

Force-Sensing Catheters During Pediatric Radiofrequency Ablation: The FEDERATION Study

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Background—Based on data from studies of atrial fibrillation ablations, optimal parameters for the TactiCath (TC; St. Jude Medical, Inc) force-sensing ablation catheter are a contact force of 20 g and a force-time integral of 400 g-s for the creation of transmural lesions. We aimed to evaluate TC in pediatric and congenital heart disease patients undergoing ablation.

Methods and Results—Comprehensive chart and case reviews were performed from June 2015 to March 2016. Of the 102 patients undergoing electrophysiology study plus ablation, 58 (57%) underwent ablation initially with a force-sensing catheter. Patients had an average age of 14 (2.4–23) years and weight of 58 (18–195) kg with 15 patients having abnormal cardiac anatomy. Electrophysiology diagnoses for the +TC group included 30 accessory pathway-mediated tachycardia, 24 atrioventricular nodal reentrant tachycardia, and 7 other. Baseline generator settings included a power of 20 W, temperature of 40°, and 6 cc/min flow during lesion creation with 11 patients (19%) having alterations to parameters. Seventeen patients (30%) converted to an alternate ablation source. A total of 516 lesions were performed using the TC with a median contact force of 6 g, force-time integral of 149 g-s, and lesion size index of 3.3. Median-term follow-up demonstrated 5 (10%) recurrences with no acute or median-term complications.

Conclusions—TactiCath can be effectively employed in the treatment of pediatric patients with congenital heart disease with lower forces than previously described in the atrial fibrillation literature. Patients with atrioventricular nodal reentrant tachycardia or atrioventricular reciprocating tachycardia may not require transmural lesions and the TC may provide surrogate markers for success during slow pathway ablation. (*J Am Heart Assoc.* 2017;6:e005772. DOI: 10.1161/JAHA.117.005772.)

Key Words: contact force • force-sensing catheter • pediatric

The estimated incidence of pediatric tachyarrhythmias ranges from 1:25 000 to as high as 1:250¹ with expanding use of transcatheter ablation for treating these patients. Technological advances in interventional electrophysiology (EP) are focused on enhancing patient outcomes by improving acute success rates and decreasing recurrence rates. One such advance in catheter technology has led to the real-time quantification of force applied by the ablation catheter at the tip-tissue interface.^{2–7} Measurements of contact force (CF) have been studied extensively in the adult population, particularly in the ablation of atrial fibrillation.

Several studies (Table S1) conducted in adult patients primarily with an EP diagnosis of atrial fibrillation (AF) have

concluded that optimal parameters for pulmonary vein isolation include the combination of a CF of 20 g-s,^{2,4,6,7} a force-time integral (FTI) >400 g, and a lesion size index (LSI) >5. The goal during pulmonary vein isolation, however, is transmural lesions with no gaps in the isolation line. In contrast to adult patients, the EP substrate for the majority of pediatric patients undergoing ablation is reentrant supraventricular tachycardia.

The goal of this study was to report on the findings of using force-sensing catheters in a pediatric EP laboratory where the majority of target EP substrates involve discrete circuits, such as atrioventricular nodal reentrant tachycardia (AVNRT) and accessory pathway (AP)-mediated tachycardia (atrioventricular

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Accompanying Tables S1 through S3 and Figure S1 are available at <http://jaha.ahajournals.org/content/6/5/e005772/DC1/embed/inline-supplementary-material-1.pdf>

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Clinical Perspective

What is New?

- This is the first study to assess the use of force-sensing catheters (specifically TactiCath, St. Jude Medical, Inc) in a pediatric electrophysiology laboratory where the majority of target electrophysiology substrates involved discrete circuits, such as atrioventricular nodal reentrant tachycardia and accessory pathway-mediated tachycardia (atrioventricular reciprocating tachycardia).
- Lower forces are required compared with the published data in the adult population with atrial fibrillation.
- Operators applied higher contact forces when ablating accessory pathway-mediated supraventricular tachycardias compared with atrioventricular nodal reentrant tachycardia.
- During atrioventricular nodal reentrant tachycardia slow pathway modification, statistically significant higher contact force was seen during lesions where junctional rhythm was observed.

What are the Clinical Implications?

- Force-sensing catheters can be effectively employed in the treatment of pediatric and congenital ablation patients.

reciprocating tachycardia [AVRT]) specifically with a focus on the CF, FTI, and LSI used in these substrates compared with the published data in the adult population with AF.

