

# ***RFA - HF***

**RadioFrequency Ablation for persistent atrial fibrillation in patients with Heart Failure and severe left ventricular dysfunction**

**Michael R MacDonald**

**Derek T Connelly, Nathaniel Hawkins, Tracey Steedman, John Payne, Morag Shaw, Martin Denvir, Sai Bhagra, Sandy Small, William Martin, John JV McMurray, Mark C Petrie**

**Golden Jubilee National Hospital, Glasgow**

# Disclosures

- Nothing to disclose

# Study funding

- Chief Scientist Office, Scotland

# Recruitment

- 2007-2009
- Out-patient heart failure clinics, Scotland

# Background

- AF is common in heart failure
- AF in heart failure is associated with increased morbidity and mortality
- **Observational** studies have reported that radiofrequency ablation can restore sinus rhythm in patients with heart failure and improve left ventricular function

# Aims

To compare:

Optimal medical therapy (rate control)

v

Radiofrequency ablation (rhythm control)

In patients with:

Symptomatic heart failure

Severe left ventricular dysfunction

Persistent AF

Primary outcome:

Change in LVEF by CMR

**Baseline assessment  
including CMR**

**Randomisation 1:1**

**Optimal medical  
therapy  
*(rate control)***

**Radiofrequency  
ablation  
*(rhythm control)***

**Repeat CMR at 1 week**

**3 months:  
Rhythm reassessed.  
2<sup>nd</sup> ablation if in AF**

**6 months: all baseline tests repeated**

# Inclusion criteria

- Persistent AF
- NYHA II - IV heart failure
- LVEF < 35%
  - by radionuclide ventriculography (RNVG)
- 18 – 80 years

# Exclusion Criteria

- Paroxysmal AF
- Broad QRS
- Unable to take oral anticoagulants

# End-points

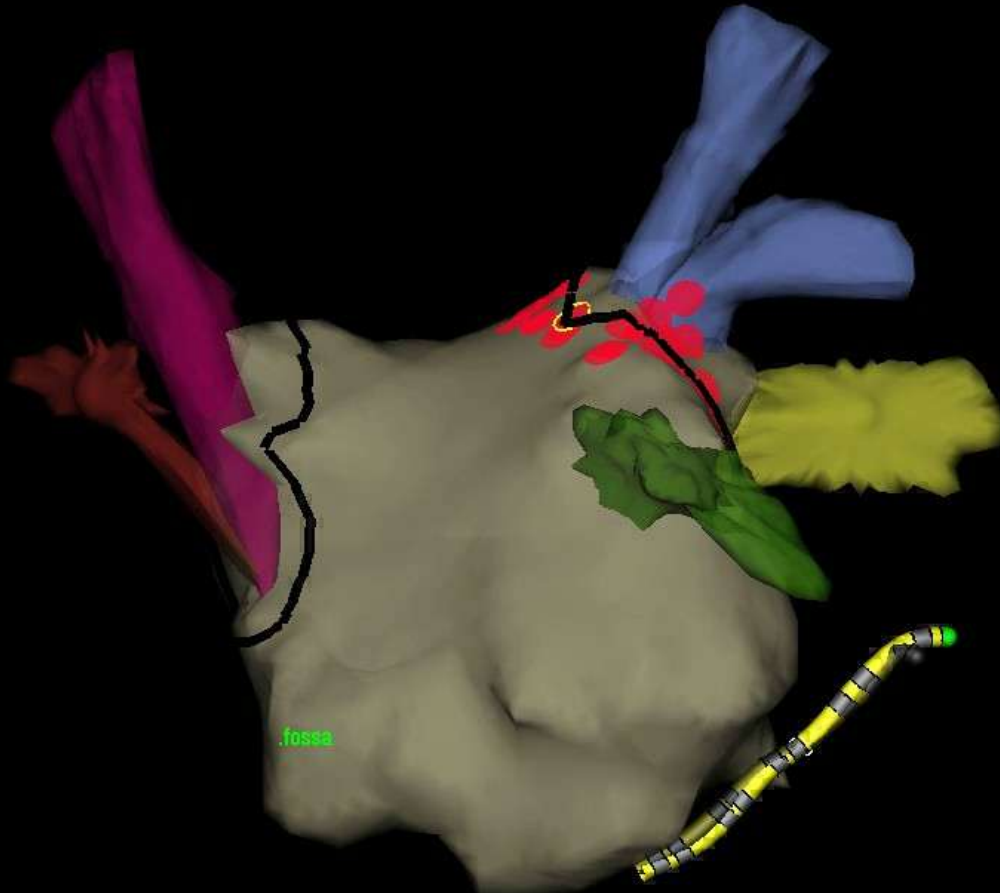
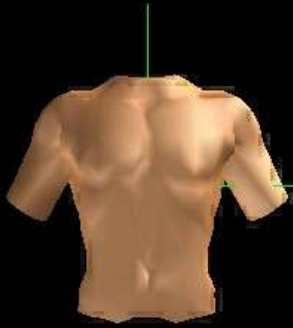
- Primary
  - Change in LVEF by cardiovascular magnetic resonance (CMR)
- Secondary
  - LVEF by RNVG
  - LVESV, LVEDV, LAEDA by CMR
  - NT pro-BNP
  - 6 minute walk distance
  - Quality of life (KCCQ, MLHFQ and SF-36).

