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Original article

One Versus 2-stent Strategy for the Treatment of Bifurcation Lesions in the Context of a Coronary Chronic Total Occlusion. A Multicenter Registry

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ABSTRACT

Introduction and objectives: There is little evidence on the optimal strategy for bifurcation lesions in the context of a coronary chronic total occlusion (CTO). This study compared the procedural and mid-term outcomes of patients with bifurcation lesions in CTO treated with provisional stenting vs 2-stent techniques in a multicenter registry.

Methods: Between January 2012 and June 2016, 922 CTO were recanalized at the 4 participating centers. Of these, 238 (25.8%) with a bifurcation lesion (side branch $\geq$ 2 mm located proximally, distally, or within the occluded segment) were treated by a simple approach (n = 201) or complex strategy (n = 37). Propensity score matching was performed to account for selection bias between the 2 groups. Major adverse cardiac events (MACE) consisted of a composite of cardiac death, myocardial infarction, and clinically-driven target lesion revascularization.

Results: Angiographic and procedural success were similar in the simple and complex groups (94.5% vs 97.3%; *P* = .48 and 85.6% vs 81.1%; *P* = .49). However, contrast volume, radiation dose, and fluoroscopy time were lower with the simple approach. At follow-up (25 months), the MACE rate was 8% in the simple and 10.8% in the complex group (*P* = .58). There was a trend toward a lower MACE-free survival in the complex group (80.1% vs 69.8%; *P* = .08). After propensity analysis, there were no differences between the groups regarding immediate and follow-up results.

Conclusions: Bifurcation lesions in CTO can be approached similarly to regular bifurcation lesions, for which provisional stenting is considered the technique of choice. After propensity score matching, there were no differences in procedural or mid-term clinical outcomes between the simple and complex strategies.

Uno frente a 2 *stents* para el tratamiento de lesiones en bifurcación en el contexto de una oclusión coronaria crónica total. Registro multicéntrico

Palabras clave:
Lesiones en bifurcación
Oclusión coronaria crónica total
Intervención coronaria percutánea

RESUMEN

Introducción y objetivos: Hay escasa evidencia sobre el tratamiento de lesiones en bifurcación en relación con una oclusión coronaria crónica total (OCT). Este estudio analiza los resultados inmediatos y a medio plazo de pacientes con lesiones en bifurcación en OCT tratados con 1 *stent* provisional frente a 2 *stents* en un registro multicéntrico.

Métodos: Entre enero de 2012 y junio de 2016, se recanalizaron 922 OCT en los 4 centros participantes. De ellas, 238 (25,8%) con lesión en bifurcación se trataron mediante estrategia simple (n = 201) o compleja (n = 37). Se calculó la puntuación de propensión emparejada para detectar sesgos entre ambos grupos. Los eventos adversos cardiovasculares mayores (MACE) se definieron como muerte cardiaca, infarto y revascularización de la lesión diana.

Resultados: Los éxitos angiográfico y del procedimiento fueron similares con la técnica simple (el 94,5 frente al 97,3%; p = 0,48) y con la compleja (el 85,6 frente al 81,1%; p = 0,49), aunque la cantidad de

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contraste, la dosis de radiación y el tiempo de fluoroscopia fueron menores con la técnica simple. Al seguimiento (25 meses), la tasa de MACE fue del 8% de los pacientes con la técnica simple y el 10,8% de los tratados con 2 *stents* (p = 0,58). En este grupo hubo tendencia a una menor supervivencia libre de MACE (el 80,1 frente al 69,8%; p = 0,08). Después del análisis de propensión, no se observaron diferencias entre los grupos en los resultados inmediatos ni al seguimiento.

Conclusiones: Las LB en OCT pueden tratarse de modo similar que las demás bifurcaciones, para las que el *stent* provisional es la técnica de elección. Después de la puntuación de propensión emparejada, no hubo diferencias en los resultados inmediatos y a medio plazo entre ambos grupos.

Abbreviations

CTO: coronary chronic total occlusion
MACE: major adverse cardiac events
MI: myocardial infarction
PCI: percutaneous coronary intervention
SB: side branch

INTRODUCTION

Randomized trials of bifurcation lesions have not demonstrated the advantages of systematic side branch (SB) stenting compared with a 1-stent strategy.[1–8] Consequently, provisional SB stenting is the current preferred strategy for the percutaneous treatment of this type of lesion.