Methods

Upon approval from the institutional review board at Washington University School of Medicine and waiver of informed consent, a detailed chart review was performed. Patient demographic data, details of EP study (EPS)/ablation including lesion data, complications, and outcome data were collected from all patients undergoing EPS from June 2015 to March 2016. Regarding lesion data, average CF was collected for all lesions, including FTI and LSI. Lesions were classified as successful, unsuccessful, or consolidation. During an AP ablation, a successful lesion was defined as a lesion that permanently (not transiently) interrupted AP conduction. Data on the use of sheaths, including the use of standard (short, 7 or 7.5 F 12-cm sheath; St. Jude Medical, Inc) versus long positioning (St. Jude Medical, Inc) sheaths, were collected.

As background, the institution acquired the St. Jude Medical, Inc, force-sensing system hardware components (TactiCath [TC], TactiSys, Ampere, and Cool Point pump; St. Jude Medical, Inc) in June 2015. Practicing interventional electrophysiologists elected to use the TC as the primary ablation catheter for the laboratory beginning June 2015, although physicians could opt out based on patient or

substrate characteristics. There were no set parameters for CF, FTI, or LSI and physicians were not blinded to the CF data. The FTI and LSI are calculated numbers to estimate lesion size and depth^{2,3,6} and are both time-dependent variables.

Baseline settings for the system for this study included a power of 20 W, a temperature of 40°C, and an irrigation flow rate during lesion formation of 6 cc/min. Additionally, preflow and postflow times on the pump were adjusted to 1 second for each parameter. Parameters were adjusted per physician discretion from these baseline parameters.

Statistical Analysis

Results are presented as median values (with interquartile range) and percentages. Statistical analyses were performed using 2-tailed *t* tests of unequal variance as well as Fisher's exact and chi-square tests as appropriate. Statistical significance was set at $P < 0.05$. All statistical calculations were performed using Excel 2016 (Microsoft Corporation) and SPSS (version 23.0; IBM Corp).

Results

Patient Data

A total of 121 patients presented for EPS during the study timeframe, with 16% (19) excluded for undergoing isolated EPS. The remaining 84% (102) of patients underwent EPS plus transcatheter ablation. The TC was used in 57% (58) of patients and as the sole ablation source in 39% (40) of patients (Figure 1). Alternate energy sources were employed in 17% (18) of patients with crossover to cryoablation in the majority of cases. Physician choice to use an alternate ablation catheter to the TC was most often because of a retrograde approach to a left-sided substrate (16 of 44, 36%) or the need for cryoablation (13 of 44, 30%) (Figure 2). Physicians elected to not use the TC during retrograde ablations as the catheter body is stiff and the team had concerns regarding potential disruption of the aortic valve.

Patients who underwent ablation with the TC were older and slightly larger than patients who underwent ablation with alternate primary energy source or catheter (Table). EP diagnoses were evenly distributed between the 2 groups, although the +TC group did have more patients with congenital heart disease (19% in the +TC group versus 9% in the -TC group) (Table and Table S2).

Lesion Data

A total of 516 lesions were performed in 58 patients using the TC with a median CF of 6 g [interquartile range, 6], FTI of 153 g·s [interquartile range, 310], and LSI of 3.4 [interquartile

