Rev Bras Cardiol Invasiva.
2014;22(1):56-63

Original Article

Left Atrial Appendage Closure With the Watchman™ Device

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ABSTRACT

Background: Stroke secondary to atrial fibrillation has been associated to a high risk of permanent, severe disability, and high early mortality, and therefore its effective prevention is of paramount importance. Warfarin therapy reduces the risk of stroke by 60%, however, half of the patients with atrial fibrillation do not receive anticoagulation. Left atrial appendage closure has emerged as an alternative strategy for stroke prevention. **Methods**: Patients with atrial fibrillation and CHADSVASc score ≥ 2, not eligible for anticoagulation, were submitted to left atrial appendage closure using the Watchman™ device. The procedure was performed under general anesthesia and was guided by transesophageal echocardiography. **Results**: Of the 11 selected patients, 2 were not treated due to thrombi presented prior or during the procedure and before device implantation. Mean age was 74 ± 5.1 years, 66% were male, CHA2DS2-VASc score was 4 ± 1.4, HASBLED score was 3.4 ± 1.1, 77% had contraindications or had unfavorable social conditions for anticoagulation. Technical success was 100% and complete occlusion was obtained in all of the cases, with a mean fluoroscopic time of 22.1 ± 10.8 minutes, and no hospital complications. At a follow-up of 78.3 ± 41.5 days, there were no clinical events but one patient had thrombus formation on the device and received anticoagulation for 3 months. **Conclusions**: Left atrial appendage closure with the Watchman™ device is feasible and may be a good alternative therapy for stroke prevention in patients with atrial fibrillation and restrictions for anticoagulation.

DESCRIPTORS: Atrial fibrillation. Atrial appendage. Stroke.

RESUMO

Oclusão Percutânea do Apêndice Atrial Esquerdo com Prótese Watchman®

Introdução: O acidente vascular cerebral secundário à fibrilação atrial tem sido associado a taxas de mortalidade e de incapacidade permanente elevada, porquanto sua prevenção eficaz é importante. O tratamento com varfarina diminui em 60% o risco de acidente vascular cerebral; todavia, até metade dos pacientes com fibrilação atrial não faz uso da anticoagulação. A oclusão do apêndice atrial esquerdo surgiu como estratégia alternativa para prevenção do acidente vascular cerebral. **Métodos**: Foram selecionados pacientes com fibrilação atrial, escore de CHA2DS2-VASc ≥ 2, não elegíveis para anticoagulação, para se submeterem ao fechamento percutâneo do apêndice atrial esquerdo com a prótese Watchman™. O procedimento foi realizado sob anestesia geral e guiado por ecocardiografia transesofágica. **Resultados**: Dos 11 pacientes selecionados, 2 não foram tratados por apresentarem trombo pré ou durante o procedimento, antes do implante do dispositivo. A idade foi de 74 ± 5,1 anos, 66,6% eram do sexo masculino, com escores CHA2DS2-VASc de 4 ± 1,4 e HAS-BLED de 3,4 ± 1,1, 77% tinham contraindicação ou condições sociais desfavoráveis para utilizarem a anticoagulação. O sucesso técnico foi de 100%, sendo alcançada a oclusão completa em todos os casos, com tempo médio de fluoroscopia de 22,1 ± 10,8 minutos e ausência de complicações hospitalares. No seguimento de 78,3 ± 41,5 dias, não ocorreram desfechos clínicos, mas um paciente apresentou trombo no dispositivo e recebeu anticoagulação por 3 meses. **Conclusões**: A oclusão percutânea do apêndice atrial esquerdo com dispositivo Watchman™ é factível e pode ser uma alternativa atrativa na prevenção de acidente vascular cerebral nos pacientes com fibrilação atrial e limitação para anticoagulação.

DESCRITORES: Fibrilação atrial. Apêndice atrial. Acidente vascular cerebral.