Bifurcation lesions in the context of a coronary chronic total occlusion (CTO) represent an additional challenge that has received little scrutiny. It is unclear whether the recommendations for the treatment of bifurcation lesions in the context of nonocclusive coronary artery disease are applicable in this scenario. Specific factors, such as the dissection frequently observed during CTO recanalization or the complexity of the procedure (ie, operator fatigue) could influence the strategy chosen and subsequently patient outcomes.

The aim of this study was to compare the procedural and mid-term clinical outcomes of patients with bifurcation lesions in CTO treated with provisional T-stenting (simple strategy) vs 2-stent techniques (complex strategy) in a multicenter registry.

METHODS

Patient Population

We included all consecutive patients who underwent CTO percutaneous coronary intervention (PCI) with successful wire crossing of the occlusion, and a SB $\geq$ 2 mm taking off at the proximal or distal cap, or within the occluded segment. Proximal and distal SB were included when the distance between the SB and the occluded segment was $\leq$ 5 mm. The procedures were performed by experienced CTO-PCI operators at the 4 participating centers between January 2012 and June 2016. A total of 922 CTO in 905 patients were recanalized. Of these, 267 CTO in 267 patients involved a bifurcation lesion (29.0%). Twenty-nine (11%) patients were excluded due to the impossibility of wiring the SB before or after main vessel stent implantation despite the operator's intention. The remaining 238 patients (26.2%) were treated by the simple approach (n = 201) or complex strategy (n = 37). The study flowchart is shown in Figure 1. Written informed consent for treatment and data analysis was obtained from all patients.

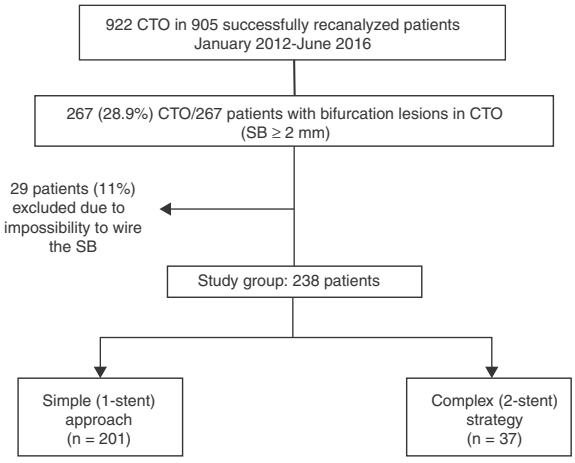

Figure 1. Flowchart of the study. CTO, coronary chronic total occlusion; SB, side branch.

Procedure

The decision to use an antegrade or retrograde approach and the CTO crossing strategy was at the operator's discretion after a thorough study of the CTO anatomy using simultaneous double injection when applicable. Bifurcation lesions were divided into 3 types regarding the SB take-off from the main vessel: bifurcation lesions within the occluded segment, those located at the distal cap, and those at the proximal cap. The type of bifurcation treatment was also at the discretion of the operator.

The patients were pretreated with dual antiplatelet medication. In the cardiac catheterization laboratory, weight-adjusted heparin was administered to maintain an activated clotting time for $>$ 300 seconds and was monitored every 30 minutes to determine whether an additional bolus of unfractionated heparin was necessary. After the procedure, all patients received 100 mg of aspirin daily indefinitely and a maintenance dose of clopidogrel (75 mg/d), prasugrel (10 mg/d) or ticagrelor (90 mg twice daily) for 6 to 12 months. In all patients, serial determinations of troponin levels were performed before and every 6 hours after the procedure for the first 24 hours.

Angiographic Data

Quantitative coronary analysis was performed before and after the procedure using the dedicated bifurcation software CAAS 5.11 (Pie Medical Imaging BV, Maastricht, The Netherlands). The following parameters were measured on the main vessel: reference vessel diameter, occlusion segment length, lesion segment length, final minimal lumen diameter, and final percentage of stenosis. In the SB, the parameters obtained were the reference diameter, minimal lumen diameter and percentage of baseline stenosis, final minimal lumen diameter, and final percentage of stenosis.

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