RELATIONSHIP BETWEEN CONTACT FORCE SENSING TECHNOLOGY AND MEDIUM TERM OUTCOME OF ATRIAL FIBRILLATION ABLATION: A MULTICENTER STUDY OF 600 PATIENTS

SHORT TITLE: CONTACT FORCE SENSING AF ABLATION OUTCOMES

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This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/jbfa.12606.

The NIHR Cardiovascular Biomedical Research Unit at the Royal Brompton & Harefield NHS Foundation Trust, and Imperial College, London supported this study.

Dr Gupta and Professor Schilling hold research grants from Biosense Webster. Drs Jarman, Markides and Wong are applying to Biosense Webster for research grant funding and the department has received funding for technology evaluation and training. Dr Markides has received speaker fees and travel support from Biosense Webster. Other authors: No disclosures.

Abstract

Introduction – Contact force sensing (CFS) technology improves acute pulmonary vein isolation durability; however, its impact on the clinical outcome of ablating atrial fibrillation (AF) is unknown.

Methods and Results – First time AF ablation procedures employing CFS from four centers were matched retrospectively to those without CFS in a 1:2 manner by type of AF. Freedom from atrial tachyarrhythmia was defined as the primary outcome measure, and fluoroscopy time the secondary outcome measure. Nineteen possible explanatory variables were tested in addition to CFS. A total of 600 AF ablation procedures (200 using CFS and 400 using non-CFS catheters) performed between 2010 and 2012 (46% paroxysmal, 36% persistent, 18% long-lasting persistent) were analyzed. The mean follow up duration was 11.4±4.7 months - paroxysmal AF 11.2±4.1 CFS vs. 11.3±3.9 non-CFS (p=0.745) - non-paroxysmal AF 10.4±4.5 CFS vs. 11.9±5.4 non-CFS (p=0.015). The use of a CFS catheter independently

predicted clinical success in ablating paroxysmal AF (HR 2.24 (95% CIs 1.29-3.90); p=0.004), but not non-paroxysmal AF (HR 0.73 (0.41-1.30); p=0.289) in a multivariate analysis that included follow-up duration. Among all cases, the use of CFS catheters was associated with reduced fluoroscopy time in multivariate analysis (reduction by 7.7 (5.0-10.5) minutes; p<0.001). Complication rates were similar in both groups.

Conclusions – At medium-term follow-up CFS catheter technology is associated with significantly improved outcome of first time catheter ablation of paroxysmal AF, but not non-paroxysmal AF. Fluoroscopy time was lower when CFS technology was employed in all types of AF ablation procedures.

Keywords

catheter ablation; atrial fibrillation; contact force; pulmonary vein isolation; atrioesophageal fistula; stroke

Introduction

Catheter ablation is superior to antiarrhythmic drugs for maintenance of sinus rhythm in patients with paroxysmal and non-paroxysmal atrial fibrillation (AF).[1,2]

The efficacy of radiofrequency ablation is to a large extent determined by the ability to create durable, transmural lesions.[3] Lesion formation, including durability, is dependent on several interacting factors including catheter tip irrigation, stability and orientation to the myocardium, power delivery, ablation duration, electrode size and catheter-tissue contact force (CF).[4] CF appears important among this plethora of factors.[5,6] Yokoyama first emphasized the relationship between CF and lesion size in a study showing a direct correlation between CF and resulting lesion volume in a canine thigh muscle preparation.[5]

This observation helped inform early adoption of steerable sheaths to improve CF during AF ablation. More recently, the advent of the contact force sensing (CFS) catheter has further evolved the technology of catheter ablation.

CFS technology has several possible benefits including improved procedural safety, reduced fluoroscopy use, and reduced arrhythmia recurrence through greater lesion durability. We previously observed that CFS significantly reduces acute pulmonary vein (PV) reconnection,[7] and others have correlated contact force with effective lesion formation[8] and avoidance of reconnections.[9] PV electrical isolation is central to catheter ablation strategies, with the most AF recurrences associated with reconnection of previously isolated PVs.[10] Extrapolation of these observations suggests that CFS might also improve longer-term ablation outcomes. However, there is a paucity of literature on the medium-term outcome of ablation utilizing this relatively new technology. In this multicenter study, we tested the hypothesis that use of CFS is associated with lower fluoroscopy times and improved freedom from arrhythmia in the medium term following first time paroxysmal and non-paroxysmal AF ablation.

