Feasibility and Safety of Same-Day Home Discharge After Radiofrequency Catheter Ablation

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Interventional cardiology in a day-case setting might reduce logistic constraints on hospital resources. However, in contrast with coronary angioplasty, few data support the feasibility and safety of radiofrequency catheter ablation (RCA). The aim of this prospective, multicenter cohort study was to evaluate the feasibility and safety of RCA in 1,342 patients (814 men; mean age 57 ± 17 years) considered eligible for ambulatory RCA, according to specific set of criteria, for common atrial flutter (n = 632), atrioventricular nodal reentrant tachycardia (n = 436), accessory pathways (n = 202), and atrial tachycardia (n = 72). Patients suitable for early discharge (4 to 6 hours after uncomplicated RCA) were scheduled for 1-month follow-up. Predictive factors for delayed complications were studied by multivariate analysis. Of the 1,342 enrolled patients, 1,270 (94.6%) were discharged the same day and followed for 1 month; no deaths occurred, and the readmission rate was 0.79% (95% confidence interval 0.30% to 1.27%). Six patients had significant puncture complications, 2 presented with symptomatic delayed pulmonary embolism, and 2 had new onset of poorly tolerated atrial flutter. None of these complications was life threatening. Multivariate analysis did not identify any significant independent predictors for delayed complications. In conclusion, these data suggest that same-day discharge after uncomplicated RCA for routine supraventricular arrhythmias is safe and may be applicable in clinical practice. This approach is known to be associated with significant patient satisfaction and cost savings and can be considered a first-line option in most patients who undergo routine ablation procedures. © 2009 Elsevier Inc. (Am J Cardiol 2009;104:254–258)

In contrast to coronary angioplasty,[1] there are few data regarding the feasibility of radiofrequency catheter ablation (RCA) in outpatients. To the best of our knowledge, RCA in outpatients has been reported only for accessory pathways (AP) and atrioventricular nodal reentrant tachycardia (AVNRT) in a limited number of patients or using retrospective methods.[2–5] Moreover, no study to date has evaluated the applicability of this approach for atrial flutter (AFL) and atrial tachycardia (AT), although these arrhythmias usually require anticoagulation, suggesting a higher risk for local complications. In this multicenter, prospective cohort study, we sought to evaluate the safety and feasibility of same-day discharge after RCA for routine arrhythmias by testing the hypothesis that patients requiring extended observation can be selected effectively and that same-day discharge does not increase the 1-month complication rate compared with the traditional hospital stay in different cohort studies published to date.[6,7]

Methods

Because of medical care and insurance particularities in Switzerland, ambulatory care has been a cost-effective alternative for many years. In 1997, the cardiology department of Hôpital de la Tour in Meyrin, Geneva, Switzerland, decided to carry out a prospective evaluation of RCA performed in consecutive outpatients. Eligible patients with uncomplicated RCA for routine arrhythmias (as defined in the following) were discharged home the same day and scheduled for 1-month follow-up. Because the preliminary results of this study, presented in 2000 at the Cardiostim Congress in Nice, France, confirmed the feasibility of the technique on an outpatient basis, another member from the Réseau Européen pour le Traitement des Arythmies Cardiaques group, based at Clinique Pasteur, Toulouse, France, decided to extend the evaluation on a prospective basis, using the same approach.

A total of 1,342 consecutive patients who underwent RCA for routine arrhythmias from November 30, 1997, to February 10, 2008, in Geneva, Switzerland, and from January 1, 2006, to November 1, 2007, in Toulouse, France, were enrolled in this prospective study (Figure 1). Patients scheduled to undergo RCA for common AFL, AVNRT, AP, and focal AT were eligible for enrollment if they arrived at the center on the morning of the procedure and did not

