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Clinical and angiographic assessment of the culotte technique for the treatment of complex coronary bifurcation lesions

Valoración clínica y angiográfica de la técnica de culotte para el tratamiento de lesiones complejas en bifurcaciones coronarias

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Abstract

Introduction: *The current standard treatment for bifurcation lesions is the provisional stent technique, by implanting only one stent in the main branch; however, in certain cases, the use of more complex techniques that require double stenting should be considered.* **Objective:** *To perform a clinical and angiographic assessment of patients with true bifurcation lesions treated with the two-stent culotte technique.* **Materials and methods:** *A prospective study was done, which included patients diagnosed with significant obstructive coronary artery disease in bifurcation areas, who were candidates for angioplasty with culotte technique. The study included 44 patients with proved diagnosis of coronary bifurcation lesions; 66% of the treated bifurcation lesions compromised the anterior descending artery and the diagonal branch and 27%, the circumflex artery with the marginal branch. It was found that 68% of the cases had Medina 1,1,1 lesions and 23% had Medina 0,1,1 lesions. Six months later, it was found that 12.5% of the patients followed up by angiography had in-stent restenosis (ISR) > 50% that involved at least one of the bifurcation areas. In 9% of these patients, the ISR was at the origin of the side branch only, and in 3%, the ISR was confined to the distal segment of the main branch stent.* **Conclusion:** *The use of the culotte technique with two new-generation stents to treat complex coronary bifurcation lesions is an effective option and does not increase the risk of complications during the procedure nor the risk of the appearance of ISR.*

Keywords: *Coronary disease. Bifurcations lesions. Culotte stenting. Drug-eluting stents.*

Resumen

Introducción: *El tratamiento estándar actual para las lesiones en bifurcaciones es la técnica de stent provisional, implantando solo un stent en la rama principal, sin embargo, en ciertos casos, se debería considerar el uso de técnicas más complejas que requieren de doble stent.* **Objetivo:** *Realizar una evaluación clínica y angiográfica de pacientes con verdaderas lesiones en bifurcaciones tratados con la técnica culotte de doble stent.* **Material y métodos:** *Se realizó un estudio prospectivo que incluyó pacientes diagnosticados con enfermedad obstructiva significativa de arterias coronarias en bifurcaciones, quienes eran candidatos a angioplastia con la técnica culotte. El estudio incluyó 44 pacientes con un diagnóstico comprobado de lesiones coronarias en bifurcaciones; el 66% de las lesiones en bifurcaciones tratadas comprometían la arteria descendente anterior y*

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la rama diagonal, y el 27% la arteria circunfleja con la rama marginal. Se encontró que el 68% de los casos tenían lesiones Medina 1,1,1 y el 23% tenían lesiones Medina 0,1,1. A los seis meses, se encontró que el 12,5% de los pacientes en seguimiento con angiografía presentaban reestenosis intrastent (RIS) mayor al 50%, que comprometía al menos una de las áreas de bifurcación. En el 9% de estos pacientes, la RIS se ubicaba únicamente en el origen de la rama lateral, y en el 3%, la RIS se restringió al segmento distal del stent de la rama principal. **Conclusiones:** *El uso de la técnica culotte empleando dos stents de nueva generación es una opción efectiva para tratar las lesiones complejas en bifurcaciones coronarias, y no aumenta el riesgo de complicaciones durante el procedimiento ni el riesgo de la aparición de reestenosis intrastent.*

Palabras clave: *Enfermedad coronaria. Lesiones en bifurcaciones. Culotte con stent. Stents liberadores de fármaco.*

Introduction

The coronary heart disease represents one of the leading causes of morbidity and mortality today[1]; thus, the diagnosis of complex coronary lesions, like those involving coronary bifurcations, representing around 15-20% of all lesions requiring treatment with angioplasty is increasingly frequent[1,2].

The current standard treatment for bifurcation lesions is the provisional stent technique that entails implanting a single stent in the main branch. However, in certain cases, the use of more complex techniques that require double stenting should be considered to treat both branches[3-5]. This study was aimed to perform a clinical and angiographic assessment of patients with true bifurcation lesions treated with the two-stent culotte technique.

