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Percutaneous occlusion of the left atrial appendage: the state-of-the-art

Oclusão percutânea do apêndice atrial esquerdo: estado da arte

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ABSTRACT – Stroke is the complication of atrial fibrillation with the greatest social and economic impact. The prevalence of this arrhythmia is epidemically growing. Although oral anticoagulants are highly effective, their contraindications, hemorrhagic complications and non-compliance of patients result in underutilization of this therapy. This review addresses aspects related to endocardial occlusion of the left atrial appendage as an alternative strategy to antithrombotic therapy, ranging from the introduction of the technique in clinical practice, the new devices being developed, technical peculiarities, and economic aspects, to uncertainties related to the intervention.

Keywords: Atrial fibrillation; Atrial appendage; Therapeutic occlusion

RESUMO – O acidente vascular cerebral é a complicação de maior impacto social e econômico da fibrilação atrial, arritmia cuja prevalência cresce de maneira epidêmica. Apesar de altamente eficazes, as contraindicações, as complicações hemorrágicas e a falta de aderência relacionadas aos anticoagulantes orais resultam em subutilização desta terapêutica. Esta revisão aborda aspectos referentes à oclusão endocárdica do apêndice atrial esquerdo como estratégia alternativa à terapia antitrombótica, desde a introdução da técnica na prática clínica até os novos dispositivos em desenvolvimento, passando por particularidades técnicas e aspectos econômicos e indefinições relacionadas à intervenção.

Descritores: Fibrilação atrial; Apêndice atrial; Oclusão terapêutica

BACKGROUND

The prevalence of atrial fibrillation (AF) in the general population grows epidemically. Projections show that the number of patients with AF in 2050 will be three-fold what it was in the year 2000.¹ Stroke is the complication of this arrhythmia of greater social and economic impact, and the prevalence of AF in patients admitted for acute presentations of stroke increased from 20% in 2003 to 24% in 2014 (40% in the group of patients over 80 years).² Consequent to the large size of the intracardiac thrombi that are formed as a result of this arrhythmia, strokes secondary to AF are more severe. They cause more sequelae, have a greater chance of recurrence, and 15% of them lead to death.³ Even short episodes of AF (<3 days) are associated with the detection of thrombi in up to 14% of patients.⁴

To prevent the occurrence of stroke in patients with non-valvular AF (NVAf) and high risk of thromboembolism, as determined by the CHA₂DS₂-VASc score, the national⁵ and international^{6,7} guidelines recommend with Class I, Level of Evidence A, the use of oral anticoagulation (OAC), either with warfarin, or one of the direct oral anticoagulants (DOAC). Although highly effective, the multiple restrictions, contraindications, hemorrhagic complications, and non-compliance related to the use of these drugs, result in underutilization. The introduction of DOAC significantly improved the risk profile of anticoagulation, however it was not a solution for all of its limitations - especially those related to patients with significant and/or recurrent bleeding, renal failure or need for prolonged dual antiplatelet therapy (DAPT).

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The application of the Virchow triad (hypercoagulability, endothelial lesions and blood stasis) to AF renders the left atrial appendage (LAA) the heart structure more prone to thrombus formation.⁸ This has been proven by echocardiographic studies, which have demonstrated that more than 90% of intracardiac thrombi formed as a result of NVAF are found within the LAA.⁹ Based on this rationale, the hypothesis was raised that LAA occlusion (LAAO) could be an alternative to OAC for treating patients with NVAF and high CHA₂DS₂-VASC score as a “local therapy”, which does not rely in compliance to long-term medication and reduces the risk of bleeding.

This review addresses aspects related to LAAO via the endocardial approach, from the introduction of the technique in clinical practice to the new devices being developed, technical peculiarities, and economic aspects and uncertainties related to the intervention.

