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Comparison between paclitaxel-coated balloon and standard uncoated balloon in the treatment of femoropopliteal long lesions in diabetics

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Abstract

Atherosclerotic diseases may include femoropopliteal artery stenosis or occlusion. Percutaneous transluminal angioplasty (PTA) is an effective and minimally invasive treatment strategy for atherosclerotic femoropopliteal artery stenosis/occlusion disease. Balloon angioplasty is a widely used technique in the management of occlusive disease in almost all arterial segments.

We enrolled 111 diabetics with long femoropopliteal lesions, among which 54 received PTA with paclitaxel-coated balloon (the Paclitaxel group), and 57 with standard balloon catheters (the Control group).

The primary outcome was set as angiographic late lumen loss (LLL) within 6 months; the secondary angiographic outcome was binary restenosis. Clinical outcomes included Rutherford clarification, ankle-brachial index (ABI) and rate of clinically driven target lesion revascularization (TLR). Two groups had similar basal clinical features, angiographic and procedural characteristics. Compared to controls, the Paclitaxel group had a significantly lower 6-month LLL rate, 12-month binary restenosis rate, 12-month TLR, lower Rutherford grades at 3 and 6 months, and higher ABI at 3 months. For all factors which might influence outcomes, fasting blood glucose was negatively correlated with ABI; the blood urea nitrogen (BUN) was positively related with the Rutherford clarification grades. In addition, the coronary heart disease (CHD) and smoking histories were positively correlated with residual stenosis after treatment.

Collectively, the paclitaxel-coated balloon angioplasty can yield more favorable angiographic and clinical outcomes than standard uncoated balloon angioplasty, even in the more challenging lesions (the long and occlusive femoropopliteal lesions) in diabetics, when it had a similar safety profile to the traditional balloon. Blood glucose, BUN, CHD, and smoking imply poor curative effects.

Abbreviations: ABI = ankle-brachial index, BMI = body mass index, BUN = blood urea nitrogen, CHD = coronary heart disease, HBP = high blood pressure, LLL = late lumen loss, MLD = minimal luminal diameter, PTA = percutaneous transluminal angioplasty, TLR = target lesion revascularization.

Keywords: diabetes, drug-coated balloon, paclitaxel-coated balloon, percutaneous transluminal angioplasty

1. Introduction

Atherosclerotic diseases may include femoropopliteal artery stenosis or occlusion.[1,2] Percutaneous transluminal angioplasty (PTA) is an effective and minimally invasive treatment strategy for atherosclerotic femoropopliteal artery stenosis/occlusion disease.[3–5] Balloon angioplasty is a widely used technique in the management of occlusive disease in almost all arterial segments.[5,6] However, current results are not fully satisfactory. Some patients may suffer from ruptured angioplasty balloon,[5] some need further balloon-expandable stent,[6] and the overall rate of restenosis/re-occlusion was high. Nearly all interventional endovascular methods were believed to cause vessel injury and consequently result in neointimal proliferation, and restenosis/re-occlusion are frequently observed soon after treatment. Generally, restenosis/re-occlusion are caused by chronic inflammatory reactions and neointimal hyperplasia.[7] To avoid inflammatory and neointimal proliferation, the strategy of drug-coated balloons was recently proposed and has shown promising utility for patients with peripheral artery diseases.[8,9] To this end, multicenter, randomized controlled and patient blinded clinical trials have reported favorable outcomes after use of drug-coated balloons in the treatment of short and long femoropopliteal lesions.[10] An important trial AcoArt I was carried out in 2016,

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Acotec I trial was the first randomized, prospective, multicenter, double blinded clinical trial in China (NCT01850056).

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which involved majorly the Chinese patient cohort.[11] Given paclitaxel has an effect of inhibiting the proliferation of smooth muscle cells, this trail used paclitaxel to coat the balloon, and found that paclitaxel-coated balloon catheters markedly improved angiographic and clinical outcomes of interventions for long superficial femoral artery lesions. We believe that paclitaxel-coated balloon can yield superior efficacy and similar safety compared to normal balloon in PTA of long femoropopliteal lesions, and the present post-hoc analysis focuses on more dimensions, especially the efficacy and safety of the coated balloon, to explore the prospect of paclitaxel-coated balloon in clinical application as an upgrade of femoropopliteal artery stenosis/occlusion treatment.

2. Materials and methods

2.1. Patients

The present study was approved by the Chinese PLA General Hospital Ethics Committee and the local ethics committees of participating hospitals. Patients were enrolled and given a written informed consent. All the patients enrolled were diagnosed with diabetes. Similar to Guo et al,[11] the inclusion and exclusion criteria were as follow.

Inclusion criteria:

1. patients showed significant claudication, rest pain, or ischemic lesions (Rutherford stages 2–5);
2. those exhibited severe stenoses or total occlusion in the superficial femoral/popliteal artery.

Exclusion criteria:

1. significant renal insufficiency (creatine level $>150\,\mu mol/l$);
2. acute thrombosis;
3. complete lack of runoff vessels;
4. serious safety issues (such as pregnancy or lactation, life expectancy <2 years);
5. known to have an allergy to paclitaxel, clopidogrel, aspirin or vehicles.