Methods

Inclusion criteria and case matching

We performed a retrospective case-control study in four hospitals (two of which, Royal Brompton and Harefield, are located on separate geographical sites within a single institution). The study was approved by an institutional review committee and all subjects gave informed consent. Inclusion criteria were patients undergoing first-time radiofrequency AF ablation using 3.5mm tipped open-irrigated catheters between 2010 and 2012, who had never previously undergone any left atrial ablation, and who completed at least 6 months

follow-up. Patients were selected by case-matching within each of three AF types – paroxysmal, persistent, long-lasting persistent. Cases utilizing a CFS catheter (ThermoCool® SmartTouch™, Biosense Webster, USA) were matched 1:2 for controls utilizing a non-CFS catheter. In the control group, surround flow SF catheter technology was used in a minority of procedures (39 (9.8%) procedures by one operator).

Ablation techniques and follow-up

All hospitals are experienced high-volume AF ablation centers. During the study period all employed very similar strategies for paroxysmal and non-paroxysmal AF ablation. A minimum contact force of 5-10g was targeted by operators before delivering power with the CFS catheter. In all cases circumferential antral pulmonary vein electrical isolation (PVI) was performed with power limited to 30-35W, and usually to 25W on the posterior wall. Adenosine testing for pulmonary vein reconnection was performed in only a minority of cases, mainly in 2012. Among patients with paroxysmal AF, additional linear ablation was performed only exceptionally. Among patients with non-paroxysmal AF, use of additional lesions varied by operator, including linear lesions at the roof, mitral isthmus, posterior wall and cavotricuspid isthmus, targeting of complex fractionated electrograms, and ablation at the endocardial and epicardial aspects of the coronary sinus. Bidirectional block was the targeted endpoint for linear lesions. Termination of AF by ablation was not targeted, patients instead being externally cardioverted when AF persisted after ablation. The VISITAG^{TM} software module was not available during the period of this study.

Patients were reviewed regularly after discharge, with reviews at 3, 6 and 12 months and as required thereafter. Patients also underwent 12-lead ECG and holter ECG recordings, lasting a minimum of 24 hours, prior to reviews.

Outcome measures & analysis strategy

Data were analyzed retrospectively. The primary outcome measure was single procedure success of ablation of either paroxysmal or non-paroxysmal AF, analyzed separately, and defined in both groups as freedom from any ≥30 second period of atrial tachyarrhythmia (fibrillation, flutter or tachycardia) by symptoms and all ECG recordings, at all follow-ups, after a 3-month 'blanking period'. The secondary outcome measure was procedural fluoroscopy time for all types of AF. Procedural complications were also pre-defined and collected for analysis.

As well as the use of a CFS catheter, nineteen possible explanatory variables were assessed as potential predictors of outcome (*Table 1*). Among baseline clinical variables, one variable, "extreme comorbidity", was predefined as any one of a group of rarely occurring comorbidities expected to greatly reduce the chance of success: severe mitral regurgitation (MR), moderate or greater mitral stenosis, mitral valve replacement, hypertrophic cardiomyopathy or structural congenital heart disease with significant on-going hemodynamic impact on the atria. The operator was included as a variable to control for technical skill and choice of lesion sets in non-paroxysmal AF, which varied between operators but were consistent for individual operators. The duration of radiofrequency energy application was also included as a further measure of the extent of substrate modification performed beyond PVI. Time at risk was taken into account by including follow-up duration as a variable in multivariate analysis.

Complications were collected according to a prespecified list: death during the admission or directly related to procedure, atrioesophageal fistula, sternotomy, pericardial drainage, PV stenosis, phrenic palsy, stroke, transient ischemic attack, atrioventricular block requiring permanent pacing, and femoral complication defined as significant by detection of atriovenous fistula or pseudoaneurym, or requirement for intervention, blood transfusion or readmission.

