Radiofrequency Catheter Ablation in Infants ≤18 Months Old

When Is It Done and How Do They Fare?
Short-Term Data From the Pediatric Ablation Registry

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Background—The objective of this study was to determine the indications, the safety, and the efficacy of pediatric radiofrequency catheter ablation (RFCA) in infants.

Methods and Results—Data from the pediatric RFCA registry were reviewed. Between August 1989 and January 1999, 137 infants, defined by age 0 to 1.5 years (median 0.7 years; weight 1.9 to 14.8 kg, median 10 kg), underwent 152 procedures in 27 of 49 registry centers (55%), compared with 5960 noninfants undergoing 6610 procedures during a comparable period. Structural heart disease was present in 36% of infants, compared with 11.2% of noninfants ($P<0.0001$). RFCA in infants was performed more commonly for drug resistance or life-threatening arrhythmias than in noninfants. No differences were found between infants and noninfants in success for all tachycardia substrates (87.6% versus 90.6%, $P=0.11$), for single accessory pathways (94.5% versus 91.5%, $P=0.4$), or for total (7.8% versus 7.4%, $P=1$) and major (4.6% versus 2.9%, $P=0.17$) complications. Neither success for infants with a single accessory pathway nor complications for the entire infant group were related to weight, age, center size, or the presence of structural heart disease. Centers that performed infant procedures, however, enrolled more patients overall in the registry than those that did not perform infant procedures, and successful procedures in infants were performed by more experienced physicians than failed procedures.

Conclusions—Compared with noninfants, RFCA in infants is usually performed for drug resistance or life-threatening arrhythmias, often in the presence of structural heart disease. The data support the use of RFCA by experienced physicians in selected infants. (***Circulation***. 2001;104:2803-2808.)

Key Words: catheter ablation ■ pediatrics ■ arrhythmia

Experience with radiofrequency catheter ablation (RFCA) in pediatric patients has been growing considerably since its first use a decade ago.[1,2] Success has been improving steadily and complication rates have been declining with increased user experience.[3,4] Because medical therapy has a lower success rate[5] and involves additional morbidity while requiring rigid compliance, RFCA is becoming the first line of therapy for many arrhythmias in most pediatric patients. There has been concern, however, about the use of RFCA for the treatment of infant arrhythmias.

Concerns about RFCA in infants are related to a number of factors, including the natural history of most tachyarrhythmias in infants, technical issues with RFCA in small hearts, and the potential for unknown long-term effects of RF applications on the maturing myocardium.[6] The most common tachyarrhythmias in infants are those that involve

accessory pathways (APs),[7] in which ≈33% of the substrates spontaneously resolve by the time the child is 1 year of age.[8,9] In addition, previous studies have shown a greater complication rate for RFCA in children weighing <15 kg.[4,10] Although limited intermediate-term follow-up studies have revealed no significant increase in ventricular arrhythmias[11,12] and no evidence of coronary abnormalities by traditional angiography at up to 6 months after ablation,[12] a report of late development of asymptomatic coronary artery stenosis after right free wall RFCA in 2 young boys with Ebstein's malformation[13] and a report from the Pediatric Ablation Registry of a very small number of procedure-related late deaths after the ablation procedure suggest some caution in the use of RFCA in the younger pediatric population in general.[14] As yet, no data have been published to assess the long-term risks of RF lesions on myocardial function, coro-

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TABLE 1. Patients

	Infants	Noninfants	*P*
Patients, n	137	5960	...
Procedures, n	152	6610	...
Substrates, n	171	7160	...
Age, y	0.7 (0.05–1.5)	13.1 (1.6–20.9)	<0.0001
Weight, kg	7.4 (1.9–14.8)	50 (8–139)	<0.0001
Structural HD, %	36%	11.2%	<0.0001

Structural HD indicates structural heart disease.

