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Original Research Article

Combined use of drug-coated balloon (DCB) and cutting balloon angioplasty (CBA) in the treatment of acute coronary syndrome

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Abstract

Purpose: *To determine the effectiveness and safety of combined use of drug-coated balloon (DCB) and cutting balloon angioplasty (CBA) in patients with acute coronary syndrome (ACS).*
Methods: *One hundred and fifty-six patients with ACS undergoing DCB or CBA from January 2019 to January 2021 served as subjects in this study. There were 30 in-stent re-stenosis (ISR) patients in group A, 31 ISR patients in group B, 61 de novo patients in group C, and 34 de novo patients in group D. Baseline characteristics, high-risk factors, biochemical indices, incidence of intervention-related complications, and major adverse cardiovascular events (MACE) were compared amongst the groups, before and after operation.*
Results: *Group B had a higher immediate minimum lumen diameter (MLD) after operation than group A, and group D had higher immediate MLD after operation than group C. Group B produced higher acute gain after intervention than group A, but post-intervention acute gain was greater in group D than in group C. There were significant differences in late luminal loss (LLL) amongst the groups (p = 0.013), but LLL was comparable in groups A and B (p = 0.411), and in groups C and D (p = 0.434). During the follow-up period, the incidence of MACE in group A was significantly greater than in group B, but MACE in group C was comparable to that in group D.*
Conclusion: *Combined treatment with CBA and DCB significantly improves postoperative immediate MLD and acute gain after intervention in patients with ISR lesions or de novo lesions, without reducing long-term effectiveness and safety. Multi-center trials involving larger number of patients will be required to validate the results from this study.*

Keywords: *Drug-coated balloon, Cutting balloon angioplasty, In-stent restenosis, de novo lesion, Clinical outcome*

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INTRODUCTION

Coronary heart disease (CHD) is associated with high morbidity and mortality, and it is the leading cause of death worldwide [1]. Percutaneous coronary intervention (PCI) has become an important strategy for the treatment of ACS [2]. Minimum lumen diameter (MLD) usually increases remarkably after PCI, but decreases during follow-up, leading to late lumen loss (LLL) mainly due to vascular elastic retraction and intimal hyperplasia [3]. In-stent restenosis (ISR) is the main cause of stent failure after PCI. Research has found that the incidence of ISR after bare metal stent implantation is about 16 - 44 %, while that after drug-eluting stent (DES) implantation is about 5 – 15 % [4-7]. Drug-coated balloon (DCB) is a novel strategy for the treatment of ACS [8], and it represents an effective treatment for patients with re-stenosis after stent implantation [9-12]. Cutting balloon angioplasty (CBA) enables uniform tearing of atherosclerotic plaques, thereby reducing the occurrence of acute vascular occlusion and reducing mortality [13]. A retrospective study demonstrated that CBA applied after rotational resection of moderately-to-severely calcified lesions resulted in good lumen gain, and reduced the risk of ISR [14].

However, only a few clinical studies have compared the efficacy of DCB alone versus combined use of DCB and CBA in the treatment of ACS. This research evaluated the effect of the combination of DCB and CBA on ACS patients (ISR and *de novo* lesions).

METHODS

Study population and ethical considerations

This study involved 156 patients with ACS (ISR and *de novo*) who were treated with DCB or CBA at Tianjin Medical University Clinical Cardiovascular Institute from January 2019 to 2021. The study received approval from the Ethics Committee of Tianjin Medical University (approval no. PJ-KS-KY-2022-299), and it met the criteria in the Declaration of Helsinki [15]. The subjects were divided into four groups: 30 ISR patients with DCB treatment (group A), 31 ISR patients with DCB + CBA treatment (group B), 61 patients with *de novo* lesions treated only with DCB (group C), and 34 patients with *de novo* lesions treated with DCB + CBA (group D).

Exclusion criteria

Patients in the following categories were excluded: those aged below 18 or over 80 years; women planning to have children within 1 year; patients with contraindications to surgery; those with intraoperative cardiac arrest or cardiogenic shock; patients unable to receive dual antiplatelet therapy; those whose conditions were complicated with malignant tumors, and patients with severe dysfunction of important organs.

