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Clinical Experience with Very High-Pressure Dilatation for Resistant Coronary Lesions

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ABSTRACT

Background: Calcific coronary lesions can be so resistant to prevent symmetric stent dilatation with high risk of ISR/thrombosis. The aim of the current study is to evaluate the safety and efficacy of super high-pressure dilatation (>30-to-45Atm) using a dedicated NC-balloon (OPN, SIS-Medical-AG, Winterthur-Switzerland).
Methods: We retrospectively evaluated 326 consecutive undilatable lesions in which conventional NC-balloons failed to achieve adequate post-dilatation luminal gain. After the failed attempt an OPN-balloon was inflated up to achieve a uniform balloon expansion (maximal dilatation pressure of 45–50 Atm). Lesions were divided into two groups according to the final inflation pressure: Group-I: lesion responsive to 30-40Atm and Group-2:>40 Atm. Angiographic success was defined as residual angiographic stenosis<30% assessed by visual estimation with TIMI3-flow. Procedural success was defined as the achievement of angiographic success without any MACE.
Results: Angiographic success was achieved in 97.5%, procedural success in 96.6%; 53% of the lesions were responsive to a slower inflation pressure (Group I) while in the remaining 47%, the optimal expansion required a pressure > 40ATM (Group II). In 3 patients coronary rupture occurred after balloon inflation and was successfully treated with stent implantation with a final TIMI3-flow. The OPN alone was able to achieve adequate expansion in >90%. 0.9% days MACE were reported.
Conclusion: The OPN-dedicated high-pressure balloon provides an effective and safe strategy for treatment of severe resistant coronary lesions.

1. Background

Percutaneous treatment of heavily resistant coronary lesions remains a challenge with poor immediate results and higher restenosis rate. The inability to optimal dilate a rigid coronary plaque might result in asymmetrical stent deployment with increased risk of ISR (in-stent restenosis) and thrombosis [1]. Increasing the pressure beyond the recommended limits during dilatation of resistant lesions often accentuates non-uniform balloon expansion with the consequent over-dilatation of the more compliant segments at the lesion edges (so called "dog-boning" effect). This leads to an increased risk of vessel wall damage including edge dissections and coronary perforation [2–4]. Conventional non-compliant (NC) balloons have more predictable responses and uniform dilatation than semi-compliant balloons but the 20 to 30 Atm (atmosphere) limit they can reach might be insufficient. Rotational atherectomy is the best option for the treatment of calcific lesion non-responsive to balloon dilatation, but both the complexity and the cost of the device have hindered its widespread use [5]. Cutting and scoring balloons present a bulky entry profile and rarely cross a truly undilatable lesion [6]. Following our favorable initial clinical experience with the use of super high pressure dilatation for treatment of severe resistant coronary lesions [7,8] we enlarged our study population focusing on the pressure eventually needed to achieve a satisfactory plaque dilatation using the OPN dedicated super-high pressure non-compliant balloon (SIS Medical AG, Winterthur Switzerland).

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2. Methods

We retrospectively evaluated 326 consecutive highly resistant coronary lesions treated with high-pressure dilatation (> 30 Atm inflation pressure) in three high volume centers (> 1000 PCI/year):

– University Heart Center Freiburg – Bad Krozingen, Germany;
– Royal Brompton & Harefield NHS Foundation Trust, London, UK;
– "Santi Antonio e Biagio e Cesare Arrigo" Hospital, Alessandria, Italy.

All lesions were initially approached with conventional non-compliant balloon inflated up to the rated burst pressure or slightly higher (maximal dilatation pressure of 30 Atm). In case of incomplete balloon expansion with visible indentation, the lesions were treated with the OPN balloon inflated up to achieve a uniform balloon expansion (maximal dilatation pressure of 45–50 Atm). OPN was also used for stent optimization when the final angiogram or IVUS/OCT control showed poor stent expansion despite conventional NC balloon post dilatation.

Lesions were divided in two groups according to the pressure needed to achieve circumferential overstretch and a satisfactory lumen expansion: Group I lesion responsive to 30–40 Atm and Group 2 lesions responsive to an inflation pressure > 40 Atm.

Modification of the vessel wall using rotational atherectomy was used in case of incomplete OPN expansion or inability of the device to cross the lesion but was reported.

