CRYOABLATION FOR PERSISTENT AND LONG-STANDING PERSISTENT ATRIAL FIBRILLATION: RESULTS FROM A MULTICENTRE EUROPEAN REGISTRY

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Background

Star AF II

% Freedom from Atrial Fibrillation

P = 0.15 for the overall comparison, by the log-rank test

- Pulmonary-vein isolation
- Isolation plus electrograms
- Isolation plus lines

Months since First Ablation

Background

- Guidelines recommend PVI for PeAF
- Unclear how or why PVI is effective
- Is Cryo PVI the same?
- Are there sub-groups poorly served by this strategy?
Hypothesis

Cryoballoon PVI for PeAF and longstanding PeAF is safe & effective at long term follow-up
Objectives

Aimed to assess

• Procedural metrics
• Safety
• Efficacy over long term follow up
• MVA to assess factors predicting failure
Methods

- Consecutive patients undergoing cryo over 7 years (2011-2017)
- 3 UK & 8 European centres with independent prospective registries
- Medical records review & phone follow-up where possible
- PeAF defined as per guidelines
  - PeAF – AF duration > 7 days but < 1 year
  - LS PeAF – AF duration > 1 year
- Patients followed up at 3, 6 and 12 months with ECG and open access to arrhythmia nurses thereafter
Procedural Practices

- No agreed protocol but some practices common to all centres
- Uninterrupted anticoagulation
- 2nd Generation cryoballoon (23 and/or 28mm) with Achieve wire
- Number and duration of freezes at centre/operator discretion
- Endpoint PVI (entrance block) determined using Achieve
End Points

Primary Efficacy End Point
• Freedom from AF/AT lasting > 30s off AAD subsequent to the 3 month blanking period

Primary Safety End Point
• Composite of procedural major complications

Secondary End Points
• Procedure/fluoroscopy times, rate of repeat ablation, pulmonary vein re-connection rates, centre variation in outcomes, multivariate analyses of factors predicting recurrent arrhythmia
Results: Study Cohort

326
Barts Heart Centre, UK
London Bridge hospital, UK
Liverpool Heart and Chest Hospital, UK
Vrije Universiteit Brussel, Brussels, Belgium
Toulouse, France
Grenoble, France
Frankfurt am Main, Germany
Rennes, France
Rouen, France
Nantes, France
Paris, France

283

## Baseline Demographics

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<tbody>
<tr>
<td><strong>N = 609</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Age, years, (mean ± SD)</strong></td>
<td>63 ± 11</td>
</tr>
<tr>
<td><strong>Sex, M, n (%)</strong></td>
<td>438 (72)</td>
</tr>
<tr>
<td><strong>AF, n (%)</strong></td>
<td></td>
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<tr>
<td>Persistent (&lt; 1yr)</td>
<td>487 (80)</td>
</tr>
<tr>
<td>Longstanding Persistent (&gt;1 yr)</td>
<td>122 (20)</td>
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<tr>
<td><strong>First AF episode to ablation, mths, (mean ± SD)</strong></td>
<td>17 ± 20</td>
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<tr>
<td><strong>Background heart disease</strong></td>
<td></td>
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<tr>
<td>Normal heart, n (%)</td>
<td>250 (41)</td>
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<tr>
<td>Ischemic heart disease, n (%)</td>
<td>134 (22)</td>
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<tr>
<td>Dilated cardiomyopathy, n (%)</td>
<td>128 (21)</td>
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<tr>
<td>Other, n (%)</td>
<td>97 (16)</td>
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<tr>
<td><strong>Previous CVA/TIA, n (%)</strong></td>
<td>49 (8)</td>
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<tr>
<td><strong>CHA₂DS₂VASC Score, (mean ± SD)</strong></td>
<td>2 ± 1.5</td>
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<tr>
<td><strong>Anticoagulation, DOAC, n (%)</strong></td>
<td>457 (75)</td>
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<td><strong>Anti-arrhythmics, n (%)</strong></td>
<td></td>
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<tr>
<td>None</td>
<td>104 (17)</td>
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<tr>
<td>Beta-blocker</td>
<td>158 (26)</td>
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<tr>
<td>Amiodarone</td>
<td>225 (37)</td>
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<tr>
<td>Other</td>
<td>122 (20)</td>
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<tr>
<td><strong>LA Diameter, cm, (mean ± SD)</strong></td>
<td>4.2 ± 1.2</td>
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# Procedural Characteristics

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<tr>
<td><strong>N = 609</strong></td>
<td></td>
</tr>
<tr>
<td><strong>General Anaesthetic, n (%)</strong></td>
<td>152 (25)</td>
</tr>
<tr>
<td><strong>Daycase, n (%)</strong></td>
<td>268 (44)</td>
</tr>
<tr>
<td><strong>Procedure Time, min, (mean ± SD)</strong></td>
<td>95 ± 65</td>
</tr>
<tr>
<td><strong>Fluoroscopy Time, min, (mean ± SD)</strong></td>
<td>13 ± 10</td>
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<tr>
<td><strong>Cryo Energy Application Time, min, (mean ± SD)</strong></td>
<td>18 ± 11</td>
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Procedural Success