THE FIRST STEPS

The pioneer device designed for LAAO was created by Michael Lech, an electrophysiologist, and implanted for the first time in 2001.¹⁰ It was the device for Percutaneous Left Atrial Perpendicular Transcatheter Occlusion (PLAATO; Medtronic), a self-expanding nitinol structure with small hooks for fixation, and coated with a PTFE membrane, which occluded the LAA in its proximal portion (Figure 1A). After the report of the first 15 patients treated in 2001,¹¹ a non-randomized multicenter study was conducted, including 111 patients with indication for the procedure. A success rate of 97.3% was obtained, with pericardial effusions and cardiac tamponade occurring in 3.6% of patients.

Figure 1. Prostheses used for percutaneous occlusion of the left atrial appendage at the initial and contemporary phases of the intervention: (A) Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO); (B) Amplatzer™ septal occluders. Devices currently used with higher number of studies: (C) Watchman™; (D) Amplatzer™ Cardiac Plug; (E) Amulet; (F) LAmbré™.

Late echocardiographic follow-up (6 months) demonstrated LAAO occlusion in all cases. There was an annual incidence of stroke of 2.2%, corresponding to a reduction by 65% in relation to the predicted CHADS₂ score for this population.¹² Another non-randomized multicenter study including 64 patients reported a rate of major procedural complications of 1.5%, and a reduction by 42% in the predicted rate of ischemic stroke after a 5-year follow-up.¹³ Despite the promising results, the production of this device was discontinued for commercial issues.

Parallel to the initial experience with PLAATO, the off-label implantation of septal occluders, devices not dedicated to the LAA (Figure 1B), was initiated in a limited number of cases. The report of the first 16 patients treated by this technique showed the feasibility of the procedure, with embolization of the device in one patient and LAAO occlusion at the late echocardiographic follow-up of the remaining 15 patients.¹⁴ Despite these challenging initial results, the subsequent analysis of 64 patients, comparing LAAO dedicated (n=32) and non-dedicated (n=32) devices, found a lower success rate (84%) and a high rate of late embolization (16%) with non-dedicated devices, although late strokes did not occur in the groups.

THE CONTEMPORARY DEVICES

Watchman™

The first versions of the Watchman™ device (Boston Scientific) were implanted in 2002,¹⁰ however their effective clinical use began in 2007.¹⁶ Watchman™ is still the only device evaluated through randomized trials and, for this reason, the only LAA occluder approved for use in the United States by the Food and Drug Administration (FDA). Currently in its fifth generation, it consists of one single nitinol strut with a proximal PTFE semipermeable membrane coating, which acts as a filter between the LAA and the left atrial cavity (Figure 1C). Device retention occurs by oversizing it (8 to 20%) in relation to the size of the LAA ostium and by small anchoring hooks located on its surface.

The randomized trial PROTECT-AF was designed with the hypothesis of proving non-inferiority of LAAO as compared to the use of OAC with warfarin, regarding the occurrence of cardiovascular death, stroke or systemic embolism. These primary endpoints occurred in, respectively, 3.0% vs. 4.9% of patients (RR=0.62; 95%CI 0.35-1.25), with non-inferiority probability >99.9%. Therefore, this study proved the concept that the LAAO is an effective alternative to OAC for stroke prevention in patients with NVAF. It also demonstrated that patients submitted to LAAO had 91% reduction in the incidence of hemorrhagic stroke.¹⁷ However, due to the early phase of the learning curve of the new procedure, there was a complication rate of 7.4% for LAAO (notably pericardial effusions and cardiac tamponade), which hindered the benefits of the procedure and led the FDA to require additional studies for its approval.

