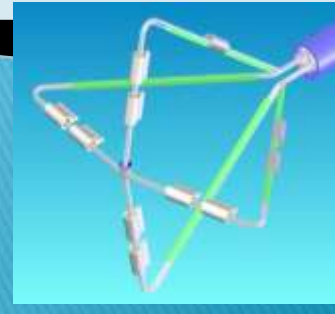


Phased RF ablation: what we know now and what we need to know in the future



Steve Murray
Regional
Cardiothoracic
Centre
Freeman Hospital
Newcastle Upon
Tyne



Disclosures

- Advisory board member for Medtronic, Boston Scientific & Sanofi Aventis
- Honoraria & travel sponsorship from St Jude, Medtronic, Boston Sci.
- Unrestricted educational grants from St Jude, Biosense Webster & Boston Scientific

Benefits of Phased RF ablation

- Excellent long term results; high success rate after a single procedure in PAF
- Speed
- Very low complication rates in experienced centres
- Very low rates of atypical flutter/atrial tachycardia

Phased RF Clinical Performance is Comparable to Irrigated RF

Recent publications have compared Phased RF and Irrigated RF technologies in patients with Paroxysmal or Persistent AF (Tivig et al; 420 pts) or in Paroxysmal AF patients only (Bulava et al; 102 pts).

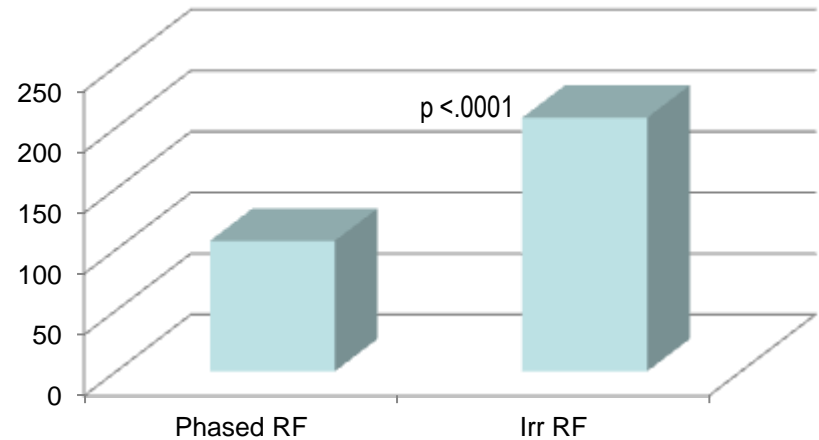
- Both studies concluded that Safety and Efficacy Performance was comparable between Phased RF and Irrigated RF.
- Efficacy endpoint of “freedom from AF” ranged between 71-87% at mean follow-up of 7-17.5 month
- In one study there were no serious complication (Bulava et al) and in other, the overall complication rate was 2.8% (Tivig et al)

- Procedure times were significantly shorter with Phased RF (107 vs 208 mins $p < .0001$; Bulava et al)

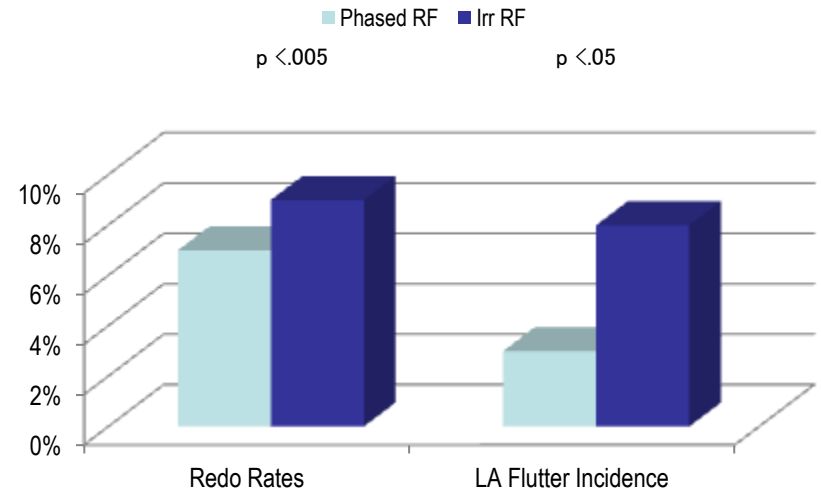
- Redo procedure rate for PV isolation was significantly lower with Phased RF (7% vs 19% $p < .005$; Tivig et al)

