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ORIGINAL RESEARCH

Sex Differences in Clinical Features and Outcomes in Patients with Acute Coronary Syndrome Treated with Bifurcation Stenting Using the Double-Kissing Culotte and Culotte Technique – 1-year Follow-up

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Purpose: Sex differences in the clinical course of coronary artery disease (CAD) particularly in Acute Coronary Syndrome (ACS), have been extensively hypothesized. Although coronary bifurcations account for approximately 20% of ACS cases, data concerning potential sex disparities in the outcomes of percutaneous interventions (PCI) remain scarce. Several data suggest the double kiss (DK) Culotte may provide advantages in bifurcation PCI. Therefore, we evaluate potential sex differences in relation to the Culotte technique.

Patients and Methods: This study retrospectively analyzes sex disparities following PCI interventions in ACS patients using the DK-Culotte or Culotte technique for bifurcation lesions. The primary endpoint was Target Lesion Failure (TLF), a composite of cardiovascular death, target vessel myocardial infarction, or clinically driven target lesion revascularization (TLR). The secondary endpoint included major adverse cardiac events MACE (myocardial infarction, cardiac death, and target lesion revascularization).

Results: There were no significant differences between sexes regarding TLF (DK-Culotte: Females 10.3% vs Males 5.7%; p=0.401; Culotte: Females 16.2% vs Males 11.8%; p=0.481) or MACE (DK-Culotte: Females 13.8% vs Males 12.5%; p=0.771; Culotte: Females 24.3% vs Males 17.6%; p=0.370) after a 1-year follow-up for both bifurcation techniques.

Conclusion: The study found no significant differences in clinical outcomes between sexes following PCI for bifurcation lesions in the ACS cohort, regardless of whether the two-stent techniques (DK- Culotte or Culotte) were used.

Keywords: sex differences, gender differences, acute coronary syndrome, coronary bifurcation, double-kiss culotte, culotte technique, percutaneous coronary intervention

Introduction

The average age of patients undergoing cardiac revascularization during an acute coronary syndrome (ACS) event is on the rise. This is in line with a broader demographic shift in modern societies. As a result, patients undergoing percutaneous coronary intervention (PCI) for ACS are more likely to have an increased prevalence of independent adverse events prognostic factors (diabetes and renal insufficiency) after percutaneous revascularization.[1–3] Furthermore, both phenomena have been demonstrated to increase the probability of the occurrence of complex lesions, which emphasizes the necessity to pay close attention to the most appropriate PCI technique.

Interestingly, these demographic changes have erased the traditional differences between sexes in the prevalence of coronary artery disease.[4] However, females still tend to be underrepresented in many contemporary clinical trials and are

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more likely to receive conservative therapy in the course of acute coronary syndrome.[5] Furthermore, even if they receive percutaneous revascularization, the comprehensiveness of treatment along with long-term outcomes is less favorable in comparison to males.[6,7] The precise mechanisms underlying these discrepancies remain elusive, despite the undeniable advancements in interventional techniques and armamentarium observed in recent times in the field of percutaneous revascularization.

Coronary bifurcation lesions are a prevalent phenomenon, representing approximately 20%[8] of percutaneous coronary intervention (PCI) cases, and continuing to present a significant challenge for interventional cardiologists, particularly in the context of acute coronary syndrome (ACS) conditions. Although the recently presented expert consensus considers the provisional single-stent technique to be the most convenient for the majority of bifurcation lesions[9] Nevertheless, in select cases, including those with significant anatomical complexity where diseases affect critical side branches, two-stent techniques may offer clinical advantages when compared with other options.[10]

An increasing body of evidence indicates that the double kiss (DK)-crush technique may offer benefits in the context of left main bifurcation, particularly in comparison with the classic crush technique.[11] A minor modification to the conventional crush methodology, which involved the incorporation of an additional kissing balloon (KB), led to a notable enhancement in the long-term outcomes of the DK crush.[12] On the other hand, since the introduction of the Culotte technique into clinical practice,[13] this bifurcation stenting technique has become one of the most commonly used procedures. It has been demonstrated to be safe and efficient[14] and its use is now widespread. A review of recent pre-clinical trials and a small number of pilot studies suggests that additional kissing dilatation before main branch (MB) stenting may improve the culotte technique in a manner similar to what was observed in the context of the crush technique.[15–17]

In light of the data presented, this study was designed to evaluate the difference between sexes in the short-term clinical outcome (one year) in ACS patients with culprit true bifurcation lesions treated with one of two stent techniques (Culotte vs DK-Culotte).

