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Original Article

Impact of very high pressure stent deployment on angiographic and long-term clinical outcomes in true coronary bifurcation lesions treated by the mini-crush stent technique: A single center experience

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ABSTRACT

Background: Percutaneous coronary intervention (PCI) for bifurcation lesions (BL) using 2 stents technique is known to be associated with high rates of procedural failure especially on the side branch (SB) mainly due to stent incomplete apposition. Stent deployment at very high pressure (SDHP) may lead to better stent expansion and apposition. However, SDHP may also be at the origin of deeper wall injury resulting into major cardiac adverse events. No data are available on evaluation of SDHP in BL treated by a mini-crush stent technique.

Methods: One hundred and thirteen consecutive patients underwent PCI for BL (Medina 1, 1, 1) using a mini-crush stent technique with SDHP defined as ≥20 atm. An angiographic follow-up was performed at 6 month and clinical follow-up was obtained at a median of 3 years.

Results: Stent deployment mean pressures were 20 ± 1.4 atm (range 20–25) in the main vessel (MV) and 20 ± 1.5 atm (range 20–25) in SB. Simultaneous final kissing balloon was used in 92% of cases. PCI was successful in 100%. Angiographic follow-up was obtained in 83% of patients. Restenosis rate was 13% (12% restenosis in the SB) with only one case (0.8%) of SB probable thrombosis. Another case of late stent thrombosis occurred at a 3 years clinical follow-up.

Conclusion: Compared with previously published studies in which stents were deployed at lower pressure, SDHP does not increase the restenosis rate in BL using mini-crush stent technique but seems to reduce the rate of stent thrombosis.

1. Introduction

The treatment of coronary bifurcation remains a challenge for interventional cardiologists. Randomized trials and meta-analysis suggest that bifurcation lesions (BL) treatment using a one-stent strategy with provisional stenting (PS) of the side branch (SB) results into better clinical outcomes when compared with two-stent techniques.[1,2] However, many cases of BL cannot be treated by a one-stent strategy. Situations such as long severe ostial stenosis on a large SB as well as major dissection or severe residual stenosis on the SB after main vessel stenting still require a two-stent technique. Therefore, various bifurcation stent techniques have been proposed.[3–7] The "crush and mini-crush" techniques are two-stent strategies that ensure a complete coverage of the SB ostium but despite the use of drug eluting stent (DES), these procedures are still associated with relatively high procedural complications and restenosis rate.[8–10] Procedural failure in PCI of BL may be explained in part by incomplete stent apposition that may occur more frequently than in simple lesions. Both stent deployment (SD) at very high pressure (HP) and HP simultaneous final kissing balloon (SFKB) may improve stent apposition and therefore reduce cardiovascular events. On the other hand, some data are in favor of less aggressive strategy for stent deployment without using HP inflation in non-BL suggesting that SDHP may be at the origin of deeper wall injury provoking a neointimal response that can be responsible for diffuse in-stent restenosis and subsequently increase in major cardiac adverse events (MACE) rates.[11,12] No data are available on evaluation of SDHP in BL treated by a mini-crush stent technique. The aim of our prospective study was to evaluate the impact of SDHP and HP SFKB with a "mini-crush" stenting technique in BL on both angiographic restenosis and clinical outcome.

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2. Methods

2.1. Study population

From May 2010 to March 2014, a total of 113 successive patients underwent a two-stent strategy in PCI for the treatment of complex coronary bifurcation lesion (Medina 1, 1, 1) using a mini-crush technique with HP implantation and HP SFKB. A signed informed consent was obtained from all patients.