The PREVAIL study followed; the complication rate was significantly lower than in the PROTECT-AF (2.2%), however non-inferiority was not met in the primary endpoints, since a higher rate of ischemic stroke occurred in the device group (1.9% vs. 0.7%), which was added to the lower than expected event rate in the warfarin group.¹⁸ Nonetheless, a meta-analysis of the 2,406 patients included in the PROTECT-AF, PREVAIL and their respective continued registries (CAP and CAP2), published in 2015, proved that after a mean follow-up of 2.7 years, patients undergoing LAAO had a significantly lower incidence of hemorrhagic stroke, cardiovascular or unexplained death, and bleeding, in addition to similar rates of stroke of any cause, and systemic embolism, despite higher rates of ischemic stroke (1.6 vs. 0.9 event/100 patients-year; $p=0.05$).¹⁹ All these results led to the FDA approval of the Watchman™ device in 2015, for the treatment of patients with $\text{CHA}_2\text{DS}_2 \geq 2$ or $\text{CHA}_2\text{DS}_2\text{-VASc} \geq 3$ scores and contraindication to prolonged OAC. The 5-year follow-up of patients included in both studies confirmed that the LAAO with the Watchman™ device is not inferior to warfarin for the reduction of all-cause stroke or systemic embolization ($p=0.87$), with different components: a numerical (but not significantly) higher rate of ischemic stroke ($\text{RR}=1.71$; 95%CI 0.94-3.11; $p=0.08$), counterbalanced by a significantly lower rate of hemorrhagic stroke ($\text{RR}=0.20$; 95%CI 0.07-0.56; $p=0.0022$) in the device group.²⁰ Notably, late follow-up data showed a significant 41% reduction in cardiovascular and unexplained mortality rates in the device group ($p=0.027$), demonstrating the true benefits of the procedure are obtained in the long run and increase with time, considering the cumulative risks of continuous OAC.

In addition to the randomized trials, the European multicenter registry EWOLUTION demonstrated a reduction by 84% in the incidence of ischemic stroke in relation to that predicted by the $\text{CHA}_2\text{DS}_2\text{-VASc}$ score, and by 48% in the incidence of major bleeding, as compared to the predicted by the HAS-BLED score, one year after LAAO with the Watchman™ device. In this registry, the rate of major procedural complications was 2.8%.²¹ Likewise, a registry conducted in the United States after FDA approval with the first 3,800 cases showed significant reduction in the rate of complications as compared to previous randomized trials (1% cardiac tamponade, 0.078% procedure-related stroke, 0.24% device embolization, and 0.078% intervention-related death).²² The combination of these results proves the efficacy and safety of the procedure, once the initial learning curve of the operators is overcome, and shows that even if there is a slightly higher rate of ischemic stroke as compared to traditional OAC use, the intervention has quite significant benefits for the population for which the procedure is most appropriate, i.e., those patients with significant restrictions to OAC therapy.

Amplatzer™ Cardiac Plug and Amulet

The medical use of the Amplatzer™ Cardiac Plug (ACP; Abbott) began in 2008. Unlike Watchman™ or PLAATO, which are single structures, the ACP is a self-expanding nitinol device consisting of three parts: a distal lobe with small fixation hooks, which anchors the device to the body of the LAA (both by hooks and by oversizing), and that must be positioned in a region about 1-cm distal to the ostium (landing zone); a proximal occluder disc, which closes the ostium of the appendage; and a flexible connector pin that unites the two structures and allows misalignment between lobe and disc, respecting the anatomy. Both the lobe and the disc are filled with polyester. The LAA is therefore occluded by three mechanisms: the lobe isolates the body of the appendage from its ostium; the disc occludes the ostium; and the polyester prevents flow through the device (Figure 1D). Although not yet available in Brazil, with the perspective of coming soon, the Amulet (Figure 1E) replaced the ACP in most countries. The structural concept of both devices is similar, however the Amulet has a wider lobe with more hooks, greater disk/lobe ratio, longer connection pin, and larger sizes that enable occlusion of wider appendages.

