

## New technologies, new complications: complications after use of new arterial closure and thrombectomy devices

Marcelo Ferreira; Marcelo Monteiro; Giafar Abuhadba; Luiz Lanzotti; Luis Fernando Capotorto\*

\* Integrated Service of Endovascular Techniques (SITE), Rio de Janeiro, RJ, Brazil.

### Correspondence

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### ABSTRACT

We describe a singular case of both ischemic and traumatic complication, referring to use of new devices used for endovascular approach, in the same patient. One is a hemostatic closure device (Angio-Seal<sup>®</sup> - St. Jude Medical) and the other is a catheter for percutaneous rotational and aspiration thrombectomy (Rotarex<sup>®</sup> - Straub Medical). We discuss indication to use these devices in severely ill patients, with hemodynamic instability, or in a state of hypercoagulability, associated with femoral atherosclerotic disease, due to its high potential of complications.

Keywords: Ischemia, arterial occlusive disease, angioplasty, thrombectomy.

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### RESUMO

Relatamos aqui um caso singular de complicação isquêmica, e também traumática, referente ao uso de dois novos dispositivos para utilização endovascular, ambos no mesmo paciente. Um é um dispositivo hemostático para selamento de punção (Angio-Seal<sup>®</sup> - St. Jude Medical) e o outro, um cateter para trombectomia rotacional aspirativa percutânea (Rotarex<sup>®</sup> - Straub Medical). Discutimos a indicação destes dispositivos em pacientes gravemente enfermos, com quadro de instabilidade hemodinâmica ou em estado de hipercoagulabilidade, associado à doença aterosclerótica femoral, por seu elevado potencial de complicações.

Palavras-chave: Isquemia, doença arterial oclusiva, angioplastia, trombectomia.

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## Introduction

Following a global trend, we live in current medicine an age of fast and creative technological evolution, in search of new, more practical solutions that are easily executed, reduce hospital stay and provide outpatients an early return to their usual activities.

The endovascular technique has been progressively setting its foundation, proving to be feasible and effective for the treatment of most surgical vascular diseases, able to offer safety and comfort using a minimally invasive technique. However, due to evolution and new devices that are constantly being launched, we occasionally face unexpected situations, complications that the "new" endovascular surgeons should know and be able to solve.

## Case report

A 73-year-old female patient was admitted to the emergency room with clinical status of acute abdomen. After abdominal ultrasound and computed tomography, the patient was referred to the surgical center, where laparotomy showed acute mesenteric ischemia affecting distal jejunum and ileum, besides the right colon, at initial stage of ischemic suffering, probably secondary to a syndrome of low cardiac output with no evidence of atheroembolic occlusion.

Mesenteric selective arteriography was indicated, followed by direct infusion of a solution of papaverine hydrochloride, 40 mg/h, in the superior mesenteric artery (SMA).

### *Technique*

1. Retrograde puncture of the left common femoral artery (CFA) with introduction of a 6-F sheath measuring 13 cm.
2. Selective catheterization of the SMA using a 5-F Mikaelson catheter (COOK).
3. Diagnostic selective angiography was performed, showing rarefaction of revascularization in the area supplied by ileal branches and right colic artery, with no signs of embolism.
4. Infusion in solution pump of papaverine 0.1%, 40 mg/h, with maintenance of the sheath in the left CFA.

The patient was maintained adapted to ventilatory prosthesis and referred to the intensive care unit (ICU) in peritoneotomy for reassessment in 24 hours.

During that control, there was significant improvement in the aspect of ileal loops, confirming anatomical success shown in angiography.

The peritoneotomy was closed and the patient returned to the ICU, with maintenance of the sheath in the left CFA and papaverine solution at the same dose for 24 hours.

The sheath was removed on the second postoperative day at the ICU, using the percutaneous device Angio-Seal® 6F (St. Jude Medical) for hemostatic arterial closure, with which there was no

complete homeostasis, requiring complementation with compressive dressing. About 12 hours after removal of the sheath, there was coldness, pallor, fixed cyanosis and absence of distal pulses in the left lower limb, compatible with acute arterial occlusion. An arterial Doppler ultrasound was performed, confirming the diagnosis and showing presence of "hypoechoogenic material, probably embolic, with hyperlucent halo surrounding it," compatible with the sealing biopolymer of the device (Figure 1A).



Figure 1 - A) Femoral angiography showing obstruction caused by the sealing device; B) infrapatellar vessels; C) lesion caused by the thrombectomy device

The patient was again referred to the surgical center, where she was submitted to percutaneous aspiratory rotational arterial thrombectomy using the Rotarex<sup>®</sup> device (Straub Medical).

#### *Technique*

1. Retrograde puncture of the right CFA for contralateral access.
2. Control angiography showed arterial occlusion of the left CFA.
3. Introduction of a device for percutaneous aspiratory rotational arterial thrombectomy, with complete removal of the proximal thrombus.
4. A critical atherosclerotic lesion of the superficial femoral artery was also diagnosed in the Hunter channel and popliteal artery, besides an aspect suggesting multiple intraarterial thrombi.
5. The device of rotational thrombectomy was used again, until the tibiofibular trunk.
6. In the control period, there was large contrast extravasation, suggesting traumatic arterial lesion of the tibiofibular trunk (Figure 1C).
7. Temporary occlusion using a 4.0 x 60 mm angioplasty balloon (ATB – COOK Medical) was attempted, followed by a 40 x 30 mm self-expandable nitinol stent, with no success in homeostasis.
8. Direct approach of infrapatellar vessels and repair of proximal lesion at the origin of the anterior tibial artery (occluded), with its proximal ligation and terminoterminal anastomosis for reimplantation of the tibiofibular trunk.