Study design and treatments

All patients received oral dose of clopidogrel (300 mg) or ticagrelor (180 mg) 24 h before operation. During operation, intravenous injection of unfractionated heparin was used for anticoagulation. After operation, all patients were given standard double antiplatelet therapy, namely 100 mg of aspirin in combination with 75 mg of clopidogrel, once a day for 1 year. The femoral artery was cannulated according to standard methods. It was pre-dilatated using a plain balloon or CBA (Boston Scientific Corporation, USA), and then implanted with a DCB (paclitaxel-coated balloon; B. Braun, Berlin, Germany).

Follow-up

Patients were followed up via telephone and outpatient service for at least 1 year. All patients were encouraged to undergo coronary angiography (CAG) at 6 and/or 12 months after operation, to measure the degree of stenosis and reference diameter.

Study end-points

The main end points were major adverse cardiovascular events (MACE) and all-cause death.

Baseline indicators

Baseline data of patients were collected after admission. The data comprised sex, age, BMI, smoking history, history of myocardial infarction, diabetes, hyperlipidemia and hypertension, and history of coronary artery bypass grafting (CABG). After complete examination, the levels of fasting blood glucose, glycosylated hemoglobin (HbA1c), total cholesterol (TC), triglyceride (TG), low density lipoprotein (LDL), high density lipoprotein (HDL), serum creatinine, high sensitivity C-reactive protein (CRP), B-type brain natriuretic peptide (BNP), left ventricular ejection fraction (LVEF) and vascular lesions were recorded. The MLD- and PCI-related complications (coronary artery rupture, dissection, pericardial effusion and myocardial infarction) were recorded after operation.

Statistical analysis

The SPSS version 22 software was used for statistical processing of data. Categorical data are presented as numbers and percentages, and Chi-squared test was employed for comparison of baseline characteristics and clinical characteristics amongst the groups. Continuous variables are expressed as mean ± standard deviation (SD). Paired *t*-test was used for comparison between preoperative and postoperative data. Two-group comparison was done with unpaired *t*-test, while one-way ANOVA was used for multi-group comparisons. Values of $p < 0.05$ indicated statistical differences.

RESULTS

Baseline profile of patients

Table 1 shows that in group A, 30 patients (86.67 %) aged 65.67 ± 7.83 years, were males. In group B, 31 patients (90.32 %) with mean age of 64.74 ± 9.79 years, were males. In group C, 30 subjects (68.85 %) with mean age of 62.47 ± 14.62 years, were males. There were 30 male subjects (76.47 %) in D, with mean age of 59.58 ± 13.44 years. There was no significant difference in baseline characteristics (age, sex and BMI); high risk factors (previous smoking history, myocardial infarction history, CABG history, diabetes history, hyperlipidemia history, and hypertension history); blood glucose, blood lipid, serum creatinine, CRP, BNP and LVEF, among all the groups of patients ($p > 0.05$).

Coronary angiography in patients

Table 2 shows that ACS types were comparable amongst the four groups ($p = 0.079$). The main locations of diseased vessels were right coronary artery (RCA), left circumflex branch (LCX) and left anterior descending branch (LAD). The locations of vessel lesions were comparable in the four groups ($p = 0.622$). The number and length of lesioned vessels were comparable in all groups. Length of diseased vessels was comparable in groups A and B (15.76 ± 6.39 mm vs 17.26 ± 6.97 mm, $p = 0.215$), and in C and D (14.19 ± 5.06 mm vs 13.41 ± 5.40 mm, $p = 0.484$). In addition, in groups A -D, the length, diameter, filling pressure and dilation time of DCB used during operation were similar.

