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## CHAPTER 8

# LOW 30-DAY MORTALITY AFTER ATRIAL FIBRILLATION ABLATION; RESULTS FROM THE NETHERLANDS HEART REGISTRATION

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Submitted

#### INTRODUCTION

Catheter ablation has become a cornerstone in the treatment of atrial fibrillation (AF). Procedural complications have been reported to be low, 3.6% of patients undergoing AF ablation develop a procedural related complication, 0.9% a life-threatening complication, and mortality is 0.00 - 0.57% depending on the study type and sample size.<sup>1:4</sup> Most large studies only report in-hospital death or provide limited data on the cause of death.<sup>2, 3</sup> Generalizability of these studies might be limited because of differences in population characteristics and ablation volume. Therefore, we assessed 30-day mortality and report the cause of death in a large-scale registry of patients undergoing catheter AF ablation in the Netherlands.

#### METHODS

We used data from the Netherlands Heart Registration, a nationwide registry in which 15 out of 16 Dutch ablation centers participate in the value-based health care program and present AF ablation outcomes.<sup>4</sup> The medical ethics board MEC-U, Nieuwegein, the Netherlands, issued a waiver for informed consent. All patients who underwent catheter AF ablation between 2013 – 2019 (inclusive) were included. Participating hospitals retrieved mortality status from the municipal death registration and obtained the cause of death from the medical chart. Thirty-day mortality was categorized in procedural and non-procedural death.

#### Statistical analysis

For the collected clinical data, continuous variables are presented with a mean ± standard deviation and categorical variables with numbers and percentages. The independent t-test, Mann-Whitney U test and Fishers' exact test were used to compare differences between the survivors and deceased patients.

#### RESULTS

In total, 25,858 patients underwent AF ablation, of whom vital status was available in 25,828 (99.9%). The mean age was 61 ±10 years, 32% were female, the average body mass index was 27.4 ±4.2kg/m<sup>2</sup>, and CHA<sub>2</sub>DS<sub>2</sub> VASc (Congestive heart failure, Hypertension, Age  $\geq$ 65years, Diabetes, Stroke (doubled), vascular disease, Age  $\geq$ 75years (doubled), Sex) was 1.6 ±1.4. On average, the ablation centers performed 246 [range 55 – 514] AF ablations/year.

Fourteen (0.05%) patients died within 30-days. Nine (0.04%) were considered procedure related, four (0.02%) were considered non-procedural, and the cause of death was unknown in one patient. Compared to survivors, deceased patients were older ( $66 \pm 7$ versus  $61 \pm 10$  year, p = 0.019) and more frequently had mitral valve regurgitation (p = 0.005) (**Table 1.**). Procedure related death included cardiac tamponade (n = 3), cardiac tamponade during elective percutaneous coronary intervention shortly after AF ablation (n = 1), atrio-oesophageal fistula (n = 1), stroke (n = 2), pneumonia and reactive pericarditis (n = 1), and right ventricular heart failure during thrombocytosis (n = 1). The non-procedural death included pancreas carcinoma (n = 1), palliative care because of pleural fluid suspected for malignancy (n = 1), non-natural death (n = 1), and exacerbation of preexisting pulmonary fibrosis (n = 1) Table 1

	Survivors (n = 25,814)	Deceased patients (n = 14)	p value
Age	61.2 ± 9.8	66.3 ± 7.2	0.019
Female	8356 (32.4)	6 (42.9)	0.402
Body mass index (kg/m²)	(22,968) 27.4 ± 4.2	(n = 13) 25.8 ± 3.0	0.089
CHA <sub>2</sub> DS <sub>2</sub> VASc	(n = 22,864) 1.6 ± 1.4	(n = 13) 2.6 ± 2.1	0.054
Left atrial volume index (ml/ m²)	(n = 11,849) 35.4 ± 11.3	(n = 8) 38.3 ± 13.0	0.561
Mitral valve regurgitation	(n = 19,942)	(n = 13)	0.005
None/Mild	18,687 (93.7)	10 (76.9)	
Moderate	1,222 (6.1)	2 (15.4)	
Severe	33 (0.2)	1 (7.7)	
AF type	(n = 23,006)	(n = 13)	0.647
Paroxysmal AF	16,538 (71.9)	11 (84.6)	
Persistent AF	5,993 (26.0)	2 (15.4)	
LS persistent AF	484 (2.1)	0	
Ablation method	(n = 23,204)	(n = 13)	0.227
Conventional RF	11,491 (49.5)	8 (61.5)	
Phased RF	3,146 (13.6)	3 (23.1)	
Cryoballoon	8,482 (36.5)	2 (15.4)	
Laser	52 (0.2)	0	
Other	33 (0.2)	0	
Previous ablation	(n = 23,289) 5,625 (24.2)	(n = 13) 3 (23.1)	1.000

Table 1 Baseline characteristics.  $CHA_2DS_2$  VASc (congestive heart failure, hypertension, age ( $\geq$ 75, doubled), diabetes, stroke (doubled), vascular disease, age ( $\geq$  65), sex), atrial fibrillation (AF), longstanding (LS), radiofrequency (RF), Phased RF including multi array septal catheter (MASC), multi array ablation catheter (MAAC). Data is presented with a mean, standard deviation ( $\pm$ ) or number (%).

#### DISCUSSION

This study presents 30-day mortality after AF ablation from all value-based health care ablation centers in the Netherlands. Only 0.1% of the mortality data was missing in the cohort of >25,000 patients, and 0.05% of patients died within 30 days. In comparison, the 2019 crude death rate in the Netherlands was 8.8/1000 persons, corresponding to a 30 day mortality of 0.07% and the crude death rate for persons aged 50-80 years was 10.8/1000 persons (0.09% for 30 days).<sup>5</sup> Thus, the 30-day mortality rate after AF ablation was lower than the crude death rate in the Netherlands.

The strength of our study relies on the cohort size, data completeness and the description of the cause of death. In comparison, Cheng et al. reported 30-day mortality after AF ablation with admission and readmission data retrieved from a large nationwide database.<sup>3</sup> They observed a tenfold higher mortality of 0.46% of patients died during the first admission or at readmission. Procedural complications and procedures performed in low-volume ablation centers (<21 AF ablations/year) were associated with increased 30-day mortality risk. As that study only included patients who died in hospital, the true death rate may be higher.<sup>3</sup> In addition, a recent systematic review and meta-analysis showed that patients undergoing AF ablation in high-volume centers ( $\geq$ 50 AF ablations/year) had a 67% lower mortality risk after AF ablation than those treated in low-volume centers.<sup>6</sup> In our study, nine deaths (64% of the deaths, 0.04% of the total) were considered procedural, and AF ablation was performed primarily in high-volume centers with cardiothoracic surgical backup onsite. The population described was relatively young and healthy, most of the patients had a history of paroxysmal AF and the average CHA<sub>2</sub>DS<sub>2</sub> VASc was low.

The main limitation of this study is that the 30-day mortality was obtained in the Dutch population, and generalizability to other countries may be limited due to differences in population characteristics or ablation volume. Secondly, because this is a registry study, the reporting of some baseline characteristics was incomplete. However, we only provide a descriptive analysis, and by using the municipal death registration, very few values were missing for 30-day mortality.

#### CONCLUSION

In a setting where AF ablation is performed in high-volume centers with cardiothoracic surgical backup onsite, 30-day mortality rate was extremely low and did not exceed the crude death rate in the Netherlands.

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