senning repair for transposition of the great vessels, or the Fontan procedure for various forms of single ventricle, atrial flutter with rapid conduction is certainly involved in the etiology of sudden death.³⁵ However, because of the frequent occurrence of premature ventricular contractions, non-sustained and sustained VT in patients who have undergone complete repair of tetralogy of Fallot and double-outlet right ventricle,⁷²⁻⁷⁸ VT has been implicated in the etiology of sudden death in this patient group. Indeed, it has been reported that postoperative tetralogy of Fallot is the most common diagnosis recorded in children aged 1-16 years who have had an episode of sudden death.⁷⁹

If VT is easily inducible during electrophysiological testing in the laboratory and is well tolerated hemodynamically, one may consider RF ablation. As most evidence supports macroreentry as the mechanism of such well-tolerated VT, techniques like entrainment pacing and mapping have been used. After one report in which direct current electrical fulguration was used to successfully ablate VT,⁸⁰ other investigators have reported successful procedures using RF energy.⁸¹⁻⁸⁶ Successful sites have included the area between the pulmonary valve and outflow tract patch,⁸³ the isthmus of ventricular tissue between an outflow tract patch and the tricuspid annulus,⁸⁶ and the region of the VSD patch.⁸¹

Hebe et al. treated 17 patients who had CHD and VT using RF ablation in Hamburg, Germany (personal communication). The most common diagnosis was tetralogy of Fallot, but other diagnoses like VSD, pulmonic stenosis, and transposition were also seen. A total of 21 VTs were induced in the 17 patients, of which 19 were mapped. Initial ablation success was achieved in 11 (53%). Of these 11 successes, 2 (18%) experienced recurrence during a follow-up interval of 5-96 months with one of these undergoing a successful second ablation. One major complication

was noted in a patient who developed complete AVB in response to ablation in the region of the rim of a VSD patch.

While well-tolerated VT can be mapped in the electrophysiological laboratory, many patients have ventricular dysfunction and/or rapid VT rates, and will not tolerate this rhythm. Several investigators have reported intraoperative mapping and ablation.^{51,81,87-89} In particular, Downer et al.⁵¹ have used intraoperative mapping of the right ventricular outflow tract in the beating heart using an endocardial electrode balloon and a simultaneous epicardial electrode shock array. Ablation of the suspected arrhythmia substrate was carried out using cryolesions developed during normothermic cardiopulmonary bypass with the heart beating, or during anoxic arrest, with good success in three patients.

In summary, based on the current experience in the ablation of sustained monomorphic VTs, success rates in patients after surgery for congenital heart defects are still limited. It may be that new mapping systems will contribute to ultimate success in this population, but there will still be the problem of lack of hemodynamic stability during VT, and the problem of adequate lesion generation. Much work in this area remains to be done.

Cost-Effectiveness Analysis in the Pediatric Population

One of the major issues in addressing cost-effectiveness is understanding what we mean by cost-effectiveness. In a simple sense, this type of analysis compares the outcome of decision options in terms of their monetary costs per unit of "effectiveness." To be meaningful, this should be done by comparing alternative treatments for the same population.⁹⁰ As Petiti et al.⁹¹ points out, "cost-effective" is frequently misused. In these cases, there may exist no data on cost and effectiveness, effectiveness may be shown with no cost data and in studies where cost data only is evaluated (i.e., cost savings relative to alternatives). A more proper way to analyze cost-effectiveness is to use the following criteria: (1) if the treatment is less costly and at least as effective; (2) if it is more effective and more costly but the added benefit is worth the cost; (3) if it is less effective and less costly but the added benefit of the alternative therapy is not worth the cost; and (4) there exists a cost saving with an equal or better outcome.

The only pediatric study to address these issues was published in 1997 by Garson and Kanter.⁹² They studied patients aged 5–21 years and compared costs with surgery, RFCA and medical treatment for WPW syndrome. Charges from hospital bills, mortality from the literature, and morbidity assessed by hours in the clinic, and hospi-

tal and intensive care unit bed costs were analyzed. In this specific disease entity, they concluded that RF ablation of an AP was preferable throughout the range of costs, mortality, and morbidity. Obviously, they were unable to evaluate long-term morbidity issues as this facet of treatment is currently under review by virtue of the Pediatric Radiofrequency Registry and a National Institutes of Health sponsored study.