Statistical analysis

Differences between populations were evaluated with Pearson's Chi-square test for categorical data, Mann Whitney U test where ordinal with >2 categories, and Student t test for continuous data. Univariate relationships to outcome were evaluated with Pearson's Chi-square or Fisher's exact test for categorical data, Mantel-Haenszel test of trend where ordinal with >2 categories, and Student t test for continuous data. Tests were performed 2-tailed, and p values <0.05 considered statistically significant. For the primary outcome, possible univariate explanatory variables were entered into multivariate stepwise binary logistic regression analyses in order of univariate significance, with primary outcome the dependent variable. Variables with p values <0.05 in the presence of other selected variables were retained in the final model, and the c statistic calculated. For the secondary outcome, non-categorical possible univariate explanatory variables were entered into a multiple regression analysis in order of univariate significance, with secondary outcome the dependent variable. Variables with p values <0.05 in the presence of other selected variables were retained in the final model, and the R^2 calculated. No adjustments was made for multiple testing because all reported results are explorative. Analyses were performed using IBM SPSS Statistics software (version 20, IBM Corporation, New York).

Results

Six hundred first time AF ablation procedures were examined, 276 (46%) paroxysmal and 324 (54%) non-paroxysmal (216 (36%) were persistent and 108 (18%) long-lasting persistent). There was a 1:2 ratio of CFS to non-CFS cases within all three types of AF. Follow-up duration was 11.4±4.7 months. Success rate was 277/600 (46%) for all types of AF.

Primary outcome in paroxysmal AF

In first time paroxysmal AF procedural success was achieved in 139/276 (50%) cases over 11.3±4.0 months follow-up (11.2±4.1 CFS vs. 11.3±3.9 non-CFS; p=0.745). Characteristics of CFS and non-CFS groups are compared in *Table 1*. There were significant differences in mitral regurgitation (greater in CFS group; p<0.001), extreme comorbidity (more frequent in CFS group; p=0.030), procedural year (later in CFS group; p<0.001), hospital (p<0.001), and operators (p<0.001).

Significant univariate predictors of procedural success were shorter follow-up duration (p<0.001), less mitral regurgitation (p=0.001), later procedure year (p=0.024), hospital (p=0.024) and use of a CFS catheter (borderline p=0.050) (*Table 2*): where a CFS catheter was used 54/92 (59%) cases were successful, whereas 85/184 (46%) were successful when CFS was not employed (*Figure 1)*.

By multivariate analysis, a model with c statistic 0.654 was constructed from variables independently predictive of the primary outcome: increasing mitral regurgitation grade reduced the chance of success (relative risk (RR) 0.28 (0.15-0.54); p<0.001), while use of CFS increased it (RR 2.24 (1.29-3.90); p=0.004) (*Table 2*) (*Figure 2*).

Primary outcome in non-paroxysmal AF

The first time procedural success rate in non-paroxysmal AF was 138/324 (43%; p=0.057 vs. paroxysmal) over 11.4±5.2 months follow-up (10.4±4.5 CFS vs. 11.9±5.4 non-CFS; p=0.015). Characteristics of the CFS and non-CFS groups are compared in *Table 1*. As well as follow-up duration, there were significant differences in left atrial diameter (lower in CFS group; p<0.001), left ventricular function (better in CFS group; p=0.022), mitral regurgitation

(greater in CFS group; p=0.024), hypertension (more frequent in CFS group; p=0.017), procedural year (later in CFS group; p<0.001), hospital (p<0.001), and operators (p<0.001).

Significant univariate predictors of procedural success were shorter follow-up duration (p<0.001), hospital (p=0.007), operator (p=0.007) and smaller left atrial diameter (p=0.009) (*Table 3*). In univariate analysis there was no difference in success rates amongst cases with or without CFS (46/108 (43%) vs. 92/216 (43%); p=1.000).

