



Comparison of long-term outcome between patients aged < 65 years vs. ≥ 65 years after atrial fibrillation ablation

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Abstract

Background Atrial fibrillation (AF) is the most frequent arrhythmia, and its prevalence is increasing with aging. We aimed to compare the long-term outcome data of patients < 65 years vs. ≥ 65 years who underwent catheter ablation (CA) for drug-refractory AF. **Methods** Consecutive patients with primary pulmonary vein isolation performed between March 2001 and December 2011, and those who completed a five-year of follow-up were divided into two groups: patients aged < 65 years into group 1, and patients aged ≥ 65 into group 2. Long-term outcome data concerning mortality, thromboembolic events (TE) and success rates were compared between these groups. **Results** A total number of 390 patients were included, group 1 contained 310 patients, and 80 patients in group 2. In group 2, patients had more often impaired renal function ($P < 0.001$) and thyroid disease ($P = 0.047$). A total of fifteen patients died during the 6.63 ± 2.1 years of follow-up, with a significantly higher incidence in the older group (8/80 vs. 7/310 patients, $P = 0.004$). The majority of fatal outcome was due to cancerous diseases in both groups. No difference was observed concerning the long-term TE rate (12/310 vs. 4/80 patients, $P = 0.75$). Rhythm control failed in 25.9% of the patients, with no difference between the groups: 26.4% in group 1 vs. 23.7% in group 2 ($P = 0.67$). **Conclusions** Despite growing prevalence of AF in aging population, the elderly patients are underrepresented in CA procedures. Similar clinical success and TE complication rate are observed between the age-groups. Our data suggest more liberal criteria might be applied while selecting patients for AF ablation.

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1 Introduction

Atrial fibrillation (AF) is the most frequent arrhythmia, and its prevalence is progressively increasing with the growing population of elderly patients.^[1,2] AF prevalence is estimated to double in the next 50 years.^[3] Due to the aging of the population and the increasing prevalence of AF as well as its associated comorbidities, AF has become an important public health issue.^[1,2] Pulmonary vein isolation (PVI) by catheter ablation (CA), is an established therapeutic option of drug-resistant AF in younger patients and implemented in guidelines. However, the optimal AF management in elderly AF patients is still unclear, as elderly adults are generally underrepresented in randomized clinical

trials.^[4,5] The survey conducted by the European Heart Rhythm Association, investigating the clinical practise in arrhythmia management Europe-wide, detected only 18.4% of the enrolled centres performed AF ablation without age limitation.^[2,6] The main reason for rejection of AF ablation in more than 10% of patients ≥ 75 years were concerns regarding procedure-related complications.^[2,6] To date, only few studies have evaluated safety and efficacy outcomes of elderly patients who underwent CA of AF and their results are contradictory.^[6–11] The present study sought to compare the long-term clinical outcome of CA of AF between patients aged < 65 years vs. ≥ 65 years.

2 Methods

Consecutive patients with drug-refractory AF who underwent PVI as the index procedure between March 2001 and December 2011, and who completed the five-year of follow-up (FU) were enrolled into the present study. Data collection for this study from our prospective registry was approved by the institutional review committee and was

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carried out in accordance with the ethical principles for medical research involving human subjects founded by Helsinki's declaration. All patients were eligible for AF ablation based on the currently accepted ACC/AHA/ESC guidelines.^[12,13] All patients provided informed consent prior the CA procedures. Patients were divided into two groups based on their age at the index procedure. Patients aged < 65 years were included into group 1. The second group of the patients were aged \geq 65 years, and will be referred to in the text as those in group 2. Long-term outcome data was retrospectively analysed and compared between these groups. Exclusion criteria were a prior PVI, severe valvular heart disease, inability to provide informed consent, contraindication to the use of anticoagulation post-ablation, presence of intracavitary thrombi detected by pre-procedural transoesophageal echocardiography and/or computed tomography. Altogether, 390 patients were selected for the final analysis.