Few would argue this finding, however, since the publication of this study, the use of RF ablation has been expanded to a host of other arrhythmias. Now that a pediatric model for cost-effectiveness for RF ablation exists, the focus of future studies should be on the use of this therapy for IART in complex CHD and postoperative VT. Only by comparing the option of surgical modification of reentry circuits in these patients with the outcomes and costs of RF ablation will we be able to conclude whether one option is preferable over the other.

Indications for RFCA

These guidelines propose consensus indications for the performance of RFCA in pediatric patients. The guidelines are based on the natural history of these arrhythmias,^{1,14,15} published results for RFCA procedures in pediatric patients,⁹³⁻⁹⁵ previously published or proposed guidelines^{90,96} and data and discussion at this conference. The guidelines are intended as a general framework for decision making and do not replace the need for individual judgment regarding a specific patient.

First, with increased experience and improvements in technology, the indications for RFCA in children have evolved over the past decade. Serial data derived from the Pediatric RFCA registry have demonstrated that RFCA is increasingly performed in children as an elective procedure, often as an alternative to chronic antiarrhythmic drug therapy.⁹⁵ Second, Registry data has consistently demonstrated that age < 4 years or weight < 15 kg are *independent risk factors* for complications associated with the procedure. Once patients reach 4 years, age does not appear to be an independent predictor of risk of complication or procedural outcome.⁹⁷ Rather, the experience of an institution/individual is the primary correlate of outcome and complication.⁷¹ Third, the long-term efficacy of the procedure is different for the various arrhythmias (i.e., whereas long-term efficacy for accessory AV connections exceeds 90%) the efficacy for intraatrial reentrant tachycardia is only 50%.³⁹ The probable benefit/risk ratio for a specific arrhythmia substrate is another factor that must be considered in such guidelines. In the authorship of these guidelines, it is recognized that other methods of treat-

ment or patient management strategies may be equally effective or preferred in a specific patient or institution. These guidelines are intended to provide a context for decision making and highlight those situations in which the indications for catheter ablation are unresolved or when the procedure is generally not indicated. Contributing to these guidelines were pediatric and adult electrophysiologists who regularly perform catheter ablation, pediatric electrophysiologists who do not perform ablations and pediatric division directors. For the purposes of this statement, conventional drug therapy is defined as other than amiodarone or sotalol.

As a consensus conference, the guidelines regarding the indications for RFCA procedures in children used the following format:

Class I. There is consistent agreement and/or supportive data that catheter ablation is likely to be medically beneficial or helpful for the patient.

Class II. There is a divergence of opinion regarding the benefit or medical necessity of catheter ablation.

II A: The majority of opinions/data are in favor of the procedure.

II B: There is clear divergence of opinion regarding the need for the procedure.

Class III. There is agreement that catheter ablation is not medically indicated and/or the risk of the procedure may be greater than benefit for the patient.

Indications for RFCA Procedures in Pediatric Patients

Class I

1. WPW syndrome following an episode of aborted sudden cardiac death.

2. The presence of WPW syndrome associated with syncope when there is a short preexcited RR interval during atrial fibrillation (preexcited R-R interval < 250 ms) or the antegrade effective refractory period of the AP measured during programmed electrical stimulation is < 250 ms.

3. Chronic or recurrent SVT associated with ventricular dysfunction.

4. Recurrent VT that is associated with hemodynamic compromise and is amenable to catheter ablation.

Class II A

1. Recurrent and/or symptomatic SVT refractory to conventional medical therapy and age > 4 years.

2. Impending congenital heart surgery when vascular or chamber access may be restricted following surgery.

3. Chronic (occurring for > 6–12 months following an initial event) or incessant SVT in the presence of normal ventricular function.

4. Chronic or frequent recurrences of intraatrial reentrant tachycardia.

5. Palpitations with inducible sustained SVT during electrophysiological testing.

Class II B

1. Asymptomatic preexcitation (WPW pattern on an electrocardiograph [ECG]), age > 5 years, with no recognized tachycardia, when the risks and benefits of the procedure and arrhythmia have been clearly explained.