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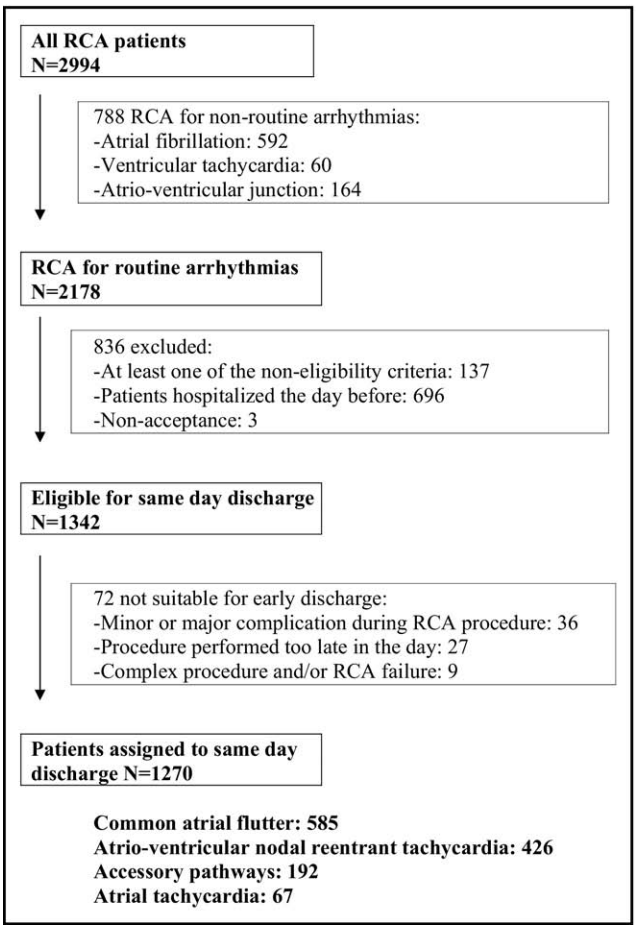

Figure 1. RCA of routine supraventricular arrhythmias in outpatients: study flow chart.

present any of the noneligibility criteria: (1) age <18 years, (2) history of stroke and/or venous thromboembolic disease, (3) prosthetic mechanical valve, (4) geographic (>120 minutes away from the intervention center) and/or familial isolation, and (5) unstable heart failure (New York Heart Association class IV) and/or co-morbid conditions warranting further hospitalization. Eligible patients gave their written informed consent before inclusion in the study. The study was approved by the institutional review boards of the 2 medical centers.

All patients underwent noninvasive evaluation with a cardiologist before referral, including clinical examination, 12-lead rest electrocardiography, and 2-dimensional transthoracic echocardiography. All patients arrived with the results of standard blood analysis, including platelet count and hemostasis. Except for AFL, all antiarrhythmic medications were discontinued for ≥48 hours before RCA. For AFL, RCA was performed with either an international normalized ratio <2.5 (n = 197) or after relay by heparin (n = 435). For patients with AFL with unclear anticoagulation status, complementary transesophageal echocardiography was performed (n = 17).[8]

Except for the left-sided approach, RCA protocols were comparable at the 2 centers. The procedure was performed in the fasting state under local anesthesia without premedication in most cases. For AFL RCA, conscious sedation with midazolam (0.1 mg/kg intravenously) was most often performed. Two to 4 multipolar electrode catheters (5Fr, 6Fr, and 8Fr) were introduced percutaneously through the femoral vein and positioned in the high right atrium, His bundle position, coronary sinus, and/or right ventricle. No patient had internal jugular or subclavian lines inserted. For left-sided AP, an additional 8Fr sheath was introduced in the femoral artery (Hôpital de la Tour), whereas the trans-septal approach was preferred at the other center (Clinique Pasteur). The electrophysiologic study was performed using standard techniques. Diagnosis of routine arrhythmias was performed according to previously published standards.[9,10] If reentrant arrhythmias could not be induced at baseline, isoproterenol was infused, and the stimulation protocol was repeated. For patients with documented AFL but in sinus rhythm at the time of the procedure, RCA was performed directly, during coronary sinus pacing, without previous induction. Cavotricuspid isthmus ablation for AFL was performed using an 8-mm tip electrode catheter or 4-mm irrigated tip catheter. For AVNRT, AP, and AT, mapping and RCA were performed using a 7Fr quadripolar temperature-controlled electrode catheter with a 4-mm tip and a deflectable curve. A 1,000-IU bolus of heparin was given intravenously after catheter placement, followed by 1,000 IU/hour thereafter. Because of the occurrence of atrial fibrillation, a few patients (n = 7) required external direct-current shock during the procedure, under transient sedation with 2% propofol in the presence of an anesthesiologist. After an observation period of 20 to 30 minutes after successful RCA, catheters and sheaths were removed, and manual compression was maintained until complete hemostasis was achieved.

After the procedure, patients were observed in a recovery cardiac electrophysiology unit with continuous cardiac monitoring for 4 hours if only venous access had been used and for 6 hours if an arterial sheath had been inserted or after a trans-septal approach. The nurses assessed the vital signs of the patients as well as the puncture sites until the time of planned discharge. The patients were then examined by the operator to determine their suitability for early discharge. Suitability included unremarkable neurologic and hemodynamic status, absence of electrocardiographic changes, and no puncture-site abnormalities; when 1 or several of these criteria were lacking, patients were admitted to the hospital for an overnight stay and discharged the following morning or later in the case of subsequent complications. Echocardiography was performed systematically after trans-septal catheterization or if there was clinical suspicion of pericardial effusion or popping during the procedure.