Materials and Methods

Study Population

The complete trial design, along with a full list of inclusion and exclusion criteria, was previously reported (the study was registered in ClinicalTrials.gov: NCT06284057).[18] In brief, the study population is constituted by all subjects included in the Lower Silesia Culotte Bifurcation Registry (LSCBR). This registry comprises clinical data from two cooperating high-volume cardiac centers of subjects with ACS who underwent percutaneous coronary intervention (PCI) of a culprit bifurcation lesion using two different two-stent techniques, the DK Culotte and the Culotte. The decision to perform PCI was based on clinical indications, in accordance with the European Society of Cardiology recommendations. The decision to perform PCI with the selected two-stent technique was left to the discretion of the operators. All PCI procedures were preformed with second-generation drug-eluting stents - Orsiro (Biotronik, Berlin, Germany), Xience (Abbott Chicago, USA), Onyx (Medtronic, Dublin, Republic of Ireland) Cruz (SMT, Mumbai, India) Biofreedom (Biosensor, Singapore), Synergy (Boston Scientific, Marlborough, USA). Prior to undergoing percutaneous coronary intervention (PCI), all patients were provided with comprehensive information regarding the procedure and its associated risks. This information was presented in a written consent form, which the patient was required to sign before the procedure could be performed. The Bioethics Committee of the Lower Silesian Medical Association (Poland), which oversees research centers in accordance with local legal restrictions, has approved this study (01/BO/2023). Furthermore, the study is in accordance with the Helsinki Declaration.

Study Endpoints

The study's main points and clinical outcomes were in line with general consensus[19] The study had composed of Primary Endpoint- Target Lesion Failure (TLF)), which consisted of cardiovascular death (CVD), target vessel myocardial infarction (TV-MI), or clinically driven target lesion revascularization (TLR). Furthermore, the study revealed the prevalence of several secondary endpoints, including major adverse cardiac events (MACE), which encompasses myocardial infarction, cardiac death, and target lesion revascularization (TLR), along with TLR, overall mortality, and selected procedural factors (radiation dose and contrast use).

Statistical Analysis

Continuous variables were evaluated using nonparametric two-sample Mann–Whitney *U*-tests, whereas categorical variables were analyzed using Fisher's exact tests. Kaplan-Meier curves were employed to illustrate the cumulative one-year rates of target lesion failure, major adverse cardiovascular events, all-cause death, and target lesion revascularization in the study groups. Log rank tests were used to assess the significance of the observed differences. The statistical cutoff point for significance was established at 0.05. The statistical analyses were conducted by an experienced medical statistician, who used the R programming language to perform analysis.

Results

Patient Characteristic

The Culotte cohort comprised 85 males and 37 females, thus the DK-Culotte arm consisted of 88 males and 29 females. With regard to the basic clinical characteristics of the Culotte cohort, a significantly lower mean age was observed in the male group compared to the female group (64.6 ± 8.7 vs 70.7 ± 8.7; p = 0.006). Furthermore, a lower prevalence of type 2 diabetes mellitus was observed in the male subjects compared to the female subjects (35 (41.2%) vs 23 (62.2%), p=0.048). Conversely, the initial creatinine levels were found to be significantly higher in the male subjects of this study arm compared to the female subjects (88.4 [75–102.5] vs 79.1 [63.6–90]; p=0.013). On the other hand, except for a similar trend in creatinine levels in the DK-Culotte group (83.2 [72.2–99.8] vs 73 [63.5–92.4]; p=0.033), no significant differences in terms of basic clinical features were observed. All basic clinical and demographic data are summarized in Table 1.

Lesions and Procedural Features

In terms of anatomical and procedural characteristics in the Culotte arm we could observe statistically lower anatomical complexity of CAD measured by Syntax I Score in the male cohort compared to females (15 [12–22] vs 18 [14–29]; p=0.046). At the same time in DK - Culotte group males compared to females were more prone to receive radial access point during index PCI (89.8% vs 69%; p=0.015). On the other hand, men in this arm received higher contrast (235.6 ± 75.4 vs 205.3 ± 63.5; p=0.039) and radiation doses (1950.5 [1324.2–3016.5] vs 1604 [693–2658]; p=0.027). Table 2 contains all lesions and procedural features.