2. SVT, age > 5 years, as an alternative to chronic antiarrhythmic therapy which has been effective in control of the arrhythmia.

3. SVT, age < 5 years (including infants), when antiarrhythmic medications, including sotalol and amiodarone, are not effective or associated with intolerable side effects.

4. IART, one to three episodes per year, requiring medical intervention.

5. AVN ablation and pacemaker insertion as an alternative therapy for recurrent or intractable intraatrial reentrant tachycardia.

6. One episode of VT associated with hemodynamic compromise and which is amenable to catheter ablation.

Class III

1. Asymptomatic WPW syndrome, age < 5 years.

2. SVT controlled with conventional antiarrhythmic medications, age < 5 years.

3. Nonsustained, paroxysmal VT which is not considered incessant (i.e., present on monitoring for hours at a time or on nearly all strips recorded during any 1-hour period of time) and where no concomitant ventricular dysfunction exists.

4. Episodes of nonsustained SVT that do not require other therapy and/or are minimally symptomatic.

Sedation Issues in the Young

The goal of sedation in pediatric patients undergoing RF ablation should be the same as for any other procedure, that is, to provide a safe non-traumatic experience for the patient and the personnel performing the procedure. To reach this goal one must minimize the discomfort and any negative psychological sequelae of the procedure. This can be achieved with various levels of sedation ranging from conscious sedation to general anesthesia.

The type of sedation used should be determined on an individual patient basis. There are

variables that will require the use of general anesthesia like young age, preexisting medical conditions, and patient choice. Other factors that can come into play include physician choice secondary to the nature of the particular procedure being performed. Patients without an indication for general anesthesia can, and should, be considered as candidates for nonanesthetic sedation.

Definitions

To determine the type of sedation to be used, one must understand the different levels of sedation. The AAP and the American Society of Anesthesiologists have developed definitions and guidelines for three stages of sedation. These include conscious sedation, deep sedation, and general anesthesia. The AAP definitions are:

Conscious sedation. A medically controlled state of depressed consciousness that allows protective reflexes to be maintained; retains the patient ability to maintain a patent airway; and permits appropriate response by the patient to physical or verbal commands.

Deep sedation. A medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused. It may be accompanied by a loss of protective reflexes. This includes the ability to maintain a patent airway independently or respond purposely to physical stimuli or verbal command.

General anesthesia. A medically controlled state of unconsciousness accompanied by a loss of protective reflexes, including the ability to maintain a patent airway independently or respond purposely to physical stimuli or verbal command.

In pediatric patients, the lines of distinction between different levels of sedation are not always clear. It often becomes a continuum of passing from one level of sedation to the next. Therefore, it is often difficult to keep a patient in a state of conscious sedation without having them pass into a deep sedation, or even into general anesthesia, requiring more aggressive management.

Published Sedation Guidelines

The AAP has also published guidelines for the use of the different levels of sedation.⁹⁸⁻¹⁰⁰ These guidelines include those for the personnel and the facility involved in the procedure. These guidelines include:

Conscious sedation. The patient must be an American Society of Anesthesiology physical status I or II. There must be facilities and personnel immediately available to manage emergency situations. There must be age and size appropriate equipment to deliver oxygen and to establish an artificial airway. Monitoring and recording is required of baseline vital signs, continuous moni-

toring of the oxygen saturation and heart rate with intermittent noninvasive monitoring of the blood pressure. Records must be kept of the date and time all medications were administered. Medical and support personnel should be certified in pediatric advanced and basic life support, respectively. The child should be mature enough to be reasoned with during the procedure.

Deep sedation. There must be the ability to continuously observe the patient and to record heart rate, blood pressure, respiratory rate, and oxygen saturation every 5 minutes. There must be one person assigned to constantly observe the vital signs, airway, and O₂ saturation and to give medications. The personnel must be certified in basic life support with certification in pediatric advanced life support strongly encouraged.

Sedation Issues Unique to Pediatrics and RF Ablation

There is a subset of pediatric patients that are likely to be high risk for sedation. In these patients a general anesthetic should be used. This group includes patients with coexisting medical problems including: cyanotic CHD, ventricular dysfunction, renal or hepatic dysfunction, gastroesophageal reflux, and neurologic dysfunction. Patients with airway issues like snoring, sleep apnea, anatomic abnormalities, and trisomy 21 are also at risk. Patients may also be at high risk due to inability to cooperate. This includes children and patients with attention deficit disorder and/or developmental delay. Any patient with a history of paradoxical response to sedation or complications during previous sedation should also be considered a candidate for general anesthesia.