Suitable patients were finally discharged after being instructed thoroughly not to undertake any strenuous activity for several days. Written instructions were given to the patients, followed by verbal explanation. Patients were advised to remove the pressure bandage the next day. In the case of adverse events, patients were instructed to contact their cardiologists or the 24-hour service of the cardiology department immediately. Patients were scheduled for a clinical 1-month follow-up evaluation at the center or with the attending physician. This evaluation consisted of a system-

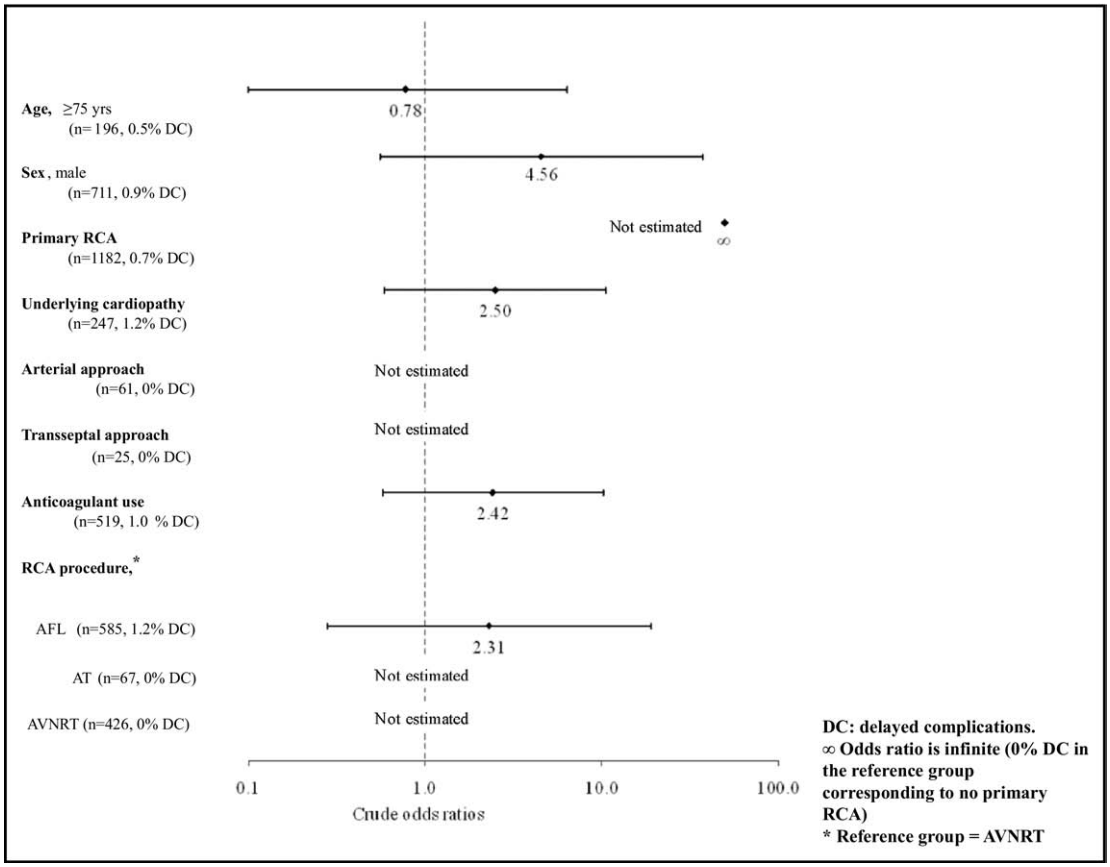

Figure 2. Predictive value of baseline characteristics of same-day discharge patients and procedure modalities for delayed complications: univariate analysis.

atic medical consultation within the first and the fourth weeks after RCA and was based on clinical examination and electrocardiographic findings. In addition, we performed systematic 24-hour Holter monitoring during this period.