Other coronary lesions could be treated, when necessary. No exclusion criteria were applied. The Institutional Review Board approved the study and patients provided informed consent. The study was conducted according to the Declaration of Helsinki.

2.1. The OPN NC balloon device

The OPN NC Super-High Pressure Balloon (SIS Medical AG, Winterthur Switzerland) is a rapid-exchange PTCA (percutaneous transluminal coronary angioplasty) catheter compatible with a 0.014″ coronary wire (Fig. 1). The most distinctive feature of the OPN balloon is the presence of a twin-layer balloon technology, which permits the use of very high-pressure inflations and ensures uniform expansion over a wide range of pressures. The balloon is highly non compliant with a nominal pressure of 10 Atm and a rated burst pressure of 35 Atm. The diameters currently available cover a range from 1.5mm up to 4.0mm with 1/2 mm intervals and the lengths are 10, 15 and 20 mm [7]. The OPN balloon is a CE mark device.

2.2. Interventional procedure

The PCI was routinely performed with standard techniques via femoral or radial approach using 6, 7 or 8 French guiding catheters. Patients not preloaded with oral aspirin and/or clopidogrel received a loading dose of intravenous aspirin (500 mg) and clopidogrel (600 mg) or prasugrel (60 mg)/ticagrelor (180 mg) as standard practice. Intravenous heparin (70 UI/Kg body weight) was administered before the procedure with subsequent boluses aiming at achieving an activating ACT (activating clotting time) between 250 and 300 s. The use of GP IIb/IIIa inhibitors was minimized and left to operator's discretion. When the OPN balloon was used before stent implantation, the diameter was slightly undersized according to conventional angiographic criteria; when the OPN NC balloon was used for stent postdilatation the diameter used was a 1:1 ratio OPN/stent. The pressure needed to achieve adequate luminal gain was then recorded. All lesions were finally treated with stent implantation.

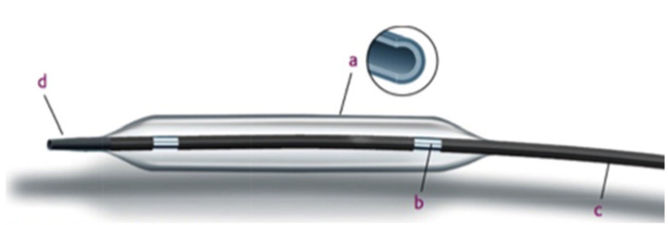

Fig. 1. The OPN NC balloon: a) Twin layer balloon construction; b) The two platinum markers; c) Patchwork coating of balloon and fully coated catheter shaft; d) 0.016″ entry profile.

2.3. Data collection, statistical analysis and follow-up

Angiographic results and in-hospital outcome were prospectively entered into a dedicated interventional cardiology database and retrospectively extrapolated for the current analysis. Data are presented as means and standard deviations when appropriate. Continuous variables were compared using unpaired student's *t*-test while categorical variables were compared using chi-square test. A p value < 0.05 was considered statistically significant. Clinical events were evaluated post-procedure, during hospitalization, approximately at 1 month after the procedure and every 12 months afterward by direct clinical examination or, more rarely, with a telephone interview.

2.4. Definitions

Angiographic success was defined as the achievement of residual angiographic stenosis <30% assessed by visual estimation with TIMI (Thrombolysis In Myocardial Infarction) 3 flow. Technical success was defined as angiographic success without the need of rotablation. Procedural success was defined as the achievement of angiographic success without any MACE (major adverse cardiovascular events) defined as acute coronary rupture, death and urgent revascularization (CABG- coronary artery bypass graft- or PTCA). Twelve-lead electrocardiograms were recorded before, immediately after the procedure and at hospital discharge. In-hospital MACE was defined as any MACE (including myocardial infarction) occurring during hospitalization for the index procedure. Follow up MACE was defined as myocardial infarction, death or target lesion revascularization (any repeat PCI or CABG at the lesion site) occurred during the follow up period.

3. Results

Patients an lesion characteristics are shown in Tables 1 and 2 respectively. Out of the 326 lesions, 246 were heavy calcified lesions (75.5%) and chronic total occlusion accounted for 20.9% of the lesions. There

Table 1
Baseline patient characteristics.