By multivariate analysis, a model with c statistic 0.727 was constructed from variables independently predictive of the primary outcome: chance of a successful outcome was reduced by increasing left atrial diameter (RR 0.94 (0.90-0.98); p=0.002), female gender (RR 0.44 (0.23-0.83); p=0.012), presence of extreme comorbidity (RR 0.38 (0.15-0.95); p=0.038), and also varied by operator (p=0.012). Use of CFS did not predict the outcome (RR 0.73 (0.41-1.30); p=0.289) (*Table 3*) (*Figure 2*). .

Secondary outcome

Among all cases, the duration of fluoroscopy was 32.0±18.0 minutes. The use of CFS was a significant univariate predictor of fluoroscopy time (26.6±15.1 minutes with CFS vs. 34.7±18.7 minutes without CFS; p<0.001) (*Figure 3*). In multivariate analysis with R^2 0.203 the following variables were independently predictive of fluoroscopy duration: increasing ablation time (p<0.0001) and increasing left atrial diameter (p=0.002) predicted increased fluoroscopy time, while the use of CFS predicted reduced fluoroscopy time (-7.7 (-5.0 to -10.5) minutes); p<0.001) (*Table 4*) (*Figure 3*).

Procedural complications

Twenty-four procedures (4%) had complications. There was one atrioesophageal fistula leading to death (0.17%; in the non-CFS group), one stroke (0.17%; non-CFS), one TIA (0.17%; CFS), one PV stenosis (0.17%; non-CFS), two phrenic palsies (0.33%; both non-CFS), seven pericardial drains (1.17%; two in CFS group), and 11 femoral complications (1.83%). Rates of complications were the same in the CFS (7/200, 3.5%) and non-CFS groups (17/400, 4.25%; p=0.163). Complications directly related to ablation (fistula, PV stenosis, phrenic palsy, and pericardial drainage) also occurred with equal frequency in the CFS (2/200, 1%) and non-CFS groups (9/400, 2.25%; p=0.158).

Discussion

This is the first large scale, multicenter study examining the impact of CFS technology on medium term clinical outcomes of first time AF ablation. The major findings are of a significantly higher first time procedural success rate with CFS following paroxysmal AF ablation, no difference in first time procedural success following non-paroxysmal AF ablation, and a significant reduction in fluoroscopy time with CFS in all procedures.

Contact force sensing technology

CFS technology has been available commercially since 2009. Two irrigated CFS catheters are available, the TactiCath™ (St. Jude Medical, USA) and the ThermoCool® SmartTouch™ (Biosense Webster, USA). The TactiCath measures CF by micro-deformations of optical fibers, whereas the SmartTouch™ catheter measures micro-deformations of a precision spring connecting the catheter shaft and tip. The greatest clinical experience has been built up with the SmartTouch™ catheter, which received FDA approval in February 2014.

The theoretically possible benefits of CFS technology are numerous. Safety may be improved by reducing the risk of perforation during catheter manipulation and ablation.[5] It may reduce reliance on fluoroscopy during navigation and the time to achieve an intact linear lesion. Avoiding ablation at sub-optimal CF may reduce late development of gaps within linear lesions with resultant loss of clinical benefit, and risk of proarrhythmia.

However, following animal studies validating the technology and correlating CF with lesion formation and incidence of steam pops,[5] only small human studies have thus far reported clinical outcomes using CFS, and usually examining only the acute procedural outcome. Three studies, including 145 patients, have compared acute procedural endpoints during AF ablation using CFS and non-CFS catheters.[7,11,12] One small randomized controlled study of 38 patients examined 6-month follow-up in paroxysmal and persistent AF.[13] Two small non-randomized studies totalling 92 patients have previously examined one-year follow-up of paroxysmal AF ablation, only one having a control arm.[14,15]

The four centers in this study were early adopters of CFS catheters. Accordingly, this is the first paper to be able to report the clinical findings of a large patient cohort with medium term follow-up, the inclusion of 600 patients greatly increasing the existing evidence base regarding the possible impact of CFS on medium term outcomes.

