GUIDELINES

Percutaneous occlusion of the left atrial appendage: An expert consensus statement

Consensus d’experts sur les modalités de l’occlusion percutanée de l’auricule gauche

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Abbreviations: ACP, Amplatzer™ cardiac plug; AF, Atrial fibrillation; CVA, Cerebral vascular accident; FLAAC, French left atrial appendage closure; LAA, Left atrial appendage; OAC, Oral anticoagulant; TOE, Transoesophageal echocardiography.

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Summary  Atrial fibrillation (AF) is the most common rhythm disturbance. Among the major thromboembolic complications associated with AF, strokes are foremost, with a 4.4% yearly incidence in the absence of preventive treatment. Therefore, the prevention of these embolic accidents is a priority. While proof of the efficacy of oral anticoagulants (OACs) for this indication is long-standing and convincing, they are associated with haemorrhagic complications. Consequently, their prescription is based on an estimate of the risk (haemorrhagic complications)/benefit (thromboembolic prevention) ratio. In a patient subset at high thromboembolic and haemorrhagic risk, whether to prescribe or abstain from prescribing an OAC is a challenging decision, and an alternative means of thromboembolic prevention is desirable. Percutaneous occlusion of the left atrial appendage (LAA) is an alternative, interventional, non-pharmacological treatment that has been used widely in Europe and for a few years in France, with encouraging results. However, it remains an invasive procedure with a low level of proof in comparison with OACs. Moreover, the indications, the procedural environment and pre-per-post procedural patient management are major questions about this technique, with consequences on its efficacy and risk/benefit ratio. This document, composed by consensus among experts in the field, is an in-depth review of this new therapy.

State of the art

Rationale

The size and morphology of the LAA, with a single or multiple lobes and an ostium located on the anterolateral aspect of the left atrium, are widely variable. While the cardiovascular sources of thromboembolisms are multiple, in non-valvular AF, the migration through the systemic circulation of a thrombus formed in the LAA is the main cause.

Background

With a nearly 2% prevalence in the general population, atrial fibrillation (AF) is the most common rhythm disturbance. Among the major thromboembolic complications associated with AF, ischaemic cerebral vascular accidents (CVAs) are foremost, with a 4.4% yearly incidence in the absence of preventive treatment. Furthermore, among the 130,000 ischaemic CVAs occurring in France every year, the estimated proportion secondary to AF is 25%, of which 70% are fatal or leave major sequelae. Therefore, the prevention of these embolic accidents is a priority. While proof of the efficacy of oral anticoagulants (OACs) for this indication is long-standing and convincing, they are associated with haemorrhagic complications. Consequently, their prescription is based on an estimate of the risk (haemorrhagic complications)/benefit (thromboembolic prevention) ratio. In a patient subset at high thromboembolic and haemorrhagic risk, whether to prescribe or abstain from prescribing an OAC is a challenging decision, and an alternative means of thromboembolic prevention is desirable. Percutaneous occlusion of the left atrial appendage (LAA) is an alternative, interventional, non-pharmacological treatment that has been used widely in Europe and for a few years in France, with encouraging results. This document, composed by consensus among experts in the field, is an in-depth review of this new therapy.
Based on anatomopathological, surgical and echocardiographic data, the LAA is the site of thrombus formation in approximately 90% of cases [1], a percentage that decreases with the non-valvular characteristics of AF, the instability of the international normalized ratio and the worsening of left ventricular systolic function [2]. Thus, it seemed fitting to examine the merit of excluding or occluding the LAA as a means of preventing thromboembolisms in AF.

Studies of LAA exclusion or occlusion

Surgical techniques
The LAA has been excluded during the surgical treatment of AF: as a part of the MAZE procedure; as a complement to valvular or non-valvular cardiac surgery; and during a dedicated procedure via thoracotomy. However, the sample sizes of these studies were generally small, precluding the drawing of firm conclusions with respect to the preventative efficacy of the procedure. The results of exclusion plus suture of the LAA have been more predictable than those of suture alone, which tends to be leaky [3]. The randomized single-centre Left Atrial Appendage Occlusion Study (LAAOS) III, comparing surgical exclusion versus preservation of the LAA with continuation of optimal conventional treatment, at the time of cardiac operations performed in patients in AF, is in progress and is expected to offer an answer to this question in 2016.