Table 1 Baseline Clinical Characteristics of Both Study Arms

	Culotte Group			DK Culotte Group		
	Male N-85	**Female N-37**	***p*-value**	**Male N-88**	**Female N-29**	***p*-value**
Age [years]	64.6 ± 8.7	70.7 ± 8.7	*p* = 0.006	67.4 ± 9.0	65.4 ± 10.5	*p* = 0.377
Unstable angina	33 (38.8%)	10 (27%)	*p* = 0.010	43 (48.9%)	13 (44.8%)	*p* = 0.958
NSTEMI	31 (36.5%)	24 (64.9%)	*p* = 0.010	30 (34.1%)	11 (37.9%)	*p* = 0.958
STEMI	21 (24.7%)	3 (8.1%)	*p* = 0.010	15 (17%)	5 (17.2%)	*p* = 0.958
Diabetes mellitus type 2	35 (41.2%)	23 (62.2%)	*p* = 0.048	25 (28.4%)	11 (37.9%)	*p* = 0.359
Oral anti-diabetic treatment	30 (35.3%)	16 (43.2%)	*p* = 0.043	20 (22.7%)	11 (37.9%)	*p* = 0.117
Insulin	5 (5.9%)	7 (18.9%)	*p* = 0.043	5 (5.7%)	5 (17.2%)	*p* = 0.117
Hypertension	70 (82.4%)	33 (89.2%)	*p* = 0.423	70 (79.5%)	24 (82.8%)	*p* = 0.793
Hyperlipidemia	59 (69.4%)	32 (86.5%)	*p* = 0.069	75 (85.2%)	23 (79.3%)	*p* = 0.561
Atrial Fibrillation	19 (22.4%)	8 (21.6%)	*p* = 1	10 (11.4%)	3 (10.3%)	*p* = 1
Post PCI status	25 (29.4%)	17 (45.9%)	*p* = 0.098	28 (31.8%)	9 (31%)	*p* = 1
Primary Diagnosis of MI	19 (22.4%)	11 (29.7%)	*p* = 0.493	24 (27.3%)	10 (34.5%)	*p* = 0.485
LVEF	55 [43–60]	45 [35–60]	*p* = 0.193	58 [45–63]	55 [50–60]	*p* = 0.514
Total Cholesterol (mmol/L)	5 ± 1.6	4.8 ± 1.4	*p* = 0.579	4.7 ± 1.3	4.5 ± 0.9	*p* = 0.490
LDL (mmol/L)	2.5 [1.9–3.6]	2.8 [1.9–3.6]	*p* = 0.923	2.7 ± 1.2	2.6 ± 0.9	*p* = 0.573
HDL (mmol/L)	1.2 [1–1.5]	1.3 [1.1–1.6]	*p* = 1	1.2 [1–1.4]	1.3 [1.1–1.8]	*p* = 0.08
Creatine (µmol/l)	88.4 [75–102.5]	79.1 [63.6–90]	*p* =0.013	83.2 [72.2–99.8]	73 [63.5–92.4]	*p* = 0.033
Maximal TnI peak	186.1 [62–1359.5]	431 [108.8–1363.8]	*p* = 0.342	155.1 [33.2–1067.6]	354.1 [113.9–702.6]	*p* = 0.295

Abbreviations: NSTEMI, no ST-Elevation Myocardial Infarction; STEMI ST-Elevation Myocardial Infarction; PCI, percutaneous coronary intervention; MI, Myocardial Infarction; LVEF, Left ventricle ejection fraction.

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Table 2 Procedural Characteristics of Both Study Arms

