

## EDITORIAL COMMENT

# A 1 Per 1,000 Mortality Rate After Catheter Ablation of Atrial Fibrillation

## An Acceptable Risk?\*

Bernard Belhassen, MD

*Tel-Aviv, Israel*

Catheter ablation of atrial fibrillation (AF) is increasingly performed in most electrophysiologic centers worldwide, resulting in long-term arrhythmia control/cure rates  $\geq 70\%$  (1). Several randomized studies showed that ablation is more effective than antiarrhythmic drug therapy in patients with paroxysmal or persistent AF (2–5). The patients undergoing these procedures usually have no overt heart disease, and their main expectations are improvement in quality of life and functional capacity resulting from the resumption of sinus rhythm or a significant decrease in AF episodes. Catheter ablation of AF is one of the most complex interventional procedures in medical practice. It involves the introduction of multiple catheters into the heart, transeptal catheterization, high levels of anticoagulation, and delivery of multiple lesions around the pulmonary vein ostia with or without additional atrial lines. The procedure has been associated with a minimal, but nevertheless important, risk of complications, some of them frequently lethal such as atrioesophageal fistula (6,7). Therefore, the possibility that such complications may occur in a relatively healthy population is of great concern.

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In a summary of a worldwide survey of 8,745 patients (181 centers) who underwent catheter ablation of AF between 1995 and 2002, Cappato et al. (8) reported at least 1 major complication in 6% of the patients. The most significant ones were tamponade (1.2%), transient ischemic attack (0.53%), stroke (0.23%), and periprocedural death (0.05%). This study was limited mainly by the diversity of the strategy of ablation used, including

techniques that are no longer in current use such as right atrial compartmentalization and ablation of the triggering focus in 22% of patients. On the basis of results from single large-volume, highly experienced centers that showed low complication rates (9–14), some investigators suggested that a reduction in complications rates could be expected with improvement of ablation technique and operator experience (15).

In this issue of the *Journal*, Cappato et al. (16) compiled the results of their first survey with those of a second survey they conducted on patients who underwent catheter ablation of AF between 2003 and 2006. The authors specifically looked for the frequency and cause of mortality that occurred early or late after the procedure.

A total of 32,569 patients undergoing 45,115 procedures in 262 centers reporting data safety were included in these 2 international surveys. Twenty-one (8%) of the 262 participating centers reported an overall mortality rate of approximately 1 per 1,000 ( $n = 32$ ). The most frequent causes of mortality were tamponade ( $n = 8$ , 25%), stroke ( $n = 5$ , 16%), and atrioesophageal fistula ( $n = 5$ , 16%). The causes of death of the remaining 14 patients were diverse. The authors (16) also noted that although tamponade was by far the most frequently encountered procedure-related complication ( $n = 331$ , 1%), it was responsible for fatality in only 2.2% of the cases. In contrast, atrioesophageal fistula was rarely diagnosed ( $n = 7$ ), but it was associated with a high mortality rate (71.4%). Stroke had an intermediate incidence ( $n = 59$ , 0.2%) and lethal prognosis (5.1%). Finally, mortality was not significantly related to the volume of ablation procedures, the technique of ablation used (CARTO vs. Lasso-guided), or the type of ablation catheter used (irrigated/cooled tip vs. standard 4 mm).

The data reported by Cappato et al. (16) are of great clinical interest, and the authors should be congratulated for a contribution that will certainly raise awareness in the electrophysiologic community of the state of contemporary AF ablation. The large number of patients and centers involved in this world survey suggests that a risk of AF ablation-related mortality of 1 per 1,000 patients is an accurate estimation of what is observed in clinical practice in most laboratories with a volume activity of  $\leq 100$  patients/year. Decreasing this risk should be a priority for the physicians involved in these procedures. The means by which to recognize, manage, and prevent complications during AF ablation have been comprehensively established by Dixit and Marchlinski (17). Although the occurrence rate of some potentially lethal complications, such as atrioesophageal fistula, may decrease in the future by implementing advanced innovative methods (17), other complications, such as tamponade, are unlikely to be affected.