Percutaneous studies
Thus far, four implantable devices have been studied: the PLAATO system, which is no longer pursued commercially; the WatchmanTM system (Boston Scientific, Maple Grove, MN, USA); the AmplatzerTM Cardiac Plug (ACP) system (St. Jude Medical, Minneapolis, MN, USA); and the WaveCrestTM system (Coherex Medical, Salt Lake City, UT, USA), which has few published data. These devices are all implanted via transseptal catheterization. The LARIAT™ system (Sentre-HEART, Inc., Redwood City, CA, USA) uses another technique for a similar purpose, by percutaneously ligating the LAA via an endocardial/epicardial approach. Cardiac imaging is indispensable for the performance of all these procedures, both to evaluate the anatomy of the LAA, which varies widely among individuals, and to look for the presence of a thrombus, in which case the procedure is contraindicated. Echocardiographic imaging, which must be performed by expert observers, is now often complemented by a sectional tomographic cardiac scan.

Data from the PLAATO system
In an initial non-randomized study of the PLAATO system in 111 patients, implantation of the device was technically feasible and lowered the estimated risk of CVAs by 40–65%, depending on the thromboembolic risk [4]. This was confirmed in 61 patients followed for 5 years, in whom the rate of CVAs was 3.8% per year, compared with a predicted risk of 6.6% per year by the CHADS2 score [5].

Data from the ACP system
The ACP has been studied by single health centres, and has been the subject of several multicentre registries, although not of randomized studies [6–10]. A comparative study with warfarin initiated in the USA has been halted. In European studies, device implantation was successful in 132 of 137 procedures (96%) and major complications were reported in 10 of 137 procedures (7%). The most common complications were pericardial effusions with or without tamponade, CVAs and migration of the device. Thromboses on the surface of the device have been reported in three patients [11].

Data from the Watchman system
The Watchman system is the only system that has been studied randomly [12]. The PROTECT-AF trial randomly assigned 707 patients with non-valvular AF to warfarin versus a Watchman device, in a 2:1 ratio. The patients, enrolled by 59 medical centres, had no contraindications to treatment with antivitamin K. This was a non-inferiority study, with efficacy endpoints including CVAs, cardiovascular death and systemic thromboembolisms, and safety endpoints including pericardial effusion, device embolization and major haemorrhage.

The recipients of Watchman devices received warfarin for 45 days after the procedure or for longer in case of residual leak around the device, at which time they underwent baseline transoesophageal echocardiography (TOE). From 45 days onward, dual antiplatelet therapy (aspirin 75 mg and clopidogrel 75 mg, daily) was administered for 6 months to allow endothelialization of the device. Continuation of aspirin (75 mg, daily) was recommended thereafter. In reality, antivitamin K therapy was discontinued in 87% of the patients assigned to the Watchman device at 45 days, and in 94% at 2 years of follow-up. Using the Rosendaal method, the recipients of Watchman devices spent 66% of their time with an international normalized ratio between 2 and 3, measured every 2 weeks.

After a 1065 patient-year follow-up, or a mean follow-up of 18 months, the non-inferiority endpoint was reached, confirming that closing the LAA in this population with AF is an alternative means of preventing thromboembolic events. With an incidence of 4.8%, pericardial effusion was the most frequent complication. The rate of complications decreased from 7.7% in PROTECT-AF to 3.7% in the CAP registry and to 2.2% in the PREVAIL study, as the experience of operators and medical centres increased [13].

The 4-year follow-up of PROTECT-AF confirmed the 2-year results, with the first demonstration of a 34% decrease in relative all-cause mortality and a 60% decrease in cardiovascular mortality by the Watchman system. It is, however, noteworthy that: this study’s sample size was small compared with the studies completed with OACs; mortality was not a primary criterion; the 2.2 ± 1.2 median CHADS2 score was low; and antivitamin K therapy was continued for several weeks after implantation of the devices, which may have contributed to the results observed in the Watchman group. The Watchman system has not been compared with direct OACs.