Procedural Characteristic	Culotte Group			DK Culotte Group		
	Male N-85	Female N-37	*p*-value	Male N-88	Female N-29	*p*-value
SYNTAX Score I	15 [12–22]	18 [14–29]	p = 0.046	15.5 [11.8–22.2]	13 [9–16]	*p* = 0.107
Logistic SYNTAX Score	3.1 [1.4–9.6]	7.1 [3–23.2]	p = 0.004	2.9 [1.4–5.9]	2.9 [2.1–5.2]	*p* = 0.682
PCI SYNTAX Score II	31.3 ± 13	43.4 ± 14.5	p <0.001	28.5 [21.8–37.4]	33.1 [24.6–43.7]	*p* = 0.233
Bifurcation location: LM	29 (34.1%)	12 (32.4%)	*p* = 1	35 (39.8%)	12 (41.4%)	*p* = 1
Non-LM (LAD/D)	28 (32.9%)	15 (40.5%)	*p* = 0.419	32 (36.4%)	16 (55.2%)	*p* = 0.085
Non-LM (Cx/OM)	24 (28.2%)	7 (18.9%)	*p* = 0.367	16 (18.2%)	1 (3.4%)	*p* = 0.067
Non-LM (RCA/PLA/PDA)	4 (4.7%)	3 (8.1%)	*p* = 0.432	5 (5.7%)	0 (0%)	*p* = 0.331
Femoral access	10 (11.8%)	10 (27%)	*p* = 0.060	9 (10.2%)	9 (31%)	*p* = 0.015
Radial access	74 (87.1%)	28 (75.7%)	*p* = 0.182	79 (89.8%)	20 (69%)	*p* = 0.015
Bail out two stent strategy	7 (8.2%)	2 (5.4%)	*p* = 0.721	7 (8%)	2 (6.9%)	*p* = 1
Side branch stent diameter, mm	3 [2.5–3.5]	2.8 [2.5–3.5]	*p* = 0.173	3 [2.8–3.5]	2.8 [2.5–3]	*p* = 0.062
Side branch stent length, mm	22 [18–28]	22 [18–26]	*p* = 0.849	20 [18–26]	18 [18–22]	*p* = 0.303
Main branch stent diameter, mm	3.5 [3–3.5]	3 [3–3.5]	*p* = 0.232	3.5 [3–3.5]	3.5 [3–3.5]	*p* = 0.386
Main branch stent length, mm	26 [18–30]	26 [18–28]	*p* = 0.418	26 [18–34.2]	18 [18–26]	*p* = 0.006
Stent to the side branch first	72 (84.7%)	31 (83.8%)	*p* = 1	74 (84.1%)	25 (86.2%)	*p* = 1
Side branch predilatation	0 (0%)	0 (0%)	*p* = 1	88 (100%)	29 (100%)	*p* = 1
Main branch predilatation	75 (88.2%)	31 (83.8%)	*p* = 0.563	63 (71.6%)	22 (75.9%)	*p* = 0.811
Pre POT	38 (44.7%)	17 (45.9%)	*p* = 1	78 (88.6%)	27 (93.1%)	*p* = 0.727
KB after the first stent implantation	0 (0%)	0 (0%)	*p* = 1	88 (100%)	29 (100%)	*p* =1
KB after the second stent implantation	83 (97.6%)	36 (97.3%)	*p* = 1	88 (100%)	29 (100%)	*p* = 1
Final POT	70 (82.4%)	28 (75.7%)	*p* = 0.459	83 (94.3%)	28 (96.6%)	*p* = 1
IVUS/OCT imaging	6 (7.1%)	0 (0%)	*p* = 0.176	14 (15.9%)	3 (10.3%)	*p* = 0.558
Rotational Atherectomy	4 (4.7%)	2 (5.4%)	*p* = 1	3 (3.4%)	2 (6.9%)	*p* = 0.596
Intravascular lithotripsy	0 (0%)	1 (2.7%)	*p* = 0.303	2 (2.3%)	0 (0%)	*p* = 1
GP IIb/IIIa use	8 (9.4%)	3 (8.1%)	*p* = 1	2 (2.3%)	0 (0%)	*p* = 1
Radiation dose (mGy)	2212 [1459–3330]	1771 [1108–2752]	*p* = 0.061	1950.5 [1324.2–3016.5]	1604 [693–2658]	*p* = 0.027
Contrast media amount (mL)	240 [200–270]	220 [180–270]	*p* = 0.263	235.6 ± 75.4	205.3 ± 63.5	*p* = 0.039
ASA	85 (100%)	37 (100%)	*p* =1	88 (100%)	29 (100%)	*p* = 1
Clopidorel	55 (64.7%)	28 (75.7%)	*p* = 0.293	50 (56.8%)	18 (62.1%)	*p* = 0.669
Ticagrelor	29 (34.1%)	9 (24.3%)	*p* = 0.395	33 (37.5%)	10 (34.5%)	*p* = 0.827
Prasugrel	0 (0%)	0 (0%)	*p* = 1	4 (4.5%)	0 (0%)	*p* = 0.571

Abbreviations: LM, Left main; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; ASA, acetylsalicylic acid.

