Failed conventional noncompliant balloon therapy in under expanded stent during acute coronary syndrome: Undersized noncompliant balloon to the rescue!

Fallo de balón convencional no complaciente en stent no expandido durante síndrome coronario agudo: ¡Balón no complaciente de menor tamaño al rescate!

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ABSTRACT

A 57-year-old man was admitted with chest pain. He was a chronic smoker with diabetes, hypothyroidism, and hypertension. He had recently fully recovered from a stroke and was treated with aspirin and clopidogrel. The ECG suggested an inferior wall myocardial infarction, and the echocardiogram revealed inferolateral and posterior hypokinesia, with a left ventricular ejection fraction (LVEF) of 48%. Cardiac catheterization showed a normal left main coronary artery, 80% stenosis of the left anterior descending (LAD) artery, 100% occlusion of the middle left circumflex artery (LCx), and 90% stenosis of the proximal nondominant right coronary artery (RCA). A decision was made to revascularize the left circumflex artery as the culprit lesion. The lesion was crossed and pre-dilated with a semi-compliant balloon. After pre-dilation, severe stenosis in the middle circumflex artery (Cx) was observed, revealing three branches. First, a stent was directly placed in the distal Cx, followed by stent implantation in the mid-Cx. A separate guidewire was used in the distal Cx, and a 2.5 × 24-mm Promus Elite stent (Boston Scientific) was deployed at 14 atmospheres. After stent implantation, a waist observed in the mid-stent segment was post-dilated with a non-compliant (NC) balloon at 16 atmospheres. However, residual stenosis persisted, and the balloon maintained a "dogbone" shape. Multiple attempts with insufflation at high pressures, up to 24 atmospheres, failed. An attempt was made with a previously used 2.5 × 15-mm OPN NC balloon, which also failed. As a last resort, a 2.0×10-mm OPN NC balloon was cautiously and gradually inflated to very high pressures, until the waist eventually disappeared 40 atmospheres. The stented segment was then post-dilated. The same lesion was then appropriately dilated with a 2.5-mm NC balloon, and a stent was deployed from the LCx to the obtuse marginal branch. TIMI 3 flow was achieved. In this case, an OPN balloon with a slightly smaller profile than the vessel diameter was used as a desperate measure to achieve adequate expansion of the underexpanded stent segment..

Keywords: non-dilatable lesions, coronary artery disease, OPN NC balloon, coronary angioplasty

RESUMEN

Paciente de sexo masculino de 57 años presentó al ingreso dolor de pecho. Es fumador crónico, diabético, hipotiroideo e hipertenso. Recientemente sufrió un accidente cerebrovascular con recuperación completa y fue tratado con aspirina y clopidogrel. El ECG fue sugestivo de infarto de miocardio de la pared inferior y el ecocardiograma mostró hipocinesia inferolateral y posterior, con FEVI 48%. La cinecoronariografía reveló tronco de la coronaria izquierda normal, estenosis del 80% de la arteria descendente anterior (LAD), oclusión del 100% de la arteria circunfleja izquierda media (LCx) y estenosis del 90% de arteria coronaria derecha proximal no dominante (RCA). Se tomó la decisión de revascularizar la arteria circunfleja izquierda por considerarla lesión culpable. La lesión fue cruzada y predilatada con un balón semicomplaciente y se observó luego de la predilatación una estenosis severa en la arteria circunfleja media, luego de lo cual se visualizaron 3 ramas. Se decidió colocar un stent directamente en la arteria circunfleja distal primero, seguido de la implantación del stent en la circunfleja media. Se utilizó otra guía metálica en la arteria circunfleja distal y se desplegó un stent Promus Elite (Boston Scientific) de 2.5x24 mm a 14 atm. Después de la implantación del stent, había una cintura en la parte media del stent que se posdilató con un balón NC a 16 atm con estenosis residual que persistía con un "hueso de perro" en el balón. Varios intentos con el insuflado hasta presiones más altas de hasta 24 atm fracasaron. Se intentó tratar con un balón OPN NC de 2,5x15 mm previamente utilizado, pero fracasó. Entonces se decidió utilizar un balón OPN NC de 2.0x10 mm como medida desesperada. Este balón fue inflado gradual y cautelosamente a presiones muy altas y finalmente rompió la cintura a 40 atmósferas. Luego se posdilató el segmento con stent. Luego, la misma lesión se dilató adecuadamente con un balón NC de 2,5 mm y se desplegó un stent desde LCx a la obtusa marginal. Se logró flujo TIMI 3. En este caso, se utilizó un balón OPN con un perfil ligeramente más bajo que el diámetro del vaso como medida desesperada para expandir adecuadamente el segmento del stent insuficientemente expandido.