# Optimal medical therapy protocol

- All patients had been on optimal heart failure therapy for  $\geq 3$  months.
  - ACE/ARB + Beta-blocker +/- spironolactone
- If mean heart rate was  $> 80$ bpm over a 24 hour period then digoxin was added to therapy.

# Radiofrequency ablation protocol

- Optimal medical therapy plus RFA as below:
- 3D reconstruction of the left atrium using Nav-X mapping system
- Irrigated tip ablation catheter



Electrode spacing: | Distal | D-2 | 2-3 | 3-4 |  
Nominal (mm) 2.0 2.0 5.0 2.0

# Radiofrequency ablation protocol

1. Wide area encirclement of the left and right pulmonary veins was performed guided by NavX, and pulmonary vein (PV) isolation was confirmed in all cases with a duodecapolar PV mapping catheter.
2. **If AF persisted** - roof line between left and right superior pulmonary veins
3. **If AF persisted** - further RF at sites of complex fractionated atrial electrograms on IAS, free wall, mitral annulus, base of LA appendage and LA roof
4. **If AF persisted** - internal cardioversion
  - After the initial ablation patients received 3 months of treatment with oral amiodarone
  - The second procedure consisted of repeat isolation of PVs which had reconnected, and further ablation at sites of CFAEs.

# Statistical Methods

- Primary and secondary outcomes assessed as change from baseline to final visit
- Means compared with an independent t-test
- Primary analysis performed intention to treat

# Results

**366 patients assessed for  
eligibility**

**366 patients assessed for eligibility**

**325 excluded**

- >80 years old - 92
- Paroxysmal AF - 45
- Broad QRS - 40
- CMR Contraindicated - 38
- LVEF > 35% - 32
- Severe valvular heart disease - 20
- NYHA I - 18
- Declined to consent - 18
- Anti-coagulation contraindicated - 12
- other reasons - 10

**366 patients assessed for eligibility**

**325 excluded**

**41 randomised**

**19 Medical therapy**

*1 withdrew from study*

**22 Ablation**

*1 withdrew after developing an indication for permanent pacemaker implantation prior to ablation*

