

Left Atrial Appendage Occlusion for Stroke Prevention in Patients with Nonrheumatic Atrial Fibrillation

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Abstract

Introduction: Atrial fibrillation is a common rhythm disorder, which is related to a higher risk of thromboembolism resulting in a high rate of cerebral stroke or transient ischemic attacks. According to the CHADS₂- or CHA₂DS₂-VASc-Score there is an indication for oral anticoagulation to prevent patients from mostly disabling strokes. However, more than 50% of patients are not adequately treated with oral anticoagulation due to different reasons, especially contraindications.

More than 90% of thrombi develop in the left atrial appendage (LAA), which lead to the idea of developing devices to exclude the LAA from the systemic circulation to prevent patients from embolisations. Another approach is surgical ligation or removal of the LAA during operation procedures.

Content: Different devices and their clinical data are discussed in this review. Available literature for most of the devices is evaluated and last but not least some surgical results are discussed at the end. Existing data of randomized and non-randomized studies show that the concept of LAA-occlusion instead of anticoagulation therapy works. However, complication rates during intervention have to be kept in mind, but with adequate training also new and inexperienced operators can do the procedure safely. Most data and the only randomized studies are available for the Watchman Device. Despite some few complications like pericardial effusions, bleeding complications and thrombus formation on the devices, the data showed a non inferiority of device-implantation in comparison with anticoagulation therapy in the first few years. In long term follow up more than 4 years after implantation, there is even a superiority of the device compared with anticoagulation therapy, safety issues are no longer significantly different despite some periprocedural complications. This has to be reflected with the background, that operators could treat 3 patients with a totally new method, thereafter all patients had to be randomized into the study. So experience was limited in the first phase of this trial.

Surgical data vary much due to different techniques of LAA-occlusion. With newer devices results are also promising.

Conclusion: LAA-occlusion is a developing field of interventional and surgical techniques. The concept of LAA-occlusion could be proved in one randomized trial. At least for patients contraindicated for anticoagulation therapy, LAA-occlusion is a real alternative to only aspirin therapy or doing nothing. With emerging techniques and lower complication rates, LAA-occlusion might develop to a real alternative to anticoagulation therapy, at least for vitamin-K-antagonists. There are no data available so far in comparison with new oral anticoagulants. Further studies are needed to compare device therapy with new oral anticoagulants.

Introduction

Atrial fibrillation (AF) is one of the most common sustained cardiac

Key Words:

Atrial fibrillation, Stroke, Left atrial appendage closure, WATCHMAN®- device, Amplatzer® cardiac plug, Lariat suture ligation of left atrial appendage, Sideris Patch occlusion, Surgical left atrial appendage occlusion

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arrhythmias. Since AF is mainly a disease of older patients, incidence of AF rises in the aging population. Lifetime risk of developing AF is one in four in patients over 40 years of age.¹ The most devastating complication of AF is stroke, which occurs in average at a 5% annual rate in non-anticoagulated patients. With increasing age the risk of stroke is up to 23.5% in the elderly patients between 80 and 89 years.²⁻⁵ Depending on different risk factors, which are summarized in the CHA₂DS₂-VASc-Score (see table 1), the risk of annual stroke is between zero without any risk factor, between 15.2% and 23.6% with all risk factors possible.^{6,7} Thus, stroke prophylaxis is a critical component of AF management strategy.

Antiarrhythmic drugs and catheter ablation therapy may help to reduce symptoms, but are not sufficiently reliable in preventing thromboembolic events. Therefore long-term anticoagulation is generally recommended to prevent thromboembolism.

Despite its proven efficacy, warfarin therapy is often not well-tolerated by patients, has a very narrow therapeutic range and carries

Table 1: Left atrial appendage exclusion for stroke prevention in patients with nonrheumatic atrial fibrillation

Score	Annual stroke rate in %	
N	1084	74538
0	0	0.78
1	1.3	2.01
2	2.2	3.71
3	3.2	5.92
4	4.0	9.27
5	6.7	15.26
6	9.8	19.78
7	9.6	21.50
8	6.7	22.38
9	15.2	23.64
literature	Lip, GYH et al Chest 2009	Olesen JB et al BMJ 2011 ;342 :124