Palabras clave: lesiones no dilatables, enfermedad coronaria, balón OPN NC, angioplastia coronaria.

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INTRODUCTION

When dealing with fibrotic and calcified coronary lesions, especially in cases where a stent is underexpanded, non-compliant (NC) balloons are an essential part in the interventional cardiologist toolbox. These balloons are designed with limited expansion capabilities, maintaining their diameter even at high pressure, which makes them ideal for post-dilation of underexpanded stents or the pretreatment of resistant lesions.

In cases of severely calcified plaque, standard balloons may not provide sufficient force to adequately dilate the lesion. Non-compliant balloons, on the other hand, can be insufflated to high pressures without overstretching, providing the radial force needed to fracture resistant calcified plaque and ensure optimal stent expansion. This is particularly valuable when deploying a stent that fails to fully expand due to lesion rigidity, which can lead to stent malapposition and adverse outcomes such as restenosis or thrombosis.

Beyond addressing underexpanded stents, NC balloons are frequently used as a preparatory step in lesions resistant to regular balloon inflation. This strategy ensures that the lesion will be adequately dilated before stenting, thus reducing the risk of future complications.

Compared to more advanced and costly techniques like la-

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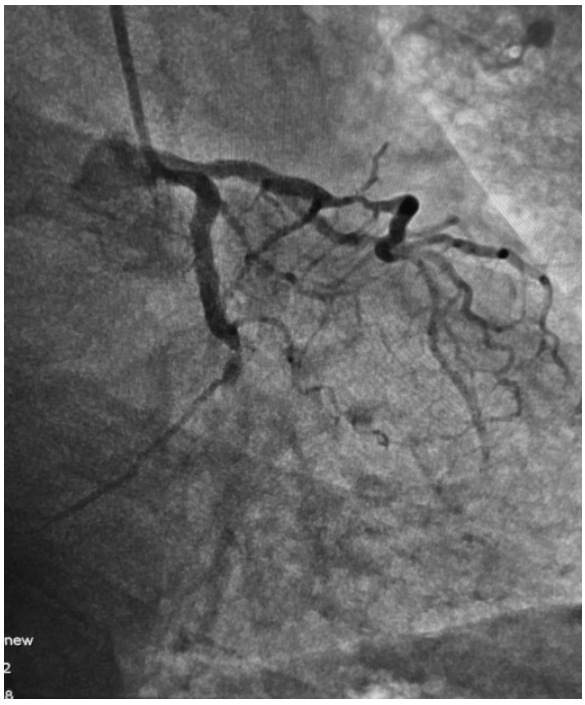

Figure 1. *Acute thrombotic occlusion of the circumflex artery in right anterior oblique view with caudal angulation.*

ser atherectomy, intravascular lithotripsy, or rotational atherectomy, NC balloons are a cost-effective solution in many cases[1].

While laser and atherectomy devices are invaluable for certain complex lesions, they involve higher equipment costs and are not always readily available. On the contrary, NC balloons offer a simpler and more affordable approach that is widely accessible and versatile to be used in a variety of challenging scenarios.

In conclusion, in the case presented, NC balloons were an essential component of the interventional toolkit, particularly within the treatment of fibrotic or calcified lesions. Their ability to generate high-pressure insufflation, combined with their cost advantages, makes these devices a practical and cost-efficient option for this type of coronary intervention.

