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CORRESPONDENCE

Dual lumen balloon spontaneous inflation during embolization

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Introduction

Balloon-assisted coil (BAC) embolization has gained acceptance during the last years for the treatment of wide-necked intracranial aneurysms. This article presents the case of a 51-year-old female with ruptured posterior communicating artery (PComA) aneurysm treated with balloon-assisted coiling using a dual lumen balloon (Eclipse 2L, Balt Extrusion, Montmorency, France). The procedure went uneventfully; however, the final control digital subtraction angiography (DSA) performed with the power injector showed a "spontaneous" inflation of the dual lumen balloon (balloon half inflated at the end of the run, impossible to deflate). "Spontaneous" inflation of balloons during any intracranial intervention can have detrimental consequences. Therefore, several macroscopic and microscopic tests were performed on the device seeking to determine the mechanism behind this spontaneous balloon inflation. This article describes several potential causes of this inopportune spontaneous balloon inflation and some recommendation are also suggested to avoid its occurrence.

Background

The management of wide-necked aneurysms is a difficult challenge for the interventional radiologist because of the risk of coil migration or coil protrusion into the parent vessel [1]. BAC firstly described by Moret et al. [1], consists of the temporary inflation of a non-detachable balloon across the aneurysm neck during each coil placement to avoid inadvertent coil protrusion. Although some specific complications in BAC, like parent artery rupture or dissection, may be observed, it has been shown that the complication rate in BAC is not statistically higher than in regular coiling [2–6]. To the best of our knowledge, no case of "spontaneous" balloon inflation during DSA has been reported in the literature so far.

Case Presentation

A 51-year-old female presented to this Institution with a sudden onset of severe headache associated with aphasia. She had no significant previous medical or surgical history. The family history was significant for an intracranial aneurysm rupture (aunt). She was an active smoker with heavy smoking history for the past 30 years. A brain computed tomography (CT) was performed and demonstrated subarachnoid hemorrhage with intraventricular hemorrhage and hydrocephalus (WFNS [World Federation of Neurosurgical Societies] grade 1, Fisher score 4). Digital subtraction angiography (DSA) demonstrated the presence of a 4.5 mm left posterior communicating (PCom) artery aneurysm as well as of a small aneurysm on the left anterior choroidal artery (Fig. 1a, b).

The PComA aneurysm was treated endovascularly by routine BAC using an Eclipse 2L (6/12 mm) and 4 coils. The final control DSA run in anteroposterior (AP) and lateral projections showed adequate occlusion of the aneurysm but, surprisingly, a "spontaneous" inflation of the dual lumen balloon at the end of the run was also seen (Fig. 1c, d). The dual lumen balloon, which was fully deflated before the last run, presented a progressive inflation during the run leading to semi-inflation at the end of the run. Additionally, it was impossible, despite many attempts, to deflate the balloon. The balloon was finally removed in the guiding catheter semi-inflated.

The first hypothesis to explain this spontaneous balloon inflation was damage of the outer wall of the dual