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Received: 01/02/2014 • Accepted: 03/04/2014

Stroke is the leading cause of cardiovascular mortality and morbidity, affecting nearly 800,000 individuals annually in the United States. Its incidence increases substantially with age, attributable to atrial fibrillation (AF) in approximately 1.5% of patients aged < 60 years and in more than 20% of patients aged > 80 years.[1] The absolute risk of systemic embolism in nonvalvular AF depends on the presence of associated factors such as hypertension, heart failure, diabetes mellitus, female gender, and a history of thromboembolic events, measured in clinical practice through the CHA2DS2-VASc score.[2]

Vitamin K antagonists are the most commonly used therapy for the prevention of thromboembolic events in AF, as they have proven efficacy, with a 60% reduction in the risk of stroke.[3] However, approximately 50% of eligible individuals do not use this class of drugs, due to limitations related to risk of hemorrhage, previous hemorrhage, treatment interruption or withdrawal, interaction with other drugs and foods, the strict therapeutic window, and the need for careful monitoring of prothrombin time.[4] Recent clinical trials have demonstrated the efficacy and safety of new anticoagulant agents when compared with warfarin, but with an annual risk of bleeding ranging from 1.4% to 3% throughout life, they have excluded patients at high risk of bleeding.[5,6]

In Latin America, unfavorable social conditions, low educational levels, and little access to health care make the use of anticoagulants more difficult, even in patients without contraindications. The development of percutaneous interventional strategies, such as occlusion of the left atrial appendage (LAA), appears to be an attractive alternative for the prevention of thromboembolism in nonvalvular AF. The aim of this study was to describe cases of the LAA closure with the Watchman™ prosthesis in individuals with difficulty and/or contraindication to oral anticoagulation.

METHODS

Study population

The Hemodynamics Services of hospitals José Carrasco Arteaga and Santa Inés, both located in Cuenca, Ecuador, started their training programs for percutaneous occlusion of the LAA in August 2013, in association with physicians of Hospital San Vicente de Paul of Medellin, Colombia. The criteria for patient selection included presence of chronic or nonvalvular paroxysmal AF, CHA2DS2-VASc score ≥ 2, previous thromboembolic events, presence of thrombus in the LAA in spite of adequate anticoagulation (but with resolution before the intervention), and limitations to anticoagulation due to clinical contraindications or due to social, cultural, or educational factors that prevented the prescription.

Device

The Watchman™ (Boston Scientific Corporation, Natick, MA) is a parachute-shaped device, percutaneously deployed in the LAA. It consists of a self-expanding nitinol metal frame, which is covered by a polyester mesh. The physical properties of nitinol allow the device to adapt to the contours of the LAA after implantation. The structure has ten anchors that help it to attach inside the LAA. The polyester membrane covering the device on the atrial side prevents the escape of blood clots to the left atrium. The Watchman™ device is currently available in five sizes (21, 24, 27, 30, and 33 mm) and allows the occlusion of LAAs measuring up to 31 mm in diameter. The delivery system has three components: the 14 F access sheath (Watchman™ Access System), the delivery catheter preloaded with the device (Watchman™ Delivery System), and a transeptal puncture sheath.

PROCEDURE

Before the procedure, patients received acetylsalicylic acid (ASA) at a dose of 100 mg/day and clopidogrel at a dose of 75 mg/day. However, patients with image of thrombus in the LAA received warfarin (international normalized ratio [INR] of 2 to 3) and ASA for at least 15 days before the procedure and were then submitted to transesophageal echocardiography (TEE) one day prior to implantation, to verify the presence of thrombi. Under general endotracheal anesthesia and TEE monitoring, the LAA was measured, as well as its inlet orifice and depth.

Vascular access was obtained with 7 F and 5 F introducers in the right femoral vein and right femoral artery, respectively. The atrial septum was punctured at a low and posterior position, followed by systemic intravenous anticoagulation. With the help of a pigtail catheter, manual angiograms were obtained in the right anterior oblique view with cranial and caudal angulation for anatomic delineation and measurement of structures. The 14 F double-curve sheath was advanced into the dominant lobe of the LAA under the pigtail catheter and a new angiography was performed to establish the relative depth of radiopaque markers, which helped in prosthesis size selection.

Simultaneously, guided by TEE, the inlet orifice of the LAA and its depth were evaluated at cuts of 0°, 45°, 90°, and 135°. The device was selected in accordance with the table provided by the manufacturer and based on the inlet orifice and the depth of the LAA primary lobe.

Once the desired depth was achieved with the double-curve sheath, the device, which was preloaded in the 12 F delivery catheter, was advanced up to its extremity and the cable was pushed to align the radiopaque markers of the delivery catheter and of the 14 F sheath. Then, the 14 F catheter (Watchman™ Access