*1 withdrew after suffering a stroke post procedure*

**Medical therapy  
(n=18)**

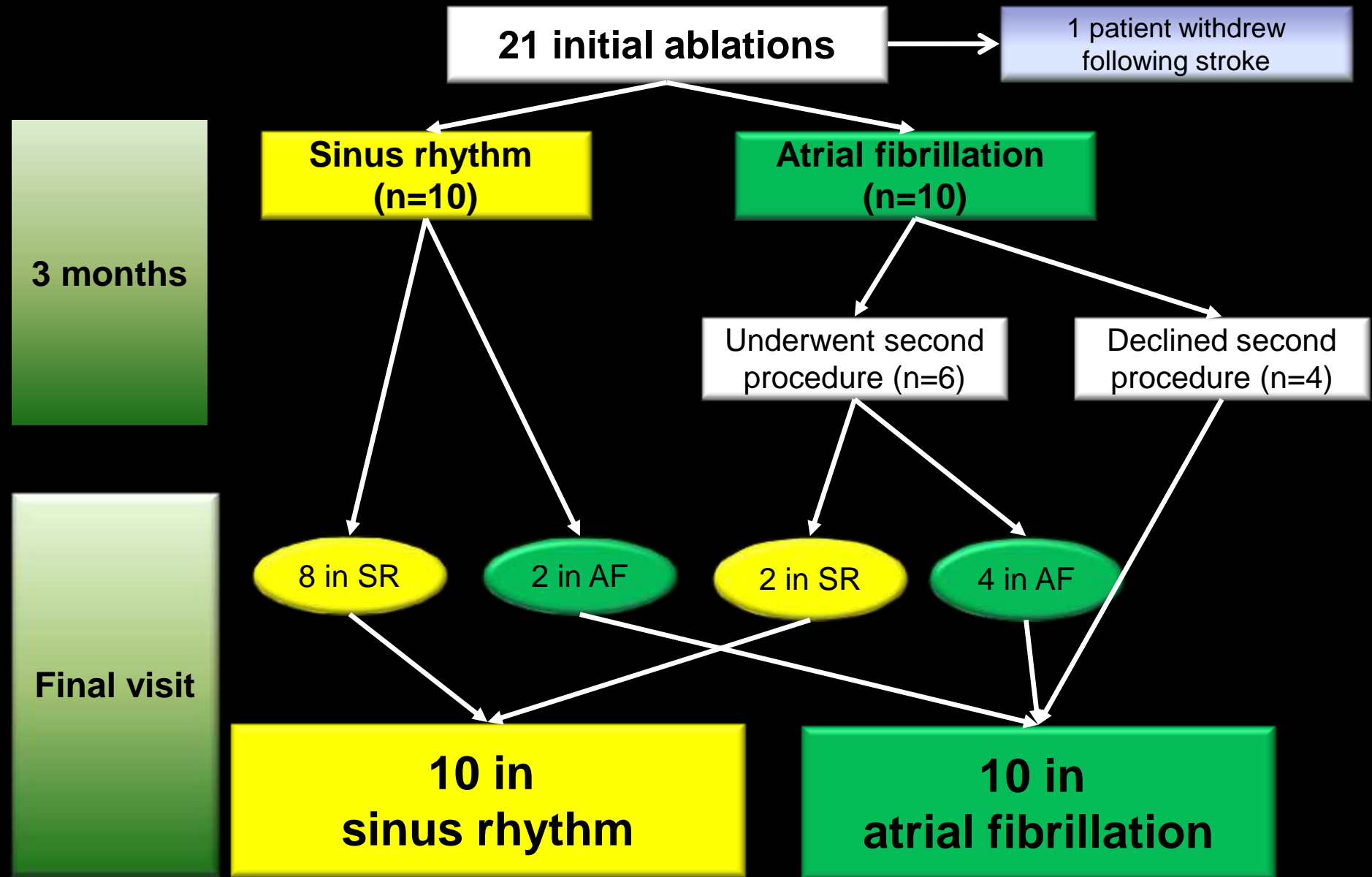
**Ablation  
(n=20)**

**Analysed**

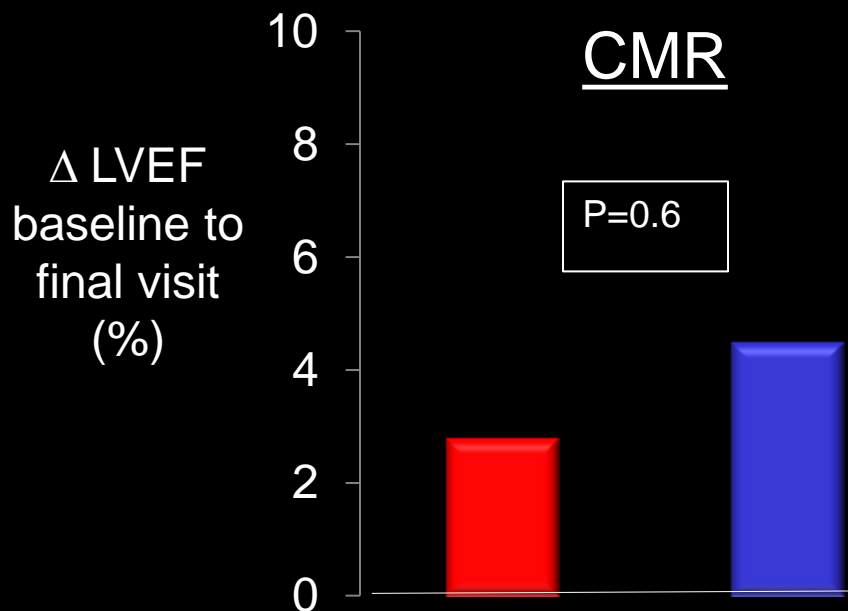
# Baseline characteristics

	Medical therapy (n=18)	Ablation (n=20)
Age (years)	64	62
Male	79%	77%
Heart rate (bpm)	72 (11)	75 (15)
LVEF by RNVG	20%	16%
Duration of persistent AF (months)	64	44
NYHA 3	90%	90%