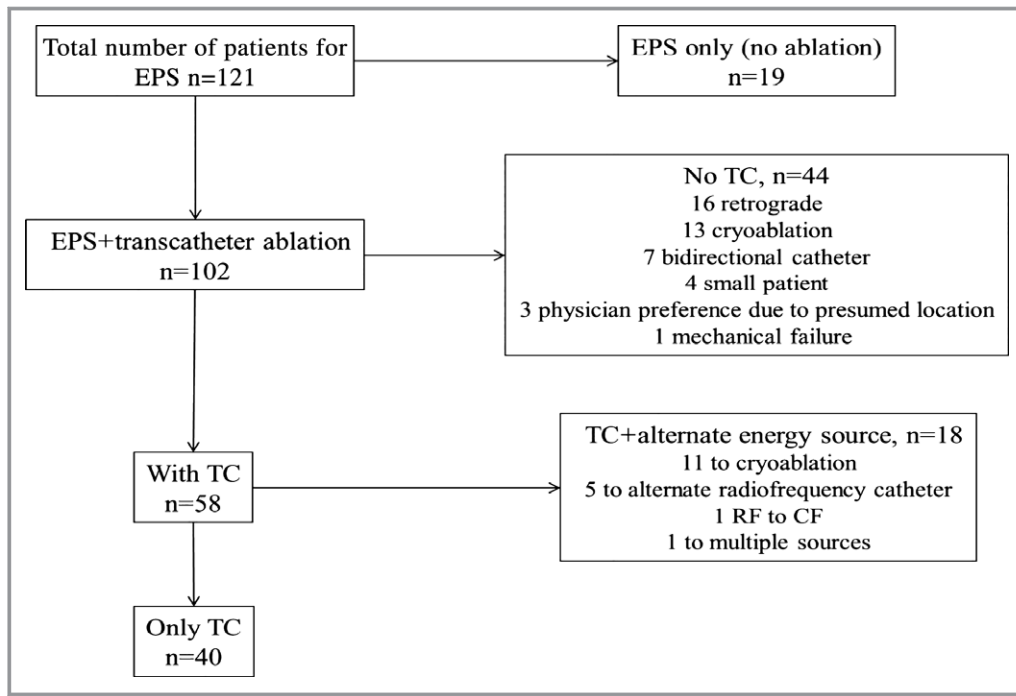


Figure 1. Flow chart demonstrating patient enrollment and patient movement through the study. CF indicates contact force; EPS, electrophysiology study; RF, radiofrequency; TC, TactiCath.

range, 1.7] (Figure 3). Parameter settings were altered in 11 patients—9 patients had increased irrigation flow (12–17 cc/min) through the catheter during lesion formation, 3 patients

had up-titration of power (25–30 W), 1 patient had increased temperature (42°), and 2 patients had alterations in multiple parameters.

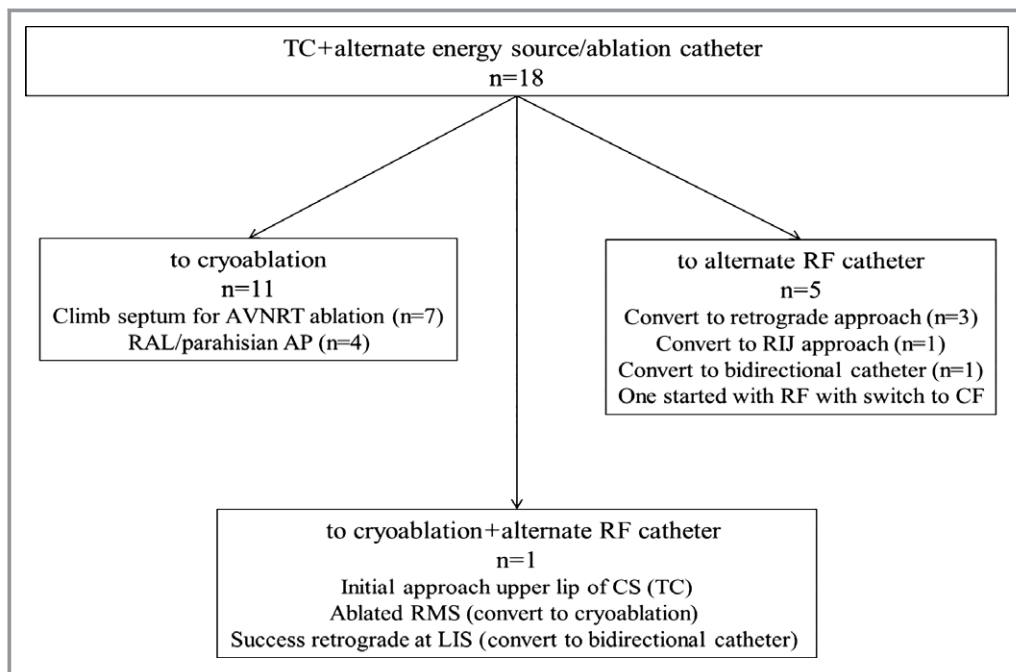


Figure 2. Alternate energy source/ablation catheter. This figure illustrates the patients who were started with the TactiCath (TC) and then converted to an alternate energy source or ablation catheter, as well as the reason for changing the energy source. AP indicates accessory pathway; AVNRT, atrioventricular nodal reentrant tachycardia; CF, contact force; CS, coronary sinus; LIS, left intermediate septal; RAL, right anterolateral; RF, radiofrequency; RIJ, right internal jugular; RMS, right midseptal.

