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"Assessment of effectiveness and security in high pressure postdilatation of bioresorbable vascular scaffolds during percutaneous coronary intervention. Study in a contemporary, non-selected cohort of Spanish patients"

Rosa A. Abellas-Sequeiros [a,*,1], Raymundo Ocaranza-Sanchez [a,1], Carlos Galvão Braga [b,1], Sergio Raposeiras-Roubin [a,1], Diego Lopez-Otero [a,1], Belen Cid-Alvarez [a,1], Pablo Souto-Castro [a,1], Ramiro Trillo-Nouche [a,1], Jose R. Gonzalez-Juanatey [a,1]

[a] Interventional Cardiology Unit, Universitary Clinical Hospital of Santiago de Compostela, 15706, Spain
[b] Interventional Cardiology Unit, Hospital de Braga, 4710 Braga, Portugal

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ABSTRACT

Objectives: To determine security and benefits of high pressure postdilatation (HPP) of bioresorbable vascular scaffolds (BVS) in percutaneous coronary intervention (PCI) of complex lesions whatever its indication is.
Background: Acute scaffold disruption has been proposed as the main limitation of BVS when they are overexpanded. However, clinical implications of this disarray are not yet clear and more evidence is needed.
Methods: A total of 25 BVS were deployed during PCI of 14 complex lesions after mandatory predilatation. In all cases HPP was performed with NC balloon in a 1:1 relation to the artery. After that, optical coherence tomography (OCT) analyses were performed.
Results: Mean and maximal postdilatation pressure were 17 ± 3.80 and 20 atmospheres (atm) respectively. Postdilatation balloon/scaffold diameter ratio was 1.01.
A total of 39,590 struts were analyzed. Mean, minimal and maximal scaffold diameter were respectively: 3.09 ± 0.34 mm, 2.88 ± 0.31 mm and 3.31 ± 0.40 mm. Mean eccentricity index was 0.13 ± 0.05. ISA percentage was 1.42% with a total of 564 malapposed struts. 89 struts were identified as disrupted, which represents a percentage of disrupted struts of 0.22%.
At 30 days, none of our patients died, suffered from stroke, stent thrombosis or needed target lesion revascularization (TLR).
Conclusions: NC balloon HPP of BVS at more than 17 atm (up to 20 atm) is safe during PCI and allows to achieve better angiographic and clinical results.

1. Introduction

New bioresorbable scaffold technology has become the great revolution in interventional cardiology. These scaffolds consist on a polymeric backbone of poly-L-lactic acid which is coated by another polymeric layer in which is embedded the antiproliferative drug. They offer all the benefits of a DES in addition to a great advantage: by two years after their implantation, the scaffolds are not more present in the coronary artery [1]. Furthermore, the artery can recover its vasomotility and compliance. Nevertheless, one limitation has been proposed for these devices: they are at risk of disruption when they are overexpanded. Clinical implications of this disarray are not yet clear.

2. Methods

2.1. Patient population

In this all-comers prospective study we included fourteen patients admitted to our centre for percutaneous coronary intervention (PCI)

Abbreviations: PTCA, percutaneous transluminal coronary angioplasty; DES, drug-eluting metallic stents; BVS, bioresorbable vascular scaffold; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; TLR, target lesion revascularization; DAPT, dual antiplatelet treatment; NC balloon, non-compliant balloon; ISA, incomplete strut apposition; LLL, late luminal loss.

* Corresponding author at: Interventional Cardiology Unit, Universitary Clinical Hospital of Santiago de Compostela, A Choupana s/n, CP 15706 Santiago de Compostela, Spain.
E-mail address: albaabellas@gmail.com (R.A. Abellas-Sequeiros).

[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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from June to December 2015. A total number of 14 lesions were treated with 25 bioresorbable vascular scaffolds (BVS) deployed.

Each patient must has been treated with a minimum of one BVS, independently of what the indication for coronary revascularization was. In fact, PCI is accepted either in the setting of an acute coronary syndrome (with or without ST segment elevation) or in stable coronary artery disease.

