Effect of paclitaxel-coated balloon angioplasty on side branch lesion and cardiovascular outcomes in patients with de novo true coronary bifurcation lesions undergoing percutaneous coronary intervention

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Abstract

Purpose

To compare the effects of paclitaxal-coated balloon (PCB) versus conventional balloon (CB) on side branch (SB) lesion and cardiovascular outcomes in patients with de novo true bifurcation lesions.

Methods

In total, 219 patients with de novo true bifurcation lesions were enrolled and divided into PCB group (102 cases) and CB group (117 cases) according to angioplasty strategy in SB. Drug-eluting stent (DES) was implanted in main vessel (MV) for each subject. All subjects underwent a 12-month follow-up for late lumen loss (LLL), restenosis and major adverse cardiovascular events (MACE) after percutaneous coronary intervention (PCI). MACEs included cardiac death, nonfatal myocardial infarction and angina pectoris.

Results

There were no differences in diameter, minimum lumen diameter (MLD) and stenosis for bifurcation lesions between the two groups before and immediately after PCI ($P > 0.05$). After 12-month follow-up, no differences occurred in MV-MLD and MV-LLL between the two groups ($P > 0.05$); SB-MLD in PCB group was higher than that in CB group (1.97 ± 0.36 mm vs. 1.80 ± 0.43 mm, $P = 0.007$); SB-LLL in PCB group was lower than that in CB group (0.11 ± 0.18 mm vs. 0.19 ± 0.25 mm, $P = 0.024$). Multivariate COX analyses indicated that PCB group had lower MACE risk than CB group (HR = 0.480, 95%CI 0.244–0.941, $P = 0.033$).

Conclusion

PCB could decrease SB-LLL and MACE risk in patients with de novo true coronary bifurcation lesion 12 months after single-DES intervention.

Introduction

Interventional therapy for coronary bifurcation diseases accounts for about 15%-20% of percutaneous coronary intervention (PCI) [1]. Coronary bifurcation lesions are complicated and diverse, difficult to intervene with high ischemic risk [2, 3]. In the drug-eluting stent (DES) era, although the single-stent intervention strategy can reduce the risks of main vessel (MV) restenosis and target vessel revascularization, late lumen loss (LLL) of side branch (SB) has not significantly relieved as expected [4, 5]. Therefore, the interventional treatment of bifurcation lesions is still full of challenges.

Drug-coated balloon (DCB) locally releases anti-cell proliferation drugs to lesion intima through delivery and dilation to inhibit restenosis [6]. In the era of stentless PCI, DCB could be considered as an interventional option for small-vessel lesion, in-stent restenosis (ISR), and bifurcation lesion [7]. However, few studies have been reported in de novo bifurcation lesion, especially lack of evidence for SB intervention based on the patients with true bifurcation lesions. Previous evidences showed that paclitaxel-coated balloons (PCB) significantly reduced ISR risk [8, 9]. Here, we hypothesize that PCB angioplasty may also decrease SB-LLL and the incidence of adverse cardiovascular events in the single-stent intervention strategy for bifurcation lesions. Therefore, this study aims to compare the effects of PCB versus conventional balloon (CB) on SB lesion and cardiovascular outcomes in patients with de novo true bifurcation lesions.

Methods

Study Design and Population

This was a retrospective cohort study, adhering to the Strengthening the Reporting of Observational Studies in Epidemiology statement. The study protocol complied with the Declaration of Helsinki and was approved by Xinqiao hospital ethics committee, Army Medical University (Chongqing, China).

