Feasibility and safety of outpatient radiofrequency catheter ablation procedures for atrial fibrillation

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Abstract: INTRODUCTION: Percutaneous catheter ablation for atrial fibrillation (AF) is a procedure performed typically in an inpatient setting. The feasibility and safety of catheter ablation in patients with paroxysmal and persistent AF were evaluated on an outpatient basis. METHODS: 230 AF ablation procedures were performed in 206 patients (74% male; mean age 56+/-9 years). Patients were admitted to the hospital outpatient facility in the morning for the AF ablation procedure on the same day. The ablation strategy consisted of wide area circumferential lines around both ipsilateral pulmonary veins. After monitoring in the outpatient service, patients were discharged on the same day, if they were clinically stable. RESULTS: Mean procedure time was 201+/-31 min. Major complications occurred in seven patients (3%). One patient (0.4%) suffered a minor stroke and six patients had pericardial tamponade requiring percutaneous drainage. Patients could be discharged on the same day following 205 (89%) procedures. Among the 148 patients whose clinical outcome was assessed at 6 months, 127 (86%) had a reduction of the total symptomatic AF episodes, compared to pre-ablation, with a complete lack of symptoms in 101 patients (68%). CONCLUSION: Catheter ablation of AF on the day of admission is feasible and safe with a low risk of complications. The vast majority of the patients can be discharged on the same day.

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Original article

Feasibility and Safety of Outpatient Radiofrequency Catheter Ablation Procedures for Atrial Fibrillation

Short title: Outpatient Ablation of AF

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Abstract:

Introduction: Percutaneous catheter ablation for atrial fibrillation (AF) is a procedure performed typically in an inpatient setting. We evaluated the feasibility and safety of catheter ablation in patients with paroxysmal and persistent AF on an outpatient basis.

Methods: 230 AF ablation procedures were performed in 206 patients (74% male; mean age 56±9 years). Patients were admitted to the hospital outpatient facility in the morning for the AF ablation procedure on the same day. The ablation strategy consisted of wide-area circumferential lines around both ipsilateral pulmonary veins. After monitoring in the outpatient service, patients were discharged on the same day, if they were clinically stable.

Results: Mean procedure time was 201±31 minutes. Major complications occurred in 7 patients (3%). One patient (0.4%) suffered a minor stroke and 6 patients had pericardial tamponade requiring percutaneous drainage. Patients could be discharged on the same day following 205 (89%) procedures. Among the 148 patients whose clinical outcome was assessed at 6 months, 127 (86%) had a reduction of the total symptomatic AF episodes, compared to pre-ablation, with a complete lack of symptoms in 101 patients (68%).

Conclusion: Catheter ablation of AF on the day of admission is feasible and safe with a low risk of complications. The vast majority of the patients can be discharged on the same day.

Keywords: Atrial fibrillation, catheter ablation, outpatient, anticoagulation, safety, outcome
**Glossary of abbreviations:**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AF</td>
<td>Atrial fibrillation</td>
</tr>
<tr>
<td>INR</td>
<td>International normalized ratio</td>
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<tr>
<td>ACT</td>
<td>Activated clotting time</td>
</tr>
<tr>
<td>LMWH</td>
<td>Low molecular weight heparin</td>
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<tr>
<td>AAD</td>
<td>Antiarrhythmic drug</td>
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<tr>
<td>LA</td>
<td>Left atrium</td>
</tr>
<tr>
<td>EF</td>
<td>Ejection fraction</td>
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</table>
Introduction:

In recent years, catheter ablation has been widely performed as an effective treatment in patients with symptomatic, drug-resistant AF. Various ablation strategies have been used to achieve a high efficacy for all types of AF. However, the procedure remains to be complex and is associated with a relatively high incidence of complications. Thromboembolic events, pericardial tamponade, pulmonary vein stenosis, and oesophageal injury are among the potential major complications of catheter-based radiofrequency ablation of AF and are known to occur 3.9 - 6% of cases. [1, 2, 3] Therefore, the procedure is typically performed in an inpatient setting, which includes overnight stay after the procedure.

Catheter ablation has become the treatment of choice for most supraventricular arrhythmias as it is safe and promotes cure in the majority of patients. [4, 5, 6] Improved catheter and mapping technologies and enhanced clinical expertise favourably influence ease and safety of ablation, resulting in an increased trend to perform these procedures on an outpatient basis. Arrhythmias, such as atrioventricular nodal reentry tachycardia and accessory pathways in patients without associated comorbidities are particularly suited for the outpatient ablation procedure. [7, 8, 9] As a result of the reduction in hospital stay, procedure-related costs are reduced and the patients return early to work, and therefore, outpatient procedures have important economic and occupational impacts. Furthermore, from a patient’s perspective, outpatient procedure contributes in early ambulation and increased patient comfort.
Given the high incidence of AF in the general population, the increasing number of ablation procedures for the treatment of this arrhythmia is likely to lead to logistic constraints. Some electrophysiology centres attempt same day discharge after AF ablation, particularly if the patient’s insurance only covers outpatient procedures.

