The Long-Term Clinical Outcome of T-Stenting and Small Protrusion Technique for Coronary Bifurcation Lesions

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Objectives This study sought to report long-term clinical outcomes in patients treated with the provisional T-stenting and small protrusion (TAP) technique.

Background Several strategies have been proposed for treating bifurcation lesions, each with its own merits and technical challenges. The TAP technique is a relatively new strategy that is technically less challenging, ensures complete coverage of the side-branch ostium, and minimizes stent overlap. Although there is reasonable amount of data for other bifurcation strategies, the long-term clinical outcomes for TAP technique are limited.

Methods We retrospectively evaluated all patients who underwent TAP technique with drug-eluting stents between July 2005 and January 2012. The measured endpoints at follow-up were major adverse cardiac events defined as composite of cardiac death, myocardial infarction, and target vessel revascularization.

Results A total of 95 patients (81.1% men) with a mean age of 64.8 years underwent TAP stenting. Procedural success was achieved in 100% of cases. True bifurcation was observed in 75 (78.9%) patients. First-generation drug-eluting stents were used in 55.8% of patients. The outcome rates at 3-year follow-up of major adverse cardiac events, cardiac death/follow-up myocardial infarction, target vessel revascularization, and target lesion revascularization were 12.9%, 3.1%, 9.7%, and 5.1%, respectively. There were no cases of follow-up myocardial infarction or stent thrombosis (definite and probable).

Conclusions These results demonstrate that TAP technique is associated with acceptable clinical outcomes with no episodes of definite and probable stent thrombosis. Further studies should compare TAP technique with other 2-stent strategies. (J Am Coll Cardiol Intv 2013;6:554–61) © 2013 by the American College of Cardiology Foundation
Although there are no formal guidelines on the strategies for percutaneous coronary intervention (PCI) involving major anatomic bifurcations, the current consensus is to consider provisional stenting as the default strategy for most bifurcations (1,2). The 2-stent approach is generally reserved for complex bifurcations. However, up to 30% of cases treated with provisional stenting require crossover to 2-stenting due to flow compromise in the side branch (SB) resulting from plaque and/or carina shift or dissection at the ostium of the SB (3–5). The bailout stenting options in such situations are reverse culotte, reverse crush, or reverse T-stenting. Reverse culotte and reverse crush stenting are technically challenging and may not be successful in all cases. In addition, they prolong procedural time, radiation, and contrast load (5,6).

Reverse SB (3–5) plaque and/or carina shift or dissection at the ostium of the SB may not be successful in all cases. In addition, they prolong procedural time, radiation, and contrast load (5,6). Reverse T-stenting can only be optimally performed in bifurcations with 90° angulation. T-stenting and small protrusion (TAP) is a relatively new technique, which is technically less challenging and ensures complete coverage of the SB ostium and minimizes stent overlap (7). Unlike other strategies, the TAP technique does not involve recrossing of the stent to perform final kissing balloon inflation (FKBI) following deployment of the SB stent. Although there are reports on the outcomes following traditional crush and culotte techniques, there is scarcity of data on the long-term clinical outcomes following TAP stenting. We performed this study to evaluate the long-term clinical outcomes of TAP technique using drug-eluting stents (DES) in our cohort of patients.

### Methods

We retrospectively evaluated all patients who underwent the TAP technique with DES for bifurcation lesions between July 2005 and January 2012 at 3 high-volume centers: 1) San Raffaele Scientific Institute, Milan, Italy; 2) New-Tokyo Hospital, Chiba, Japan; 3) EMO-GVM Centro Cuore Columbus, Milan, Italy. The initial intended strategy for the bifurcation lesions was the provisional stenting technique, with crossover to TAP stenting when at least 1 of the following conditions was met: residual stenosis ≥50%; type B or higher grade of dissection; or TIMI (Thrombolysis In Myocardial Infarction) flow grade <3.

#### Procedure

The following steps were employed for TAP stenting:

- Wiring of the main branch (MB) and SB;
- Pre-dilation of MB and/or SB at the operator’s discretion;
- Stenting of the MB by jailing the SB (Fig. 1A);
- Angiographic evaluation of the result; and
- Decision whether to perform kissing balloon inflation. If yes, rewiring the SB through the stent, followed by balloon dilation to open the stent struts and MB balloon dilation (Fig. 1B).