We evaluated 413 patients with true bifurcation lesion undergoing PCI who admitted to cardiology department between September 2016 and March 2019 in our hospital. The inclusion criteria were as follows: (1) de novo bifurcation disease, lumen stenosis ≥50%; (2) age ≥18 years old; (3) true coronary bifurcation lesions (Medina classification 1.1.1, 1.0.1, 0.1.1); (4) second-generation drug-eluting stent (DES) into the main vessel (MV) and balloon angioplasty in side branch (SB); (5) residual stenosis <50% after pre-dilation. The exclusive criteria were as follows: (1) previous PCI; (2) previous coronary artery bypass grafting (CABG); (3) acute myocardial infarction; (4) stenting in SB; (5) contraindications for dual antiplatelet therapy; (6) malignant disease; (7) arterial dissection; (8) severe calcified lesions that cannot be successfully dilated; (9) primary kidney diseases (including primary nephritis syndrome, primary nephrotic syndrome, interstitial nephropathy and hereditary nephropathy), severe hepatic dysfunction, bleeding and coagulation diseases. In our hospital, CABG was the only way of revascularization for unprotected left main disease (UPLM), so UPLM and its bifurcation were included in CABG. Finally, a cohort of 219 patients was enrolled in this study. According to balloon angioplasty strategy in SB, the subjects were divided into conventional balloon (CB) group (117 cases) and paclitaxel-coated balloon (PCB) group (102 cases).

PCI Procedure

Everolimus-coated DES (Promus Premier, Boston Scientific, Marlborough, USA) was implanted in MV. CB (Quantum Maverick, Boston Scientific, Marlborough, USA) or PCB (SeQuent Please, Braun Melsungen, Berlin, Germany) was used for SB angioplasty. Hydrophilic coating and lipophilic paclitaxel were evenly distributed on the balloon surface that made paclitaxel easier to penetrate from balloon surface to vascular intima [10]. After pre-dilation for MV and SB, if no dissection or type A/B dissection existed in SB

and residual stenosis of SB was less than 30% with TIMI grade 3 blood flow; DES was firstly implanted into MV with guide wire or balloon for SB protection; guide wire passed the stent mesh to exchange; then balloon was utilized to dilate the ostial lesion and SB, respectively; the standard balloon to artery ratio (0.8-1: 1) was mandated in procedure. If pre-dilation was not successfully (C-F type dissection or TIMI grade 0 or 1 blood flow in SB), double-stent interventional strategy was directly performed (Culotte or Crush could be considered by means of the characteristics of bifurcation lesion).

Definition

Coronary bifurcation disease was the lesion with severe stenosis in the MV and SB, respectively or together [11]. True bifurcation lesions referred to the ones in which both the MV and SB were affected and corresponded to Medina classification 1.1.1, 1.0.1, and 0.1.1 [12]. Medina classification was based on the order of the proximal/distal MV and SB, and was displayed as with (1) or without (0) lesion [13]. Unprotected left main was defined as the absence of protective vessels that no collateral circulation was established or no CABG grafts [14]. Restenosis was defined as diameter stenosis ≥50% at follow-up. Late lumen loss (LLL) referred to the difference in MLD between stenting and follow-up [15]. Acute myocardial infarction refer to the fourth universal definition, when troponin value exceeds the 99th percentile upper reference limit and combines at least one of following characteristics: (1) symptoms of myocardial ischemia; (2) new changes in ischemic electrocardiogram or emerging pathological Q waves; (3) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality [16]. Angina pectoris was defined as ischemic chest pain that drived readmission, based on symptom, electrocardiogram characteristics and troponin.

Data Collection and Follow-up

Clinical data were collected from medical records by trained physicians including demographic data, medical history, laboratory indicators and essential drug therapy. Coronary angiography data were independently assessed by two interventional cardiologists including bifurcation site, Medina classification, diameters, minimum lumen diameter (MLD) and lumen stenosis, and the two interventional cardiologists were blind as to treatment. All angiography was performed under the same standard conditions, and quantitative coronary analysis (QCA) was performed using the QAngio XA system version 7.3.74.0 (Medis Medical Imaging Systems, Leiden, Nertherlands) [17].