We report baseline clinical and angiographic characteristics of the 14 patients (14 lesions treated) in addition to OCT baseline analyses of the 25 BVS deployed. Moreover, all patients have undergone a 30-day clinical follow up, and half of them have also been interviewed three months after intervention.

Regarding to anatomical lesions characteristics, we only excluded lesions when minimum vessel diameter was less than 2 mm or when maximum vessel diameter exceeded 4 mm. Other exclusion criteria include: heparin or aspirin intolerance, high risk of bleeding (patients under chronic anticoagulation treatment, with previous history of life-threatening bleeding or with coagulation diseases), patients expected not to be able to maintain long dual antiplatelet treatment(DAPT) and terminal disease with life-expectancy less than a year.

2.2. Devices and optical coherence tomography

In our study we only used the Abbot bioresorbable scaffold (Abbott Vascular, Santa Clara, California): the Absorb 1.1 BVS. This device consists on a polymeric backbone of poly-L-lactic acid which is coated by another polymeric layer. This external layer is the one which supports and controls the everolimus eluting process. The scaffold is available in different diameters (2.5, 3.0, 3.5 mm) and lengths (15, 18, 23 and 28 mm), and we have chosen the most appropriate ones according to each lesion characteristics. Radial tension of this bioresorbable device is comparable to previously described radial tension in most bare metal stents. Its strut thickness has been quantified in 156 μm and its mean contact area with the vessel is 25% [1].

Intravascular imaging evaluation has been performed by a frequency-domain OCT analysis. We used the Lunawave Coronary imaging console® (Terumo Corp., Tokyo, Japan) and the FastView Catheter®(Terumo Corp. Tokyo, Japan). This catheter is advanced distally to the scaffold area at least 5 mm and then, it is automatically pulled back with simultaneous infusion of 4–10 mL of iodinated contrast at a rate of 3-5 ml/s. In very large stented artery segments, consecutive pullbacks can be performed in order to allow an adequate assessment of the treated segment. We performed the pullback at a 20 mm/s speed. In each pullback the achieved frame rate was 160 frames /sec.

2.3. Procedure

Scaffold size was selected according to visual and QCA assessment and, if more than one scaffold were needed, they must be implanted overlapping. According to current recommendations, all lesions must be predilatated with semicompliant balloons before scaffold deployment. In addition to this, all devices were postdilatated at high pressure with a non-compliant (NC) balloon in a 1:1 relationship. In our cathlab two brands of non-compliant balloons are available: Open NC® super High Pressure PTCA balloon Sismedical AG Winterthur Switzerland and NC Trek® Coronary Dilatation Catheter Abbott Vascular Sta. Clara California. A minimum pressure of, at least, 10 and 12 atm were used to achieve minimum diameter of each balloon. Maximal expected diameter for 3 mm and 3.5 mm Open NC balloon were 3.36 mm and 3.78, maximal expected diameter for 3 and 3.5 mm NC Trek balloon were 3.21 and 3.78 mm respectively. Election of posdilatation balloon was defined by its availability at the moment of the PCI. After that, OCT analyses were performed as it was explained above.

In our study we enrolled patients with indication of PCI either in the setting of an acute coronary syndrome or for chronic coronary artery disease. Primary PCI was performed by an on-call group of interventional cardiologists, according to current guidelines. Thrombus aspiration was not mandatory in all culprit lesions and GP IIbIIIA inhibitors could be used in a bail-out indication.

All percutaneous coronary interventions have been performed under unfractioned heparin treatment. At discharge, dual antiplatelet therapy was mandatory with aspirin and a P2Y12 inhibitor (ticagrelor, prasugrel or clopidogrel). Of note, in line with current guidelines, new generation P2Y12 inhibitors should be used after PCI in acute coronary syndrome.

2.4. OCT offline analysis

The OCT analysis was performed with the off-line software provided by Terumo® (Terumo Corp., Tokyo, Japan). We measured 1 mm distally and proximally out of the stented vessel segment, and the total scaffolded segment. Each millimeter of the pullback contains 8 frames.

In the 1 mm proximal and distal to the BVS edge we measured for each frame: lumen and vessel area and diameter. These data allowed us to calculate mean lumen and vessel area and mean, maximum and minimum lumen and vessel diameters.