Clinical Outcome

The one-year study results revealed no statistically significant differences between the two sexes in the two primary study outcomes at the one-year follow-up and the index procedure. However, a noticeable unfavorable trend for female subjects in terms of higher rates of primary outcome was observed in both study groups (Culotte 16.2% vs 11.8%; p=0.481; DK-Culotte 10.3% vs 5.7%; p=0.401). It is also noteworthy that women in the DK-Culotte arm suffered from restenosis in the target lesion more often than men (10.3% vs 1.1%; p=0.018). Clinical outcomes were presented in Table 3. Moreover, Figure 1 (TLF) and Figure 2 (MACE) demonstrate Kaplan–Meier curves, indicating 12-month survival rates for both study cohorts, respectively.

The data presented in Table 4 indicates that there were no statistically significant differences between the female Culotte and DK Culotte arms in terms of TLF and MACE. However, the female Culotte group exhibited higher rates of target lesion failures and major adverse cardiac events (MACE) compared to the DK Culotte group (primary outcome: 16.2% vs 10.3%, p = 0.401; and principal secondary outcome: 24.3% vs 13.8%, p = 0.114). The 1-year Survival-Free Kaplan-Meier curves for both composite outcomes are presented in Figure 3.

Table 3 Clinical Outcomes in Both Study Arms

Clinical outcomes	Culotte Group			DK Culotte Group		
	Male N-85	Female N-37	*p*-value	Male N-88	Female N-29	*p*-value
1-Year Follow up						
Primary outcome: Target lesion failure (cardiac death, target vessel myocardial infarct, target lesion revascularisation)	10 (11.8%)	6 (16.2%)	*p* = 0.481	5 (5.7%)	3 (10.3%)	*p* = 0.401
Principal secondary outcome: MACE (myocardial infarct, cardiac death, target lesion revascularization)	15 (17.6%)	9 (24.3%)	*p* = 0.370	11 (12.5%)	4 (13.8%)	*p* = 0.771
Target lesion-revascularisation	8 (9.4%)	3 (8.1%)	*p* = 0.878	3 (3.4%)	3 (10.3%)	*p* = 0.149
All - cause mortality	4 (4.7%)	5 (13.5%)	*p* = 0.090	4 (4.5%)	2 (6.9%)	*p* = 0.632
Stent thrombosis	4 (4.7%)	1 (2.7%)	*p* = 0.620	3 (3.4%)	0 (0%)	*p* = 0.318
Stent restenosis	6 (7.1%)	2 (5.4%)	*p* = 0.792	1 (1.1%)	3 (10.3%)	*p* = 0.018

Abbreviation: MACE, major adverse cardiac events.

Discussion

To the best of our knowledge presented study is among the first to examine the effect of sex on the results of percutaneous coronary intervention (PCI) of bifurcation lesions treated with the novel two-stent technique – DK Culotte– in the ACS subset in routine clinical practice.

The study results demonstrated that there was no statistically significant difference between the two genders in terms of the one-year follow-up outcomes of the two investigated two-stent techniques. However, a trend towards a lower incidence of one-year TLF and MACEs was observed in male subjects when the two investigated bifurcation techniques were considered. Furthermore, a similar reduction in composite outcomes was observed in the DK culotte group compared with the classic culotte group in both genders, although this did not reach statistical significance.

There are well-established sex differences with respect to the pathophysiology, clinical presentation, and prognosis of CAD. Although women are less likely to have extensive CAD and more favorable plaque characteristics than men,[20,21] the long-term prognosis and outcomes of revascularization, particularly percutaneous, remain less favorable in females. Several factors have been postulated to be involved in phenomena. Females due to slower progression of CAD tend to be older and have more comorbid conditions at the time of initial diagnosis. Furthermore, the less typical clinical manifestations of the disease result in longer delays in diagnosis and treatment, particularly with regard to revascularization procedures in the acute subset.[22,23] The present study's findings offer partial confirmation of the hypothesis that the

