ORIGINAL ARTICLE

# Evaluation of a Strategy for Treating Bifurcated Lesions by Single or Double Stenting Based on the Medina Classification

Daniel Todaro, Francesco Burzotta, Carlo Trani, Salvatore Brugaletta, Maria De Vita, Giovanni P. Talarico, Maura Giammarinaro, Italo Porto, Antonio Maria Leone, Giampaolo Niccoli, Rocco Mongiardo, Mario Attilio Mazzari, Giovanni Schiavoni, and Filippo Crea

Instituto de Cardiología, Universidad Católica, Roma, Italy

**Introduction and objectives.** The Medina bifurcated lesion classification has been widely adopted because of its simplicity. However, no data are available on its use in helping select the best stenting technique for bifurcations.

**Methods.** Consecutive patients with bifurcated lesions (side branch ≥2.25 mm) were prospectively assessed using the Medina classification. The treatment strategy studied involved implanting two stents in lesions with a Medina classification of 1,1,1 (M3 group) and one stent in only the main vessel in lesions with other Medina classifications (OM group). Clinical endpoints were a major adverse cardiac event (MACE) and target lesion revascularization (TLR) during hospitalization and at 12-month follow-up.

**Results.** The study included 120 patients: 25 in the M3 group and 95 in the OM group. There was no difference in baseline characteristics between the groups. The treatment strategy was successfully implemented in 97% of the OM group and 68% of the M3 group (*P*<.001). No death or TLR was recorded during hospitalization, though three myocardial infarctions occurred postoperatively (2.1% in the OM group vs 4.0% in the M3 group; *P*=.6). At 12 months, there was no difference in clinical outcome between the two groups (MACE: 12.6% in the OM group vs 8% in the M3 group; *P*=.4; TLR: 13.7% in the OM group vs 8% in the M3 group; *P*=.5). Multivariate analysis showed that bare metal stent implantation (only in patients receiving a single stent) was the only independent predictor of TLR.

**Conclusions.** The planned treatment strategy of implanting a single stent in patients with bifurcated lesions not classified as Medina 1,1,1 lesions was associated with a very low rate of second stent implantation. Moreover, bare metal stent use was a predictor of TLR, suggesting that drug-eluting stents should be used routinely to treat bifurcated lesions regardless of their angiographic complexity.

**Key words:** *Percutaneous transluminal coronary angioplasty. Bifurcated lesion classification. Stent. Drug-eluting stent. Medina.*

SEE EDITORIAL ON PAGES 595-8

Correspondence: Dr. F. Burzotta.
Via Prati Fiscali 158, 00141 Roma. Italia.
E-mail: f.burzotta@rm.unicatt.it

Received April 15, 2008.
Accepted for publication February 10, 2009.

## Evaluación de una estrategia de implantación de *stent* único o doble para tratar lesiones bifurcadas basada en la clasificación de Medina

**Introducción y objetivos.** La clasificación de Medina de las lesiones bifurcadas ha alcanzado gran difusión debido a su simplicidad. No hay datos sobre el uso de la clasificación de Medina para orientar la técnica de implantación de *stents* que utilizar en las bifurcaciones.

**Métodos.** Se clasificó prospectivamente a pacientes consecutivos con lesiones bifurcadas (rama lateral ≥ 2,25 mm) utilizando la clasificación de Medina. La estrategia estudiada consistió en implantar dos *stents* en las lesiones Medina 1,1,1 (grupo M3) e implantar un *stent* tan sólo en el vaso principal en las lesiones con otras clasificaciones de Medina (grupo OM). Las variables de valoración clínicas fueron los eventos cardiacos adversos mayores (MACE) y la revascularización de la lesión diana (RLD) durante la hospitalización y en un seguimiento de 12 meses.

**Resultados.** Se incluyó en el estudio a un total de 120 pacientes. De ellos, 25 formaron el grupo M3 y 95 el grupo OM. Los 2 grupos no diferían en lo relativo a las características basales. La estrategia programada se aplicó satisfactoriamente en el 97% de los casos del grupo OM, frente al 68% de los del grupo M3 (p < 0,001). Durante la hospitalización, no se observó ninguna muerte ni RLD y se registraron 3 infartos de miocardio tras la intervención (el 2,1% del grupo OM y el 4% del grupo M3; p = 0,6). A los 12 meses, la evolución clínica no presentó diferencias entre ambos grupos (MACE, el 12,6% del grupo OM y el 8% del grupo M3; p = 0,4. RLD, el 13,7% del grupo OM y el 8% del grupo M3; p = 0,5). En el análisis multivariable, la implantación de *stents* metálicos sin recubrimiento (que se utilizaron solamente en los pacientes tratados con un solo *stent*) fue el único factor independiente predictivo de RLD.

**Conclusiones.** Una estrategia intencionada de implantación de un único *stent* en pacientes con lesiones bifurcadas, sin lesiones de tipo Medina 1,1,1, se asocia a una tasa muy baja de necesidad de implantación de un segundo *stent*. Además, la elección de un *stent* metálico sin recubrimiento predice la RLD y ello indica que deben emplearse de manera habitual *stents* liberadores de fármacos para tratar las lesiones bifurcadas, sea cual fuere su complejidad angiográfica.