- Incidence of left atrial flutter and therefore repeat ablation was lower with Phased RF (3% vs 8% $p < .05$; Tivig et al)

Procedure Time Difference in PAF Patients



Redo Rate and LA Flutter Incidence in PAF Patients (Tivig et al.)



Personal results

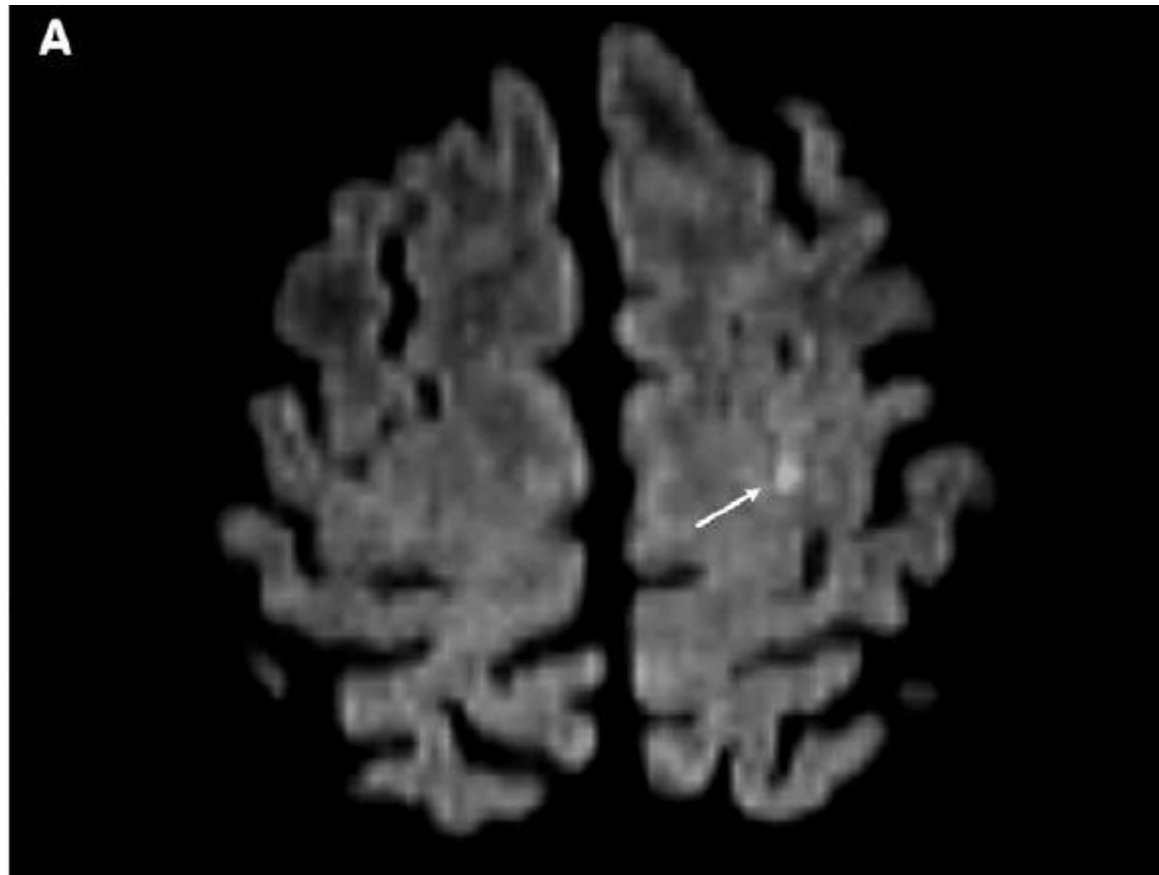
- Audit period Dec 2008 – July 2010
- PAF (n=58)
 - Mean follow up 15.1 months (minimum 6/12)
 - 1st procedure success 79.3%
 - Redos: 12 for PAF, 5 for flutter
 - Overall success 89.6%, off all drugs 82.7%
 - Complications – 1 late reactive effusion (post-cardiotomy syndrome) + 1 TIA (pre warfarin peri case)