No randomized trial has compared ACP/Amulet with OAC, although there are randomized studies in the recruitment phase to compare Amulet and Watchman™ (Amulet IDE study), and Amulet and medical treatment for patients with NVAF who have suffered hemorrhagic stroke (STROKE-CLOSE study).²³ However, in addition to several smaller registries,²⁴⁻²⁸ there are two large multicenter registries with both devices. The European registry with the ACP included 1,047 patients and showed 59% reduction in stroke, and 61% reduction in bleeding in the late follow-up, as compared to the expected rates according to the $\text{CHA}_2\text{DS}_2\text{-VASc}$ and HAS-BLED scores, respectively, for this population. Reflecting the early learning curve of many operators, the overall complication rate was 5%.²⁹ In the more contemporary registry of the multicenter experience with Amulet, 1,088 patients (more than 80% with absolute contraindication to OAC) were treated with this device, with a complication rate of 3.2%. At the one-year follow-up, there was 57% reduction in the stroke rate, as compared to the predicted by the $\text{CHA}_2\text{DS}_2\text{-VASc}$ score.^{30,31}

The first results of the *Registro Brasileiro de Oclusão do Apêndice Atrial Esquerdo* were published in 2017.³² Eleven centers in the country voluntarily reported their initial experiences with the implantation of ACP and Watchman™ devices, which were only those available in Brazil at the time. Although it includes a relatively small number of patients, due to the logistical difficulties of conducting the procedure in Brazil, the registry had the merit of dealing with the population with the highest mean $\text{CHA}_2\text{DS}_2\text{-VASc}$ score, and the highest proportion of patients with a HAS-BLED score ≥ 3 among all studies available at the time. Nevertheless, there was reduction by 68.5% in stroke (annual rate of

1.7%), and by 77% in major bleedings in the late follow-up, as compared to the rates predicted by the CHA₂DS₂-VASc and HAS-BLED scores. However, probably due to the little experience of the operators with the procedure, the major complication rate in this registry was 7.6% - similar to that of the PROTECT-AF study.

LAmbre™

The LAmbré™ (Lifetech) device also comprises three parts: a disc designed to close the LAA through the ostium, a connector pin, and an eight-armed umbrella with small attachment hooks, which anchors the device to the body of the LAA. Nonetheless, unlike the ACP or the Amulet, which have a lobe that expands as a single structure, the umbrella of the LAmbré™ is armed by an active bearing mechanism of the arms, which - when completed, enables each arm to be independently anchored to the trabeculae of the LAA, increasing the stability of the device. In addition, there are two versions of LAmbré™: standard, in which disk and umbrella are proportional (Figure 1F), and special, in which the disk is 12 to 14mm larger than the umbrella, enabling its fixation to smaller lobes of the LAA.

Since it is a recently launched device, the formal literature on LAmbré™ is still scarce, although more than 3,000 implants have already been made in China. The publication with the largest number of patients (153) showed a follow-up yearly stroke rate of only 1.3% (vs. 6.4% predicted by the CHA₂DS₂-VASc score), with 3.3% complication rate, with no case of device embolization.³³ The initial European experience with 60 cases had similar results (complications: 3.3%, annual stroke rate at follow-up: 1.6%).³⁴ Because of the relative safety and easy implantation, which allows for less selective transseptal puncture, the creator of the device, Dr. Y. Y. Lam described, as the precursor Bernhard Meier used to,²⁵ his initial experience of 17 LAAO patients with the LAmbré™ device using a minimalist approach: under local anesthesia and fluoroscopic control, with no transesophageal echocardiography, achieving success in all procedures with no complications.³⁵ Available in Brazil since 2018, the report of the first 15 implants of the LAmbré™ device in the country showed excellent immediate results: 100% success and 0% complications (F. Chamié et al., Congenital and Structural Interventions Symposium, Frankfurt, 2019).

Other devices

Ultraseal (Cardia) is a device consisting of a distal bulb with anchoring hooks, attached by a pivotal connector pin to a proximal “sail”, formed by three foam and polyester leaflets (Figure 2A).