Annual risk of stroke according to the CHA2DS2-VASC-Score (modified after Lip et al, Chest 2009 and Olesen et al British Medical Journal 2011)

a significant risk for bleeding complications.⁸

New oral anticoagulants were developed during the last years like Rivaroxaban, Dabigatran and Apixaban,⁹⁻¹¹ all of them meanwhile approved for clinical use in patients with atrial fibrillation to prevent stroke. There is, however, a persisting risk of bleeding complications also with new anticoagulants,⁸ there are also unknown interactions with certain drugs and foods, which has also main influence on effectiveness of anticoagulation with warfarin even with frequent monitoring and dose adjustment. Therefore a lot of patients are outside therapeutic range in up to half of blood drawings.¹² As an alternative approach, based upon multiple echocardiography and autopsy studies implicating the LAA as the source of thrombi in >90% of patients with non-valvular AF,¹³⁻¹⁵ catheter-based devices have been developed to close and thereby effectively exclude the LAA from systemic circulation.

This article will review the different devices already available and will have a look at upcoming new devices. The PLAATO-Device was the first clinically used device, which is, however, no longer available. There are two devices already CE-marked available at least in Europe, which is the Watchman-Device from Boston-Scientific (former Atritech) and the ACP-Device from St. Jude Medical, former AGA. The LARIAT-Device, which is a device for pericardial suture of the LAA is already in clinical use in the USA. Other devices are in development, like the Coherex left atrial appendage occluder and a new device of the Cardia-Company or the Sideris-Patch occluder.

The PLAATO-System

The PLAATO-System (figure 1) was one of the first LAA-Occlusion devices ever used. Primarily it was intended for use in patients contraindicated to warfarin therapy. First experience was

reported by Ostermayer and Sievert et al,¹⁶ who reported about two prospective, multi-center trials, where LAA occlusion was attempted in 111 patients with contraindication for anticoagulation therapy and at least one additional risk factor for stroke. Primary endpoint was incidence of major adverse events (MAEs), a composite of stroke, cardiac or neurological death, myocardial infarction, and requirement for procedure-related cardiovascular surgery within the first month. Implantation was successful in 108 of 111 patients, who underwent 113 procedures. One patient (0.9%) experienced two MAEs within the first 30 days: need for cardiovascular surgery and in-hospital neurological death. Three other patients underwent in-hospital pericardiocentesis due to a hemopericardium, two patients experienced stroke. No migration or mobile thrombus was noted on transesophageal echocardiogram at one and six months after device implantation. 64 patients were observed in a prospective multicenter study published by Block et al.¹⁷ After up to 5 years of follow-up, the annualized stroke/transient ischemic attack (TIA) rate was 3.8%.

The anticipated stroke/TIA rate according to the CHADS₂-score was 6.6%/year. Treatment success was 100%, Complication rate was low with only one event (cardiac tamponade) adjudicated as related to the implant procedure. Major complications in another study by Park et al¹⁸ were one death and one open heart surgery due to embolisation of the device. There was no stroke reported at all, and no other relevant complications were described. The largest overview was given by Bayard and Sievert et al,¹⁹ who reported about 180 patients with an annual stroke rate of 2.3% being less than half of the expected stroke rate of 6.6% per year according to the CHADS₂-score. Implantation was successful in 90% of patients (162/180), successful closure was achieved in 90% of patients with follow up (140/180), however there were two patients, who died within 24 hours after the procedure (1.1%), in 3.3% cardiac tamponades were seen, in 1.1% surgical drainage was necessary. The device is no longer available.

The Cardiac Plug-Device (St. Jude Medical Company)

The cardiac plug device (figure 2) is a self expanding nitinol mesh graft with two parts, the so called lobe, which is fixed in the proximal region of the LAA body around 10-15mm behind the ostium. The disc is the second part of the device and covers the entrance of the LAA. The lobe is adapted at the diameter of the LAA and some barbs or hooks at the circumference lead to a stable fixation within the body of the LAA. The additional disc at the entrance of the LAA covers the entrance and leads to additional stability of the whole system.