2.2. Interventional procedure

All patients were given a loading dose of 300 mg clopidogrel when not pretreated and 100 mg aspirin the day before the procedure. Bolus intravenous injection of unfractionated Heparin (5000 UI) and 250 mg aspirin was administered at the beginning of the procedure. All patients received DES. Different generations of DES were used including sirolimus eluting stents (SES, Cypher, Cordis Corporation), zotarolimus eluting stents (ZES, Resolute, Medtronic), everolimus eluting stents (EES, Xience, Abbott Vascular) and biolimus eluting stents (BES, Biomatrix, Biosensor). Procedures were performed using either transfemoral or transradial approach. A 6 Fr arterial sheath was used for transradial approach and 6 Fr, 7 Fr or 8 Fr arterial sheaths were used for transfemoral approach. In some cases, we used a simultaneous dual vascular access site (radial–radial, radio-femoral or femoro-femoral) that allows simultaneous positioning of the two-stent delivery systems through 2 individual guiding catheters. Once the guiding catheter was positioned in the ostium of the coronary artery, a first guidewire was advanced into the distal main vessel (DMV) and a second guidewire was advanced into the side branch (SB). Balloon pre-dilatation was performed at the discretion of the operator. An appropriately sized stent (1:1 stent-to-artery diameter ratio) was first implanted in the SB using quantitative coronary analysis sizing and positioned to cover the whole lesion with the distal part of the stent in an angiographically healthy arterial segment. When a 6 Fr sheath was used, a non-compliant balloon (Quantum Maverick Balloon, Boston Scientific Corporation) with a size matched to the main vessel diameter was positioned in front of the SB stent to avoid main vessel occlusion during SB stent deployment or difficulty to make progress material into the DMV after SB stent deployment. The SB stent was first deployed at 12 atm to avoid downstream dissection and after a slight pullback of the stent balloon, another inflation was systematically performed at 20 atm to ensure optimized stent apposition. The guidewire and the balloon used for the stent deployment were then removed from the SB. The non-compliant balloon located in the main vessel was then inflated at 20 atm to crush the 1–2 mm proximal side branch stent. When a 7 Fr sheath was used, the SB stent was directly crushed by the main vessel stent. For the main vessel, a stent was chosen with a size matched to the diameter of the DMV (diameters ratio = 1:1) using a quantitative coronary analysis system and it was first deployed at 12 atm. After initial stent deployment in the main vessel, proximal optimization technique was used to match the stent size to the proximal main vessel diameter with the same stent balloon using inflation at very high pressure (20–25 atm) or with another larger non-compliant balloon. Finally, a floppy or hydrophilic guidewire was advanced across the stents struts into the side branch and a HP SFKB was performed using 2 non-compliant balloons. The SB non-compliant balloon was first inflated at 20 atm and deflated after 10 s. The SB non-compliant balloon was shorter than the SB stent for avoid downstream dissection and this size was the same as that of the SB stent (which was determined by QCA). Then, the MV balloon was inflated at 20 atm (the size was chosen with de DMV stent also determined by QCA). Finally, a SFKB was done with a simultaneous inflation of the balloon at median of 17 and 18 atm. The two balloons were pulled back to the part proximal of the MV stent and another inflation was done. Angiographic success was defined as residual stenosis less than 20% in both branches with a TIMI flow grade 3.

2.3. Angiographic and clinical follow-up

All patients were planned to have a routine control coronary angiogram at a mean of 6 months. Binary angiographic restenosis was defined as $\geq$50% diameter stenosis by a visual analysis. Stent thrombosis was defined according to the Academic Research Consortium definition.[13] Major cardiac adverse were defined by all cause death, cardiovascular death, non-cardiovascular death, *Q* wave myocardial infarction, no *Q* wave myocardial infarction, target vessel revascularization (TVR), target lesion revascularization (TLR), strokes and hospitalization for cardiac failure. All major events were obtained by direct contact with the patient or their relatives.

2.4. Statistical analysis

Continuous variables are expressed as mean $\pm$ standard deviation. A 2-tailed Student's *t* test was used to test differences among continuous variables. Differences between categorical variables were analyzed with a chi-square test or Fisher's exact test. A *p* value of $<$0.05 was considered significant. All data were processed using the Statistical Package for Social Sciences, version 15 (SPSS Inc., Chicago, Illinois).

3. Results

Population baseline characteristics are summarized in Table 1 and main angiographic data are presented in Table 2. Procedural characteristics are shown in Table 3. The total procedural success rate was 100%. Immediate procedural success rate after "mini-crush" stent technique alone was 85%. In 12% of cases, an additional in-stent stent was implanted in the side branch using a T and Protrusion technique (TAP) with repeat SFKB due to a non-acceptable angiographic result on the side branch after the first SFKB. As well in 3 cases (3%) with non-satisfactory angiographic result after mini-crush technique and SFKB, an additional in-stent simultaneous kissing stenting was performed using two DES simultaneously deployed at 20 atm. All the side branches and 98% of main vessels received a DES. Two patients had implantation of a bare metal stent in the main vessel due to a large diameter (4 and 4.5 mm, respectively). The mean maximal pressure of stent deployment in the main vessel was 20 $\pm$ 1 atm, ranging from

Table 1
Population characteristics (n = 113).