Primary outcomes and bifurcation lesions were included in the follow-up process. Primary outcomes were major adverse cardiovascular events (MACE) defined as the composite of cardiac death, nonfatal myocardial infarction and angina pectoris. Reassessment of bifurcation lesions involved MLD, LLL and restenosis for MV and SB, respectively. All patients had a 12-month follow-up for angiography and cardiovascular events after PCI, and related data were obtained from hospital records and by interviewing patients and their families.

Statistical Analysis

PASS software version 11.0 was used to calculate power and determined the sample size based on previous studies and our estimates [18, 19]. Calculation formula for sample size as follow: **see formula 1 in the supplementary files.**

Finally, each group needed 98 cases at least.

SPSS software version 24.0 (SPSS, Inc, Chicago, Illinois) was utilized for statistical analyses. Continuous variables were expressed as mean ± SD and categorical variables were expressed as frequencies with percentages. The *t* test was used to compare continuous data and differences in categorical data were assessed by the Chi-squared test or Fisher exact test (two-sided). Cox regression analyses were performed to evaluate the association of PCB angioplasty with SB restenosis and MACE. Multivariate Cox models were adjusted for established cardiovascular risk factors (age, male, hypertension, diabetes, smoking, hyperlipidemia, bifurcation site and Medina classification). P values of less than 0.05 were considered statistically significant.

Results

Characteristics of Study Population

A total of 219 patients with de novo true coronary bifurcation lesions were involved in this study including 117cases in CB group and 102 cases in PCB group, and no patients were lost to follow-up. No adverse cardiovascular events occurred during PCI procedure such as malignant arrhythmia, cardiac death, salvage PCI and acute CABG. Blood flow immediately after PCI was TIMI grade 3. No differences appeared in clinical characteristics between the two groups (P>0.05) (Table 1). There were no significant differences in diameter, MLD and stenosis between the two groups before and immediately after PCI (P>0.05) (Table 1). In this study, PCB group had more left main bifurcation lesions (58.82% vs. 39.32%) and more Medina 1.1.1 lesions (26.47% vs. 17.95%) compared with CB group (Table 1).

Reassessment of Bifurcation Lesions

All patients underwent coronary angiography review at 12-month follow-up after PCI to assess the severity of coronary bifurcation lesions. At the follow-up point, there was no significant differences in MV-MLD and MV-LLL between the two groups (P>0.05); SB-MLD in PCB group was higher than that in CB group (1.97±0.36 mm vs. 1.80±0.43 mm, P=0.007); SB-LLL in PCB group was lower than that in CB group (0.11±0.18 mm vs. 0.19±0.25 mm, P=0.024) (Table 2).

Clinical Outcomes

Cox proportional risk regression model was performed to evaluate the association of PCB angioplasty with MACE and component events. PCB group had 5 cases (4.90%) in SB restenosis and 13 cases (12.75%) in MACE; while CB group had 9 cases (7.69%) in SB restenosis and 28 cases (23.93%) in MACE. There was no significant difference in restenosis (HR=0.620, 95%CI 0.208-1.850, P=0.383) between the two groups, but PCB group had lower MACE risk than CB group (HR=0.489, 95%CI 0.253-0.945, P=0.028).

After adjustment for possible compounding factors (including clinical parameters and bifurcation characteristics), multivariate analyses indicated that PCB group still had lower MACE risk than CB group (HR=0.480, 95%CI 0.244-0.941, P=0.033), the increased MACE risk was mainly attributed to more angina in CB group (HR=0.515, 95%CI 0.247-1.076, P=0.078) (Table 3).

Discussion

PCI for coronary bifurcation lesions was challenging. Compared with simple lesions, bifurcation lesions had more severe plaque burden and was more vulnerable to erosion and rupture [20]. Even if PCI procedure was gradually improving, displacement of crest and plaque, plaque rupture, and SB ostium elastic retraction still often occurred during PCI for bifurcation lesions [21]. In single-stent intervention, even if "wire jailed" or "balloon jailed" was utilized, severe stenosis or occlusion of SB often occurred and the risk of long-term restenosis was still high [22]. In double-stent strategy, there were still also many shortcomings such as complicated procedure, long duration and high radiation exposure; furthermore multiple stent trabeculars and polymers mediated intimal proliferation and delayed endothelialization, thereby increasing the risks of in-stent restenosis (ISR) and delayed stent thrombosis that required longer dual antiplatelet therapy and brought higher bleeding risk and financial burden to patients [23].