**Palabras clave:** *Angioplastia coronaria transluminal percutánea. Clasificación de lesiones bifurcadas.* Stent. Stent *liberador de fármacos. Medina.*

## INTRODUCTION

Bifurcation lesions are a frequently encountered, complex subset of coronary lesions. The management of these lesions by percutaneous coronary intervention (PCI) represents a challenge associated with a lower procedural success rate when compared with nonbifurcation lesions.[1-3] Various techniques using 1 or 2 stents have been developed.[4,5] However, there is no consensus on the choice of any of these techniques based on the anatomical features of the bifurcation lesion. A recent classification of bifurcation lesions according to plaque distribution has been proposed by Medina et al[6] and has gained popularity due to its simplicity.[7]

The purpose of this study was to evaluate the clinical outcome in patients with bifurcation lesions prospectively treated with 1 of 2 different strategies (single or double stent technique) according to the Medina classification.

## METHODS

### Study Population

Between February 2005 and January 2006, consecutive patients with significant coronary artery disease in a bifurcation lesion with a side branch (SB) measuring 2.25 mm or more (on visual estimation) were enrolled and treated by means of single or double stent according to plaque distribution in the main vessel (MV) and in the SB. All patients gave written informed consent to PCI.

Patients with in-stent restenosis at the bifurcation or chronic total occlusion were excluded. Patients with ST elevation acute myocardial infarction (AMI) with pain onset within the preceding 48 hours, with cardiogenic shock and emergency PCI, with known contraindications to dual antiplatelet therapy were also excluded.

Based on the Medina lesion classification,[6] the patients were divided into 2 groups: *a)* bifurcation lesions involving proximal MV, distal MV, and ostial SB (Medina 1,1,1) (Medina with involvement of 3 segments, the M3 group); *b)* all the other types of Medina bifurcations (Medina 1,0,1; 0,0,1; 0,1,1; 1,1,0; 1,0,0; 0,1,0) (other Medina or OM group).

### Revascularization Procedure and Stenting Strategies

Heparin (initial weight-adjusted intravenous bolus, followed by additional boluses administered for the purpose of obtaining an activated clotting time of 250 to 300 seconds) was administered to all the patients. They were all also treated with dual antiplatelet therapy: aspirin and ticlopidine (250 mg × 2/day) or clopidogrel (loading dose of 300 mg followed by 75 mg/day) for 1 month in the case of bare-metal stent (BMS) implantation and at least 12 months in case of drug eluting stent (DES) implantation. Glycoprotein IIb/IIIa inhibitors were not used.

The stenting strategy was selected on the basis of the Medina classification[6] by choosing a double stenting technique in the M3 group and a provisional approach with a single stent in the OM group.

In the M3 group, a double stenting technique (MV and SB stent implantation) was chosen at the outset, implanting only DES. The decision to choose a specific double stenting technique was left up to the operators' discretion, who could use any of the main techniques: crushing,[8,9] T-stenting,[10,11] and kissing-stent[12] techniques. Reasons for not implanting double stents (crossover) were recorded. Kissing balloon[13-15] inflation was attempted in all the patients treated by double stenting. In the OM group, a single stent technique (MV stent implantation with or without kissing balloon) was used at the outset and the choice between DES or BMS was left up to each operator. However, according to the internal guidelines of our institution, DES implantation is usually selected in diabetic patients, in small vessels (≤2.75 mm) and in long lesions (≥25 mm). After stenting, the decision to perform kissing balloon inflation was left up to the operator. The operator was allowed to implant a second stent in the SB at his discretion in the case of unsatisfactory angiographic results. The enzyme creatine kinase (CK), its MB fraction (CK-MB), and cardiac troponin T (TnT) were determined in all the patients before the procedure, 6 hours later and 24 hours later. Thereafter, further cardiac enzyme assessments were performed every 8 hours only in patients with suspected post-PCI AMI.

### Angiographic Analysis

The qualitative analysis included: *a)* Medina classification of the bifurcation lesion[6]; *b)* ACC/AHA lesion type[16]; *c)* degree of the calcifications, graded as "none," "mild," or "moderate/severe"; and *d)* thrombolysis in myocardial infarction (TIMI) flow[17] in MV and SB before and after the revascularization procedure.

Quantitative coronary angiography (QCA) was performed with a previously validated automated edge detection method (CMS Medis Imaging System, Wallingford, Connecticut), using a guiding or diagnostic catheter as a reference for calibration.

The following parameters were obtained by QCA: *a)* reference diameter of the MV proximal and distal to the lesion and the origin of the SB; *b)* length of the lesion in the MV and in the SB; *c)* minimum MV and SB lumen diameter; *d)* percent stenosis in MV and SB; and *e)* acute gain in MV and SB. Post-PCI percent diameter stenosis of less than 30% in both the MV and the SB was considered to be an optimal angiographic result.

### Clinical Follow-up and Study End-Points

The in-hospital clinical course was recorded prospectively. After discharge, the patients were followed by telephone calls or office visits to assess major adverse clinical events (MACE) at 6 months and 12 months. The MACE included death, AMI (defined as appearance of new pathological Q-waves in at least 2 contiguous ECG leads together with an increase in creatine kinase levels to at least 3-fold the upper normal limit with no new pathological Q-waves on ECG) or target lesion revascularization (TLR) by either PCI or coronary surgery. The latter was defined as repeat revascularization to treat in-stent or in-segment restenosis.

Stent thrombosis (ST) included definite and possible ST according to the ARC criteria[18]: "definite" being defined as angiography- or autopsy-confirmed ST; "probable" as any unexplained death within the first 30 days or an AMI in the territory of the stent in the absence of any other obvious cause; and "possible" as any unexplained death after 30 days.

The predefined primary end-points of the study were the comparison of the M3 and OM groups in terms of MACE and TLR during the hospital stay and during the 12-month follow-up.