TABLE 2. Structural Heart Disease

Heart Disease	Count, n	% of Infants
Ebstein's malformation of tricuspid valve	11	8.3
LV dysfunction	9	6.6
Single-ventricle/L-TGA complex	5	3.6
TOF	5	3.6
HCM	3	2.2
ASD or PAPVR	3	2.2
VSD	3	2.2
Aortic stenosis or coarctation of the aorta	2	1.5
Tricuspid atresia	2	1.5
Tumors	2	1.5
TGA	1	0.7
Other	3	2.2
Total	49	36.1

LV indicates left ventricular; L-TGA, physiologically corrected transposition of the great arteries; TOF, tetralogy of Fallot; HCM, hypertrophic cardiomyopathy; ASD, atrial septal defect; PAPVR, partial anomalous pulmonary venous return; VSD, ventricular septal defect; and TGA, transposition of the great arteries.

nary perfusion, or arrhythmogenicity in a group of developing infants and children. Animal studies, however, suggest that RF lesions in the developing myocardium may have the potential to expand with time[6] and may effect coronary perfusion.[15] Thus, the potential for spontaneous arrhythmia resolution as well as the short- and long-term risks associated with infant RFCA have been arguments against infant RFCA.

There are also several reasons why RFCA may be desirable in infants. Arrhythmias in infants may produce more problems than in older children and are often difficult to manage medically.[9,16–20] Infants with congenital heart disease are at particular risk of hemodynamic compromise with arrhythmias before or after surgery. In addition, because infants are unable to communicate, arrhythmia recurrence and drug side effects are more likely to go unrecognized until symptoms have progressed further than in older children. Thus, in the absence of safety issues, a definitive cure with RFCA may be even more appealing in infants than in older children. This investigation was undertaken to determine whether the efficacy and risks of infant RFCA warrant its use in selected infants.

Methods

Data from the pediatric RFCA registry were reviewed to determine the indications, safety, and efficacy of RFCA in infants, defined as age 0 to 1.5 years, who underwent RFCA between August 1989 and January 1999. The infant data were compared with those for noninfants (1.6 to 21 years old) who underwent RFCA during a comparable period (1991 to 1998). Registry data were submitted by any member of the Pediatric Electrophysiology Society performing RFCA in any of the 49 centers participating during the study periods. All RFCA procedures were done in accordance with each center's respective institutional guidelines. Data were collected on a standardized form. Selection criteria for data parameters were chosen by the center submitting the data and were not validated. Thus, how some of the parameters were chosen, such as indications, may have varied by center.

Statistical Analysis

Indications and complications were determined for each procedure. Success was based on individual substrate elimination rather than all substrates for a given patient. Group comparisons were made by Pearson's χ^2 for multiple group comparisons, Yates' χ^2 for 2×2 comparisons, or Student's unpaired *t* test wherever applicable.

Results

During the study period, 137 infants underwent 152 procedures for 171 substrates. Infants were younger, weighed less, and had a greater presence of structural heart disease than noninfants (Table 1). Forty-nine infants (36.1%) had structural heart disease (Table 2), compared with 11.2% of the noninfants.

From August 1989 to January 1999, 28 of the 49 centers (57%) that contributed data to the registry performed at least one infant RFCA. The number of infant procedures fluctuated yearly and peaked in 1993 but was greater over the last 5 years than the first 5 years (Figure 1A). Compared with an increase in the number of procedures in noninfants, however, the number of infant procedures dropped in 1994 and 1995. Centers performing infant RFCA submitted more RFCA procedures to the registry than those that did not perform infant RFCA (271±163 versus 149±78 procedures, *P*=0.003). A majority of the infant procedures (98/152, 65%) were performed at 5 centers that performed ≥10 infant RFCAs (Figure 1B). The centers that performed ≥10 infant procedures also reported more procedures overall to the registry than those that performed fewer infant procedures (437±136 versus 235±148 procedures, *P*<0.01).

Indications

The distribution of indications differed significantly between the infant and noninfant groups (*P*<0.001, Figure 2). The presence of a life-threatening rhythm or rhythm refractory to drug therapy was the most frequent indication in the infant group (Figure 2). Whereas just over 50% of the noninfant procedures were done by patient or guardian choice versus 4.2% of infant procedures, a life-threatening rhythm was the indication for 33% of infant procedures versus 7.7% of noninfant procedures. Thus, infant procedures were more likely to be done for rhythms that were perceived to be more dangerous. Infants with structural heart disease were perceived to have a much greater incidence of life-threatening rhythms than either the infants with normal hearts or the noninfants.