N. of patients		326	
N. of treated patients		318	
	Group I (168 pts)	Group II (150 pts)	p
Sex (male/female)	126/42 (75%, 25%)	116/34 (77.3%, 22.7%)	ns
Age (mean ± standard deviation)	69.2± 10.1	70.9 ± 9.6	ns
Risk factors			
Hypertension	142 (84.5%)	134 (89.3%)	ns
Smoking	73 (43.5%)	78 (52%)	ns
Diabetes	78 (46.4%)	77 (51.3%)	ns
Prior CABG	44 (26.2%)	40 (26.7%)	ns
GFR < 60	45 (26.8%)	47 (31.3%)	ns
LVEF > 50%	124 (73.8%)	117 (78%)	ns
Clinical presentation			
Stable angina	134 (79.8%)	131 (87.3%)	ns
Unstable angina	24 (14.3%)	14 (9.3%)	ns
NSTEMI	10 (5.9%)	5 (3.3%)	ns

CABG: coronary artery bypass graft; GFR: glomerular filtration rate; LVEF: left ventricular ejection fraction; NSTEMI: non-ST elevation myocardial infarction.

Table 2
Lesion and procedural characteristics of the 318 lesions successfully treated.

	Group I	Group II	p
Number of treated lesions	168	150	
Vessel			
Left main	6 (3.6%)	0 (0%)	< 0.05
LAD	86 (51.2%)	79 (52.7%)	ns
LCX	24 (14.2%)	23 (15.3%)	ns
RCA	44 (26.2%)	48 (32%)	ns
SVG	8 (4.8%)	0 (0%)	< 0.01
Multivessel disease	101 (60.1%)	92 (61.3%)	ns
Lesion characteristics			
Length (mm)	28.5 ± 23	28.8±21	ns
True bifurcation	71 (42.3%)	68 (45.3%)	ns
Ostium involved	19 (11.3%)	21 (14%)	ns
CTO	31 (18.4%)	36 (24%)	ns
Radian calcification >270°	23 (12.7%)[a]	83 (46.1%)[a]	< 0.001
Procedural characteristics			
Femoral/radial	42/126 (25%, 75%)	39/111 (26%–74%)	ns
Sheath size (6F–7F)	160/8 (95, 2%, 4.8%)	139/11 (92.6%–7.3%)	ns
Number of OPN balloon/lesion	203/168 (1.2)	210/150 (1.4)	ns
Lesions treated with OPN for pre dilatation	101 (60.1%)	88 (58.6%)	ns
Lesions treated with OPN for stent post dilatation	67 (39.9%)	62 (41.4%)	ns
Rotational atherectomy	29 (17.3%)	1 (1.5%)	< 0.001
Number of stent/lesion	226/168 (1.34)	220/150 (1.46)	ns
IVUS guided	69 (41.1%)	65 (43.3%)	ns
OCT guided	24 (14.3%)	22 (14.7%)	ns

LAD: left anterior descending; LCX: left circumflex; RCA: right coronary artery; SVG: saphenous vein graft; CTO: chronic total occlusion; IVUS: intravascular ultrasound; OCT: optical coherence tomography.
[a] analysis performed for the 180 lesions evaluated with intravascular imaging (IVUS/OCT).

were no significant differences in baseline clinical and characteristics between the two groups except for a more extensive use of rotational atherectomy in Group I (17.3% vs 1.5%, p < 0.001).

A total of 413 OPN balloon were used (*1.26* per lesion). OPN was used before stent implantation because of unsatisfactory conventional NC balloon dilatation in 198 lesions (60.7%) while in the remaining 128 cases was used for stent optimization because of poor stent apposition at the final IVUS/OCT control despite conventional NC balloon postdilatation (39.3%). During lesion preparation the pressure required to achieve symmetrical balloon expansion was >40 Atm in 88 lesions (44.5%) while a post dilatation pressure > 40 Atm was required in 62 cases (Fig. 2).

Of the 180 lesions evaluated with intravascular imaging (IVUS/OCT), 106 presented a radian calcification >270° and this subgroup of lesions, the dilatation pressure necessary to achieve a uniform balloon expansion was >40 Atm in 83 lesions (Group I vs Group II: 12.7% vs 46.1%; p < 0.001).

