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Prolonged High-Pressure is Required for Optimal Stent Deployment as Assessed by Optical Coherence Tomography

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Aims: Optimizing stent deployment is important for both acute- and long-term outcomes. High-pressure balloon inflation is the standard for coronary stent implantation. However, there is no standardized inflation protocol. We hypothesized that prolonged high-pressure balloon inflation until stabilization of inflation pressure is superior to a rapid inflation/deflation sequence for both stent expansion and strut apposition. Methods and Results: A high-pressure rapid inflation/deflation sequence was deployed followed by angiography to assure no residual stenosis. Optical coherence tomography (OCT) was then performed followed by prolonged inflation until balloon pressure was stabilized for 30 sec using the same balloon at the same pressure as the rapid sequence. A second OCT run was then done. Thirteen thousand nine hundred thirteen stent struts were evaluated by OCT in 12 patients undergoing successful stenting. Stent expansion improved with prolonged (206 ± 115 sec) vs. rapid (28 ± 17 sec) inflation for both minimal stent diameter (3.0 ± 0.5 vs. 2.75 ± 0.44 mm, $P < 0.0001$) and area (7.83 ± 2.45 vs. 6.63 ± 1.85 mm^2, $P = 0.0003$). The number of malapposed struts decreased (45 ± 41 vs. 88 ± 75, $P = 0.005$) as did the maximal malapposed strut distance (0.31 ± 0.2 vs. 0.43 ± 0.2 mm, $P = 0.0001$). Factors related to strut malapposition after rapid inflation included localized asymmetry in 67%, stent underexpansion in 75%, and stent undersizing in 67%. Conclusions: These data demonstrate that prolonged inflation is superior to a rapid inflation/deflation technique for both stent expansion and strut apposition. We recommend for routine stent deployment a prolonged inflation protocol as described above to optimize stent deployment.

Key words: drug eluting stent; stent deployment; percutaneous coronary intervention; optical coherence tomography; stent expansion; stent apposition

INTRODUCTION

The universal approach for deployment of balloon-expandable coronary stents is the use of high pressure inflation. This consensus is based on data demonstrating that high-pressure improves stent expansion and apposition and markedly decreases the incidence of acute and subacute stent thrombosis (ST) [1–4]. There is not, however, an accepted standard protocol for the duration of high-pressure inflation. It has been our casual observation that when stent expansion with balloon inflation is initiated, the inflation pressure tends to gradually decrease over time (Fig. 1). This phenomenon implies either a leak in the inflation system, longitudinal balloon expansion, or further stent expansion. We hypothesize that the primary reason for the pressure drop is due to delayed stent expansion in the more recalcitrant areas of the stenosis. That the stent may further expand with the same inflation pressure suggests a rapid inflation/deflation sequence may be inadequate to fully expand the stent, even if optimal angiographic appearance is achieved, and that sustained inflation until pressure stabilizes may be necessary to produce optimal stent deployment. Likewise, the possibility of incomplete strut apposition may also be heightened if inadequate time is allowed for stent expansion. With the advent of optical coherence technology (OCT),

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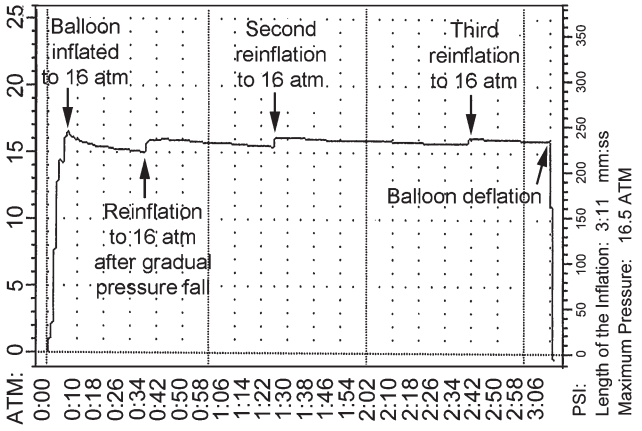

Fig. 1. This figure shows the phenomenon of gradual decrease of balloon inflation pressure over time during stent implantation. The drop in pressure is compatible with gradual stent expansion. The balloon was initially inflated to 16 atm. With the passage of time, the pressure gradually decreased. Arrows indicate reinflation to 16 atm until relative pressure stability is maintained for at least 30 sec. In this particularly case, pressure stability required over 3 min.

with markedly increased resolution to evaluate stent apposition, this issue can now be more fully addressed.