Table. Patient Demographic and Substrate Data

	Total No.	+TC	-TC	P Value
Total patients, No.	102	58	44	
Sex, % (No.)				
Female	41 (42)	60 (25)	40 (17)	0.68
Male	59 (60)	55 (33)	45 (27)	
Age, y	14±4	15±3.2	12.6±5	0.01
Weight, kg	60±30	64.8±31	54±27	0.07
Height, cm	159±21	164±16	154±25	0.07
EP diagnosis	108			
AP-mediated, % (No.)	54 (59)	51 (30)	49 (29)	
Right-sided accessory pathways, % (No.)		40 (12)	41 (12)	
Left-sided accessory pathways, % (No.)		60 (18)	59 (17)	
AVNRT, % (No.)	36 (39)	62 (24)	38 (15)	
Typical, % (No.)		88 (21)	100 (15)	
Atypical, % (No.)		12 (3)	0	
PVCs/VT, % (No.)	5 (5)	20 (1)	80 (4)	
AFL, % (No.)	3 (3)	100 (3)	0	
AT, % (No.)	2 (2)	100 (2)	0	
Structurally abnormal hearts, % (No.)	15 (15)	19 (11)	9 (4)	
CHD		9 (5)	5 (2)	
Ebstein's anomaly		2	0	
Aortic valve disease		1	2	
Cor triatriatum		1	0	
Tricuspid atresia s/p Fontan		1	0	
CM (hypertrophic)	2 (2)	2 (1)	2 (1)	
CS abnormalities/diverticulum	4 (4)	5 (3)	2 (1)	
OHT	1 (1)	2 (1)	0	
No. of lesions	10±8	11±9	8±5	0.02
Acute success, % (No.)	89 (91)	88 (51)	91 (40)	
Recurrence, % (No.)	7 (7)	8 (5)	5 (2)	

AFL indicates atrial flutter; AP, accessory pathway; AT, atrial tachycardia; AVNRT, atrioventricular nodal reentrant tachycardia; CHD, congenital heart disease; CM, cardiomyopathy; CS, coronary sinus; OHT, orthotopic heart transplant; PVCs, premature ventricular contractions; TC, TactiCath; VT, ventricular tachycardia.

Overall, ablation lesions placed during AP ablation had higher CF when compared with slow pathway modification lesions placed for AVNRT (8 ± 6.5 versus 5 ± 3.7 , $P<0.01$), higher FTI (284 ± 306 versus 153 ± 176 , $P<0.01$), and higher LSI (3.7 ± 1.2 versus 2.9 ± 0.8 , $P=0.01$) (Figure 3).

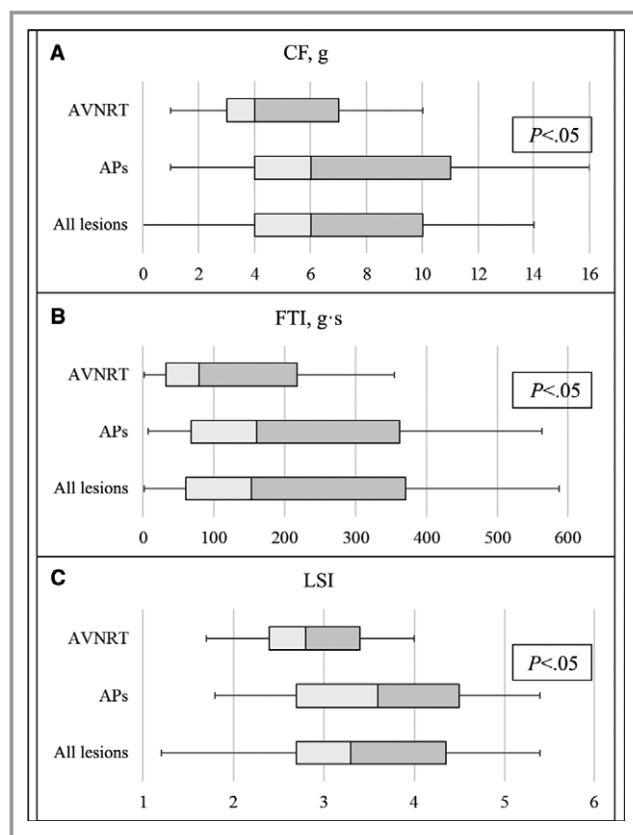


Figure 3. Box whisker plots for all lesions placed with the TactiCath. A, Demonstrates that lesions placed during accessory pathway (AP) ablations had significantly higher contact force (CF) than lesions placed for atrioventricular nodal reentrant tachycardia (AVNRT) ($P<0.01$). B and C, Iterate that finding for force-time integral (FTI) and lesion size index (LSI) ($P<0.01$ for each).