3.1. Procedural and clinical outcome

Angiographic success was achieved in 318 cases (97.5%), procedural success was achieved in 315 lesions (96.6%) and technical success was achieved in 288 patients (90.5%). The remaining 8 cases (2.5%) were undilatable lesions for which both rotational atherectomy and excimer laser therapy were deemed not suitable and were addressed to optimal medical therapy; 3 of these 8 patients finally received CABG because of refractory angina symptoms (Table 3).

In 3 patients (0.9%) coronary rupture occurred after balloon inflation and was successfully treated with stent implantation with a final TIMI flow 3. Vessel rupture was not associated with balloon rupture; two cases required covered stents while the other patient was successfully treated with prolonged balloon inflation, protamine administration and DES (drug eluting stent) implantation.

In all of these 3 patients the coronary rupture occurred when OPN was used before stent implantation with an inflation pressure of 30–40 Atm (Group I); in all three cases the OPN balloons used were sized only according to the angiographic estimation with no additional intravascular imaging.

The OPN balloon alone was able to achieve adequate expansion in 288 cases (90.5%) while in 30 patients rotational atherectomy was performed because of the impossibility to cross the lesion with a proper sized OPN balloon.

Of the 180 lesions that received additional intravascular imaging (IVUS/OCT), 106 presented a radial calcification >270°. Interestingly in these subgroup of lesions the pressure required for an optimal OPN expansion was >40 ATM in 83 cases (78.3%).

All lesions were finally treated with stent implantation (DES 91.8%, BMS (bare metal stent) 7.6%, Covered stent 0.6%). 0.9% 30 days MACE were reported. Clinical follow-up data was available for 298 patients (91.5%; mean follow-up period, 14 ± 36 months). No cardiovascular death was reported while death for any cause was reported in 3 cases (1%). Myocardial infarction was reported in 4 cases and in none of them the culprit lesion was the OPN-treated lesion (1.3%); finally, 19 patients underwent TVR (target vessel revascularization) due to a severe ISR (6.4%).

4. Discussion

This multicenter study reports the largest clinical experience on the use of super high-pressure dilatation for treatment of severe resistant coronary lesions using the OPN-dedicated balloon. In our registry involving 3 high volume European centers, we collected data from 326 consecutive highly resistant coronary lesions unresponsive to conventional high pressure NC-balloon dilatation. The results can be summarized as follows: i) OPN balloon alone was able to achieve adequate expansion in 288 cases (90.5%) while in 30 patients rotational atherectomy was needed because of the impossibility to cross the lesion with a proper sized OPN balloon, ii) in 153 lesions (46.9%) the pressure required for proper plaque expansion was >40 ATM, iii) acute coronary rupture occurred in 3 cases (0.9%) and were not associated with OPN balloon rupture. In all of the three cases the OPN balloons were sized only according angiographic estimation with no additional intravascular imaging. Calcification of the vessel wall or thick neointimal hyperplasia imposes a rigid obstacle to optimal balloon expansion, so that, during treatment of extended coronary calcifications, the inflation pressure needed to achieve circumferential overstretch might be higher than conventional 20–30 Atm usually reached during conventional balloon dilatation. Moreover, during treatment of resistant coronary lesions the non-uniform balloon expansion with the consequent over-expansion of the more compliant segment may lead to an increased risk of vessel wall damage including edge dissections and coronary perforation. Non-compliant balloons have more predictable responses and uniform dilatation than semi-compliant balloons but dog boning also occurs, especially when the lesion is short and the balloon relatively long. Cutting balloons present a theoretical mechanical advantage offered by a focal concentration of force along 3 or 4 blades (generally assembled over a semi-compliant balloon) on the intimal plaque but their bulky profile together with the risk of balloon entrapment can limit their routinely use during treatment of calcified coronary lesions [9–12]. Scoring balloons have lower profile and accept higher pressure but data on their real efficacy is limited [13,14].

The use of Excimer Laser therapy during treatment of resistant coronary lesions has been reported but mostly in anedoctical cases and without clear evidence in correctly sized registry [15].