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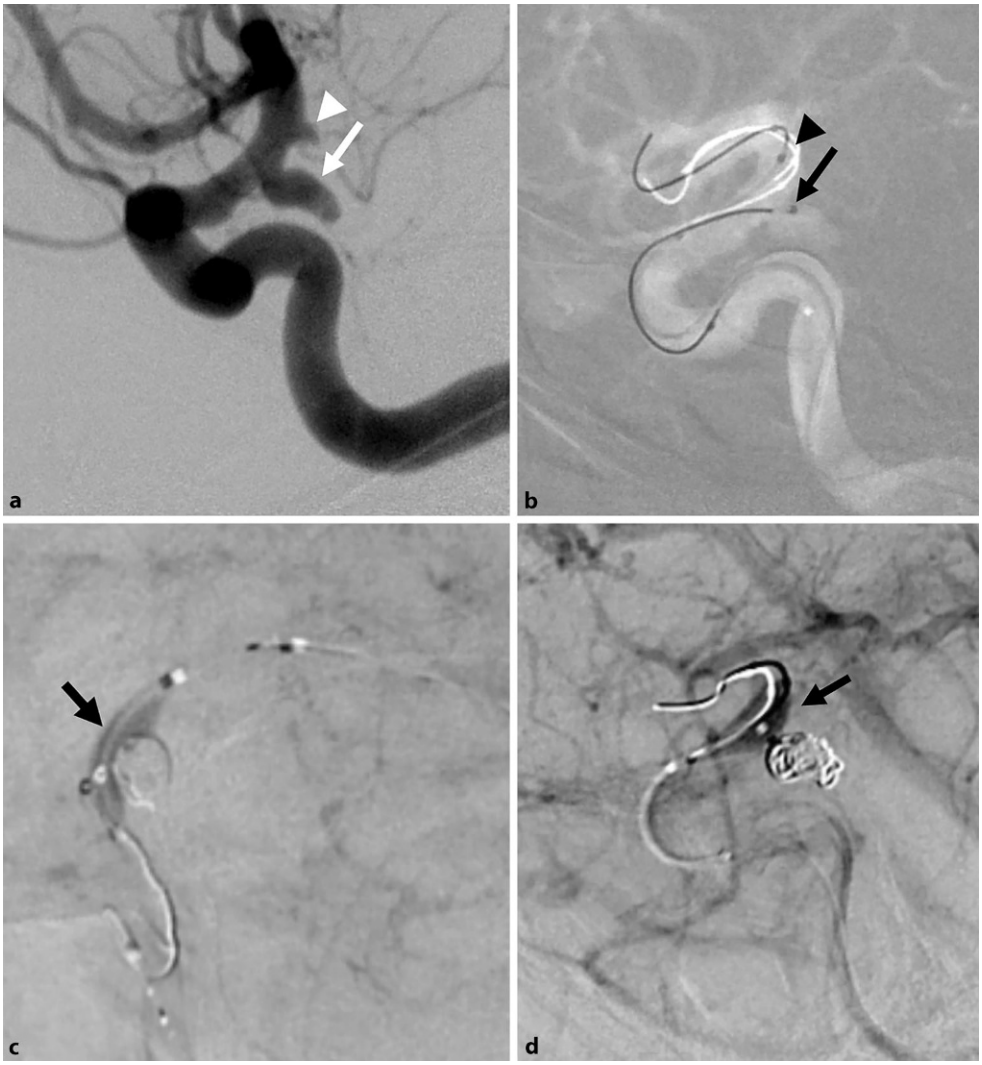

Fig. 1 Aneurysm balloon-assisted coiling and subsequent "spontaneous" balloon inflation. a Pretreatment left internal carotid artery (*ICA*) digital subtraction angiography (*DSA*); working projection. A 4.5 mm left PcomA small-necked aneurysm is seen (*white arrow*) as well as a small anterior choroidal artery aneurysm (*white arrow head*). **b** Snapshot of the left ICA roadmap in working projection. The microcatheter tip is positioned inside the aneurysm's sac (*black arrow*). The dual lumen balloon catheter is navigated across the aneurysmal neck (*black arrow head*). **c**, **d** Final control DSA run in anteroposterior (*AP*) (**c**) and lateral (**d**) projections. Satisfactory occlusion of the aneurysm by balloon-assisted coiling is seen. At the end of the run, a "spontaneous" inflation of the dual lumen balloon is also depicted (*black arrow*)

lumen balloon catheter shaft with subsequent contrast medium infiltration into the inflation lumen during the DSA run. Nonetheless, on examining the balloon catheter shaft macroscopically, no obvious damage was found on the device. Additionally, nothing happened during the previous intermediate DSA runs performed by hand injection during the procedure ($n=2$). Moreover, direct infiltration of contrast medium into the inflation lumen would have probably resulted in balloon rupture (volume for balloon inflation $\approx$0.2 ml). No such event occurred when the balloon was tested outside the patient.