AP-Mediated Tachycardia

During AP ablations, higher forces were applied to left-sided pathways compared with right-sided pathways (9.2 ± 6.4 versus 7.7 ± 6.6 , $P=0.08$), thus leading to higher FTI (365 ± 337 versus 223 ± 275 , $P<0.01$) and LSI (4 ± 1.3 versus 3.5 ± 1.1 , $P<0.01$) for left-sided lesions (Figure 4, Table S3). Successful lesions, compared with unsuccessful lesions, had higher CF (11 ± 6.6 versus 7.9 ± 6.6 , $P=0.02$), FTI (614 ± 330 versus 199 ± 255 , $P<0.01$), and LSI (4.8 ± 1.2 versus 3.3 ± 1 , $P<0.01$).

Atrioventricular Nodal Reentrant Tachycardia

When modifying slow pathway during AVNRT ablation cases using a combined anatomic and electrogram-based approach, ablation lesions that had an accelerated junctional rhythm during the lesion had higher CF compared with lesions that did not have junctional rhythm (6 ± 4.2 versus 4.4 ± 2 , $P<0.01$) and higher FTI (189 ± 202 versus 89 ± 89 , $P<0.01$) and LSI (3.1 ± 0.8 versus 2.8 ± 0.6 , $P=0.01$) (Figure S1).

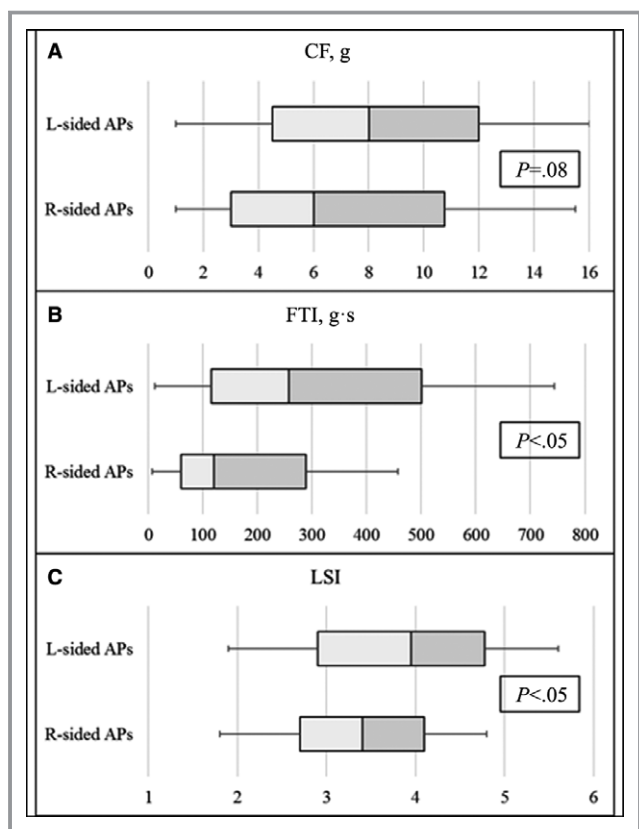


Figure 4. Box whisker plots for lesion data made during accessory pathway (AP) ablations. A, Illustrates that there was no significant difference in contact force (CF) applied to right-sided (R-sided) or left-sided (L-sided) APs. B and C, Demonstrate that the force-time integral (FTI) and lesion size index (LSI) were significantly higher for L-sided lesions. This finding may be explained by longer duration of lesions on the L-sided atrioventricular valve annulus.

Other Substrates

There were 6 patients who underwent TC ablation with other tachycardia substrates including atrial tachycardia (n=2; 3 foci with 2 left atrial and 1 right atrial), atrial flutter (n=3; 3 right atrial flutter circuits, 1 left atrial flutter), and left ventricular (Belhassen) ventricular tachycardia (n=1) (Table S3).

Standard (Short) Sheath versus Long Positioning Sheaths

Of the total 516 CF lesions placed, 396 (77%) were placed using a long positioning sheath, most commonly SR0 and Mullins transseptal sheaths (St. Jude Medical, Inc). Figure 5 demonstrates that for those lesions placed on the right-sided atrioventricular valve annulus (AVVA), lesions applied with standard (short) sheaths achieved higher CF (9.9 ± 8.2 versus 5.7 ± 4 , $P < 0.05$), FTI (324 ± 345 versus 155 ± 170 , $P < 0.05$), and LSI (3.7 ± 1.3 versus 3.2 ± 0.8 , $P < 0.05$) compared with

lesions applied with long (positioning) sheaths. Conversely, for lesions applied to the left-sided AVVA, lesions applied with long (positioning) sheaths (following a transseptal puncture) achieved higher CF (12 ± 9.9 versus 6.5 ± 3.6 , $P < 0.05$), FTI (506 ± 555 versus 263 ± 133 , $P < 0.05$), and LSI (4.4 ± 1.3 versus 3.6 ± 0.8 , $P < 0.05$) compared with left-sided lesions placed with a short (standard) sheath via patent foramen ovale.