Drug-eluting stents (DES) are the "gold standard" in percutaneous coronary intervention (PCI) for the reduction of in-stent restenosis and target lesion revascularization [5–7]. An ideal stent deployment protocol for DES takes into account the aforementioned consequences that can occur as a result of suboptimal deployment, particularly in-stent restenosis and stent thrombosis. In-stent restenosis, for both bare metal and drug-eluting stents, is strongly associated with stent underexpansion by intravascular ultrasound (IVUS) [8–10], while late and very late stent thrombosis appear to be influenced by both underexpansion [11–13] and malapposition [14–17]. Recently, these associations have been confirmed in studies utilizing OCT for measurement of stent expansion and apposition [18–21]. The use of OCT offers the advantage over IVUS of 10 times higher resolution which allows for an accurate strut-by-strut evaluation of stent apposition [22].

We present data demonstrating that, as shown by OCT, prolonged inflation as opposed to a rapid inflation/deflation sequence is required to optimize both stent expansion and strut apposition. We also demonstrate that strut malapposition in a particular case may be due to asymmetric vessel enlargement or positive remodeling, strut underexpansion, and/or relative stent undersizing.

METHODS

Patients referred for angiography and undergoing single-vessel PCI for standard clinical indications were included in this evaluation. Patients were excluded for clinical reasons if they had ST-elevation myocardial infarction (STEMI), hemodynamic instability, or abnormal renal function. Angiographic exclusions included total coronary occlusion, overlapping stents, a major side branch (>2.5 mm) as part of the stented area, or left main stenting.

Once the decision to intervene was made, initial angiography-guided PCI was performed. To remove stent physical characteristics as a confounding factor, all stents deployed were the Xience V DES (Abbott Vascular, North Chicago, IL). The stent diameter was chosen by visual estimation of the reference diameter. Predilatation of the lesion was performed at the operator's discretion. The rapid inflation/deflation stenting technique was then employed as follows: the stent balloon was inflated to high-pressure (defined as >14 atm) to a pressure chosen by the operator and then deflated 30–60 sec after full balloon expansion. This inflation was meant to simulate the commonly observed operator approach of fully expanding the stent balloon with a high pressure and then deflating. Repeat angiography was performed to assure an angiographic result of 0% residual stenosis. Then OCT to evaluate stent apposition and expansion was performed and recorded.

The prolonged inflation technique was then employed in each case as follows: the balloon catheter used during the rapid technique was reintroduced. The balloon was inflated to the same maximal inflation pressure as in the rapid technique, with the added requirement that the inflation pressure be maintained for 30 sec with <0.3 atm pressure decrease. For example, if the rapid technique employed a maximum of 16 atm, the prolonged inflation would require a steady pressure of 15.8–16.0 atm for at least 30 sec. Once the target pressure was maintained for at least 30 sec, the balloon was deflated. If at any point during the prolonged inflation sequence hemodynamic or electrocardiographic instability was noted, the balloon was deflated to allow for clinical recovery, and reinflated until at least 30 sec of stability was obtained.

Optical Coherence Tomography

OCT was performed using the C7 LightLab Dragonfly OCT catheter (St. Jude Medical, Little Canada, MN) after the rapid inflation-deflation and prolonged inflation methods. A nonocclusive image acquisition technique was performed, using 14–16 mL of contrast media, injected at a rate of 4 ml sec^{-1} to flush the guide catheter during rapid automated OCT pullback (20 mm sec^{-1}).

