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Prevalence and Causes of Fatal Outcome in Catheter Ablation of Atrial Fibrillation

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Objectives The purpose of this study was to provide a systematic multicenter survey on the incidence and causes of death occurring in the setting of or as a consequence of catheter ablation (CA) of atrial fibrillation (AF).

Background CA of AF is considered to be generally safe. However, serious complications, including death, have been reported.

Methods Using a retrospective case series, data relevant to the incidence and cause of intra- and post-procedural death occurring in patients undergoing CA of AF between 1995 and 2006 were collected from 162 of 546 identified centers worldwide.

Results Thirty-two deaths (0.98 per 1,000 patients) were reported during 45,115 procedures in 32,569 patients. Causes of deaths included tamponade in 8 patients (1 later than 30 days), stroke in 5 patients (2 later than 30 days), atrioesophageal fistula in 5 patients, and massive pneumonia in 2 patients. Myocardial infarction, intractable torsades de pointes, septicemia, sudden respiratory arrest, extrapericardial pulmonary vein (PV) perforation, occlusion of both lateral PVs, hemothorax, and anaphylaxis were reported to be responsible for 1 death each, while asphyxia from tracheal compression secondary to subclavian hematoma, intracranial bleeding, acute respiratory distress syndrome, and esophageal perforation from an intraoperative transesophageal echocardiographic probe were causes of 1 late death each.

Conclusions Death is a complication of CA of AF, occurring in 1 of 1,000 patients. Knowledge of possible precipitating causes is key to operators and needs to be considered during decision making with patients. (J Am Coll Cardiol 2009;53:1798–803) © 2009 by the American College of Cardiology Foundation

Catheter ablation (CA) around the pulmonary vein (PV) region is increasingly used to treat atrial fibrillation (AF) (1–4). The procedure is generally effective and safe (5,6), but devastating complications may occasionally occur, some of them ultimately leading to death of the patient (5,7). Systematic assessment of death rates and precipitating causes is difficult, because of the rare occurrence of death, making its description anecdotal in single-center reports (8–10), and because of reluctance to publicize this information (7). As a consequence, physicians performing CA of AF sometimes discuss this complication, but a clear picture about its incidence in the real-world practice is lacking. Yet, mortality data remain important and may serve as a guide to

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clinicians considering CA of AF. We provide a systematic report on the incidence and causes of death associated with CA of AF obtained in a large retrospective case series.

Methods

Study design. Data relevant to determining the incidence and the precipitating causes of death were derived from 2 consecutive questionnaires developed by an independent steering committee (represented in the authors' list) with the aim of investigating the methods, efficacy, and safety of CA of AF as observed in a large number of electrophysiology (EP) laboratories worldwide between 1995 and 2002 (5) (first questionnaire) and between 2003 and 2006 (second questionnaire) (Online Appendix). In both questionnaires, centers were asked to report the number of early (i.e., within 30 days from intervention) and late (i.e., after 30 days from, but as a consequence of, intervention) deaths and to provide a description of the sequence of precipitating events and ultimate cause of death. The surveys were approved by the institutional review board at Policlinico, San Donato.

Overall, questionnaires were sent to 546 EP centers (823 physician contacts) worldwide. Centers were selected from the following sources: the Heart Rhythm Society member list, the European Society of Cardiology member list, and official lists of national working groups on arrhythmias in different countries of Europe; Asia; North, Central, and South America; Africa; and Oceania. Between November 2001 and June 2002 for the first questionnaire, and between March and November 2006 for the second questionnaire, selected addresses were contacted by fax, and contact was re-enforced by means of e-mail in all cases. For addresses not responding after the first contact, a second contact was attempted 1 month later using the same modalities. Each nonresponder was telephoned to confirm the contact information. All questionnaires were submitted under the assumption that the identity of physicians and institutions would remain anonymous. Completed questionnaires were sent to an independent statistical center (Statistical Unit of Policlinico, San Donato, Italy) for analysis. All data were entered into a database using Excel (Microsoft, Redmond, Washington), and the statistical analysis was performed using the SPSS software (SPSS Inc., Chicago, Illinois).

Of the 546 identified EP centers, 39 were excluded because they did not perform interventional EP, and 141 because they declared no active program for CA of AF. Of all interviews submitted to the remaining 366 centers (eligible centers), 162 were complete (i.e., more than 80% of all questions were answered with full disclosure of efficacy and safety data) (11), 99 were incomplete, and 105 were not returned. This yielded a response rate of 71%. Causes of incomplete interviews included omitted information about efficacy in 64 centers and absence of a prospectively maintained database in 29 centers.