Certainly ablating a lesion using rotational atherectomy appears the best option during treatment of long calcified plaques [16]. However,

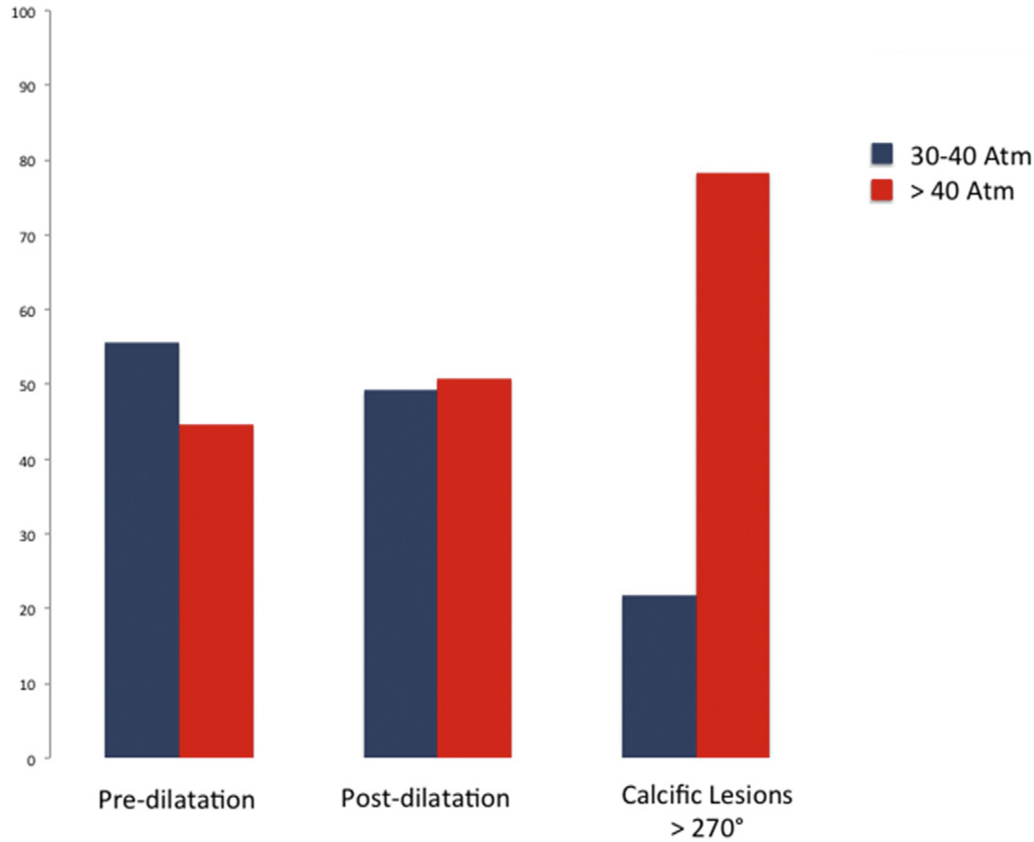

Fig. 2. Bar Graph showing the pressure inflation needed to achieve optimal balloon expansion pre pre-dilatation, post-dilatation and during treatment of severe calcified plaques evaluated with intravascular imaging (IVUS/OCT) and with a radian calcification >270°.

from one side this technique is expensive and requires specific expertise in handling a poorly steerable uncoated 0.010 in wire and advance the burr and from the other is still unknown whether routine usage of aggressive rotational atherectomy is superior to conventional balloon dilatation as a means of lesion modification followed by DES implantation, because of the lack of systemic long-term results of such a strategy [17,18]. Furthermore, rotational atherectomy is a contraindication for the treatment of under-expanded coronary stents.

Conversely, our purposed strategy of super-high pressure dilatation only requires the availability of the OPN dedicated device, a plain rapid exchange PTCA catheter that can be easily attempted in case of failure of conventional balloons. Thanks to its twin-layer technology, it allows the use of very high-pressure inflations ensuring uniform expansion over a wide range of pressures [19,20]. In our multicenter consecutive experience of more than 300 severely calcified coronary lesions treated with super high pressure dilatation we experienced a relatively low rate of coronary perforations, approximately double than the percentages of perforations reported in a general population, promptly solved with covered stent implantation and/or prolonged balloon inflation and protamine administration. Interestingly, in all of these 3 patients the balloons used were selected only following visual angiographic estimation with no additional intravascular imaging techniques (IVUS or OCT) to obtain a more accurate assessment of the reference vessel diameter and optimize the sizing of the OPN balloon used. A proper estimation of the vessel diameter is one of the most important issue when treating heavily resistant coronary lesion with extremely high pressure dilatation. In fact, we believe that the tendency to a slight oversize of the balloon diameter during treatment of resistant plaques non responsive to balloon dilatation and the well known "dog-boning" effect might account for the vast majority of vessel damages and coronary perforations. With OPN balloons, the bog-boning effect is minimized but still a more prudent attitude to under rather than overestimation should be followed, especially in the absence of confirmation of the true vessel size with intravascular imaging. Moreover, as a consequence of the OPN uniform expansion and the hardly twin layer technology, OPN rupture occurred only in 3 cases in more than 400 OPN often inflated higher than the 35 Atm rated burst pressure and none of the cases was followed by coronary rupture, probably because the rupture is limited at the inner layer, while the outer still protect the vessel from an acute damage.