Percutaneous occlusion of the LAA in patients with contraindications to OACs
In nearly 30% of patients, treatment with an OAC was discontinued by the end of 3 years because of an excessively
high estimated risk of haemorrhagic complications. These patients, who are often frail, remain exposed to a high risk of thromboembolic events [14]. In the ORBIT-AF registry, 13% of 10,130 patients who needed OACs for AF had a contraindication at the time of inclusion: a history of haemorrhage was present in 28%; 28% of patients declined; 18% presented with a high haemorrhagic risk ascertained by the ATRIA score; 18% were frail or fell frequently; 10% needed dual antiplatelet therapy; 6% could not be controlled or comply with warfarin treatment; 5% had concomitant illnesses; 5% had histories of haemorrhagic CVAs; and 16% had miscellaneous contraindications [15]. These patients at high risk of ischaemic CVAs are in need of alternative non-pharmacological treatment, such as percutaneous occlusion of the LAA.

ASAP, a prospective registry of Watchman system recipients presenting with absolute contraindications to warfarin, included 150 patients with a median CHADS2 score of 2.8 ± 1.2 and a median CHA2DS2-VASc score of 4.7 ± 1.7. These patients received aspirin (75 mg, daily) and clopidogrel (75 mg, daily) for 6 months after the procedure. The implantation success rate was 96%. At a mean follow-up of 14.4 months, 13 of 150 patients (8.7%) experienced a major complication, including: five pericardial effusions, two of which were evacuated percutaneously because of tamponade; two device embolizations, one of which migrated to the descending aorta during the procedure, and both of which were percutaneously extracted; and six device thromboses, one of which caused a CVA, while the other five were detected during a follow-up echocardiogram. The rates of ischaemic and haemorrhagic CVAs were 1.7% and 0.6%, respectively, representing a 64% lower relative risk than in a similarly ill population, after correction for the putative protection conferred by dual antiplatelet therapy [16]. Similar results were observed, with a 55–65% decrease in the rate of CVAs compared with the expected rate, as a function of the risk score, in studies of the ACP in the presence of contraindications to OACs [8,11,17]. These encouraging results need to be confirmed in a randomized study, although the control group remains to be defined (absence of antithrombotic treatment, antiplatelet treatment), with a target population estimated at between 10,000 and 30,000 patients, according to the report issued by the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) [18].

Complications related to percutaneous occlusion of the LAA

The most frequent complications of the procedure are immediate and, to some degrees, related to the experience of the operators. The inescapable learning curve, estimated at 30 procedures, also depends on previous experience with transseptal catheterization, closure of atrial septal defects, AF ablation, mitral valvuloplasty, etc. The various studies mentioned earlier (PROTECT-AF, CAP and PREVAIL) have confirmed a significant decrease in the incidence of complications with increasing experience.

In a recent literature review, the incidences (95% confidence intervals) of complications such as pericardial effusion and device embolization were 4.3% (3.1–5.9) and 3.9% (2.7–5.6) with the ACP and Watchman systems, respectively, while the incidence of CVAs was 0.7% (0.2–1.2) [19]. The need to proceed with a post-procedural surgical intervention was 2.2% [20]. Thus, while rarely needed, one must be ready to proceed with surgery expeditiously in these patients, who are usually old and frail.

Once the learning curve is left behind, one may anticipate the following outcomes: deaths directly related to the procedure, ≤ 1%; tamponade requiring a thoracotomy, ≤ 1%; tamponade requiring subxiphoid drainage, 1.5%; device embolization, 1%; intraprocedural air embolism, ≤ 1%; device thrombosis usually occurring within weeks after device implantation, 4%, causing an ischaemic or haemorrhagic CVA in < 1%.