In order to investigate the contribution of center experience in determining the risk of intraprocedural or post-procedural death, the incidence of death was compared in 3 groups selected according to the number of patients treated (i.e., fewer than 100 patients, between 100 and 250 patients, and more than 250 patients). The contribution of the type of CA technique in determining the risk of intraprocedural or post-procedural death was calculated by comparing the incidence of death in subgroups of patients undergoing CARTO-guided left atrial ablation versus Lasso-guided PV isolation. The former technique implied 3-D–assisted electroanatomical reconstruction of the target ablation area (2), whereas the latter technique referred to segmental PV isolation using a circular multipolar mapping catheter advanced at the PVs, guiding energy delivery through an ablation catheter proximal to it under fluoroscopy guidance (3). The contribution of the type of catheter used in determining the risk of intraprocedural or periprocedural death was calculated by comparing the incidence of death in subgroups of patients receiving radiofrequency (RF) delivery by means of a 4-mm–tip catheter versus an irrigated or cooled-tip catheter. These ablation techniques and ablation catheters were selected post hoc, as they were those most frequently used by centers participating in the surveys. Subgroups were formed based on patients treated in centers with exclusive experience in the analyzed strategies.

Abbreviations and Acronyms

AF = atrial fibrillation
CA = catheter ablation
EP = electrophysiology
PV = pulmonary vein
RF = radiofrequency
SV = supraventricular
TEE = transesophageal echocardiographic

Statistical analysis. Data are expressed as percentages for the nominal variables, as medians for the ordinal variables, and as means for continuous variables. Discrete variables were compared using the chi-square or Fisher exact test as appropriate. A value of $p < 0.05$ was considered statistically significant.

Results

During the time period covered by the questionnaires, 32,569 patients underwent 45,115 attempts at CA of AF (median procedures per center, 275; range 2 to 1,328). Table 1 reports the main characteristics of the 2 surveys. Thirty-one centers reported 32 deaths. A detailed list of the different causes of death is reported in Table 2. Twenty-five deaths occurred within 30 days, and 7 deaths occurred later than 30 days after the procedure. Among early deaths, 13 occurred intraoperatively including 5 due to tamponade leading to irreversible pump failure, 2 due to stroke, 1 due to myocardial infarction leading to irreversible pump failure, 1 due to extrapericardial PV perforation, 1 due to torsades de pointes refractory to multiple attempts of electrical defibrillation and intravenous antiarrhythmic drug therapy (not further specified), 1 due to irreversible sudden respiratory arrest, and 1 due to anaphylaxis secondary to intravenous prothamine administration in the setting of tamponade. Thirteen more early deaths occurred in the hours or days

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Table 1 Main Characteristics of the Present Survey

No. of centers reporting data on efficacy and safety	162
No. of centers reporting data on safety	262
No. of patients	32,569
No. of procedures	45,115
Male, %	61.9
Lower and upper age limit for entry, yrs	18–90
Proportion (%) of centers based on no. of procedures per year	
<20	35
21 to 50	28
51 to 100	24
>100	13
Proportion (%) of centers with experience in one ablation technique	
Lasso-guided	27
CARTO-guided	48
Other techniques	4
Combination	21

following the ablation procedures and included atrioesophageal fistula in 5 patients, cardiac arrest secondary to anoxic encephalopathy in 2 patients experiencing intraoperative tamponade, massive pneumonia refractory to antibiotic therapy in 2 patients, massive hemothorax from the site of subclavian puncture several hours after an uneventful procedure in 1 patient, acute occlusion of both lateral PVs in 1 patient, cardiac arrest secondary to ischemic cerebral damage in 1 patient, and septicemia unrelated to PV stenosis or atrioesophageal fistula in 1 patient. Among late deaths, 5 were due to complications from intraoperative or perioperative early events including cardiac arrest secondary to stroke in 2 patients, fatal tracheal compression from subclavian hematoma in 1 patient receiving subclavian puncture at time of procedure, acute respiratory distress syndrome possibly related to oral amiodarone therapy in 1 patient, and esophageal perforation from an intraoperative transesophageal echocardiographic probe in 1 patient. Two more late deaths were related to acutely precipitating events and included tamponade leading to irreversible pump failure occurring 50 days after the procedure in 1 patient with post-operative stroke, and intracranial bleeding under oral anticoagulation therapy in 1 patient with post-operative stroke. The incidence of death according to the type of complication is reported in Table 3.