Age, yrs (mean ± SD)	67.93 ± 11.8
Men (%)	73.5
Smokers (%)	34.5
Hypertension (%)	49.5
Dylipidemia (%)	48.7
Diabetes (%)	21.2
Artheriopathy of the lower limbs (%)	8
Family history (%)	35.4
Renal insufficiency (%)	3.5
Left ventricular ejection fraction (%)	60 ± 13.4
Stress test or SPECT (%)	35.5
Stable angina (%)	15.9
Instable angina (%)	27.4
STEMI (%)	21.2

STEMI, ST elevation myocardial infarction; SPECT, single photoemission computed tomography.

Table 2
Angiographic characteristics of bifurcations lesions ($n = 113$).

Medina (1, 1, 1) (%)	100
Localization of BLs	
Left main (%)	2.65
Left anterior descending artery (%)	62.83
Circumflex artery (%)	26.54
Right coronary artery (%)	6.19
Main vessel size (mm)	3.01 ± 0.39
Distal vessel size (mm)	2.37 ± 0.17
Main vessel lesion length (mm)	23.90 ± 6.34
Side branch lesion length (mm)	16.96 ± 5.89

Table 3
Procedural characteristics ($n = 113$).

Sheath size 6 Fr/7 Fr/8 Fr (%)	48/49/3
Dual access (%)	5.3
Radial access (%)	50.44
Femoral access (%)	54.86
BMS stents SB (%)	0
DES stents SB (%)	100
BMS stents MV (%)	1.76
DES stents MV (%)	98.23
Max pressure inflation MV (atm)	20 ± 1.4
Max pressure inflation SB (atm)	20 ± 1.46
HP SFKB (%)	92.03
Max pressure MV SFKB (atm)	18.63 ± 3.55
Max pressure SB SFKB (atm)	17.08 ± 3.36
T and protrusion (%)	12.38
Simultaneous kissing stent (%)	2.65
Failing re-wire (%)	0
Slow flow SB during crush (%)	2.65

BMS, bar metal stent; DES, drug eluting stent; SB, side branch; MV, main vessel; SFKB, simultaneous final kissing balloon; HP, high pressure.

20 to 25 atm and it was 20 ± 1 atm in the SB, ranging from 20 to 25 atm. A SFKB was used in 92% of cases with non-compliant balloon inflation mean pressure of 19 ± 3 atm (range 16–30 atm) in the MV and 17 ± 3 atm in the SB (range 16–25 atm). In 9 cases, the operator did not perform any SFKB because of an optimized angiographic result. There was no failure to re-cross the crush stent with a guide wire. In one case, a specific guide-wire with higher stiffness (Miracle 3, Asahi Intecc, Osaka, Japan) was used to re-cross the stents struts. We documented 3 cases of transient slow flow after crushing the SB stent that disappeared immediately after nitroglycerin intracoronary injection. No case of vessel rupture and major dissections was noted. No acute or subacute stent thrombosis occurred in the 30 days.

3.1. Angiographic follow-up

Angiographic follow-up was obtained in 94 patients (83%). Global angiographic restenosis at 6 months occurred in 15 patients (13%) including restenosis at the SB in 13 patients (11%) and restenosis at the main vessel in 2 cases (2%). One case of probable SB stent thrombosis was found at control angiogram. Restenosis occurred in 2 of the 16 cases (12.5%) in which in-stent stents had been implanted using either a TAP technique or a simultaneous kissing stenting. Dyslipidemia, diabetes, smoking, hypertension, male gender, stent deployment pressure, stent length, generation of stent and BL location were not significantly predictive factors of restenosis. Global restenosis was higher in first generation DES than in second generation DES (20% vs 13%) but the difference did not achieve statistical significance ($p = 0.3$). All non-occlusive restenoses were focal.