• Acute success defined as PVI using cryoballoon alone

• Achieved in 585/609 patients (96%)
Follow-up

- Available on 602/609 patients (98.8%)

- Median follow-up 2.4 yrs (IQR 1.0 – 4.0 yrs)

- All patients got an ECG on follow-up

- Ambulatory monitoring was guided by symptoms
Primary Efficacy End Points

Freedom from Arrhythmia (%)

62% at 24 mths

55.6% at final follow-up

Time (months)
Primary Efficacy End Points

**Freedom from Arrhythmia (%)**

- PeAF: 63.9% at 24 mths, P = 0.02
- LS PeAF: 58.1% at 24 mths

**Time (months)**
Efficacy End Points: Centre Variation

Centre variation 59 – 66%
P = 0.42
Duration of PeAF and Left atrial diameter had a significant association with arrhythmia-free survival.
Arrhythmia Outcome on Follow-up

• Recurrence of AF/AT was seen in 229/602 patients (38%)

Presenting Rhythm

- PAF: 2%
- PeAF: 14%
- AT: 19%
- Afl(typical): 65%
• Repeat ablation in 134 patients (~60% of those with recurrence)

• The rate of repeat procedures in PeAF versus Longstanding PeAF (20% versus 32%, p = 0.006)

• Repeat ablation findings available in 79/134 procedures:

  - PVs re-connected: 71%
  - PVs isolated: 29%
Pulmonary Vein Re-connection

% of PVs re-connected

- Right PV(s): 27
- Left PV(s): 23
- Both: 50

Number of PVs Re-connected

- Zero: 29
- One: 21
- Two: 28
- Three: 12
- Four: 10

Pulmonary Veins Re-connected
Safety End Points

Complication rate 4.1%

Cardiac Tamponade: 0.6%
Phrenic Nerve Palsy: 3%
Transient Ischaemic Attack: 0.2%
Vascular: 0.3%
Phrenic Nerve Palsy

Temporal Trend

% of PNPs

Y2013 13
Y2014 10
Y2015 5
Y2016 3
Y2017 1

Temporal Trend
Safety End Points

- No significant centre variation
- Tamponade (n=4): all made uneventful recovery. None required cardiac surgery
- PNP (N=19): all fully recovered over a mean follow-up of 8 months
- TIA (N=1): no further recurrence or CVA
- Haematoma (n=1): required blood transfusion but no vascular surgical intervention
Conclusions(1)

- Cryoablation for persistent AF is quick, safe & successful for PVI

- Outcomes at long-term follow-up comparable to PVI with RF

- Little variability between centres in outcome – highly reproducible

- Cryo reasonable for PVI in PeAF and LS-PeAF
Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation

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Conclusions(2)

- Patients with PeAF have less recurrence and have a lower rate of repeat ablation than LS-PeAF
- Predictors of arrhythmia recurrence: duration of AF and LA diameter
- Patients with LS-PeAF and severely dilated LA have poor outcome → may be better served by another strategy → further research needed on strategies for this group
- Short procedure time may help increase capacity for AF ablation
- If time spent waiting in AF can be reduced may improve outcomes
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## Results: Baseline Demographics

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<td>Dilated cardiomyopathy, n (%)</td>
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<tr>
<td>Hypertrophic cardiomyopathy, n (%)</td>
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<tr>
<td>Valvular, n (%)</td>
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<tr>
<td>Others, n (%)</td>
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<td><strong>Hypertension, n (%)</strong></td>
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<td><strong>Diabetes mellitus, n (%)</strong></td>
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<td><strong>Previous CVA/TIA, n (%)</strong></td>
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<td><strong>EHRA Classification, n(%)</strong></td>
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<tr>
<td>Class I</td>
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<td>Class II</td>
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<td>Class III</td>
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<td>Class IV</td>
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<tr>
<td><strong>NYHA Grade</strong></td>
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<tr>
<td>Class 1</td>
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<td>Class ≥2</td>
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<td>Flecainide</td>
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Study Population
N = 609
11 centres

Persistent AF
N = 487

Longstanding Persistent AF
N = 122

Second Generation Cryoballoon

Acute Ablation Success
96%

Predictors of Success
Duration of AF
LA Diameter

Mean Follow-up 2.4 yrs
F/UP on 602/609
(99%)

Sinus Rhythm
62%

Recurrence
38%

Paroxysmal AF
N = 43
(19%)

Persistent AF
N = 149
(65%)

Atrial Tachycardia
N = 37
(16%)

Repeat Ablation using RF, N = 134
PeAF vs Longstanding PeAF
20% vs 32%, p = 0.006

Ablation Data on 79/134
(59%)

PV(s) Re-connected
(71%)

PV(s) Isolated at start
(29%)

Lateral PVs
23%

Septal PVs
27%

Lateral and Septal PVs
50%