Images were record at 0.20-mm intervals for 270 frames as per the standard device settings. On each OCT frame within the stent, all struts were counted, and each

TABLE I. Baseline Demographic and Angiographic Characteristics

Age (years)	65.3 ± 10.7
Males (%)	91.7
Hypertension (%)	83.3
Hyperlipidemia (%)	83.3
Diabetes mellitus (%)	75.0
Current cigarette smoking[a](%)	16.7
Serum creatinine (mg%)	1.12 ± 0.17
Prior myocardial infarction (%)	25.0
Prior PCI[b] (%)	50.0
Prior CABG (%)	16.7
Multivessel disease (%)	83.3
Left ventricular dysfunction (%)	33.0
Vessel treated (LAD/LCX/RCA)	8/1/3
Stable angina/ACS	4/8
Lesion severity (%)	82.9 ± 11.1
Stent length (mm)	24.5 ± 8.88
Stent diameter (mm)	2.98 ± 0.41

ACS = acute coronary syndrome; CABG = coronary artery bypass surgery; LCX = circumflex; LAD = left anterior descending; LVEF = left ventricular ejection fraction PCI = percutaneous coronary intervention; RCA = right coronary artery.

[a]The other 10 patients were former cigarette smokers.

[b]The six patients had PCI on other lesions than those treated in the study.

strut evaluated for stent apposition. A strut was defined as a dense symmetric opacity, usually, but not necessarily, resulting in optical dropout behind it. A strut was considered to be fully apposed if the degree of separation between the strut and the vessel wall was less than the width of the stent strut [23].

For each patient, the number and percentage of struts malapposed was determined for both inflation strategies. The largest separation between the strut and the vessel wall was measured. If a stent strut fell over a minor side branch, it was not included in the analysis. Any thrombus and plaque protrusion were identified according to a recent OCT consensus statement [23]. A consensus of two independent observers for each frame was obtained, with any disagreement resolved by a third observer.

Quantitative analysis of the OCT images was then performed for each vessel. The frame with the minimal stent lumen diameter (MSD) and area (MSA) was determined by visual inspection and measured semiautomatically using the device software. The same frame was used for analysis of MSD and MSA after prolonged inflation. Proximal and distal reference segment MSD and MSA were measured as part of the first OCT run. The MSA, MSD, and the maximum degree of stent malapposition (in mm) were recorded for each stent after the rapid and prolonged inflation techniques for comparison.

The mechanism of malapposition after the rapid inflation/deflation sequence was studied for each stent (local asymmetry or positive remodeling, strut underexpansion, and/or, stent undersizing). (Fig. 1 epub appendix). The frame demonstrating the maximum strut malapposition was used. To determine localized remodeling (or asymmetry of the vessel lumen) at the malapposed stent strut, the parallel and perpendicular vessel diameters were measured, and ratio calculated with the malapposed diameter as the numerator. If the ratio was >1.0, it was concluded that localized vessel positive remodeling at the malapposed strut was present. To determine relative stent underexpansion, the measured stent diameter at the malapposition site was compared with the expected stent diameter at the inflation pressure, as per the manufacturer compliance chart. Finally, if the expected stent diameter at the inflation pressure was less than the actual diameter of the vessel at the malapposition site, then it was considered that relative stent undersizing was present.

The protocol was reviewed and approved by the Little Rock VA Hospital Institutional Review Board.

Statistical Analysis

The endpoint used to determine sample size was the number of malapposed stent struts per patient. We assumed an average of 800 stent struts/patient, that the prolonged inflation method would produce 20% fewer malapposed stent struts as compared with rapid inflation/deflation, and that the standard deviation would be 100 struts for both study groups, assuming a P value of <0.05 with 80% power to detect a difference. Based on this calculation, the minimum number of subjects required to show a difference in malapposition was 11; we therefore chose a sample size of 12 patients.

To compare the rapid vs. prolonged states, a paired Student's t test was utilized. Categorical end-points were compared using either Chi-square or Fisher's exact test, depending on cell sizes.

RESULTS

Twelve patients underwent successful single vessel, single stent intervention. As noted in Table I, there was a high prevalence of cardiovascular risk factors. All interventions were of de novo lesions, all were predilated prior to stent implantation, and were successful with no angiographic residual stenosis after high-pressure stent balloon inflation of relatively short duration ("rapid" inflation). The mean duration of the rapid inflation was 28 ± 17 sec. To obtain pressure stability, prolonged inflation required 206 ± 115 sec ($P <$ 0.0001 vs. rapid). No patient developed intolerable chest pain, arrhythmia, or hemodynamic instability during the prolonged inflation. Angiography and OCT in a representative case is shown in Fig. 2 (epub appendix).