### Statistical Analysis

Continuous variables are presented as the mean plus or minus the standard deviation and categorical variables as the frequency (%). Continuous variables were compared using the independent sample *t* test. Categorical variables were compared with the $\chi^2$ test. An exploratory univariate analysis was performed to identify covariate variables to construct a Cox regression model. Only variables with a *P* value less than .1, as well as age and sex (as possible confounding factors), were included in the Cox regression model to identify the predictors of TLR. The results are presented as the hazard ratio (HR) with exact 95% confidence interval (CI) and exact *P* value. Statistical significance was accepted for a 2-sided *P* value less than .05. The analyses were performed with SPSS version 13.

## RESULTS

### Baseline and Procedural Characteristics

During the study period, 120 consecutive patients with bifurcation lesions were enrolled. According to the Medina classification, 95 patients were assigned to the OM group and 25 patients to the M3 group. Overall, baseline clinical and non-target lesion angiographic characteristics were similar between the 2 study groups (Table 1). Target lesion angiographic characteristics were obviously different in terms of bifurcation involvement, but the ACC/AHA lesion type,[16] length, and severity of MV involvement did not differ (Table 1). The M3 group had greater involvement of left anterior descending coronary artery (Table 1).

Table 2 summarizes the main procedural characteristics. The approach adopted was mainly transradial in both groups (M3, 64% vs OM, 76.8%) and 6F guiding catheters were those most frequently used in both groups. The percentage of pre-dilation was significantly higher in the M3 group (88% vs 60%; *P*=.009).

The planned strategy (single stenting) was adopted in the majority of the patients in the OM group (96.8%), as SB stent implantation was performed in only 3 patients (3.2%). Two of them had a significant preintervention SB ostial stenosis (Medina 1,0,1 and 0,1,1), which was even narrower after MV stenting and kissing-balloon post-dilation.[14-16] In a third patient, the SB ostium was not stenotic prior to PCI (Medina 1,1,0), but SB stenting was required due to a major plaque shift over the SB ostium after MV stenting.

The planned strategy (double stenting) was successfully carried out in 68% of the patients in the M3 group using mainly T-stenting[10-12] and crush stenting[8,9] (Table 2). In the remaining 8 patients (32%), however, a single stent technique was used because the operator considered the lesion anatomy to be

TABLE 1. **Clinical and Angiographic Characteristics of the Study Population**

| Variables | All Patients | Other Medina | Medina 1,1,1 | *P* |
|---|---|---|---|---|
| Males / females, % | 84/16 | 86/14 | 76/24 | .2 |
| Age, mean (SD), y | 64.9 (9.8) | 65.4 (9.8) | 62.7 (10) | .3 |
| Risk factors | | | | |
| Smoking, % (n) | 27.5 (33) | 27.4 (26) | 28 (7) | .9 |
| Hypertension, % (n) | 67.5 (81) | 66.3 (63) | 72 (18) | .6 |
| Hypercholesterolemia, % (n) | 61.7 (74) | 57.9 (55) | 76 (19) | .1 |
| Diabetes mellitus, % (n) | 22.5 (27) | 20 (19) | 32 (8) | .2 |
| Positive family history, % (n) | 33.3 (40) | 34.7 (33) | 28 (7) | .5 |
| Clinical history | | | | |
| Stable angina pectoris/silent ischemia, % (n) | 39.2 (47) | 41 (39) | 32 (8) | .2 |
| Unstable angina/NSTEMI, % (n) | 60.8 (73) | 59 (56) | 68 (17) | .4 |
| Previous STEMI, % (n) | 32.5 (39) | 34.7 (33) | 24 (6) | .3 |
| Previous coronary surgery, % (n) | 7.5 (9) | 8.4 (8) | 4 (1) | .5 |
| Site of bifurcation | | | | |
| Left anterior descending/diagonal, % (n) | 60.8 (73) | 55.8 (53) | 80 (20) | .012 |
| Circumflex/marginal artery, % (n) | 30 (36) | 32.6 (31) | 20 (5) | .012 |
| Right/descending posterior, % (n) | 9.2 (11) | 11.6 (11) | 0 (0) | NA |
| Lesion ACC/AHA classification | | | | |
| Type A, % (n) | 0 (0) | 0 (0) | 0 (0) | NA |
| Type B1, % (n) | 25.8 (31) | 24.2 (23) | 32 (8) | .4 |
| Type B2, % (n) | 39.2 (47) | 42.1 (40) | 28 (7) | .2 |
| Type C, % (n) | 35 (42) | 33.7 (32) | 40 (10) | .5 |
| Degree of calcification | | | | |
| None, % (n) | 85 (102) | 85.2 (81) | 84 (21) | .9 |
| Mild, % (n) | 3.3 (4) | 3.2 (3) | 4 (1) | .8 |
| Moderate/severe, % (n) | 11.7 (14) | 11.6 (11) | 12 (3) | .9 |
| Type of bifurcation according to the Medina classification | | | | |
| 1,1,1, % (n) | 20.8 (25) | 0 (0) | 100 (25) | NA |
| 1,0,1, % (n) | 3.3 (4) | 4.2 (4) | 0 (0) | NA |
| 1,1,0, % (n) | 25.8 (31) | 32.6 (31) | 0 (0) | NA |
| 0,1,1, % (n) | 5 (6) | 6.3 (6) | 0 (0) | NA |
| 0,0,1, % (n) | 3.3 (4) | 4.2 (4) | 0 (0) | NA |
| 0,1,0, % (n) | 26.7 (32) | 33.7 (32) | 0 (0) | NA |
| 1,0,0, % (n) | 15 (18) | 18.9 (18) | 0 (0) | NA |
| True bifurcation, % (n) | 29.2 (35) | 10.5 (10) | 100 (25) | .0001 |
| TIMI flow grade | | | | |
| 3, % (n) | 92.5 (111) | 91.6 (87) | 96 (24) | .6 |
| 2, % (n) | 4.2 (5) | 4.2 (4) | 4 (1) | .6 |
| 1, % (n) | 3.3 (4) | 4.2 (4) | 0 (0) | .6 |