Table 1: Comparison of patients' baseline data

Parameter	Group A	Group B	Group C	Group D	*P*-value
N	30	31	61	34	
Age (years)	65.67±7.83	64.74±9.79	62.47±14.62	59.58±13.44	0.271
Male (n (%))	26 (86.67)	28 (90.32)	42 (68.85)	26 (76.47)	0.067
BMI (kg/m^2)	25.42±3.68	26.22±4.03	25.93±4.15	26.41±3.88	0.536
Smoking history (n (%))	11 (36.67)	15 (48.39)	25 (40.98)	14 (41.18)	0.377
MI history (n (%))	15 (50.00)	14 (45.16)	24 (39.34)	7 (20.59)	0.076
CABG history (n (%))	2 (6.67)	2 (6.45)	0 (0.00)	0 (0.00)	0.094
Diabetes history (n (%))	12 (40.00)	12 (38.71)	28 (45.90)	13 (38.24)	0.907
Hyperlipidemia history (n (%))	3 (10.00)	1 (3.23)	6 (9.84)	4 (11.76)	0.205
Hypertension history (n (%))	20 (66.67)	23 (74.19)	44 (72.13)	23 (67.65)	0.112
Fasting blood glucose (mmol/L)	6.35±1.83	6.02±2.06	7.11±2.77	6.34±1.78	0.149
HbA1c (%)	0.07±0.01	0.06±0.02	0.07±0.02	0.06±0.01	0.976
TC (mmol/L)	4.33±1.48	3.76±0.73	4.35±1.10	4.34±1.33	0.119
TG (mmol/L)	1.72±0.81	1.46±0.63	2.14±1.43	2.17±1.61	0.056
LDL (mg/dL)	2.50±1.16	2.23±0.53	2.46±0.73	2.47±0.93	0.725
HDL (mg/dL)	0.94±0.21	1.00±0.25	1.03±0.57	0.84±0.13	0.234
Creatinine (umol/L)	77.38±26.47	124.85±167.05	113.71±172.34	72.46±23.40	0.429
High sensitivity CRP (mg/L)	3.68±7.45	7.44±13.11	4.14±8.53	2.74±3.39	0.346
BNP (ng/L)	146.67±239.14	210.53±723.88	175.08±287.65	188.21±529.01	0.959
LVEF (%)	54.32±7.93	55.34±5.71	53.11±7.68	57.05±3.06	0.124

LVEF: left ventricular ejection fraction; BMI: body mass index; MI: myocardial infarction; CABG: coronary artery bypass grafting; HbA1c: glycosylated hemoglobin; TC: total cholesterol; TG: triglyceride; LDL: low density lipoprotein; HDL: high density lipoprotein; BNP: B-type brain natriuretic peptide

Table 2: Coronary angiography results in the four groups

Parameter	A	B	C	D	*P*-value
N	30	31	61	34	
Type of ACS					0.079
UA (n (%))	22 (73.33)	22 (70.97)	30 (49.18)	18 (52.94)	
NSTEMI (n (%))	7 (23.33)	8 (25.81)	22 (36.07)	14 (41.18)	
STEMI (n (%))	1 (3.33)	1 (3.22)	9 (14.75)	2 (5.88)	
Location of diseased vessels					0.622
RCA (n (%))	12 (40.00)	13 (41.94)	18 (29.51)	8 (23.53)	
LCX (n (%))	8 (26.67)	5 (16.12)	28 (45.90)	15 (44.12)	
LAD (n (%))	10 (33.33)	13 (41.94)	15 (24.59)	11 (32.35)	
Number of diseased vessels					0.519
(n (%))	12 (40.00)	12 (38.71)	28 (45.90)	18 (52.94)	
(n (%))	10 (33.33)	11 (35.48)	25 (40.98)	12 (35.29)	
(n (%))	8 (26.67)	8 (25.81)	8 (13.11)	4 (11.76)	
Length of diseased vessels (mm)	15.76±6.39	17.26±6.97	14.19±5.06	13.41±5.40	0.048
Length of DCB (mm)	28.18±8.96	31.17±7.39	27.62±7.22	26.87±7.49	0.144
Diameter of DCB (mm)	2.98±0.43	3.28±0.44	3.16±0.49	3.09±0.51	0.083
Filling pressure of DCB (atm)	9.57±0.64	11.46±0.83	10.47±0.76	9.11±0.52	0.105
Dilation time of DCB (sec)	39.55±11.38	44.28±13.64	41.65±12.84	38.42±11.45	0.091