Occlusion of the LAA

Indications, non-indications and contraindications

Indications

The results of the PROTECT-AF study have validated the concept of percutaneous occlusion of the LAA as an alternative to antivitamin K in the prevention of thromboembolism in non-valvular AF. However, the level of proof of the safety and efficacy of OACs in this context is extremely high, supported by several concordant studies in several thousands of patients. The power of these studies and the level of evidence have unquestionably positioned OACs on the frontline in the prevention of thromboembolic events. The 2012 European professional practice guidelines regarding the management of AF are clear: it is premature to offer this technique to all patients who are at high risk of thrombotic events and candidates for OACs. In the European guidelines, percutaneous occlusion of the LAA can be considered for patients at high risk of thromboembolism, in whom long-term OACs are contraindicated (class IIb, level of evidence B) [21].

Gauging the absolute or relative contraindications to OACs may be challenging, although help can be found in the use of CHA2DS2-VASc scores to estimate thromboembolic risk, and HAS-BLED scores to estimate the haemorrhagic risk during OAC treatment [21]. What is the rationale behind these contraindications? How should a haemorrhage developing during poorly prescribed OAC treatment or of potentially curable origin be considered? How should we deal with a non-compliant patient or a patient declining long-term OACs for questionable reasons? These contraindications must, therefore, be the subject of a multidisciplinary conversation, in which experts in the organ at the origin of the haemorrhagic event must participate.

The indication for the occlusion of the LAA cited in the European guidelines does not correspond to the indication applied in the only published randomized study on the efficacy of the procedure, although it is clearly the main indication in clinical practice. In the European ACP registry, nearly 80% of the indications were related to a high haemorrhagic risk, 9% to the development of a haemorrhage and 11% to the development of a CVA during OAC treatment [9].

While the choice candidates for occlusion of the LAA are patients who are not candidates for OACs, prudence
is required when posing the indication for the procedure because, in this often frail population: the risk of perioperative complications is high; the incidence of other potential causes of CVAs is high; the absence of OAC treatment, left ventricular dysfunction and a history of CVAs are associated with a high prevalence of thrombi outside the LAA [2]; and a formal contraindication to OAC raises the issue of what antithrombotic strategy must be adopted after occlusion of the LAA.

In some cases, several questions related to complicated individual circumstances will need to be addressed. The indications will, therefore, be based on multidisciplinary evaluations. The role of various AF therapies will, in some cases, be discussed with cardiologists specialized in the treatment of arrhythmias, particularly if ablation of AF is contemplated, which should be performed before occlusion of the LAA.

Occlusion of the LAA has been considered for patients who have had a CVA despite optimal OAC treatment. While this indication seems reasonable, the level of evidence in its favour remains weak, and other treatment options must be considered, such as a different antithrombotic or its combination with an antiplatelet agent. Other putative sources of CVAs will need to be excluded and the indication validated by targeted studies.

Non-indications
In view of the strong evidence of safety and efficacy of OACs, reluctance of the patient to be anticoagulated does not represent a valid indication for occlusion of the LAA. Neither are AF developing in recipients of valvular prostheses or patients presenting with rheumatic mitral valve disease, given the high risk of thrombi elsewhere in the atrium.

Contraindications
The presence of a thrombus in the LAA or the left atrial cavity is a temporary contraindication for implantation of an occlusion system. In special cases, this contraindication might be waived after discussion among experts. Rare anatomical variants of the LAA preclude the implantation of any device currently available.

Preprocedural evaluation
Multidisciplinary confirmation of the indication
The indication for the implantation of a LAA occlusion system must be based upon consensus of experts in multiple disciplines, including an interventional cardiologist or arrhythmia specialist with personal experience with the procedure, a non-interventional cardiologist specialized in echocardiography and in this technique, a specialist in the organ responsible for the contraindication to OAC and, if appropriate, a geriatrician. The various AF treatments and, in particular, the possible use of ablation must be discussed with an arrhythmia specialist. The patient must be informed of the various treatment options and respective risks, including that of general anaesthesia, which must be gauged during a dedicated consultation.