NA indicates not available; NSTEMI, non-ST elevation myocardial infarction; SD, standard deviation; STEMI, ST elevation myocardial infarction; TIMI, thrombolysis in myocardial infarction.

unsuitable for double stenting. These unfavorable features were: *a)* diffuse SB disease resulting in the absence of a nondiseased landing zone for the SB stent (three patients); *b)* highly focal stenosis (<3 mm) at the SB ostium (2 patients); *c)* distal occlusion of SB (1 patient); and *d)* presence of another bifurcation lesion immediately distal to the treated bifurcation (2 patients). Accordingly, the rate of planned strategy change was significantly lower in the OM group: 3% versus 32% in M3 ($P<.001$) (Figure 1).

The majority of the patients (75%) were treated by DES. These stents were used in 23 patients (92%) of the M3 group, whereas BMS were implanted in the remaining 2 patients (8%), (including all cases of MV stenting only). Drug-eluting stents were used in approximately 70% of the OM group patients (including the 3 patients who required SB stenting). As a consequence, DES were implanted in all bifurcations treated by double stenting. The types of DES were Cypher (Cordis, Warren, NJ), Endeavor (Medtronic AVE, Minneapolis, MN) and Taxus Libertè (Boston Scientific, Natick, MA) in 20%, 16.7%, and 38.3% of all the patients, respectively.

In the M3 group, kissing balloon post-dilation was used more often than in the OM group (84% vs 49.5%; $P=.002$). Moreover, kissing balloon dilation was successfully performed in all the cases of double stenting.

TABLE 2. **Procedural Characteristics of the Study Population**

| | All Patients | Other Medina | Medina 1,1,1 | *P* |
|---|---|---|---|---|
| Approach | | | | |
| Transradial, % (n) | 74.2 (89) | 76.8 (73) | 64 (16) | .2 |
| Transfemoral, % (n) | 25.8 (31) | 23.2 (22) | 36 (9) | .2 |
| Switch to transfemoral approach, % (n) | 3.2 (3) | 3.2 (3) | 0 (0) | .9 |
| Guiding catheter size | | | | |
| 6 Fr, % (n) | 79.1 (95) | 82.1 (78) | 68 (17) | .3 |
| 7 Fr, % (n) | 14.2 (17) | 12.6 (12) | 20 (5) | .3 |
| 8 Fr, % (n) | 6.7 (8) | 5.3 (5) | 12 (3) | .3 |
| Procedure time, mean (SD), min | 86.5 (126.0) | 86.7 (140) | 85.6 (56.1) | .4 |
| Fluoroscopy time, mean (SD), min | 18.4 (12.9) | 15.8 (9.7) | 29.6 (18.8) | .01 |
| Pre-dilation, % (n) | 65.8 (79) | 60 (57) | 88 (22) | .009 |
| Direct stenting, % (n) | 34.2 (41) | 40 (38) | 12 (3) | .009 |
| Kissing-balloon after stenting, % (n) | 56.7 (68) | 49.5 (47) | 84 (21) | .002 |
| Drug-eluting stents used, % (n) | 75 (90) | 70.5 (67) | 92 (23) | .028 |
| Stents used in bifurcation | | | | |
| Stenting of MV only, % (n) | 83.3 (100) | 96.8 (92) | 32 (8) | .0001 |
| Stenting of MV and SB, % (n) | 16.7 (20) | 3.2 (3) | 68 (17) | .0001 |
| Two stent techniques | | | | |
| Kissing-stent, % (n) | 0.8 (1) | 0 (0) | 4 (1) | NA |
| T stenting, % (n) | 7.5 (9) | 3.2 (3) | 24 (6) | .0001 |
| Crushing, % (n) | 8.3 (10) | 0 (0) | 40 (10) | NA |
| Main vessel stent | | | | |
| Length, mean (SD), mm | 25.6 (9.9) | 24.7 (9.8) | 29.1 (0.4) | .04 |
| Diameter, mean (SD), mm | 2.9 (0.4) | 2.9 (0.4) | 2.9 (0.3) | .5 |
| Side branch stent: | | | | |
| Length, mean (SD), mm | 17 (5.5) | 12.7 (5.03) | 17.8 (5.3) | .8 |
| Diameter, mean (SD), mm | 2.5 (0.3) | 2.4 (0.1) | 2.5 (0.4) | .1 |
| Final TIMI flow grade in MV | | | | |
| 3, % (n) | 100 (120) | 100 (95) | 100 (25) | NA |
| 2, % (n) | 0 (0) | 0 (0) | 0 (0) | NA |
| 1, % (n) | 0 (0) | 0 (0) | 0 (0) | NA |
| 0, % (n) | 0 (0) | 0 (0) | 0 (0) | NA |

MV indicates main vessel; NA, not available; SB, side branch; SD, standard deviation; TIMI, thrombolysis in myocardial infarction.

The lengths and diameters of the implanted stents were not significantly different between the two groups.