UA: unstable angina; NSTEMI: non-ST segment elevation myocardial infarction; STEMI:ST segment elevation myocardial infarction; RCA: right coronary artery; LCX: left circumflex branch; LAD: left anterior descending branch; DCB: drug-coated balloon

Table 3: Angiographic follow-up results in the four groups

Parameter	A	B	C	D	*P*-value
N	30	31	61	34	
Pre-PCI MLD (mm)	0.37±0.33	0.50±0.42	0.36±0.34	0.40±0.30	0.343
Post-PCI MLD (mm)	2.61±0.61	2.87±0.34*	2.21±0.47	2.52±0.56$^{\#}$	0.000
MLD during follow-up (mm)	2.48±0.49	2.79±0.31*	2.09±0.29	2.45±0.45$^{\#}$	0.006
acute gain after PCI (mm)	2.23±0.48	2.35±0.49*	1.86±0.42	2.11±0.51$^{\#}$	0.001
LLL (mm)	0.12±0.18	0.09±0.09	0.11±0.20	0.08±0.13	0.013
PCI-related complications	1 (3.33)	0 (0.00)	1 (1.64)	0 (0.00)	0.648

MLD: minimum lumen diameter; LLL: late luminal loss

Angiographic follow-up results

As shown in Table 3, the pre-PCI MLD values of groups A, B, C and D were 0.37 ± 0.33 mm, 0.50 ± 0.42 mm, 0.36 ± 0.34 mm and 0.40 ± 0.30 mm, respectively (no significant differences were seen amongst groups (p = 0.343)). The post-PCI MLD of group B was larger than that of group A (2.87 ± 0.34 mm vs. 2.61 ± 0.61 mm, p = 0.013). The post-PCI MLD of group D was larger than that of group C (2.52 ± 0.56 mm vs 2.21 ± 0.47 mm, p = 0.008). Post-PCI acute gain was higher in group B than in group A (2.35 ± 0.49 mm vs 2.23 ± 0.48 mm, p = 0.026), and it was higher in group D than in group C (2.11 ± 0.51 mm vs 1.86 ± 0.42 mm, p = 0.011). There was no significant difference amongst the different groups (A vs. B, p = 0.411; C vs. D, p = 0.434). Only one patient in each group (A and C) had pericardial effusion.

Clinical follow-up outcomes

During the one-year follow-up period, the patients with non-fatal myocardial infarction in groups A, B, C and D were 2 (6.67 %), 0 (0 %), 1 (1.64 %) and 0 (0 %), respectively. Non-fatal myocardial infarction rate was comparable amongst the four groups (p = 0.224). There were 6 cases (20.00 %), 2 cases (6.45 %), 3 cases (4.92 %) and 1 case (2.94 %) of TVR in groups A, B, C and D, respectively (p = 0.042). Thus, TVR was comparable in the different groups (A vs. B, p = 0.117, C vs. D, p = 0.0646). During the follow-up period, there was 26.67 % occurrence of MACE in group A. This was noticeably greater than the corresponding incidence in group B (6.45 %, p = 0.033, p = 0.449).

Table 4: Comparison of clinical follow-up results in the four groups

Parameter	A	B	C	D	*P*-value
N	30	31	61	34	
Non-fatal MI (n (%))	2 (6.67)	0 (0)	1 (1.64)	0 (0)	0.224
TVR (n (%))	6 (20.00)	2 (6.45)	3 (4.92)	1 (2.94)	0.042
MACE (n (%))	8 (26.67)	2 (6.45)*	4 (6.25)	1 (2.94)	0.005
Angina-related hospitalization (n (%))	4 (13.33)	2 (6.45)	4 (6.56)	2 (5.88)	0.548
Heart failure-related hospitalization (n (%))	0 (0)	1 (3.23)	0 (0)	0 (0)	0.528
Non-target vascular reconstruction (n (%))	1 (3.33)	0 (0)	1 (1.64)	0 (0)	0.648
All-cause death (n (%))	0 (0)	0 (0)	1 (1.64)	1 (2.94)	0.518

MI: myocardial infarction; TVR: target vascular revascularization; MACE: major adverse cardiovascular events

In contrast, MACE occurrence was comparable in groups C and D (6.25 vs 2.94 %). There were no significant differences in angina-related hospitalization rate, heart failure-related hospitalization rate, non-target vascular reconstruction and all-cause death among the four groups (p = 0.548, 0.528, 0.648, 0.518), as shown in Table 4.