In the initial multicenter trial with this device, which is not yet available in Brazil, the procedural success rate was 97%, with 2.4% complication rate, and 60% reduction in the incidence of strokes in the medium-term follow-up, as compared to the rate predicted by the CHA₂DS₂-VASc score.³⁶ Other devices designed for transcatheter LAAO with less evidence in the literature, or still in the

preclinical or improvement stages, include the WaveCrest® (Biosense Webster), Occlutech (Occlutech Int.), PFM (PFM Medical), SeaLA (MedTech), and Sideris patch (Custom Medical) (Figures 2B to 2F).

Figure 2. Devices used for percutaneous occlusion of the left atrial appendage in the early phases of clinical experience. (A: Ultraseal; B: WaveCrest®); and devices in the phase of pre-clinical and/or improvement trials; (C: Occlutech; D: Pfm; E: SeaLA; F: Sideris patch)

COMPARING DEVICES

Except for the Amulet IDE and Wavecrest2 trial, comparing respectively, Amulet and WaveCrest® with the Watchman™ (both still in the recruitment phase), there are no randomized head-to-head trials comparing devices. Among the few registries published on the subject, there were no significant differences in success rates, complications, residual leak or late stroke when comparing the ACP to Amulet,³⁷ Watchman™ to ACP/Amulet³⁸ or Watchman™ to ACP/Amulet to LAmbré™,³⁹ suggesting that LAAO has a class effect, which does not depend on the device implanted, as long as the anatomical requirements are respected.

LIMITATIONS AND UNCERTAINTIES OF THE INTERVENTION

Anatomical limitations

Because of its high anatomical variability,⁴⁰ the LAA has been compared to fingerprints. Therefore, although in more than 90% of cases it can be occluded with any of the devices available in the market, one single prosthesis cannot be compatible with all anatomies. In addition, there are specific anatomical requirements, beyond which a particular device should not be used: Watchman™ requires depth of the LAA no less than the maximum diameter of its ostium, which, in turn, may vary from 17 to 31mm. The ACP requires a minimum depth of 10mm and landing zone with the largest diameter between 13 and 27mm. Amulet, in turn, can be implanted in LAAs with minimum depths of 12mm and landing zones between 11 and 31mm. Since the umbrella of the LAmbré™ device allows more flexible strategies of oversizing (up to 40% in bench tests), the size

of the ostium of the LAA is, therefore, what is taken into account for the implantation of this device and it should not exceed 38mm in its largest diameter.

For more complex anatomies that are not compatible with any of the available devices, there are descriptions that prove the feasibility of the off-label implant of a double occluder device, using two dedicated devices or one dedicated device associated with another non-dedicated device.⁴¹⁻⁴³ Such interventions, however, should be considered as an exception, knowing that there is neither enough experience nor follow-up to determine their validity.

Residual leak

Residual flow around the occluding devices are not uncommon, and have been detected in 12.5% of patients in the multicenter registry with ACP, in 32% of patients in the PROTECT-AF study, 12 months after the implantation of Watchman™, and in rates of up to 60% of cases, if the research tool is computed tomography angiography (CTA) rather than transesophageal echocardiography (TEE).^{29,44,45} These leaks are classified as minimal (<1mm in diameter), mild (1 to 3mm), moderate (3 to 5mm) or severe (>5mm) and may appear immediately or late after the procedure.⁴⁶ The eccentricity and irregularity of the LAA ostium, lack of left atrial repletion (and consequent underestimation of the size of the LAA) secondary to fasting before the procedure, pivoting or displacement of the device consequent to inadequate fixation, and late remodeling of the LAA after the occlusion, were mechanisms implicated in the appearance of post-LAAO residual leaks.⁴⁵⁻⁴⁸ If significant, such leaks can add to the potential risks of formation and embolization of thrombi adjacent to the device. However, rates of stroke or thromboembolism were similar between patients with complete LAA occlusion and those with smaller leaks, in such a way that, consensually, procedural success is defined as an LAAO that does not leave residual flow >5 mm.⁴⁴⁻⁴⁶ For patients with severe leaks, it is recommended - on individualized basis, to maintain OAC or close the leak with plugs, coils or other occluders.⁴¹