At this stage, if the result was acceptable, the procedure was concluded. However, if there was compromise to the SB flow, a second stent was deployed as follows.

- A stent was positioned in the SB with the aim to protrude as minimally as possible, ensuring complete coverage of the ostium of SB.
- The SB stent was deployed, while the uninflated balloon remained parked in the MB at the bifurcation (Fig. 1C).
- The SB stent balloon was pulled backward slightly, ensuring that it was still within the MB stent. Subsequently, simultaneous FKBI was performed using the SB balloon and the previously positioned MB balloon at high pressure (Fig. 1D).
- The SB balloon was deflated last.
- The SB stent completely covered the ostium (Fig. 1E).

Clinical data was collected during hospital visit or by telephone consultation. The antiplatelet regimens were low-dose aspirin, which was recommended indefinitely, and a thienopyridine (200 to 250 mg of ticlopidine bid or 75 mg of clopidogrel daily) for a minimum of 6 months after PCI.

#### Quantitative coronary angiographic measurements

Matched orthogonal views were used for quantitative analysis before and after treatment. Angiography was performed after intracoronary injection of nitroglycerine (100 to 200 µg). Angiograms were analyzed by means of the Clinical Measurements Solutions system (QCA-CMS, version 5.1, Medis Medical Imaging Systems, Leiden, the Netherlands). Quantitative coronary analysis measurements were performed at baseline and after stent implantation on both MB and SB. Minimal lumen diameter, diameter stenosis, acute gain, and reference vessel diameters were measured.

#### Endpoint definitions

The measured endpoints were major adverse cardiac events (MACE) during the follow-up period. MACE was defined as composite of cardiac death, myocardial infarction (MI), and target vessel revascularization (TVR). Death was considered cardiac in origin unless obvious noncardiac causes could be identified. MI was defined as the presence of pathological and new Q waves on an electrocardiogram, or an increase in creatine kinase-myocardial band level to >3 × the upper limit of the normal range. TVR was
defined as repeat PCI or coronary artery bypass graft for the target vessel. Target lesion revascularization (TLR) was defined as repeat PCI or coronary artery bypass graft for the lesion in the previously stented segment or in the adjacent 5 mm. The occurrence of stent thrombosis (ST) was defined on the basis of the Academic Research Consortium definitions (8). Bifurcation lesions were classified according to Medina class by 2 independent physicians (9). The EuroSCORE (European System for Cardiac Operative Risk Evaluation) (10) and the SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score were calculated (11). Procedural success was defined as completion of the procedure with no in-lab complications, final TIMI flow grade 3 with residual stenosis <20% in MB and SB.

Statistical analysis. The values were presented as mean ± SD or median (interquartile range [IQR]) for continuous variables or as counts and percentages for categorical variables. Time-to-event curve was generated using Kaplan-Meier methods. Analyses were carried out using SPSS for Windows (version 19.0, SPSS Inc., Chicago, Illinois).

Results

Patient demographics. During the study period, 2,396 bifurcation lesions in 2,360 patients were treated by PCI using DES. Of these, 95 lesions (4%) in 95 patients with a mean age of 64.8 ± 9.5 years (range 40 to 85 years) underwent TAP stenting: 46 at San Raffaele Scientific Institute, Milan, Italy; 32 at New-Tokyo Hospital, Chiba, Japan; 17 at EMO-GVM Centro Cuore Columbus, Milan, Italy. The reasons for TAP stenting were: type B or higher grade of dissection in the SB in 31 (32.6%) patients; residual stenosis defined as >50% at the SB ostium with TIMI flow grade 3 in 58 (61.1%) patients; residual stenosis defined as ≥50% at the SB ostium with TIMI flow grade <3 in 6 (6.3%) patients. The baseline clinical characteristics are shown in Table 1. The majority of patients were male (n = 77, 81.1%).