Nine patients started with a short sheath, which was then upsized to a positioning sheath (right-sided AP, n=5; AVNRT, n=2; left-sided AP, n=1; and left-sided AFL, n=1). In this cohort of patients, when comparing lesions placed with short versus long sheaths, there was no statistically significant difference in CF (7 ± 7 versus 8.3 ± 6.5 , $P = 0.4$), FTI (179 ± 223 versus 262 ± 306 , $P = 0.06$), or LSI (3.3 ± 1 versus 3.7 ± 1 , $P = 0.08$).

Patient Follow-Up and Complications

There were no complications noted during the study period. There were a higher number of recurrences noted in the +TC group (10% in +TC group versus 5% in -TC group, $P = 0.4$) (Table). This difference likely reflects the operator learning curve with the new technology, but it is noteworthy that all 3 left-sided lesions that recurred required more than one approach to the AP and more than one energy source. One of the +TC recurrences was in a patient with atypical AVNRT requiring ablation within a coronary sinus diverticulum. The final recurrence in the +TC cohort was a complex flutter case in a patient with orthotopic heart transplant. This underscores the difficulty of these cases.

Discussion

To our knowledge, this is the first study to evaluate the utility and safety of force-sensing catheters during RF ablation in pediatric and congenital patients. Furthermore, it is the first study to evaluate purely macroreentrant EP substrates, such as AVRT and AVNRT. This study demonstrates that the TC can be used safely for patients undergoing AVRT and AVNRT ablations in both the right and left atrium and that successful lesions require dramatically lower CF than that reported in the adult AF literature (Table). Additionally, we found that operators applied higher CFs when ablating AP-mediated supraventricular tachycardias compared with AVNRTs. During AVNRT slow pathway modification, statistically significant higher CF was seen during lesions where junctional rhythm was observed. Lastly, there was an increased recurrence rate noted in the TC group.

These findings are different than the published literature on AF. This difference is likely attributable to the different

