ADVANCES IN CARDIAC ARRHYTHMIAS

GREAT INNOVATIONS IN CARDIOLOGY

XXVI Giornate Cardiologiche Torinesi

Directors Fiorenzo Gaita Sebastiano Marra

Turin October 23-25, 2014 Galleria D'Arte Moderna

Centro Congressi Unione Industriale di Torino







Scientific Committee Malcolm Bell, Usa Martin Borggrefe, *Germany* Amir Lerman, Usa Jean François Leclercq, *France* Dipen Shah, Suisse

Organization Committee Monica Andriani, *Italy* Matteo Anselmino, *Italy* Carlo Budano, *Italy* Davide Castagno, *Italy*

No fluoroscopy EP Lab, No Compromises

Impact of contact force TactiCath measurement on outcome, reduction of rx and procedure time in AF ablation

Alessio Borrelli, MD

Division of Electrophysiology Policlinico Casilino, Rome

Evolution





Evolution?

Author and year	pts	technique	fup	PAF	PEF
Pappone C. JACC '03	589	Circumferential	30 m	81.5%	75.4%
Stabile G. EHJ '06	68	Circumferential	12 m	56%	56%
Bhargava M. JCE '04	323	Circumferential	15 m	86%	78%
Oral H. Circ '03	40	Circumferential	6 m	88%	
	40	Segmental		67%	
Karch M.R. Circ '05	50	Circumferential	6 m	42%	
	50	Segmental		66%	
Mantovan R. JCE '05	30	Circumferential	15 m	57%	
	30	Comb (segm + circ)		83%	
Tse H.F. JACC '03	52	Segmental	12 m	58%	43%
Bourke J.P. Heart '05	100	Segmental	6 m	73%	45%
Arentz T. Circ '03	55	Segmental	12 m	70%	44%
Nademanee K. JACC '04	121	Fragmented EGM	12 m	95%	87.5%
Jais P. HRS '06	74	Segmental, lines, fragmented EGM	18 m	91%	
Oral H. Circ '06	153	Circumferential, fragmented EGM	11 m	77%	
Oral H. NEJM '06	77	Circumferential			74%
Calò L. JACC '06	41	Lines (left atrium)	14 m		61%

Up-dated Worldwide Survey on the Methods, Efficacy and Safety of Catheter Ablation for Human Atrial Fibrillation Cappato R et al. Circulation Arrh 2009

Type of AF	No. of	No.	Success without AADs		Suc	cess with AADs	Overall Success		
	Centers	of Pts	No.	Rate	No. Rate		No.	Rate	
			of Pts	*Median	of Pts	of Pts *Median		*Median	
				[Interquartile range]		[Interquartile range]		[Interquartile range]	
Paroxysmal	85	9,590	6,580	74.9	1,290	American Heart Association 9.1	7,870	84.0	
·		ŕ		\smile		Lonen and Has.		\bigcirc	
Persistent	73	4,712	2,800	[64.9-82.6] 64.8	11595		3,395	[79.7-88.6]	
				Ar <u>[52,4172,0]</u> ia ar	d Electrop	hysiol _[0,8-15.2]		[66.1-80.0]	
Long-lasting	40	1,853	1,108	JOURNAL OF THE A	4erican Heart A 162	Association 7.9	1,270	71.0	
				[53.3-71.4]		[0.9-15.9]		[67.4-76.3]	









-N DECENDER











Lab Routine

Contact sensor





Contact sensor



Litterature

TOCCASTAR

- Effectiveness and Safety with TactiCath™
- Supplement with new generation

EFFICAS II

• Significant better outcome at using Contact Force guidelines

EFFICAS I

- Contact Force guidelines
- Minimum Contact Force
- Minimum Force Time Integral

TOCCATA

- Safety and feasability of Force Sensing
- Importance of average Contact Force and Force Time Integral

Clinical Case

Supraventricular Arrhytmias

Case 1 55 y/o patient Symptomatic for palpitation and fatigue NYHA Class IIb Admitted for AF e FLA Failed Amiodarone, Flecainidis worsening, Propafenone some benefit, better in Verapamil+metoprolol (fatigue) Scheduled Procedure PVIs + CTI

Basal ECG



Intracavitary signals



Activation Map



AF during Mapping Ganglia?





Poor Contact



45 sec 35 W

FTI very low



2° Ablation Lateral Force > 10 gr



Ablazione efficace 10 gr







15 min later

What to do?

- 1. Change Catheter
- 2. Increase Power
- 3. Use a steerable Sheath
- 4. Change operator



AGILIS



Finally



More Ventricular Signal



More Balanced Signal

A little better



Single erogation Drop down to 30 W 45 sec

Sinus Rhythm (1)

Sinus Rhythm at the end of the procedure.