Stenting in MV combined with angioplasty for SB was a common interventional procedure for bifurcation lesions, but long-term follow-up showed that severe stenosis tended to occur in SB [24]. DK-CRUSH study demonstrated that stenting in MV combined with angioplasty for SB or stenting in SB could not prevent long-term restenosis in SB [25]. DCB released cytotoxic agent to inhibit intimal proliferation, thus alleviating restenosis. Lots of evidences indicated that DCB could replace DES for ISR treatment and similar findings had also been reported in the intervention of de novo lesions [26]. However, few studies had explored DCB intervention, especially PCB intervention, on de novo true bifurcation lesions. Current evidence still mainly focused on the effect of DCB intervention on de novo lesions and its ISR.

In bifurcation studies, Lee *et al*. [27] reported 114 patients with ISR of LM bifurcation lesions were assigned to DES group and DCB group according to SB intervention strategy; the one-year follow-up results showed that DCB group had lower cardiogenic mortality than DES group (0% vs. 10.7%). Harada *et al.* [28] investigated the effects of different PCBs on ISR of bifurcation lesions, and the results showed no significant difference. Most DCB-related studies based on bifurcation lesions had small sample sizes and no adequate control group. In de novo lesion studies, DEBSIDE study and PEPCAD V study showed DCB safe and effective for de novo bifurcation lesions, and the risks of ISR and target lesion revascularization decreased significantly [29, 30]. However, considering no CB control group in the above studies, the external validity of the results was low and required for further verification. The DEBIUT study compared the effects of DCB + bare metal stent (BMS), CB + BMS, and CB + DES on the cardiovascular outcomes in patients with bifurcation lesions. The results indicated that DCB+BMS group did not exceed the other two groups in the risks of SB restenosis and MACE [31]. BABILON study also explored the effects of DCB+BMS versus CB+DES on the prognosis of de novo bifurcation lesions, and it found that no significant difference occurred between the two groups in SB-LLL [32]. Although both DEBIUT study and

BABILON study revealed that DCB was not superior to CB for de novo bifurcation lesions; BMS was implanted in MV for DCB group while DES was implanted in MV for control group in both studies. As known, since BMS could not effectively reduce the risks of long-term restenosis and MACE compared with DES, such grouping might offset the potential benefits of DCB.

Our study compared the effects of PCB+DES versus CB+DES on the efficacy for de novo true bifurcation lesions. The results indicated that PCB increased SB-MLD, deceased SB-LLL and the incidence of MACE significantly after 12-month follow-up compared with CB. Although statistical analysis revealed no difference between the two groups in risk of restenosis, given short follow-up period and high standard definition of restenosis, the results were still interpretable and were required to be fully verified in the future. The effect of PCB on reducing MACE risk could be attributed to the following points: (1) PCB effectively lowered SB-LLL to ameliorate myocardial perfusion, thereby decreased the risk of angina or ischemia-driven revascularization [33]. (2) Through balloon carrier, paclitaxel exerted anti-cell proliferation effect to strongly inhibit the occlusion of SB ostium, thus avoiding SB loss [34]. (3) Successful pretreatment for target lesion before PCB angioplasty could help improve blood perfusion [35]. Our study still had several limitations. Firstly, this was a single center study with potential bias. Secondly, our sample size was small and follow-up duration was short. Thirdly, PCI was not completed by the same interventional cardiologist for each subject. In view of the complexity of bifurcation lesions and the difficulty of intervention, PCI procedure might affect cardiovascular outcomes. Finally, our study population was of Chinese origin.

