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Off-label device closure of residual shunt after surgical ligation of the left atrial appendage

Fechamento de shunt residual após cirurgia de oclusão do apêndice atrial esquerdo com uso de dispositivo off-label

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ABSTRACT – Significant residual shunts may occur after surgical ligation of left atrial appendage and may be associated with increased cerebral and systemic embolization risk. Transcatheter left atrial appendage residual shunt occlusion procedure may be a safe and effective therapeutic alternative and the choice of the more appropriate device should be made on a case-by-case basis. The objective of this study was to report on a case of transcatheter closure of residual shunt after surgical left atrial appendage ligation with an off-label device.

Keywords: Vascular closure devices; Ligation; Atrial appendage

RESUMO – *Shunts* residuais significativos podem ocorrer após a ligadura cirúrgica do apêndice atrial esquerdo, associando-se a maior risco de embolização cerebral e sistêmica. O procedimento de oclusão transcatheter de *shunts* residuais do apêndice atrial esquerdo pode ser uma alternativa terapêutica segura e eficaz, sendo a escolha do dispositivo feita caso a caso. Nosso objetivo foi relatar um caso de fechamento transcatheter de *shunt* residual após cirurgia de oclusão do apêndice atrial esquerdo com uso de dispositivo *off-label*.

Descritores: Dispositivo de oclusão vascular; Ligadura; Apêndice atrial

INTRODUCTION

Left atrial appendage (LAA) plays a major role in thrombus formation in atrial fibrillation (AF) patients. Is known to be the main thromboembolic source, responsible for more than 90% of left atrial (LA) thrombus in non-valvular AF.^{1,2} This knowledge led to consider LAA exclusion for thromboembolic prophylaxis, initially performed by surgery in 1949, widely adopted during valvar surgery in 1990's.¹ Although becoming a promising method for prophylaxis of thromboembolic accidents, residual flow after surgical LAA ligation limits its therapeutic efficacy. Surgical LAA exclusion, particularly by suture ligation, may result in many instances of incomplete closure in more than one third of patients.³⁻⁵ Both mitral prosthesis and valvular rings are associated with increased risk of incomplete surgical LAA closure.

This study was evaluated and approved by the Research Ethics Committee (CAAE: 07659219.7.0000.5227).

CASE REPORT

A 54-year-old female patient with severe rheumatic mitral valve regurgitation underwent surgical mitral annuloplasty by implantation of a valvular ring, associated with LAA suture ligation, in 2012. Soon afterwards, she presented with persistent AF and was submitted to catheter ablation, twice, with no sustained results. Later, on her cardiac assessment, a transesophageal echocardiography (TEE) depicted a 10×12-mm orifice with residual shunt and the presence of a thrombus inside the LAA, despite oral anticoagulation (OAC) with warfarin. In view of the significant risk of systemic

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thrombus embolization, she was referred for transcatheter residual shunt closure and scheduled for new CA.

The procedure was performed in May 2018, under general anesthesia and TEE monitoring. Transesophageal echocardiography performed during procedure confirmed the presence of the residual orifice but no LAA thrombus was detected.

Transeptal puncture was performed in the usual fashion, and intravenous cefazolin (2g) and unfractionated heparin (10,000IU) were administered after obtaining access to the LA.

An 8-F Mullins™ sheath was positioned in LA, and the LAA was carefully entered with a 0,035"/150-mm hydrophilic guidewire inside a multipurpose 5-F catheter. The latter was exchanged for a 5-F Pigtail catheter, and angiographies in right anterior oblique (RAO) cranial (30°-30°) and RAO caudal (30°-30°) incidences were obtained (Figure 1).

A 0,035"/260-cm extra stiff guidewire was inserted inside the LAA, and a 10-F Lifetech sheath was cautiously introduced over the wire. A 25-25mm CERA® Multifenestrated ASD Occluder Flex (Lifetech, Shenzhen, China) device was implanted with the distal disk completely apposed to the opening of the defect from inside LAA, and the proximal disk covering the entire LAA ostium (Figure 2). The TEE showed that the device was correctly positioned, and no residual shunt was observed at color Doppler.