Death rates did not significantly differ in centers with ≤100 overall performed procedures (0.11% in 1,765 patients undergoing 2,400 procedures in 93 centers), centers with 100 to 250 overall performed procedures (0.11% in 6,100 patients undergoing 8,418 procedures in 37 centers), and in centers with >250 overall performed procedures (0.09% in 24,704 patients undergoing 37,250 procedures in 32 centers) ($p = 0.87$). Similarly, no differences were found in death rates between patients undergoing CARTO-guided CA (0.18% in 4,665 patients undergoing 6,438 procedures in 21 centers) and patients undergoing Lasso-guided CA (0.08% in 2,385 patients undergoing 3,387 procedures in 17 centers) ($p = 0.51$). Finally, death rates did

Table 2 Causes and Proportions of Death in 32,569 Patients From 162 Centers

Cause of Death	Intraoperative (n)	Post-Operative (n)	Total (n)	Proportion (%)
Early death (within 30 days from procedure)				
Tamponade with subsequent cardiac arrest	5	2	7	21.8
Atrioesophageal fistula	0	5	5	15.6
Peripheral embolism				
Stroke	2	1	3	9.4
Myocardial infarction	1	0	1	3.1
Massive pneumonia	0	2	2	6.3
Extrapericardial pulmonary vein perforation	1	0	1	3.1
Irreversible torsades de pointes	1	0	1	3.1
Septicemia (3 weeks after procedure)	0	1	1	3.1
Sudden respiratory arrest	1	0	1	3.1
Acute pulmonary vein occlusion of both lateral veins	0	1	1	3.1
Hemothorax	0	1	1	3.1
Anaphylaxis	1	0	1	3.1
Late death (after 30 days from procedure)				
Complications from prior perioperative events				
Stroke			2	6.3
Tracheal compression from subclavian hematoma			1	3.1
Acute respiratory distress syndrome			1	3.1
Esophageal perforation from intraoperative TEE probe			1	3.1
Acutely precipitating events				
Tamponade with subsequent cardiac arrest in prior stroke			1	3.1
Intracranial bleeding under oral anticoagulation therapy in prior stroke			1	3.1

TEE = transesophageal echocardiographic.

Table 3 Fatality Rates According to Type of Complication

Complication	Death/Overall Events (n)	Rate (%)
Tamponade	7/331	2.3
Atrioesophageal fistula	5/7	71.4
Massive pneumonia	2/2	100.0
Peripheral embolism		
Stroke	3/59	5.1
Myocardial infarction	1/3	33.3
Torsades de pointes	1/1	100.0
Septicemia (3 weeks after procedure)	1/3	33.3
Sudden respiratory arrest	1/1	100.0
Acute pulmonary vein occlusion of both lateral veins	1/6	16.7
Internal bleeding (includes hemothorax, subclavian hematoma, and extrapericardial pulmonary vein perforation)	3/21	14.3
Anaphylaxis	1/6	16.7
Acute respiratory distress syndrome	1/1	100.0
Esophageal perforation from intraoperative TEE probe	1/1	100.0
Intracranial bleeding under oral anticoagulation therapy in prior stroke	1/4	25.0

TEE = transesophageal echocardiographic.

not significantly differ between patients undergoing CA with the use of a 4-mm–tip catheter electrode (0.19% in 13,470 patients undergoing 4,771 procedures in 21 centers) and patients undergoing CA with the use of an irrigated/cooled-tip electrode (0.23% in 5,271 patients undergoing 7,327 procedures in 9,413 centers) ($p = 0.19$). Centers reporting death events did not differ with other centers with regard to efficacy and safety rates ($p = 0.78$ and $p = 0.82$, respectively).

Discussion

Death is an uncommon complication associated with CA techniques. In previous surveys conducted in patients undergoing ablation, death was reported as a procedure-related complication in 0.11% to 0.30% of patients with regular supraventricular (SV) tachycardias (12,13) and 0.31% in patients with ventricular tachycardias (13). In these surveys, causes of death were either incompletely reported or not reported. Systematic evaluation of causes is impaired by small numbers even in multicenter studies with large populations of investigated patients (12,13).

Catheter ablation for curative treatment of AF is associated with unique considerations that may precipitate fatal complications. These include transseptal puncture, prolonged catheter manipulation in the left atrium, and large doses of cumulative RF energy delivered in the left atrium in the context of a high level of systemic anticoagulation. In a recent survey, transseptal catheterization was shown to be a cause of death in 0.2% of procedures (14).

