

Contact force ablation of accessory pathways in pediatric patients

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Abstract

Introduction: Contact force (CF) catheters provide feedback confirming adequate tissue contact for optimal lesion size and minimal complications. CF ablation catheters have resulted in decreased procedure times and improved outcomes for ablation of atrial fibrillation in adults. There is limited data evaluating CF use for accessory pathway (AP) ablation or in pediatric patients. The aim of our study was to compare a cohort who underwent AP ablation with a CF catheter to historical controls, evaluating for differences in procedure times, number of lesions, and outcomes. **Methods:** A retrospective chart review of CF ablation cases at Children’s Wisconsin performed between June 2015 to April 2018 was compared to a historical control cohort of traditional radiofrequency (RF) ablations between June 2012 to June 2015. 43 patients with APs underwent 49 CF ablation procedures (18 males, 13.6 ± 3 years old) and a control cohort consisted of 77 procedures in 69 patients (38 males, 12.4 ± 4 years). **Results:** The groups did not differ significantly on procedure time (CF 2.01 ± 0.48 hr, control 1.53 ± 0.48 hr, $p = 0.37$), or total lesions administered (CF and control 7 ± 6 lesions, $p = 0.89$). CF cases showed a trend toward improvement in acute success (98% CF, 90% controls, $p = 0.15$) though with increased recurrence compared to controls (13% CF, 5% controls, $p = 0.16$), neither being statistically significant. **Conclusion:** Our study suggests that ablation outcomes using CF are comparable to traditional RF ablation in pediatric patients with APs.

Background

Contact force (CF) between the catheter tip and target tissue is a known determinant of lesion quality and therefore procedural success during catheter ablation. Complications related to catheter ablation can be due to the increased temperature and lesion size with increasing CF.¹ Real time CF feedback is provided by the TactiCath radiofrequency (RF) ablation catheter (Abbott Laboratories, Abbott Park, IL) which allows operators to achieve optimal lesion size without excessive tissue damage and resulting complications. CF ablation catheters have been used for years in the treatment of atrial fibrillation in adult patients with evidence of more durable lesions resulting in decreased procedure times and better outcomes.² However, this catheter has also been used increasingly in pediatric patients for different arrhythmias³, most commonly for reentrant supraventricular tachycardia, the outcomes for which have not been as extensively studied.

Children’s Wisconsin started using CF ablation techniques in June 2015 for catheter ablation of accessory pathways. The aim of this study was to complete a comprehensive chart review of patients who have undergone CF ablation and compare their procedure times, number of lesions, and outcomes with a historical control group of standard RF catheter ablation patients.

Methods

Patient Selection

This retrospective study was completed with approval from the institutional review board at Children’s Wisconsin. Comprehensive chart review was carried out on all patients with atrioventricular reciprocating tachycardia (AVRT) who underwent contact-sensing catheter ablation from September 2015 to April 2018 at

Children’s Wisconsin (n = 43). A historical control cohort was also created from all patients who underwent RF catheter ablation of an accessory pathway using a standard RF ablation catheter from June 2012 to June 2016 (n= 69). Patients with anteroseptal or midseptal pathways were excluded from this cohort, since CF catheters were not used for ablating pathways in these locations. Cases utilizing multiple ablation modalities to interrupt the accessory pathway during a single procedure were excluded from the present study to evaluate the technologies in isolation. For several patients, multiple accessory pathways were ablated during their procedure, and for clarity these were treated as separate cases resulting in 49 CF and 77 control cases.

Electrophysiologic Study and Catheter Ablation

Informed consent was obtained, and antiarrhythmic medications stopped the week prior to every procedure. All cases were performed intubated under general endotracheal anesthesia by cardiac anesthesia. Vascular access was attained with placement of sheaths and diagnostic catheters in the right internal jugular, left femoral, and right femoral veins, with sheath and catheter sizes and locations varying based on operator preference. Three-dimensional electroanatomic mapping (EnSite/Velocity NavX, Abbott Laboratories/St Jude Medical, Plymouth, MN; Carto 3, Biosense Webster, Irvine, CA) was utilized for all procedures to minimize the use of fluoroscopy for catheter placement and manipulation. For ablation of left-sided APs, a transseptal or retrograde approach was utilized at the discretion of the electrophysiologist. When necessary, a long sheath was utilized to improve catheter positioning and stability during ablation. In most cases, multiple lesions were required to terminate AP function. During CF cases, the ideal ablation was delivered with > 3 g of force for 60 seconds or a maximum of 400 gs as standard procedure at Children’s Wisconsin. Significant complications related to the ablation procedure were noted.

