Cryoballoon versus RF Ablation in Paroxysmal Atrial Fibrillation: Results from the German Ablation Registry

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German Ablation Registry-Different Energy Sources in AF Ablation. Background: Catheter ablation is used extensively with curative intention in atrial fibrillation. Radiofrequency ablation has long been a standard of care, while cryoballoon technology has emerged as a feasible approach with promising results. Prospective multicenter registry data referring to both ablation technologies in AF ablation therapy are lacking.

Methods: Between January 2007 and August 2011, a total of 3,775 consecutive patients with symptomatic paroxysmal AF who underwent PV ablation in their respective centers were enrolled. The cohort was divided into 2 groups according to the ablation energy source used: cryoballoon ablation (group 1, n = 905 [24.0%], median age 63 years, 64.3% men) and RF ablation (group 2, n = 2870 [76.0%], median age 63 years, 62.7% men). Comorbidities and baseline clinical characteristics were similar in both groups.

Results: Acute success rate was similar in both groups (97.5% in cryo vs 97.6% in RF; P = 0.81). Procedure times were similar, ablation and fluoroscopy times were higher in cryoballoon when compared to RF ablation. Overall complication rate was similar in cryo- (4.6%) and RF-ablation (4.6%; P = 1.0). Phrenic nerve palsy was more often in cryo versus RF ablation (2.1% in cryo vs 0.0% in RF; P < 0.001). Other complications were more common in RF compared to cryoablation (4.6% in RF vs 2.7% in cryo; P < 0.05).

Conclusion: RF ablation is the most widespread ablation method in Germany, but use of cryoballoon increased significantly. Procedure times were similar, but ablation and fluoroscopy times were longer in cryoballoon ablation. No significant differences were found in terms of acute success and overall complication rate. (J Cardiovasc Electrophysiol, Vol. 25, pp. 1-7, January 2014)

atrial fibrillation, catheter ablation, cryoablation, cryoballoon, registry

Introduction

Atrial fibrillation is the most common arrhythmia and is a major cause of stroke, adversely affecting quality of life and is associated with increased mortality. Catheter ablation is becoming more extensively used with curative intention. There is a general trend favoring pulmonary vein isolation (PVI) alone for treatment of paroxysmal AF (px AF). Radiofrequency (RF) technology has been the standard of care since the pioneering work from Haïssaguerre et al. RF ablation strategies then evolved and new ablation technologies such as cryoballoon ablation are increasingly performed in AF ablation. Published outcome data show variable results dependent on the ablation method used, patient selection and follow-up. RF ablation has shown high success rates in the treatment of patients with paroxysmal and persistent AF. The RF ablation procedure itself remains technically challenging with a significant number of complications, including tamponades, atrial-esophageal fistula, thromboembolic strokes and left atrial flutter.

Cryothermal energy source has been introduced in the field of PV ablation. The cryoballoon technology (Arctic
Front, Medtronic, Minneapolis, MN, USA) has emerged a feasible approach with promising results with respect to efficacy and safety in short and long-term follow-up.\textsuperscript{11-13} Two different sizes of the cryoballoon are currently available: a smaller 23 mm balloon and a larger 28 mm balloon referring to the ostial diameter of the PVs. Current experience with the cryoballoon therapy is primarily based on feasibility and nonrandomized clinical studies.\textsuperscript{11-15}

Prospective multicenter registry data referring to both ablation technologies in AF ablation therapy are lacking. Therefore, the goal of the registry was to prospectively enroll consecutive patients undergoing PV ablation for px AF with different energy sources to assess efficacy and complication rates.

Methods

Study Design and Recruiting Centers

The German ablation registry is a multicenter prospective registry including a total of 55 German electrophysiological centers. The aim was to monitor the current use and outcome of PV ablation methods including RF and cryoballoon ablation in patients with px AF in daily clinical practice. The registry is completely independent from industry, driven by the scientific interest of the participating hospitals and financed by the Institute für Herzinfarktforschung (IHF) Ludwigshafen, Germany.

Patients

Between January 2007 and August 2011, a total of 3,775 consecutive patients with symptomatic px AF who underwent PV ablation in their respective centers were enrolled. All patients gave written informed consent prior to the ablation procedure and also gave written consent for inclusion in the registry and processing of their anonymous data.

Paroxysmal AF was defined as AF lasting < 7 days with spontaneous termination.\textsuperscript{16} All patients underwent their first AF ablation procedure. Most of the patients were refractory to at least 1 antiarrhythmic drug.