Paroxysmal AF

Multivariate analysis of 276 first time paroxysmal AF ablation procedures found that the use of a CFS catheter and severity of mitral regurgitation were the only significant independent predictors of the arrhythmia outcome over 11 months follow-up. Worsening MR severity may be expected to be correlated with a poorer outcome given its relationship to progressive left atrial dilatation and fibrosis.[16] By univariate analysis, the success rate in paroxysmal AF increased in later years, while it did not increase in non-paroxysmal AF. Multivariate analysis

suggested that this improvement in paroxysmal AF outcomes was associated with the introduction of CFS technology, procedure year no longer being significant when the use of CFS was controlled for. The association between CFS and improved arrhythmia outcomes are consistent with the findings of our previous study in which the use of CFS significantly reduced the incidence of acute PV reconnection following a one-hour waiting period.[7] A mechanism of reduction in the incidence of subsequent reconnections in additional areas of suboptimal ablation seems highly likely, the arrhythmia outcome in this group of patients being known to depend largely on the ability to achieve durable integrity of linear circumferential lesions.[10]

Non-paroxysmal AF

Increasing left atrial diameter, female gender and presence of extreme comorbidity reduced the chance of a successful arrhythmia outcome. It also varied by operator. All of these factors are intuitive, and the impact of left atrial diameter and female gender on persistent AF ablation outcomes are previously described in multiple studies,[17] tending to validate the quality of the data collected in the current study. The association between operator and procedural outcome may plausibly be explained either by variation in technical skills, or by choice of lesion sets. Extreme comorbidity, a composite of comorbidities each associated with progressive left atrial dilatation but individually resistant to individual analysis due to their rarity in an AF ablation population, is described for the first time as an independent predictor of procedural failure.

It is of interest that, in contrast to the paroxysmal AF group, CFS did not affect the procedural outcome. Non-durability of the ablation lesion is a critical issue in paroxysmal AF, any gap in the circumferential line potentially leading to reconnection of one or even two PVs, which in turn is a critical determinant of the chance of arrhythmia recurrence.[10] In non-paroxysmal AF, while gaps in linear lesions are an important mechanism of recurrence, other

mechanisms are also important, demonstrated most strikingly by the ability of AF to persist at the end of all ablation in most procedures: the more advanced atrial substrate may often fibrillate in the presence of intact lesions. The non-paroxysmal AF population may thus have less sensitivity in demonstrating the benefit of CFS technology in creating durably intact linear lesions, with effectively a smaller signal to noise ratio for its detection.

Fluoroscopy time & complications

Increasing ablation time and increasing left atrial diameter both predicted increased use of fluoroscopy, whereas the use of a CFS catheter predicted reduced fluoroscopy. These observations are clinically plausible. The possibility of zero-fluoroscopy ablation of right and left atrial (LA) substrates has been documented by the use of CFS.[18] The reduction in fluoroscopy observed with CFS in this study may relate to increased confidence during navigation, increased confidence in the validity of geometry produced by CFS feedback, or reduction in time required to complete contiguous lesions. The reduction in fluoroscopy time observed, 7.7 minutes, is clinically meaningful.

Complications, including those related directly to ablation, occurred with the same frequency in both groups; howeve,r it is noteworthy that this study was not powered to detect a clinically important difference in the rate of complications between groups, and particularly not a clinically important difference in the even lower rate of directly ablation related complications.

Limitations

This is a retrospective study and therefore has the expected limitations of possible selection bias and confounding from other variables that were not measured. There were several significant population differences at baseline, including a small difference in follow-up duration between the CFS and non-CFS groups; however, these factors were controlled for by inclusion in multivariate analysis, demonstrating that they were not significantly associated with the outcome. The different operators contributing to this study had similar but not identical ablation techniques, and this was not standardized with a formal protocol. While lesion sets were almost identical in paroxysmal AF, techniques varied more widely in non-paroxysmal AF. The operator and duration of ablation were included as variables in multivariate analysis to adjust for this variation, with the former being a significant determinant of outcome. Finally, although bidirectional block was the targeted endpoint when linear lesions were deployed, the proportion of cases in which this was achieved was not included as a variable in the study.