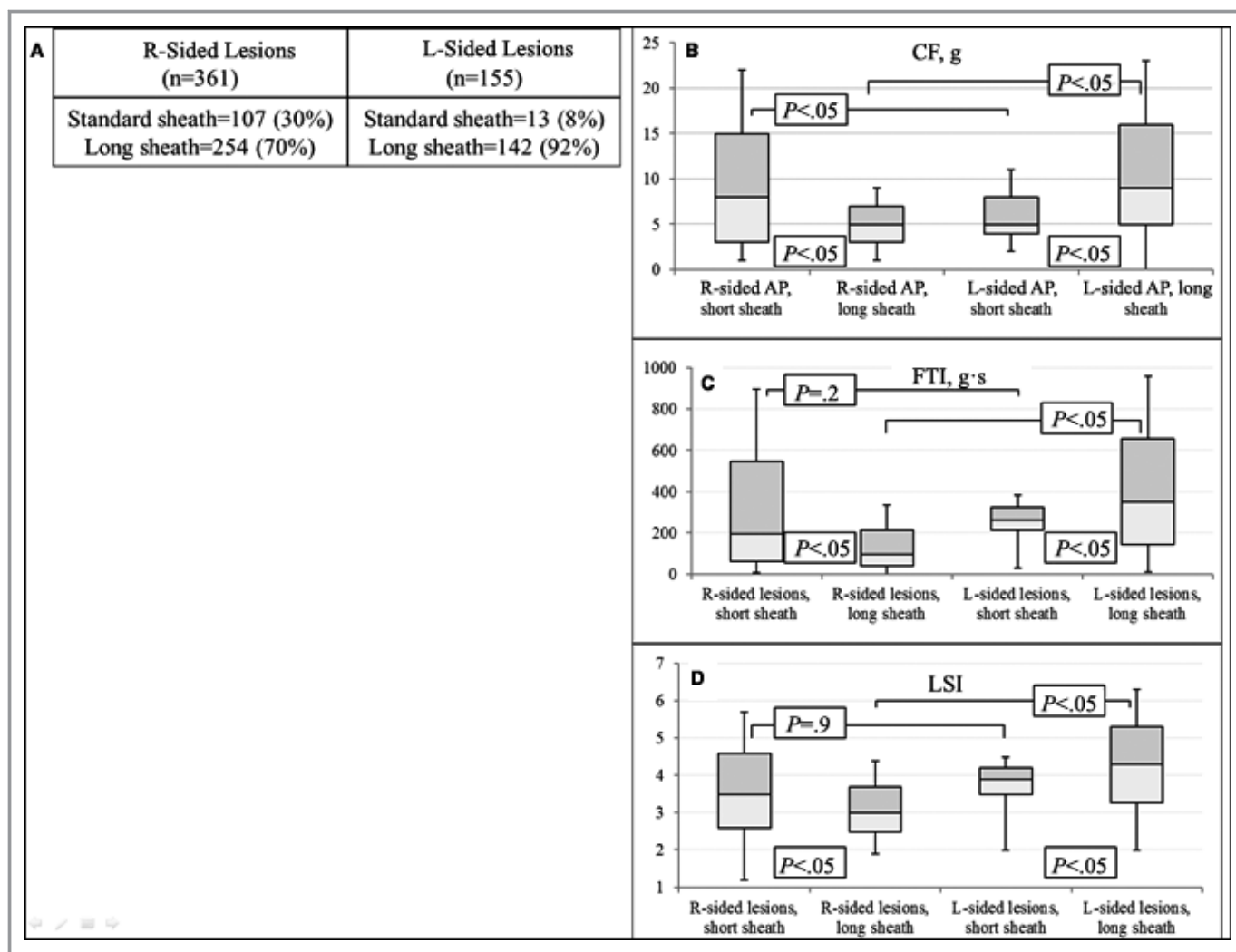


Figure 5. Use of standard (short) vs long positioning sheaths comparing right-sided (R-sided) vs left-sided (L-sided) lesions, contact force (CF), force-time integral (FTI), and lesion size index (LSI) data. A, Demonstrates that the majority of lesions on both the R- and L-sided atrioventricular valve annulus (AVVA) were placed using long sheaths. In (B), CF (in grams) is compared by R- and L-sided AVVA as well as sheath. There was significantly more contact applied during R-sided short sheath lesions compared with R-sided long sheath lesions, with the converse noted on the L-sided AVVA. For lesions placed exclusively by short sheaths, there were greater forces applied to the R-sided vs L-sided lesions and the converse was seen with lesions applied with long sheaths, where L-sided lesions had greater forces than R-sided lesions. C, Illustrating that the FTI (in g·s) and (D) the LSI both demonstrate that higher FTI/LSI were achieved on R-sided lesions using short compared with long sheaths, with the converse for L-sided lesions where long sheath lesions achieved greater FTIs.

substrate and end goals in the reported populations. Transmural lesion creation is a goal for patients undergoing AF ablation. Pulmonary vein isolation remains the primary therapeutic strategy for transcatheter ablation of this substrate and a full thickness lesion is thought to be needed for electrical isolation.

Conversely, both AVNRT and pathway-mediated AVRT have more discrete ablation targets that theoretically should not require transmural lesions. In the case of typical AVNRT, the ablation target is slow pathway modification in the region of the lower to mid third of the triangle of Koch. Aggressive transmural lesions low in the triangle could conceivably result

in inadvertent damage of the coronary artery system.^{8–11} Likewise, deep lesions higher in the triangle of Koch can result in damage to the atrioventricular node.^{8,11} Similarly, the majority of APs are thought to usually be endocardial structures, as evidenced by transient mechanical interruption of pathway conduction during catheter manipulation. As such, ablation of these substrates typically should not require transmural lesions. The findings in this study are consistent with previous conclusions.

During slow pathway modifications for typical AVNRT ablations, junctional rhythm was seen in those lesions with higher CF. Indeed, during the use of non-force-sensing

radiofrequency catheters for AVNRT ablation, the presence of accelerated junctional rhythm has been used as a surrogate marker of successful lesion formation.⁷ In this study, we confirmed that lesions with a higher CF did have more junctional rhythm during lesion creation.

Interestingly, lesions placed with long (positioning) sheaths did not necessarily result in increased CF. In fact, lesions placed on the right AVVA with short (standard) sheaths had higher CF than those placed with long sheaths. Long sheaths are often employed for catheter stability. This is particularly important when performing AVNRT slow pathway modifications where balancing a septal location without sliding into the coronary sinus is critical, or on regions on the right AVVA where it can be difficult to balance, such as the lateral wall. This is in direct contrast to left-sided lesions, where lesions placed though long sheaths did have higher CF than those lesions placed via short (standard) sheaths. However, it is important to note that long positioning sheaths are placed into the left atrium following a transseptal puncture. For patients with an atrial level shunt, no long sheaths were placed into the left atrium. In general, traversing the atrial septum through a patent foramen ovale to access the left AVVA results in a catheter orientation that is challenging for the operator to balance and achieve high CF. This may account for less CF applied during those lesions placed with a short sheath on the left AVVA.