For each frame along the scaffolded segment of the vessel, we measured all parameters mentioned above, in addition to scaffold area and diameter.

Automatically, Terumo software provided us plaque area, maximum and minimum plaque thickness and eccentricity index. OCT baseline analysis has been done according to previous literature [2–5] in offline setting. We defined lumen area as delimitated by the endoluminal surface of the struts. In case of malapposed struts were present, at that angular section of the vessel, lumen area would be delimitated by the endoluminal wall of the vessel. Scaffold area was measured thanks to the circumference formed by the points in the middle of the black core of each strut. Vessel area has been described based on the circumference marked by external elastic membrane. In those cases where this membrane was not so clear in first pullback, we performed additional pullbacks until its correct visualization. Incomplete strut apposition (ISA) was considered when axial distance between the abluminal surface of struts and the endoluminal surface of the vessel wall was larger than strut thickness (in our case: 156 μm) [6].

Acute scaffold disruption was diagnosed when two struts were in the same angular sector of the lumen either if they were in contact ("stacked struts", Fig. 1) or if they were one above the other but with a space between them ("overhung struts"). In addition to this, isolated malapposed struts (Fig. 2) were also considered as a mark of scaffold disruption when they were alone in lumen, with no connection with the stent circumference [7,8].

Thanks to all previous data we calculate all the following parameters: percentage of ISA (defined as the percentage of malapposed struts from the total of struts) [6] and percentage of disrupted struts from the total number of struts.

2.5. Study endpoints

Primary endpoint: to determine the percentage of disrupted struts after postdilatation of a BVS in percutaneous coronary intervention (PCI).

Secondary endpoints: to determine the percentage of malapposed struts after postdilatation, and rates of mortality, stroke or target lesion revascularization (TLR) at 30 days.

2.6. Statistical analyses

In this report we include results from both strut-level and lesion-level analyses. Continuous variables were expressed as mean and standard deviation while categorical variables are presented as a

Fig. 1. Image of stacked disrupted strut. Letter A marks "stacked strut" type disruption from one of the analyzed BVS.

percentage. Statistical analyses were performed using SPSS software, version 21.

3. Results

Fourteen patients were included in this first report of our study. 25 BVS were deployed in 14 treated lesions. All baseline clinical characteristics are included in Table 1. Most patients were men (only 2 from 14 were women), with a mean age of 56 years old and almost 43% of them have been smokers in the past. Attending to cardiovascular main risk factors: 57.1% had arterial hypertension, 78.6% suffered from dyslipidemia and 28.6% were diabetic (all of them in treatment with oral antidiabetic drugs). It is remarkable that all of them have a body mass index equal or higher than 25, which means all of them were overweight.

The most frequent indication for PCI was effort angina (50%), nevertheless we want to notice that almost a third of the total population (28.6%) were patients who presented at our center with STEMI, so