3.2. Clinical follow-up

Clinical follow-up was completed for all patients with a median of 37 ± 18 months. During the whole follow-up, TVR and TLR were performed in 13 patients (11%) and 9 patients (8%), respectively. TVR or TLR were clinically ischemia driven in only 4 patients whereas in 7 patients, repeat revascularization was performed based on the findings at 6 months control angiogram in asymptomatic patients. Seven of the 15 patients with restenosis underwent repeat PCI with in-stent stenting using new DES and the remaining 8 restenotic patients were treated medically without PCI as they were asymptomatic with an intermediate stenosis (50–70% diameter stenosis) on the SB. Four patients died during the follow-up. Among these 4 deceased patients, one patient presented a very late stent thrombosis. This patient suffered a very late probable stent thrombosis 5 years after stent implantation but this patient was only under oral anticoagulation treatment for atrial fibrillation without any antiplatelet therapy. The three other patients died from ischemic stroke (Table 4).

Table 4
Main events in angiographical and clinical follow up.

Angiographic FU (%)	83
Restenosis at 6 month FU (%)	13
Restenosis SB (%)	11
Restenosis MV (%)	2
Thrombosis (%)	1.8
Death all cause (%)	3.6
Death CV (%)	3.6
Death non-CV (%)	0
MI Q wave (%)	1.8
TLR (%)	8
TVR (%)	11

FU, follow up; SB, side branch; MV, main vessel; CV, cardiovascular; TLR, target lesion revascularization; TVR, target vessel revascularization.

4. Discussion

To our knowledge, the present study is the first one to report a large series of true coronary bifurcation lesions treated by PCI using a mini-crush stent technique with DES deployment at very high inflation pressure (≥20 atm). The main findings of our study are: (1) the absence of acute or subacute stent thrombosis, (2) an extremely low rate of late stent thrombosis (0.9%), (3) a low angiographic restenosis rate, (4) a low cumulative MACE rate in the follow-up and a very low rate of clinically ischemia driven repeat revascularization (4%) at a 3 years follow-up.

The rationale for using very high-pressure stent deployment is to maximize stent expansion and to avoid malapposition of the stent struts to the vessel wall[14] that is recognized to be a major mechanism for stent thrombosis.[15,16] Conversely, experimental animal studies[17–19] have suggested that high-pressure implantation could increase the major adverse cardiac events. There is, however, very few published clinical data regarding the impact of stent deployment inflation pressure level on angiographic and clinical outcomes. In a non-randomized study, Uretsky et al.[11] found that very high inflation pressure had similar acute and short-term results when compared with less aggressive inflation pressure strategy but very high inflation pressure was associated with a poorer long-term outcome including both higher rates of MACE and TLR. By contrast, in a randomized trial, Dirschinger et al.[12] found no significant difference between low- and high-pressure dilatation during stent placement on early and late angiographic and clinical outcome. However, in both these latter studies,[11,12] only bare metal stents were used and no details were available regarding the subgroup of bifurcation lesions. The concept of high inflation pressure to optimize stent apposition may actually be more clinically relevant in true bifurcation lesions treated by DES using a 2-stent technique rather than in simple lesions receiving bare metal stents or in bifurcations treated by one-DES technique. In particular, intravascular ultrasound studies

Table 5
Overview of previous studies with crush technique stenting in BL with angiographic follow up.

Study author	Year	Patients with angio F-U (%)	Pressure kissing balloon (atm)	Pressure stent deployment (atm)	Restenosis (%) MV/SB	Thrombosis (%)	Center
Tanabe et al.	2004	68	–	–	23	6.5	Mono
Hoye et al.	2006	77	–	–	25	5.6	Multi
Galassi et al.	2007	93	–	–	12/2	2.2	Mono
Erglis et al.	2009	88	–	–	12	1.4	Multi
Galassi et al.	2009	82	–	–	12/9	2	Mono
Chen et al.	2011	92	–	–	5/4	2.7	Multi
Cheema et al.	2013	87	–	–	28	2	Mono
Kervinen et al.	2013	–					
Ge et al.	2005	80	–	15.3	12/22	4.5	Mono
Ge et al.	2006	79	–	15.2	16/19	3.3	Mono
Chen et al.	2008	83	16.5	20	3.2	Mono	
Yang et al.	2009	83.9	8.6	14.7	2/13	2	Mono
Colombo et al.	2009	86	–	14.3	5/13	1.7	Multi

