

Original article

The Impact of Side Branch Predilatation on Procedural and Long-term Clinical Outcomes in Coronary Bifurcation Lesions Treated by the Provisional Approach



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ABSTRACT

Introduction and objectives: It is uncertain whether side branch predilatation before main vessel stenting is necessary. We evaluated the effect of side branch predilatation on outcomes in percutaneous coronary intervention for true nonleft main bifurcation determined by the Medina classification using the provisional approach.

Methods: Target vessel failures (composite of cardiac death, myocardial infarction, or target vessel revascularization) were compared between patients who underwent side branch predilatation (predilatation group, n = 175) and those who did not (nonpredilatation group, n = 662).

Results: Final kissing-balloon inflation (57.1% vs 35.8%; $P < .001$) was performed more frequently and the cross-over rate to a 2-stent technique (14.9% vs 5.1%; $P < .001$) was higher in the predilatation group. During a median follow-up of 21 months, the predilatation group had a higher incidence of target vessel failures (14.3% vs 6.8%; $P = .002$) and target vessel revascularization (12.0% vs 5.6%; $P = .003$), but not of cardiac death or myocardial infarction compared with the nonpredilatation group. On multivariate analysis, side branch predilatation was associated with a higher occurrence of target vessel failures (adjusted hazard ratio = 2.11; 95% confidence interval, 1.27-3.50; $P = .004$). These results remained consistent after a propensity score-matched population analysis (for target vessel failures, adjusted hazard ratio = 2.63; 95% confidence interval, 1.09-6.34; $P = .0031$) and they were also constant among the various subgroups, according to the bifurcation angle, calcification, and diameter stenosis of the side branch.

Conclusions: Side branch predilatation before main vessel stenting may be associated with an increased risk of repeat revascularization in patients with true nonleft main bifurcation treated by the provisional approach.

Trial registration: ClinicalTrials.gov number: NCT00851526.

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Efecto en los resultados de la intervención y los resultados clínicos a largo plazo de la predilatación de la rama lateral para lesiones coronarias en bifurcación tratadas con la técnica de *stent* condicional

RESUMEN

Introducción y objetivos: No está claro si es necesaria la predilatación de la rama lateral antes de implantar *stents* en el vaso principal. Se ha evaluado el efecto de la predilatación de la rama lateral en los resultados obtenidos con la intervención coronaria percutánea en una lesión en bifurcación verdadera, no situada en el tronco principal izquierdo según la clasificación de Medina, empleando la técnica de *stent* condicional.

Métodos: Se compararon los fallos en el vaso diana (objetivo combinado de muerte cardiaca, infarto de miocardio o revascularización del vaso diana) entre los pacientes a los que se predilató la rama lateral (grupo de predilatación, n = 175) y los que no (grupo sin predilatación, n = 662).

Palabras clave:

Angioplastia coronaria transluminal percutánea
Lesión en bifurcación
Predilatación de la rama lateral

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Resultados: En el grupo de predilatación el hinchado del *kissing-balloon* final (el 57,1 frente al 35,8%; $p < 0,001$) se realizó con mayor frecuencia y el porcentaje de cambio a una técnica de dos *stents* fue mayor (el 14,9 frente al 5,1%; $p < 0,001$). Durante una mediana de seguimiento de 21 meses, el grupo de predilatación presentó incidencias de fallos en el vaso diana (el 14,3 frente al 6,8%; $p = 0,002$) y de revascularización del vaso diana (el 12,0 frente al 5,6%; $p = 0,003$) superiores que el grupo sin predilatación, pero no de muerte cardíaca e infarto de miocardio. En el análisis multivariable, la predilatación de la rama lateral se asoció con mayor frecuencia de fallos en el vaso diana (razón de riesgos ajustada = 2,11; intervalo de confianza del 95%, 1,27-3,50; $p = 0,004$). Estos resultados se mantuvieron constantes después de aplicar un análisis de la población igualada por puntuaciones de propensión (para los fallos en el vaso diana, razón de riesgos ajustada = 2,63; intervalo de confianza del 95%, 1,09-6,34; $p = 0,0031$) y fueron uniformes también en los diversos subgrupos definidos según el ángulo de la bifurcación, la calcificación y la estenosis diametral de la rama lateral.