2.1 Study variables

Baseline characteristics and clinical data were retrieved from the "Elpado" system, which is a computerized, institutional electronic patient dossier system. The advantage of this system is that it contains all patient-related health issues, also provided by peripheral health institutes in a scanned letter form. Thus, all relevant health events investigated in the present study including stroke, TIA and mortality which were recorded not only at the Cardiology Department of Erasmus MC but also at different Subspecialty's Department, could be tracked with high probability as well. The following data were compared between the investigated groups: age, gender, AF type, AF duration.

Cardiovascular comorbid diseases were retrieved as diabetes mellitus (DM), hyperlipidemia (HLP), hypertension (HT). Furthermore, the function of the renal and thyroid system was investigated. The following echocardiographic parameters were compared: left atrial (LA) size, ejection fraction (EF) and mitral insufficiency (MI). The stroke risk stratification (CHA₂DS₂-VASC) score was calculated from the individual stroke risk factors: congestive heart failure, hypertension, age \geq 75 years, diabetes mellitus, stroke or TIA, vascular disease, sex category (female) and age 65–74.9 years.

2.2 CA and peri-procedural management of anticoagulation

Complete electrical isolation of all pulmonary veins controlled by multipolar circular catheter was the procedural endpoint in all patients. Wide variety of techniques including cryoballoon (CB) in 66.6% and radiofrequency (RF) ablation in 33.3% of the entire patient cohort was performed.

Single PVI was performed in 51.5% (67/130) of the RF ablated patients. Additional linear lines were placed in 34.6% (45/130) of the RF ablations, while PVI+cavotricuspidal isthmus (CTI) ablation was performed in 15.3% (18/130).

The peri-ablation approach of anticoagulation and anti-arrhythmic drug management as well as the follow-up methodology was determined by the patient's electrophysiologist based on the currently accepted guidelines. Unsuccessful ablation was defined as rhythm control failure even despite repeated CA procedure and/or being on rhythm-control anti-arrhythmic drug (AAD) therapy. These patients were maintained on rate control AAD management with or without pacemaker (PM) backup. Otherwise, a MAZE procedure or a His-bundle ablation following PM implantation was accomplished.

2.3 Follow-up

The follow-up period started in all participants at the date of the PVI procedure and continued until outcome event (stroke/TIA after PVI), death, loss to follow-up or December 31, 2016, whichever came first.

2.4 Statistical analysis

Continuous variables are expressed as mean \pm SD or median and quartiles (Q1–Q3). Categorical data are shown as percentages. For statistical comparison, the not-normally distributed variables were compared with the Man-Whitney test, while ordinal variables were analyzed with the Chi-square test and nominal variables with the Student *t*-test. Statistical analysis was performed with SPSS Statistics for Windows, Version 24.0.

3 Results

Altogether, 390 patients were included into the final analysis, which 310 and were enrolled into group 1 and 80 were selected into group 2.

3.1 Patient characteristics

The baseline demographic and clinical data of the patients are summarized in Table 1. In the elderly cohort, more female patients were present ($P = 0.023$). Patients in group 2 also suffered more often from impaired renal function ($P < 0.001$) and from thyroid disease ($P = 0.047$). There was no significant difference between the study groups regarding comorbid conditions such as hypertension, diabetes, hyperlipidaemia, and heart failure. Similarity was observed among the groups concerning smoking habits, and body mass index (Table 1).

Table 1. Patient demographic and echocardiographic data.