Persistent AF

- N=45
- Mean F/U 20.2 months
- 1st procedure success rate 46%
- Final success after 2 phased RF procedures = 64%
- Redo cases in 21/45:
 - 13 for AF, 8 for flutter

- These figures were reflected almost identically in the phased RF European retrospective registry by Christoph Scharf and colleagues
- So how come we're not all using it...?

Asymptomatic silent cerebral emboli



- Diffusion Weighted – MRI
 - Detects the lesion created by an embolus. Is very sensitive to acute ischemic injury as early as 30 minutes and up to 2-4 weeks. It is much more sensitive during this period than a T1 or T2 image.
 - Ischemia causes a disruption in the potassium/sodium exchange pump in the cell membrane and induces edema. Water diffusion across cells is compromised following acute ischemic injury. DW-MRI measures the rate of water diffusion across a region of the brain cells.

Recently published DW MRI studies show a higher acute microembolism rate for Phased RF

- Non-randomized, comparative study designs
- Neurological exams post-procedure were negative in all patients.
- No patients had symptomatic cerebrovascular events

Author / Publication	Irrigated RF	Phased RF	Cryoballoon
Gaita et al. JCE Mar 31, 2011	8.3% (3/36)	38.9% (14/36)	5.6% (2/36)
Herrera et al German JACC June 8, 2011	7.4% (2/27)	37.5% (9/24)	4.3% (1/23)

Summary of June 8, 2011 Journal of American College of Cardiology

- Study purpose: To compare the safety of different devices by screening for new subclinical embolic lesions using MRI pre and post PVI using Irrigated RF, Cryoballoon or Phased RF.
- 74 patients: 27 Irrigated RF, 23 Cryoballoon, and 24 PVAC. Rate of new embolic lesions: Irrigated RF 7.4%, Cryoballoon 4.3%, and PVAC 37.5%
- PVAC usage was the only significant predictor of new acute ischemic events with an odds ratio 9.4 [2.2, 39.3] $p = 0.002$
- Neurological exams in all patients were normal pre and post procedure. Long-term follow-up MRI was not performed.
- Conclusion
 - PVI performed with the PVAC presents a notably higher incidence of subclinical intracranial embolic events than if performed with an externally irrigated RF catheter or a cryoballoon.
 - Improvement in PVAC technology and further studies to clarify the origin of these embolic lesions are mandatory to reduce the rate of silent embolisms during ablation procedures in the LA.

Summary of July 4, 2011 Heart Rhythm Journal Article

Study Purpose: Single center, cross-sectional study to investigate the clinical course and long-term characteristics of acute silent cerebral lesions found on DW-MRI post AF ablation.

Study Results:

- **Acute Results:** 33 of 86 patients (38%) had 119 new lesions (3.6 lesions/patient).
- 30/72 (42%) of Phased RF and 3/14 (21%) of irrigated RF patients had new lesions
- **Chronic results:** 14 patients (11 PVAC and 3 IRF) had long-term follow-up MRI (2 weeks – 1 year post ablation). Remaining 19 patients did not consent or were not eligible for chronic follow-up.
- Lesions were detected in 3/14 patients (2/11 with PVAC and 1/3 with IRF); one lesion in each patient
- In the 14 patients, 94% of the lesions were <10 mm and the remaining 6% >10 mm during the acute MRI. In chronic MRI, all 94% of lesions <10 mm regressed. Only the 6% (3 patients) with acute lesions >10 mm showed chronic lesions.
- Neurological exams showed no clinical abnormalities at acute or chronic follow-up.