## Angiographic Analysis

The angiographic results are shown in Table 3. Most of the lesions were located in the bifurcation of the left anterior descending and diagonal arteries and were not calcified. An optimal angiographic result was obtained in all the patients. In QCA, the 2 groups did not differ significantly regarding baseline and post-procedural results in the MV. As expected, the SB baseline percentage stenosis was significantly higher in the M3 group (43.5% vs 23.6%; *P*=.0004), while the post-procedural results in the 2 groups did not differ. Accordingly, the acute gain in the M3 group at the SB ostium was significantly higher (0.72 vs 0.07, *P*=.003).

## Clinical Outcome

Table 4 shows in-hospital results and clinical follow up outcomes. The clinical outcome during the hospital stay was available for all patients. After discharge, the mean duration of clinical follow-up was 12.5 (2.9) months; all the patients underwent at least 9 months of clinical follow-up. No stent thrombosis was observed during follow-up.

There were no deaths or TLR during the hospital stay and 3 (2.5%) post-procedural non-Q wave AMI were recorded: 2 in the OM group (2.1%) and 1 in the M3 group (4%) (*P*=.6).

After discharge, the rate of cumulative MACE was 12.6% in the OM group versus 8% in the M3 group (*P*=.4). No deaths or myocardial infarctions were observed during the follow-up in the M3 group, where there was one death and 2 myocardial infarctions in the OM group. One OM patient

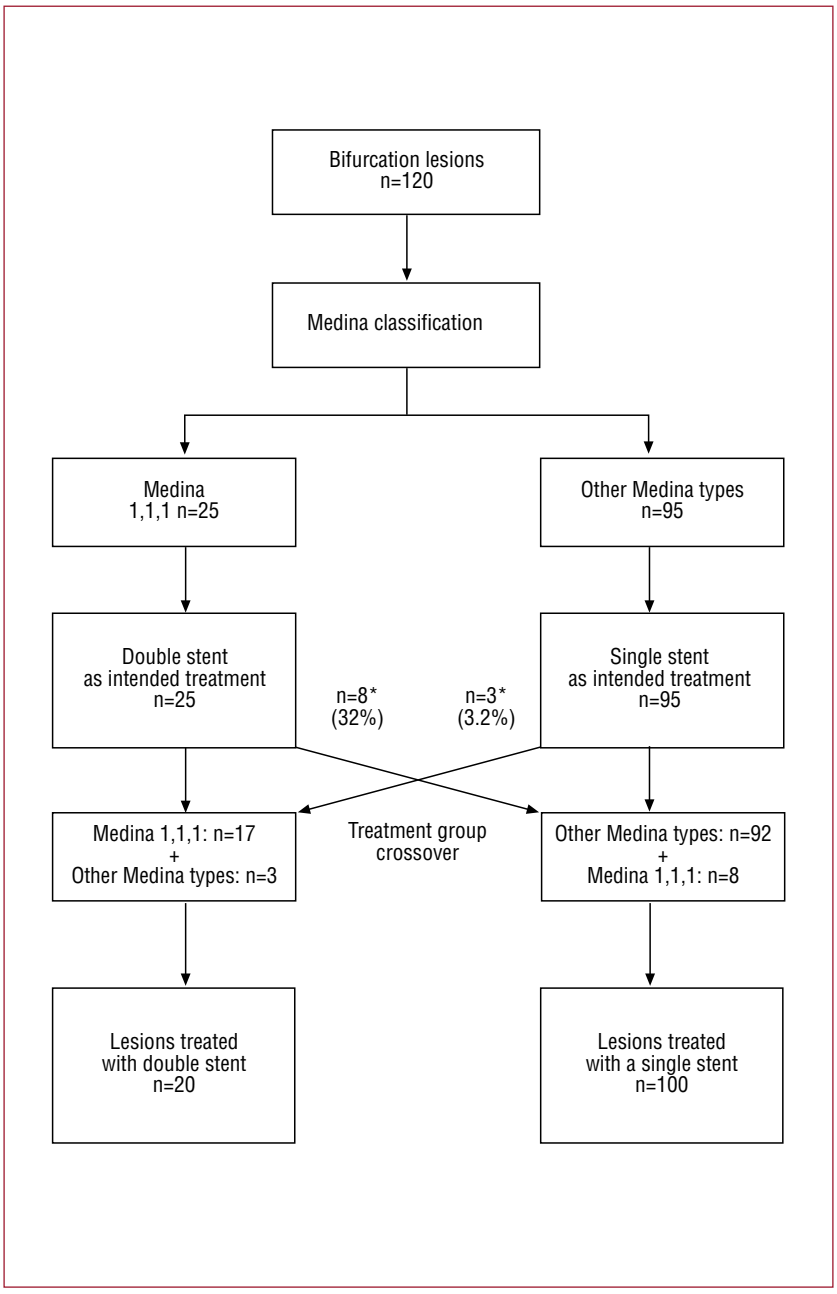


**Figure.** Flow-chart for the assignment of lesions to one treatment or another. *$P$<.001.

(Medina 0,1,0, treated by means of a single DES in MV) died suddenly 8 months after PCI on the third postoperative day following coronary surgery (required for target lesion restenosis). The 2 OM patients who had non-Q wave myocardial infarctions, 5 and 13 months, respectively, after the index PCI, were treated by DES in the MV alone. They underwent repeat coronary angiography, which showed nonocclusive in-stent restenosis, and TLR was performed.

The TLR rate was similar in the 2 groups (OM 13.7% vs M3 8%; $P$=.5).

In the multivariable analysis, BMS implantation (which had been chosen more often in the OM group) was the only independent predictor of the occurrence of TLR during follow-up ($P$=.04).