Conclusiones: La predilatación de la rama lateral antes del implante de *stent* en el vaso principal puede asociarse con un aumento del riesgo de nueva revascularización para los pacientes con una lesión coronaria en bifurcación verdadera no situada en el tronco principal izquierdo tratados con la técnica de *stent* condicional.

Registro del ensayo: ClinicalTrials.gov número: NCT00851526.

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Abbreviations

PCI: percutaneous coronary intervention
SB: side branch
TVF: target vessel failure
TVR: target vessel revascularization

INTRODUCTION

Based on the results of numerous randomized trials, the provisional approach of selective side branch (SB) intervention after main vessel stenting is now considered the first-line treatment for most bifurcation lesions.¹⁻⁵ However, it is unclear whether predilatation of a SB before main vessel stenting can improve procedural and clinical outcomes in percutaneous coronary intervention (PCI) for a bifurcation lesion using the provisional approach. The aim of the present study was to assess the impact of SB predilatation before main vessel stenting on procedural and long-term clinical outcomes in patients with true nonleft main coronary bifurcation lesions, using a large, dedicated bifurcation registry.

METHODS

Study Population

The COBIS^{6,7} registry is a retrospective multicenter registry of patients with coronary bifurcation lesions undergoing PCI with drug-eluting stents. A total of 1668 consecutive patients from 16 major coronary intervention centers in South Korea were enrolled between January 2004 and June 2006. Details of the COBIS registry have previously been published and the registry has been used for other retrospective analyses.^{6,7}

To assess the effect of SB predilatation before main vessel stenting on procedural and clinical outcomes, we selected 1163 patients with true nonleft main bifurcation, as determined by the Medina classification.⁸ Eighty-one patients were excluded due to suboptimal images that were insufficient to evaluate SB predilatation. Of the remaining patients ($n = 1082$), 245 were excluded; 56 patients were excluded due to the presence of total SB occlusion on the preprocedural evaluation; we also excluded 189 patients who underwent a nonprovisional, 2-stent procedure of the SB. A total of 837 patients were finally included in this study (Figure 1).

Percutaneous Coronary Intervention

All patients were prescribed acetylsalicylic acid (300 mg) and clopidogrel (300 or 600 mg) unless these antiplatelet medications had previously been administered. Decisions to perform SB predilatation, the 2-stent procedure, or final kissing-balloon inflation were made by the individual operators.

Data Collection and Angiographic Analysis

Demographic, clinical, angiographic, procedural, and outcome data were collected with the use of a web-based reporting system. Additional information was obtained from the medical records or by telephone contact, if necessary. All outcome data reported from the participating center were reviewed by an independent clinical event adjudicating committee. Angiographic and procedural characteristics of all cine-angiograms were reviewed and analyzed at the angiographic core laboratory (Cardiac and Vascular Center, Samsung Medical Center, Seoul, South Korea) with an automated edge-detection system (Centricity CA1000, GE; Waukesha, Wisconsin, United States) using standard definitions.^{9,10}

Bifurcation lesions were classified according to the Medina classification.⁸ Medina classification (1,1,1), (1,0,1) or (0,1,1)

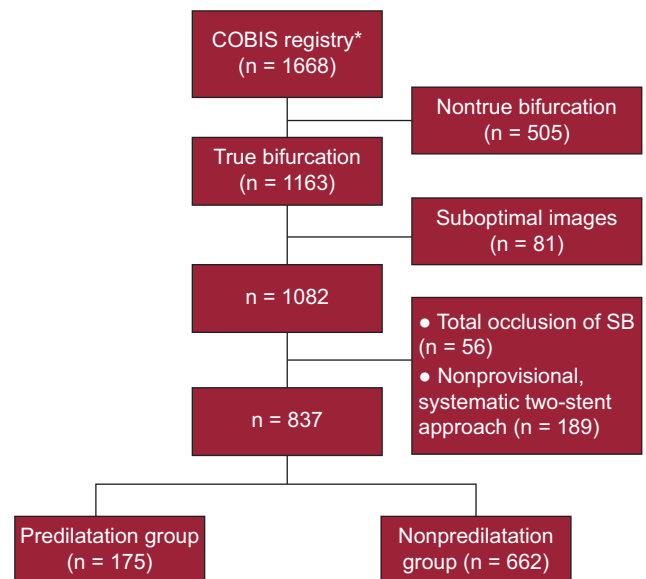


Figure 1. Patient flowchart. COBIS, Coronary Bifurcation Stent; SB, side branch. *Performed from January 2004 and June 2006.

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