Tachycardia Mechanisms

As with noninfants, most infant RFCA procedures were performed in patients with AP-mediated tachycardias
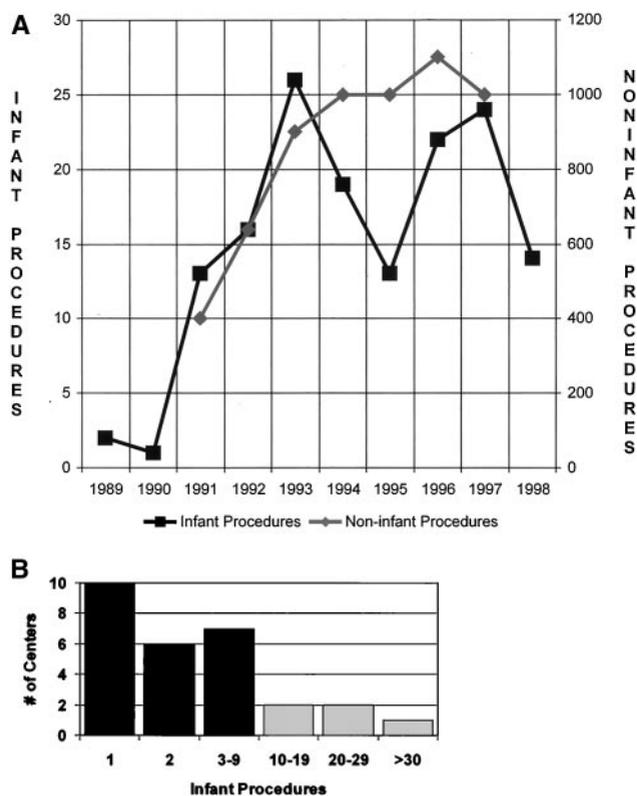
Figure 1. A, Infant RFCA procedure numbers, 1989 to 1998. Number of infant procedures fluctuated yearly, peaked in 1993, but was greater over last 5 years than first 5 years. B, Centers: 65% of infant RFCA procedures were done at 5 centers depicted in gray. These 5 centers also had more overall previous pediatric RFCA experience than 23 other centers performing infant RFCA (black), which had more previous pediatric RFCA experience than centers not performing infant RFCA (437 vs 235 vs 149 previous pediatric procedures, $P<0.01$). Thus, infant RFCA was performed at the most experienced centers.

(P=NS, Table 3). Ectopic atrial tachycardia, however, was the second most common infant substrate ablated and was more prevalent in the infant than the noninfant procedures ($P<0.0001$). Not surprisingly, AV nodal reentrant tachycardia was uncommon in infants, whereas it was the second most common substrate ablated in noninfants

($P<0.0001$). Although uncommon in both groups, ventricular tachycardia and junctional ectopic tachycardia were more prevalent in infants ($P<0.03$), whereas atrial flutter was equally uncommon in both groups (P=NS).

Other Procedure Variables
Procedure times varied widely (25 to 580 minutes, median 210 minutes), as did fluoroscopy times (5 to 194 minutes, median 33 minutes). Although 5F, 6F, and 7F ablation catheters were used, 6F were used most commonly (5F 31%, 6F 38%, 7F 31%). Procedures involved a median of 6 RF applications (1 to 46 applications). Anticoagulation with heparin was used during 79% of the procedures and continued postprocedure with heparin or aspirin in 69% of the procedures.

Procedure Success
There was no statistical difference in the elimination of individual substrates for infants versus noninfants with regard to all substrates taken together (87.6% versus 90.9%) or for any individual substrate (Table 3). Successful procedures occurred when individual physicians were significantly more experienced (171 ± 155 previous reported RFCA procedures versus 81 ± 55 previous reported RFCA procedures, $P<0.01$). Catheter French size did not influence success. To eliminate potential confounding effects due to differences in the distribution of substrates, success for AP-mediated tachycardias, the largest substrate group for infants and noninfants, was analyzed separately. Again, there was no statistical difference in success between infants and noninfants in this subset of patients (88% versus 91%, P=NS).