angiographic and procedural details. Angiographic and procedural characteristics are shown in Table 2. Bifurcation lesions were located as follows: left anterior descending/diagonal artery 51 (53.8%); left circumflex/obtuse marginal artery 22 (23.2%); distal left main coronary artery 18 (18.9%); and right coronary/posterior descending artery 4 (4.2%). According to the Medina classification, true bifurcation (type 1.1.1, type 1.0.1, and type 0.1.1) was observed in 75 (78.9%) patients. First-generation DES were used in 53 (55.8%) patients, whereas the remaining 42 patients received second-generation DES. FKBI was performed in 89 (93.6%) patients. In the remaining 6 patients, FKBI was not performed because the operator did not feel the necessity due to excellent angiographic result following stenting. Intravascular ultrasound was performed in 41 (43.2%) patients. Procedural
success was achieved in all patients with no procedure-related deaths or complications. However, there was 1 case (1.1%) of periprocedural MI recorded. Quantitative coronary angiography measurements at baseline and at the end of the procedure are reported in Table 3. The frequency domain optical coherence tomography (C7 XR, OCT Imaging System, St. Jude Medical, St. Paul, Minnesota) and intravascular ultrasound images of a patient treated with TAP stenting are shown in Figures 2 and 3, demonstrating complete ostial coverage with minimal overlap.

Clinical follow-up. The median follow-up period was 36.2 months (IQR: 20.8 to 52.1) and 50 (52%) patients completed 36 months of follow-up. During the follow-up period, 12 (12.6%) MACE occurred: 3 (3.2%) cardiac deaths (6 all-cause deaths); 9 (9.5%) TVR; and 5 (5.3%) TLR. Kaplan-Meier curves for MACE and TVR at 3-year period, 12 (12.6%) MACE occurred: 3 (3.2%) cardiac deaths, 1 patient died suddenly at home about 21 months after the procedure was performed with sirolimus-eluting stents. The other 2 patients died suddenly at 31 and 36 months after implantation of paclitaxel-eluting stents. Consequently, possible ST was adjudicated in these 3 patients. There were no cases of definite or probable ST. Nine (9.5%) patients required TVR in the form of repeat PCI. Five (5.3%) patients required TLR: 3 had focal restenosis involving the SB ostium (bifurcation type 0.0.1); 1 had focal restenosis in the body of the MB stent (bifurcation type 0.1.0); and 1 had focal restenosis on the proximal edge of the MB stent. All of the 5 patients who required TLR had undergone FKBI.
Discussion

The main findings from our study of the long-term outcomes of the TAP technique are:

1. The outcome rate of cardiac death was 3.1% at 3-year follow-up.
2. The outcome rates of TVR and TLR were 9.7% and 5.1% at 3-year follow-up, respectively.
3. There were no cases of follow-up MI or ST (definite and probable).

Although there are various techniques that can be used for converting provisional stenting to 2-stent strategy when required, most techniques (reversed culotte or crush) are laborious and may not achieve complete success due to technical difficulties. Although procedural success has been reported to be over 95% in 2-stenting strategies, FKBI was not performed in more than 20% of cases (12). FKBI is considered mandatory for 2-stenting strategies (especially crush and culotte) to reduce the rates of restenosis and clinical events (3). The TAP technique has some procedural advantages, such as it does not require recrossing of the SB struts to perform FKBI. In our cohort, the procedure was completed

Table 3. Quantitative Coronary Angiographic Measurements (N = 95)

<table>
<thead>
<tr>
<th></th>
<th>Main Branch</th>
<th>Side Branch</th>
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<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RVD, mm</td>
<td>3.12 ± 0.54</td>
<td>2.50 ± 0.43</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>1.04 ± 0.60</td>
<td>1.15 ± 0.59</td>
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<tr>
<td>DS, %</td>
<td>66.4 ± 17.3</td>
<td>55.2 ± 20.6</td>
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<tr>
<td>Lesion length, mm</td>
<td>14.7 ± 8.7</td>
<td>11.6 ± 6.3</td>
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<tr>
<td>Final</td>
<td></td>
<td></td>
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<tr>
<td>RVD, mm</td>
<td>3.45 ± 0.68</td>
<td>2.70 ± 0.43</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>3.14 ± 0.65</td>
<td>2.38 ± 0.46</td>
</tr>
<tr>
<td>DS, %</td>
<td>9.3 ± 6.5</td>
<td>11.7 ± 8.3</td>
</tr>
<tr>
<td>Acute gain, mm</td>
<td>2.09 ± 0.83</td>
<td>1.24 ± 0.70</td>
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Values are mean ± SD.