For each case, overall success and recurrence, total case time, time spent mapping and ablating, number of unsuccessful and consolidation lesions, and total time for each successful lesion were investigated. A successful lesion was defined as the lesion that permanently interrupted the AP while unsuccessful and consolidation lesions were delivered before and after the determined successful lesion, respectively. Overall acute success was defined as the termination of the AP conduction during the procedure and absence of AP conduction during post-ablation testing with isoproterenol and adenosine. Follow-ups typically 4-6 weeks, and occasionally 1-year, post-ablation were reviewed in order to determine long term recurrence, with patients lost to follow-up assumed to not have recurrence.

Statistical analysis

Results were compiled as mean \pm SD, median, and percentage values as appropriate. Discrete variables between groups were compared with chi-square or Fisher exact testing as appropriate based on populations. Continuous variables were compared with 2-tailed Student t-tests. Recurrence rates were compared with Kaplan-Meier analysis. Statistical significance was set at $p < 0.05$.

Results

Demographics

112 patients were included in the study, 43 CF and 69 control, with demographics shown in Table 1. A small number of patients had multiple APs identified, so each pathway was recorded as a separate case for clarity. Ablations of 126 total aberrant pathways causing SVT were performed, 49 of which were monitored by real-time contact force feedback. No initial statistical differences were noted between case and control cohorts with regards to age, gender, diagnosis, or AP location. Of note, 5 patients were recorded to have congenital heart disease, while 19 patients underwent previous ablation with recurrence of their AP conduction.

Electrophysiologic Procedure

A summary of procedural findings is displayed in Figure 2. Average procedure time did not differ between the CF procedures and the controls (CF 2.01 ± 0.48 hr, control 1.53 ± 0.48 hr, $p = 0.37$), and we also did not find a difference in the average successful lesion time (CF 50 ± 30 sec, control 42 ± 24 sec, $p = 0.105$). There was great variability in the time spent mapping and ablating the pathway in both the CF and control

cohorts, yielding no significant difference between them (CF 46.87 ± 47.8 min, control 50.47 ± 49.7 min, $p = 0.689$) Similar variation was also observed in the total number of lesions delivered, yielding an average of 7 ± 6 ($p = 0.89$) for both CF and control.

Ablation Outcomes

We observed a slightly higher acute success and long-term recurrence for the CF cases compared to control (Table 2), however the results were not statistically significant. Long term recurrence of patients' APs occurred sooner in the control group, all within 2.2 months of the procedure, while CF cases resulted in more overall recurrences over a longer 3.7 month period (Figure 1). AP location was not found to affect acute or long-term ablation outcomes when comparing ablation catheters.

Complications

Only four patients (2.0% of CF and 3.9% of control patients) experienced complications. One CF case was successful but resulted in mild aortic insufficiency on follow up echocardiogram. Three control cases had complications including ischemia and ventricular fibrillation (VF), cardiac perforation during transseptal puncture, and a groin hematoma. The ischemic event was identified by ST segment depression, T wave inversion, bradycardia, and hypoxemia; it was likely secondary to sustained ventricular pacing during mapping. The patient went into sustained VF requiring defibrillation to return to normal sinus rhythm. All patients recovered fully from their complications. Minor complications that did not require intervention or extend the patient's hospital stay were considered insignificant and not recorded.

Discussion

The present study revealed no statistical difference between CF ablation technology and traditional RF methods. There was wide variability in the total procedure time, successful lesion time, time spent mapping and ablating the pathway, and number of lesions delivered, resulting in similar averages in both cohorts. Although a trend toward higher acute success was observed in the CF group, we also saw more long-term recurrence compared to control, though neither outcome achieved statistical significance. To our knowledge, this is the first pediatric study directly comparing ablation outcomes for CF and standard RF catheters for AVRT.