Factors associated with successful AP elimination within the infant group were sought. Success was not related to age, weight (Figure 3), the presence of structural heart disease, or physician experience. Although there was a difference in the frequency of APs in different locations (left free wall 51%, septal 34%, right free wall 15%), success was not statistically different between any of these locations. The approach to left-sided APs (antegrade across the atrial septum or retrograde from the left ventricle) did not affect elimination of these pathways. Success was significantly reduced for the 9
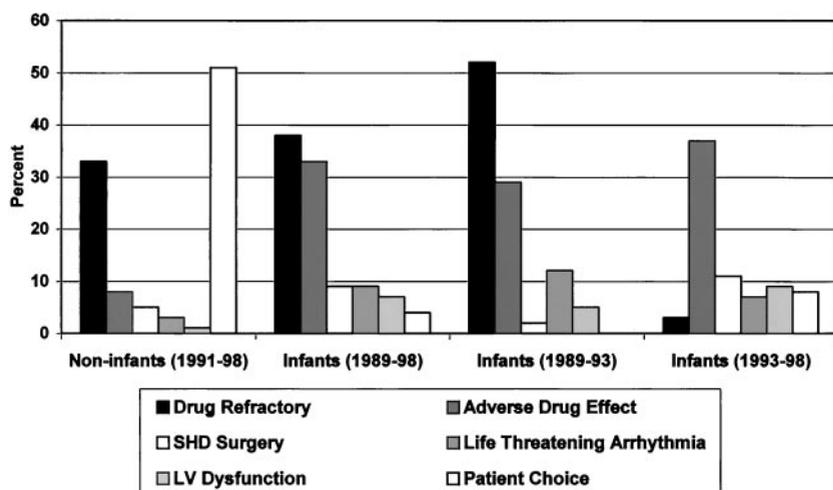
Figure 2. RFCA indications. Distribution of RFCA indications for infants is significantly different from that for noninfants. In addition, distribution of infant RFCA indications changes significantly during 1994 to 1998 vs 1989 to 1993.

TABLE 3.   Substrates

| Substrate	Infants			Noninfants		
	n	Prevalence, %	Success, %	n	Prevalence, %	Success, %
Accessory pathway	115	67.3	87.8	4731	66.1	90.9
AVNRT	7	4.1	100	1576	21.6	97
EAT	29	17.1	89.7	332	4.9	87.3
JET	6	3.5	100	13	0.3	76.9
Atrial flutter	4	2.4	50	312	4.3	76
VT	10	5.9	70	196	2.8	65.3

AVNRT indicates AV nodal reentrant tachycardia; EAT, ectopic atrial tachycardia; JET, junctional ectopic tachycardia; and VT, ventricular tachycardia.

$P=$NS for infants vs noninfants for success for all substrates.

procedures in the 9 infants (6.6%) who had multiple APs ($P<0.003$). These 9 infants had 21 APs: 6 had 2 APs and 3 had 3 APs. Only 14 of 21 APs (67%) were eliminated, and in only 5 of 9 patients (56%) were all APs eliminated in a single procedure.

Complications

A total of 12 complications occurred in the infant group, and these are divided into major and minor categories (Table 4). Neither the total nor the major complication rates were statistically different in infants versus noninfants (7.8% versus 7.4% and 4.6% versus 2.9%, $P=$NS). One death occurred in an infant with Ebstein's anomaly undergoing RFCA for ventricular tachycardia. Complications in infants were not related to age, weight (Figure 4), the presence of structural heart disease, individual physician experience, procedure time, fluoroscopy time, catheter French size, number of RF applications, or the approach to left-sided APs, but the low number of complications made correlations difficult to assess. Patients who developed complications had undergone RFCA for elimination of an AP ($n=8$), ectopic atrial tachycardia ($n=3$), or ventricular tachycardia ($n=1$). Within the AP subset, the complication rate was significantly greater for septal APs than for left free wall or right free wall (15.4% versus 3.4% versus 0%, respectively, $P=0.03$).
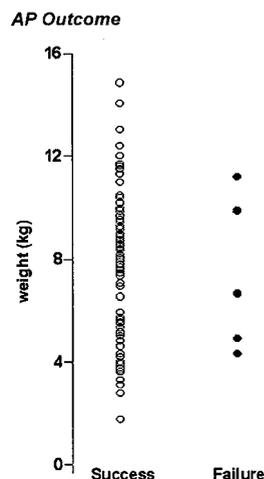
Figure 3. AP elimination and patient weight. Distribution of infant weights is plotted according to whether or not single AP was eliminated. This graph demonstrates a large overlap of weight, suggesting that within group of infants with a single AP, weight did not influence success.