Materials and methods

A prospective study was done, which included patients diagnosed with significant obstructive coronary artery disease (over 70% blockage) in bifurcation areas (coronary bifurcation lesions), who were candidates for angioplasty (percutaneous coronary intervention [PCI]) using the culotte technique and had vessels with a diameter > 2.0 mm and long side branches that involved significant myocardial territory. The patients were included regardless of any clinical and/or angiographic presentation of their disease, that is, patients with acute coronary syndromes and patients in cardiogenic shock, with the presence of intracoronary thrombi, severe coronary calcification, multivessel coronary disease, and chronic total occlusions, were included in the study. The study received institutional (Caribbean Cardiovascular Clinic) ethics committee approval, complied with the Declaration of Helsinki[6]; the verbal informed consent of the study was carried out during the standard coronary angioplasty procedure in the cardiac catheterization laboratory, including patients who were conscious enough to understand the information regarding the study. The description of the study information that had been previously approved by the ethics committee of the Caribbean Cardiovascular Clinic, was subsequently provided to each participant and their families in the recovery room, where written informed consent was obtained.

It was established that a lesion was a bifurcation lesion if the origin of the branch that the operator considered as the side branch had over 50% blockage (true bifurcations, Medina 1:1:1, 1:0:1, 0:1:1), or when this criterion was not met, but it was considered that the side branch could pose a risk of significant flow compromise during angioplasty of the main vessel.

The patients received a loading dose of 300 mg of aspirin and 600 mg of clopidogrel or 180 mg of ticagrelor if they had not received a previous dose of the medicines. In the procedure, unfractionated heparin was used as an anticoagulant at a dose of 70-100 U/kg. The right radial artery access route was the one selected by default, leaving the left radial or right femoral route as a second option if there were any limitations to carry out the right radial procedure. Drug-eluting stents (DESs) were used in all patients. The first choice was the stent coated with Zotarolimus Medtronic Resolute Onyx, and the stent coated with Sirolimus Terumo Ultimaster, was used at the operator's choice. The use of glycoprotein IIb/IIIa inhibitor was at the operator's choice, depending on the clinical situation.

To perform the culotte technique, a 0.014" angioplasty guide wire was advanced to the distal bed of the main branch and a second 0.014" angioplasty guide wire to the distal bed of the side branch. Both branches were pre-dilated with a semi-compliant balloon (SC) 0.5-1 mm diameter smaller than the estimated diameter of the vessel to be treated, inflated at a nominal pressure. Then, the first stent was implanted in the most angulated branch, considered by the operator as a side branch, taking the diameter of the side branch as a reference, in a reverse culotte technique. Then, the 0.014" guide wire was crossed through the cell closest

to the carina and the stent cell was opened towards the branch considered as the main branch, using the same semi-compliant balloon or a new balloon of smaller diameter, depending on the level of difficulty to pass the balloon through the cell, the second DES was implanted in the main branch through the stent cell of the side branch, considering the diameter of the distal main branch. Afterward, the 0.014" guide wire is crossed again toward the side branch through the stent cell and the cell is opened with a semi-compliant balloon, next, the post-dilation of the stents is performed in the side branch and main branch with non-compliant balloons (NC) with a 1:1 ratio with the diameter of the stents, performing simultaneous kissing inflation of the balloons in the carina, to reshape it. Finally, a dilation is performed by proximal stent optimization technique (POT) with a non-compliant balloon with a diameter of 0.5-1 mm larger than the stent diameter of the main branch, at high pressure (using the diameter of the vessel proximal to the bifurcation, as a reference). In some cases, a sequential dilation was chosen, with NC non-compliant balloons (vessel diameter ratio of 1:1) in the proximal main branch, the side branch, and the proximal main branch again (POT-side-POT). Having angiographic evidence of TIMI III coronary flow in both branches, without evidence of residual stenosis in any stent was considered an optimal result.