	General patient cohort	Patients aged < 65 yrs	Patients aged ≥ 65 yrs	P-value
Female sex	105/390 (26.92%)	75/310 (24.19%)	30/80 (37.50%)	0.023
Paroxysmal AF	352/390 (90.25%)	280/310 (90.32%)	72/80 (90.0%)	0.833
AF duration	3.60 ± 5.03	3.64 ± 5.30	3.73 ± 3.85	0.869
LA size, mm	43.16 ± 6.52	43.22 ± 6.63	42.91 ± 6.25	0.719
Ejection fraction, %	61.19 ± 14.26	61.21 ± 14.28	61.08 ± 14.32	0.955
Mitral insufficiency	45/390 (11.53%)	35/310 (11.29%)	10/80 (12.50%)	0.699
Congestive heart failure	19/390 (4.87%)	13/310 (4.19%)	6/80 (7.50%)	0.243
Hypertension	180/390 (46.15%)	135/310 (43.54%)	45/80 (56.25%)	0.059
Diabetes	73/390 (18.71%)	17/310 (5.48%)	8/80 (10.0%)	0.197
Hyperlipidemia	25/390 (6.41%)	52/310 (16.77%)	21/80 (26.25%)	0.076
COPD	9/390 (2.30%)	8/310 (2.58%)	1/80 (1.25%)	0.693
Thyroid dysfunction	35/390 (8.97%)	23/310 (7.41%)	12/80 (15.0%)	0.047
Pulmonary embolism	2/390 (0.51%)	2/310 (0.64%)	0/80 (0%)	1.000
Stroke/TIA before PVI	22/390 (5.64%)	14/310 (4.51%)	8/80 (10.0%)	0.097
Vascular disease	15/390 (3.84%)	10/310 (3.22%)	5/80 (6.25%)	0.203
Smoking	35/390 (8.97%)	31/310 (10.0%)	4/80 (5.0%)	0.192
Body mass index	27.79 ± 10.29	28.66 ± 11.74	25.31 ± 3.20	0.123
GFR	79.45 ± 16.52	81.95 ± 15.66	69.96 ± 16.40	< 0.001
CHA ₂ DS ₂ VASC score	1.24 ± 1.14	0.94 ± 0.93	2.41 ± 1.15	< 0.001
CHA ₂ DS ₂ VASC score 0	117/390 (30.0%)	114/310 (36.77%)	3/80 (3.75%)	< 0.001
CHA ₂ DS ₂ VASC score 1	141/390 (36.15%)	128/310 (41.29%)	13/80 (16.30%)	< 0.001
CHA ₂ DS ₂ VASC score 2	81/390 (20.76%)	50/310 (16.12%)	31/80 (38.75%)	< 0.001
CHA ₂ DS ₂ VASC score 3	33/390 (8.46%)	14/310 (4.51%)	19/80 (23.75%)	< 0.001
CHA ₂ DS ₂ VASC score 4	13/390 (3.33%)	2/310 (0.64%)	11/80 (13.75%)	< 0.001
CHA ₂ DS ₂ VASC score 5	4/390 (1.0%)	2/310 (6.45%)	2/80 (2.50%)	0.188
CHA ₂ DS ₂ VASC score 6	1/390 (0.25%)	0/310 (0%)	1/80 (1.25%)	0.205

Data are presented as mean ± SD or *n* (%). AF: atrial fibrillation; CHA₂DS₂VASC: stroke stratification score; COPD: chronic obstructive pulmonary disease; GFR: glomerular filtration rate; LA: left atrial appendage; PVI: pulmonary vein isolation; TIA: transient ischemic attack.

No significant difference could be identified between the investigated groups concerning the echocardiographic parameters such as EF, LA size, and mitral valve insufficiency (Table 1). While, no difference was observed between the groups studying the thromboembolic history, the CHA₂DS₂VASC score profile was significantly higher in group 2 ($P < 0.001$).

