EDITORIAL

Is Percutaneous Closure of the Left Atrial Appendage a Valid Alternative to Oral Anticoagulation?

Cierre percutáneo de la orejuela izquierda: ¿una alternativa terapéutica válida a la anticoagulación oral?

JAVIER GÁNAME[1, MD, PHD, FASE]

The prevalence of atrial fibrillation (AF) has risen in parallel with increased life expectancy and cardiovascular risk factors. Atrial fibrillation produces a five-fold increase in the risk of stroke and one out of five strokes is estimated to be a consequence of AF. Atrial fibrillation is probably associated with an unknown number of "cryptogenic strokes". (1) A significant proportion of these strokes in patients with AF may be prevented with anticoagulation therapy. Therefore, the prevention of stroke is an important aspect in the management of patients with AF from a social, economic and clinical point of view.

Oral anticoagulation with warfarin and more recently with the new oral anticoagulants which do not need therapeutic dose monitoring is the treatment of choice to reduce the risk of thromboembolism in patient with non-valvular AF. A significant proportion of patients with high risk of bleeding cannot receive oral anticoagulants. The risk of major bleeding in patients receiving oral anticoagulants is about 3% per year and the annual risk of minor bleeding is 13-15%. (2) The balance between the risk of thromboembolism and the risk of bleeding is crucial for the management of oral anticoagulation in patients with AF.

About 90% of thrombi in patients with non-valvular AF originate in the left atrial appendage. (3, 4) This has led to the development of alternative therapies to isolate the left atrial appendage from the rest of the left atrium. The WATCHMAN™ device was developed to occlude the left atrial appendage more than 10 years ago. The device is introduced by a percutaneous intervention via the femoral vein and requires a transseptal approach, the use of fluoroscopy and transesophageal echocardiography guidance. The procedure is associated with adverse events, which may be severe, as cardiac tamponade or even stroke. (5)

The PROTECT AF randomized trial demonstrated that implantation of the WATCHMAN™ device was possible in 91% of the patients undergoing the procedure, and was not inferior to warfarin anticoagulation assessed by a primary composite endpoint of stroke, cardiovascular death, and systemic embolism at 18 months in a group of patients with a relatively low CHADS2 score. (5) However, the rate of adverse events was higher in the group undergoing device implantation. These complications included cardiac tamponade (5%), stroke (2%) and major bleeding (3%). Peri-device residual flow was observed with transesophageal echocardiography in 32% of the patients at 1-year follow-up. (6) In the PROTECT AF trial, the long-term follow-up demonstrated that the rate of complications at the moment of device implantation decreased as the operator experience increased, with a long-term risk of cardiac tamponade of 2%. (7)

The PREVAIL trial was conducted to document the long-term reduction of complications after the implantation of the WATCHMAN™ device and to confirm the clinical efficacy demonstrated in the PROTECT AF trial in patients with higher CHADS2 score. This study demonstrated a reduction in the rate of complications during the procedure or immediately after in 2.2% of the patients who received the device. (8) However, the PREVAIL trial did not demonstrate that the WATCHMAN™ device was noninferior to warfarin therapy for the prevention of stroke, cardiovascular mortality or systemic embolism after 18 months of follow-up.

In the current issue of the Argentine Journal of Cardiology, Carrizo et al. present the initial experience and the short-term outcome of percutaneous closure of the left atrial appendage with the WATCHMAN™ device in a single center in Canada in a limited number of patients with a CHADS2 score higher than the one reported by other studies. (9) The procedure was successful (21/22 patients) in a greater proportion of patients compared to that reported by the PROTECT AF trial and similar to the one reported by the PREVAIL and CAP trials where the procedure was performed by more experienced operators.

The rate of periprocedural complications was

Rev Argent Cardiol 2015;83:499-500. http://dx.doi.org/10.7775.rac.v83.i6.7612

SEE RELATED ARTICLE: Rev Argent Cardiol 2015;83:512-518. http://dx.doi.org/10.7775/rac.v83.i6.7272

Address for reprints: Javier Gáname - 50 Charlton Ave East - Hamilton, Ontario, Canada, L8N 4A6 - Tel: +1 905 522 11 55 x32800 - Fax: +1 905 521 60 68 - e-mail: javierganame@gmail.com

[1] Associate Professor of Medicine - Department of Cardiology, McMaster University, Hamilton - Ontario, Canada
[FASE] Fellow of the American Society of Echocardiography

higher than the one observed in previous studies. This could be due to the relatively low number of complications in the small number of patients included in the study, where each complication significantly increased its rate, or because the population studied by Carrizo et al. (9) was older, with more severe comorbidities and had a higher risk of bleeding than the patients included in the PROTECT AF and PREVAIL trials. None of the patients developed stroke immediately after the procedure or during the short-term follow-up.

Of interest, the authors demonstrate the challenges related with this complex procedure. The device was implanted under general anesthesia, requiring transesophageal echocardiography guidance and transseptal puncture in all the patients. In half of the patients the device had to be repositioned.

The fact that none of the patients presented thromboembolic events or device-related complications is encouraging. These potential complications include device migration, atrial wall erosion and thrombosis. Probably, the risk of thrombosis decreases over time with device endothelialization. If these results are confirmed in the long-term, anticoagulation could be discontinued in these patients and the risk of bleeding would decrease.

The clinical significance of peri-device residual flow is controversial. (6, 10) Carrizo et al, (9) mention that the left atrial appendage was excluded in 95% of patients, but this percentage included patients with small residual flow (< 3 mm). Further studies assessing long-term follow-up are necessary to establish if these patients with peri-device residual flow still have higher risk of stroke compared with those in whom the LAA is completely excluded.

The left atrial appendage is a structure with complex and variable anatomy. (11, 12) We do not know yet if these anatomic differences predispose to a higher rate of peri-device residual flow. Probably, the anatomy and the shape of the left atrial appendage should be considered in the decision-making process when the procedure is being planned in order to ensure the best possible outcome. However, the authors of this study do not mention how many patients who were evaluated for percutaneous closure were unable to undergo the procedure due to anatomic issues or the inhability to carry out the procedure. In these patients, surgical closure of the left atrial appendage might be a valid option.

Most patients referred for percutaneous closure of the left atrial appendage have a strong contraindication for oral anticoagulation. The ASAP registry demonstrated that in patients not eligible for oral anticoagulation, percutaneous closure of the left atrial appendage was associated with a significantly lower rate of stroke than the one expected according to their CHADS2 score. (13) These results suggest that percutaneous closure of the left atrial appendage could be considered in patients with contraindications for anticoagulation.

This study confirms the existence of an unmet need of new procedures to reduce the incidence of thromboembolism in patients with AF, and that percutaneous closure of the left atrial appendage is feasible in tertiary care centers, with a high success rate and relatively low rate of complications in patients with multiple comorbidities and high risk for chronic oral anticoagulation.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms in the website/Supplementary material).

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