One-year comparative outcomes of DK culotte and culotte techniques in left main bifurcation in acute coronary syndrome: Sub-study of Lower Silesia Culotte Bifurcation Registry

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INTRODUCTION

Coronary bifurcations constitute a significant portion of all percutaneous coronary intervention (PCI) procedures [1] and, particularly in cases involving two-stent techniques during acute coronary syndromes (ACS), are associated with an increased risk of stent thrombosis, in-stent restenosis, and subsequent target lesion revascularization (TLR). Interventions involving bifurcation of the left main coronary artery (LMCA) carry even greater risks due to the large area of myocardium supplied. The provisional stenting technique is an effective treatment for the majority of bifurcations. However, in the case of true bifurcation lesions, an up-front two-stent strategy might provide a potential advantage [2]. The choice of the optimal two-stent technique remains the subject of ongoing debate [3, 4], with observed better outcomes for LMCA true bifurcations using the double-kissing (DK) crush technique among other techniques [5], and this indeed is the preferred technique for LMCA bifurcation stenting [6]. A 2020 bench test by Toth et al. [7] shed new light on the two-stent culotte technique, showing that during the implantation of the second stent, there is a risk of displacing the multiple struts of the first stent in the bifurcation area. This displacement may pose a risk of rewiring under the displaced struts during the final kissing balloon inflation (KBI).

A modification of culotte called the DK culotte technique, utilizing additional KBI (Supplementary material, *Figure S1*), may facilitate the procedure and reduce the risk of strut displacement at the bifurcation area, potentially ensuring complete coverage of the bifurcation and translating to improved patient prognoses. Until now, the DK culotte technique has not been distinguished from the standard culotte technique in randomized trials. Recently, we published the results of a one-year follow-up of the Lower Silesia Culotte Bifurcation Registry (LSCBR) [8] comparing ACS patients treated using either the DK culotte or the culotte technique. This showed a favorable trend for the DK culotte technique in reducing target lesion failure (TLF) and major adverse cardiac events (MACE). Similar observations have been made by Tu et al. [9], who noted a reduction in TLF and MACE in a five-year follow-up of patients treated with the nano-DK culotte compared to the nano-culotte technique.

This sub-analysis of the LSCBR registry presents initial results comparing the DK culotte and culotte techniques in a subgroup of patients treated with the two-stent technique in the LMCA.

METHODS

The LSCBR (ClinicalTrials.gov: NCT06284057) is a retrospective analysis from 2 high-volume cardiac centers in the Lower Silesia region of Poland, covering the period from September 2013 to December 2022, focusing on the outcomes of bifurcation PCI in ACS patients treated with either the DK culotte or the culotte technique. Both true bifurcation lesions and bail-out stenting with a second stent after a provisional approach were included in the analysis. Patients who had been previously treated for a bifurcation lesion under investigation, or who had suffered pre-hospital cardiac arrest, were excluded. The choice of PCI technique was left to the discretion of the interventional cardiologist. Sub-analyses were performed on patients treated specifically for LMCA bifurcation, identifying 41 patients in the DK culotte group and 47 patients in the culotte group. This study was approved by the Bioethics Committee of the Lower Silesian Medical Association of Poland (01/BO/2023). All patients provided written informed consent for PCI. The patients were followed up *via* outpatient visits and telephone interviews.

The primary outcome of the study was TLF, comprising a composite of cardiovascular mortality, myocardial infarction of the target vessel, or clinically necessitated TLR within one year. The study also examined several secondary outcomes, including the frequency of MACE — encompassing myocardial infarction, cardiac death, and TLR — as well as the individual rates of TLR and all-cause mortality. The study also assessed procedural variables such as contrast volume used and cumulative radiation dose received during the PCI. The definitions and study endpoints used were in accordance with the consensus document on terminology for the treatment of coronary bifurcations [10]. More details regarding the methodology have been described previously [8].

