

CORRESPONDENCE

Letters to the Editor

WATCHMAN for Stroke Prevention: An Out-of-Date Procedure

With interest we read the article by Sick et al. (1) about the WATCHMAN left atrial appendage (LAA) system for stroke prevention in atrial fibrillation (AF). We have concerns about the rationale of this technique and questions about the results, which prompt us to challenge the authors' conclusion that LAA occlusion with the WATCHMAN system is safe and effective.

First, there is no evidence that thromboembolism in AF exclusively derives from LAA thrombi detected by transesophageal echocardiography (TEE). When prospectively investigating clinically stable outpatients with AF and no recent embolism by TEE, the prevalence of LAA thrombi was only 2.5%, and during a follow-up of 58 months, LAA thrombus did not predict stroke/embolism (2).

Second, the LAA has properties that render device implantation difficult and might impede patency of the occlusion. The LAA myocardium has a higher distensibility than the left atrial myocardium. This might induce oversizing of the device and lead to compression of neighboring structures like the circumflex branch of the left coronary artery (3). Progressive dilation of the LAA occurs in AF, possibly leading to undersizing of the device and leakage of a primarily completely closed LAA (3). Left atrial appendage–endocardial fibroelastosis, occurring frequently in AF, makes fixation of the device difficult. The LAA is a place of secretion of atrial natriuretic peptide (ANP) (3). Possibly, continuous ANP secretion into the LAA cavity even after closure might contribute to leakages.

Third, incomplete LAA closure creates a pouch with stagnant blood flow, which enhances thrombus formation and might necessitate oral anticoagulation (OAC), although this was the intention to prevent first. Thus, we cannot understand why WATCHMAN placement was assessed as “successful” even in cases with a jet <3 mm around the device. In how many patients were small jets visible after implantation? And did the width of the jets increase during follow-up? Were they associated with thrombus formation or embolism?

How many patients were screened altogether? What was the kind and frequency of exclusion criteria? The listed comorbidities are frequent in AF patients and would thus prompt OAC.

Were the patients investigated by a neurologist and cranial-computed tomography or magnetic resonance imaging to look for cerebral ischemia? Which was the indication for warfarin therapy in 8% of the patients at 6-month follow-up?

It is reported that embolized devices were retrieved percutaneously. In the meantime, embolization of a WATCHMAN device has been reported, which could be retrieved only by surgery, where it was removed from the aortic valve and an aortic bioprosthesis and a pacemaker had to be implanted (4).

Even if technical improvements would lead to a more effective LAA occlusion, potential further side effects have to be considered. The LAA plays an important role in hemodynamic and body fluid regulation (3). Left atrial appendage elimination might impede physiologic regulations of heart failure and thirst perception. The ANP contributes to physiological control of lipid mobilization in humans, whereas LAA elimination might promote development of obesity (5). In view of global warming and the obesity epidemic, LAA elimination has to be strongly questioned as a beneficial procedure for stroke prevention in AF patients living in the 21st century.

***Claudia Stöllberger, MD
Josef Finsterer, MD**

*2nd Medical Department Krankenhaus Rudolfstiftung
Steingasse 31/18
A-1030 Wien
Austria
E-mail: claudia.stoellberger@chello.at

doi:10.1016/j.jacc.2007.04.077

REFERENCES

1. Sick PB, Schuler G, Hauptmann KE, et al. Initial worldwide experience with the WATCHMAN left atrial appendage system for stroke prevention in atrial fibrillation. *J Am Coll Cardiol* 2007;49:1490–5.
2. Stöllberger C, Chnupa P, Kronik G, et al. Transesophageal echocardiography to assess embolic risk in patients with atrial fibrillation. *Ann Intern Med* 1998;128:630–8.
3. Stöllberger C, Schneider B, Finsterer J. Elimination of the left atrial appendage to prevent stroke or embolism? Anatomic, physiologic, and pathophysiologic considerations. *Chest* 2003;124:2356–62.
4. Stöllberger C, Schneider B, Finsterer J. Serious complications from dislocation of a Watchman left atrial appendage occluder. *J Cardiovasc Electrophysiol* 2007;18:880–1.
5. Moro C, Crampes F, Sengenès C, et al. Atrial natriuretic peptide contributes to physiological control of lipid mobilization in humans. *FASEB J* 2004;18:908–10.