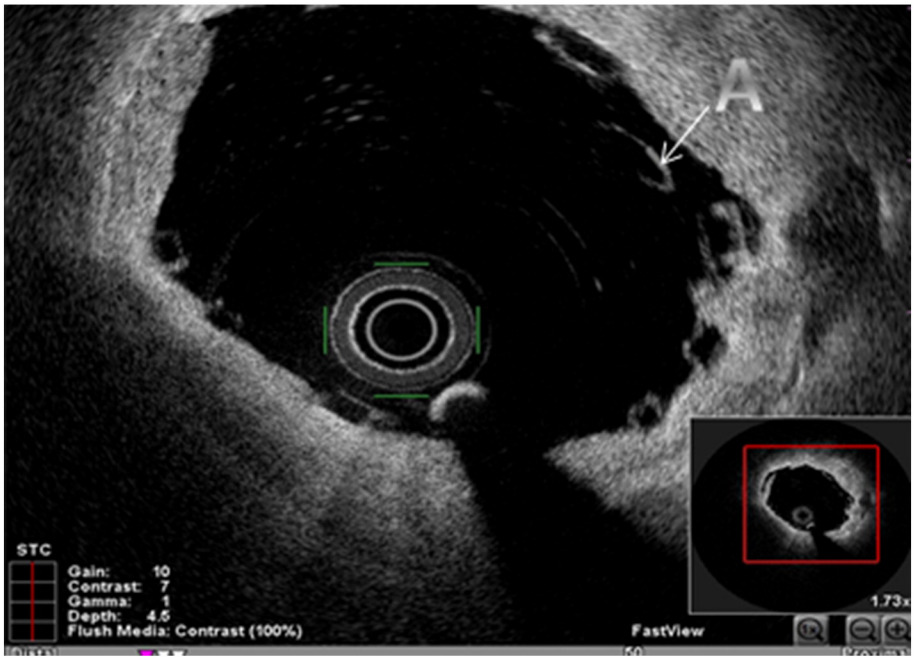

Fig. 2. Image of an isolated disrupted strut. Example of acute strut disruption presented as an isolated strut.

Table 1
Clinical characteristics of our patients.

Number of patients n:14	
Age (years)	56.79 ± 11.38
Women n(%)	2 (14.3)
Current smokers n(%)	4 (28.6)
Ex-smokers	6 (42.9)
Non-smokers	4 (28.6)
Arterial hypertension n(%)	8 (57.1)
Dislypemia n (%)	11 (78.6)
Diabetes Mellitus on AOD n(%)	4 (28.6)
Diabetes Mellitus on insulin n(%)	0
Body mass index	
<25 kg/m^2	0
25–29.9 kg/m^2	8 (57.1)
> = 30 kg/m^2	6 (42.9)
Previous stroke n(%)	0
Peripheral artery disease n (%)	1 (7.1)
Atrial fibrillation n(%)	0
Previous CAD n (%)	1(7.1)
Previous target vessel revascularization	0
HbA1c %	6.05 ± 0.99
Haemoglobine g/dL	14,72 ± 0.82
Platelets × 10^3/μL	270,071 ± 93,403
Creatinine mg/dl	0.77 ± 0.16
eGFR mL/min/1.73 m^2	112.31 ± 37.48
Minimun eGFR	81.80
Previous treatment with statins n (%)	3 (21.4)
Mortality rate at 30 days %	0
Stroke rate at 30 days %	0

This table includes all baseline clinical characteristics of the patients included.
AOD: antidiabetic oral drugs. CAD: coronary artery disease eGFR: estimated glomerular filtration rate.

they underwent primary PCI. Only 1 of the 14 patients had been previously diagnosed of coronary artery disease, with no target vessel revascularization before.

Baseline angiographic data are showed in Table 2. None of our patients has undergone circumflex artery revascularization, being the most frequent treated artery: the anterior descendent one (9 of 14 patients), with a mean artery size of 3.46 mm. Only patients with STEMI had initial TIMI flow 0 with angiographic thrombus. 100% of our patients received predilatation of the coronary lesion. In most cases one or two devices were deployed, with only one case where 4 stents were needed. Mean treated vessel distance was 40.21 mm. In 100% of cases, postdilatation was performed with one of the two available balloons previously described, with a mean length of 13 mm. Mean postdilatation balloon pressure was 17 atmospheres (atm), with a maximal postdilatation pressure of 20 atm. Postdilatation balloon/scaffold diameter ratio was 1.01. Exceptional angiographic results were achieved with a TIMI III flow in all cases.

All OCT baseline measurements are collected in Table 3. A total of 39,590 struts were analyzed within a total of 563 mm of stented vessel in 25 BVS. We detected acute disruption of the scaffold in three of fourteen treated lesions, with a total number of disrupted struts of 89. The percentage of disrupted struts was 0.22%. Malapposition of the scaffold was detected in 3 treated lesions. The total number of malapposed struts was 564. ISA percentage was estimated of 1.42%.

Mean, minimal and maximal scaffold diameter were respectively: 3.09 ± 0.34 mm, 2.88 ± 0.31 mm and 3.31 ± 0.40 mm. Mean eccentricity index was 0.13 ± 0.05.