Statistical analyses were performed using R programming language. Depending on the normality of distribution (assessed by the Shapiro–Wilk test), the data was presented as mean with standard deviation or median with interquartile range. Continuous variables were analyzed using the Mann–Whitney U test, and categorical variables using the Fisher's exact test. The significance threshold was set at a p-value of 0.05. Data for 1-year follow-ups was fully available.

RESULTS AND DISCUSSION

The average age of the patients was 69 (8.8) years in the DK culotte group and 68.6 (8.8) years in the culotte group, with a predominance of men in both groups. There were no significant differences in comorbidities, although atrial fibrillation was notably less present in the DK culotte group (12.8% vs. 29.3%; $P = 0.07$). Patients were administered dual antiplatelet therapy in accordance with the existing clinical guidelines for ACS.

The Syntax score was comparable between the groups (18 [14–26.2] vs. 21 [14-28]; $P = 0.33$). A bail-out two-stent strategy following a provisional stent was implemented in 3 patients from the DK culotte group and 2 from the culotte group; none of these patients suffered endpoints. Both the culotte and DK culotte techniques were performed mostly using an inverse approach, with stenting of the side branch first. The characteristics of stents used for the side branch and main branch were similar. TLF occurred in 5 patients (10.6%) in the DK culotte group compared to 7 (17.1%) in the culotte group ($P = 0.29$). There was a notable reduction in MACE in the DK culotte group (7 patients vs. 10 patients; $P = 0.11$). All demographic and procedural data, along with a summary of the endpoints, is set out in Table 1.

It is important to emphasize that we are presenting the first prognostic results comparing the DK culotte and culotte techniques in patients undergoing ACS with involvement of the LMCA bifurcation. The main findings of our study are: 1) The DK culotte technique showed a trend towards lower rates of TLF (10.6% vs. 17.1%; $P = 0.29$) and MACE (14.9% vs. 24.4%; $P = 0.11$), although these differences did not reach statistical significance; 2) The additional KBI in the DK culotte group did not result in excessive usage of contrast media (237.9 ml [71.2] vs. 245.7 ml [68.4]; $P = 0.60$) or cumulative radiation dose (2122 mGy [1643.5–3286] vs. 2513 mGy [1475–3786]; $P = 0.51$).

Further long-term follow-ups and prospective studies distinguishing the DK culotte technique from the culotte technique are warranted. It is also necessary to verify whether the favorable long-term outcomes for the DK crush technique will have the same advantage over DK culotte as is the case with the culotte technique [11], or if the additional KBI will eliminate these differences. Understanding the nuances of these techniques will help optimize treatment strategies and improve patient outcomes in complex bifurcation lesions.

This sub-study analysis has certain limitations that must be recognized. The study was of a retrospective observational nature, with all the inherent limitations of that type of study. In addition, the study population was relatively small, and external core lab validation was missing. Furthermore, a low percentage of intravascular imaging was used in both groups. However, we would like to underscore that the scientific value of the data is enhanced by the novelty of this study, and its strong relevance to daily practice.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/polish_heart_journal.

Article information

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Table 1. Clinical, procedural and outcome data