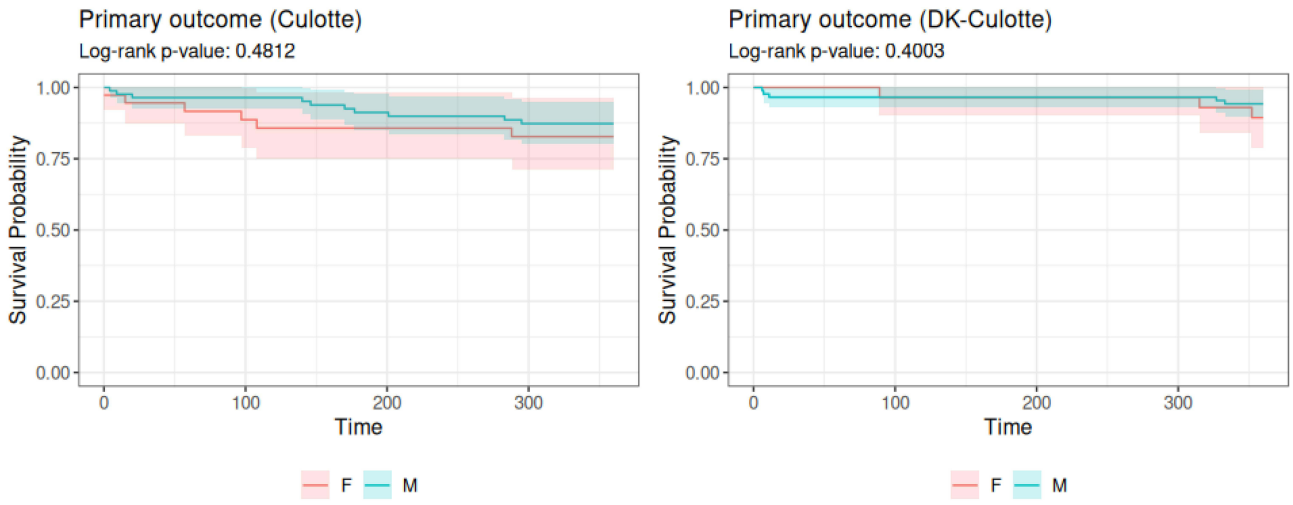

Figure 1 Target lesion failure 1-year Survival-Free Kaplan–Meier curves.
Abbreviations: F, Female; M, Male; DK, Double Kiss.

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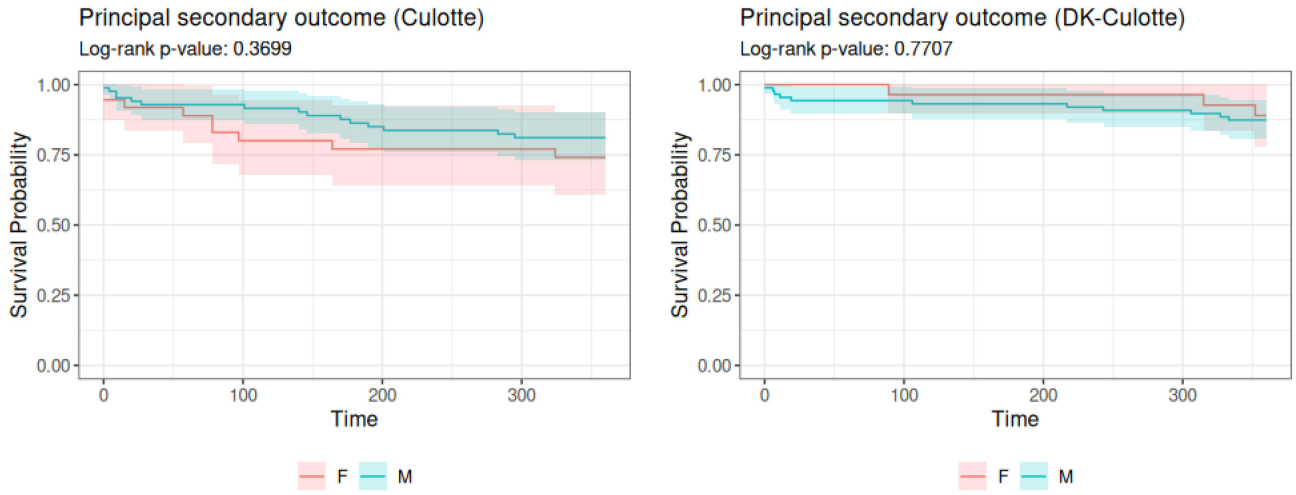

Figure 2 MACE 1-year Survival-Free Kaplan–Meier curves.
Abbreviations: F, Female; M Male.

female population who undergo PCI are generally of more advanced age. A statistically significant disparity in age between males and females was identified in the Culotte cohort, with the female population exhibiting a higher mean age than their male counterparts (70.7 ± 8.7 vs 64.6 ± 8.7; p = 0.006). Still, this observation was not confirmed in the DK-Culotte arm, and a reverse trend was observed, noteworthy without statistical significance. We can generally confirm the findings of previous studies regarding a higher burden of comorbidities at the time of hospital admission for primary PCI,[24,25] although women undergoing coronary intervention in our study cohort only had a statistically higher prevalence of diabetes mellitus (DM) type 2, still notable trend was observed for other cardiovascular risk factors.