Given that cardiac tamponade is the most frequently observed complication of AF ablation and the main cause of procedure-related mortality, it is of paramount impor-

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From the Cardiac Electrophysiology Laboratory, Department of Cardiology, Tel-Aviv Sourasky Medical Center, and Sackler School of Medicine, Tel-Aviv University, Tel-Aviv, Israel.

tance that the operators themselves have good experience in percutaneous pericardiocentesis or have immediate access to another physician who has mastered these skills (18). In experienced laboratories, a surgical approach was required in 14% of cases when percutaneous pericardiocentesis failed (19,20). Original nonsurgical techniques of pericardial drainage have been described by several investigators (21–23), but these techniques are unlikely to be applicable on a large scale. The Cappato et al. (16) study did not provide information on the availability of surgical backup for the patients who died due to tamponade, precluding the possibility of further elaborating the role of such backup in a course lethal to the patient. As such, the question of whether AF ablation procedures should only be performed in electrophysiologic centers where surgical backup is available remains unresolved. My personal view is that surgical backup is mandatory and that it may prevent a lethal outcome in some patients.

**Study limitations.** The study of Cappato et al. (16) has important limitations, most of them acknowledged and addressed by the authors:

1. The data are based on retrospective, volunteer-based surveys and may underestimate the true prevalence and nature of events. As stated by the authors (16), mortality rates in prospective surveys are higher than those of retrospective studies (24,25), and some fatalities that were a direct consequence of the procedure but occurred very late after the procedure may have been unreported.
2. No comparison can be made between the mortality rates reported in the first and second surveys. Taking into account the number of patients included in each of them, and assuming that there had been no overlap between the 2 groups, the mortality rate rose from 0.05% in the first survey to 0.12% in the second one ( $p = 0.07$  by Fisher exact test). Such an increase in mortality rate could be explained by the inclusion of more difficult cases (chronic and persistent AF vs. paroxysmal AF) and/or higher-risk patients (elderly, organic heart disease, cardiac failure, associated comorbidity). The authors did not provide any information on the type of AF that was ablated or the patients' clinical status.
3. The causes of death are only descriptive with no detailed verification. Possible precipitating causes of the complications are not provided, for example, the cause of tamponade or the level of anticoagulation in those patients with stroke.
4. The relevance of sex of the AF patients is not adequately discussed. Several studies have shown a female prevalence of cardiac perforation in patients undergoing percutaneous coronary interventions (26) and catheter ablation of AF (27) and accessory pathways (28). Since there is a male prevalence in the patient population undergoing catheter ablation of AF, it would have been interesting to assess a possible sex difference in the incidence of complications, especially of tamponade.

Hutchinson and Callans (15) recently recommended the creation of a procedural registry for AF ablation, similar to the Society of Thoracic Surgeons National Cardiac Surgery Database that has revolutionized our understanding of coronary artery bypass and valve surgery. The data provided by the Cappato et al. (16) study should prompt the institution of such registries by both national and international electrophysiologic societies.

Can a mortality rate of approximately 1 per 1,000 be considered an “acceptable risk” for a procedure for which the main expectation is improvement in quality of life? Although it is our responsibility to provide all of the facts about the risks and benefits of the procedure, it is the informed patient who will ultimately decide whether or not to undergo it. Until the publication of the Cappato et al. (16) study, our patients who were scheduled for AF ablation were informed about the relatively low complication rate associated with the procedure. Now, after the publication of this report, they will be aware of the 1 per 1,000 mortality rate. It is possible that some of them will prefer alternative options to manage their arrhythmias such as another antiarrhythmic drug trial, a rate-control policy, or even a visit to their local emergency room. Since AF itself is associated with an increased mortality rate (29), only long-term large randomized trials for comparing mortality following ablation or nonablation therapy of AF will tell whether they had decided wisely.

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**Reprint requests and correspondence:** Dr. Bernard Belhassen, Department of Cardiology, Tel-Aviv Sourasky Medical Center, Weizman Street 6, Tel-Aviv 64239, Israel. E-mail: [bblhass@tasmc.health.gov.il](mailto:bblhass@tasmc.health.gov.il)

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