There were no complications during procedure. Venous hemostasis was obtained by manual compression and the patient transferred to the intensive care unit. After the procedure, she was prescribed aspirin (100mg) and clopidogrel (75mg) by her attending physician, who considered no need for oral anticoagulation immediately after procedure. Atrial fibrillation persisted and she was submitted to another catheter ablation and is now in sinus rhythm. No stroke or embolic phenomenon was related so far.

DISCUSSION

Fibrillating atrium has minimal contraction, leading to local stasis and predisposition for thrombus formation.^{6,7} Surgical occlusion or excision of the LAA was suggested by the American College of Cardiology (ACC) in patients undergoing mitral valve surgery.⁸ Its benefits are more evident in patients with preoperative AF, and are associated with a significant decrease in mortality and lower rates of thromboembolism, but no difference in hemorrhagic stroke rates.^{9,10}

Incomplete LAA closure may increase the risk of systemic embolization, especially when there is large LAA-LA communications.³ It occurs in up to 60% of patients, a significant factor determining success, because both residual leak from incomplete ligation and residual stump after stapled excision have been associated with atrial thrombus formation in approximately 50% of patients.¹¹ Another randomized study demonstrated early closure-failure rate was highest in stapler exclusion (failure rate 60%), compared to 13% in internal ligation and 20% in surgical excision ($p=0.06$).¹²

Thromboembolic events occur in 15% to 20% of patients with incomplete closure.¹³ Almahameed et al. showed that surgical LAA exclusion does not provide optimal protection against thromboembolic events, and the rates are even higher among patients who are not on warfarin prior to hospital discharge.¹⁴

Incomplete closure is characterized by different arbitrary criteria that consider either a remnant cavity between mitral valve base and left pulmonary vein (warfarin ridge) or the mere presence of persistent flow in LAA after surgical exclusion.¹⁵ Persistent LAA flow after exclusion indicates incomplete closure; hence, theoretically, thrombus formed inside the LAA can cross the communication and embolize.

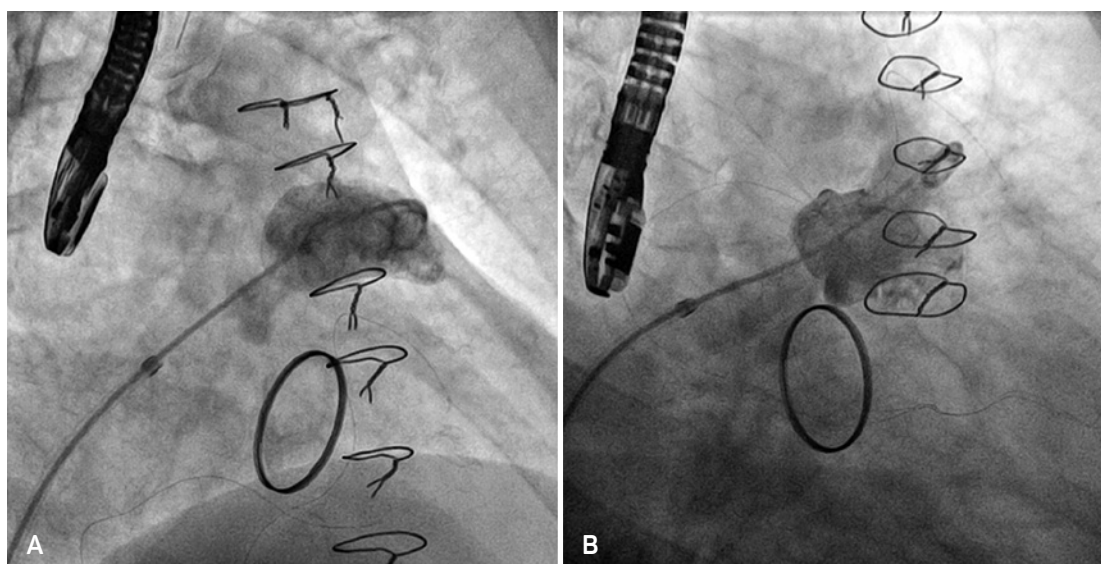


Figure 1. Left atrial appendage angiographies. (A) Right anterior oblique 30°-30° cranial. (B) Right anterior oblique 30°-30° caudal.