Post-intervention anticoagulation protocol and the formation of device-related thrombus

Pre-clinical studies have demonstrated that the permeable Watchman™ polyester coating is endothelialized within 45 days.⁴⁹ Based on this, in the United States, the post-LAAO anticoagulation protocol of patients treated with Watchman™ recommends the use of warfarin within the first 45 days after the procedure, then replace it by DAPT with acetylsalicylic acid (ASA) + clopidogrel for 6 months (or maintain the prescription if leak >5mm is detected). After this period, clopidogrel is discontinued and the patient remains indefinitely on ASA.¹⁷ Using this protocol, the development of device-related thrombus (DRT) was noted in 3.7% of 1,739 patients who took part in the PROTECT-AF and PREVAIL trials and in their continued registries CAP and CAP2. Most of these thrombi

were identified in the 6 or 12-month follow-up, and 25% of patients with DRT suffered stroke (RR=3.9; 95%CI 2.3-6.8; $p<0.001$), suggesting that, although infrequent, this is not a benign finding.⁵⁰ In Europe, the post-LAAO medication protocol with Watchman™ is more flexible than the American. More than half of the patients in the EWOLUTION registry received only DAPT following the procedure, and 4% of them had DRT detected at follow-up. Only one of these patients, however, suffered stroke during follow-up (0.2% of the total).⁵¹ The ASAP-TOO is an ongoing multicenter study that randomizes patients with contraindication for OAC for medical treatment with none or one antiplatelet drug, as compared to LAAO with Watchman™ followed by aspirin only.⁵² There are also occasional reports of the use of DOACs in place of warfarin within the first 45 days after Watchman™ implantation, with a low incidence of bleeding or DRT.⁵³

From the beginning of the experience with ACP/Amulet, the standard protocol already recommended interrupting OAC and introducing DAPT for 6 months from the device implantation. With this protocol, DRT detection was 3.2% in the multicenter ACP registry, with no ischemic events related to the finding.⁴⁶ In the Amulet multicenter registry, DRT was noted in 1.7% of patients (half of them more than 90 days after the intervention), with 17% of these patients (or 0.3% of total treated patients) suffered stroke during the follow-up.³¹

A systematic review of 30 studies, including almost 2,200 Watchman™, ACP, and Amulet implants, determined a 3.9% incidence of DRT, and in 95% of these cases, complete resolution of the thrombus occurred after temporary use (median of 45 days) of OAC, and the detection of DRT was associated with ischemic events in only 0.3%.⁵⁴ In contrast, the RELEXAO trial studied the progress of 469 patients who, after LAAO with Watchman™, ACP or Amulet, received different anticoagulation protocols (no medication, single or dual antiplatelet therapy, OAC with or without concurrent antiplatelet agents), and found DRT in 7.2% of cases, with more than four-fold higher stroke rate in these patients.⁵⁵ Isolated studies in the literature also reported the use of less orthodox anticoagulation protocols, using only aspirin⁵⁶ or short-term DAPT (6 weeks), followed by aspirin,⁵⁷ after the implantation of the Watchman™ or Amplatzer™. In both cases, the DRT rates were less than 2%, with no relation between DRT and stroke.