Conclusion

Our study revealed that PCB could decrease SB-LLL and MACE risk in patients with de novo true coronary bifurcation lesions 12 months after single-DES intervention. For true bifurcation lesions, after sufficient pre-dilation, PCB angioplasty in SB combined with DES stenting in MV can effectively reduce the cardiovascular events, which can be performed as reliable option for intervention. Given the limitations of current study, further multicenter, large-scale, long follow-up duration studies are required to validate the implication of these results.

Declarations

Author Contributions

Qi Mao contributed to the study conception and design. Youmei Li and Huanyun Liu analyzed the patient data regarding coronary angiograph. Data collection was performed by Denglu Zhou and Jianhua Zhao. The first draft of this manuscript was written by Youmei Li and Qi Mao. All authors commented previous versions of the manuscript. All authors read and approved the final manuscript.

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Compliance with Ethical Standards

Conflicts of Interest

The authors have no conflicts of interest to declare.

Ethics Approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institution (ethics committee of Xinqiao hospital, Chongqing). Informed consent was obtained from all individual participants of this study.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

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Tables

Table 1 Baseline characteristics

N=219	CB group (n=117)	PCB group (n=102)	*P* value
Clinical parameters			
Age, years	63±10	64±11	0.530
Male, n(%)	95(81.2)	82(80.4)	0.880
Diabetes, n(%)	32(27.4)	33(32.4)	0.419
Hypertension, n(%)	65(55.6)	52(51.0)	0.498
Hyperlipidemia, n(%)	28(23.9)	24(23.5)	0.944
Smoking, n(%)	63(53.9)	58(56.9)	0.654
ACEI/ARB, n(%)	74(63.3)	66(64.7)	0.823
β–blocker, n(%)	84(71.8)	70(68.6)	0.609
Statins, n(%)	115(98.3)	100(98.0)	0.890
P2Y12 antagonist, n(%)	117(100.0)	102(100.0)	1.000
Aspirin, n(%)	117(100.0)	102(100.0)	1.000
Bifurcation site			
LM/LAD/LCX	46(39.3)	60(58.8)	0.004
LAD/Diagonal	61(52.1)	37(36.3)	0.019
LCX/OM	10(8.6)	5(4.9)	0.287
Medina classification			0.030
1.1.1	21(18.0)	27(26.5)	
1.0.1	86(73.5)	58(56.9)	
0.1.1	10(8.6)	17(16.7)	
Pre-procedure			
Main vessel diameter (mm)	3.01±0.35	2.96±0.43	0.297
Main vessel MLD (mm)	0.98±0.38	0.93±0.38	0.298
Main vessel stenosis (%)	67.66±11.80	68.80±11.34	0.470
Side branch diameter (mm)	2.47±0.38	2.52±0.35	0.296
Side branch MLD (mm)	0.59±0.33	0.62±0.33	0.474
Side branch stenosis (%)	75.95±13.17	75.37±12.38	0.737
Post-procedure			
Main vessel MLD (mm)	2.51±0.32	2.46±0.39	0.408
Main vessel stenosis (%)	16.70±4.58	16.53±5.16	0.802
Side branch MLD (mm)	1.98±0.32	2.06±0.33	0.079
Side branch stenosis (%)	20.05±5.13	18.59±6.16	0.057

Data are expressed as the mean±SD or n (%). ACEI: angiotensin converting enzyme inhibitor; ARB: angiotensin receptor blocker; LM: left main; LAD: left anterior descending; LCX: left circumflex; OM: obtuse marginal; MLD: minimum lumen diameter.

Table 2 Procedure characteristics after the 12-month follow-up

N=219	CB group (n=117)	PCB group (n=102)	*P* value
Main vessel MLD (mm)	2.37±0.34	2.35±0.46	0.805
Main vessel LLL (mm)	0.13±0.14	0.12±0.14	0.443
Side branch MLD (mm)	1.8±0.43	1.97±0.36	0.007
Side branch LLL (mm)	0.19±0.25	0.11±0.18	0.024

Data are expressed as the mean±SD. MLD: minimum lumen diameter; LLL: late lumen loss.