The clinical and angiographic follow-up of the patients began 180 days after the coronary intervention, and it was directly done by the research team, through personal interviews, telephone interviews, review of health records and performing a follow-up angiography, documenting the presence of symptoms related to coronary heart disease (angina, dyspnea, or equivalent), the appearance of new myocardial infarctions, strokes, death from cardiac cause or any cause during follow-up, treated vessel revascularization (TVR) or treated lesion (TLR) revascularization, stent thrombosis, or angiographic evidence of in-stent restenosis (ISR) > 50% in any of the components of the bifurcation (proximal, distal, side branch, or confluence zone). The data obtained were recorded and processed using averages, ranges, and percentages to handle the variables.

Results

The study included 44 patients with proved diagnosis of coronary bifurcation lesions from June 2017 to June 2018, clinical follow-up was achieved at 30 and 180 days in 43 patients of the patients initially included, and angiographic follow-up at 180 days in 32 patients; 68% were male and 32% of female. The average age was 68 years old, with a range from 48 to 82 years old; 68% of the patients were diagnosed with systemic high blood pressure, 23% with diabetes mellitus, 18% with heart failure, and 9% with chronic kidney disease. At the time of the angiography, 57% had been diagnosed with non-ST-segment elevation acute coronary syndrome and 16% with ST-segment elevation acute coronary syndrome. The average left ventricular ejection fraction, evaluated by Simpson's biplane method, was 50% (Table 1).

Table 1. Clinical characteristics of patients undergoing angioplasty using culotte technique in bifurcation lesion

	%	Total
Male	68%	30
Female	32%	14
Average age (years)	68	Range (48-82)
High blood pressure	68%	30
Diabetes	23%	10
Heart failure	18%	8
Chronic kidney disease	9%	4
Non-ST-segment elevation acute coronary syndrome	57%	25
ST-segment elevation acute coronary syndrome	16%	7
Left ventricular ejection fraction using Simpson's biplane method (average)	50%	

The angiographic characteristics of the patients were as follows: 66% of treated bifurcation lesions compromised the anterior descending artery with diagonal branch (D-ADA); 27%, the circumflex artery with marginal branch (M-CXA); 7% had a bifurcation lesion in posterior interventricular and posterior lateral branch from the right coronary artery (PIV-PL-RCA); 73% of the patients had a coronary disease in other vessels in addition to the treated vessel (multivessel coronary disease). Based on the Medina classification of bifurcation lesions, 68% had Medina 1.1.1 lesions, 23% had Medina 0.1.1 lesions, and 2% of the patients had lesions classified as Medina 0.0.1, Medina 1.0.1, Medina 0.1.0, and Medina 1.1.0 (Table 2).

As to the angioplasties, 77% were performed by radial artery approach, the right side was the approach by default, 23% were performed by femoral approach.

Table 2. Angiographic characteristics of bifurcation lesions in patients undergoing angioplasty using culotte technique

	%	Total
D-LAD lesions	66%	29
OM-CxA lesions	27%	12
PIV-PL-RCA lesions	7%	3
Multivessel disease	73%	32
Medina 1,1,1	68%	30
Medina 0,1,1	23%	10
Medina 0,0,1	2%	1
Medina 1,0,1	2%	1
Medina 0,1,0	2%	1
Medina 1,1,0	2%	1

The average diameter of the main branch was 2.86 mm; the average diameter of the side branch was 2.58 mm; the average length of the main branch lesion was 32 mm; and the average length of the side branch lesion was 22 mm. The average stent used to treat the lesions was 2.54 stent/lesion; 93% of the stents used released zotarolimus (Medtronic Resolute) and 7% released sirolimus (Terumo Ultimaster). In 52% of the cases, simultaneous kissing balloon inflation was performed; in 41% of the cases, a proximal balloon optimization technique (POT) was performed with high pressure dilation in the side branch (POT-side-POT); and in the remaining 7% of the cases, the use of both techniques was required to optimize the result (Table 3).

There were no complications during the procedure of 84% of the patients; in 9% of the patients, it was not possible to open the cell toward the side branch to perform the final kissing; 2% of the patients showed a cardiogenic shock in the procedure due to acute coronary syndrome; 4% (2 patients) presented coronary dissection after pre-dilation of the lesions, which was treated with stent implantation; and 2% of the patients presented subacute stent thrombosis in the proximal segment to the main branch of the bifurcation, 7 days after the angioplasty (Tables 4-5).