There has been significant research on use of CF in the adult population, however there have been fewer pediatric studies, and even less standard of practice recommendations for use of CF. Extensive research of CF in adult atrial fibrillation shows several benefits, however through our study we saw the outcomes do not differ from using traditional RF ablation. It is difficult to tell whether these results are due to the unique pediatric population with APs, or if it reflects our early experience with this new technology and further research could elucidate statistically significant benefits from CF in pediatrics.

Contact force technology has largely been studied in adult patients with atrial arrhythmias and is overall shown to decrease procedure times and improve outcomes.² However, even within the adult population, variation exists depending on specific study parameters and arrhythmia characteristics, as seen by Jarman et al with improved outcomes in ablation of paroxysmal atrial fibrillation, but not in non-paroxysmal atrial fibrillation.⁴ While some groups found that CF did not change total procedure length, fluoroscopy exposure, or one-year follow-up outcomes^{5,6}, other studies dispute this showing CF reduced procedure times and number of touch-up ablation lesions.⁷ Some variation in the adult literature can be attributed to the lack of unified protocol amongst the studies. Although studies such as the TOCCATA and EFFICAS I trials attempted to consolidate and hone recommendations, different facilities are still free to use their own criteria for adequate contact force.^{8,9} Similarly, to date there are no pediatric specific recommendations for CF and force-time measurements for successful ablation.

Radiofrequency ablation has been used for decades in the pediatric population and newer CF technology is successfully being implemented as well, but more research on the amount of force and outcomes is required to better define the role of this technology in pediatric patients. The early research on CF in pediatrics has been mainly on safety and force recommendations. The FEDERATION study looked at the original

adult protocol formed in the TOCCATA trial of 2012, and investigated the recommendations specifically in a pediatric population, concluding CF can safely be used in a pediatric population and significantly less force is needed for successful ablation.³ Although the study indicated patients with AVNRT and AVRT may not require transmural lesions, a concrete protocol for use of CF in pediatrics still does not exist and there remains minimal evidence on the benefit of CF in ablation of pediatric APs.

Currently, recommendations for transmural lesions in adult atrial fibrillation ablation include a CF of 20 g and force-time integral (FTI) > 400 gs.⁸ Pediatric studies have shown that less force may be necessary in ablation of APs in children, suggesting CF of 6 g and FTI of 153 gs may be sufficient.³ Children's Wisconsin used these recommendations and operator experience to identify a protocol suggesting ideal ablations with > 3 g of force for 60 seconds or a maximum of 400 gs, but further research is needed in order to create solid CF criteria for ideal ablation outcomes. Though not statistically significant, we observed a trend towards more long-term recurrence in the CF cohort than in the control. This recurrence rate could be attributed to the Children's Wisconsin protocol, and different criteria may improve outcomes in the future.

Only four patients (2.0% of CF and 3.9% of control patients) in our study experienced complications including mild aortic insufficiency on follow up echocardiogram, ischemia and VF secondary to ventricular pacing, cardiac perforation during transseptal puncture, and a groin hematoma. The aortic insufficiency was observed while using the TactiCath CF catheter for ablation of a left-sided pathway using a retrograde approach. Aortic insufficiency is a known complication of this approach,¹⁰ and it is unclear whether the stiffer nature of the TactiCath catheter would increase this risk. However, the remainder of the complications observed are related to the procedure itself, unrelated to the ablation catheter used, and all patients made a full recovery. Mansaur et al and several other studies have shown low complication rates using CF ablation, and the technology has been proven effective and safe both in adult and pediatric populations.^{2,11}

The CF catheters used in our study cost approximately \$1900 more than our typical non-irrigated, non-CF catheters, reflecting an almost three-fold cost difference per catheter. Given the comparable outcomes presented in our study, it is challenging to justify this additional cost in the absence of any identifiable benefit. However, should further experience and refinement of protocols using this catheter ultimately result in improved procedural outcomes and lower recurrence rates, then the overall cost-effectiveness of the catheter may improve when compared to the cost of repeat ablation procedures. Alternatively, further studies may identify particular pathway locations where catheter contact may be associated with higher recurrence rates, such as right free wall pathways, where outcomes are improved with using CF technology.¹²

Limitations and future studies

Our study experienced limited power as a single institution retrospective study with only 49 CF cases and 77 controls. As more children undergo cardiac ablation with CF technology, larger cohorts for both control and CF could elucidate patterns that were not statistically significant in this small initial study. In addition, it would prove useful to carry out a prospective multi-center study using a standard CF ablation protocol. It has been shown with many new medical technologies, especially technically intricate catheter ablation, that procedure times significantly shorten as a function of experience.¹³ By collecting data at multiple institutions, future research would include more operators who may be more or less familiar with CF technology. Widening this scope will allow a better analysis of CF outcomes without interference of individual user variability.