<b><i>Medical history</i></b>		
Hypertension	58%	64%
CABG	37%	27%
CHD	53%	50%
<b><i>Baseline treatment</i></b>		
ACE or ARB	95%	95%
Beta-blocker	95%	82%
Digoxin	47%	55%

# Procedural success rate

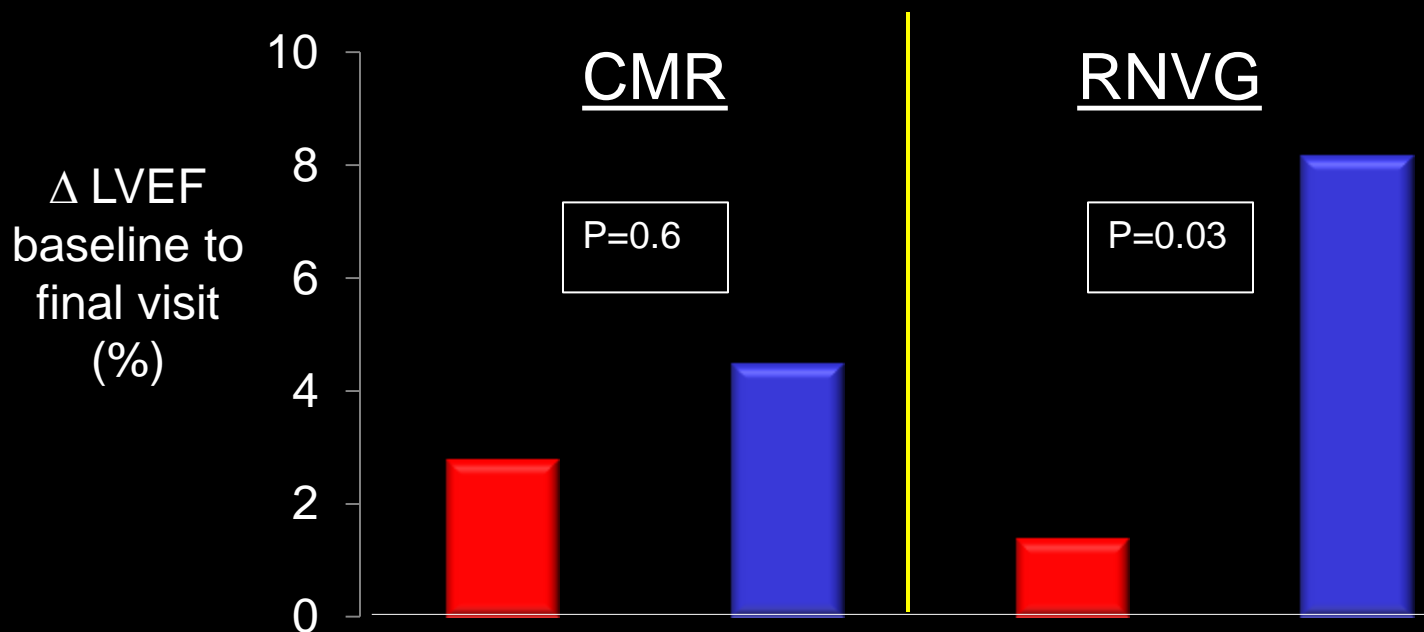


# Results: Change in LVEF



	Medical therapy (n=18)		Ablation (n=20)		
<u>Primary outcome</u>	Baseline	Change	Baseline	Change	P-value: medical therapy v ablation
LVEF by CMR	42.9	+2.8	36.1	+4.5	0.6