To further understand the mechanism behind this spontaneous balloon inflation it was decided with the aid of the balloon manufacturer company (Balt Extrusion), to perform several tests:

Bench Testing

Within 24 h postprocedure, series of tests were performed on the dual lumen balloon used during the procedure by the quality engineers Team from the Balt Extrusion company (Table 1). Firstly, to evaluate the conformity of the catheter, the balloon and the catheter lumen were tested for any obvious leakage sites but none were found. The balloon could be inflated and deflated using 1 ml syringe with no obvious

Table 1 Table 1

Test	Result
Balloon inflation lumen	No leakage
Leakage into the working lumen	No leakage
Balloon inflation with syringe	Good
Visual inspection without magnification	Good
Balloon deflating with syringe	Good

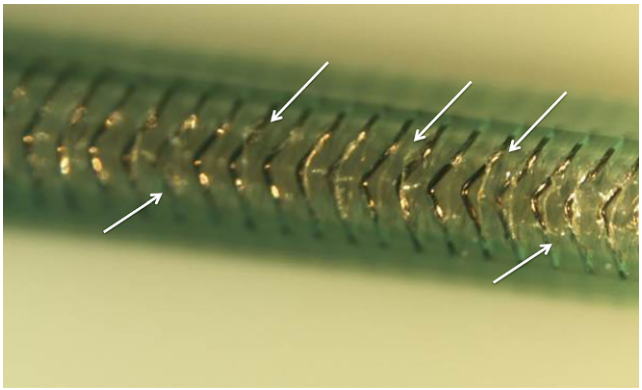

Fig. 2 Microscopic analysis of the balloon catheter. Stepped striping (*white arrows*) perpendicular to the long axis of the catheter shaft is seen on a segment located 20 cm from the hub. Bending of the braided shielding wire is also depicted on the same portion of the catheter shaft

problem. On visual inspection without magnification, the catheter appeared intact.

Microscopic overall analysis of the catheter and particularly along the first 20 cm from the hub was performed. A localized striping of the external polymer tube layer (numerous tears perpendicular to the long axis of the shaft) approximately 10 cm in length was observed. Bending of the braided shielding wire was also found (Fig. 2).

Secondly, to assess the impact of pressure from the injector, the balloon catheter used during the case was positioned in a 0.070″ guiding catheter connected to an automatic injector on bench test. This test was performed using graded pressure levels in the guiding catheter starting from 100 pounds per square inch (PSI) and up to 750 PSI (maximum system capacity). The same test was repeated but with gradual introduction (step by step procedure) of the balloon catheter inside the guiding catheter to assess the effect of changing balloon catheter position within the guiding catheter. Similarly, each balloon catheter position was tested against different pressure levels (100–750 PSI). Only one combination resulted in slow and mild (<50%) "spontaneous" balloon inflation. Test conditions at which spontaneous balloon inflation occurred were as follow:

1. 750 PSI (maximum capacity),
2. positioning of the balloon catheter shaft at about 20 cm from catheter's proximal aspect (hub) inside the hemostasis valve.

Discussion

This was the first case of spontaneous balloon inflation that occurred in this Institution during a DSA run when performing endovascular BAC for an intracranial aneurysm. To our knowledge, no similar cases have been reported previously.

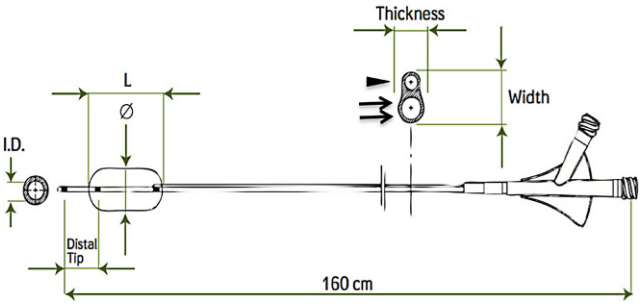

Fig. 3 Drawing of the design of the Eclipse 2L balloon (Balt Extrusion). Note that the inflation (*black arrow head*) and working (*double black arrows*) lumens are sitting side by side. *L* balloon length, *I.D.* inner diameter

Balloon catheters can be divided into two groups based on device design: single lumen and double lumen balloons. In single lumen catheters the guide wire must enter the balloon lumen to achieve mechanical sealing for balloon inflation [7]. On the contrary, in double lumen catheters, the inflation lumen is independent from the working lumen [8]. Different designs of dual lumen balloons are available. The inflation lumen may surround the working lumen in some devices (Ascent and Scepter balloons), or the two lumens may be side by side (the so-called flat catheter concept, Eclipse and Copernic 2L; Fig. 3). The advantage of the latter design is that it allows a faster inflation/deflation.