However, outpatient ablation for AF is more challenging not only due to the complexity of the procedure itself, but also due to the need for anticoagulation prior to and after the procedure. By feasibility we meant the practicability of performing catheter ablation procedures for patients with atrial fibrillation on an outpatient basis without admission.
Methods:

Study patients: Consecutive patients with symptomatic paroxysmal or persistent AF in the absence of a significant structural heart disease undergoing a percutaneous catheter ablation procedure at the Royal Jubilee Hospital in Victoria B.C. (Canada) over the time period of one and a half year were included in this study. Demographic and clinical data were collected prior to the procedure. All patients gave informed consent prior to the procedure.

Ablation procedure: All patients were admitted to the outpatient facility on the morning of the procedure and were brought to the electrophysiologic laboratory in a non-sedated state. The procedures were started at 8:30 am lasting three to four hours. Three femoral vein sheaths were inserted under local anaesthesia. A 6F steerable decapolar electrophysiology catheter LivewireTM (St. Jude Medical Inc., St. Paul, MN, USA) was placed into the coronary sinus. After double transseptal puncture performed by a BRK™ transseptal needle (St. Jude Medical Inc., St. Paul, MN, USA), a 5F circular decapolar catheter Supreme Spiral SC™ (St. Jude Medical Inc., St. Paul, MN, USA) and a 7F non-irrigated 4 mm tip bi-directional ablation catheter RF Conductr™ MC (Medtronic Inc., Minneapolis, MN, USA) were passed transseptally through two 8F transseptal guiding introducers Swartz™ SL1™ (St. Jude Medical Inc., St. Paul, MN, USA). The catheter ablation was performed using radiofrequency energy under Ensite NavX™ mapping system (St. Jude Medical Inc., St. Paul, MN, USA) guidance.

The ablation strategy consisted of continuous wide-area circumferential lines around both ipsilateral pulmonary veins. Lesions were delivered for 30 seconds, using RF energy up
to 35 Watts for a maximum target temperature of 58° Celsius. For patients with persistent AF, additional linear lesions were performed: a left atrial roof line connecting both upper left and right pulmonary veins and a left atrial isthmus line between the mitral valve annulus and the left inferior pulmonary vein. The additional left atrial lines were not routinely mapped and checked for conduction block and no ablation within the coronary sinus was performed. The endpoint of the procedure in both paroxysmal and persistent AF patients was electrical isolation of all pulmonary veins, which was assessed using the circular spiral catheter. In patients with persistent AF an electrical cardioversion was required to terminate AF. Atrial tachycardia or atrial flutter developing during the procedure were not mapped and only ablated if clinical recurrence was present. The procedure was performed under conscious sedation using midazolam and fentanyl. After the procedure the patients were monitored for at least five hours and discharged if they were stable on the same day. The minimum bedrest regime was four hours. No routine echocardiogram was performed. All patients were primarily eligible for discharge on the same day prior to 8 pm. Local patients were discharged home. Patients from remote areas were asked to stay overnight in-town either in a local hotel or in a relative’s home. Patients with no accompany were allowed to stay overnight. There were no other predefined criteria to keep patients overnight. The outpatient facility was staffed overnight and could accommodate outpatient patients if overnight observation and care were required.

**Anticoagulation Strategy:** Warfarin was discontinued three days prior to the procedure to allow international normalized ratio (INR) to drop in a subtherapeutic range the day of the procedure (INR<2.0). After insertion of the transseptal catheters, therapeutic
anticoagulation was initiated with a bolus of intravenous heparin (100 IU/kg bodyweight). Activated clotting time (ACT) was monitored in 30 minute intervals followed by additional boluses of heparin to keep the ACT levels between 250 and 300 seconds. The sheaths were removed at the end of the procedure if ACT was below 180 seconds. No protamin was given to reverse heparin. Oral anticoagulation was resumed on the same day of the procedure for at least 3 months. Patients who presented with persistent AF were administered subcutaneous low molecular weight heparin (LMWH) until an INR value above 2.0 was reached. Aspirin 81 mg/day was given to all patients for the four weeks following the procedure. Transoesophageal echocardiogram was performed in patients with persistent AF and subtherapeutic or absent anticoagulation prior to ablation, but otherwise was not a prerequisite.