We enrolled >1,000 patients, and the study had >80% power at the 0.05 significance level to detect an increase of 0.8% complications with RCA for routine arrhythmias performed on an outpatient basis compared with figures usually reported with traditional hospitalization (fixed at 1.5%).[6,7] Categorical variables are expressed as numbers and percentages and continuous variables as mean ± SD. Baseline and procedural characteristics were compared between the 2 centers using the chi-square test for categorical variables and z test for continuous variables. A p value <0.05 was considered statistically significant, and 95% confidence intervals (CIs) were used. Logistic regression models were used to identify variables associated with the development of delayed complications within the 1-month follow-up period (as defined by complications requiring new hospital admission). Univariate analysis was performed, and estimations of crude odds ratios associated with the variables evaluated as potential predictors were carried out (see variables in Figure 2). For multivariate analysis, only variables with p values <0.25 in univariate analysis were included. A stepwise forward selection method was then used as a means of selecting variables that were the most predictive. All data were analyzed in the IRSN Epidemiology Department, Fontenay-aux-Roses, France, using SAS version 8.02 (SAS Institute Inc., Cary, North Carolina). This report was prepared in compliance with the Strengthening the Reporting of Observational Studies in Epidemiology statement.[11]

Table 1
Radiofrequency catheter ablation for routine supraventricular arrhythmias: suitability rate and baseline characteristics of patients suitable for same-day discharge

Variables	AFL	AVNRT	AP	Focal AT
Suitability rate				
Eligible for same-day discharge	632	436	202	72
Suitable for same-day discharge	585	426	192	67
Suitable/eligible ratio	92.6%	97.7%	95.0%	93.1%
Baseline characteristics				
Mean age (yrs)	66 ± 11	52 ± 16	40 ± 15	57 ± 17
Men	466 (80%)	151 (35%)	120 (62%)	34 (51%)
Primary RCA	533 (90%)	412 (97%)	175 (91%)	62 (93%)
Underlying cardiopathy	194 (33%)	15 (4%)	17 (9%)	21 (31%)
Left ventricular ejection fraction	56 ± 8%	59 ± 5%	61 ± 4%	58 ± 7%
Arterial access	0	0	61 (32%)	0
Trans-septal access	0	0	25 (13%)	0
In-course anticoagulation therapy	504 (86%)	2 (<1%)	0	11 (16%)

Data are expressed as mean ± SD or as number (percentage).

Table 2
Predictive value of baseline characteristics or procedure modalities for delayed complications: multivariate analysis

Variable	Crude Odds Ratio	Adjusted Odds Ratio	95% CI	p Value
Men	4.56	3.54	0.41–30.80	0.25
Anticoagulant use	2.42	1.57	0.35–7.08	0.56
Underlying cardiopathy*	2.50	1.82	0.41–8.01	0.43

* Underlying cardiopathy was defined as a left ventricular ejection fraction <45%.

Results

During the enrollment period, a total of 2,994 RCAs were performed. Ultimately, 1,342 consecutive patients (n = 771 in Geneva, n = 571 in Toulouse) were considered eligible for same-day home discharge and were enrolled in the study (Figure 1). This patient population consisted of 814 men and 528 women ranging in age from 18 to 94 years (mean 57 ± 17 years). Among the whole group, 47 patients (3.5%) were aged ≤20 years, and 207 (15.4%) were aged ≥75 years old. Two hundred sixty-one patients (19.4%) had underlying cardiopathy, with a mean ejection fraction of 41.9 ± 6.3%, and 93 patients (6.9%) had already been treated by RCA previously.

Seventy-two eligible patients were not finally considered suitable for early discharge after RCA: occurrence of minor or major complications in 36 patients (50%); procedure performed too late in the afternoon, not allowing ≥4 hours of monitoring in 27 patients (37.5%); and complex and/or failure of RCA in 9 patients (12.5%). Finally, 1,270 of the 1,342 eligible patients (94.6%) were considered suitable for same-day home discharge. The baseline characteristics of these 1,270 patients according to RCA indication are listed in Table 1.