The cohort was divided into 2 groups according to the ablation energy source used: cryoballoon ablation (group 1, \( n = 905 \) [24.0\%], median age 63 years, 64.3\% men) and RF ablation (group 2, \( n = 2,870 \) [76.0\%], median age 63 years, 62.7\% men).

PV Ablation Procedure

The cornerstone of all ablation strategies was the disconnection of the PVs from the left atrium. The electrical endpoint of ablation was PVI. At least PV entrance block had to be documented for each PV by use of a circular mapping catheter.

PV ablation procedures were performed according to the operator’s and the performing institution’s preference. All patients underwent transthoracic echocardiography to assess LA diameter, left ventricular ejection fraction (LVEF) and transseophageal echocardiography to rule out LA thrombus formation prior to ablation. Within 24 hours postablation, transthoracic echocardiography was performed routinely to rule out pericardial effusion, in the case of symptoms as hypotension, tachycardia, chest pain, or shortness of breathing, a repeat echocardiography was performed.

In some centers preprocedural imaging of the left atrium and PVs using cardiac MRI, CT scan, or PV angiography was performed according to the treating physician’s and the institution’s preference.

Anticoagulation: During the procedure, the activated clotting time was kept between 250 and 400 seconds by intravenous heparin administration. All patients had to be anticoagulated using phenprocoumon aiming an INR of 2.0–3.0 at least 3 months after the procedure.

Cryoballoon Ablation Procedure

After venous access, a single or double transseptal puncture was performed. PV potentials were recorded at least before and after PV isolation with a circular mapping catheter or periprocedural by use of a 6- or 8-pole microcircular mapping catheter that was introduced into the central lumen of the cryoballoon catheter. The choice of the cryoballoon size and the treatment of a left common ostium was left to the center’s experience, e.g., the decision of the operating physician. A single big balloon strategy using the 28 mm cryoballoon only or an individualized approach using the 28- or the 23-mm cryoballoon according to the diameter of the PVs based on preprocedural imaging was performed. The upper limit of cryoenergy applications was left to the discretion of the physician. Additional touch-up freezes with a conventional cryocatheter (Freezor MAX, CryoCath, Medtronic) or an RF catheter could be performed if deemed necessary. In all patients, the aim was to completely isolate the PVs. Continuous monitoring of the phrenic nerve during ablation of the right superior and inferior PV either by fluoroscopy or by pacing maneuvers were performed in all patients to reduce the risk of phrenic nerve palsy.

RF Ablation Procedure

RF ablation strategies were used according to the decision of the treating physician and institution preference. Ablation strategies beyond pure PVI, including ablation of complex fractionated potentials or deployment of additional linear lesions in the left as well as the right atrium, could be performed if required.

RF ablation was guided by fluoroscopy and in some centers by use of an electroanatomic mapping system (CARTO, Biosense Webster, Diamond Bar, CA, USA or NavX, St. Jude Medical, St. Paul, MN, USA) with or without integration of preprocedural imaging. In other centers, intracardiac echocardiography (ICE)-guided mapping was performed using a 10-Fr 64 element phased-array ultrasound imaging catheter (AcuNav, Siemens Medical Solution, Malvern, PA, USA). The catheter was introduced through an 11-Fr sheath via the left femoral vein and positioned, fluoroscopically guided, into the right atrium. A diagnostic multipolar catheter was placed in the coronary sinus and an RF single tip ablation catheter was used for ablation. After single or double transseptal puncture the ablation catheter and the circular mapping catheter were introduced to the left atrium. For the rest of the procedure, the introducer was irrigated with a heparinized saline solution.

The temperature and power settings were left to the discretion of the treating physician. RF ablation was interrupted if the impedance increased, or in the case of a sudden increase in micro-bubble density observed during ablation.
According to the center’s preference, a periprocedural visualization of the esophagus or online monitoring of the esophageal temperature was performed to reduce RF energy application at the posterior wall in areas adjacent to the esophagus to prevent esophageal damage.

Procedures were performed under deep sedation utilizing fractionated intravenous bolus of midazolam and fentanyl or continuous infusion of propofol with preservation of spontaneous breathing and continuous monitoring of oxygen saturation.

Registry Management

The IHF Ludwigshafen was responsible for project development and management, data management, and was the central contract research organization for the registry. All statistical analysis was planned and performed by the IHF.