Conclusion

Use of CFS technology significantly improves medium term arrhythmia-free survival following first time paroxysmal AF ablation when compared to a standard ablation catheter. However, its use did not change the medium term procedural outcome of non-paroxysmal AF ablation. CFS also significantly reduced fluoroscopy exposure in all patients.

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Table 1. Population Characteristics for CFS cases and non-CFS controls

	ALL AF			PAROXYSMAL AF			NON-PAROXYSMAL AF		
	CFS cases	Non-CFS controls		CFS cases	Non-CFS controls		CFS cases	Non-CFS controls	
Variable	**(n = 200)**	**(n = 400)**	**p Value**	**(n = 92)**	**(n = 184)**	**p Value**	**(n = 108)**	**(n = 216)**	**p Value**
Age (years, mean±SD)	63±12	61±10	0.261	61±12	61±11	0.893	64±11	62±10	0.079
Female sex	51 (26)	118 (30)	0.305	28 (30)	70 (38)	0.213	23 (21)	48 (22)	0.849
Long-standing persistent AF (>1 year)	36 (18)	72 (18)	1.000	N/A	N/A	N/A	36 (33)	72 (33)	1.000
Left atrial diameter (mm, mean±SD) †	42±7	44±7	0.011*	41±6	40±6	0.876	44±7	47±7	<0.001*
Left ventricular function			0.108			0.633			0.022*
Normal	163 (82)	302 (76)		80 (87)	163 (89)		83 (77)	139 (64)	
Mildly impaired	17 (9)	49 (12)		5 (5)	13 (7)		12 (11)	36 (17)	
Moderately impaired	14 (7)	32 (8)		5 (5)	7 (4)		9 (8)	25 (12)	
Severely impaired	6 (3)	17 (4)		2 (2)	1 (1)		4 (4)	16 (7)	
Mitral regurgitation grade			<0.001*			<0.001*			0.024*
None	123 (62)	314 (79)		61 (66)	157 (85)		62 (57)	157 (73)	
Mild	70 (35)	67 (17)		29 (32)	27 (15)		41 (38)	40 (19)	
Moderate	7 (4)	13 (3)		2 (2)	0 (0)		5 (5)	13 (6)	
Severe	0 (0)	6 (2)		0 (0)	0 (0)		0 (0)	6 (3)	
Valvular heart disease‡	10 (5)	27 (7)	0.401	4 (4)	10 (5)	0.684	6 (6)	17 (8)	0.444

Extreme comorbidity[§]	21 (11)	31 (8)	0.259	12 (13)	10 (5)	0.030*	9 (8)	21 (10)	0.684
Hypertension	80 (40)	119 (30)	0.012*	33 (36)	54 (29)	0.299	47 (44)	65 (30)	0.017*
Diabetes mellitus	21 (11)	34 (9)	0.424	10 (11)	11 (6)	0.156	11 (10)	23 (11)	1.000
Coronary artery disease	19 (10)	51 (13)	0.242	6 (7)	15 (8)	0.614	13 (12)	36 (17)	0.273
Thyrotoxicosis[ǂ]	0 (0)	5 (1)	0.041*	0 (0)	1 (1)	0.359	0 (0)	4 (2)	0.067
Stroke or TIA	19 (10)	27 (7)	0.233	9 (10)	10 (5)	0.187	10 (9)	17 (8)	0.700
Renal dysfunction	3 (2)	9 (2)	0.536	0 (0)	1 (1)	0.359	3 (3)	8 (4)	0.664
Procedure year			<0.001*			<0.001*			<0.001*
2010	0 (0)	144 (36)		0 (0)	72 (39)		0 (0)	72 (33)	
2011	30 (15)	162 (41)		14 (15)	67 (36)		16 (15)	95 (44)	
2012	170 (85)	94 (24)		78 (85)	45 (24)		92 (85)	49 (23)	
Hospital			<0.001*			<0.001*			<0.001*
1	96 (48)	300 (75)		49 (53)	145 (79)		47 (44)	155 (72)	
2	49 (25)	23 (6)		30 (33)	11 (6)		19 (18)	12 (6)	
3	25 (13)	40 (10)		0 (0)	14 (8)		25 (23)	26 (12)	
4	30 (15)	37 (9)		13 (14)	14 (8)		17 (16)	23 (11)	
Operator[#]	N/A	N/A	<0.001*	N/A	N/A	<0.001*	N/A	N/A	<0.001*
Radiofrequency energy time (minutes)	55±23	54±24	0.435	45±16	48±22	0.355	64±24	59±24	0.077
Follow up duration (months)	10.8±4.3	11.6±4.8	0.030*	11.2±4.1	11.3±3.9	0.745	10.4±4.5	11.9±5.4	0.015*