One-month follow-up of patients discharged the same day was completed in all patients. Eight patients experienced rehospitalization for delayed complications (0.63%, 95% CI 0.19% to 1.07%), related to direct local complications of the procedure in 6 patients (3 hematomas, 2 arteriovenous fistulas, and 1 femoral pseudoaneurysm, all except 1 needing either vascular surgery or blood transfusion) and to symptomatic pulmonary embolism in 2 patients (with documented femoral venous thrombosis from the side of venous puncture). Arrhythmia recurrence at 1 month was 1.10% (95% CI 0.53% to 1.68%): n = 6 for AFL, n = 5 for AVNRT, n = 3 for AT, and n = 0 for AP. Two of these patients experienced poorly tolerated new onset of AFL and were readmitted to the hospital, giving an overall readmission rate at 1 month of 0.79% (95% CI 0.30% to 1.27%), after a mean time of discharge of 5 ± 3 days. We observed no difference in terms of delayed and immediate complications between the 2 centers, even after adjustment for different variables. The crude odds ratios of delayed complications associated with potential predictive factors are shown in Figure 2. None was statistically significant, but male gender (odds ratio 4.56, 95% CI 0.56 to 37.20), the presence of underlying cardiopathy (defined as a left ventricular ejection fraction <45%; odds ratio 2.50; 95% CI 0.59 to 10.55), and anticoagulant use (odds ratio 1.57, 95% confidence interval 0.35 to 7.08) appeared to be the strongest potential predictors of delayed complications. In multivariate analysis (Table 2), associations with male gender, anticoagulant use, and the existence of underlying cardiopathy were slightly attenuated and remained nonsignificant.

Discussion

This study represents the first evaluation of supraventricular arrhythmias, including AFL, performed in outpatients. In >90% of cases, eligible patients can be discharged from the hospital the same day, confirming the potential efficiency of such a strategy to reduce logistic constraints due to the increasing number of RCA procedures performed in daily practice. After same day home discharge, we observed a comparable level of complications to that reported previously in large cohorts of inpatients.[6,7]

The lack of data regarding RCA in outpatients contrasts strongly with the daily practice of a number of centers performing coronary angioplasty on an outpatient basis.[1] The growing number of RCA procedures provides a rationale to draw on the experience of angioplasty departments. Factors supporting short-stay hospitalization (a few days) after RCA for routine arrhythmias in patients with no other co-morbidities are based on peripheral access site complications as well as the potential occurrence of cardiac tamponade or complete delayed atrioventricular block. However, most of these major complications occur mainly during the first few hours after RCA, or in a few cases after a significant time delay after RCA. In other words, a traditional short hospitalization of 2 or 3 days, despite a much higher cost, would not appear to be any safer than an ambulatory approach with short-time postprocedural monitoring.[2,12] The low rate of delayed complications as well as a prolonged mean time delay (5 days) for the occurrence of local complications in our study seems to confirm this issue. Moreover, although our patients were less selected than in the 2 previous reports regarding AP and AVNRT (in which patients aged >70 years, those with at-risk AP locations, those with the trans-septal approach, and overweight patients were not considered eligible to be treated on an outpatient basis),[2,3] our 1-month complication rate remained low and was similar to that reported previously in large worldwide registries of inpatients.[6]

AFL RCA now represents approximately 50% to 75% of overall procedures at many high-volume centers and certainly more at low-volume centers. The finding that anticoagulation does not significantly increase the risk for delayed complications after same day home discharge emphasizes the feasibility of performing RCA for AFL. Furthermore, our results also give preliminary information on the feasibility of trans-septal catheterization on an outpatient basis, although these data need to be confirmed in larger studies. In a retrospective study of 60 consecutive outpatients, Sorbera et al[13] reported no complications after trans-septal RCA of left-sided AP.[13]

Same-day home discharge after uncomplicated RCA for routine arrhythmias imposes a dramatic change in practice. Beyond the safety aspects, many hurdles need to be recognized that could influence the acceptance of this practice. Outpatient RCA may significantly reduce the cost of the

procedure even if this economic aspect was not a specific goal of the present study. Kalbfleisch et al[2] showed that the cost of RCA of accessory connections can be reduced by 33% when the procedure is performed on an outpatient basis or with only an overnight stay, and in another study, the total cost of definitive therapy was directly related to the length of hospital stay.[14] These health economics should be evaluated by applying local legislation. However, in the interest of patients, and from the social point of view, it would be more appropriate to allocate maximum resources to the procedure and shift to outpatient practice wherever it is feasible and safe.

To date, no comments on outpatient procedures are included in the guidelines for intracardiac electrophysiologic and catheter ablation procedures published by the American College of Cardiology, American Heart Association, and European Society of Cardiology Task Force.[6] We hope that these preliminary results will lead to further evaluations and the recommendation for outpatient RCA in selected patients.

It is possible that the results of our study were determined in part by the experience of the operator or center volume. Nevertheless, the number of procedures performed annually per operator remained smaller in Geneva compared with Toulouse, with no difference in terms of suitability and delayed complication rates. In addition, the absence of a control group and randomization process may represent a limitation of the study design. However, this prospective evaluation of a large cohort of selected eligible patients, enrolled on an "intent to treat" basis, with a complete 1-month follow-up rate, provides new and important information on the feasibility of RCA in outpatients.

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