The system is available in 8 different diameters, ranging from 16 to 30mm in 2mm steps for the lobe, resulting in a disc diameter of 4-6mm more. The system has to be prepared periprocedurally using a loading device to compress the device to the diameter of the guiding catheter after connecting the delivery wire with the tip of the device. This is usually performed below water to avoid air bubbles within the device. A Y-connector with a hemostatic valve helps to introduce the device through the guiding catheter without losing too much blood or getting air into the catheter.

After a transseptal puncture, which should be performed inferior and posterior in the fossa ovalis to get an axial access to the LAA, anticoagulation with heparin with an activated clotting time of at least 250 seconds has to be performed. A pigtail catheter helps to find the LAA anatomically and to take the correct measurements



Figure 1: The PLAATO-Device (picture taken officially from the internet)

of the LAA by injecting contrast dye into the LAA. Measurements of the LAA in diameter and length are performed simultaneously by angiography and transoesophageal echo. The correct size of the device (lobe diameter) should be chosen 2-4 mm larger than the largest diameter of the body of the LAA around 10mm behind the orifice. Dependant on the size of the device, the correct diameter of the guiding catheter has to be chosen. A stiff wire with a flexible tip is introduced through the pigtail into the LAA and the pigtail catheter is exchanged with the guiding catheter, which has a dilator with a short tip and has to be introduced very carefully into the LAA. The dilator and the wire are removed and the delivery system with the loaded device is advanced into the LAA. After delivery of the lobe by pulling back the guiding cath the shape of the lobe is controlled by angio and echo, then the disc is developed outside the LAA to cover the entrance. After checking the shape, measurements of the device, proof of seal of the LAA by echo and angio, the delivery cable is unscrewed and the whole system can be removed. Safety criteria for correct placement of the device are size of the lobe with adequate compression, lobe and disc are apart from each other to have tension between both and the disc has a concave shape. In contrast to the Watchman system usually no tugging test is performed. If the release criteria are not fulfilled, the device can be partially retrieved and redeployed, however if complete recapture is necessary, the device has to be exchanged, as the hooks might be flexed or destroyed by pulling back the device into the guiding catheter.

Clinical Data for Cardiac Plug System

First interventional occlusions were attempted by B. Meier et al.²⁰ using ASD-occluder devices for closure of LAA. The concept was interesting, but embolization rate in a device not designed for the LAA was high. On this basis the cardiac plug system was developed. Clinical Trials with the Cardiac plug system are still very rare. An initial retrospective European experience was presented in 2011 by Park et al. In 137 of 143 patients, LAA occlusion was attempted, and successfully performed in 132 (96%). There were serious complications in 10 (7.0%) patients (three patients with ischemic stroke (2.1%); two patients experienced device embolization (1.4%), both percutaneously recaptured; and five patients with clinically

significant pericardial effusions (3.5%)). Minor complications were insignificant pericardial effusions in four, transient myocardial ischemia in two, and loss of the implant in the venous system in one patient.²¹ Another prospective multicenter registry was performed in Europe with 15 participating centers from Germany, Spain, United Kingdom, Ireland and Czech Republic. Enrolment of patients was finished in September 2011, first data were presented on the PCR in Paris in 2012. 204 patients with nonvalvular atrial fibrillation were enrolled and followed for 6 months. There was no periprocedural stroke or TIA, three serious pericardial effusions (1,5%) and three device embolisations (1.5%). Device related thrombus formation was seen in 5 patients (2.4%), resulting in a total number of safety events of 11 (5.4%).²² According to the CHADS-Score of 2.6 the expected annual stroke rate in this patient cohort would have been 5.6%, the actual stroke rate, however, was only 1.98%, a 65% reduction from the estimated stroke risk. There are some more reports about LAA-Closure with the Amplatzer Cardiac Plug-System in a registry of the Asia Pacific experience²³ and in some small single center studies, which report some critical points of high rate of thrombus formation²⁴ and in one report a high rate of serious complications (one cardiac tamponade, two device embolizations) and one low-rate response AF requiring artificial pacing in overall 34 patients with an implantation success of 91.9% (34/37patients).²⁵ The second generation Cardiac Plug system is called Amulet device. This next-generation occlusion device is built with a longer lobe and waist than previous versions to allow for easier placement. The end screw is flush with the disc to create a smooth surface within the left atrium, and the larger disc diameter offers increased orifice coverage. The AMPLATZER Amulet device is offered in eight sizes to accommodate varying anatomies. Additionally, the device is pre-loaded into the delivery catheter, which simplifies device preparation, but there are no systematic data available so far, as it was released in spring this year.