To assess whether the different distribution of DES usage between the 2 study groups influenced the comparisons, a separate analysis was performed restricted to the 90 DES-treated patients. Among patients treated by means of DES, the rate of TLR was 6.3% in the OM group and 8% in the M3 group ($P$=.85); the 2 groups showed no statistically significant differences in terms of the rate of cumulative MACE either.

TABLE 3. **Quantitative Coronary Angiography**

| | All Patients | Other Medina | Medina 1,1,1 | *P* |
|---|---|---|---|---|
| Main vessel characteristics pre-PCI | | | | |
| Proximal reference diameter, mean (SD), mm | 2.74 (0.47) | 2.76 (0.49) | 2.67 (0.37) | .4 |
| Distal reference diameter, mean (SD), mm | 2.45 (0.46) | 2.49 (0.47) | 2.30 (0.38) | .08 |
| Minimum lumen diameter, mean (SD), mm | 1.08 (0.56) | 1.09 (0.58) | 1.04 (0.48) | .6 |
| Lesion length, mean (SD), mm | 9.58 (5.68) | 9.25 (5.40) | 10.84 (6.63) | .2 |
| Percent stenosis, mean (SD), % | 60.4 (19.9) | 60.4 (20.0) | 60.2 (19.9) | .9 |
| Side branch characteristics pre-PCI | | | | |
| Reference diameter, mean (SD), mm | 2.14 (0.49) | 2.14 (0.51) | 2.11 (0.40) | .8 |
| Minimum lumen diameter, mean (SD), mm | 1.41 (0.66) | 1.49 (0.71) | 0.98 (0.36) | .002 |
| Lesion length, mean (SD), mm | 3.04 (3.27) | 2.72 (3.14) | 4.10 (3.51) | .07 |
| Percent stenosis, mean (SD), % | 27.8 (25.5) | 23.6 (23.9) | 43.5 (25.4) | .0004 |
| Main vessel characteristics post-PCI | | | | |
| Proximal reference diameter, mean (SD), mm | 2.96 (0.46) | 2.97 (0.49) | 2.91 (0.35) | .6 |
| Distal reference diameter, mean (SD), mm | 2.69 (0.43) | 2.71 (0.45) | 2.62 (0.35) | .4 |
| Minimum lumen diameter, mean (SD), mm | 2.58 (0.43) | 2.59 (0.44) | 2.52 (0.39) | .5 |
| Lesion length (mm) | 1.95 (3.01) | 1.96 (3.16) | 1.92 (2.48) | .9 |
| Percent stenosis, mean (SD), % | 12.77 (9.16) | 12.4 (8.69) | 13.35 (9.72) | .6 |
| Acute gain, mean (SD), mm | 1.47 (0.82) | 1.5 (0.72) | 1.48 (0.63) | .9 |
| Side branch characteristics post-PCI | | | | |
| Reference diameter, mean (SD), mm | 2.18 (0.55) | 2.15 (0.57) | 2.30 (0.44) | .2 |
| Minimum lumen diameter, mean (SD), mm | 1.72 (0.69) | 1.66 (0.71) | 1.93 (0.59) | .1 |
| Lesion length, mean (SD), mm | 1.74 (1.75) | 1.81 (1.82) | 1.50 (1.45) | .5 |
| Percent stenosis, mean (SD), % | 17.87 (19.37) | 19.2 (19.9) | 12.71 (16.5) | .1 |
| Acute gain, mean (SD), mm | 0.2 (0.98) | 0.07 (0.98) | 0.72 (0.85) | .003 |

PCI indicates percutaneous coronary intervention; SD, standard deviation.

TABLE 4. **Clinical Outcomes**

| | All Patients | Other Medina | Medina 1,1,1 | *P* |
|---|---|---|---|---|
| In-hospital MACE, % (n) | 2.5 (3) | 2.1 (2) | 4 (1) | .6 |
| Cardiac death, % (n) | 0 (0) | 0 (0) | 0 (0) | NA |
| AMI, % (n) | 2.5 (3) | 2.1 (2) | 4 (1) | .6 |
| Q wave, % (n) | 0 (0) | 0 (0) | 0 (0) | NA |
| Non-Q wave, % (n) | 2.5 (3) | 2.1 (2) | 4 (1) | 0.6 |
| TLR, % (n) | 0 (0) | 0 (0) | 0 (0) | NA |
| TLR (Re-PCI), % (n) | 0 (0) | 0 (0) | 0 (0) | NA |
| TLR (CABG), % (n) | 0 (0) | 0 (0) | 0 (0) | NA |
| Cumulative 12-month MACE, % (n) | 11.7 (14) | 12.6 (12) | 8 (2) | .4 |
| Cardiac death, % (n) | 0.8 (1) | 1.1 (1) | 0 (0) | .6 |
| AMI, % (n) | 1.7 (2) | 2.1 (2) | 0 (0) | .1 |
| Q wave, % (n) | 0 (0) | 0 (0) | 0 (0) | NA |
| Non-Q wave, % (n) | 1.7 (2) | 2.1 (2) | 0 (0) | .5 |
| TLR, % (n) | 12.5 (15)[a] | 13.7 (13)[a] | 8 (2)[b] | .5 |
| TLR (Re-PCI), % (n) | 11.7 (14) | 12.6 (12) | 8 (2)[b] | .5 |
| TLR (CABG), % (n) | 0.8 (1) | 1 (1) | 0 (0) | .6 |
| Stent thrombosis, % (n) | 0 (0) | 0 (0) | 0 (0) | NA |

AMI indicates acute myocardial infarction; CABG, coronary artery bypass graft; MACE, major adverse cardiac events; NA, not available; PCI, percutaneous coronary intervention; TLR, target lesion revascularization.
[a]In one case, the same patient underwent both percutaneous and surgical TLR.
[b]Crush technique in both cases.