Table II shows the OCT results after rapid and prolonged stent balloon inflation. There were over 13,000

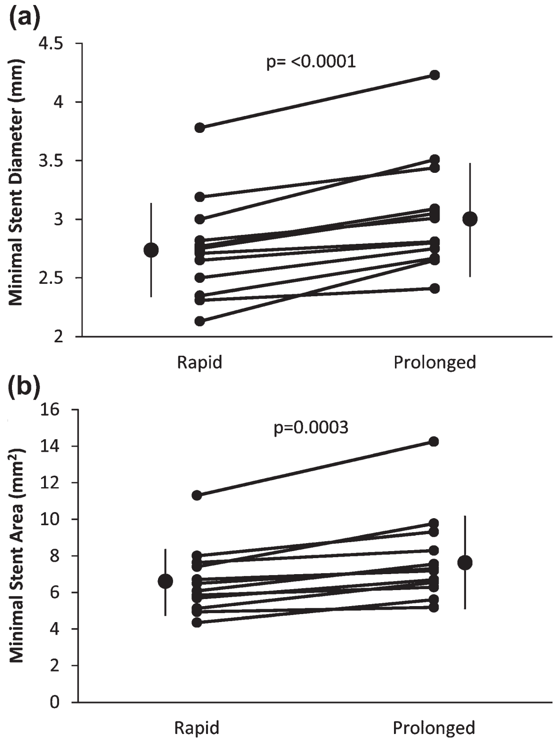

Fig. 2. This figure shows the individual responses after rapid and prolonged stent inflation in the 12 patients. There is a uniform increase in minimal stent diameter (a) and area (b) in all patients after prolonged vs. rapid inflation.

TABLE II. Procedural and optical coherence tomography (OCT) findings

	Rapid inflation/ deflation	Prolonged inflation	*P* =
Inflation time (sec)	28 ± 18	206 ± 120	0.0002
Inflation pressure (atm)	17 ± 1	17 ± 1	NS
Total struts evaluated	13,913	13,430	NS
Struts evaluated/pt (*n*=)	1159 ± 363	1119 ± 353	NS
Minimal stent area (mm^2)	6.63 ± 1.85	7.83 ± 2.45	0.0003
Minimal stent diameter (mm)	2.75 ± 0.44	3.0 ± 0.5	<0.0001
Struts malapposed (*n*=)	88 ± 75	45 ± 41	0.005
% struts malapposed	8.1 ± 6.8	4.8 ± 5.6	0.002
Maximal stent malapposition (mm)	0.43 ± 0.20	0.31 ± 0.20	0.001
Plaque protrusion (% of pts)	75	75	NS

TABLE III. Contributing factors to stent malapposition

Patient number	Localized positive remodeling/asymmetry	Relative strut underexpansion	Relative stent undersizing
1.	++	−	++
2.	+	+	+
3.	+	+	+
4.	−	++	−
5.	−	+	−
6.	++	−	++
7.	++	+	+
8.	+	+	−
9.	−	++	−
10.	−	+	+
11.	++	+	+
12.	+	−	++

Localized remodeling (or asymmetry of the vessel lumen) indicates that, at the malapposed stent strut, the ratio of the parallel and perpendicular vessel diameters was was >1.0. (+ = ratio of 1.01–1.19; ++ ratio >1.20). Relative strut underexpansion indicates that the measured stent diameter at the malapposition site was less than the expected stent diameter at the inflation pressure as per the manufacturer compliance chart. (+ = 1–19% underexpanded ; ++ >20% underexpanded). Relative stent undersizing indicates that the expected stent diameter at the inflation pressure per the compliance chart was less than the actual diameter of the vessel at the malapposition site (+ =1–19% undersized; ++ = > 20% undersized).

struts evaluated in each condition (P = NS). The minimal stent diameter (MSD) and minimal stent area (MSA) increased after prolonged inflation compared with rapid inflation (Table II, Fig. 2). MSD increased from 2.75 ± 0.44 to 3.0 ± 0.5 ($P < 0.0001$) and MSA from 6.63 ± 1.85 to 7.83 ± 2.45 ($P = 0.003$). On average the MSD increased by 9.1% and MSA by 18.1%.