4. Discussion

Interventional cardiology has experienced great development since Grüentzig introduced PTCA in 1977 [9]. The main problem of this technique is the high likelihood of acute reocclusion due to elastic recoil of the vessel. In order to avoid these complications, first bare metal stents were introduced in late eighties. Either acute recoil or constrictive

Table 2
PCI procedural aspects.

Current indication for PCI n (%)	
Effort angina	7 (50)
ACS without ST segment elevation	3 (21.4)
STEMI	4 (28.6)
Treated artery n(%)	
Left anterior descendent artery	9 (64.3)
Right coronary artery	5 (35.7)
Mean vessel diameter mm	3.46 ± 0.23
Thrombus n (%)	4 (28.6)
Predilatation n (%)	14 (100)
Mean diameter balloon predilatation mm	3.2 ± 0.36
Mean length balloon predilatation mm	19.2 ± 4.37
Mean predilation balloon pressure atm	12.4 ± 3.04
Mean number of BVS deployed per lesion	1.79
Mean diameter of BVS mm	3.22 ± 0.32
Mean length of BVS mm	22.5 ± 5.34
Mean total length scaffolded per lesion mm	40.21 ± 22.14
Mean pressure used in BVS deployment atm	14.08 ± 2.73
Postdilatation n (%)	14 (100)
Mean diameter of postdilatation balloons mm	3.5 ± 0.32
Mean length of postdilatation balloons mm	13 ± 3.55
Mean postdilatation balloon pressure atm	17 ± 3.80
Maximum postdilatation balloon pressure atm	20 ± 3.80
Postdilatation balloon/scaffold diameter ratio	1.01
Pre-PCI TIMI flow n (%)	
0	4 (28.6)
I	3 (21.4)
II	1 (7.1)
III	6 (42.9)
Post-PCI TIMI III flow n(%)	14 (100)
Type of lesion n (%)	
A	0
B	2 (14.3)
C	12 (85.7)
Bifurcations n(%)	3 (21.4)
Chronic total occlusions n(%)	3 (21.4)
Target lesion revascularization at 30 days %	0

This table includes the most important procedural aspects of the performed PCI.
ACS: acute coronary syndrome BVS: bioresorbable vascular scaffold, PCI: percutaneous coronary intervention STEMI: ST segment elevation myocardial infarction.

Table 3
Baseline OCT measurements within stented segment of the vessel.

Total number of BVS: 25	
Mean lumen area mm^2	6.84 ± 1.64
Mean lumen diameter mm	2.93 ± 0.35
Minimal lumen diameter mm	2.71 ± 0.72
Maximal lumen diameter mm	3.15 ± 0.41
Mean vessel area mm^2	13.1 ± 2.88
Mean vessel diameter mm	4.04 ± 0.46
Minimal vessel diameter mm	3.88 ± 0.44
Maximal vessel diameter mm	4.21 ± 0.49
Mean scaffold area mm^2	7.59 ± 1.64
Mean scaffold diameter mm	3.09 ± 0.34
Minimal scaffold diameter mm	2.88 ± 0.31
Maximal scaffold diameter mm	3.31 ± 0.40
Mean plaque area mm^2	6.17 ± 1.79
Maximal plaque thickness mm	0.80 ± 0.16
Minimal plaque thickness mm	0.36 ± 0.10
Mean eccentricity index	0.13 ± 0.05
Total number of struts	39,590
Disrupted struts	89
Malapposed struts	564
Percentage of disrupted struts %	0.22
Percentage of ISA %	1.42

This table includes the results of baseline intracoronary studies by OCT within the stented segments.
BVS: bioresorbable vascular scaffold ISA: incomplete strut apposition.

remodeling are avoid in presence of these devices thanks to their radial tension [10]. However, there was a negative point on them: an excessive healing arterial process which results in a reduction in lumen area. With the development of DES, intimal hyperplasia is controlled [11], with the only problem of a higher risk of arterial thrombosis , which is mitigate with longer dual antiplatelet therapies.

Since they were introduced at the beginning of this decade, BVS have become some of the most promising devices in interventional cardiology. They offer all the previous stents ' beneficial properties in addition to one significant difference: the resorption of their polymeric strut at 2 years after its implantation [1].