DISCUSSION

Drug-coated balloon (DCB) was loaded with an anti-proliferative drug (paclitaxel). Paclitaxel is quickly absorbed by the vascular intima when the balloon is inflated against the vessel wall, thereby effectively blocking early cell proliferation and inhibiting coronary restenosis. Moreover, DCB inhibits the migration of smooth muscle cells and attenuates the proliferative inflammatory response in the intima, thereby significantly reducing LLL [16]. Currently, DCB, a new choice for the treatment of coronary ISR, may compensate for many disadvantages of DES. Numerous clinical studies have confirmed that DCB plays a role in reducing ISR [17,18].

However, there are also some problems with DCB, such as the possibility of acute vessel occlusion, as well as dissection and vessel rupture caused by excessive dilation [19]. The CBA reduces vessel dissection and rupture by slowly and evenly cutting the intima longitudinally, rather than causing uncontrolled destruction of atherosclerotic plaques [20]. Studies have shown that immediate post-PCI MLD is closely linked to the incidence of ISR after stent implantation [21]. Pre-dilation of the target vessels by CBA increases the lumen diameter, thereby improving the efficacy of ISR treatment by DCB. In addition, CBA dilates blood vessels with less tension, a situation which may reduce vascular proliferative response and neointimal hyperplasia, resulting in reduction in occurrence of ISR [22]. Extant investigations have shown that pretreatment of coronary lesions with CBA reduced TLR and ISR [23]. However, few clinical studies have compared the clinical effect of combined use of DCB with CBA versus DCB alone in the treatment of ISR. In addition, there is a paucity of comparative data on treatment of *de novo* lesions with DCB alone versus combined use of DCB and CBA.

In this study, the types of coronary heart disease were UA, NSTEMI and STEMI, and the main sites of diseased vessels were RCA, LCX and LAD. The incidence of poly-vascular disease was high in each group. Peng *et al* have shown that, compared with patients with ISR lesions treated with DCB alone, the MLD in the CBA+DCB group was larger [24]. We found that for patients with both ISR and *de novo*, the immediate post-PCI MLD and acute gain after PCI were greater in the DCB+CBA group than in DCB-alone group, revealing that the use of CBA may effectively improve the benefits of DCB in patients with ISR and *de novo* stenosis. Interestingly, the combined use of DCB and CBA still showed a good therapeutic effect in patients with *de novo* stenosis. There were significant differences in LLL among the four groups, but the LLL of patients treated with DCB alone was similar to that of those treated with DCB in combination with CBA, indicating that the use of CBA did not reduce the long-term effect on patients. The reason for this may be that CBA pretreatment increased the acute benefit of lumen diameter before DCB implantation, while a little intimal rupture caused by CBA enhanced drug transport between intima and media, and increased the uptake of antiproliferative drugs in the vascular wall, thereby improving the efficacy of DCB [25].

At the same time, we observed that one patient each in groups A and C had pericardial effusion, but there was no significant difference in PCI-related complications among the four groups, indicating that the application of CBA did not cause additional intervention-related complications, and also showing that DCB in

combination with CBA treatment was safe. The incidences of TVR, angina-related hospitalization, non-fatal myocardial infarction, heart failure-related hospitalization, non-target vascular reconstruction and all-cause death, were similar in DCB+CBA group and DCB group. These results suggest that CBA did not increase the incidence of TVR, heart failure-related hospitalization, and all-cause death in ISR and *de novo* lesion patients. This is consistent with the finding in a previous study [24]. However, the incidence of MACE was lower in ISR patients given DCB plus CBA treatment during follow-up. For patients with *de novo* lesions, the incidence of MACE during follow-up was similar, regardless of whether or not CBA was used. The reason for this may be that the pretreatment of ISR with cutting balloon reduced the occurrence of severe dissection, rupture and elastic retraction of blood vessels, thereby decreasing the long-term re-stenosis rate of target lesions [24].