The level of sedation required to perform a RF ablation in a pediatric patient is often that of deep sedation rather than conscious sedation. This is secondary to the need for near immobility of the patient during the procedure. To reach this level of sedation, many practitioners use a combination of medications including benzodiazepines, narcotics, and barbiturates. When using such medications it is important to remember that they are respiratory depressants and sedatives. The patient's airway must be continuously monitored when these medications are used.

In determining the method of sedation to be used during a pediatric RF ablation procedure, it is important that the physician meet with the family to discuss sedation options. During this visit, all modes of sedation should be presented. Particular attention should be paid to the patient's preferences. Some patients absolutely do not want to take any chance of awakening during the procedure or even to know what is going on while others are concerned about the use of anesthesia. All

patient and family concerns should be addressed at the time of the previsit.

Sedation Without General Anesthesia

In those patients where deep conscious sedation is chosen, the use of topical and local anesthetics like topical lidocaine and prilocaine (EMLA Cream, AstraZeneca LP) can be helpful in diminishing discomfort around the injection site used for infiltration with injectable anesthetic agents prior to the placement of the catheters. The topical anesthetic must be placed in the area of the catheter insertion site at least 1 hour prior to the procedure. The use of a premedication is also helpful in these procedures. There are a number of premedications that can be used including oral or intravenous (IV) benzodiazepines, narcotics, or barbiturates. Once the patient is in the catheterization laboratory and is being adequately monitored, additional IV sedation may be used. Common agents used for IV sedation include midazolam, fentanyl, morphine, ketamine, pentobarbital, and other IV barbiturates. Once the catheters are placed, the use of long-acting anesthetics like marcaine is often helpful in maintaining patient comfort.

General Anesthesia Versus Conscious/Deep Sedation

It has been proposed that general anesthesia be used for all RF ablation procedures in pediatric patients. One reason given is the ability of general anesthesia to prevent patient movement at critical times during the procedure. This may be particularly important during the performance of a transeptal puncture or during the delivery of a lesion. Another potential advantage is the ability to control ventilation with the ability to hold the patient at full inspiration or end expiration. This is sometimes helpful in allowing a more uniform delivery of energy during the lesion. A third possible indication for general anesthesia is when venous access from the neck is required. There is a concern that it takes deeper sedation to maintain patient comfort during access from the neck than it does from the groin. Other potential advantages to using anesthesia during the procedure is that there is another physician in the room to monitor the patient, and the airway is better protected during the procedure when the patient has been intubated. There is likely an age at which patients are too young to have a procedure as long and invasive as a RF ablation without the use of general anesthesia. This age will vary from patient to patient but as a general rule general anesthesia should be considered in those patients age 10 years or less.

Potential disadvantages of the use of general anesthesia include the fact that the patient will likely require intubation and many patients will complain of a sore throat following the procedure. There is also a potential increased risk of position injuries like brachial plexus pull from the arm(s) placed over the patient's head or pressure necrosis in patients who do not move at all during a 6–8 hour procedure. There are situations in which the anesthetic agents may actually hinder the ability to induce a tachycardia. This is most commonly seen in those patients with an automatic mechanism rather than reentry tachycardia. Studies have shown that the effect of general anesthetics on refractory periods and conduction velocity is generally minimal. Other potential disadvantages include scheduling limitations due to a lack of resources and the increased cost to the patient for the procedure.

Summary of Sedation Issues

The goals of sedation in a patient undergoing RF ablation should primarily be that of patient safety. Each patient should be individualized with the decision as to whether or not to proceed with general anesthesia or sedation. Careful preprocedure evaluation by the physician performing the procedure is often helpful in assessing patient needs in terms of whether or not general anesthesia will be required. In those patients in which general anesthesia is not used, it is important that personnel and facilities be available to deal with any complication that may arise from the sedation protocol that is used.