The registry used a web-based electronic case report form (eCRF) for data collection that was based on the software solution EBogen©, developed by the IHF (Appendix S1). Each study coordinator at each participating center received an individual login information for the eCRF. The data base was kept on the server of the IHF. Data were entered by each participating center directly into the internet based electronic CRF via an SSL-secured Internet line. The electronic data collection forms contain a built-in consistency check tool that carries out plausibility checks automatically, and further data checks were done in SAS before the statistical analysis.

Statistical Analysis

Continuous variables are expressed as median and interquartile range, and categorical variables as percentages. Comparison of continuous variables was performed using the Mann–Whitney–Wilcoxon test.

For comparison of categorical variables, the chi-square test was used, respectively. All statistical tests were 2-tailed, and a $P < 0.05$ was considered significant.

Analysis was performed using the SAS 9.2 software package (SAS Institute Inc., Cary, NC, USA). All authors have read and agreed to the written manuscript.

Results

Baseline Characteristics

A total of 3,775 patients were included, with a mean age of 63 (54–69) years; 2,381 (63.1%) of them were males. The proportion of males was similar in both the RF and cryoballoon group (62.7% vs 64.3%; $P = 0.38$). Comorbidities and the rates of structural heart diseases were similar in both groups, and no statistical differences were found in baseline clinical characteristics (Table 1). A total of 92.9% of cryoballoon and 91.4% of RF ablation treated patients had normal LVEF ($P = 0.17$); 1.2% of cryoballoon patients but 2.4% of RF patients showed a reduced LVEF ($≤40\%$) ($P<0.05$). History of symptomatic AF and palpitations was similar in both groups; the SAF score analysis is shown in Table 2. The SAF scale has been validated to qualify AF related symptoms and their functional consequences on patient’s daily life with respect to AF documentation and therapy. The SAF score is rated on a scale from 0 (asymptomatic) to 4 (severe impact of symptoms on the quality of life)$^{17,18}$ Frequent AF episodes ($≥1$ episode per month, 93.2% vs 90.2%; $P < 0.01$) and drug resistant AF episodes (94.0% vs 71.6%; $P < 0.0001$) were more frequent in patients undergoing RF ablation.

In 1.8% of patients undergoing cryoablation and 1.1% undergoing RF ablation a second arrhythmia apart from AF was present ($P = 0.13$).

Ablation Procedure

The majority of patients in Germany have been ablated in more experienced centers performing >200 ablations per year, with 69.2% of the RF patients and 67.5% of the patients undergoing cryoablation ($P = 0.18$). RF ablation was performed more frequently in sinus rhythm using cryoablation (88.1%) compared to RF ablation (82.5%; $P < 0.001$).

In RF ablation, most commonly the 3.5 mm irrigated tip electrode (83.4%), in 5% irrigated tip catheters of other length, in 12% nonirrigated 4 mm tip catheters and in 1% 8 mm tip catheters were used. During cryoablation, the cryoballoon catheter was used in all patients, with additional use of the cryo-tip catheter in 10.6% of the patients.

In RF ablation $3.1 ± 0.8$ transvenous sheaths were used vs $2.5 ± 1.1$ in cryoablation ($P < 0.0001$). An arterial sheath was used more often in cryoablation (65.6% vs 25.6% in RF ablation; $P < 0.0001$). More transseptal access and sheaths were used in RF than in cryoablation ($1.8 ± 0.4$ vs $1.2 ± 0.4$; $P < 0.0001$).

Conventional mapping was more common in cryoablation (67.6% vs 28.5% in RF ablation, $P < 0.0001$), whereas 3D electroanatomical mapping was favored in RF ablation (71.2% vs 25.4% in cryoablation, $P < 0.0001$). Preprocedural imaging was performed more frequently in cryoablation (43.5%) using cardiac MRI in 3.8%, cardiac CT in 32.0% and ICE in 7.7% compared to RF ablation (25.2%) using cardiac MRI in 3.4%, cardiac CT in 21.0% and ICE in 2.5%.

Mean total procedure time was similar with both ablation methods (160 minutes in cryoablation vs 165 minutes in RF ablation; $P = 0.39$). Mean ablation time was longer in cryo than in RF ablation and also fluoroscopy time and radiation dose per ablation were significantly higher in cryoablation compared to RF ablation (Table 3).