Limitations of this study

Potential bias may exist considering the apparently small number of ACS patients that were observed.

CONCLUSION

This study demonstrates that the combined use of DCB and CBA for re-stenosis and *de novo* lesions significantly improves the immediate post-PCI MLD and acute gain after PCI, without reducing long-term outcomes and safety. Multi-center trials involving a larger number of patients should be conducted to validate the results obtained from this study.

DECLARATIONS

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Ethical approval

None provided.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

No conflict of interest associated with this work.

Contribution of Authors

We declare that this work was done by the authors named in this article, and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. Yuguo Liu, Ning Yang and Yuming Li conceived and designed the study, and drafted the manuscript. Lei Guo, Ji Zhao, Shaoke Meng, Bo Zhang and Hao Zhu collected, analyzed and interpreted the experimental data. Ning Yang and Yuming Li revised the manuscript for important intellectual contents. All authors read and approved the final manuscript.

REFERENCES

1. *Moreira PVL, de Arruda Neta A, Ferreira SS, Ferreira F, de Lima R, de Toledo Vianna RP, de Araujo JM, de Alencar Rodrigues RE, da Silva Neto JM, et al. Coronary heart disease and stroke mortality trends in Brazil 2000-2018. PloS One 2021; 16: e0253639.*
2. *Hirlekar G, Libungan B, Karlsson T, Back M, Herlitz J, Albertsson P. Percutaneous coronary intervention in the very elderly with NSTE-ACS: the randomized 80+ study. Scand Cardiovasc J 2020; 54: 315-321.*
3. *Okada K, Honda Y, Kitahara H, Ikutomi M, Kameda R, Brooke Hollak M, Yock PG, Popma JJ, Kusano H, Cheong WF, et al. Scaffold under expansion and late lumen loss after bioresorbable scaffold implantation: Insights from ABSORB JAPAN trial. Int J Cardiol Heart Vasc 2020; 31: 100623.*
4. *Jia B, Zhang X, Ma N, Mo D, Gao F, Sun X, Song L, Liu L, Deng Y, Xu X, et al. Comparison of drug-eluting stent with bare-metal stent in patients with symptomatic high-grade intracranial atherosclerotic stenosis: a randomized clinical trial. JAMA Neurol 2022; 79: 176-184.*
5. *Ahmed W, Shah MA, Thaver AM, Mirza J. Drug-eluting balloon (DEB) for de-novo coronary artery disease and in-stent restenosis: immediate and intermediate term*

results from a prospective registry. J Pak Med Assoc 2011; 61: 157-160.