The disappearance of the strut lets the vessel to restore its own vasomotility and compliance and it is followed by an increased luminal area. Moreover, the no longer existence of the scaffold would allow future coronary revascularization surgery if necessary [12].

However, the main drawback of the BVS is its low radial tension strength. First generation everolimus bioresorbable vascular scaffolds (Absorb 1.0 Abbott Vascular, Santa Clara, California) only offered adequate radial support for the first post-implantation weeks [1]. Its mean percent acute recoil was 6.85 ± 6.96%, which represented a significant higher rate of acute recoil versus metallic everolimus-eluting stents (e.g. Xience V stent®, Abbott Vascular, Santa Clara, California) which has a mean percent acute recoil of 4.27 ± 7.08%) [13]. In addition to this, intracoronary imaging studies demonstrated that first generation Absorb 1.0 devices had a high late luminal loss (LLL) of 0.44 mm at six months (versus 0.10 mm of six-months LLL for the Xience V stent). In order to correct these defaults, second generation Absorb 1.1 was redesigned. New distribution of the scaffold struts allows to reduce the maximum circular unsupported cross sectional area and some chemical variations of the polymer (which imply a slower polymeric hydrolysis process) let the scaffold maintain its radial tension for a longer period of time [1]. Nevertheless, BVS radial strength remains slightly lower than metallic ones do, and this is the reason why optimal predilatation of the lesion before the scaffold deployment should be done. 100% of lesions treated in our study were predilatated without complications, being the mean balloon pressure applied of 12.4 atm.

However, there is no general consensus between interventional cardiology community about the necessity of high pressure postdilatation after the BVS deployment. Previous evidence had recognized risk of strut rupture as the main limitation of these kind of devices. For the first time, Absorb A trial investigators reported a single case of strut disruption in a patient with persistent angina. They proposed this complication was related to over –expansion of the device [14]. Going along with this theory, in 2011 Ormiston et al. [15] reported a case of strut disruption in a second generation BVS: an Absorb 1.1 scaffold which had been postdilatated for two times at 24 atm and 16 atm. Further studies with second generation BVS also show low rates of strut disruption but only in OCT analyses, not on IVUS ones [2,3].

Although clinical implications of these changes were not clear, BVS were not recommended to be overexpanded by high pressure balloon post-dilatation process in order to avoid acute struts disruption. However, clinical evidence has reported same angiographical and OCT findings as risk factors for intrastent thrombosis either in DES or BVS: stent underexpansion, malapposition and incomplete strut coverage [16]. In this line, Campodanno et al. [17] have recently reported high rates of intrastent thrombosis for BVS (1.5% at 30 days, 2.1% at six months) however we consider necessary to point out that only 49% of treated lesions had been postdilatated.

We support the importance of postdilatation when BVS is deployed in order to avoid incomplete apposition of the device and further complications related to this like aforementioned ones (Fig. 3). We postdilatated at high pressure the 100% of the 25 BVS deployed. Thanks to a mean high postdilatation pressure of 17 atm. we achieved a very low rate of malapposition of the scaffolds implanted. ISA percentage showed by OCT analyses was 1.42% (in line with recent published studies [8]).

Acute scaffold disruption was also evaluated by OCT images. Although high postdilatation pressure was applied to the 25 BVS, only 89 struts from a total of 39,590 were identified as disrupted, what represents a minimal percentage of disrupted struts of 0.22%. Previous studies had already reported low rates of acute scaffold disruption after BVS deployment [7]. Nevertheless, low rates of postdilatation were suggested as the main reason of this low frequency complication (e.g. only 57% of total lesions underwent postdilatation in Yosinobu et al. study [7]).

Based on our results (which are consistent with one recently published study reported by Fabris et al. [8].) we can state acute struts disruption is a very uncommon technical complication after high pressure postdilatation of BVS.