Facilities and Equipment

During the 4-year period from 1989 to 1992, the number of patients undergoing catheter ablation procedures in the United States increased more than 30-fold from an estimated 450 procedures in 1989 to 15,000 procedures in 1993.¹⁰¹ Since catheter ablation is also being performed more commonly in children,^{27,54,102} the current state of knowledge about the facilities, equipment, and personnel needed to achieve excellent outcomes in this group of patients requires review. It is hoped that the following will provide a guideline for those institutions performing this procedure on children.

Facilities

Catheter ablation procedures should be performed in a cardiac catheterization laboratory, which has been specifically set up for performing catheter ablation procedures and electrophysiological studies. The minimum standards for fluoroscopy equipment include a rotatable C-arm flu-

oroscopy unit. A video recording system is also recommended. Biplane fluoroscopy equipment is preferred by many electrophysiologists but is not mandatory. State of the art fluoroscopy equipment is recommended to minimize radiation exposure.^{64,103} The laboratory should also be equipped to care for patients with acute complications (i.e., tamponade, coronary spasm or thrombus, or AVB). In addition, facilities for temporary and permanent pacemaker insertion should be available.

There was general agreement at this consensus conference that catheter ablation procedures in young children (see below under "Personnel") should be performed in a hospital that has the capability of caring for pediatric patients, including cardiac surgery in children. This goal could be accomplished by performing the ablation procedures in a children's hospital or by performing these procedures in a general hospital that also cares for pediatric patients.

Equipment

The major equipment that is needed to perform catheter ablation procedures includes: (1) an amplifier and recording system, (2) a stimulator, (3) a RF generator, and (4) a cardiac defibrillator. Additional equipment that may be beneficial in complex cases includes the use of an advanced mapping system that improves three-dimensional visualization of positioning the catheter tip. An amplifier and recording system capable of recording a minimum of 12 intracardiac electrograms (in addition to multiple surface ECG tracings) is essential. Most electrophysiological laboratories currently have systems capable of recording and displaying more than 20 electrograms.

Catheter ablation is now performed primarily using RF energy. Up to 50 W of RF energy is delivered for 30–60 seconds as a continuous, unmodulated, sinusoidal waveform with a frequency of approximately 500,000 cycles per second, between the tip of a deflectable ablation catheter and a ground plate positioned on the patient's back or chest. The majority of catheter ablation systems in use today monitor the temperature of the ablation electrode and automatically adjust power output to achieve a targeted electrode temperature of between 60 and 70°C.¹⁰⁴ Knowledge of the electrode temperature at a particular ablation site may be useful in determining whether an unsuccessful application of RF energy failed due to inaccurate mapping or to inadequate tissue heating. Automatic adjustment of power output using closed-loop temperature control has been demonstrated to reduce the incidence of coagulum development. This may also facilitate catheter ablation by

reducing the number of times the catheter has to be withdrawn from the body to have a coagulum removed from the electrode tip,¹⁰⁴ and in the case of left-sided ablations, eliminate the risk of a thromboembolic event. Recently, methods for improved cooling of the electrode have been developed to allow delivery of higher RF power. These include the use of larger (8 mm) electrodes,¹⁰⁵ which receive greater convective cooling by the blood and saline-irrigated electrode tips, in which the electrode is actively cooled.^{106,107} Safety has not been demonstrated in children and thus recommendations for their use cannot be made at this time. Most ablation catheters are specifically designed for the delivery of RF current, although ultrasonic,^{108–110} microwave,^{111–113} laser,^{114–117} and cryoablative¹¹⁸ techniques have also been investigated. It is extremely rare that ablation systems capable of creating lesions larger than standard RF ablation systems are needed in the pediatric population.

As the range of arrhythmias that can be treated with RF ablation has broadened, the ablation procedures have, in some cases, become more technically challenging. In such cases, particularly when targeting atrial or VTs, visualization of the catheter tip in relation to the cardiac anatomy is crucial. Since a single fluoroscopic view displays the catheter only against the cardiac silhouette, biplane fluoroscopy is a useful addition to the electrophysiological laboratory. When the two fluoroscopic planes are placed orthogonal to each other, the position of the catheter in three-dimensional space can be inferred. New technology has provided a means for nonfluoroscopic tracking of catheter tip position and orientation in three-dimensional space including electromagnetic field positioning, non-contact mapping (electrical positioning), and ultrasonic ranging.^{119–124}

External defibrillators, specifically designed for use in children, that is, appropriately sized external pads and paddles and those systems allowing for lower dose shocks appropriate for the age and size of a child should be available.

