G Model
IHJ-983; No. of Pages 5

ARTICLE IN PRESS

Indian Heart Journal xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj

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

Antoine Gerbay [*], Jeremy Terreaux, Alexis Cerisier, Marco Vola, Karl Isaaz

Division of Cardiology, University of Saint Etienne, Saint Etienne, France

A R T I C L E I N F O

Article history:
Received 10 March 2016
Accepted 21 May 2016
Available online xxx

Keywords:
Coronary artery disease
Bifurcation lesion
"Mini-crush" stent technique
High-pressure stent deployment

A B S T R A C T

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.

* Corresponding author at: Service de cardiologie, Hôpital Nord, Centre Hospitalo-Universitaire de Saint Etienne, 42055 Saint Etienne Cedex 2, France.
E-mail address: antoinegerbay@hotmail.com (A. Gerbay).

http://dx.doi.org/10.1016/j.ihj.2016.05.013
0019-4832/

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 ≥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 ± 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 ± 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.

Please cite this article in press as: Gerbay A, et al. 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, *Indian Heart J.* (2016), http://dx.doi.org/10.1016/j.ihj.2016.05.013