Pacing Post Ablation (1)



Pacing Post Ablation (2) + Isoproterenol



Report final

Event		System inform
Screen	11	WorkStation
Ablation details - Procedu	TactiSys Quartz S/N	
Forces	[g]	100 -
Min force	3	80-
Avg force	11	60 -
Max force	30	× 40-
StdDev force	8	40
5 th percentile force	4	20-
95 th percentile force	29	0 5 10 20
		Force
FTI™	[gs]	100 -
Min FTI	133	80 -
Avg FTI	734	60 -
	4000	*

information QuartzClientPC0

009811

		100										
		100-										
_		80 -										
		60 -										
	*	40 -										
		20 -										
					Г							
		0-					_					
		() 5	1	LO	20	30	40	50	60	70	100
					For	rce d	istrit	oution	1 [a]			

FTI™	[gs]
Min FTI	133
Avg FTI	734
Max FTI	1928
StdDev FTI	497
5 th percentile FTI	136
95 th percentile FTI	1811

LSI	
Shorter than 6 sec	0
Min LSI	2.3
Avg LSI	4.7
Max LSI	7.2
StdDev LSI	1.1
5 th percentile LSI	2.9
95 th percentile LSI	6.9





Impact of contact force TactiCath measurement on outcome, reduction of rx and procedure time in AF ablation

Time spared almost 45 min (mapping, ablating and waiting)

Clues > Lateral contact

Usless erogation < 10 grs

Impact of contact force TactiCath measurement on outcome, reduction of rx and procedure time in AF ablation



Outcome recurrences?

How To optimize Pulmonary veins deconnection

- Adenosin and isoproterenol
- •Exit Block
- Entrance block
- Voltage Map
- Reinduction

2013

Pace and ablate

Contact force sensors

TactiCath Why Measure Contact Force?

 Risk of tamponade Non-transmural lesion •Risk of Esophagus Edema Lengthy procedure injury Risk of pops Inconsistent outcomes BALANCING ACT EFFICACY SAFETY **Creation of durable and** complete lesions

TOCCATA – Results



High variability of Contact Force depending on anatomy





Reddy et al.; The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study. Heart Rhythm, 2012 Nov;9(11):1789-95.

QUANTITATIVE MAGNETIC RESONANCE IMAGING ANALYSIS OF THE RELATIONSHIP BETWEEN CONTACT FORCE AND LEFT ATRIAL SCAR FORMATION AFTER CATHETER ABLATION OF ATRIAL FIBRILLATION

HEART RHYTHM SOCIETY, MAY 2013, DENVER, CO.

AUTHORS :

Christian Sohns', Rasehd Karim', James Harrison', Aruna Arujuna', Nick Linton', Ebrahim Palkhi', Hendrik Lambert', Giovanni Leo?, Steven Williams', Reza Razavi', Matt Wright', Tobias Schaeffter', Mark O'Neill' and Kawal Rhode.

¹Division of Imaging Sciences and Biomedical Engineering, King's College London, London, United Kingdom, United Kingdom, Zindosense SA, Geneva, Switzerland, Switzerland.

INTRODUCTION

Catheter contact force (CF) is an important determinant of radiofrequency (RF) lesion quality during pulmonary vein isolation (PVI) for paroxysmal AF (PAF). Late gadolinium enhancement MRI (LGE-MRI) allows visualization of acute and chronic ablation lesions. This study describes a new technique to examine the relationship between contact force achieved during RF delivery and LGE signal intensity following PVI.

METHODS

Six patients underwent PVI for PAF using a CF-sensing catheter TactiCath®, Endosense and following pre-procedural MRI. During ablation, contact force-time integral (FTI) and position was documented for each 40s RF application (25W, 42oC). All patients underwent repeat LGE MRI three months later. The LGE signal intensities were projected onto a 3D shell and the CF maps were generated on the same shells. Using custom-made software, the entire LA surface was divided into 3mm2 segments. The force and DE maps were superimposed and compared for each 3mm2 zone (Fig. 1). An effective lesion was defined when scar occupied >90% of a 3mm2 analysis zone.

RESULTS

268 RF lesions were tagged on the MR shells and given a lesion-specific FTI. Increasing FTI correlated with increased LGE signal intensity (Fig 1) which was greater when the FTI was > 1200gs.

CONCLUSIONS

There is a correlation between FTI and LGE MRI following AF ablation. Real-time FTI maps are feasible and may prevent inadequate lesion formation.



EFFICAS I – Results



Each ablation should be made with FTI > 400 gs !

Neuzil et al. Electrical reconnection after pulmonary vein isolation is contingent on contact force during initial treatment: results from the EFFICAS I study. Circ Arrhythm Electrophysiol. 2013 Apr;6(2):327-33.

Protocol-Specified Descriptive Endpoint Analysis: Optimal CF Impact on Success and Repeat Ablations



Repeat ablation after the protocol defined 3 month blanking period; protocol defined success used for analysis

2. Optimal CF cohort defined as those patients where $\ge 90\%$ lesions $\ge 10g$

1.

3. Non-optimal CF cohort defined as those patients where < 90% lesions ≥10g

The TactiCath[™] Quartz Set is currently undergoing FDA review for premarket approval CAUTION: Investigational device in the United States. Limited by Federal (or U.S.) law to investigational use. Not available for sale in the U.S.