Reply

Although we are pleased that Drs. Stöllberger and Finsterer read our article with interest, their letter titled “An Out-of-Date-Procedure” seems to be part of their series of editorials against left atrial appendage (LAA) occlusion, made particularly odd in this instance by the claim that use of these devices will contribute to the obesity epidemic and global warming. We are also puzzled by the characterization of this technology as “out of date,” considering that it is currently undergoing its first randomized prospective trial.

Drs. Stöllberger and Finsterer state that they are prompted “to challenge the authors' conclusion that LAA occlusion with the WATCHMAN system is safe and effective.” We are unable to find any allusion to “safe and effective” in our report (1). Claims for efficacy are not, as they might not be aware, designed into pilot trials. Indeed we were careful to state that the study was not

powered to address efficacy and that the data are preliminary, suggesting safety and feasibility only. We hope safety and efficacy will be shown by the randomized PROTECT-AF pivotal trial, with currently over 400 patients enrolled (2).

With regard to the prevalence of thrombus in the LAA in un-anticoagulated patients, the rate of 2.5% to which the letter's authors allude comes from their data (3) and varies from the rest of the published data, reporting left atrial thrombus in up to 25% of un-anticoagulated atrial fibrillation (AF) patients (4-6). Their concerns relating to possible significance of the proximity of the circumflex coronary artery, possible undersizing of devices, potential difficulties with device fixation, and leakage "of a primarily completely closed LAA," although important to consider, are based only on speculation, in some cases refer to the surgical rather than percutaneous experience, and have as yet no evidence base for support. Drs. Stöllberger and Finsterer do reference their case report of a patient with device embolization who was not part of this trial. We are puzzled by their pre-publication of that particular case despite its being part of an ongoing study in which they have no involvement.

Our study was too small to address a number of their queries that will be part of the analysis of the large pivotal study under way. As the authors must be aware, pilot trials generally exclude the highest-risk patients, in this case so as not to withhold anticoagulation until feasibility is shown. Regardless, the patient population in our pilot study is from a vast pool of AF patients, the majority of whom worldwide are not anticoagulated, despite the well-reported 6:1 ratio of embolic events in the absence of anticoagulation (7).

We are pleased to have in common with Drs. Stöllberger and Finsterer our considerable enthusiasm for eliminating the obesity and global warming epidemics, but their implicating LAA-occlusion in these "epidemia" is, like their letter, a bit extreme. Far from needing to be "strongly re-considered," the device is just now being considered in the first place with the crucible of a carefully

designed, conducted, and monitored randomized trial. If the WATCHMAN is in fact safe and effective, it has the potential of contributing uniquely to the welfare of AF patients. We look forward to analyzing those results based on the scientific method.

***Peter Sick, MD**

*Krankenhaus Barmherzige Brüder Regensburg
Medizinische Klinik III/Kardiologie
Prüfeningenstrasse 86
93049 Regensburg
Germany
E-mail: peter.sick@barmherzige-regensburg.de

doi:10.1016/j.jacc.2007.05.022

REFERENCES

1. Sick PB, Schuler G, Hauptmann KE et al. Initial worldwide experience with the WATCHMAN left atrial appendage system for stroke prevention in atrial fibrillation. *J Am Coll Cardiol* 2007;49:1490-5.
2. Fountain RB, Holmes DR, Chandrasekaran K, et al. The PROTECT AF (WATCHMAN Left Atrial Appendage System for Embolic PROTECTION in Patients with Atrial Fibrillation) trial. *Am Heart J* 2006;151:956-61.
3. Stollberger C, Chnupa P, Kronik G, et al. Transesophageal echocardiography to assess embolic risk in patients with atrial fibrillation. *Ann Intern Med* 1998;128:630-8.
4. Dawn B, Varma J, Singh P, et al. Cardiovascular death in patients with atrial fibrillation is better predicted by left atrial thrombus and spontaneous echocardiographic contrast as compared with clinical parameters. *J Am Soc Echocardiogr* 2005;18:199-205.
5. Stoddard MF, Singh P, Dawn B, et al. Left atrial thrombus predicts transient ischemic attack in patients with atrial fibrillation. *Am Heart J* 2003;145:676-82.
6. Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg* 1996;61:755-9.
7. Caro JJ, Groome PA, Flegel KM. Atrial fibrillation and anticoagulation: from randomised trials to practice. *Lancet* 1993;341:1381-4.