Medication

Antiarrhythmic agents: At time of discharge, 48.0% of patients after cryoablation and 56.2% of patients after RF ablation were on antiarrhythmic drugs ($P < 0.0001$); 25.1% of the patients undergoing cryoablation were on class I antiarrhythmics compared to 33.1% of the patients undergoing RF ablation ($P < 0.0001$); class III antiarrhythmic drugs were used similarly in both groups (21.3% in cryoablation and 20.6% in RF ablation; $P = 0.67$) (Table 4).

Anticoagulation: Phenprocoumon was less common in patients at discharge after cryoablation (85.0%) compared to RF ablation (90.5%; $P < 0.0001$), antithrombotic agents were used in 14.3% after cryo- and in 11.9% after RF ablation ($P = 0.06$), and low molecular weight heparin was used in 54.1% of patients after cryoablation compared to 67.1% of patients after RF ablation ($P < 0.0001$).

Efficacy

Acute success rates were similar in both groups (97.5% in cryo vs 97.6% in RF; $P = 0.92$). Mean duration of hospital
TABLE 1
Patient Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>RF Ablation (n = 2,870)</th>
<th>Cryoballoon (n = 905)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender (%)</td>
<td>62.7</td>
<td>64.3</td>
<td>0.38</td>
</tr>
<tr>
<td>Age (years) [range]</td>
<td>63 [54–69]</td>
<td>63 [53–69]</td>
<td>0.95</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>7.2</td>
<td>8.2</td>
<td>0.32</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>55.8</td>
<td>57.8</td>
<td>0.47</td>
</tr>
<tr>
<td>Underlying heart disease (%)</td>
<td>31%</td>
<td>32.5%</td>
<td>0.40</td>
</tr>
<tr>
<td>Coronary artery disease (%)</td>
<td>16.4</td>
<td>16.4</td>
<td>0.95</td>
</tr>
<tr>
<td>Cardiomyopathy (%)</td>
<td>2.2</td>
<td>1.7</td>
<td>0.32</td>
</tr>
<tr>
<td>Valve disease (%)</td>
<td>8.1</td>
<td>3.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Prior stroke (%)</td>
<td>5.5</td>
<td>3.8</td>
<td>0.18</td>
</tr>
<tr>
<td>Prior pacemaker implant (%)</td>
<td>4.5</td>
<td>3.9</td>
<td>0.40</td>
</tr>
<tr>
<td>Prior ICD implant (%)</td>
<td>1.3</td>
<td>1.1</td>
<td>0.72</td>
</tr>
<tr>
<td>Chronic kidney disease (%)</td>
<td>2.7</td>
<td>1.8</td>
<td>0.30</td>
</tr>
<tr>
<td>Ejection fraction (&gt;50%) (%)</td>
<td>91.4</td>
<td>92.9</td>
<td>0.17</td>
</tr>
<tr>
<td>Ejection fraction (&lt;40%) (%)</td>
<td>2.4</td>
<td>1.2</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

TABLE 2
Symptoms Prior to Ablation

<table>
<thead>
<tr>
<th>Variable</th>
<th>RF Ablation (n = 2,870)</th>
<th>Cryoballoon (n = 905)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palpitations</td>
<td>2,821 (98.3%)</td>
<td>886 (98.7%)</td>
<td>0.44</td>
</tr>
<tr>
<td>Palpitations at least monthly</td>
<td>2,673 (93.2%)</td>
<td>774 (90.2%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>SAF I</td>
<td>88 (3.5%)</td>
<td>10 (3.3%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>SAF II</td>
<td>290 (24%)</td>
<td>83 (27.5%)</td>
<td>0.21</td>
</tr>
<tr>
<td>SAF III</td>
<td>682 (56.5%)</td>
<td>101 (33.4%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>SAF IV</td>
<td>148 (12.3%)</td>
<td>108 (35.8%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

SAF = severity in atrial fibrillation scale.