The percentage of malapposed struts after a rapid inflation/deflation sequence ranged from 1.3 to 25.9%. After prolonged inflation, there was a decrease in number (88 ± 75 to 45 ± 41, $P = 0.005$) and percentage of malapposed struts (8.1% ± 6.8% to 4.8% ± 5.6%, $P = 0.0015$) (Table II, Fig. 3). The maximal strut malapposition distance decreased significant from rapid to prolonged (0.43 ± 0.2 vs. 0.31 ± 0.2, $P = 0.0012$).

The contributing factors to strut malapposition for each patient after the rapid inflation/deflation sequence are shown in Table III. Localized positive remodeling was present in 67%, strut underexpansion contributed in 75%, and stent undersizing in 67% of patients.

DISCUSSION

The primary study finding is that a standardized prolonged inflation is superior to a rapid inflation-deflation protocol for both stent expansion and apposition, assuming the same inflation pressure. It has been our casual observation that most interventional cardiologists employ a rapid inflation/deflation sequence, based on the notion that high-pressure alone assures optimal expansion and apposition [1]. The operator's confidence of optimized stent deployment may be heightened by an angiographic appearance of no residual stenosis (as observed uniformly in our study after rapid inflation). However, we demonstrate unequivocally that by prolonging inflation time at the same inflation pressure, until balloon pressure is maintained, there is further stent expansion and strut apposition. This important finding suggests that currently employed high-

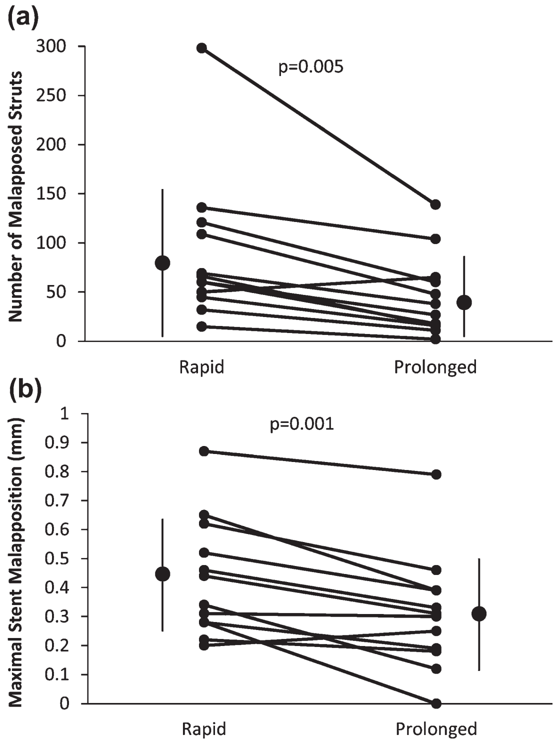

Fig. 3. The number of malapposed struts (a) and the maximal malapposed strut distance (b) after rapid and prolonged inflation are shown. In 11 of 12 cases, the number of malapposed struts decreased with prolonged inflation.

pressure rapid inflation/deflation may not be adequate for optimal stent deployment.

To our knowledge, there have been only two in vivo studies prior to the present study that have examined prolonged inflation as a deployment strategy, both of which employed IVUS to evaluate stent expansion and utilized a pre-specified inflation time [24,25]. Neither IVUS study evaluated strut apposition as a function of the duration of balloon inflation. Further, the lower resolution with IVUS compared with OCT renders evaluation of strut apposition with IVUS problematic. Asano randomized 92 patients receiving a sirolimus DES to either a rapid inflation (14 atm for 10 sec), or a prolonged inflation (14 atm for 60 sec). They demonstrated that prolonged inflation resulted in a larger MSA (4.9 ± 1.6 mm^2) vs. a shorter high-pressure inflation (4.3 ± 1.4 mm^2), or a 14% increase in MSA [24]. Kawasaki randomized 81 patients into a high-pressure rapid inflation/deflation strategy (20 atm for 20 sec) or a prolonged strategy (20 atm for 60 sec) in DES patients. They demonstrated that the prolonged strategy significantly increased the stent MSD and MSA [25].