In the context of high haemorrhagic risk from OACs, the indication for occlusion of the LAA is often posed by practitioners faced with a major haemorrhagic event and high risk of recurrence, which might involve all systems (e.g. central nervous, musculoskeletal, digestive, urogenital, etc.). One must determine whether an underlying curable cause of haemorrhagic event is present and is being treated.

Peri- and post-procedural antithrombotic strategy
Non-cardiologists specialized in the organ that has bled must be asked about the antithrombotic coverage that can be prescribed with an acceptable risk of bleeding during and after the procedure, in view of the risk of thrombus formation on the surface of the device. Anticoagulation, using unfractionated heparin, is recommended during the implantation procedure, aiming for an activated clotting time of >250 seconds. Antithrombotic prevention is recommended after implantation, while endothelialization of the device is taking place. In PROTECT-AF, warfarin was administered for 6 weeks, followed by an antiplatelet regimen for ≥ 6 months, in the protocol described earlier. That antithrombotic protocol, however, was reserved for antivitamin K candidates. Even when administered briefly, an anticoagulant may be risky and contraindicated in patients with histories of cerebral haemorrhage. The optimal antithrombotic strategy for candidates for percutaneous occlusion of the LAA is chosen by the “Heart-Team” and the specialist who determined that OAC was contraindicated, depending on the patient’s haemorrhagic risk. Dual antiplatelet therapy was studied for 6 months in the ASAP registry, with noteworthy results [5]. Other options that can be considered on a case-by-case basis include single antiplatelet therapy or no antithrombotic treatment, as long as approved by consensus, as mentioned earlier. No data are available on the use of direct OACs in this context, although this new pharmaceutical class needs to be studied.

Imaging of the LAA
Detailed imaging of the LAA, including, at a minimum, TOE, must be performed before the procedure to confirm its feasibility and exclude possible contraindications. A scan enabling tridimensional reconstruction of the appendage is recommended. These different imaging techniques reveal the shape, depth and dimensions of the LAA and its ostium, and the number of its lobes, and allow confirmation of the absence of thrombus and selection of the type and size of device.

Procedural environment
The procedure must be performed under general anaesthesia in order to guide it by mandatory TOE. The activated clotting time needs to be measured regularly throughout the procedure to verify the proper anticoagulation level.

The X-ray equipment must possess a number of characteristics. The C arm must enable all fluoroscopic projections, including extremes. The use of a mobile C arm of the kind used in operating rooms is discouraged because of the low
quality of the image, which does not allow visualization of poorly radio-opaque devices.

The X-ray tube and image intensifier or flat plate must be of high quality and regularly maintained.

The imaging chain must be digital (real-time digital scope and graphics), enabling the immediate review of all sequences. A quantification system with or without automatic calibration must be available to carry out the angiographic measurements of the LAA and compare them with the echocardiographic measurements.

The procedural space must be equipped with the instrumentation needed to monitor various signals during the procedure, including continuous, two-channel electrocardiography, non-invasive blood pressure and oxygen saturation, and intracardiac pressures. In accordance with current regulation, the reanimation equipment (which must be regularly checked) must be present in the room, including: pharmaceutical solutions; a defibrillator and external cardiac pacing system; pericardiocentesis; instruments for extraction and retrieval of intracardiac devices; oxygenation, intubation and ventilation equipment; perfusion kits; electric syringes; pharmaceutical carts; and a cell saver-type system of blood salvage. The staff must be trained to use this equipment in an emergency, to handle complications or prepare the transfer of an unstable patient to a reanimation unit or operating room. The device implantation room must fulfill the norms of an interventional cardiology or cardiac arrhythmia treatment room, or of a so-called hybrid suite. It must, in particular, be spacious enough to allow rapid mobilization of the staff around the patient to proceed with reanimation or emergency surgery, if necessary.

A post-procedural recovery room must be near the interventional procedure suite to receive and watch the patients after the procedure, and must be equipped with all the previously described reanimation essentials, including electrocardiographic, blood pressure and oximeter oscilloscopes. The recording of a complete electrocardiogram must be possible, if needed.