The Watchman-Device (Boston Scientific)

The Watchman-Device (figure 3) is a nitinol cage with a 160µm Polytherephthalat-membrane spanned over the surface of the device. There are also some hooks at the middle circumference of the device to engage the device in the left atrial appendage wall.

In contrast to the Amplatzer device, implantation procedure defers little. Transseptal puncture has to be performed according to the anatomical axis of the LAA. If the orientation is cranial, a low and posterior puncture site has to be chosen, if the orientation is anterior, a high and posterior puncture site should be aimed at. This can be easily done under TEE-control. There is only one guiding cath suitable for all sizes of the device, which is introduced over a stiff wire usually placed in the left upper pulmonary vein. After removal of the dilator and the wire, a small pigtail is introduced to guide the 14 F guiding cath under fluoroscopic control with contrast dye into the LAA as deep as possible. The pigtail is removed and the delivery system inserted. The device is implanted by pulling back the guiding cath to avoid pushing the tip of the device against the wall of the LAA, which could mean a some risk of perforation. After proof of correct placement, size, stability and seal by TEE- and angiographic control the delivery system can be descrewed and the complete system can be removed leaving the device behind. In case of misplacement of the device it can be partially retrieved and pulled back for second release, however it should not be pushed forward with only partial recapture.

In this case it has to be exchanged as in case of complete recapture



Figure 2: ACP-Occluder of the St. Jude company (© St. Jude Medical, 2012)

the hooks might be flexed in the wrong direction, so fixation in the LAA might not be longer safe.

Clinical Data for the Watchman Device

Feasibility of the device was first examined in a small pilot study.²⁶ Until January 2006 in 66 patients the device has been implanted successfully with a mean follow up of 740 (mean 341) days. Two patients experienced device embolization, both successfully retrieved percutaneously. No embolizations have occurred in additional 50 patients, since fixation barbs were enhanced. Two pericardial effusions with tamponade, one major air embolism, all without long term sequelae and one delivery system fracture (first generation design) have been reported. Four patients developed flat thrombus on top of the device at 6 months, two patients suffered from transient ischemic attack (TIA), one of them without visible thrombus. After another 6 months of warfarin therapy all thrombi had disappeared. This fact resulted in a double antiplatelet therapy in all following studies until six months after implantation of the device. Two patients died during follow up, neither were determined to be device related. One available autopsy documented a stable, well endothelialized device.

In a large randomized trial against warfarin therapy, the PROTECT-AF-trial,²⁷ the device was tested for non inferiority compared with warfarin therapy in terms of efficacy and safety. After 1588 patient-years of follow-up (mean 2.3 ± 1.1 years), the primary efficacy event rates were 3.0% and 4.3% (percent per 100 patient-years) in the Watchman and warfarin groups, respectively (relative risk, 0.71; 95% confidence interval, 0.44%-1.30% per year), which met the criteria for noninferiority (probability of noninferiority >0.999). There were more primary safety events in the Watchman group (5.5% per year; 95% confidence interval, 4.2%-7.1% per year) than in the control group (3.6% per year; 95% confidence interval, 2.2%-5.3% per year; relative risk, 1.53; 95% confidence interval, 0.95-2.70).²⁸

However in long term follow up after 4 years, there was a significant superiority for primary efficacy as determined by stroke, death or embolisation (event rate 2.3 versus 3.8 with a Hazard ratio of 0.61

(0.38; 0.97, $p=0.035$). In terms of primary safety endpoints there was no longer statistical difference between both groups, event rates for device embolisations, bleeding complications, pericardial effusions and procedure related strokes were 3.6 in the device group vs. 3.1 in the control group with a hazard ratio of 1.17 (0.78;1.95, $p=0.40$). This difference was no longer statistically significant.²⁹ All cause mortality was also significantly lower in the device group compared to warfarin therapy. In a per protocol analysis of efficacy and safety endpoints, which means counting event rates after the prespecified 45 day follow up date, there was also a 40% relative risk reduction in primary efficacy and a 60% risk reduction in primary safety events, as complications related to the implant procedure were excluded. These results proved the principle concept of LAA-occlusion as a therapeutic option.