Within 30 days after the procedure, two patients died from causes related to their heart disease (acute myocardial infarction), two patients reported angina, two reported dyspnea, and one claimed feeling heart palpitations (no arrhythmia was documented). The patient

Table 3. Characteristics of angioplasties using culotte technique in bifurcation lesions

	%	Total
Radial approach	77%	34
Femoral approach	23%	10
Main branch diameter (average)	2.86 mm	
Side branch diameter (average)	2.58 mm	
Main branch lesion length	32 mm	
Side branch lesion length	22 mm	
Stent/lesion (average)	2.54	112
Zotarolimus-eluting stent, Medtronic	93%	
Sirolimus-eluting stent, Terumo	7%	
Number of balloons (average)	2.9	
Number of guiding catheters (average)	2.0	
Fluoroscopy time (average)	17 min	
Final kissing	52%	23
POT-side-POT	41%	18
Overlap (kissing plus POT-side-POT)	7%	3

POT: proximal optimization technique.

Table 4. Immediate complications associated with angioplasty procedure using culotte technique in bifurcation lesions

	%	Total
None	84%	37
Cardiogenic shock	2.2%	1
Impossibility for side branch final cell opening	9%	4
Coronary dissection	4.4%	2

Table 5. Clinical events at 180 days of follow-up after angioplasty procedure using culotte technique in bifurcation lesions (43 followed up patients)

	Total
Death from cardiac cause	2
Angina	2
Dyspnea	2
Palpitations	1
Target lesion revascularization (TLR) (definite stent thrombosis)	1

with definite subacute stent thrombosis required a new revascularization of the treated lesion. No patient had cerebrovascular accidents in the 1st month of follow-up and one patient refused to complete the clinical or angiographic follow-up due to personal reasons (Table 5).

After 6 months, 32 patients were followed up by angiography. The results of each control study were reviewed by an expert operator other than the operator who performed the initial procedure; 4 of which (12.5%) showed evidence of ISR > 50%, which involved at least one of the bifurcation areas; in 3 patients (9%), the ISR was at the origin of the side branch only (first 5 mm), and in the other patient (3%), the ISR was confined to the distal stent segment of the main branch. Any patient with significant restenosis reported symptoms during follow-up (Tables 6-7).

On assessing the patients who had ISR, it was evident that in one of them, the final kissing technique had not been performed during the procedure, which was completed with POT-side-POT technique because the angle of the lesion limited the advance of the two balloons simultaneously through the stents. In the three remaining patients, the final kissing was performed; two of them were completed with final POT and one without using POT (Table 7). In all patients with ISR, DES with zotarolimus had been used; in one of the four patients with ISR, the diameter of the stent used in the side branch was 2.25 mm and the diameter of the stent used in the other three patients was ≥ 2.5 mm. In all patients with ISR, the diameter of the main branch stents was > 2.5 mm (Table 6).

Discussion

When a bifurcation lesion requires a PCI, it should be considered what segments of the bifurcation area are involved, for which the Medina classification is used, thus standardizing as true bifurcation lesions those with significant stenosis involving the side branch (Medina 1:1:1, 1:0:1, and 0:1:1). However, the estimate of the distal angle, the level of calcification, the characteristics of the plaque, and the diameter of the vessels are also relevant, and predicting the dynamic changes that occur in the lesion during angioplasty is not less important[1].