6. *Paramasivam G, Devasia T, Ubaid S, Shetty A, Nayak K, Pai U, Rao MS. In-stent restenosis of drug-eluting stents: clinical presentation and outcomes in a real-world scenario. Egypt Heart J 2019; 71: 28.*
7. *Zhang Y, Zhang X, Dong Q, Chen D, Xu Y, Jiang J. Duration of dual antiplatelet therapy after implantation of drug-coated balloon. Front Cardiovasc Med 2021; 8: 762391.*
8. *Corballis NH, Wickramarachchi U, Vassiliou VS, Eccleshall SC. Duration of dual antiplatelet therapy in elective drug-coated balloon angioplasty. Catheter Cardiovasc Interv 2020; 96: 1016-1020.*
9. *Bausback Y, Wittig T, Schmidt A, Zeller T, Bosiers M, Peeters P, Brucks S, Lottes AE, Scheinert D, Steiner S. Drug-eluting stent versus drug-coated balloon revascularization in patients with femoropopliteal arterial disease. J Am Coll Cardiol 2019; 73: 667-679.*
10. *Scheller B, Ohlow MA, Ewen S, Kische S, Rudolph TK, Clever YP, Wagner A, Richter S, El-Garhy M, Bohm M, et al. Bare metal or drug-eluting stent versus drug-coated balloon in non-ST-elevation myocardial infarction: the randomised PEPCAD NSTEMI trial. EuroIntervention 2020; 15: 1527-1533.*
11. *Fanelli F, Cannavale A, Citone M, Santoni M, Gazzetti M, Falcone GM, Miele V. Provisional stenting using the zilver PTX drug-eluting stent after drug-coated balloon angioplasty: initial experience from the double drug dose "3D" study. J Endovasc Ther 2020; 27: 34-41.*
12. *Tepe G, Laird J, Schneider P, Brodmann M, Krishnan P, Micari A, Metzger C, Scheinert D, Zeller T, Cohen DJ, et al. Drug-coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and popliteal peripheral artery disease: 12-month results from the IN. PACT SFA randomized trial. Circulation 2015; 131: 495-502.*
13. *Lee MS, Singh V, Nero TJ, Wilentz JR. Cutting balloon angioplasty. J Invasive Cardiol 2002; 14: 552-556.*
14. *Kong J, Hou J, Ma L, Xing L, Jia H, Liu H, Zhang S, Yu B, Jang IK. Cutting balloon combined with paclitaxel-eluting balloon for treatment of in-stent restenosis. Arch Cardiovasc Dis 2013; 106: 79-85.*
15. *World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013; 310(20): 2191-2194.*
16. *Jackson D, Tong D, Layland J. A review of the coronary applications of the drug-coated balloon. Int J Cardiol 2017; 226: 77-86.*
17. *Hu P, Sun Y, Li CL, Jin R, Xie Q, Jiang XJ, Wu LP, Jiang JJ, Qiu XB, Cao Y, et al. A randomized comparison of two paclitaxel-coated balloons for the treatment of in-stent restenosis: The LONGTY ISR China randomized trial (LONGTY DCB vs. SeQuent Please DCB). Catheter Cardiovasc Interv 2021; 97 Suppl 2: 988-995.*
18. *Ullrich H, Olschewski M, Munzel T, Gori T. Coronary in-stent restenosis: predictors and treatment. Dtsch Arztebl Int 2021; 118: 637-644.*
19. *Sauguet A, Philippart R, Honton B. Directional atherectomy with antirestenotic therapy for the treatment of no-stenting zones. J Cardiovasc Surg (Torino) 2019; 60: 198-204.*
20. *Han B, Aboud M, Nahir M, Noem F, Hasin Y. Cutting balloons versus conventional long balloons for PCI of long coronary lesions. Int J Cardiovasc Intervent 2005; 7: 29-35.*
21. *Sato T, Tsuchida K, Yuasa S, Taya Y, Koshikawa T, Tanaka K, Fujita S, Ikeda Y, Takahashi M, Okabe M, et al. The effect of the debulking by excimer laser coronary angioplasty on long-term outcome compared with drug-coating balloon: insights from optical frequency domain imaging analysis. Lasers Med Sci 2020; 35: 403-412.*
22. *Park SJ, Kim KH, Oh IY, Shin DH, Park KI, Seo MK, Chung JW, Park KW, Lee HY, Kang HJ, et al. Comparison of plain balloon and cutting balloon angioplasty for the treatment of restenosis with drug-eluting stents vs bare metal stents. Circ J 2010; 74: 1837-1845.*
23. *Bague N, Nasr B, Chaillou P, Costargent A, Gouailler-Vulcain F, Goueffic Y. The role for DCBs in the treatment of ISR. J Cardiovasc Surg (Torino) 2016; 57: 578-585.*
24. *Zheng YC, Lee WC, Fang HY, Chen CJ, Yang CH, Wu CJ, Fang CY. Cutting balloon combined with drug-coated balloon angioplasty for the treatment of in-stent restenosis. Int Heart J 2021; 62: 1213-1220.*
25. *Tan Z, Chan S, Da Zhuang K, Urlings T, Leong S, Chua JME, Patel A, Irani FG, Chandramohan S, Tay KH, et al. Recurrent stenoses in arteriovenous fistula (AVF) for dialysis access: cutting balloon angioplasty combined with paclitaxel drug-coated balloon angioplasty, an observational study (Institution Study). Cardiovasc Intervent Radiol 2022; 45: 646-653.*