## DISCUSSION

The optimal strategy for percutaneous treatment of bifurcation lesions is one of the most widely debated issues in interventional cardiology. To date, available data suggest that, in clinical practice, single stent implantation, when feasible, is not inferior to double stenting techniques.[19] However, it is also well established that a remarkable proportion of treated lesions may require double stenting to

obtain angiographic success.[20,21] The relevance of the involvement of atherosclerosis in bifurcation lesions is underlined by the existence of a number of attempts to categorize these lesions, including the Duke,[22] the Sanborn,[23] the Safian,[24] the ICPS,[25] and the Medina[6] classifications. Among these, the Medina classification is considered the most simple one and has recently been recognized in a consensus report by European experts as the gold standard for bifurcation evaluation.[7] The best classification, however, should not only provide a simple description of the anatomy but should also help in selecting the appropriate stent implantation strategy. Taking these assumptions as a starting point, we used the Medina classification prospectively in a consecutive series of patients with bifurcation lesions undergoing PCI in order to assign them to a single or double stenting strategy. To the best of our knowledge, this is the first study to assess the value of an angiographic classification as a guideline for stenting strategy in bifurcation lesions. The result of this original approach was promising as the selection of a provisional SB stenting strategy in patients without Medina 1,1,1 lesions resulted in a 3% rate of bailout SB stenting, the lowest ever reported. Moreover, the angiographic results obtained in MV and SB with a single stent in the OM group did not differ from that obtained with 2 stents in the M3 patients. Similar results may have been obtained using other classifications as the class defined as complete involvement of the bifurcation is considered in all the classifications, and we decided to greatly simplify the approach by pooling the remaining, less complex patients.

On the other hand, the selection of double stenting techniques in patients with the more complex Medina 1,1,1 lesions resulted in a high rate of angiographic success and warranted, over the long term, a clinical outcome that was comparable to that observed in patients with less complex bifurcations treated with single stenting. The selection of Medina 1,1,1 further restricted the number of patients considered for double stenting in the present study compared to the classical definition of "true bifurcation" which also comprises Medina 1,0,1 and Medina 0,1,1 lesions. The latter lesions were successfully managed with a single stent in the present study. Moreover, some patients with Medina 1,1,1 lesions may be treated by single stenting due to the presence of a SB anatomy that is not ideal for a second stent implantation (diffuse disease with absence of an appropriate stent landing zone, distal SB occlusion, presence of further division of the SB in multiple distal branches, etc). All together, these observations support the concept that only a minority of bifurcation lesions should be considered for double stent implantation techniques.

Finally, as previously shown by other groups,[26,27] DES implantation seems to be necessary to treat bifurcation lesions as it is associated with a lower TLR rate and is an independent predictor of better clinical outcome as compared to BMS.

### Study Limitations

This is a single-center study assessing the feasibility of a "tailored" approach to bifurcation lesions in which a relatively small number of patients were enrolled. As a consequence, the study is not conclusive, as it lacks sufficient statistical power to detect late clinical outcome differences.

In this study, we have arbitrarily hypothesized that the use of double stenting techniques may be reserved to treat Medina 1,1,1 lesions. This assumption has not been previously well established and remains controversial.

A possible major limitation of the present study is represented by the fact that DES usage differed between the 2 study groups. Indeed, it could be expected that an extensive use of DES in the OM group might reduce the MACE rate. Yet, the subanalysis limited to those patients treated by DES did show an absence of significant differences in TLR rates between the Medina 1,1,1 group and the non-Medina 1,1,1 group, thus supporting the overall validity of the findings.

Another possible major confounder may have been the heterogeneous use of kissing balloon dilation between M3 patients and the rest of the patients, since that was probably triggered by a bias in favor of applying the kissing balloon in double stenting procedures.

Finally, the failure to use dedicated software for the quantitative analysis of bifurcation lesions and the lack of systematic angiographic follow-up represent important limitations in the comparison of the acute angiographic results and the long-term outcome.

## CONCLUSIONS

The selection of a single stenting strategy based on the absence of Medina 1,1,1 lesions is associated with a high rate of optimal angiographic results and with a low rate of bailout SB stenting.

The selection of a double stenting strategy only in patients with Medina 1,1,1 lesions is associated with a high rate of optimal angiographic results. Both stenting strategies selected on the basis of the Medina classification are associated with a low rate of MACE. In the absence of randomized trials, our observational study might help in the selection of a personalized stenting strategy for bifurcation lesions.