TABLE 3
Procedural Characteristics

| Procedure duration (minutes)    | 165 [120–210]           | 160 [130–200]        | 0.39    |
| Ablation time (seconds)         | 1,980 [1,252–3,018]     | 2,722 [2,400–3,447]  | <0.0001 |
| Fluoroscopy time (minutes)      | 24 [16–37]              | 34 [26–46]           | <0.0001 |
| Dose area product (cGy*cm²)     | 2,799 [1,463–5,560]     | 4,971 [2,640–8,965]  | <0.0001 |

TABLE 4
Antiarrhythmic Medication at Time of Hospital Discharge

| Antiarrhythmic drug (%)         | 56.2                    | 48.0                 | <0.0001 |
| Class III antiarrhythmics (%)   | 20.6                    | 21.3                 | 0.67    |
| Class I antiarrhythmics (%)     | 33.1                    | 25.1                 | <0.0001 |
| Class IV antiarrhythmics (%)    | 3                      | 0.6                  | <0.0001 |

stay was shorter in patients undergoing RF ablation (3 [2–5] vs 4 [3–6] days; P < 0.0001). AF recurrence rates until discharge were similar after cryo (5.9%) and RF ablation (5.6%; P = 0.81).

Safety

Procedural MACCE was similar in both groups (0.4% in cryo vs 0.2% in RF; P = 0.15). Overall complication rate was similar in cryo (4.6%) and RF ablation (4.6%; P = 1.0). Phrenic nerve palsy was more often in cryo vs RF ablation (2.1% in cryo vs 0.0% in RF; P < 0.001). The procedural complication rate excluding phrenic nerve palsy was higher in RF versus cryoablation (4.6% in RF vs 2.7% in cryo; P < 0.05, Table 5). Also, minor bleedings not requiring interventions were more common in RF ablation (3.8% in RF vs 2.3% in cryo; P < 0.05). In both groups, a pacemaker had to be implanted in 0.2% of patients after the AF ablation procedure (P = 0.90). All patients left the hospital post-AF ablation; there were no procedure related deaths.

Discussion

Since ablation techniques and strategies in ablation therapy of px AF vary considerably among EP centers, a comparison of the cryoballoon approach with RF ablation in px AF
patients was addressed in this analysis of the German ablation registry, introduced in January 2007. The presence of an underlying structural heart disease was similar in both groups of patients. However, a reduced ejection fraction (≤40%) and valve diseases were slightly more common in patients undergoing RF compared to cryoballoon ablation.

### Procedural Findings

Cryoballoon technology has been developed to simplify and shorten the demanding procedure of RF point-by-point PV ablation. In 4 trials comparing RF and cryoballoon PVI in AF patients mean procedure and fluoroscopy times were reported to be lower in cryo compared to RF ablation. In RF ablation, a wide range of procedural and fluoroscopy times has been reported over the past decade of AF ablation. In the majority of the participating centers RF ablation has been introduced earlier than cryoablation and prior to the registry onset. Thus, at least partly the learning curve in RF ablation might have been overcome prior to the center’s entry to the ablation registry. This might in part explain our procedural findings.

### Acute Success

Acute efficacy rates of both RF and cryoablation were comparable and well in line with previously reported data from metaanalysis in cryoballoon and RF ablation. Andrade et al. found an acute success rate of 98.81% of patients and of 98.47% of targeted PVs in their analysis of 23 cryoballoon studies. In studies using the cryoballoon exclusively without additional use of cryo or RF tip catheters, the overall acute success rate was 98.74% of patients and 99.23% of targeted PVs.

### Safety

The overall incidence of procedural complications was similar in RF and cryoballoon ablation (4.6% in both cohorts).

In cryoballoon ablation, the most frequent but reversible complication is PNP with reported incidences up to 10%. We found a significantly higher rate of post-procedure persistent PNP of 2.1% in cryoballoon ablation compared to RF ablation (P < 0.001). The deployment of undersized balloons well inside the right-sided PVs is known to possibly result in increased risk of PNP, since the transfer of the freezing to deeper tissue areas is promoted by less convective warming of the cryoballoon by atrial blood flow. Andrade et al. found in their review that nearly 2 out of 3 (64.7%) PNP occurred with use of the smaller, 23 mm cryoballoon size. Thus, it would have been of interest also for the registry to analyze cryoballoon sizes with respect to PV diameter and PNP; however, this was beyond the scope of the ablation registry but will be addressed in future registries analyzing cryoballoon ablation.