In neuroendovascular procedures, a hemostasis valve is commonly used for continuous irrigation of guide and microcatheters to decrease the risk of thromboembolism and to avoid blood reflux on the surgical drape. A conventional hemostasis valve has a rotating seal at its proximal aspect, which is turned open or closed each time a wire or microcatheter/guidewire is introduced or extracted. For BAC, if only one guiding catheter is used, 2 hemostasis valves can be connected to introduce the balloon in the first one and the microcatheter in the second one. In our Institution, the more proximal hemostasis valve is use (i.e. the "direct" hemostasis valve, which is closer to the operator) for the microcatheter since this configuration seems easier for catheter manipulation during coiling (Fig. 4a; [9]). The second hemostasis valve (i.e. the "indirect" hemostasis valve) is used for the balloon.

The main hypothesis explaining balloon spontaneous inflation is that the sharp angle in the indirect hemostasis valve may have damaged the proximal part of the balloon during insertion (Fig. 4a, b), which may have led to entrapment of contrast medium between the 2 layers of the inflation lumen wall. This contrast medium entrapment may have led to subsequent spontaneous inflation by pushing the diluted contrast medium inside the inflation lumen, especially if the hemostasis valve was closed tightly (Fig. 4c). Theoretically, this adverse event could potentially

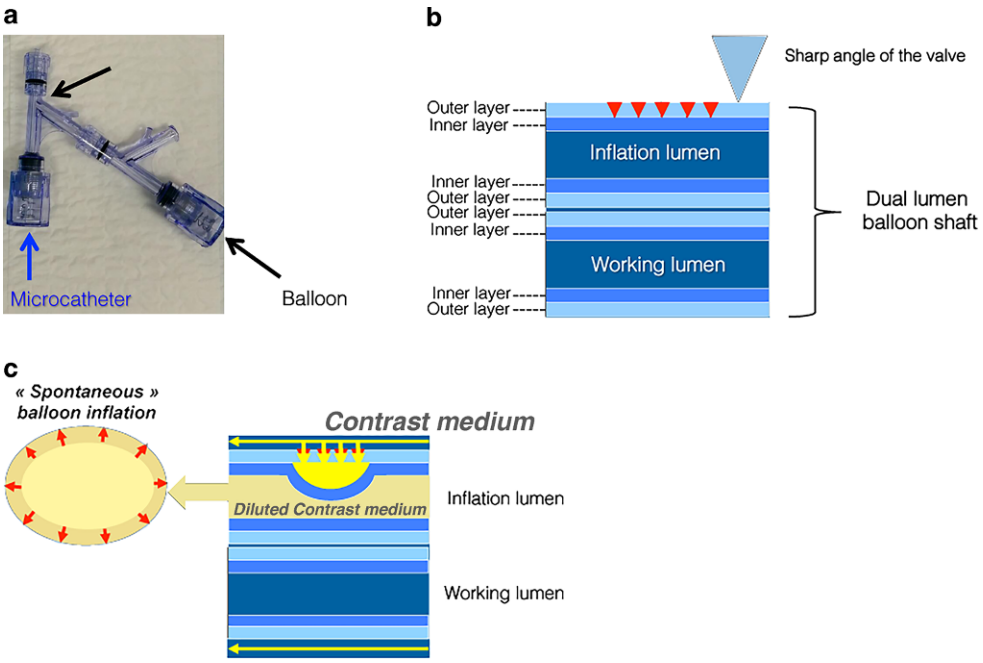

Fig. 4 Mechanism proposed to explain the balloon "spontaneous" inflation. **a** Macroscopic picture of the hemostasis valve connections used. The so-called "direct" valve is used for the introduction of the microcatheter; the "indirect" valve, for the balloon. Note the sharp angle of the indirect valve (*black arrow*), that may be responsible for balloon catheter damaging. **b** Drawing of the dual lumen balloon shaft, demonstrating the inflation lumen and the working lumen located side by side. During the introduction of the balloon through the "indirect" valve, damaging of the outer layer of the inflation lumen wall may occur due to the sharp angle. **c** Schematic drawing showing the proposed final explanation behind the "spontaneous" balloon inflation. During the contrast medium injection with the power injector (8 ml, 4 ml/s; 450 PSI), contrast medium may penetrate through the tears on the outer layer of the catheter wall and go between the two layers (inner and outer). The inner layer may thus be displaced medially, resulting in pushing diluted contrast medium inside the inflation lumen, eventually leading to inflation of the balloon

arise when using balloons of any type (single/dual lumen) or size.