## REFERENCES


1. Al Suwaidi J, Berger PB, Rihal CS, Garratt KN, Bell MR, Ting HH, et al. Immediate and long-term outcome of intracoronary stent implantation for true bifurcation lesions. J Am Coll Cardiol. 2000;35:929-36.
2. Chevalier B, Glatt B, Royer T, Guyon P. Placement of coronary stents in bifurcation lesions by the culotte technique. Am J Cardiol. 1998;82:943-9.
3. Yamashita T, Nishida T, Adamian MG, Briguori C, Vaghetti M, Corvaja N, et al. Bifurcation lesions: two stents versus one stent —immediate and follow-up results. J Am Coll Cardiol. 2000;35:1145-51.
4. Iakovou I, Ge L, Colombo A. Contemporary stent treatment of coronary bifurcations. J Am Coll Cardiol. 2005;46:1446-55.
5. Louvard Y, Lefèvre T, Dzavik V, Zelizko M, Ludman P, Hildick-Smith D, et al. Classification of coronary artery bifurcation lesions and treatments: Time for a consensus! Catheter Cardiovasc Interv. 2008;71:175-83.
6. Medina A, Suárez de Lezo J, Pan M. Una clasificación simple de las lesiones coronarias en bifurcación. Rev Esp Cardiol. 2006;59:183.
7. Thomas M, Hildick-Smith D, Louvard Y, Albiero R, Darremont O, Stankovic G, et al. Percutaneous coronary intervention for bifurcation disease. A consensus view from the first meeting of the European Bifurcation Club. Eurointervention. 2006;2:149-53.
8. Colombo A, Stankovic G, Orlic D, Corvaja N, Liistro F, Airoldi F, et al. Modified T-stenting technique with crushing for bifurcation lesions: immediate results and 30-day outcome. Catheter Cardiovasc Interv. 2003;60:145-51.
9. Daemen J, Lemos PA, Serruys PW. Multi-lesion culotte and crush bifurcation stenting with sirolimus-eluting stents: long-term angiographic outcome. J Invasive Cardiol. 2003;15:653-6.
10. Teirstein PS. Kissing Palmaz-Schatz stents for coronary bifurcation stenosis. Cathet Cardiovasc Diagn. 1996;37:307-10.
11. Carrie D, Karouny E, Chouairi S, Puel J. T-shaped stent placement: A technique for the treatment of dissected bifurcation lesions. Cathet Cardiovasc Diagn. 1996;37:311-3.
12. Sharma SK, Choudhury A, Lee J, Kim MC, Fisher E, Steinheimer AM, et al. Simultaneous kissing stents (SKS) technique for treating bifurcation lesions in medium-to-large size coronary arteries, Am J Cardiol. 2004;94:913-7.
13. Castriz JL, Canales ML, Reynolds DW. Kissing balloon technique in complex PTCA: Single guiding catheter and dual wire rapid exchange system. Cathet Cardiovasc Diagn. 1993;28:358-60.
14. Finci L, Meier B, Divernois J. Percutaneous transluminal coronary angioplasty of a bifurcation narrowing using the kissing wire monorail balloon technique. Am J Cardiol. 1987;60:375-6.
15. George BS, Myler RK, Stertzer SH, Clark DA, Cote G, Shaw RE, et al. Balloon angioplasty of bifurcation lesions: The kissing balloon technique. Cathet Cardiovasc Diagn. 1986;12:124-38.
16. Ellis SG, Vandormael MG, Cowley MJ, DiSciascio G, Deligonul U, Topol EJ, et al. Coronary morphologic and clinical determinants of procedural outcome with angioplasty for multivessel coronary disease. Implications for patient selection. Circulation. 1990;82:1193-202.
17. Weaver WD, Simes RJ, Betriu A, Grines CL, Zijlstra F, Garcia E, et al. Comparison of primary coronary angioplasty and intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review. JAMA. 1997;278:2093-8.
18. Laskey WK, Yancy CW, Maisel WH. Thrombosis in coronary drug-eluting stents: report from the meeting of the Circulatory System Medical Devices Advisory Panel of the Food and Drug Administration Center for Devices and Radiologic Health, December 7-8, 2006. Circulation. 2007;115:2352-7.
19. Niccoli G, Ferrante G, Porto I, Burzotta F, Leone AM, Mongiardo R, et al. Coronary bifurcation lesions: to stent one branch or both? A meta-analysis of patients treated with drug eluting stents. Int J Cardiol. 2008 Nov 21 [Epub ahead of print].
20. Assali AR, Assa HV, Ben-Dor I, Teplitsky I, Solodky A, Brosh D, et al. Drug-eluting stents in bifurcation lesions: to stent one branch or both? Catheter Cardiovasc Interv. 2006;68:891-6.
21. Steigen TK, Maeng M, Wiseth R, Erglis A, Kumsars I, Narbute I, et al. Nordic PCI Study Group. Randomized study on simple versus complex stenting of coronary artery bifurcation lesions: the Nordic bifurcation study. Circulation. 2006;114:1955-61.
22. Popma JJ, Leon MB, Topol EJ. Atlas of interventional cardiology. Philadelphia: Saunders; 1994.
23. Spokojny AM, Sanborn TM. The bifurcation lesion. En: Ellis SG, Holmes DR, editores. Strategic approaches in coronary intervention. Baltimore: Williams & Wilkins; 1996. p. 288.
24. Safian RD. Bifurcation lesions. En: Safian RD, Freed MS, editores. The manual of interventional cardiology. Royal Oak: Physician's Press; 2001. p. 222.
25. Lefevre T, Louvard Y, Morice MC, Dumas P, Loubeyre C, Benslimane A, et al. Stenting of bifurcation lesions classification, treatments, and results. Catheter Cardiovasc Interv. 2000;49:274-83.
26. Thuesen L, Kelbaek H, Kløvgaard L, Helqvist S, Jørgensen E, Aljabbari S, et al; SCANDSTENT Investigators. Comparison of sirolimus-eluting and bare metal stents in coronary bifurcation lesions: subgroup analysis of the Stenting Coronary Arteries in Non-Stress/Benestent Disease Trial (SCANDSTENT). Am Heart J. 2006;152:1140-5.
27. Colombo A, Moses JW, Morice MC, Ludwig J, Holmes DR Jr, Spanos V, et al. Randomized study to evaluate sirolimus-eluting stents implanted at coronary bifurcation lesions. Circulation. 2004;109:1244-9.