ID-2001165 B EN (06/14) 7

Litterature

TOCCASTAR

- Effectiveness and Safety with TactiCath™
- Supplement with new generation

EFFICAS II

• Significant better outcome at using Contact Force guidelines

EFFICAS I

- Contact Force guidelines
- Minimum Contact Force
- Minimum Force Time Integral

TOCCATA

- Safety and feasability of Force Sensing
- Importance of average Contact Force and Force Time Integral

Impact of contact force TactiCath measurement on outcome, reduction of rx and procedure time in AF ablation



German Ablation registry (7300 pcd)

Avg Rx time 27 min

DAP: 34 Gyxcm2

7 mSv

Catheter-tissue contact force for pulmonary veins isolation: a pilot multicentre study on effect on procedure and fluoroscopy time





Stabile G, Solimene F et al Europace 2014

Catheter-tissue contact force for pulmonary veins isolation: a pilot multicentre study on effect on procedure and fluoroscopy time



Contact force during RFCA for PV isolation affects procedural parameters, in particular procedural and fluoroscopy times, without increasing complications.

Stabile G, Solimene F et al Europace 2014

Own Data submitted

	TCc (a)	STc (b)	SFc (c)	ANOVA P- value
Identified PVs per patient (n)	4.00±0.00	4.05±0.22	3.95±0.22	a vs b: NS
				a vs c: NS
				b vs c: NS
Isolated PVs (n)	81	83	80	a vs b: NS
				a vs c: NS
				b vs c: NS
% isolated PVs (%)	96%	98%	96%	a vs b: NS
				a vs c: NS
				b vs c: NS
RF time (min)	41.3±13.2	30±14	30±9	a vs b p=0.013
				a vs c p⊲0.01
				b vs c NS
Fluoroscopy time (min)	34±18	20±10	21±13	a vs b p⊲0.001
				a vs c p=0.02
				b vs c NS
Procedural time (min)	181±53	140±53	170±51	a vs b p⊲0.001
				a vs c NS
				b vs c p⊲0.001
% of isolated PVs at 30 min (%)	89%	95%	95%	a vs b p<0.05
				a vs c p⊲0.05
				b vs c NS



Impact of contact force TactiCath measurement on outcome, reduction of rx and procedure time in AF ablation



What else What's next What is a rotor

CAFE mapping why contact force



One Map: CFE Mean Map

We have performed a Left Atrium One Map: Geometry+CFE Mean Map. The CFE Mean Map tool enabled us to point out the followings areas which are characterized by fragmented signals (analyzed in terms of average cycle lenght).



Passively Fragmented Channel

By using a more narrow color scale we can better show the passively fragmented channel



Overlapping Areas and CFE ST. DEV.

We have also performed a CFE Standard Deviation Map in order to point out the most regular activity in the left atrium. By looking at the CFE Mean and the CFE Standard Deviation Map (on the right side), we have found that the two high fragmented areas (placed on the posterior septal wall and on the anterior roof area respectively), have been very regular too (below 20 ms as standard deviation).



First Rotor

As a consequence we wanted to better study these two interesting areas using a High density Circular Catheter. Firstly we have placed it on the the fragmented area located on the anterior roof. See how this area switches from high fragmented to high fast regular activity



Second Rotor

After then we placed the High density Circular Catheter on the the fragmented area located on the posterior septal wall . See again how this area switches from high fragmented to high fast regular activity



Rotors Ablation

After the mapping phase we have performed the Ablation of the two Rotors by achieving Sinus Rhythm during the ablation of the red coloured area in the image. It was **the earliest activated** area previously described.



Pacing Post Ablation: Not AF

The following burst did not trigger any atrial fibrillations.



Impact of contact force TactiCath measurement on outcome, reduction of rx and procedure time in AF ablation

Good contact = Good Signal = Good Map = Less Substrate ablation

Better outcome > less Time > more safety

Change of Role









Criteria

- 1. Substrate mapping should be carried on with contact force sensor
- 2. Take note of are with not good contact force >4 (waiting for contact and voltage map on the same panel)
- 3. Erogate only when contact > 10 g
- 4. At least FTI > 550 e LSI > 5 (depending on arrhytmias)
- 5. Remap voltage with unipolar for AF in sites where contact was not optimal)
- 6. When possible use Agilis or any Steerable sheath



Exploratory Analysis: Deflectable Sheath Impact



Protocol Defined Treatment Success by Sheath Usage – All Subjects ²



 CF subjects treated with deflectable sheath had higher average CF vs. those treated without a deflectable sheath

1. Per protocol contact force cohort; CF data unavailable on one patient

2. Per protocol cohort

The TactiCath[™] Quartz Set is currently undergoing FDA review for premarket approval CAUTION: Investigational device in the United States. Limited by Federal (or U.S.) law to investigational use. Not available for sale in the U.S.

FTI density map

A



CF density map



Ragu Vijaykumar, BSc1, Andrew H. Locke, BA2, Stepan Kralovec3, Petr Neuzil, MD3, Edouard Fonck, PhD4, David Harari4, and6CONFIDENTIAL-Internal Use6Vivek Y. Reddy, MD2. Presented at HRS 2011

In conclusion is it a must to ???





In conclusion 2 is it a must to ???





Thank you for attention

I can resist everything except temptation