Data analysis: All patients admitted to the outpatient facility for the purpose of catheter ablation of AF were entered into our database. Information was collected on patient and clinical demographics, procedure characteristics, periprocedural complications and clinical results at follow-up including rhythm control status and late complications using a patient assessment form at 6 months after the intervention. Six month success was defined as complete lack of symptoms from atrial fibrillation regardless the intake of antiarrhythmic drugs.
Results:

**Patient and clinical demographics:** A total of 230 catheter ablation procedures were performed consecutively on 206 patients with AF (table 1). The patients could be discharged on the same day following 205 (89%) of these procedures (figure 1). The remaining were kept inpatient overnight either due to major complications listed below, minor groin bleeding requiring prolonged compression and bed rest in 10 patients (4.3%), or due to late completion of the procedure or reduced overall well-being from conscious sedation. There were no differences of the same day discharge rate whether the patients had paroxysmal or persistent AF.

**Procedural characteristics and periprocedural complications:** Major complications occurred in 7 patients (3%). One patient (0.4%) suffered a minor stroke immediately after the procedure with no long term deficits. No late peripheral or cerebral thromboembolic events were observed at the 6 month follow-up. Six procedures were complicated at the end of the intervention by a pericardial effusion requiring percutaneous drainage. None of the procedures were complicated by vascular access complications requiring transfusion or surgical interventions (table 2).

**Clinical results:** Among the 148 patients whose clinical outcome was assessed at 6 months, 127 (86%) had a reduction of the total symptomatic AF episodes, compared to pre-ablation, with a complete lack of symptoms in 101 patients (68%) and partial success (defined as >90% improvement in symptoms) in the remaining 26 (18%) (figure 2). 20 patients (16%) out of 127 patients with a reduction of the total symptomatic AF episodes needed a repeat procedure on an outpatient basis. The remaining patients were lost to
follow-up and could not be reached because of the large distance between the ablation centre and the remote areas where the patients were referred from within Canada. No late complications were observed.
Discussion:

Our study showed that catheter ablation of AF on an outpatient basis in a single centre seems to be feasible and safe with risk of complications as low as for inpatient AF ablation. [1, 2, 3] Among 230 patients admitted for paroxysmal and persistent AF ablation, 89% could be discharged on the same day following the procedure. Major complications occurred in seven patients (3%) requiring hospital admission. Eighteen patients were admitted to stay overnight because of minor groin bleeding, late completion of the procedure or reduced well-being after deep conscious sedation. There were no differences for patients with paroxysmal or persistent AF in terms of procedure time, complication rate and same day discharge rate. Among the patients assessed at 6 month follow-up, 68% remained symptom free from atrial fibrillation.

Catheter ablation on an outpatient basis is an established safe treatment of supraventricular tachyarrhythmias and reports on the feasibility and safety are available. [7, 8] To the best of our knowledge, this study reports for the first time data on the feasibility and safety of outpatient ablation for paroxysmal or persistent AF.

Same day discharge allows not only cost reduction, but renders substantial logistic benefits for the clinic. A majority of patients do not require a hospital bed after the procedure. Furthermore, from a patient’s perspective, outpatient procedure contributes in early ambulation, increased patient comfort and early return to work. Therefore, outpatient procedures have important economic and occupational impacts. The use of our outpatient model for AF catheter ablation saved eighty-nine overnight hospital
accommodations per hundred patients treated and primarily admitted for a same day discharge procedure.

AF ablation is a challenging intervention because of the risk for potential of thromboembolic events on one hand, and bleeding complications due to periprocedural anticoagulation on the other. [1, 2, 3] There are published guidelines for anticoagulation in patients undergoing AF ablation. [10, 11] However, there is a great variability in pre- and post-procedure anticoagulation protocols, and no unified strategy exists to date. Most centers discontinue warfarin and use subcutaneous LMWH or intravenous heparin to bridge anticoagulation before and after ablation. [12, 13, 14] However, bridging anticoagulation may increase the risk of bleeding and thrombosis, especially early after ablation. [15] Prior studies have indicated a 0.5% to 7% risk of stroke and transient ischemic episodes after radiofrequency ablation. [1, 2, 3, 16, 17, 18, 19, 20, 21] Oral et al. [12] described a strategy in which LMWH was given prior to and after the intervention as bridging to warfarin showing 7 thromboembolic events in a group of 755 patients (0.9%). The present study showed a low risk of embolic events, with only one case of minor stroke (0.4%) occurring following the procedure. The average maximum intra-procedural ACT was 266 seconds. However, the thromboembolic events in our group were low. At the time when the study was performed non-irrigated ablation catheters were still used for AF catheter ablation, but since then irrigated ablation catheters are widely used with the advantage of deep lesion creation and decreased thrombosis rates. No routine echocardiogram was performed in all, unless AF catheter ablation was complicated and/or there were signs for pericardial effusion, which occurred intraprocedurally or immediately postprocedurally.
Catheter ablation for AF and discharge on the day of admission seems to be feasible for most patients. However, given the complexity of the procedure, outpatient AF ablation services should allow extended observation period or overnight stay for the occasional patient whose clinical condition is not suitable for discharge. Having this possibility on hold, the strategy of AF ablation on the day of admission with the intention for same day discharge can be applied for most patients.