There were no adverse events reported during the study period either acutely (during the procedure) or during median-term follow-up. This is particularly noteworthy since irrigated tip radiofrequency ablation catheters are not routinely used in pediatric patients with structurally normal hearts. Our strategy of limiting flow through the catheter both during and pre/post lesion formation perhaps contributed to mitigating this risk. There was an increase in the recurrence rate in patients in the TC group, attributable to: (1) increased incidence of structurally abnormal hearts, and (2) operator learning curve, resulting in potentially less aggressive lesion sets.

Limitations

There are inherent study limitations attributable to the learning curve associated with adopting new technology. This was particularly important in this study since before using the TC, most radiofrequency ablations at this institution used standard, dry-tip radiofrequency ablation catheters rather than irrigated tip catheters. Additionally, the decision to convert to a different catheter or mode of ablation limited the number of patients in the study. Patient enrollment was further limited by the unidirectional curve on the CF ablation catheter, as the operators chose bidirectional catheters when approaching certain APs, or during premature ventricular contractions/right ventricular outflow tract–ventricular

tachycardia ablations. Importantly, operators were not blinded to force measurements during ablations. Therefore, changes to ablation technique (guiding therapy based on force data), although not intentional or deliberate, may have biased the operators. The long-term success of CF in pediatric patients cannot be properly extrapolated from this study, and therefore lesion data cannot consistently be correlated to patient outcome. Finally, the number of patients in this single institution study was small, and additional data acquisition is required to better understand the role of CF in pediatric patients.

Conclusions

TactiCath can be effectively employed in the treatment of pediatric and congenital patients with lower forces than previously described in the adult AF literature. Patients with AVNRT or AVRT may not require transmural lesions and the TC may provide surrogate markers for success during slow pathway ablation in AVNRT. Use of long sheaths did not universally correspond with increased CF.

Disclosures

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SUPPLEMENTAL MATERIAL

Table S1. Published clinical trials evaluating TactiCath.

Trial	# of subjects	Substrate	Findings
TOCCATA	76	34 AF 42 SVT	CF is safe in RA and LA Target CF 20gms Minimum CF 10gms
EFFICAS-I	46	AF	Target CF 20gms Minimum target FTI 400gms•sec
EFFICAS-II*	46	AF	Target CF 20gms Minimum CF 10gms Minimum FTI >400gms•sec
TOCCASTAR*	317	AF	Safety and efficacy endpoints for paroxysmal AF ablation

*operators in these studies were not blinded to CF measurements

Abbreviations: AF=atrial fibrillation, SVT=supraventricular tachycardia, CF=contact force, RA=right atrium, LA=left atrium, FTI=force time integral.

Table S2. Other Electrophysiologic Substrates.

	# of patients	CF (gms)	FTI (gms·sec)	LSI
EAT	2	10 [IQR 21]	318 [IQR 1248]	3.9 [IQR 2.5]
AFL	3	13 [IQR10.5]	468 [IQR 403]	4.7 [IQR 1.9]
VT	1	3 [IQR 5.5]	121 [IQR 317]	3.2 [IQR 1.6]

Abbreviations: CF=contact force, FTI=force time integral, LSI=lesion size index, EAT=ectopic atrial tachycardia, AFL=atrial flutter, VT=ventricular tachycardia

Table S3. Locations of Accessory Pathways for patients undergoing ablation with (left) and without (right) TactiCath.

WITH TACTICATH	
AP Location	# of patients
Right sided AP	12
anterolateral	4
parahisian	1
lateral	1
posteroseptal	3
posterolateral	3
Left sided AP	18
anterolateral	2
lateral	4
posterolateral	4
posterior	3
posteroseptal	4
intermediate septal	1

WITHOUT TACTICATH	
AP Location	# of patients
Right sided AP	12
anteroseptal	1
parahisian	4
lateral	2
posteroseptal	2
midseptal	2
Left sided AP	17
anterolateral	3
lateral	5
posterolateral	1
posterior	3
posteroseptal	3
intermediate septal	2

Abbreviation: AP=accessory pathway.

Figure S1. Box Whisker Plots for lesion data during AVNRT slow pathway modification. **Panel A** demonstrates that lesions during which junctional rhythm was noted had statistically significant higher contact force (CF) when compared to those lesions where there was no junctional rhythm observed. **Panels B and C** also consistently demonstrate significantly higher force-time integral (FTI) and lesion size index (LSI) in those lesions where junctional rhythm was observed.