The current study is the first to employ OCT to compare a new algorithm developed to maximize both stent expansion and apposition. Rather than a prespecified fixed time of 20 or 60 sec as performed in previous studies, the current protocol was designed to maintain inflation until there was no evidence of downward pressure drift, suggesting maximal stent expansion. In fact, the average inflation time in this study was 206 sec, or 3- to 10-fold greater than the prolonged inflation time in previous studies, suggesting that even more gain may have been achieved in those studies had they used the current method. We posit that the balloon pressure decline itself is likely related to an increase in balloon size, which can only be accomplished if the lumen increases, although it is possible that the balloon may also elongate to some extent longitudinally. We hypothesize that delayed stent expansion occurs in areas of decreased compliance, requiring longer inflation times for the diseased tissue to ultimately yield. As such, this protocol maximizes the effectiveness of the stent balloon at a certain inflation pressure. The results of the study confirm the previous IVUS studies demonstrating a larger MSD, and further show that stent apposition is significantly improved. OCT is inherently more sensitive for strut malapposition as compared with IVUS as a result of significantly 10 times higher axial resolution of OCT compared with IVUS [22].

Previous IVUS studies have also demonstrated the relationship between inadequate stent expansion and stent thrombosis and stent restenosis [8–17]. Recently Guagliumi employed OCT to examine patients presenting with ST [21] demonstrating that patients with ST showed a greater percentage of nonapposed stent struts compared with controls (4.6% vs. 1.81%, $P < 0.001$). Thus, the extent of strut apposition by OCT as well as stent expansion may be crucial in determining clinical outcomes. We therefore recommend the current high-pressure inflation algorithm to optimize stent deployment with the idea that it will improve clinical outcomes. Long-term follow-up studies are required to determine if such an improvement in stent expansion and apposition translate to better long-term outcomes.

This study also provides insight into the mechanism of localized malapposition after rapid inflation/deflation. Interestingly, two-thirds of malapposed strut sites showed localized positive remodeling as expressed by an increased diameter in the malapposed site compared with the diameter perpendicular to it at an apposed strut. In addition, three-quarters showed relative strut underexpansion despite high-pressure inflation. It is also noteworthy to point out that two-thirds of patients had an undersized stent as estimated by angiography, three of which were undersized by at least 20%, a finding that has been previously demonstrated by IVUS [26]. This observation emphasizes that prolonged inflation is only one measure to optimize stent deployment, and that imaging preprocedure may be useful whenever stent size is in doubt. This study also raises the question as to whether noncompliant balloon inflation would have been more effective than the semicompliant stent balloon for areas in which the stent struts were incompletely expanded. These questions are the subject of future investigations.

Limitations

This study is relatively limited by its small sample size. However, the data are internally very consistent. Additionally, over 13,000 stent struts were evaluated. The results showed an improvement in minimal stent diameter and area in all patients and improved stent apposition in all but one patient. The second study limitation was that it was not blinded. However, measurements were obtained by a semiautomated program and strut apposition was evaluated by at least two independent observers. On the positive side, the study was prospective and the stent type was the same for all cases, thus eliminating stent type as a variable. It is possible that our results only apply to the Xience V stent but we consider this possibility highly unlikely.

Long-term follow-up in a larger study cohort is required to determine if these results translate to improvements in patient outcomes.

CONCLUSION

The results of this study demonstrate that a prolonged inflation protocol for high-pressure stent deployment, requiring at least 30 sec of pressure stability, is superior to a rapid inflation/deflation protocol for both stent expansion and strut apposition. As underexpansion and malapposition are strongly associated with adverse outcomes, including in-stent restenosis and stent thrombosis, the results strongly recommend a prolonged inflation protocol for routine stent deployment. Further randomized studies will be required.

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