3.2 Procedural data

The procedural data are summarized in Table 2. Of the entire patient population, 66% (260/390) underwent cryoballoon ablation as an index procedure, while 33% (130/310) received radiofrequency CA. There was no difference regarding the energy source of ablation (RF and CB) between the age-groups (Table 2). Cryoballoon ablation was utilized in 68% (211/310) in the group 1, whilst in 61% (49/80) in group 2. Radiofrequency energy was applied in 32% (99/310) among patients aged less than 65 years and in 39% (30/80) in group 2. There was no significant difference in

the radiation and procedure time between the examined groups (Table 2). Redo ablation was executed in 47% (184/390) within the entire patient population, significantly more often performed in the group 1 (156/310, 50.3%) as compared to group 2 (28/80, 35%) ($P = 0.017$).

Furthermore, His-bundle ablation was done in 4.8% (15/310) in the group 1 similarly to 8.7% (7/80) in the group 2. In addition, 22 out of 310 (7%) in group 1, likewise 7 out of 80 patients (8.7%) in group 2 underwent a MAZE procedure after PVI. There was no significant difference in PM implantation performed prior to or after the PVI procedure between the studied groups.

3.3 Mortality, thromboembolic events

The long-term clinical outcome data are shown in Table 3. Altogether 15 patients died during the mean 6.63 ± 2.1 years of FU. In group 2, a total of 8 out of 80 (10.0%) patients died, which is a significantly higher incidence compared to 7 out of 310 deaths (2.3%) in group 1 ($P = 0.004$). The

Table 2. Procedural data.

	General patient cohort	Patients aged < 65 yrs	Patients age ≥ 65 yrs	P-value
Cryoballoon ablation	260/390 (66.6%)	212/310 (68.38%)	48/80 (60.0%)	0.183
Radiofrequency ablation	130/390 (33.33%)	98/310 (31.61%)	32/80 (40.0%)	0.183
Redo ablation	184/390 (47.2%)	156/310 (50.32%)	28/80 (35.0%)	0.017
Number of redo ablations per patient	0.58 ± 0.69	0.71 ± 0.4	0.58 ± 0.65	0.004
Radiation time, min	52.65 ± 28.1	53.64 ± 26.62	48.86 ± 25.86	0.161
Procedure time, min	217.50 ± 86.2	218.17 ± 86.13	214.77 ± 87.14	0.768
MAZE procedure after PVI	29/390 (7.43%)	22/310 (7.09%)	7/80 (8.75%)	0.634
His-ablation after PVI	22/390 (5.64%)	15/310 (4.83%)	7/80 (8.75%)	0.179
PM implantation before PVI	14/390 (3.58%)	10/310 (3.22%)	4/80 (5.0%)	0.498
PM/CRT implantation after PVI	29/390 (7.43%)	31/310 (10.0%)	8/80 (10.0%)	1.000
Failed rhythm control strategy	101/390 (25.89%)	82/310 (26.45%)	19/80 (23.75%)	0.670

Data are presented as mean ± SD or *n* (%). CRT: cardiac resynchronization therapy; PM: pacemaker; PVI: pulmonary vein isolation.

Table 3. Outcome data after PVI for AF.

	General patient cohort	Patients aged < 65 yrs	Patients aged ≥ 65 yrs	P-value
Mortality	15/390 (3.84%)	7/310 (2.25%)	8/80 (10.0%)	0.004
Stroke/TIA occurrence	16/390 (4.10%)	12/310 (3.87%)	4/80 (5.00%)	0.750
Stroke-alone occurrence	6/390 (1.53%)	4/310 (1.29%)	2/80 (2.5%)	0.607
TIA-alone	10/390 (2.56%)	8/310 (2.58%)	2/80 (2.50%)	1
Stroke/TIA occurrence after PVI, yrs	4.71 ± 3.11	5.17 ± 3.38	3.30 ± 1.79	0.186
Stroke occurrence after PVI, yrs	5.83 ± 3.10	7.33 ± 2.29	2.84 ± 2.33	0.008
TIA occurrence after PVI, yrs	4.03 ± 3.08	4.10 ± 3.42	3.75 ± 1.84	0.859
Follow-up period, yrs	6.63 ± 2.10	6.78 ± 2.15	6.05 ± 1.80	0.002