Values shown are number (%) unless otherwise indicated. * Statistically significant $p < 0.05$. † Transthoracic echocardiographic left parasternal long axis anteroposterior diameter at end-systole. ‡ Moderate or greater stenosis or regurgitation, replacement or repair of any left sided valve. § See text for definition. ǂ Within the last year. # 17 operators (median 22; interquartile range 8 to 67 procedures). TIA, transient ischaemic attack.

Table 2. Paroxysmal AF: Predictors of Procedural Success.

	Univariate Analyses	Multivariate Analyses	
Variable	**p Value**	**HR (95% CI)***	**p Value**
Mitral regurgitation grade	0.001	0.28 (0.15-0.54) †	<0.0001
Contact force sensing catheter	**0.050**	**2.24 (1.29-3.90)**	**0.004**
Follow-up duration	<0.001		
Procedure year	0.024		
Hospital	0.024		
Stroke or TIA	0.103		
Diabetes mellitus	0.104		
Female sex	0.110		
Operator	0.132		
Left atrial diameter	0.142		
Left ventricular function	0.239		
Age	0.448		
Hypertension	0.466		
Thyrotoxicosis	0.496		
Renal dysfunction	0.504		
Valvular heart disease	0.564		
Coronary artery disease	0.794		
Radiofrequency energy time	0.808		
Extreme comorbidity	1.000		

*Relative Risk (95% CI) for successful outcome. †Ordinal variable negatively correlated with success.

Table 3. Non-Paroxysmal AF: Predictors of Procedural Success.

	Univariate Analyses	Multivariate Analyses	
Variable	**p Value**	**HR (95% CI)***	**p Value**
Left atrial diameter (mm)	0.009	0.94 (0.90-0.98) †	0.002
Female sex	0.155	0.44 (0.23-0.83)	0.012
Operator	0.007	N/A‡	0.025
Extreme comorbidity	0.064	0.38 (0.15-0.95)	0.038
Follow-up duration	<0.001		
Hospital	0.007		
Renal dysfunction	0.226		
Procedure year	0.323		
Longstanding persistent AF (>1 yea	0.340		
Thyrotoxicosis	0.361		
Radiofrequency energy time	0.410		
Mitral regurgitation grade	0.532		
Stroke or TIA	0.542		
Coronary artery disease	0.558		
Diabetes mellitus	0.578		
Valvular heart disease	0.728		
Age	0.783		
Hypertension	0.868		
Left ventricular function	0.883		
Contact force sensing catheter	**1.000**	**0.73 (0.41-1.30)**	**0.289§**

* Relative Risk (95% CI) for successful outcome. † Continuous variable negatively correlated with success.
‡ Categorical variable with multiple values, hence no hazard ratio presented despite being a statistically significant variable. § Not statistically significant.

Table 4. Predictors of Fluoroscopy Time: All Types of AF.

	Multivariate Analyses	
Variable	**B coefficient (95% CI) (minutes)***	**p Value**
Contact force sensing catheter	-7.7 (-5.0 to -10.5)	<0.001
Radiofrequency ablation time (s)	0.005 (0.004 to 0.006)†	<0.001
Left atrial diameter (mm)	1.8 (0.6 to 2.9) ‡	0.002

* B coefficient (95% CI) for relationship between variable and fluoroscopy time. † Continuous variable positively correlated with fluoroscopy time. ‡ Left atrial diameter group (<40mm, 40-<45mm, 45-<50mm, 50->55mm, ≥55mm), ordinal variable positively correlated with fluoroscopy time.