This technique is associated with a periprocedural risk that is accentuated by the old age and frailty of the population, often presenting with major concomitant disorders. The main risk is tamponade due to injury to the LAA, caused by the device, a guide or a catheter, or by a traumatic transseptal puncture. This complication must be directly manageable on site by percutaneous drainage by the operator, using special instrumentation. The precise cause of bleeding must be rapidly identified, which might require a surgical subxyphoid puncture or, less often, a sternotomy. Device migration is another major, although more rare, complication; its percutaneous retrieval is often highly challenging when the device has migrated to the abdominal aorta. Because of their size, most devices remain in the left cardiac chambers, exposing the valves to traumas or dysfunction and mandating surgical intervention.

In recent years, the LAA has been occluded by experienced operators in high-volume medical centres equipped with a cardiac surgery or cardiothoracic surgery service staffed with operators capable of performing a sternotomy (or any other cardiothoracic approach, if necessary) and repairing a cardiac tear. These recommendations were formulated by the device manufacturers, based on publications and on their experience in the marketing of these products. Since 2013, all procedures carried out in France have been entered in the French Left Atrial Appendage Closure (FLAAC) registry. As in several other European countries, the French High Authority for Health has issued support for the creation of a document stipulating the performance of this procedure, underscoring the need for an environment offering back-up cardiac surgery. This provisional document will help to determine the reimbursement by insurance companies, which, for the time being, are considering coverage for the Watchman system and, recently, the ACP system. These recommendations will need to be re-evaluated on the basis of results, complications, the use of back-up surgery and the conditions prompting the use of surgery. For example, using the FLAAC registry, the rate of complications requiring emergency cardiac surgery will need to be examined after 1 or 2 years of activity. Participation in this registry must be compulsory and the data collection comprehensive, to evaluate French medical practice in detail. Until then, it is imperative that operators barred from performing this procedure despite their qualification can obtain authorization from cardiothoracic centres to implant LAA occluding devices by contractual agreement.

Occlusion of the LAA is a preventive, non-pharmacological treatment, which, except for its complications, is elective. No intent to proceed with the device implantation within the shortest delay can justify its performance in an environment that does not fulfill the safety criteria described earlier.

Treatment centre activity and operator experience

The benefit expected from this preventive treatment hinges directly on the risk associated with the procedure. The data available have been gathered from medical centres and for operators whose procedural activity is variable. The post-hoc analysis of PROTECT-AF revealed that “the operator’s experience is an important factor when evaluating the efficacy and safety of the procedure” [22]. Overall, the studies show a decrease in the incidence of procedural complications with an increase in the experience of the medical centre and an inescapable learning curve. In order to limit the worst consequences, the LAA occlusion system must be implanted by a general interventional cardiologist or cardiac arrhythmia specialist experienced in cardiac catheterization and the management of its complications. The LAA is anatomically widely variable in its location, size and shape, mandating a sufficient number of procedures to acquire the necessary proficiency. Transseptal puncture, a major procedural step with known risks, must be mastered by the operating team, while the medical centre must be in possession of a “level 3” authorization to perform highly complex interventions, defined by the regional health agencies (ARS) in the master plans for the organization of healthcare (SROS).

Because the technique is new and often used sparingly, especially in France, no study has clearly identified a threshold number of procedures beyond which the risk of complications diminishes. Whatever the interventional procedure performed in cardiology, low-volume centres
are notoriously observing a higher risk of complications. In the case of AF ablation, a North American registry of 93,801 procedures found that fewer than 25 procedures per operator and 50 procedures per centre predict poor results [23].

TOE guidance is key to the success of the procedure, making it possible to: take the measurements needed for selection of device and site of implantation; confirm the accurate and effective placement of the device before its release; and detect possible complications, particularly the development of a pericardial effusion or dislodgement of the device. Thus, the interventional team must include an expert echocardiographer trained in transoesophageal procedures and in the handling of the various implantable devices.