Discussion

The most important findings of this study were that (1) RFCA in infants is performed for more serious indications than in noninfants, and only rarely for patient choice; (2) although APs are the most common ablation substrate, the distribution of substrates was significantly different than for noninfants; and (3) despite these differences between infants and noninfants, procedure success and complications were not significantly different from procedures in noninfants. An additional interesting finding was that RFCA for infants is performed in the centers that report the most data to the registry.
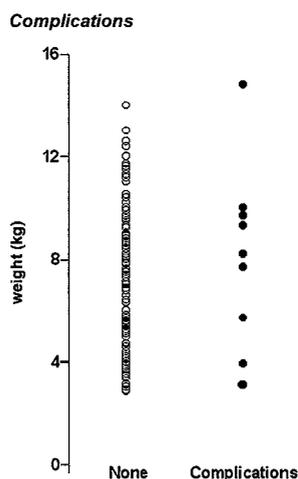
Indications

In agreement with the literature,[9,16–19] the differences in indications between infants and older children demonstrate that infants who underwent an ablation procedure were sicker on presentation and were perceived to be at greater risk from their arrhythmia. These perceptions appear to be heightened for infants with structural heart disease, who made up a much larger proportion of the infants than noninfants; the incidence of structural heart disease does not entirely account for these findings, however, because the differences were also present for infants with structurally normal hearts.

TABLE 4.   Complications

Complications	n	Substrate	Heart Disease
Major			
Pericardial effusion	2	L lateral AP/P septal AP	ASD
Pneumothorax	2	A septal AP/R EAT	VSD
2° AVB	1	M septal AP	
3° AVB	1	M septal AP	
Horner's syndrome	1	L lateral AP	
Death	1	RV-VT	Ebstein's
Minor			
Transient 3° AVB	2	A septal AP/P septal AP	VSD
Hematoma	1	R EAT	
Sinus bradycardia	1	R EAT	LV dysfunction

2° AVB indicates 2nd-degree AV block; 3° AVB, 3rd-degree AVB; L lateral, left lateral; P septal, posteroseptal; A septal, anteroseptal; R EAT, right atrial ectopic atrial tachycardia; M septal, midseptal; and RV-VT, right ventricular tachycardia.

Figure 4. Complications and patient weight. Distribution of infant weights is plotted according to whether or not RFCA was associated with acute complication. This graph demonstrates a large overlap of weight, suggesting that, within infant group, weight did not influence presence of acute complications.

Success

This study demonstrated that successful elimination of each arrhythmia substrate was not statistically different in infants and noninfants. This finding is in agreement with other large pediatric RFCA studies, in which lower weight was not a factor in predicting the success of substrate elimination.[4,10] Importantly, success was related to increased individual physician personal experience. Unlike the former registry studies involving the entire pediatric age span,[10] substrate elimination in infants was not influenced statistically by the presence of structural heart disease. Thus, beliefs that RFCA will be less successful for infants with heart disease are not necessarily correct and should not deter attempts in those infants who might benefit from RFCA. Another interesting difference between infants and older children was that infant AP elimination was not shown to be related to AP location.[4,10,21] This difference, however, may arise because relatively few infants had right free wall APs. As in reports in adults,[21] the presence of multiple APs was associated with a lower rate of AP elimination. These infants, however, are often also the most difficult to manage medically, which probably accounts for the higher frequency of multiple APs in this small group.

Complications

This study did not confirm previous registry findings demonstrating a higher complication rate in cases involving patients weighing <15 kg.[10] The data set studied here was different from the previous ones. First, it spanned >5 additional years, at a time when increasing experience was clearly affecting outcomes.[3] Furthermore, this study confined the patient base to those <1.5 years old, regardless of weight. Thus, we did not analyze the data of the 231 patients weighing <15 kg but >1.5 years old in the pediatric RFCA registry. This group of patients suffered 17 complications, of which 12 were major. When these patients are combined with the "infants" from this study, the major but not the total

complications become significantly different from the rates for children weighing >15 kg. Also different from the previous registry studies, infant RFCA complications were not associated with the presence of structural heart disease. As in reports in older children,[4] however, RFCA for septal APs is associated with a higher incidence of heart block, indicating that great caution must be used when approaching these pathways. Thus, one still needs to be cautious in patient selection and in the technical aspects of the procedure.