Figure 1. Procedural success in paroxysmal AF with and without CFS. By univariate analysis there was a borderline significantly higher rate of procedural success with CFS (59% vs 46%, p = 0.05)

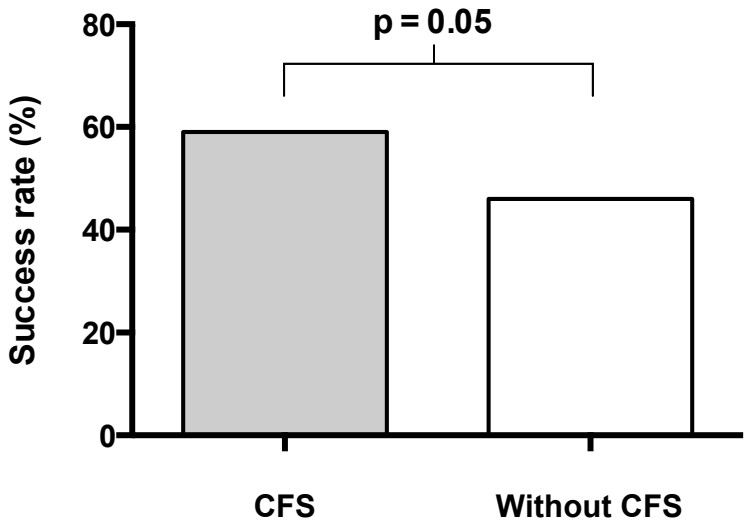

Figure 2. Relative risk of procedural success using CFS by multivariate analysis. CFS predicted procedural success in paroxysmal AF (RR 2.24 (1.29-3.90); p=0.004), but not in non-paroxysmal AF (RR 0.73 (0.41-1.30); p=0.289)

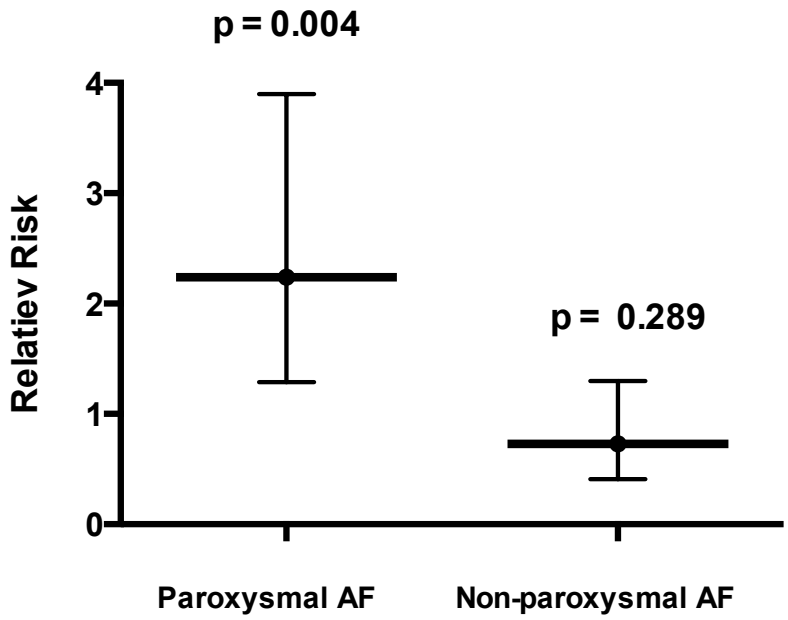

Figure 3. Fluoroscopy time amongst all types of AF. 3A – Univariate analysis: CFS associated with reduced fluoroscopy time (26.6±15.1 vs. 34.7±18.7 minutes; p<0.001). 3B – Multivariate analysis: CFS associated with reduction of fluoroscopy time by 7.7 (5.0 to 10.5) minutes; p<0.001.