DS = diameter stenosis; MLD = minimal lumen diameter; RVD = reference vessel diameter.

Figure 2. Coronary Angiography and FD-OCT Images

(A) Coronary angiography showing bifurcation lesion of the left anterior descending artery (LAD) and diagonal artery (DA). (B) Coronary angiography showing dissection in the DA ostium after stent implantation in the LAD and kissing balloon inflation (panel C in Fig. 2B indicates the site of the optical coherence tomography [OCT] image). (C) Frequency domain optical coherence tomography (FD-OCT) showing the coronary dissection (arrows) at the DA ostium.
successfully in all patients. In addition, as the name suggests, there is minimal protrusion of the SB stent into the MB, leading to minimal stent overlap and, more importantly, ensuring ostial coverage. These advantages may theoretically reduce the rates of restenosis and ST. In our study, there were no cases of definite or probable ST in the relatively long-term follow-up. Furthermore, the cardiac death rate was low, and there were no cases of MI during the follow-up. In addition, the outcome rates of TVR and TLR were 9.7% and 5.1% at 3-year follow-up, which are acceptable considering that the majority were true bifurcation. Although our study did not compare the TAP technique with other 2-stent strategies, referring to previous studies reporting culotte and crush techniques, the rates of TVR have ranged between 3% and 10% within the first year of follow-up (3,4,6,13). The 5-year outcome from the Nordic Bifurcation Study recorded 3% cardiac death, 6.3% MI, 1.5% definite ST, and 18.3% TVR in the 2-stent group, which suggests that our results are acceptable (14). In addition, these

Figure 3. Coronary Angiography, FD-OCT, and IVUS Images

(A) Coronary angiography following TAP stenting showing angiographically successful result. (B, E) FD-OCT showing good stent apposition in the LAD. (C) FD-OCT showing complete stent coverage at the superior aspect of the DA ostium (proximal part of the bifurcation) with 2 layers of stent struts (arrows). (D, D′) FD-OCT and intravascular ultrasound (IVUS) at the bifurcation showing the DA stent struts (arrows) with creation of a neo-carina following final kissing balloon inflation. (F) FD-OCT pulled back from DA also showing complete stent coverage (arrows) at the DA-ostium. BES = biolimus-eluting stent(s); other abbreviations as in Figures 1 and 2.
studies reported cases of definite or probable ST, which was not encountered in our cohort. However, the possibility of a chance finding could not be excluded due to a relatively small number of patients in our study and the rarity of this event. The majority (55.8%) of stents used in our study were first-generation; however, with the use of newer generation stents, these results may further improve.

In this study, we used the TAP technique in patients requiring bailout SB stenting during a provisional stenting strategy. However, there are no data comparing TAP to other bailout strategies, and this should be the aim of future studies. Furthermore, we should point out that this technique can also be used in conjunction with dedicated bifurcation stents, which facilitate a provisional approach, when stenting of the SB is required (15). Indeed, our data suggest that TAP technique can certainly be considered for bailout stenting during provisional stenting strategy.

**Study limitations.** This was a retrospective observational study with a small number of patients.

- First, we did not compare the TAP technique with other 2-stent strategies to claim technical and clinical advantage.
- Although the TAP technique ensures complete ostial coverage with minimal overlap, we were not able to confirm this by intravascular ultrasound or frequency domain optical coherence tomography imaging in all patients.
- The complete 3-year follow-up was not achieved in all the patients.
- The majority of clinical presentation in our study was stable angina. Therefore, this study cannot comment on the feasibility and long-term success of TAP stenting in all situations (such as acute coronary syndromes).
- Finally, we cannot exclude the possibility that the “oculostenotic reflex” could have played an important role to trigger SB stenting as the criteria were not based on the reduction of functional flow reserve in the SB.

**Conclusions**

These results demonstrate that the TAP technique is associated with acceptable clinical outcomes with no episodes of definite and probable ST. Further studies
should compare TAP technique with other 2-stent strategies.

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REFERENCES


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