Many AP locations were included in the present study, and we did not find significant differences in procedure details or long-term outcomes. Although our data is not significant, it is not unlike early studies of CF in adult patients with results varying depending on the arrhythmia specifics and study parameters. This may represent an era effect as operators are becoming more familiar with the utility and limitations of new technology. In future studies, differences between pathway locations and details such as transseptal or retrograde approach may prove to be important factors in determining differences in CF and traditional RF ablation. Overall, further investigation with higher power studies is necessary to show trends that may exist in the use of CF in pediatric AP ablation.

Conclusions

Our study suggests that ablation outcomes using CF are comparable to traditional RF ablation in pediatric patients with APs in regard to procedural outcomes, total lesions, and case time.

Tables and Figures

TABLE 1 *Patient Demographics*

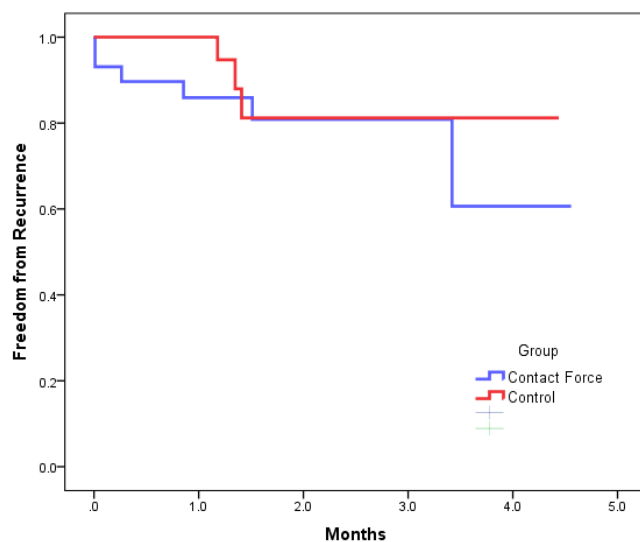
	Contact Force (N=43*)	Control (N=69*)	P-Value
Age (Years)	13.6 ± 3.1 (Med 14.2)	12.4 ± 3.9 (Med 13.2)	0.082
Gender	M 18 F 25	M 38 F 31	0.244
Diagnosis	WPW 30 AVRT 19 PJRT 0	WPW 48 AVRT 28 PJRT 1	1
Previous Ablations	8	11	0.803
CHD	1	4	0.647
Multiple APs*	2	5	0.706

*Multiple APs/procedures for some patients resulted in a total of 49 CF and 77 control studies. **Abbreviations:** AVRT, Atrioventricular reciprocating tachycardia; CHD, Congenital Heart Disease; PJRT, Permanent junctional reciprocating tachycardia; WPW, Wolff Parkinson White.

TABLE 2 *Procedural results and outcomes*

	Contact Force (N=43*)	Control (N=69*)	P-Value
Case Time (Hr)	2:01 ± 0:48 (Med 1:44)	1:53 ± 0:48 (Med 1:48)	0.37
Total Ablation Time (Hr)	0:46 ± 0:47 (Med 0:31)	0:50 ± 0:49 (Med 0:34)	0.69
Total Lesions	6.92 ± 5.6 (Med 6)	7.06 ± 5.9 (Med 5)	0.89
Acute Success	98%	90%	0.149
Long-Term Recurrence	13%	4.8%	0.156

*Multiple APs/procedures for some patients resulted in a total of 49 CF and 77 control studies



*p= 0.50 for comparison of groups over the first five months using log rank test.

FIGURE 1 *Kaplan-Meier freedom from recurrence for first 5 months following procedure*

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