### TABLE 5

Procedural Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>RF Ablation (n = 2,870)</th>
<th>Cryoballoon (n = 905)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>0.40</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>1 (0.1%)</td>
<td></td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>9 (0.3%)</td>
<td>3 (0.3%)</td>
<td>0.83</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>30 (1.1%)</td>
<td>5 (0.6%)</td>
<td>0.16</td>
</tr>
<tr>
<td>PV stenosis</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Atrial-esophageal fistula</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Aneurysma spurium/AV fistula</td>
<td>33 (1.1%)</td>
<td>7 (0.8%)</td>
<td>0.33</td>
</tr>
<tr>
<td>Tamponades</td>
<td>37 (1.4%)</td>
<td>7 (0.8%)</td>
<td>0.17</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>8 (0.3%)</td>
<td>0</td>
<td>0.10</td>
</tr>
<tr>
<td>Hemothorax</td>
<td>6 (0.2%)</td>
<td>0</td>
<td>0.16</td>
</tr>
<tr>
<td>Sepsis</td>
<td>1 (0.0%)</td>
<td>0</td>
<td>0.57</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>1 (0.0%)</td>
<td>0</td>
<td>0.57</td>
</tr>
<tr>
<td>Surgical accident</td>
<td>3 (0.1%)</td>
<td>0</td>
<td>0.32</td>
</tr>
<tr>
<td>AV block III</td>
<td>0</td>
<td>1 (0.1%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Phrenic nerve palsy</td>
<td>1 (0.0%)</td>
<td>18 (2.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total</td>
<td>132 (4.6%)</td>
<td>42 (4.6%)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

AV block III = atrioventricular block grade III; AV fistula = arteriovenous fistula; PV stenosis = pulmonary vein stenosis; RF ablation = radiofrequency ablation; TIA = transient ischemic attack.
Excluding PNP the rate of procedural complications was 4.6% in RF and 2.7% in cryoballoon ablation (P < 0.05). Complication rate in RF ablation was mainly driven by vascular complications (1.1%; cryo 0.8%), major bleedings (1.1%; cryo 0.6%) and tamponades (1.4%; cryo 0.8%). No case of a left atrial-esoophageal fistula and no PV stenosis was reported in both cohorts of patients.

The complication rate of 4.6% in the RF ablation cohort in the German ablation registry was well in line with previous reports of unselected AF patients undergoing RF ablation. The worldwide survey from Cappato et al. reported a complication rate of 4.5%,24 Calcins et al. found a complication rate of 4.9% in their meta-analysis of RF ablation trials,26 and the largest published single center experience from Leipzig revealed a rate of 3.9% of relevant complications in more than 1,000 RF ablation procedures in AF ablation.28

The procedural complication rate of 2.7% excluding PNP in our cohort of patients undergoing cryoballoon ablation was lower than that in the recently published meta-analysis of cryoballoon ablation trials.23 Andrade et al. reported a complication rate of 3.99% in their meta-analysis among 1,349 patients.

**Limitations**

The validity of the data from the registry certainly depends on the degree of registry coverage and the uniformity of local forming policy. Voluntary participation will limit the reliability of the registry, if institutions with lower success and higher complication rates do not join the registry. Furthermore, we cannot exclude a selection bias with respect to the intention to include patients with RF or cryoballoon ablation according to the centers’ preference.

In all patients the first-generation cryoballoon catheter (Arctic Front, Medtronic, USA) was used since the second generation (Advance, Medtronic, USA) was not available during the registry period between January 2007 and August 2011. Use of the second-generation cryoballoon might have had an impact on procedural and outcome parameters as promising results have been reported recently.29

Evaluation of success and complication rates is complex. Complications occurring during the ablation procedure may be registered adequately in a registry, but the management of the coverage of problems at a later stage after the ablation procedure may have some limitations.

Since this analysis addresses procedural aspects and complications of the ablation methods used in the participating 55 centers, atrial-esoophageal fistula and PV stenosis occurring beyond the periprocedural hospital stay may be missed and underreported.

A more specific questionnaire for catheter ablation details would have been of interest, certainly to gain more insights into the cryoballoon procedure with respect to the occurrence of PNP. This will be addressed in future registry trials.

**Conclusion**

The German ablation registry provides consistent data of RF compared to cryoballoon ablation in paroxysmal atrial fibrillation. RF ablation is the most widespread ablation method in Germany, but use of cryoballoon increased significantly. Procedure times were similar but ablation and fluoroscopy times were longer in cryoballoon ablation. No significant differences were found in terms of acute success and overall complication rate. Phrenic nerve palsy was more frequent in cryoballoon ablation; other complications were more frequent in RF ablation. Important lessons have to be learned from the ongoing analysis of follow-up data with respect to efficacy and safety of both ablation methods.

**References**


Supporting Information

Additional Supporting information may be found in the online version of this article at the publisher’s website:

Appendix S1.