CLINICAL CASE

A 57-year-old man presented with intense chest pain lasting 3 hours. He was a chronic smoker for 30 years, had type II diabetes for 15 years, hypothyroidism for 12 years, and hypertension for 10 years. Eight months before, he had suffered a stroke in the right middle cerebral artery, from which he fully recovered with medical treatment. His current medical treatment included aspirin, clopidogrel, atorvastatin, metformin, glimepiride, levothyroxine, telmisartan, and pantoprazole. His hemodynamic parameters were heart rate at 85 beats per minute, blood pressure at 100/70 mmHg, and oxygen saturation by pulse oximetry of 98%. The ECG showed sinus rhythm, with an inferior wall myocardial infarction, and the echocardiogram revealed inferolateral and posterior hypokinesia with an LVEF of 48%. He received aspirin 325 mg, ticagrelor 180 mg, and atorvastatin 80 mg, before being transferred to the cardiac cath lab. Coronary angiography via right radial access showed a normal left main coronary artery, 80% tubular stenosis of the left anterior descending artery (LAD), 100% thrombotic occlusion of the middle left circumflex artery (LCx) (**Figure 1**), and 90% stenosis of the proximal non-dominant right coronary artery (RCA). A decision was made to revascularize the left circumflex artery, considering it the culprit lesion. The left coronary artery was accessed with a 6-Fr Extra Back Up (EBU) 3.5 guiding catheter, and the lesion was crossed with a 0.014" Runthrough guidewire (Terumo, Japan) and pre-dilated with a 2.0 × 12-mm semi-compliant balloon at 12 atmospheres. About 90% stenosis was observed in the middle circumflex artery, followed by the visualization of 3 branches: obtuse marginal (OM), left posterior descending, and distal circumflex artery (**Figure 2**). The OM and distal circumflex artery showed significant stenosis: 80%. A decision was made to first place a stent directly in the distal circumflex artery (**Figure 3**), followed by stent implantation in the middle circumflex artery up to the major OM artery. A separate 0.014" guidewire was used in the distal circumflex

Figure 2. *Initial result after Cx rechanneling and distal angioplasty.*

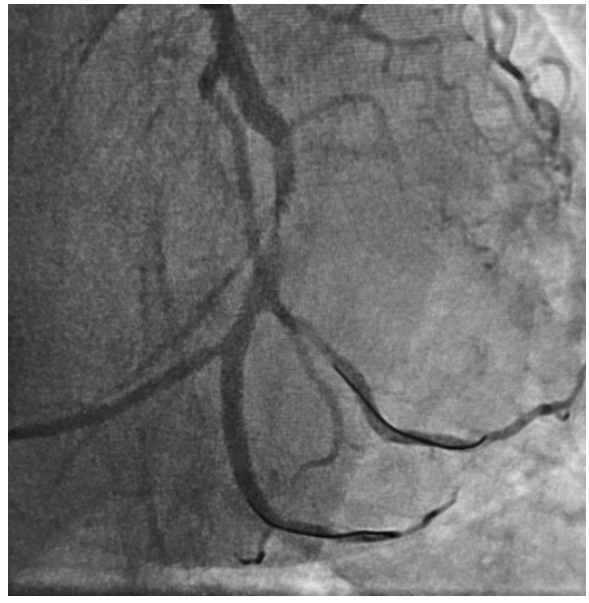

Figure 3. *Angiographic result after stent implantation in the distal third of the circumflex artery.*