Data are presented as mean ± SD or *n* (%). AF: atrial fibrillation; PVI: pulmonary vein isolation; TIA: transient ischemic attack.

cause of death in all but two patients was cancerous disease. One patient died from intracranial bleeding and in the other patient the fatal outcome was caused by ischemic stroke. Both patients were aged above 65 years. Neither the long-term stroke/TIA occurrence [4/80 patients (5%) in group 2 vs. 12/310 (3.9%) patients in group 1] nor the stroke-alone [2/80 (2.5%) in group 2 vs. 4/310 (1.3%) patients in group 1], and the TIA-alone [2/80 (2.5%) in group 2 vs. 8/310 (2.5%) patients in group 1] occurrence differed significantly between the age-groups. However, stroke-alone in group 1 occurred significantly later following the PVI with a mean of 7.33 ± 2.29 years as compared to a 2.84 ± 2.33 years in the older age group ($P = 0.008$).

3.4 Clinical outcome

Unsuccessful ablation was observed altogether in 25.9% of the patient cohort, with no statistically significant difference among the groups: 82/310 (26.4%) patients in group 1 vs. 19/80 (23.7%) patients in group 2 ($P = 0.67$). In the present mixed AF cohort, 289 out of 390 (74.1%) patients could be maintained in SR with or without AAD-therapy. In total, a mean of 0.58 ± 0.69 redo procedures was performed. No difference in long-term clinical success was found be-

tween the two age groups as 228/310 (73.5%) patients in the younger age group with a mean of 0.71 ± 0.4 procedures remained in SR, while in 61/80 (76.2%) patients in the elderly group after a mean of 0.58 ± 0.65 procedures SR could be retained (Table 3).

4 Discussion

The major finding of the present study is that the long-term clinical success and thromboembolic complication rate after PVI do not differ between patients aged < 65 years as compared to elderly patients aged ≥ 65 years. Moreover, similar clinical success rate can be achieved between the age-groups, despite the fact that more redo procedures per patient were performed in the group with younger patients. Interestingly enough, stroke-alone occurred significantly later among younger patients as compared to those aged above 65 years. Our data suggest that, more liberal selection criteria for CA of AF should be considered, irrespective of the age of the patients. This would be especially important given the fact that, despite the increasing prevalence of AF among the elderly patients, they are generally underrepresented in AF ablation procedures.

4.1 Long-term mortality

The study by Srivasta, *et al.*,^[14] investigating 6207 patients undergoing AF ablation, showed that age ≥ 80 years was an independent predictor factor leading to more than 8-fold increase in probability of 30-day death after PVI. Hoffman, *et al.*,^[15] demonstrated with the German ablation registry, that age was an independent predictor of death and severe, nonfatal peri-procedural complications. On the contrary, Moser, *et al.*,^[2] reported that the in-hospital death rate was not higher in the elderly cohort aged ≥ 75 years as compared to younger patients after CA of AF. At a first glance, our long-term analysis appears to show a higher mortality rate among the elderly patients after PVI. However, the AF ablation related mortality was not excessively high in the elderly groups. Furthermore, it is essential to emphasize that the majority of the fatal outcomes were caused by cancerous disease.