**Limitations:** This is an observational cohort study, and is not a prospective, randomised trial. In the absence of a direct randomised comparison of same day discharge with overnight hospital stay, only limited conclusions regarding the safety of an outpatient AF ablation procedure can be made. No complete data on readmission to other hospitals for minor or major complications after discharge were available as the majority of the patients were referred from remote areas in Canada. In addition, the clinical outcome was assessed based on symptoms reported by the patients only, and therefore, the reliability of the presented data on outcome is limited due to known difficulties of survey-based studies. Further prospective, randomised trials of patients referred for AF catheter ablation comparing an inpatient and an outpatient procedure setting are required.
Main messages

- Catheter ablation is an established treatment in patients with symptomatic AF and is performed mostly in an inpatient setting due to technique’s complexity and potential complications.

- An outpatient setting is an attractive alternative in light of increasing numbers of procedures leading to logistic and health-economical constraints.

- Outpatient ablation of AF may contribute to patient comfort and early ambulation.

- This paper shows that catheter ablation of AF performed in an outpatient setting is feasible and safe with a low risk of complications.

Current research questions

- What are the complication rates of outpatient ablation of AF as compared to inpatient ablation?

- What are the economical and occupational impacts of the outpatient procedure?
**Conclusion:**

Catheter ablation of AF on the day of admission seems to be feasible and safe with a low risk of complications. The majority of the patients may be discharged on the same day. However, it needs to be investigated in prospective randomised studies if catheter ablation of AF offers a safe alternative strategy to the inpatient procedure in different patient groups with AF.
### Table 1: Patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td><strong>n=206</strong></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>56±9.3</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>152 (74%)</td>
</tr>
<tr>
<td>Type of AF</td>
<td></td>
</tr>
<tr>
<td>• Paroxysmal AF</td>
<td>171 (83%)</td>
</tr>
<tr>
<td>• Persistent AF</td>
<td>35 (17%)</td>
</tr>
<tr>
<td>Number of AF episodes per month</td>
<td>14±16</td>
</tr>
<tr>
<td>History of AF (yrs)</td>
<td>7.6±6.5</td>
</tr>
<tr>
<td>Number of AAD</td>
<td>1.5±0.99</td>
</tr>
<tr>
<td>Transthoracic echocardiography</td>
<td></td>
</tr>
<tr>
<td>• LA size (mm)</td>
<td>39.9±6.4</td>
</tr>
<tr>
<td>• EF (%)</td>
<td>59.2±4.7%</td>
</tr>
</tbody>
</table>

AAD=antiarrhythmic drug, LA=left atrium, EF=ejection fraction
**Table 2: Procedural data**

<table>
<thead>
<tr>
<th></th>
<th>n=230</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Average procedure time (minutes)</strong></td>
<td>201±31</td>
</tr>
<tr>
<td>• paroxysmal AF patients</td>
<td>214±30</td>
</tr>
<tr>
<td>• persistent AF patients</td>
<td>197±31</td>
</tr>
<tr>
<td><strong>Fluoroscopy time (minutes)</strong></td>
<td>42.5±10.3</td>
</tr>
<tr>
<td>• paroxysmal AF patients</td>
<td>42±10</td>
</tr>
<tr>
<td>• persistent AF patients</td>
<td>46±11</td>
</tr>
<tr>
<td><strong>Average heparin dose (IU)</strong></td>
<td>13519±3532</td>
</tr>
<tr>
<td><strong>Average minimum ACT (seconds)</strong></td>
<td>209±23</td>
</tr>
<tr>
<td><strong>Average maximum ACT (seconds)</strong></td>
<td>266±38</td>
</tr>
<tr>
<td><strong>Pulmonary vein isolation</strong></td>
<td>225 (98%)</td>
</tr>
<tr>
<td><strong>Major complications</strong></td>
<td></td>
</tr>
<tr>
<td>• Minor stroke with no long-term disability</td>
<td>1</td>
</tr>
<tr>
<td>• Pericardial tamponade</td>
<td>6</td>
</tr>
<tr>
<td>• Vascular access complications</td>
<td>none</td>
</tr>
</tbody>
</table>

ACT=activated clotting time, IU=international units
Figure 1: Same day discharge rate

Figure 2: Outcome at 6 month follow-up
References:


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