# Results: Change in LVEF

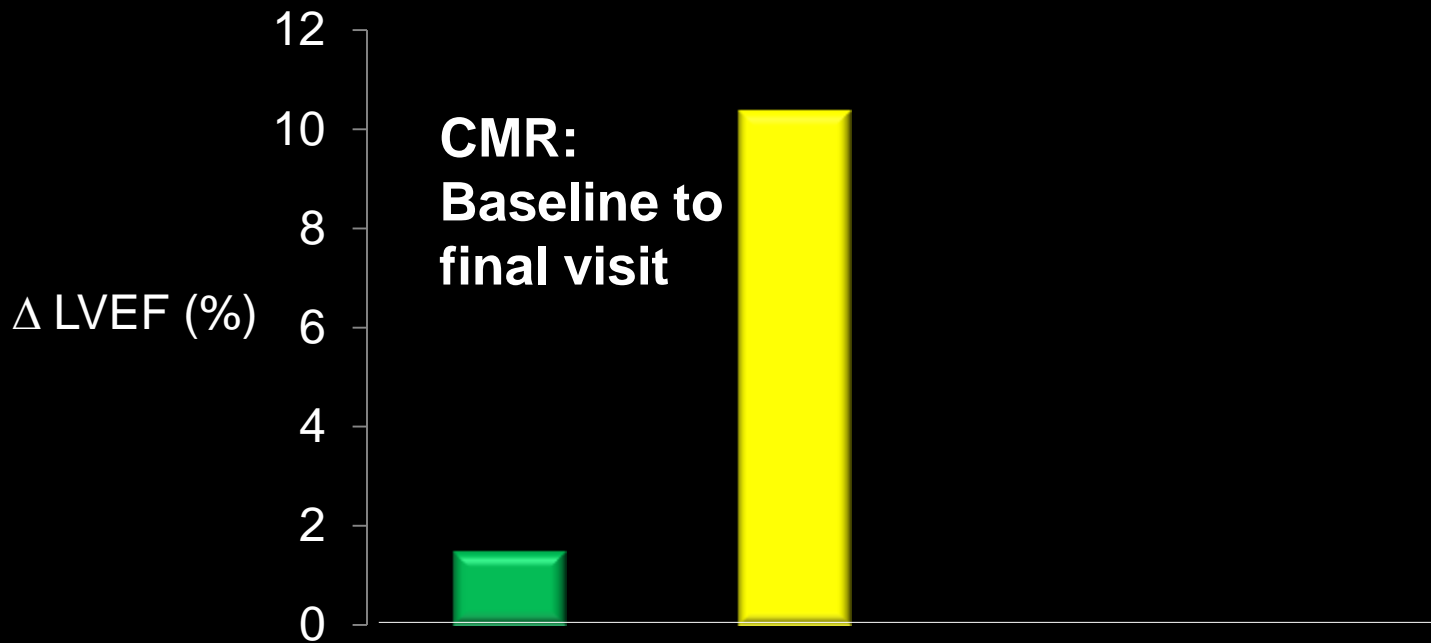


	Medical therapy (n=18)		Ablation (n=20)		
<u>Primary outcome</u>	Baseline	Change	Baseline	Change	P-value: medical therapy v ablation
LVEF by CMR	42.9	+2.8	36.1	+4.5	0.6
<u>Secondary outcome</u>					
RNVG LVEF (%)	20	+ 1.4	15	+ 8.2	0.03