Study Conclusions:

- Lesions detected acutely on MRI after AF ablation are mostly small in size and usually regress
- Acute lesions with diameter > 10 mm produce chronic scars
- Long-term follow-up using specific neuropsychological testing is required to evaluate the clinical consequence of the chronic lesions

Microembolism Has Been Observed in Other Cardiac Procedures

- Acute MRI lesions without neurological symptoms have been observed in some of the studies with invasive cardiac procedures

Procedure	Studies (n) (Total # pts)	Average % of procedures with new lesions & without neuro symptoms (Range in various studies)
Cardiac Valve Replacement	1 (30)	47%
CABG	3 (80)	34% (26 - 45%)
Coronary Angiography	1 (48)	15%
Carotid Artery Stenting	2 (53)	30% (22 - 50%)
Carotid Thromboendarectomy	2 (73)	4%

Association between Cerebral Emboli and Cognitive Decline in the Kruis Study

- Kruis et al performed an independent review of 22 CABG studies from the past 3 decades
- 15 used TCD (n=1,829 pts) and 7 used DW-MRI (n=379 pts)
- 66% of all studies reviewed showed no association between cerebral emboli and risk of cognitive decline
- 34% of all studies reviewed did find an association
- The authors concluded that based on the review of published studies they could not confirm a causal link between microemboli and Post Operative Cognitive Decline (POCD)
- POCD is a multifactorial problem in which procedural microemboli may be a contributing factor

Stroke & ASCE are not the same

- These are not part of a spectrum
- Animal data and some human data suggest vulnerable moments during PVAC procedure are:
 - Trans-septal puncture
 - Micro-bubble formation during phased RF

How can ASCE be minimised?

- Several strategies
 - Patient preparation
 - Trans-septal puncture
 - Delivery of catheter
 - Delivery of RF ablation
- PVAC has several problems which can be overcome with revised handling, whilst design tweaks are introduced at the manufacturing level

Patient preparation

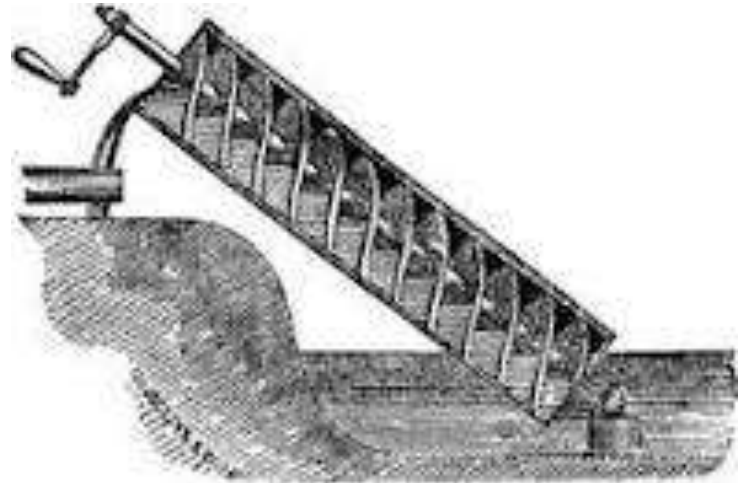
- Continue warfarin with therapeutic INR
 - Range in Newcastle 2.0 – 3.5
- IV heparin given at trans-septal access, aiming for ACT > 300s

Trans-septal approach

- Needle loaded with stylet in situ
- Attached to continuous flush thereafter prior to entry in RA
- Scrupulous sheath management

PVAC loading

- ‘Bleed back’ on sheath, rather like device closures ASD/LAA
- Minimal use of the loading device
 - C.f. Archimede’s screw



RF delivery

- Importance of high temperature/low wattage
 - New knowledge, in contradiction to early advice
- Avoid moving 'live' catheter
- Pay attention to relationship of electrode 1 and 10