The most important decision when facing a coronary angioplasty of a bifurcation is whether to use a single-stent or a complex 2-stent strategy[3,5]. If using a single-stent strategy, the decision involves the completion of the provisional stenting technique, in which after

Table 6. Characteristics of patients with in-stent restenosis > 50% at 6 months of follow-up after the treatment of bifurcation lesion with culotte technique

Patient	Sex	Age	Diabetes	HBP	Dyslipidemia	STSE ACS	Multivessel	Medina	Approach	D-LAD	OM-CxA	MB stent	SB stent	DES
1	M	72	No	Yes	No	No	Yes	0,1,1	Radial	No	Yes	2.5 × 30 MM-2.75 × 22 MM	2.25 × 18 MM	ZES
2	M	70	No	No	Yes	Yes	Yes	1,1,1	Radial	No	Yes	3.0 × 12 MM-3.5 × 30 MM	2.5 × 30 MM	ZES
3	M	76	No	Yes	No	No	No	0,1,1	Radial	Yes	No	3.0 × 26 MM	2.75 × 22 MM	ZES
4	M	78	No	No	No	No	Yes	1,1,1	Radial	No	Yes	3.5 × 26 MM	3.0 × 22 MM	ZES

DES: type of drug released by the stent used; D-LAD: bifurcation in diagonal branch of the left anterior descending coronary artery; HBP: systemic high blood pressure; MB STENT: measures of stents used to treat the lesion located in the main branch; MEDINA: type of bifurcation lesion according to the Medina classification; MULTIVESSEL: diagnosis of obstructive coronary artery disease of multiple vessels; OM-CxA: bifurcation between circumflex artery and obtuse marginal branch; SB STENT: measures stent used to treat lesion located in the lateral branch; STSE ACS: ST-elevation acute coronary syndrome.

Table 7. Relation of completion of final kissing technique, POT proximal optimization technique, or POT technique followed by post-lateral dilation followed by POT (POT-side-POT) with the appearance of in-stent restenosis > 50% at 6 months of follow-up after the treatment of bifurcation lesion with culotte technique

Patient	Final kissing	POT/POT-side-POT	Immediate complications	Location of in-stent restenosis
1	No	Yes	None	Restenosis of 60% at side branch origin
2	Yes	Yes	None	Restenosis of 70% at side branch origin
3	Yes	Yes	None	Restenosis of 90% distal segment of main branch
4	Yes	No	None	Restenosis of 100% at side branch origin

POT: proximal optimization technique.

implanting the stent in the main branch, it will be decided whether a balloon dilation or a second stent implantation in the side branch should be performed, establishing as criteria to treat the side branch, the presence of residual stenosis > 50%, TIMI <3 flow, or of side branch ostial dissection[2]. The provisional stent technique is currently the most accepted, due to its benefits regarding long-term final clinical outcomes[4].

Although the two-stent strategy is more demanding in terms of the operator learning curve, fluoroscopy time, amount of contrast used, and structural changes of the lesion during the procedure, there are situations where the use of two stents should be considered as the first option, like cases with > 2 mm diameter side branches, significant obstructive lesions > 70% in the origin of the side branch, diffuse lesions (> 20 mm) involving the origin and third proximal of the side branch, and left coronary artery main trunk lesions. The most relevant angioplasty techniques involving two stents are skirt, T stenting, TAP, culotte, V stenting, Y stenting, Crush, and DK-Crush, using for the planning of the procedure the MADS (main, across, distal, and side) classification that presents stenting procedures step by step, depending on the technique chosen[3,5].

In the era of the new DES, there are no significant differences as to the use of single-stent or two-stent strategies, providing that angiographic criteria are taken into account before the procedure (choosing the best strategy) and technical criteria, during the procedure (use of kissing and/or proximal optimization technique, POT). This applies to the clinical outcomes (cardiovascular death, general death, and MI) and the safety points (TLR and TVR)[7].

Based on the results of our follow-up study, we consider that the culotte technique was successfully used in most cases, with a very low rate of procedure-related complications, even though most patients had pre-procedural acute coronary syndromes, which entail that the general complexity level of the procedure is very high. In this regard, it is worth mentioning that the main technical complication was that it was not possible to fully dilate the side branch cell (9% of the cases), which prevented the completion of the kissing with the two simultaneously inflated balloons in these patients. However, that was not reflected in clinical or angiographic outcomes unfavorable to these patients, as evidenced by the fact that three out of the four cases in which no final kissing was performed due to the limitation to dilate the side branch cell, the patients did not show new clinical events within the following 30 days and did not had significant angiographic restenosis at the 6-month follow-up.