In summary, there is no consensus yet to define the most appropriate drug protocol to be used after LAAO, although the DAPT regimen seems to be acceptable, especially for this high-risk population for use of OAC. DRT occurs in 3 to 4% of patients, may develop more than 6 months after the procedure, and the literature diverges as to its significance in terms of stroke occurrence. However, one should consider most patients with DRT do not suffer stroke, and for most patients presenting post-LAAO stroke, there is no history of DRT. Patients with evidence of DRT appear to respond

well to temporary reuse of OAC, but there are suggestions that only those thrombi with increased embolization potential (mobile and heterogeneous, in contrast to fixed and lamellar) deserve this treatment.⁵⁸

Left atrial appendage occlusion vs. direct oral anti coagulants

DOACs have improved the use and safety profile of the OAC in relation to warfarin. Although widely used and recommended in the guidelines for stroke prevention in patients with NVAF,⁵⁻⁷ there are no head-to-head studies in the literature to compare DOACs and LAAO, although for this purpose the PRAGUE-17 studies, with results projected for the year 2020,⁵⁹ and the newly initiated Occlusion-AF (NCT03642509) are ongoing. For the moment, there is only indirect data that addresses the issue: Sahay et al. published a meta-analysis of 19 randomized trials, including more than 87 thousand patients with NVAF treated with warfarin, placebo, DAPT, DOAC, or LAAO. By establishing warfarin as a common comparator, the authors were able to make indirect comparisons between LAAO and other forms of treatment. The study findings suggest that LAAO is superior to placebo and DAPT, and similar to DOACs for prevention of death, stroke, or systemic embolism. The risk of major bleeding was similar across all therapeutic strategies.⁶⁰

COST-EFFECTIVENESS AND IMPACT ON QUALITY OF LIFE

Even with higher initial costs, from the point of view of the American reimbursement payer, LAAO has proved to be a better cost-effective option than warfarin and DOACs, over a 20-year survival horizon, considering the costs of therapeutic strategies for the treatment of associated events, and of long-term support after a debilitating stroke. In addition, time to achieve this cost-effectiveness was lower for LAAO than for DOACs, as compared to warfarin.⁶¹ This cost-effectiveness was also demonstrated in the scenario of the prevention for stroke recurrence in patients with NVAF and high CHA₂DS₂-VASc and HAS-BLED scores (secondary prevention).⁶²

Although often overlooked in the analysis, the impact of the procedure on health-related quality of life is probably the most significant outcome from the patients' standpoint. LAAO promotes a significant improvement in the physical component of quality of life scores and in the number of quality-adjusted life years (QALY) in the scenario of both primary and secondary stroke prevention.⁶¹⁻⁶³

CONCLUSION

There are still gaps in the body of favorable evidence related to percutaneous left atrial appendage occlusion, such as the impact of the operator's learning curve, complications still occurring in about 3% of patients,

slightly higher rates of ischemic stroke as compared to oral anticoagulants, and uncertainties regarding residual leak, device-related thrombus, adjuvant drug protocols, and head-to-head comparison with direct oral anticoagulants. However, the benefit of the procedure has been proven and it is unquestionable for the majority of the population of patients with non-valvular atrial fibrillation, high risk of thromboembolic events, and difficulties or contraindications to oral anticoagulants. This is the niche of patients for whom occlusion of the percutaneous left atrial appendage brings the greatest benefits, and the national guidelines recommend (Class IIa) the occlusion of the left atrial appendage for this indication, added to the patients who have suffered a stroke even in an adequate use of oral anticoagulants. With this rationale, it is expected that, as has been the case for some time in Europe and North America, soon the percutaneous left atrial appendage occlusion will finally be included in the procedures of the Agência Nacional de Saúde (ANS) in Brazil, and may be offered more broadly as an effective and necessary treatment strategy for a population that today, in our country, has no other choice rather than pay for the costs of the procedure, or live with the daily risk of suffering a disabling stroke.

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DECLARATION OF CONFLICTS OF INTEREST

Both authors are proctors at Abbott for left atrial appendage occlusion.

CONTRIBUTION OF AUTHORS

Study conception and design: EEG and FC; data collection: EEG and FC; data interpretation: EEG and FC; text writing: EEG and FC; approval of the final version to be published: EEG and FC.

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