Several techniques are proposed that may be helpful to avoid such a side effect. Firstly, one could consider the use of 2 guiding catheters (one for the balloon and another one for the microcatheter). Another solution could be to advance the balloon through the direct hemostasis valve as the indirect hemostasis valve has a sharp angle and therefore, it could lead to balloon damage. The use of a "W" shape hemostasis valve (e.g. Sequel; eV3/Medtronic, Plymouth, MI, USA) may also be safer. Finally, the hemostasis valve should not be closed too tightly to avoid damaging the balloon catheter shaft.

Learning Points/Take Home Messages

Although rare, "spontaneous" balloon inflation may occur during DSA runs when performing BAC embolization. This is likely caused by damage to the catheter shaft. Recognition of this issue and taking steps to minimize the risk of its occurrence ae essential to avoid potential complications.

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Conflict of interest A. Al Raaisi and J. Gabrieli declare that they have no competing interests. N.-A. Sourour is consultant for Covidien, MicroVention; proctor and investor for the Medina Embolization Device (Medtronic). F. Clarençon is consultant for Codman Neurovascular (paid core lab) and for Medtronic (lecturing fees).

References

1. Moret J, Cognard C, Weill A, Castaings L, Rey A. The "remodelling technique" in the treatment of wide neck intracranial aneurysms. Angiographic results and clinical follow-up in 56 cases. Interv Neuroradiol. 1997;3:21–35.
2. Liu YQ, Wang QJ, Zheng T, Zhang X, Li XF, Cui XB, Gao YY, Lai LF, Su SX, He XY, Duan CZ. Single-centre comparison of procedural complications, clinical outcome, and angiographic follow-up between coiling and stent-assisted coiling for posterior communicating artery aneurysms. J Clin Neurosci. 2014;21:2140–4.
3. Fiorella D, Arthur AS, Chiacchierini R, Emery E, Molyneux A, Pierot L. How safe and effective are existing treatments for wide-necked bifurcation aneurysms? Literature-based objective performance criteria for safety and effectiveness. J Neurointerv Surg. 2017;9:1197–201.
4. Baldi S, Mounayer C, Piotin M, Spelle L, Moret J. Balloon-assisted coil placement in wide-neck bifurcation aneurysms by use of a new, compliant balloon microcatheter. AJNR Am J Neuroradiol. 2003;24:1222–5.

5. Pierot L, Spelle L, Leclerc X, Cognard C, Bonafé A, Moret J. Endovascular treatment of unruptured intracranial aneurysms: comparison of safety of remodeling technique and standard treatment with coils. Radiology. 2009;251:846–55.
6. Shapiro M, Babb J, Becske T, Nelson PK. Safety and efficacy of adjunctive balloon remodeling during endovascular treatment of intracranial aneurysms: a literature review. AJNR Am J Neuroradiol. 2008;29:1777–81.
7. Piotin M, Blanc R. Balloons and stents in the endovascular treatment of cerebral aneurysms: vascular anatomy remodeled. Front Neurol. 2014;5:41.
8. Pukenas B, Albuquerque FC, Weigele JB, Hurst RW, Stiefel MF. Use of a new double-lumen balloon catheter for single-catheter balloon-assisted coil embolization of intracranial aneurysms: technical note. Neurosurgery. 2011;69(1 Suppl Operative):ons8-12; discussion ons12-3.
9. Namba K, Song JK, Niimi Y, Heran NS, Berenstein A. A new hemostasis valve for neuroendovascular procedures. Interv Neuroradiol. 2007;13:51–3.