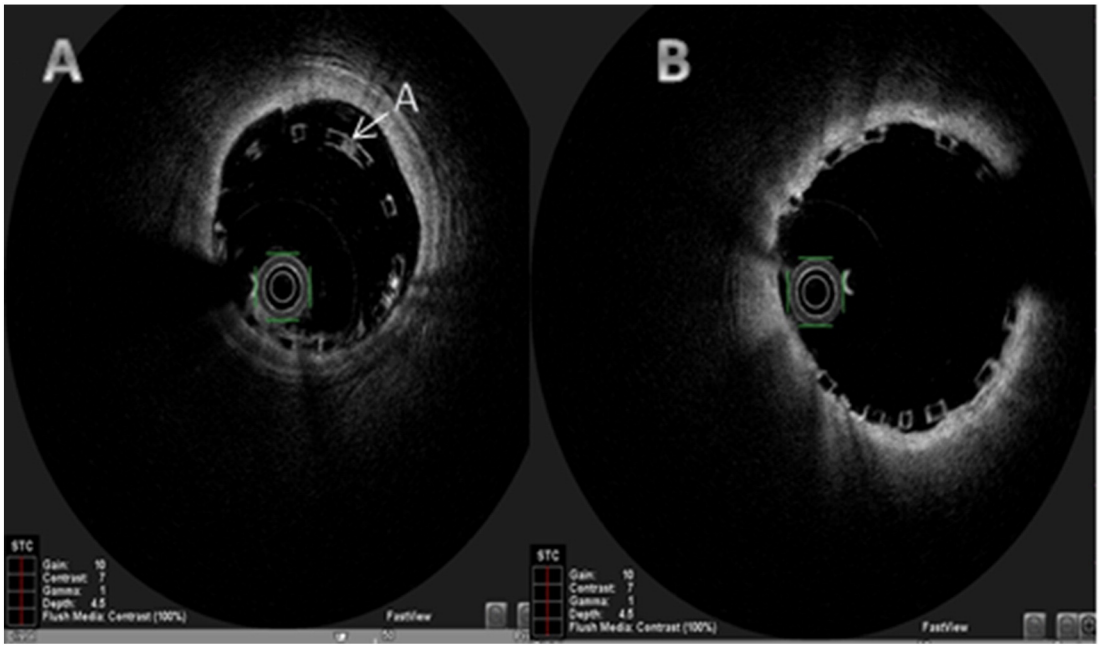

Fig. 3. Resolution of scaffold malapposition after postdilatation. Imagen 3A demonstrates the presence of malapposed struts after BVS deployment. After high pressure postdilatation, in Fig. 3B ISA was corrected and right expansion of the BVS was achieved.

In addition to this, we want to remark that although Fabris et al. [8]. performed very high pressure postdilatation of the BVS (up to a maximal balloon inflation of 28 ± 3.8 atm) without procedural complications, our OCT results are better. With a lower mean postdilatation pressure of 17 atm (being the maximal pressure applied 20 atm) in our study, we achieved larger luminal and scaffold areas (6.84 ± 1.64 mm^2 Vs 6.79 ± 1.4 mm^2 and 7.59 ± 1.64 mm^2 Vs 6.83 ± 1.42 mm^2 respectively) and slightly larger values for mean, minimal and maximal scaffold diameters (3.09 ± 0.34, 2.88 ± 0.31, 3.31 ± 0.40 mm Vs 2.9 ± 0.31, 2.7 ± 0.28 and 3.1 ± 0.36). Furthermore, we achieved better results attending to eccentricity index (0.13 ± 0.05 Vs 0.86 ± 0.02) with a lower percentage of ISA (1.42% vs1.84%).

From our knowledge, the present study is the first one which correlates angiographic and OCT data with clinical follow up of the patient. In addition to this, we find it of special clinical relevance as it is the first one which includes a real-world cohort of patients with no exclusion criteria related to indication of coronary revascularization or type of coronary lesion. Patients who underwent primary PCI had been excluded previously from studies on scaffold disruption [7,8]; however, 28.6% of our study population are STEMI patients (Fig. 4). We neither did exclude bifurcations (21.4%), chronic total occlusions (21.4%) or aorto-ostial lesions. In fact, Szabo technique was performed in treatment of two different proximal LAD lesions, with excellent angiographic result, as recently described by our group.