In the cases of patients who showed coronary dissection during the procedure, the strategy chosen was not modified because the dissections were short, did not limit flow, and were in the pre-dilated lesion. Therefore, the dissections were successfully treated with the stenting planned for the procedure. One of the two patients showing coronary dissection after pre-dilatation had no clinical complications in the 30-day follow-up nor did he had significant angiographic restenosis at the 6-month follow-up; and the other patient died within the 1st week after the procedure from cardiac complications due to pre-procedure acute coronary syndrome.

The subacute stent thrombosis was successfully treated with a new kissing dilation and the use of tirofiban IIb/IIIa inhibitor. The clinical progress was satisfactory, without new events at 30 days or significant restenosis at 6 months. We believe that the probable cause of thrombosis was the prothrombotic state conditioned by the non-ST-segment elevation acute coronary syndrome. However, one of the limitations of this study was the lack of availability of intracoronary imaging methods, such as IVUS or OCT, that could determine the possible causes of stent thrombosis more specifically.

There were two deaths related to cardiovascular causes during the follow-up in the first 30 days after the procedure. One of the deaths was mentioned above, in the section that refers to the coronary dissections that were present during the procedure, and the second death was caused by a cardiogenic shock due to acute coronary syndrome.

The presence of significant ISR was evidenced in 12.5% of the patients followed up by angiography. In three of these patients, the treated artery was the circumflex artery at the bifurcation with the marginal branch, evidencing that the ISR was at the origin of the side branch, which could have been conditioned by the wider angle of the lesions in this position. In the case of the other patient, the ISR was in the distal stent segment in the main branch, which was, in this case, the anterior descending artery, thus the precise cause thereof could not be established because the angle was < 70° and both vessels had good diameter. The technique was concluded with kissing – POT and there were no complications during the procedure.

There was no evident correlation regarding the occurrence of ISR and the diameter of the stent implanted in the side branch or main branch, since a 2.25 mm stent was used in the side branch in just one case with ISR, which could have caused early restenosis. However, in the other three patients, stents of more than 2.5 mm were used in the side branch and of more than 2.75 mm in the main branch. We did not find a correlation between the presence of ISR and the optimization of the final outcome after stent implantation with kissing balloon, since only in one of the three patients with ISR in the side branch, the final kissing had not been performed, and the procedure was completed with the POT-side-POT technique; and the patient with ISR in the distal segment of the main branch had been treated with kissing and POT at the end of the angioplasty (Tables 6 and 7).

There was no correlation between the presence of ISR and the presence of cardiovascular symptoms, since all the patients who had restenosis were asymptomatic at the time of angiographic follow-up at 6 months.

The use of the double DES technique in culotte for the treatment of complex bifurcation lesions is safe and effective, especially when compared to other two-stent techniques[8-10]. This could be due to the fact that the use of new generation stents has proved to reduce the occurrence of ISR and the occurrence of adverse events in this population of patients[11-15].

There were limitations because the angiographic follow-up at 6 months was only achieved in 72% of patients. However, clinical follow-up was achieved in 98% of initially registered patients. Not having the option of using IVUS or OCT for the assessment before and after the angioplasty did not affect the planning or decision making during the culotte technique. However, it is clear that using IVUS or OCT, the exact diagnosis of the mechanism whereby the ISR occurred in the patients affected could have been established.

The fact that the patients affected with ISR were completely asymptomatic at the angiographic assessment at 6 months raises the possibility that these lesions (ISR) were not truly functionally significant despite the angiographic degree of stenosis or that the myocardial territory irrigated by the vessels with ISR showed no viability and/or residual ischemia due to the degree of necrosis of the tissue or the hibernating tissue as a result of previous coronary events. Therefore, not having the possibility of measuring intracoronary pressure FFR (coronary fractional flow reserve), which would help clarify these doubts, was a clear limiting factor.

Conclusion

The use of the culotte technique with two new-generation drug-eluting stents to treat complex coronary bifurcation lesions is an effective option and does not increase the risk of complications during the procedure nor the risk of ISR.

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Conflicts of interest

No potential conflicts of interest exist with any of the authors.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that no patient data appear in this article.

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