Table 3 Cardiovascular outcomes during the 12-month follow-up

	CB group	PCB group	HR(95% CI)	*P* value	Adjusted HR(95% CI)	*P* value
Restenosis, n(%)	9(7.7)	5(4.9)	0.620(0.208-1.850)	0.383	0.536(0.176-1.634)	0.273
MACE, n(%)	28(23.9)	13(12.8)	0.489(0.253-0.945)	0.028	0.480(0.244-0.941)	0.033
Angina pectoris, n(%)	23(19.7)	11(10.8)	0.515(0.251-1.057)	0.062	0.515(0.247-1.076)	0.078
Nonfatal MI, n(%)	7(6.0)	3(2.9)	0.485(0.126-1.877)	0.283	0.453(0.111-1.849)	0.270
Cardiac death, n(%)	1(0.9)	1(1.0)	1.142(0.071-18.260)	0.925	1.089(0.065-18.219)	0.953

Results are expressed as n (%); MACE: major adverse cardiovascular events; MI: myocardial infarction.

Figures

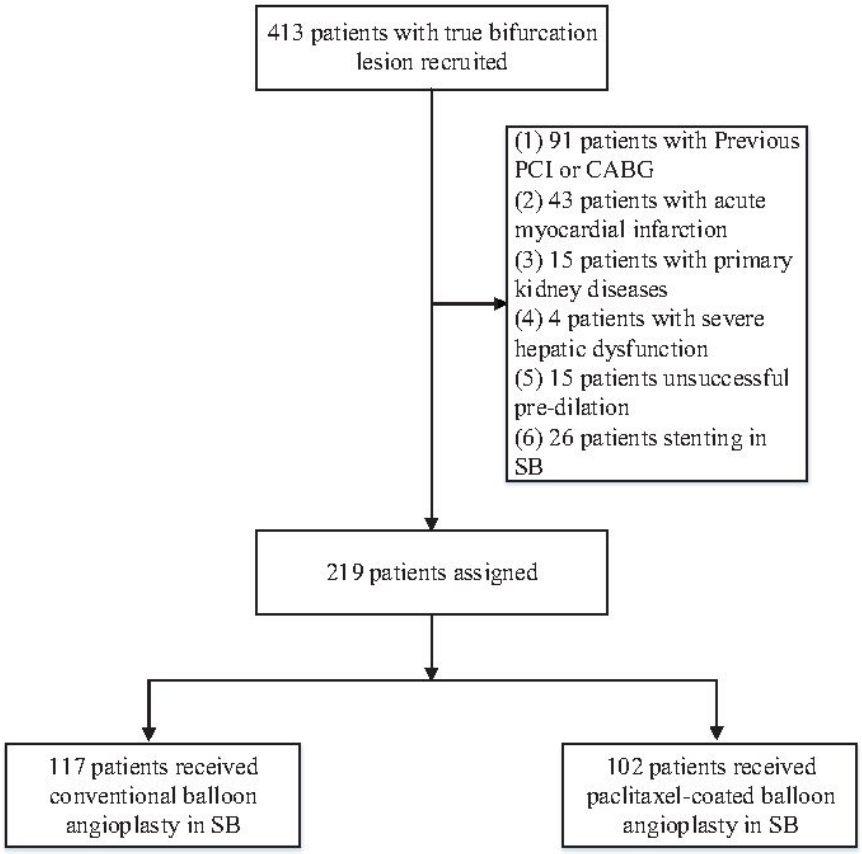

Figure 1

Flow chart

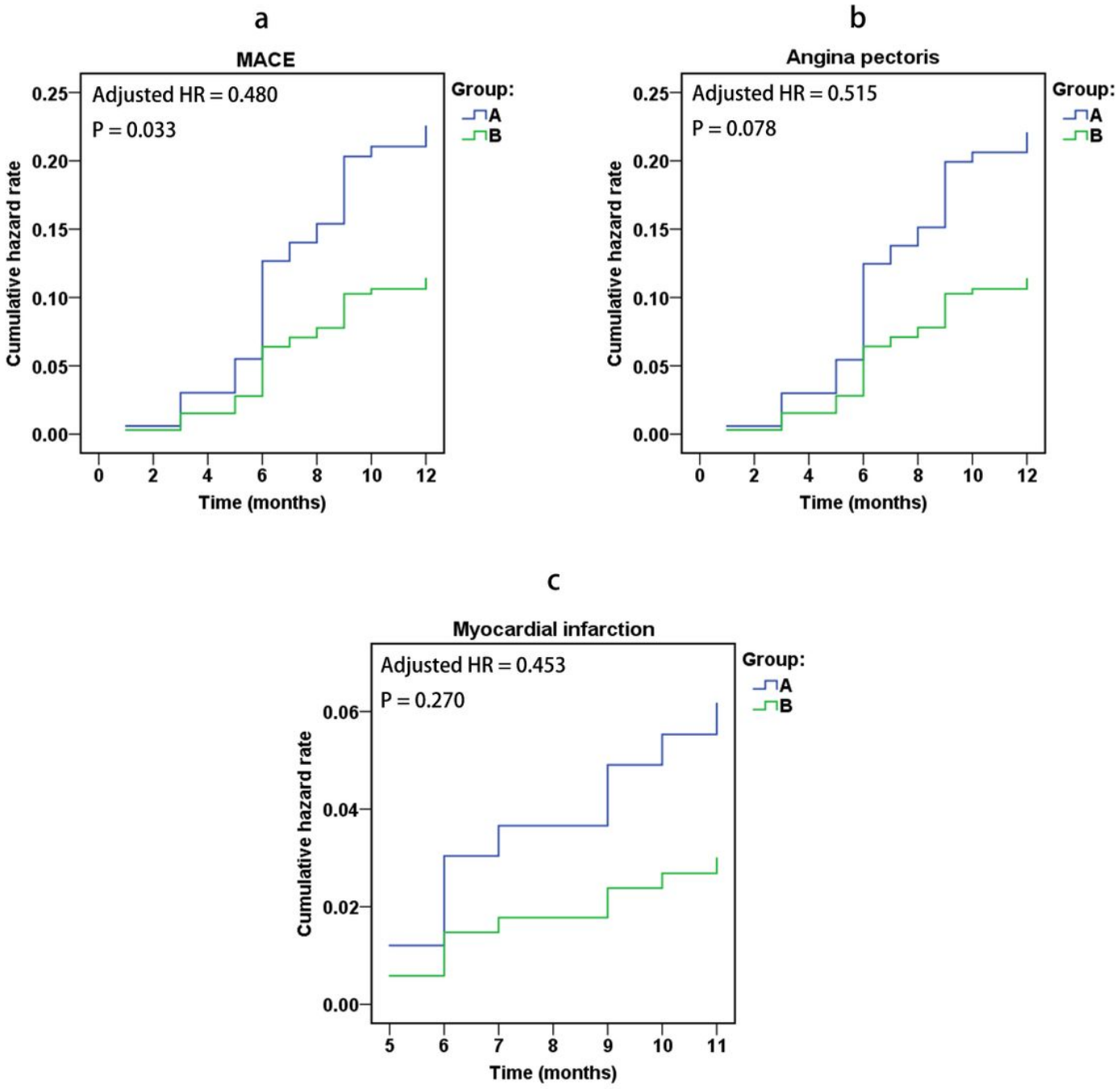

Figure 2

Cumulative risk of cardiovascular events in patients with de novo true bifurcation lesion undergoing PCI
Group A: CB group; Group B: PCB group

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- formula.docx