Personnel

Physicians

Three types of cardiac specialists are often involved in the performance of RF ablation procedures in pediatric patients: adult electrophysiologists, pediatric electrophysiologists, and pediatric cardiologists. It is not the purpose or responsibility of this Consensus Conference to define what is meant by each of these designations or to set training guidelines. However, it is generally agreed that for each of the three specialties, the practitioner

has a special interest in the area, devotes the great majority of their time to it, and has undergone special training in the specialty. For pediatric cardiology and adult electrophysiology in the United States, board certification by the American Board of Pediatrics or the American Board of Internal Medicine is the standard indicator of specialized training. However, in countries other than the United States other mechanisms exist and other practice models may be operative. The specialty of pediatric electrophysiology does not have a board certification process in the United States, and there is ongoing discussion concerning what constitutes adequate specialized training. However, a pediatric electrophysiologist is generally understood to be a pediatric cardiologist who devotes a majority of their time to Electrophysiological practice and has undergone specialized training.

Prior standards for training and credentialing of any of these types of cardiologists performing catheter ablation procedures in pediatric patients do not exist. In 1992 NASPE issued a Policy Statement on Catheter Ablation Procedures in adult patients, and suggested that the minimum requirements for physician performance of catheter ablation procedures include completion of training that would establish eligibility for the Electrophysiological Sub-Board of the American Board of Internal Medicine.¹²⁵ While this option is not available for board-certified pediatric cardiologists or pediatric electrophysiologists, several of the requirements mentioned in that document are appropriate. The individual should have been the primary operator for a minimum of 30 pediatric catheter ablation procedures, including at least 15 AP ablation procedures. It was also considered desirable by that Board that two physicians be involved in complex ablation procedures. This role could be filled by a cardiac electrophysiological fellow, a second pediatric or adult electrophysiologist, or a pediatric cardiologist adept in catheter manipulation. Continued competence in performing catheter ablation procedures could be achieved by having a physician perform at least 20 pediatric ablation procedures per year with an overall success rate > 80% (or within 2 SD of the Registry data).

There was uniform agreement in this conference that only physicians who are highly skilled in catheter ablation should perform these procedures in children, be they pediatric or adult electrophysiologists. As a general indicator of such skill, the guidelines previously developed for performing catheter ablation procedures in adults are generally applicable to pediatric and adult electrophysiologists performing pediatric ablation procedures. However, as there is no qualifying sub-Board for pediatric electrophysiologists, the

requirement for having previously taken the qualifying examination in electrophysiology would not apply to pediatric electrophysiologists.

There was consensus on the part of the conference experts that it is highly desirable, and probably mandatory, that a pediatric cardiologist or pediatric electrophysiologist be involved in catheter ablation procedures performed in younger patients. While no consensus was reached on any "cut-off" age (i.e., what is "younger"), there was general agreement that the involvement of a pediatric cardiologist is less important when patients reach the late teen years, but extremely important in children in their early teens (15 years) or younger. Such pediatric cardiology involvement could be achieved by having a pediatric electrophysiologist perform the procedure, having an adult and a pediatric electrophysiologist involved in the procedure, or having the procedure performed by an adult electrophysiologist with direct involvement by a pediatric cardiologist. Catheter manipulation in small children is a learned skill and should be performed by those operators who have had supervised training in such techniques. Teenagers, despite their larger size, may also benefit from pediatric facilities and the specialized services that are available at children's medical centers. These include pediatric nursing, intensive care unit personnel and facilities, and anesthesiologists who are attuned to the special needs of this group of patients who "straddle" the line between child and adult, and child life services. There was general consensus concerning the additional importance of input from a pediatric cardiologist on all younger patients prior to the procedure for purposes of patient selection, cardiac evaluation, pre- and postcatheterization care and proper dosing of medications based on the patient age and underlying or coexistent medical condition(s) and planning of the procedure.