As safety events in the Protect AF-study were a crucial point for missing approval by the FDA so far, further analyses were performed in comparison with the so called continued access registry. The study cohort for this analysis included patients in the PROTECT AF trial who underwent attempted device left atrial appendage closure ($n=542$ patients) and those from a subsequent nonrandomized registry of patients undergoing Watchman implantation (Continued Access Protocol [CAP] Registry; $n=460$ patients).³⁰ The safety end point included bleeding- and procedure-related events (pericardial effusion, stroke, device embolization). There was a significant decline in the rate of procedure- or device-related safety events within 7 days of the procedure across the 2 studies, with 7.7% and 3.7% of patients, respectively, experiencing events ($P=0.007$). The authors concluded, that as with all interventional procedures, there is a significant improvement in the safety of Watchman left atrial appendage closure with increased operator experience. A post hoc analysis of these two studies combining rates of thrombo-embolism, intracranial haemorrhage, major adverse events, and death allows objective comparison of the benefit and risk of device therapy vs. anticoagulation in patients with AF. The net clinical benefit of LAA closure was greatest for patients at a higher risk of stroke.³¹

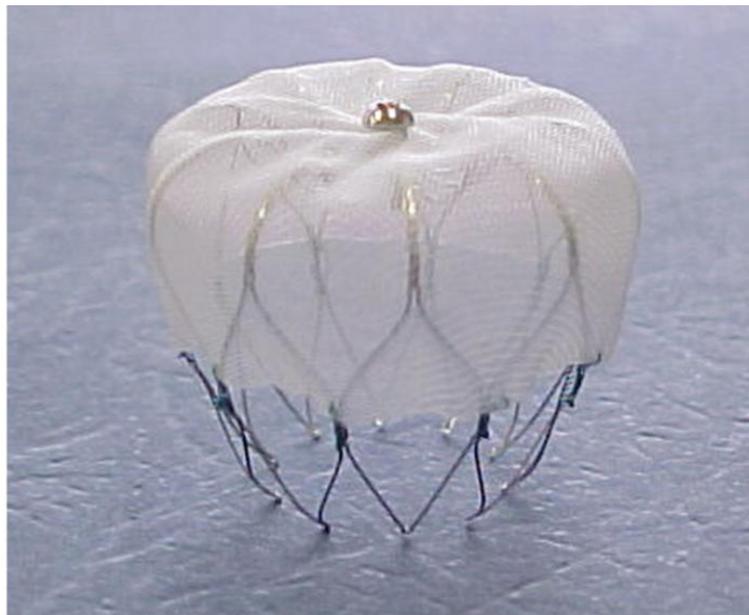


Figure 3: The Watchman-system (with permission of Boston Scientific)

Based on these data the FDA wanted to have another trial to see, if additional internet based training of inexperienced operators, practical courses by taking part in interventions in experienced centers and proctored first implants would achieve same results as in the CAP-registry. This was the basis for the Prevail- Trial, which included sicker patients with a CHADS₂-score of >2. Procedural success was significantly better compared with the Protect-AF Trial. First primary endpoint in terms of device- or procedure related complications within the first 7 days as well as third primary endpoint stroke and systemic embolisation were met, only second primary endpoint stroke, systemic embolisation and death at 18 months after procedure failed to reach non inferiority. However, only 88 of the 461 patients have reached 18 month follow up so far. Additionally event rate for stroke and systemic embolisation in the control group was nearly half of other large randomized atrial fibrillation trials.³²

As in all the above mentioned trials patients had to be able to take warfarin due to randomisation procedures and to a 45 day oral anticoagulation regimen after implantation, there is a registry of patients with contraindications for warfarin therapy, the ASAP-Trial.³³ These patients were treated with ASA and Clopidogrel immediately after the implantation procedure for 6 months and lifelong aspirin thereafter. Serious procedure- or device-related safety events occurred in 8.7% of patients (13/150 patients). All-cause stroke or systemic embolism occurred in 4 patients (2.3% per year); ischemic stroke in 3 patients (1.7% per year) and hemorrhagic stroke in 1 patient (0.6% per year). This ischemic stroke rate was less than that expected (7.3% per year) based on the CHADS₂ scores of the patient cohort. The authors concluded, that LAA closure with the Watchman device can be safely performed without a warfarin transition, and is a reasonable alternative to consider for patients at high risk for stroke but with contraindications to systemic oral anticoagulation.