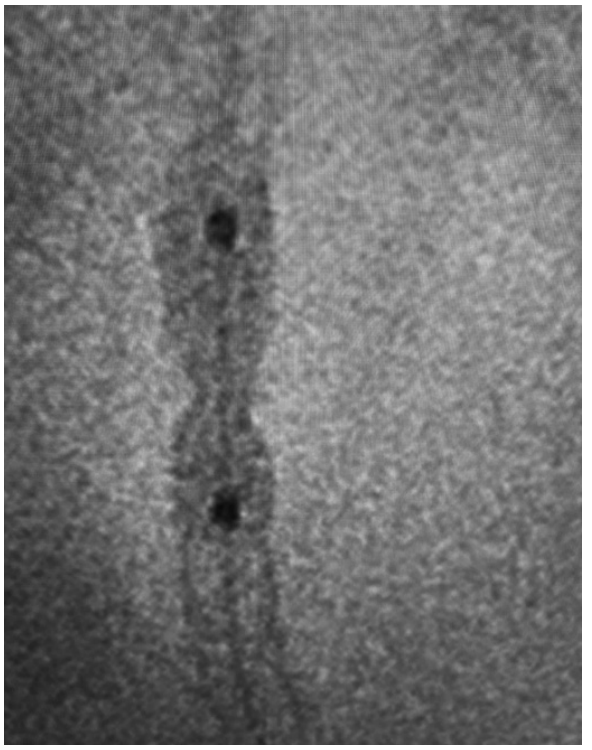

Figure 4. *"Dogbone" shaped stent underexpanded in its middle third.*

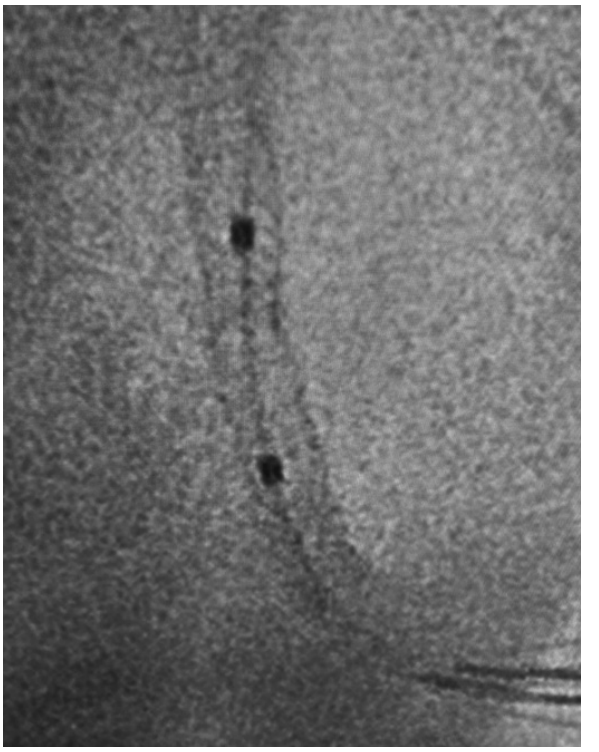

Figure 5. *Final result of the expanded stent after using the OPN balloon at 50 atmospheres.*

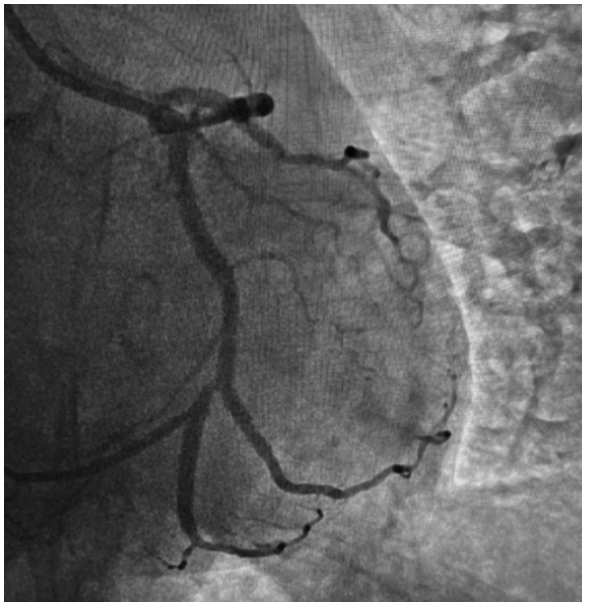

Figure 6. *Final angiographic result after total stent expansion at high pressure.*