In the present study, we found that the incidence of death associated with CA of AF is 1 of every 1,000 patients. Cardiac tamponade was the most frequent fatal complication leading to intraoperative irreversible pump failure secondary to myocardial hypoperfusion, post-operative early cardiac arrest, or sudden pericardial bleeding occurring 50 days after the procedure. Late tamponade represents an unreported complication. Development of atrioesophageal fistulas was the second most frequent cause of death. This complication has been reported to present between 10 and 16 days after the ablation procedure, and to be fatal in the majority of patients (7–10). Causes of death in these patients include cerebral air embolism, massive gastrointestinal bleeding, and septic shock (15). Ischemic brain or myocardial damage was the third most frequent cause of death. Modes of death associated with this complication included intraprocedural acute myocardial infarction as well as intra- or post-procedural stroke. The fourth most common cause of death was extrapericardial bleeding mostly due to subclavian or PV perforation. Another cause of death included massive pneumonia refractory to antibiotic therapy. Conditions such as torsades de pointes, sudden respiratory arrest, and acute respiratory distress syndrome appear to be unspecific causes of death; it is likely that they represented the final event of unrecognized causes ultimately leading to a fatal outcome. Some of the complications leading to death in this series, such as bleeding from the subclavian access site, are clearly unrelated to CA of AF and could be observed for EP procedures requiring the same access; however, it is possible that the anticoagulation strategies operated for the purpose of this specific procedure may have influenced the outcome.

The larger prevalence of causes of death such as tamponade, peripheral embolism, and internal bleeding reflects a higher frequency in these complications, but their probability to cause death once they have developed is smaller as compared with more occasional complications such as atrio-esophageal fistula, septicemia, and acute respiratory distress syndrome.

Center experience did not appear to influence the incidence of death. CARTO-guided left atrial ablation and

Lasso-guided PV isolation were not associated with different risks of death. A 2.5-fold increase in death rate observed in patients undergoing irrigated or cooled-tip ablation versus 4-mm–tip ablation raises some concern with regard to the potential harm of the first type of catheter, although this difference did not reach statistical significance. Careful prospective monitoring is advised to exclude a greater degree of harm with use of more powerful ablation catheters.

The incidence of perioperative death in this survey did not differ from the incidence of perioperative death observed in catheter ablation of regular SV tachycardias as previously assessed with a similar retrospective method (12). Although the comparison is limited by the time interval between the 2 surveys, which may have improved the performance standards and experience of investigators, this observation suggests that procedural challenges exclusively associated with CA of AF may not be associated with an additional risk of death when compared with catheter ablation of regular SV tachyarrhythmias.

Study limitations. First, this survey reflects the experience of those centers that volunteered to respond to our call and does not correspond to the experience of all contacted centers. Therefore, the incidence of perioperative mortality and the distribution of causes of death observed in the entire population of patients undergoing CA of AF may be different from that observed in the present study. In a recent study that also used an anonymous volunteer method for data collection (7), at least 4 more cases of fatal atrioesophageal fistula were reported, which were not made available to the present surveys. Second, the retrospective nature of the study may lead to underestimation of the true incidence of events. Prior studies in CA of regular SV tachycardias have documented a 3-fold increase in the mortality rates of prospective surveys (13) when compared with mortality rates of retrospective studies (12). The risk of a higher incidence of procedure-related death and other complications when collecting data according to a prospective method needs to be highlighted, particularly when considering that about one-third of patients require multiple procedures for curative treatment. Third, systematic assessment of predictors of perioperative death was limited by the lack of individual patient data in the study database as well as by the very low incidence of fatal events and their variable nature. This limit is reflected in the inability to gather individual data on the victims' ages, sex, type of AF, or comorbidities according to a systematic data collection mode. Also, the subgroup analyses performed in this study were based on an arbitrary selection of identifiable parameters or cutoff limits made available by the specific questions raised by the questionnaires, and excluded investigation on the role of intermediate conditions such as those observed in centers experiencing a variety of techniques or catheters throughout their experience. It is possible that designing questionnaires with more-detailed questions or selecting alternative cutoff values may have led to different results. Similarly, different results may have been obtained using the same questionnaires according to a prospective design. However, it should be noted that the very low incidence of the target event evaluated in this study makes it unlikely that any investigated clinical and instrumental parameter would result in being a significant predictor of outcome. Finally, description of precipitating causes reflects the clinical accuracy of responding physicians. Although the vast majority of reported causes appears obvious, some (e.g., torsades de pointes and sudden respiratory arrest) likely represent the final event of unspecified or unrecognized conditions primarily responsible for a fatal outcome.

Conclusions

Despite these limitations, the present study provides an unprecedented view on the causes and incidence of death in patients undergoing CA of AF, which may be of help in designing more appropriate and efficient EP settings for increasing current standards of procedural safety, planning start programs in EP centers with limited facilities or experience, delivering recommendations by regulatory authorities, and developing safer technologies. Finally, awareness about this complication needs to be considered during decision making with patients.

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Key Words: atrial fibrillation ■ catheter ablation ■ supraventricular ■ radiofrequency ■ pulmonary vein.

APPENDIX

For the AF survey I and II and a list of the participating centers, please see the online version of this article.