4.2 Long-term thromboembolic complications

The world-wide survey of CA of AF by Cappato, *et al.*,^[13] revealed that major complications occurred in 4.5% after PVI in patients aged between 15 and 90 years. The study by Corrado, *et al.*,^[9] Bertaglia, *et al.*,^[16] Bunch, *et al.*,^[17] and Zado, *et al.*,^[7] demonstrated that there is no increased risk of adverse event among elderly patients after PVI. Furthermore, studies by Bunch, *et al.*,^[17] Santageli, *et al.*,^[8] and Metzner, *et al.*,^[11] analyzing patients aged ≥ 75 years found that stroke rates ranged from 0 to 0.7% and TIA rates from 0 to 0.3%. Moser, *et al.*,^[2] found a 0.2% peri-procedural complication rate which is in line with the previous results, however there was a significant difference among age-groups with a 1.3% peri-procedural stroke rate in patients ≥ 75 years vs. 0.1% in younger patients ($P = 0.001$). In contrast, Oral, *et al.*,^[18] could find an increase in TE events in patients aged above 70 years after PVI. Also, Guiot, *et al.*,^[19] could show that age > 75 years is an independent predictor of late cerebrovascular event after AF ablation. Our results confirm that long-term TE event does not differ significantly between younger patients aged < 65 years as compared to elderly ones aged ≥ 65 years ($P = 0.75$). However, our overall TE event rate is higher than reported in previous studies, as all the stroke/TIA occurrence was observed in 16 out of 390 (4.1%) patients, with 4/310 (3.87%) patients in the younger age group and with 4/80 (5%) patients in the elderly age group. This extensional result might be explained by the used FU methodological specialties. The “Elpado” electronic patient dossier dataset including all patient-related health issues, also those provided by peripheral health centers, made possible to gather all relevant outcome data. Our present study had an ex-

tended FU as compared to the studies mentioned above, with a mean FU duration of 6.63 ± 2.1 years. In our opinion, this is the essential minimal duration of a FU period needed to recognize TE events after PVI, as all stroke/TIA events happened with a mean of 5.17 ± 3.38 years in the younger and with a mean of 3.30 ± 1.79 years in the older patient cohort. Furthermore, it is important that the stroke-alone event occurred significant later after PVI with a mean of 7.33 ± 2.29 in the younger age group as compared to 2.84 ± 2.33 year in the elderly age group ($P = 0.008$). One could argue that because of the length of these intervals, that these TE complications are not primary being caused by the ablation procedure itself, but could for example being caused by diminished atrial transport function. Based on these findings, better anticoagulation management and clearer guidelines on long-term FU methodologies following PVI procedures are required.

4.3 Long-term clinical success

Catheter ablation for AF was associated with a comparable long-term clinical outcome among both investigated groups, despite the fact that more redo procedures in the younger age-group were performed. In the present mixed AF cohort, SR could be maintained in 74.1% of the patients with a mean of 0.58 ± 0.69 redo procedures. No difference in long-term clinical success was found between the age-groups, as in 73.5% of the younger patients and in 76.2% of the elderly patients, SR could be preserved. Our findings are in line with the results of Metzner, *et al.*,^[11] who demonstrated a 76% clinical success rate after a mean of 1.5 procedures of CA of paroxysmal AF in pts older than 75 years. Our results are also comparable with the findings published by Santageli, *et al.*,^[8] who found a 87% success rate of AF ablation in a mixed AF cohort aged > 80 years with a mean FU of 18 ± 6 months. Our data confirms that AF ablation in the elderly patients can provide a favorable long-term clinical outcome. Moreover, better understanding of AF mechanism evolving technological developments are essential to further improve the long-term AF ablation outcomes.^[20]

4.4 Study limitations

The present study is a retrospective, single-center study, investigating a relatively small patient cohort of patients who underwent CA for AF. Besides, a wide variety of energy sources for PVI and ablation strategies were used. Only a limited number of patients with persistent or long-stranding persistent AF were analyzed. This study aimed to investigate as much elderly patients as possible, but still only few patients of the cohort were aged above 75 years.

4.5 Conclusions

Catheter ablation for atrial fibrillation in patients ≥ 65 years has a similar safety profile as compared to a younger patient cohort. No significant difference in thromboembolic complications following PVI is observed between the age-groups. Older patients have a comparable long-term clinical success rate compared to younger ones, despite less redo procedures were performed among the elderly patient population. Our data suggests, that more liberal selection criteria for drug-refractory AF ablation could be introduced, irrespective of the age of patients. Prospective, randomized, control trials with long-term follow-up are necessary to confirm our results.

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