	DK culotte group (n = 47)	Culotte group (n = 41)	*P*-value
Age, years	69 (8.8)	68.6 (8.8)	0.85
Male sex	35 (74.5%)	29 (70.7%)	0.81
Clinical presentation			0.21
Unstable angina	23 (48.9%)	20 (48.8%)	
NSTEMI	15 (31.9%)	15 (36.6%)	
STEMI	9 (19.1%)	6 (14.6%)	
Clinical history			
Diabetes mellitus type 2	23 (48.9%)	23 (56.1%)	0.53
Hypertension	40 (85.1%)	37 (90.2%)	0.53
Hyperlipidemia	43 (91.5%)	31 (75.6%)	0.08
Atrial fibrillation	6 (12.8%)	12 (29.3%)	0.07
COPD/asthma bronchial	3 (6.4%)	6 (14.6%)	0.29
Previous PCI	19 (40.4%)	14 (34.1%)	0.66
Previous MI	17 (36.2%)	12 (29.3%)	0.51
LVEF, %	53.2 (11.8)	49 (16.2)	0.18
Laboratory values			
Total cholesterol, mmol/l	4.8 (1.3)	4.3 (1.2)	0.07
LDL, mmol/l	2.7 (1.1)	2.3 (1.1)	0.11
HDL, mmol/l	1.2 (1–1.4)	1.3 (1.1–1.5)	0.19
Hemoglobin, baseline, g/dl	13.7 (12.6–14.8)	14 (13.1–14.8)	0.84
Creatinine, µmol/l	88 (71.6–96.4)	90 (72.5–103.6)	0.40
Antiplatelets and anticoagulants at discharge			
ASA	47 (100%)	41 (100%)	N/A
Clopidogrel	27 (57.4%)	28 (68.3%)	0.38
Ticagrelor	18 (38.3%)	11 (26.8%)	0.27
Prasugrel	1 (2.1%)	0 (0%)	1.00
NOAC	7 (14.9%)	10 (24.4%)	0.29
VKA	0 (0%)	3 (7.3%)	0.10
Vessel and clinical assessment			
SYNTAX score I	18 (14–26.2)	21 (14–28)	0.33
Logistic SYNTAX score	4.6 (2.1–7.8)	6.2 (3.1–13)	0.13
Medina [1,1,1]	26 (55.30%)	20 (48.78%)	0.59
Medina [1,0,1]	10 (21.27%)	11 (26.83%)	0.49
Medina [0,1,1]	8 (17.01%)	7 (17.07%)	0.89
Procedural characteristics			
Bail out two stent strategy	3 (6.4%)	2 (4.9%)	0.47
Side branch stent diameter, mm	3.5 (3–3.5)	3.5 (3–3.5)	0.32
Side branch stent length, mm	22 (18–26)	22 (18–28)	0.70
Main branch stent diameter, mm	3.5 (3.5–4)	3.5 (3.5–4)	0.31
Main branch stent length, mm	23 (18–29)	22 (18–28)	0.35
Stent to side branch first	38 (80.9%)	32 (78%)	0.80
Final POT	46 (97.9%)	39 (95.1%)	0.60
IVUS/OCT imaging	9 (19.1%)	5 (12.2%)	0.40
Rotablation	4 (8.5%)	4 (9.8%)	1.00
Intravascular lithotripsy	1 (2.1%)	1 (2.4%)	1.00
GP IIb/IIIa use	1 (2.1%)	3 (7.3%)	0.33
Radiation dose, mGy	2122 (1643.5–3286)	2513 (1475–3786)	0.51
Contrast media amount, ml	237.9 (71.2)	245.7 (68.4)	0.60
1-year follow up primary outcome			
Primary outcome: Target lesion failure (cardiac death, target vessel myocardial infarct, target lesion revascularization)	5 (10.6%)	7 (17.1%)	0.29
1-year follow up secondary outcome			
Principal secondary outcome: MACE (myocardial infarct, cardiac death, target lesion revascularization)	7 (14.9%)	10 (24.4%)	0.11
Target lesion revascularization	4 (8.5%)	4 (9.8%)	0.65
All-cause mortality	2 (4.3%)	5 (12.2%)	0.16
Stent thrombosis	0 (0%)	0 (0%)	N/A
Stent restenosis	4 (8.5%)	4 (9.8%)	0.65

Values are n (%), mean (standard deviation) or median (interquartile range)

Abbreviations: ASA, acetylsalicylic acid; DK, double kiss; GP, glycoprotein; HDL, high-density lipoprotein; IVUS, intravascular ultrasound; LDL, low-density lipoprotein; LVEF, left ventricular ejection fraction; MI, myocardial infarction; N/A, not applicable; NOAC, non-vitamin K antagonist oral anticoagulant; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; POT, proximal optimization technique; VKA, vitamin K antagonist

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