# Results: Other secondary outcomes

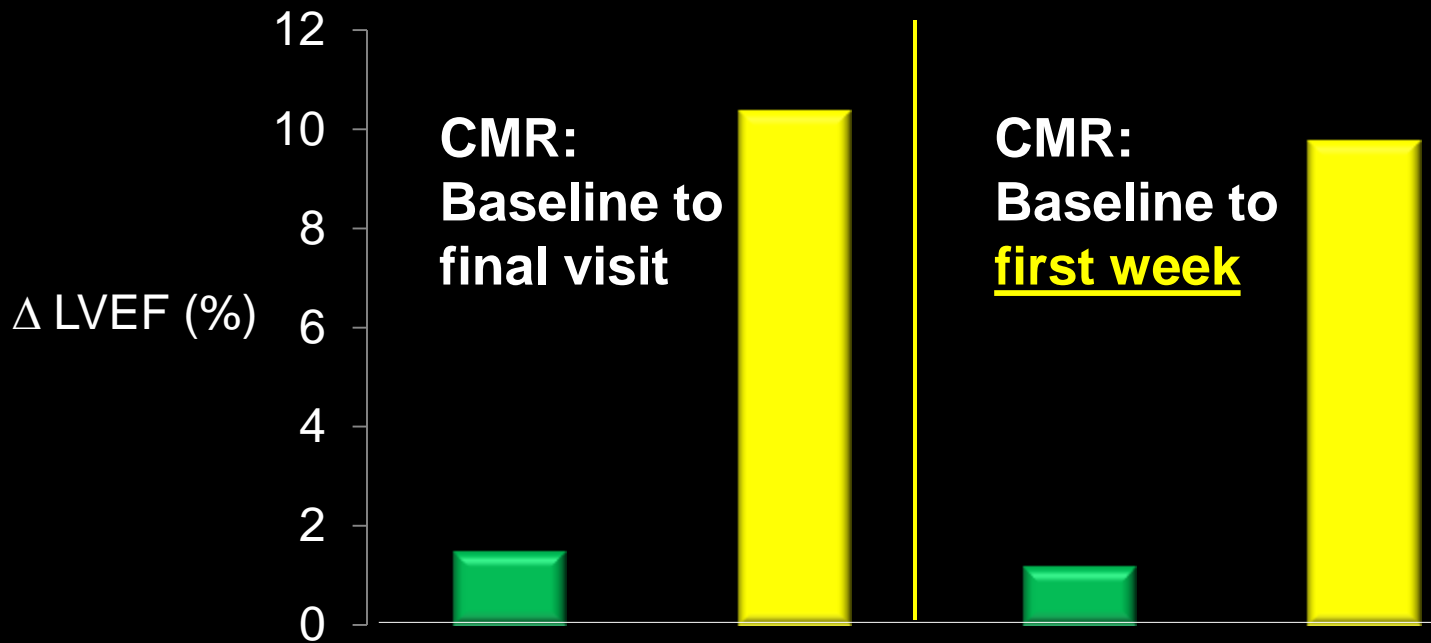
	Medical therapy (n=18)		Ablation (n=20)		P-value Medical therapy v ablation
	Baseline	Change	Baseline	Change	
LVESV (ml)	126	- 11	164	- 20	0.5
LVEDV (ml)	215	- 9	244	- 13	0.8
LAEDA (mm <sup>2</sup> )	3215	+35	3291	- 237	0.06
BNP (pg/ml)	1846	+85	2550	-196	0.5
6 minute walk (m)	352	+ 21	318	+20	1.0
SF-36 PCS	30	- 1	30	+ 4	0.04
SF-36 MCS	37	+ 6	41	+ 0.4	0.07
KCCQ	37	+ 6	42	+ 7	0.8
MLHFQ	59	- 3	56	- 6	0.7