Implantation of the available devices requires specific training. Under current circumstances, the interventional team, which includes the cardiologist or the interventional arrhythmia expert and the cardiologist echocardiographer involved in the procedure, must have completed the training offered and be certified by the device manufacturers. The initial procedures carried out in a centre that fulfils all the conditions mentioned earlier, by operators whose training has been certified by the device manufacturers, must be backed by a physician-trainer accredited by each manufacturer, until the operator is fully autonomous. Consequently, based on current information, it seems legitimate to request from the centres that implant or wish to implant LAA occluders, that they: are able to gather a multidisciplinary team to pose the indication; reach, within 3 years, a minimum of 25 procedures per year, to acquire the highest technical proficiency and a risk of complications consistent with the most recent published data [21,23]; train all members of the interventional team in the use of the implanted system; attain proficiency of the interventional team in the performance of ≥ 30 transseptal catheterization per year; include a reanimation service, a cardiac intensive care unit, a cardiothoracic service and an expeditious procedure for the management of embolic complications.

Post-implantation follow-up

An LAA occlusion device must be followed after its implantation. A thrombus on the surface of the device, a pericardial effusion with or without tamponade, and dislodgement of the device with or without embolization, are among the reported complications occurring in the weeks after implantation. In the PROTECT-AF trial and the CAP registry, follow-up was based on a clinical and TOE evaluation at 45 days and at 6 months and 12 months to verify, in particular, the absence of residual periprosthetic leak. A follow-up programme with a first TOE before discontinuation of anticoagulation or bi-antithrombotic therapy and a second one between 4 and 6 months later to verify the absence of thrombus and residual periprosthetic leak seems sufficient to detect and treat the possible complications attributable to the device and allows an individual adaptation of the antithrombotic treatment. As the repetitive performance of TOE might be risky in an elderly population, cardiac scanning may be an acceptable alternative. The tolerance of, and compliance with, the temporary antithrombotic regimen evaluated before the procedure should be re-evaluated and reconsidered during follow-up, if necessary.

Conclusions

The benefit of percutaneous occlusion of the LAA in paroxysmal, persistent or permanent AF has been demonstrated in a randomized controlled trial in patients at risk of thromboembolism with an indication for OACS and without contraindication to OACS. Nowadays, this non-pharmacological treatment is an option recommended for patients in AF and in whom long-term OAC treatment is indicated but contraindicated, based on data acquired by registries and preliminary studies.

The Rhythm and Cardiac Pacing and the Atheroma and Interventional Cardiology Groups of the French Society of Cardiology believe, from both the literature and the actual therapeutic needs of a selected population, that percutaneous occlusion of the LAA may play a key role in preventing thromboembolisms in non-valvular AF.

The challenging indication must emanate from a multidisciplinary consensus after a case-by-case estimation of the risk–benefit ratio. This preventive therapy is associated with major complications, which can limit its benefit. However, a clear decrease in the incidence of these complications has been documented as experience is gained in the performance of the procedure. The rate of major complications in the hands of an experienced team is currently estimated at < 3%, in contrast to the > 8% per year risk of CVAs in patients presenting with a CHA2DS2-VASc score ≥ 2 in the absence of OAC treatment [24].

In the current state of knowledge and in accordance with the European consensus published at the time this statement was written [25], this procedure must be performed by trained cardiologists, whose activity is sufficient to justify its performance and who practice under the safest possible conditions. As the expertise of the medical centres increases, the risk–benefit ratio decreases. Some potentially serious complications might require urgent management by the interventional or surgical team, or by both.

In this context, the FLAAC registry has been initiated by the French Society of Cardiology, with a view to including all patients who undergo this procedure. Inclusion in this registry should be mandatory and comprehensive, in order to evaluate reliably the long-term results and complications of this technique, as well as the appropriateness of the regulatory constraints imposed on its performance.

Finally, the implantation of LAA occlusion devices for indications other than those discussed in this consensus statement should take place within carefully planned clinical research protocols.

Disclosure of interest

O.P. Consultant for the company Saint-Jude Medical.

The other authors declare that they have no conflicts of interest concerning this article.
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