This study had one death in a patient with structural heart disease. Although this is one instance and therefore not significantly different from the noninfant procedures, the 0.74% mortality for infant RFCA is higher than that reported by Schaffer et al[14] for all children in the registry, 0.12%. Schaffer's study included data from follow-up forms sent to the registry and also contained the report of an infant with a structurally normal heart who died 2 weeks after RF ablation of an AP-mediated tachycardia. Through the period of Schaffer's study, ≈111 infant RF procedures were performed, yielding an associated infant mortality of 0.9%. Although another 18-month-old patient with congenital heart disease died of fever and hypotension on the day after RF ablation, no details are given except that no definitive link between the death and the procedure was established. Our infant death was not included in the Schaffer report because of differing study periods and because no subsequent follow-up data are available. Interestingly, despite the perception that medical management of supraventricular tachycardia in infants is benign, mortality rates of ≈5% have been reported in infants with Wolff-Parkinson-White syndrome and supraventricular tachycardia who were treated medically.[22,23] Furthermore, no comparable mortality data exist for medical management of only those infants who have life-threatening arrhythmias or a group with congenital heart disease.

Infant Procedure Modifications

Several modifications from the standard procedure can be used when undertaking RFCA in infants. A transesophageal catheter can replace an intracardiac catheter for atrial pacing. A single catheter can be used to record the His-bundle electrogram and to pace the ventricle, and a smaller 5F catheter can be used for the ablation. Tanel et al[24] demonstrated in vivo in animals that the maximum lesion size is much smaller when a 5F rather than a 7F tip is used, with an average lesion size for a 5F, 4-mm tip of only 1.0×3.0 mm. Although catheter size did not appear to influence success or complications, this study was not prospectively controlled and may not have adequately investigated this factor. Furthermore, "test" RF applications with a lower-temperature set point (50°C) and short duration (5 seconds) can be used to limit tissue damage to the single location at which success is achieved.[25,26] Application times can then be extended to 15 to 30 seconds only if both AP conduction is lost and AV conduction is preserved. Despite lack of conclusive proof regarding these techniques, similar modifications have been used and reported elsewhere by centers contributing to the registry.[27]

Study Limitations

Because this study was a retrospective review of short-term results, certain data were not obtainable. Other procedure-related variables, such as catheter tip length, may have been related to outcome, but because the data had not been recorded in the registry, this could not be analyzed. Clearly, any concerns regarding the long-term effects of RF ablation remain unanswered in this short-term study. Follow-up studies are needed to determine these risks.

Conclusions

Compared with noninfants, RFCA in infants is usually performed for drug resistance or life-threatening arrhythmias, often in the presence of structural heart disease. No significant differences were found for success and complication rates between infants and noninfants. The data support the use of RFCA by experienced physicians for arrhythmia management in selected infants. Finally, this retrospective analysis of the short-term results of infant RFCA procedures may have important implications for the management of arrhythmias in sick infants.

Appendix

Members of the Pediatric Catheter Ablation Registry that performed infant ablations during the study period: Arkansas Children's Hospital, Little Rock; Arrhythmia Associates, Fairfax, Va; Atlanta Children's Heart Center, Ga; Boston Children's Hospital, Mass; Children's Hospital of Philadelphia, Pa; Children's Hospital of Pittsburgh, Pa; Children's Hospital of San Diego, Calif; Children's Hospital of the King's Daughters, Norfolk, Va; Children's Memorial Hospital, Chicago, Ill; Cook Children's Medical Center, Fort Worth, Tex; Floating Hospital for Children, Boston, Mass; Long Island Jewish Medical Center, New Hyde Park, NY; Miami University School of Medicine, Fla; Michigan University Medical Center (Mott), Ann Arbor; Minneapolis Children's Heart Clinic, Minn; Mount Sinai Medical Center, New York, NY; Oregon Health Science University, Portland; Rainbow Babies & Children's Hospital, Cleveland, Ohio; South Carolina Children's Heart Program, Charleston; St Louis Children's Hospital, Mo; Stanford University, Stanford, Calif; Tampa General, Fla; Texas Children's Hospital, Houston; Toronto Hospital for Sick Children, Canada; University of Texas Southwest Medical Center, Dallas; University of Alabama, Birmingham; University of California, San Francisco; and Vanderbilt University, Nashville, Tenn.

Acknowledgments

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