One of the main finding in our registry is that, despite non responsive to the conventional 30 Atm of inflation pressure, more than 95% of the lesions were responsive to higher pressures. We found that in almost half of our cases, the pressure eventually needed for achieve optimal balloon expansion was higher than 40 ATM. Moreover, a super-high inflation pressure (> 40 Atm) was required in up to 78.3% of the cases when we considered the lesions that presented at IVUS/OCT evaluation a radian calcification extended for more than 270°. These lesions are

Table 3
Procedural and clinical outcome.

	Tot.	Group I	Group II	p
Angiographic success	318 (97.5%)	168	150	
Technical success	288 (90.5%)	139 (82.7%)	149 (99.3%)	< 0.001
Procedural success	315 (96.6%)	165 (98.2%)	150 (100%)	ns
Acute MACE	3 (0.9%)	3 (1.8%)	0	ns
30-days follow up MACE	3 (0.9%)	3 (1.8%)	0	ns
Long-term follow up MACE[a]				
Death	3 (1%)	1 (0.6%)	2 (1.3%)	ns
CV death	0	0	0	ns
MI	4 (1.34%)	1 (0.6%)	3 (2%)	ns
TVR	19 (6.4%)	9 (5.3%)	10 (6.6%)	ns

CV: cardiovascular; MI: myocardial infarction; TVR: target vessel revascularization.
[a] Data available for 298 patients.

usually appointed as untreatable lesions referred to an inadequate medical therapy or surgical revascularization therapy. Our findings, conversely shows that in the vast majority of cases a higher inflation pressure performed with an easy, dedicated balloon might be sufficient for uniform expansion without a significant increase of vessel damage and coronary perforation.

5. Limitations

The main limitation of the OPN balloon is the high profile that, together with the stiffness of the twin-layer technology, in the vast majority of cases undermines any attempt to recross when inflated. In our registry, despite rotational atherectomy was used only when it was impossible to cross the lesion with a properly sized OPN balloon and with the smallest burr (1.25 mm), we must admit that atherectomy might also have influenced response to balloon dilatation. Moreover our results come from a retrospective and non-randomized analysis, without a standardized pre-specified procedural protocol including number and maximal initial conventional NC-balloon dilatation pressure amongst the various operators which is certainly susceptible to possible selection bias. Definition of MACE used in this study is not standard and might have artificially drop the rate of events; however we focused on percutaneous treatment of truly resistant coronary lesion unresponsive to conventional high pressure (30 ATM) NC dilatation in which poor results and/or a real failure is not so infrequent. Finally, the use of additional intravascular imaging was employed to guide a clinically oriented strategy, avoiding unnecessary IVUS pull-backs when the angiographic result was grossly inadequate. This can explain the frequent occurrence of missing values in the various procedural steps; a more extensive use of intravascular imaging modalities (IVUS/OCT) together with a standardized protocol would have certainly improved the results of the current study and would have probably provide interesting insights regarding possible morphological changes in the plaque/coronary vessel wall created by the extremely high-dilatation pressure.

6. Conclusions

The unique possibility offered by the OPN super-high pressure dedicated balloon provides an effective and easy strategy for treatment of resistant coronary lesions non-responsive to conventional NC balloon dilatation. Moreover, our data suggest that the unique twin-layer technology offered by the OPN balloon achieves uniform balloon expansion reducing the use of additional debulking devices. The frequency of adverse events and in particular of coronary rupture was low but ultimately the safety of the procedure should be established in randomized studies of comparison with existing debulking techniques.

Conflict of interest

Dr. Gioel Gabrio Secco received speaker honoraria from SIS-Medical-AG, Winterthur-Switzerland.

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