# Post-hoc analysis: AF v SR



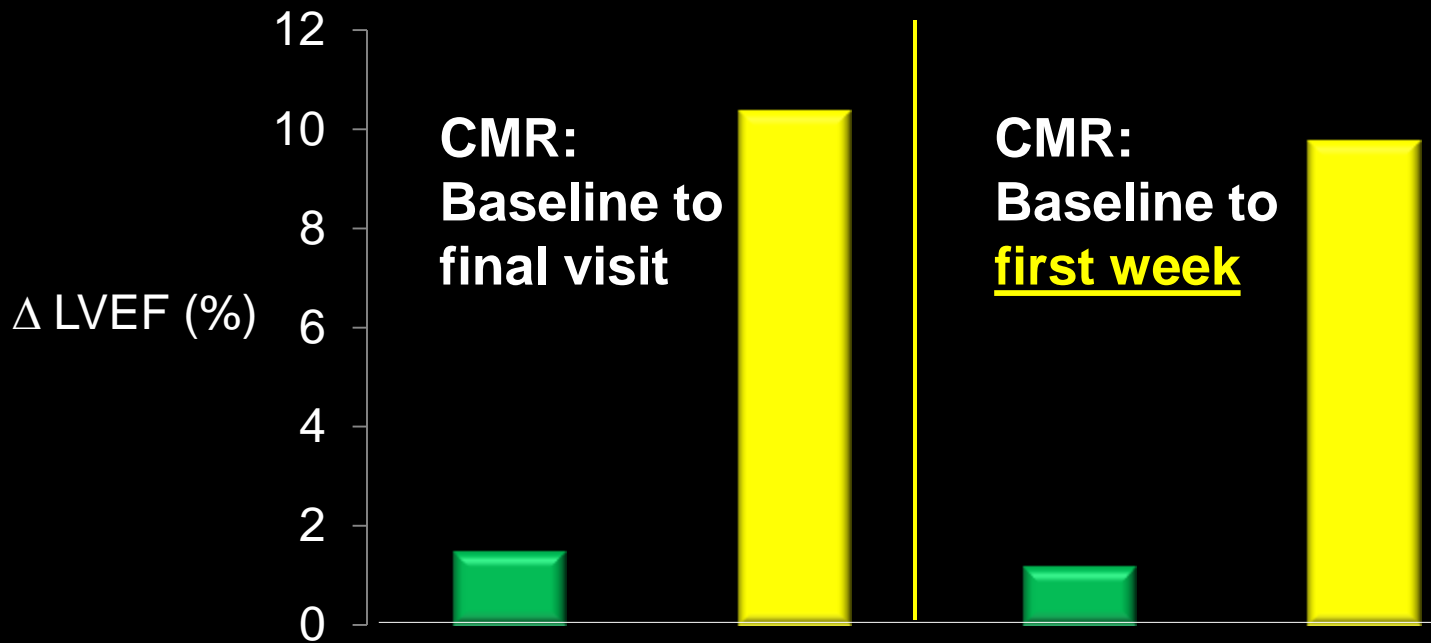
	Atrial fibrillation(n=28)		Sinus rhythm (n=10)		
<u>Primary outcome</u>	Baseline	Change	Baseline	Change	P-value
LVEF by CMR	39		38		
<i>Change by final visit (%)</i>		+1.5		+10.4	0.008

# Post-hoc analysis: AF v SR



	Atrial fibrillation(n=28)		Sinus rhythm (n=10)		
<u>Primary outcome</u>	Baseline	Change	Baseline	Change	P-value
LVEF by CMR	39		38		
<i>Change by final visit (%)</i>		+1.5		+10.4	0.008
<i>Change in first week (%)</i>		+1.2		+9.8	0.007

# Post-hoc analysis: AF v SR



	Atrial fibrillation(n=28)		Sinus rhythm (n=10)		
<u>Primary outcome</u>	Baseline	Change	Baseline	Change	P-value
LVEF by CMR	39		38		
<i>Change by final visit (%)</i>		+1.5		+10.4	0.008
<i>Change in first week (%)</i>		+1.2		+9.8	0.007
<u>Secondary outcome</u>					
RNVG LVEF (%)	17.5	+2.1	16.5	+13.2	0.045

# Complications

- 4 major complications – 14.8%
  - 1 Stroke (6 days after initial procedure)
  - 2 Cardiac tamponade
  - 1 Heart failure hospitalisation (within 1 week of procedure)

# Limitations

- Lower than predicted procedural success rate
  - sample size based on a predicted 80% procedural success rate
  - increased chance of type 2 error
- Groups imbalanced at baseline
- Single centre study, single operator

# Conclusions

- Low procedural success rate
- No difference in primary outcome: LVEF CMR
- Improvement in LVEF as measured by RNVG (secondary outcome)
- High complication rate
- Future studies needed in patients with
  - greater chance of procedural success
  - lower risk of complications

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