Electrophysiology Laboratory Personnel

Personnel in the electrophysiological laboratory should include two nurses (or a combination of nurses and technicians). One nurse (or physician assistant) is required to administer sedation and carefully monitor vital signs throughout the procedure. There was a consensus that ablation procedures should only be performed in centers with the ready availability of cardiac surgical support (to handle complications like perforation) and percutaneous transluminal angioplasty teams (to handle complications of coronary occlusion). It is essential that the laboratory personnel have experience with performing cardiac procedures in pediatric patients, particularly if the procedure is being performed in younger patients. It is not nec-

essary that a pediatric cardiovascular surgeon or anesthesiologist be present, but they should be immediately available and "on-site" for emergencies. It is not necessary to perform these procedures in the operating room.

Depending on patient age, the specific ablation procedure being performed, and the type of underlying heart disease, patients receive conscious sedation or general anesthesia.

Nursing Care, Psychological, and Family Issues

Nursing personnel should be familiar with the NASPE Expert Consensus Statement on "Use of IV (Conscious) Sedation/Analgesia in Patients Undergoing Arrhythmia Specific Diagnostic, Therapeutic and Surgical Procedures."¹²⁶ Staffing of the electrophysiological laboratory should include at least one registered nurse and an anesthesiologist or two registered nurses with pediatric experience for monitoring and maintaining safe sedation for the child. Registered nurses should have training in basic life support and pediatric life support, competence in drug dosing, and skill in rhythm recognition and cardioversion/defibrillation (see Sedation section).

Child Life Services and Psychosocial Issues

The overall adjustment of children with cardiac arrhythmias does not differ from normal controls. This contrasts significantly with the findings in adults with recurrent arrhythmias and supports the greater resilience of children. DeMaso et al.¹²⁷ reported on 38 patients, mean age 13.1 years, who underwent RF ablation, predominantly for SVT.

Psychometric studies included the Pediatric Symptom Checklist (PSC) for measures of general adjustment, Short Mood and Feeling Questionnaire (SMFQ) for measurement of depression, and the Revised Children's Manifest Anxiety Scale (RCMAS) and Arrhythmia Anxiety Query (AAQ) for anxiety measurement. The RCMAS showed a significant difference from pre- to postcatheter ablation in terms of worry/oversensitivity and the AAQ demonstrated a significant difference in the same time periods with respect to keeping the children from doing things they enjoyed. Thus, those patients who were cured of their rhythm disturbances had a better functional level than those without improvement. These data are also important components of measuring cost-effectiveness and justify further studies of this kind in conjunction with medical outcomes. Closer attention to psychological screening and intervention of those patients where less than curative ablation may occur also should be considered.

Conclusion

Catheter ablation procedures in young children should be performed in hospitals that are familiar with all of the needs of children. These procedures should be performed by experienced pediatric electrophysiologists, by experienced adult electrophysiologists with direct involvement of a pediatric cardiologist, or both. It is anticipated that adherence to these general principles will help maximize the safety and efficacy of catheter ablation procedures in the pediatric population.

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Appendix

Participants in the NASPE Consensus Conference: Catheter Ablation in Children, Adolescents, and Patients with Congenital Heart Disease

May 17, 2000, Washington, D.C.

Cochairs

George F. Van Hare, M.D. and Edward P. Walsh, M.D.

Moderators

Barbara Deal, M.D., William G. Stevenson, M.D., George F. Van Hare, M.D., Michael J. Silka,

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Presenters

Timothy K. Knillans, M.D., J. Philip Saul, M.D., J. Blake Long, M.D., Mark Alexander, M.D., Thomas Paul, M.D., Frank Fish, M.D., John D. Kugler, M.D., John K. Friedman, M.D., Anne M. Dubin, M.D., Richard A. Friedman, M.D., Bertrand A. Ross, M.D., Frank Cecchin, M.D., George J. Klein, M.D., Barbara J. Deal, M.D., James C. Perry, M.D., Frank McGowan, M.D., Larry A. Rhodes, M.D., Debra G. Hanisch, RN, PNP, David Demaso, M.D., Macdonald Dick II, M.D., Hugh Calkins, M.D., Edward P. Walsh, M.D., Leslie A. Saxon, M.D., Michael J. Silka, M.D.