At the end of the procedure, the sheath was removed from the right CFA and a percutaneous arterial sealing device was used (Angio-Seal<sup>®</sup> 6F), with reestablishment of distal pulses.

On the third postoperative day, there was new progressive ischemic decompensation of the lower

limb, this time on the right limb, and again presenting pallor, coldness and slow capillary filling. The patient presented hemodynamically stable, dependent on low dose amines. The puncture site was directly approached through exposure of femoral vessels (Figure 2), followed by thromboembolectomy using a 3-F Fogarty catheter (Edwards Lifesciences). There was anatomical success on angiography, associated with clinical improvement that was maintained for 14 days, when the patient died due to infectious respiratory insufficiency.

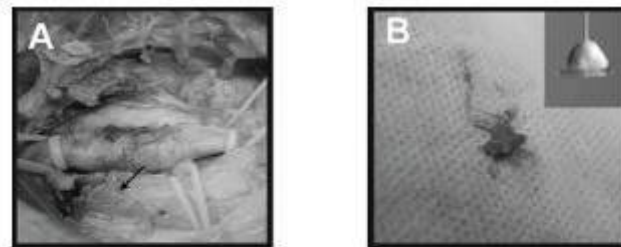


Figure 2 - A) Isolated femoral artery, with sealing device inside and external wire (arrow); B) device removed from the artery (detail of the device used: internal polymer, foam and external wires)

## Discussion

Arterial puncture sealing devices were developed to replace the manual compression method and reduce permanence time at postprocedure rest.

Their safety has been documented, with reduction in risk of hematoma formation, vessel occlusion, bleeding, formation of arteriovenous fistulas and pseudoaneurysms, as well as reduction in time to regain walking ability and hospital discharge, when compared with the standard method of manual compression.<sup>1</sup> Some studies showed the safety and efficacy of the device routinely used by our service, Angio-Seal®.<sup>2,3</sup> We have used so far 98 devices in 76 patients, with two previous episodes of complications similar to those reported herein.

Efficacy of these mechanisms is also confirmed in patients who need massive platelet antiaggregation, achieving efficacious homeostasis in more than 95% of patients, with a rate of hemorrhagic, non-surgical complications lower than 4%.<sup>4</sup> In another series, Chevalier et al. reported, in a randomized study including 612 patients, reduction in mean homeostasis time from 52 to 5 minutes.<sup>5</sup>

Hemorrhagic complications are the most common, with rates ranging between 5-7.4%, with 1.9% of episodes progressing with infection. There is a discussion as to whether this device could be a risk factor for infection for two reasons: excessive formation of hematomas, due to a risk known as endarteritis, and presence of a foreign body in the lumen and arterial wall, thus creating a niche for infection.<sup>6</sup>

Occlusive complications are rare, with few reports in the literature.<sup>7,8</sup> One hypothesis is that this is due to massive platelet antiaggregation, to which these patients are usually submitted.

With regard to the rotational thrombectomy catheter, it is a device indicated for removal of fresh thrombotic material or that is partially organized inside an occluded vessel acutely or subacutely,

with some studies showing a 61% patency after 1 year.<sup>9</sup> Reported complications are arterial perforation, attributed to presence of severely calcified arteries and formation of arteriovenous fistulas, besides distal embolisms, all of which can be conveniently submitted to endovascular treatment.<sup>10,11</sup>

What should be questioned, since there are few available data, is safety and efficiency of percutaneous arterial sealers to be used in critically ill patients, hypotensive, tending to hypercoagulability, poor distribution of water, in need of vasoactive amines to maintain arterial pressure, and those who may need endovascular intervention. All these factors are much worsened in case there is obstructive arterial disease located in the punctured femoral artery. In addition, it should be questioned whether it is necessary, due to sealer inefficiency, characterized by active bleeding after its use, complementary to manual compression and maintenance of compressive dressing.

The Rotarex<sup>®</sup> device, in our practice, proved to be efficient in cases of acute and subacute occlusion, but we stress the risk of arterial lesion when used in grossly calcified or lower caliber vessels, such as infrapatellar vessels.

Questioning use of these devices, based on presence of severe atheromatous or in case of small-caliber veins, makes this a complex task, since in many series with a high number of patients there is no mention about the importance of such variables when there is stenotic complication, usually attributed to inadequate use of a sealing device.

Endovascular surgeons should be alert, therefore, not only to new devices that are launched every day, but also to their possible complications, which will naturally occur when used more frequently and, above all, they should be prepared to solve them.

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 Correspondence:

Marcelo Ferreira

Rua Siqueira Campos, 59/203, Copacabana

CEP 22031-070 – Rio de Janeiro, RJ, Brazil

Tel.: (21) 2236.1637

Email: [mmvf@uol.com.br](mailto:mmvf@uol.com.br)

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