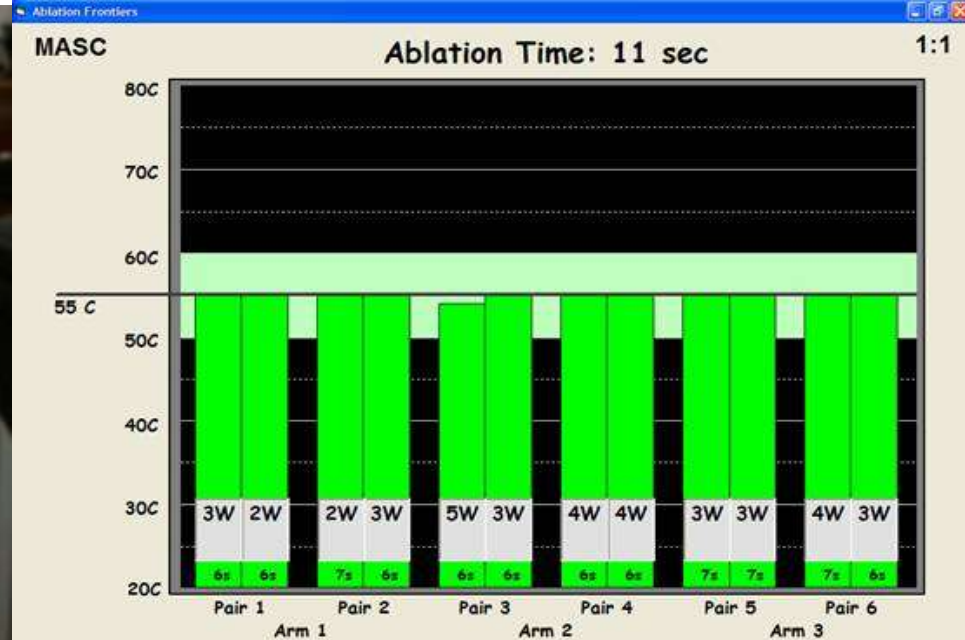


GENius™

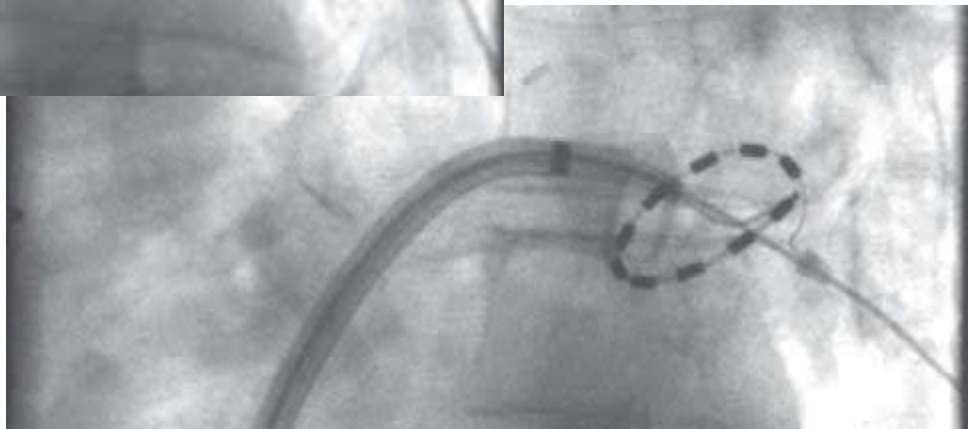
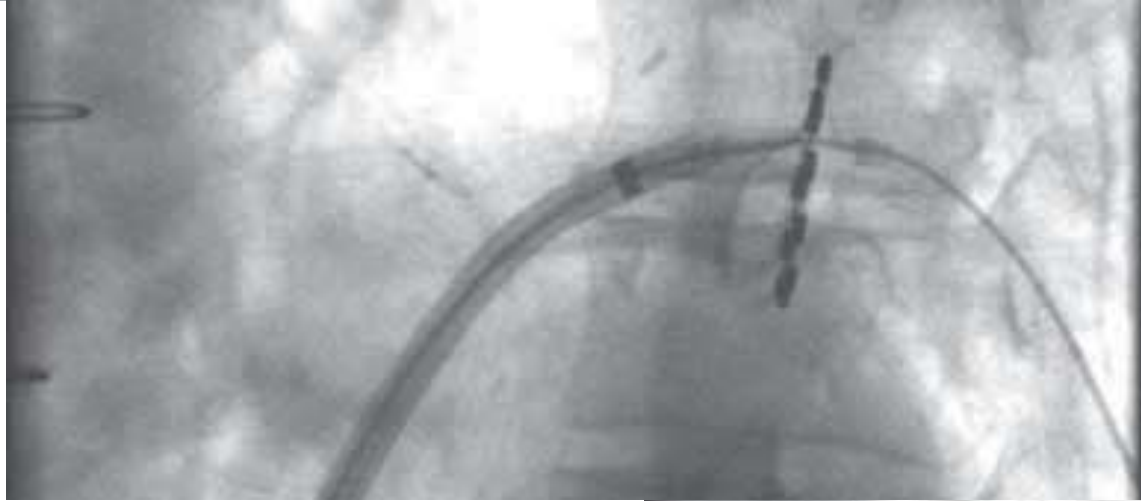
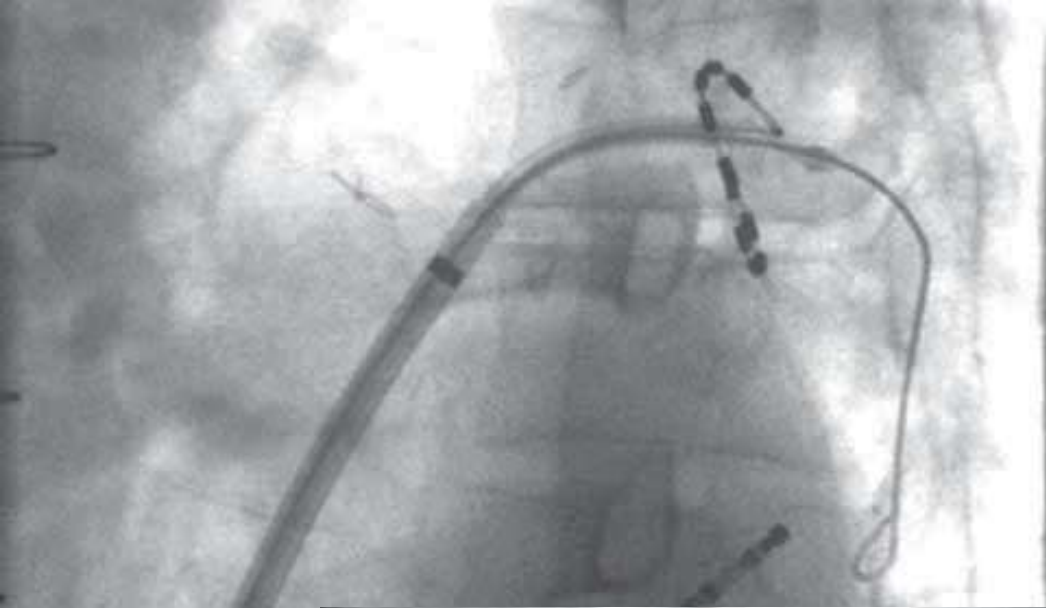
GENERATOR FOR ABLATION CATHETERS



RF Generator is CE Mark Approval



- User-friendly interface (remote control access capable)
- Individual channel / electrode temperature and power control/delivery
 - Power mode identification
 - Catheter
 - Ablation time



What effect do these changes in practice bring?

- Early human data from Europe suggests ASCE rates at around 10%
- Comparable to irrigated-tip PVI