suggest that optimized stent apposition is mandatory in crushing techniques,[20] a frequently used 2-stent approach, to improve angiographic and clinical outcomes. However, no clinical data exist regarding the impact of DES deployment at very high inflation pressure in crushing techniques. Several studies on BL treated by crushing techniques with routine angiographic follow-up have been previously published[6,8–10,21–30] but only a few studies[8,10,28–30] have provided details on stent deployment pressures (Table 5). In these 5 latter previously reported studies,[8,10,28–30] maximal pressures used for stent deployment were lower than in our study (15 vs 20 atm). The final kissing balloon mean inflation pressure was also high in our study since it was 19 atm for the MV and 17 atm for the SB. Comparison with other studies regarding the impact of inflation pressure level during final kissing balloon in bifurcation lesions treated by 2-stent technique remains difficult since details on inflation pressure are usually not provided in previously published studies.[6,8–10,21–30] Final kissing balloon in crushing techniques has been shown to correlate with more favorable long-term outcomes.[25] We believe that final kissing balloon at high-pressure in 2-stent technique following initial SDHP may also improve stents apposition and therefore contribute to reduce acute and sub-acute occlusion rates as well as to achieve better angiographic and clinical long-term outcomes.

Indeed, in our study we did not observe any case of acute or sub-acute stent thrombosis (0%) and only one patient (0.9%) presented a late stent thrombosis. One additional case of probable very late stent thrombosis occurred at 5 years and the total rate of stent thrombosis over a mean follow-up of 3 years was therefore only 1.8%. These numbers appear to be quite low when compared with other previously published studies on crushing techniques[8,10,28–30] in which stent deployment inflation pressures were lower since, in these latter studies, the mean rate of stent thrombosis was 2.3% (1.7–3.2%) over relatively short follow-up ranging from 8 to 12 months. Our results appear to be even more encouraging considering the fact that all our patients (100%) had Medina type [1, 1, 1] bifurcation that is expected to be the most unfavorable lesion in term of restenosis rate.

By contrast with findings of Uretsky et al.,[11] we did not find that patients treated with aggressive SDHP strategy were associated with increased long-term MACE. In a series of 136 patients undergoing PCI with bare metal stents, Uretsky et al.[11] found at a 405 days follow-up that very high inflation pressures were associated with more frequent pattern of diffuse restenosis and higher rates of TLR than lower inflation pressures (71% vs 16% and 27% vs 8%, respectively). Our own data are in disagreement with those of Uretsky et al.[11] since despite a longer follow-up (mean of 1110 days), the total TLR rate was only 6% in our study including only a 4% of clinically ischemia driven TLR with no case of diffuse restenosis. The differences between our study and that of Uretsky et al.[11] may be largely explained by the current use of DES in our work. When compared with bare metal stents, DES might require higher inflation pressures to ensure optimized stent apposition and to improve both angiographic and clinical outcomes.

The cumulative MACE rate in our study was only 14% during a 37 months follow-up whereas it was 23% (range 16–27%) at shorter follow-up periods of 8–12 months in the other previously published studies on crush techniques with DES deployment lower inflation pressures.[8,10,28–30]

It has been suggested that a double kissing balloon might avoid slow flow in the SB during crushing and might facilitate recrossing of the MV stent struts into the SB with the guidewire and the balloon.[28] In our work, we had only three transient slow-flow in the SB during crushing and we did not have any failure of recrossing the MV stent struts into the SB with the guidewire followed by the balloon. The use of high inflation pressures may probably facilitate the maneuvers of recrossing the stent struts by the guidewire and the balloon to achieve a final kissing balloon.

4.1. Study limitation

The main limitation of our study is the absence of a control group of patients with lower stent deployment inflation pressures. Despite the good results of our study when compared with those of studies previously published by others, a randomized trial comparing very high with lower inflation pressures is necessary to definitely confirm our findings. This is a single center experience. The advantage is the consistent technology and the disadvantage the limited generalization of the data.

5. Conclusion

Our data suggest that very high inflation pressures during drug eluting stent placement in true bifurcation lesions treated by a mini-crush technique show feasibility with promising results that need to be verified in larger, preferably randomized trials.

Conflicts of interest

The authors have none to declare.

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