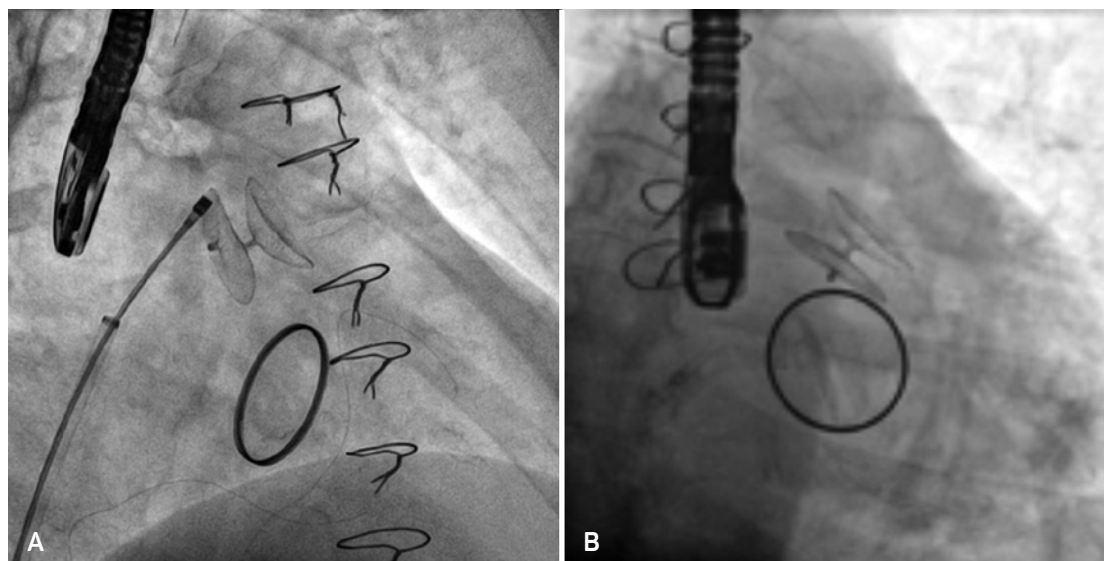


Figure 2. Device deployment. (A) Device totally configured, still attached to delivery system by a nitinol wire loop. (B) Device totally detached from delivery system.

Although specific reasons are not totally clear, incomplete LAA closure may be associated to a low flow state, with blood stasis predisposing thrombus formation with high risk for thromboembolic events.¹⁶ Some studies showed that incomplete closure bears a 12-fold greater risk for stroke or systemic embolization when compared to complete closure.^{4,5} Therefore, despite the lack of more robust evidence, there is a rationale for residual surgical shunt closure, especially in patients who are not candidates for OAC.¹⁷

Several approaches and different techniques have been suggested for LAA exclusion in patients who are at high risk of stroke and in whom OAC is contraindicated. Transcatheter device LAA closure has become increasingly popular due to its safety and efficacy.^{18,19} It is commonly assumed that adequate LAA device closure may present residual shunts less than 5mm wide. Residual shunts after LAA closure using catheters and intracardiac devices do not appear to be significantly associated with strokes.¹¹

There is no dedicated device designed for transcatheter residual shunt closure. Several devices with different design, such as ventricular septal occluders, multifenestrated atrial septal defect (ASD) occluders, patent foramen ovale (PFO) occluders, vascular plugs and LAA occlusion devices could be utilized. Device selection is based on the size, morphology of the orifice and operator's personal experience with the chosen device.²⁰ In the present case, a symmetric double-disk with a connecting pin device was considered the best choice, confirmed by the final result obtained.

The indication for LAA occlusion in this case could be debated, because it should be noted that, despite complete closure of the residual shunt, patient should maintain OAC due to follow-up protocol post-ablation, which was

performed later. In the present case, the presence of a thrombus inside LAA, despite OAC, would be considered a valid indication for LAA device closure, although TEE was not capable of detecting a thrombus during the procedure. Percutaneous LAA residual shunt occlusion with a device is off-label and, should be carefully indicated.

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