There is a discussion if incomplete closure of the LAA might lead to a higher event rate.³⁴ Two analysis, however, one with the PLAATO-system and one with the Watchman-system, showed

no increased event rate of thromboembolism.^{35,36} Sometimes it's possible to close gaps with different devices to achieve full closure of left atrial appendage.³⁷

Lariat Device (Sentreheart Company)

The Lariat device (figure 4) is quite a different concept of LAA-closure. After transseptal puncture a wire with a magnetic tip is brought up to the inner part of the left atrial appendage. Then a dry pericardiocentesis is performed to bring up a second wire with a magnetic tip to the tip of the LAA. Endocardial and epicardial magnet-tipped guide wires are positioned under fluoroscopic guidance to stabilize the LAA. Transesophageal echocardiography is used as guidance for positioning a marker balloon at the ostium of the LAA. An over-the-wire approach is used to guide the Lariat snare device over the LAA to allow closure and suture ligation of the LAA. Contrast fluoroscopy and TEE are used to confirm acute closure of the LAA. The Lariat device was first used in a canine model by Lee et al.³⁸ Feasibility was shown by Bartus et al³⁹ and first clinical experience was published later⁴⁰ with 85 of 89 patients (96%), who underwent successful LAA ligation. Eighty-one of 85 patients had complete closure immediately. Three patients had a ≤2-mm residual LAA leak by TEE colour Doppler evaluation. One patient had a ≤3-mm jet by TEE. There were no complications due to the device. There were 3 access-related complications (2 during pericardial access and one due to transseptal puncture). Adverse events included two severe pericarditis post-operatively, one late pericardial effusion, two unexplained sudden death and two late strokes thought to be non-embolic. At 1 month (81 of 85) and 3 months (77 of 81) post-ligation, 95% of the patients had complete LAA closure by TEE. Of the patients undergoing 1-year TEE (n = 65), there was 98% complete LAA closure, including the patients with previous leaks. In the first American experience reported by Massumi et al⁴¹ twenty patients (100%) had successful LAA exclusion that was preserved at 96 ± 77 days. No patient had a stroke during an average of 352 ± 143 days of follow-up. One patient had right ventricular perforation and



Figure 4: The LARIAT-Device (courtesy Sentreheart Company)

tamponade that required surgical exploration and repair. Two patients required prolonged hospitalization: 1 because of pericardial effusion that required repeat pericardiocentesis and 1 because of noncardiac co-morbidities. Three patients developed pericarditis <1 month after the procedure, of whom 1 had associated pericardial effusion that required drainage. The authors concluded that percutaneous LAA exclusion can be achieved successfully and with an acceptable incidence of periprocedural and short-term complications. However, further studies are certainly needed to proof this concept.

Other Devices

There are more devices in development with small clinical experience so far. The Sideris patch⁴² is a bioabsorbable device that can be adjusted for the shape and size of the LAA without the risk of perforation. It is attached by a 2-stage polyethylene glycol surgical adhesive that is applied to the distal half of the device. Activation of the adhesive is achieved by direct injection of alkaline solution. Fluoroscopy and transesophageal echocardiography was used for device placement in 17 patients. The procedure was successful in all cases. In the 3 patients in whom angiography was performed, the patch did not attach probably due to contrast dye and was retrieved. In 1 case, the patch was placed beyond the mouth of the appendage, resulting in a residual opening. There was further improvement of the occlusion rate on the follow-up transesophageal echocardiography. There was 1 complication related to the procedure, namely, thrombus was released from the long sheath in the left atrium upon withdrawal and required treatment to be dissolved. No recurrent strokes were reported.

There are more devices under preclinical and clinical examination like the Coherex wavecrest device, the Occlutech LAA-Occluder and the Cardia LAA-occlusion system, but clinical results are not yet available.