Despite the underrepresentation of females in studies conducted so far, the available evidence suggests that the clinical outcomes following PCI are less favorable, particularly concerning an increased incidence of periprocedural complications, predominantly related to an elevated risk of bleeding,[5,26,27] yet outcomes are not focused on patients with bifurcation lesions.

Generally, it can be assumed that the technical and clinical complexities associated with bifurcation lesions have led to less favorable outcomes following PCI than those observed in non-bifurcation lesions. Furthermore, women with ACS are less likely to receive evidence-based therapies and undergo cardiac catheterization and complete revascularization.[28,29] Notwithstanding the fact that, in accordance with good clinical practice, all physicians involved in the therapeutic process in our study were encouraged to achieve complete revascularization, this aspect of CAD management was not addressed at the

Table 4 Clinical Outcomes in the Female Subgroup in Both Study Arms

Clinical outcomes	Culotte Female (n=37)	DK-Culotte Female (n=29)	*p*-value
1 Year Follow up			
Primary outcome: Target lesion failure (cardiac death, target vessel myocardial infarct, target lesion revascularisation)	6 (16.2%)	3 (10.3%)	*p* = 0.401
Principal secondary outcome: MACE (myocardial infarct, cardiac death, target lesion revascularization)	9 (24.3%)	4 (13.8%)	*p* = 0.114
Target lesion-revascularisation	3 (8.1%)	3 (10.3%)	*p* = 0.932
All - cause mortality	5 (13.5%)	2 (6.9%)	*p* = 0.343
Stent thrombosis	1 (2.7%)	0 (0%)	*p* = 0.341
Stent restenosis	2 (5.4%)	3 (10.3%)	*p* = 0.578

Abbreviation: MACE, major adverse cardiac events.

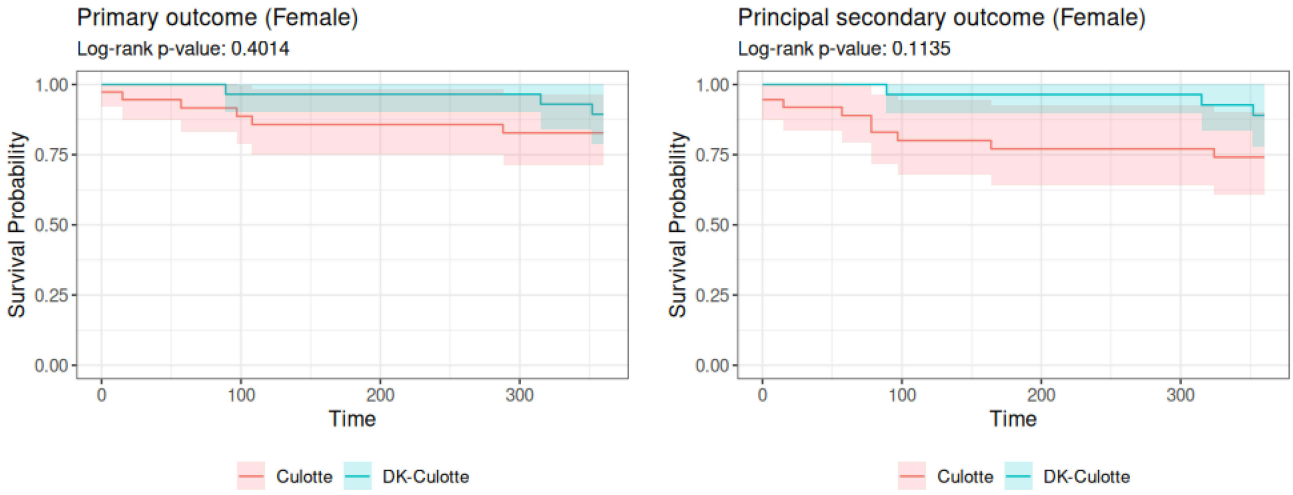

Figure 3 Females cohort 1-year Survival-Free Kaplan–Meier curves of Primary and Principal secondary Outcome.
Abbreviations: DK, Double Kiss.

time of discharge. This appears to be a significant study limitation, given the potential prognostic significance in terms of future unfavorable clinical outcomes.