Besides, our study is the one which includes the highest percentage of complex lesions: 85,7% of the total treated lesions are type C according to ACC/AHA criteria(with no A type lesions treated) with a mean length of stented vessel by lesion of 40.21 mm.

Nevertheless, even in presence of such complexity, none of our patients died, suffered from stroke, stent thrombosis or needed TLR in 30 days after intervention. Neither did those who complete a 3 months-follow-up.

At sight of the reported data, we can state postdilatation at high pressure with NC balloon is safe in PCI with BVS and It lets us achieve better angiographical and clinical results even in complex lesions. Although more evidence is needed, we propose high pressure postdilatation of BVS in order to avoid malapposition and to acquire correct expansion of the device, especially in those lesions with high probability of reocclusion like CTO or very long lesions (e.g. more than 20 mm).

5. Limitations

While we acknowledge that the study major limitation is the relatively small number of patients included, we want to highlight we reviewed 25 BVS with a very high total number of struts analyzed (39,590). We expect to support the results achieved with the inclusion of new patients in the near future. Another limitation of the study comes from the fact that it is a single-center study.

6. Conclusion

High pressure postdilatation between 17 to 20 atm. with NC balloon of BVS, is safe and improves angiographical and clinical results in PCI of complex coronary lesions.

Conflict of interests

Authors declare they don't have any kind of relationship with industry that could lead to a conflict of interests.

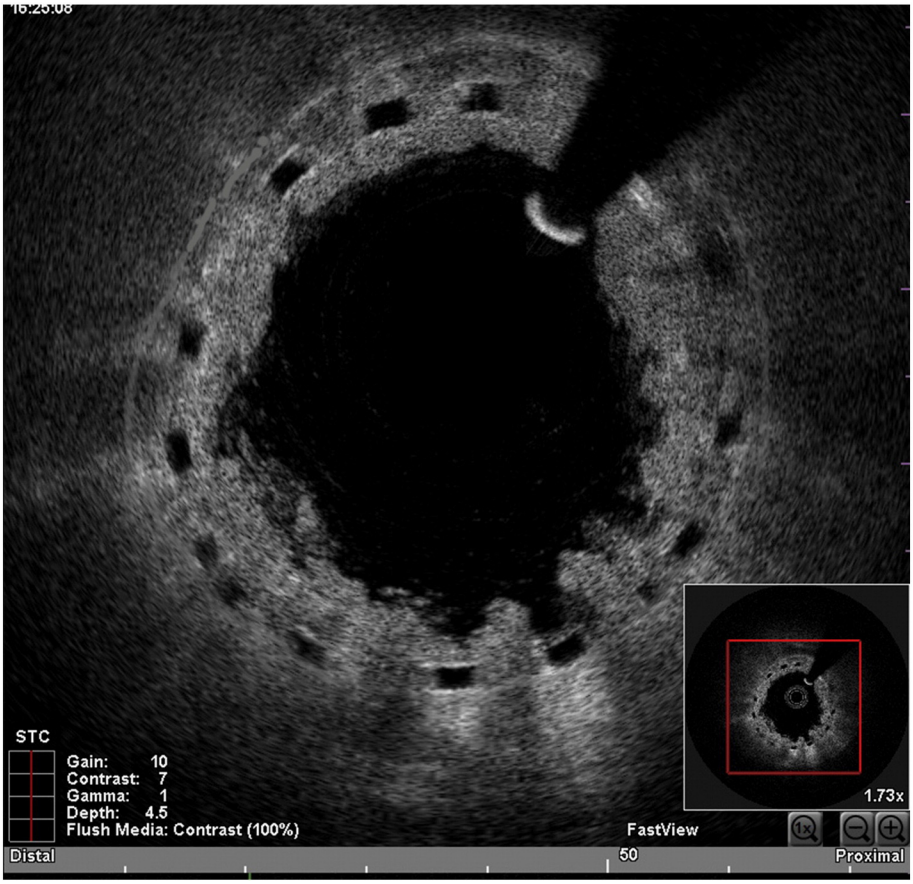

Fig. 4. Embedded BVS after primary PCI. The image shows an adequate expansion of BVS after postdilatation which is embedded in thrombus burden during primary PCI.

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