artery, and a 2.5 × 24-mm Promus Elite stent (Boston Scientific) was deployed at 14 atmospheres in the middle third. After stent implantation, a waist observed in the mid-stent segment was post-dilated with a 2.75 × 8-mm non-compliant balloon at 16 atmospheres. However, residual stenosis persisted, and the balloon maintained a "dogbone" shape (**Figure 4**). Several attempts at gradual, controlled, and cautious insufflation at high pressure, up to 24 atmospheres, failed. An attempt was made with a previously used 2.5 × 15-mm OPN balloon (SIS MEDICAL AG, Switzerland), which also failed. A decision was then made to use a 2.0 × 10-mm OPN NC balloon as a last resort. This balloon went over the lesion and was gradually and cautiously insufflated at very high pressure, until the waist ultimately disappeared at 40 atmospheres (**Figure 5**). The stented segment was then post-dilated with the 2.75 × 8-mm NC balloon at 14-18 atmospheres. The LCx-OM lesion was then adequately dilated with a 2.5-mm NC balloon, and a 2.75 × 33-mm Xience Prime (Abbott, USA) stent was deployed from LCx-OM at 12 atmospheres. The stented segment was finally post-dilated with good final TIMI III flow (**Figure 6**).

DISCUSSION

Fibrotic and calcified lesions are occasionally found during primary angioplasty[2]. They are more commonly seen in elderly patients with hypertension, diabetes, and renal insufficiency.

Fluoroscopic visualization of calcium is usually inadequate unless the lesion is highly calcified. Assessing highly fibrotic lesions using conventional angiography is also very difficult. In this case, direct stent implantation in the circumflex artery was initially considered as feasible and, possibly, the best alternative, considering acute coronary syndrome (ACS) as the clinical presentation. In ACS, direct stent implantation has been found to be superior to routine balloon pre-dilation as it avoids distal microembolization, slow flow, and thrombi migration[3]. However, we did not expect the highly fibrotic nature of the lesion. Since intravascular imaging was not available in the cath lab, we were unsure whether the lesion was fibrotic, calcified, or a combination of both.

The stented segment failed to dilate with a large non-compliant balloon at quite high pressure[4]. A smaller OPN NC balloon, which was 0.5 mm smaller than the vessel size, was very helpful and ultimately dilated the stent at 40 atmospheres.

While manufacturer guidelines recommend insufflating this balloon up to a maximum pressure of 35 atmospheres[5], there have been reports of this balloon being used with up to 50 atmospheres. The key is to reduce the balloon size 0.25-0.5 mm smaller than vessel size before moving to higher pressures.

Furthermore, insufflation should be gradual and slow. There should always be a lined stent ready in case of rupture or urgency, especially when exceeding the recommended maximum pressure. We should note that other approaches include Shockwave IVL balloons and laser, but these options are quite expensive compared to the one we chose on this occasion[6,7].

There are several ongoing studies to elucidate between using high-pressure non-compliant balloons and coronary ultrasound system Shockwave IVL (Shockwave Medical, Inc. Santa Clara, CA, USA).

The high-pressure OPN balloon is being compared with Shockwave IVL in the ISAR-CALC2 (Comparison of Strategies to Prepare Severely Calcified Coronary Lesions; NCT05072730) study**8**, a trial in patients with severely calcified coronary lesions where non-dilatable coronary lesions are randomized to OPN or IVL. The primary endpoint of that study is the final minimal luminal diameter after stent implantation.

Finally, the VICTORY (Value of IVL Compared to OPN Non-Compliant Balloons for Treatment of Refractory Coronary Lesions; NCT05346068) study is a non-inferiority study to compare the impact of IVL with that of high-pressure balloons on final expansion, as assessed with optical coherence tomography in 280 patients with calcified coronary lesions.

CONCLUSION

In our case, an OPN balloon with a slightly smaller profile than the vessel diameter was used as a desperate measure to achieve adequate expansion of the severely underexpanded stent segment. Calcified and highly fibrotic lesions are a challenge for cardiologists and require careful management. Other approaches include the use of IVL balloons and laser atherectomy, but these approaches are limited by their higher cost and may not be routinely available in all cath labs.

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