Surgical Approach

Ligation of the LAA during mitral valve operations is a common

procedure and reduced later embolic events,⁴³ however there are multiple conflicting surgical studies.⁴⁴ A significant issue with ligation is incomplete closure in up to 36% and more of operated patients with exclusion of left atrial appendage.⁴³ Results of different studies do not clearly show a benefit for appendage occlusion during operation. Indeed of the five studies, only one showed a statistical benefit for LAA occlusion, with three giving neutral results and in fact one demonstrating a significantly increased risk. One reason for this may be the inability to achieve acceptably high rates of successful occlusion on echocardiography when attempting to perform this procedure. The highest success rate was 93%, but most studies reported only a 55–66% successful occlusion rate when attempting closure in a variety of methods including stapling, ligation and amputation. Another study ruled out, that excision of the LAA has a success rate of 73%, suture alone leads to only 23% complete closure, sometimes with a recanalisation of the suture.⁴³ Stapler exclusion has had mixed results as well, from totally ineffective to quite effective.⁴³ Very often, however, surgical closures are reported to be incomplete in many cases.⁴⁵

Epicardial left atrial appendage clip occlusion with a novel epicardial LAA clip device in patients undergoing cardiac surgery seems to be safer and more effective and durable as other procedures before.⁴⁶ Forty patients with AF were enrolled in this prospective 'first-in-man' trial. The inclusion criterion was elective cardiac surgery in adult patients with AF for which a concomitant ablation procedure was planned. Intraoperative transoesophageal echocardiography (TEE) was used to exclude LAA thrombus at baseline and evaluate LAA perfusion after the procedure, while computed tomography (CT) was used for serial imagery workup at baseline, 3-, 12-, 24- and 36-month follow-up. Early mortality was 10% due to non-device-related reasons, and thus 36 patients were included in the follow-up with a mean duration of 3.5 ± 0.5 years. On CT, clips were found to be stable, showing no secondary dislocation 36 months after surgery. No intracardial thrombi were seen, none of the LAA was reperfused

and with regard to LAA stump, none of the patients demonstrated a residual neck >1 cm. Apart from one unrelated transient ischaemic attack (TIA) that occurred 2 years after surgery in a patient with carotid plaque, no other strokes and/or neurological events were demonstrated in any of the studied patients during follow-up. So in the future, new surgical techniques may also help to avoid longterm anticoagulation due to atrial fibrillation after surgical procedures.

Conclusions:

Left atrial appendage occlusion is a growing field of interventional and surgical procedures. The principal concept of LAA exclusion from systemic circulation seems to work, which could be demonstrated in one randomized and in various non-randomized trial. The only randomized data in comparison with Coumadin therapy are available for the Watchman-device, where superiority in efficacy of the device could be proved over anticoagulation therapy after four year follow up in terms of stroke, death and systemic embolisation. So most robust data are available only for the Watchman system. In non-randomized data, however, efficacy for other devices could also be demonstrated in judgment for expected event rates without therapy, but there is no other randomized trial in comparison with anticoagulation therapy. There are also no data available so far in comparison with new oral anticoagulants overall.

There are only two CE-marked endovascular devices so far available, the Watchman and the Cardiac plug system followed by the Amulet system, which are different in construction. As left atrial appendage anatomy varies, different devices might be more or less suitable for the individual anatomy. So the Cardiac plug/Amulet system might be more useful in short appendages or in anatomies with an early split in two lobes, as the landing zone of this device needs only 10mm behind the orifice of left atrial appendage.

Implantation of a device in the left atrial appendage always bears the risk of thrombus formation on the surface of the device, at least during the early phase after implantation. In this sense the LARIAT-Device might have an advantage, leading to LAA-occlusion by a suture from outside the appendage thus leaving no foreign body behind in contact with blood. Data are promising so far, however there are some restrictions in terms of anatomy. The LARIAT-Device is not suitable for appendages, which are located posterior, as the access is a pericardial puncture site anterior, so the orientation of the left atrial appendage should be to the front or lateral, but not posterior. Besides leaving no material inside the appendage it is suitable for larger appendages up to 40 mm, whereas the other two devices are only accepted up to 32mm in case of the Watchman device and 31mm in case of the St. Jude Amulet-Device, which is the second generation of the Cardiac plug system.

Further devices are in development and may improve the technology of left atrial appendage closure, but most of them are still in first phases of clinical trials and not yet approved for routine use.

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