Despite, data on potential sex differences between different two-stent bifurcation techniques are limited surprisingly the vast majority of available studies suggest no significant differences in clinical outcomes.[30–32] The results of the current study did not demonstrate significant disparities between males and females in the clinical outcomes of the investigated bifurcation stenting technique. However, the increased rate of composite unfavorable outcomes was notable and is partially consistent with the few studies published to date.[33,34] Surprisingly, despite the lower complexity of CAD progression as measured by the Syntax Score in our study cohort, we observed a trend towards a higher rate of stent thrombosis in men compared to women. Although this trend did not reach statistical significance, potential mechanisms underling under this observation remain unclear. In the present study, all subjects were treated with novel second-generation drug-eluting stents (DES). No significant differences were observed in terms of dual antiplatelet therapy (DAPT) agents between sexes still, females tend to more often receive clopidogrel instead of novel antiplatelet agents (ticagrelor/prasugrel). Furthermore, females tended to have a lower average stent diameter implanted in the main and side branches. In the theoretical domain, considering the fact that females tend to have lower compliance in terms of pharmacological treatment after PCI[35,36] this should result in a higher probability of thrombotic events in the female cohort. Surprisingly, the opposite relationship was observed in our study. It is even more confusing when we analyze the basic demographic characteristics between the study cohorts, women in both study arms had higher rates of diabetes, hypertension, and lower Left ventricular ejection fraction (LVEF). Conversely, no substantial disparities were observed between the sexes with regard to peak TnI levels. This marker has been documented as a well-established independent risk factor for future cardiovascular incidents.[37]

Although the above observation did not reach statistical significance, it was observed in both study arms (Culotte and DK-Cullote) and further large scale studies are needed to fully evaluate this issue.

It is interesting to note that, despite the growing body of evidence supporting the mandatory use of proximal optimalization technique (POT) and kissing balloons inflation (KBI) in terms of bifurcation lesions, the numbers reported for these two optimization techniques from everyday clinical practice still show utility of approximately 20–40% of all bifurcation PCI performed, with this figure rising to 60–70% in two-stent techniques.[30,38] In this context, data from our real-life cohort (POT: 76%-97%, final KBI: 97%-100%) demonstrates good compliance with the recommendations of the best medical practices, thereby confirming the high value of the preceding data and the relatively low prevalence of intravascular imaging in the study population.

Despite the fact that data focused on the impact of KBI on clinical outcomes might be inconsistent[39,40] Previous reports from bench tests[15,41] suggest a potential significant role for additional KBI during the performance of the classic

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Culotte technique. Nevertheless, the data from the study cohort did not confirm a significant impact on one-year outcomes. Nonetheless, a favorable trend has been observed in terms of the clinical outcomes of the 'Double Kiss-Culotte' technique in comparison to 'classical' Culotte techniques for both sexes. Furthermore, this observation has been already recently postulated.[16,18,42–44]

Limitations

This study has several limitations. Firstly, data were collected retrospectively with a relatively brief observation period (1-year follow-up). Secondly, the relatively small group size resulted in the underrepresentation of females in both study cohorts. Thirdly, prevalence of IVUS/OCT imaging use is low in the study cohort, and might have an impact on clinical outcomes. Although all operators were encouraged to achieve complete revascularisation, particularly concerning multi-vessel disease, no data were collected on residual syntax score at discharge. Finally, it should be noted that data from angiography had not been subject to external core lab evaluation, particularly in the case of quantitative coronary angiography.

Conclusion

The present study has revealed no significant differences in clinical outcomes between ganders in terms of percutaneous coronary intervention in bifurcation lesions in the ACS cohort after utilization of two different two-stent techniques (Culotte and DK Culotte). Still future randomized, large-scale studies are necessary to fully evaluate potential sex disappearance in clinical outcomes of both stenting techniques.

Data Sharing Statement

Deidentified data may be released to investigators whose proposed use of the data has been approved by an independent review committee appointed for this purpose. The data-sharing process should be conducted in line with local legal restrictions. The proposal should be submitted to the corresponding author.

Disclosure

Prof. Dr. Maciej Lesiak reports personal fees from Abbott Vascular, Boston Scientific, Medtronic, and Terumo Medical, outside the submitted work. The authors report no other conflicts of interest in this work.

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