Patients were randomly divided to either study group. The Control group received Admiral Xtreme peripheral balloon catheter (Medtronic, Minneapolis, Minnesota) treatment, and the Paclitaxel group received Orchid paclitaxel ($3\,mg/mm^2$)-coated peripheral balloon catheter (Acotec Scientific, Beijing, China) treatment with magnesium stearate as carrier.

2.2. Treatments

Antiplatelet therapy (75 mg/day clopidogrel and 100 mg/day aspirin) was given 3 days before intervention. Besides, heparin (0.5–0.6 mg/kg, an additional half dose after 2 h.) was administrated during intervention. Except for catheters with different coated balloons, each treatment was basically identical in both groups. For all patients, the lesion was recommended pre-dilation with uncoated balloon catheters (not mandatory). The length of the balloon was set sufficient to cover at least 1 cm distal and proximal to the lesion. If the lesion plus 2 cm surpassed the balloon length, an overlap of 1 cm between balloon-treated segments was recommended during 30 to 60 seconds of the inflation time. In case of an unsatisfactory primary result or flow-limiting dissection, a post-dilation and implantation of self-expanding stents were performed. Angiograms of the treated segment were captured before and after treatment, and we documented at least 2 orthogonal-view radiographs of the inflated balloons.

After surgery, each patient received a post-procedural treatment (aspirin and clopidogrel for 6 months). Routine examinations were performed before discharge. Clinical data and parameters about the efficacy were collected at the following time points: before the intervention, the date discharge from the hospital, 12 weeks, 6 months and 12 months after treatment. Especially, the following clinical data were collected for analysis: Body Mass Index (BMI), fasting blood glucose, blood urea nitrogen (BUN), coronary heart disease (CHD) history, high blood pressure (HBP) history, hyperlipidemia history, etc.

2.3. Endpoints

The primary endpoint was achieved when

1. late lumen loss (LLL) was significantly noticed in the treated segment, or
2. at the time of clinically driven target lesion revascularization (TLR).

LLL was defined as the difference between the minimal luminal diameter (MLD) soon after the procedure and at 6-month time point. The angiographic parameters, including the primary efficacy endpoint, were evaluated by the quantitative angiography center at the Chinese PLA General Hospital Vascular Center, which was blinded to the treatment program. The QVA system (Pie Medical Imaging, Maastricht, the Netherlands) was used for measurement.

The secondary efficacy endpoints included angiographic indicators of lesion restenosis based on MLD and clinical indicators such as clinically driven TLR, changes in Rutherford classification and ankle-brachial index (ABI), and major amputation of the treated leg.

Restenosis was identified as Doppler ultrasound peak systolic velocity ratio ≤ 2.4. For post-hoc analysis, the following parameters were documented: angiographic outcome, binary restenosis, the Rutherford classification, ABI, and rate of clinically driven TLR.

2.4. Statistical analysis

For all continuous variables, data were expressed as mean $\pm$ SD and compared using Student t test. Categorical variables were expressed as frequencies or percentages and compared using Fisher exact test between groups. In case of data not normally distributed, Wilcoxon rank test was used for comparison. The correlation between 2 factors was investigated using Pearson correlation or linear correlation analysis. A P value of less than .05 was considered statistically significant.

3. Results

Overall, we enrolled 111 diabetics (54 in the Paclitaxel group and 57 in the Control group) between April 2013 and June 2014 at 10 clinical sites. The basal clinical features and procedural summary were listed in Tables 1 and 2. No significant differences were observed in all indexes between groups. More than 40% lesions were large than 150 cm in diameter, and about half cases had occlusion lesions. For all patients, the balloon diameters ranged from 3 to 6 m. The length of the uncoated Admiral balloons ranged from 20 to 150 mm, and that of the Paclitaxel coated Orchid balloons ranged from 40 to 300 mm. After surgery, we noticed no serious adverse events, and the device success rate in each group was 100%. In the course of surgery, stents were

Table 1

Clinical features of 2 groups.

	Paclitaxel (n = 54)	Control (n = 57)
Sex (Male/Female)	33/21	42/15
Age	66.70 ± 9.04	66.51 ± 8.40
BMI	24.48 ± 2.9	23.82 ± 2.8
History		
CHD	14 (26%)	9 (33%)
HBP	37 (69%)	44 (77%)
hyperlipidemia	14 (26%)	21 (37%)
Smoking	43 (80%)	41 (72%)
Lesion		
length	153.3 ± 15.5	142.87 ± 15.8
≥15cm	22 (41%)	24 (42%)
Occlusion	27 (50%)	26 (46%)
Rutherford Classification		
2	8 (15%)	6 (11%)
3	20 (37%)	23 (40%)
4	13 (24%)	15 (26%)
5	13 (24%)	13 (23%)

Data are presented as mean ± SD or n (%). $P > .05$ for all features.
CHD = coronary heart disease, HBP = high blood pressure.

Table 2

Procedural summary of 2 groups.

	Paclitaxel (n = 54)	Control (n = 57)
Crossover access	46 (85%)	42 (74%)
Lesions/devices	54/110	57/61
Pre-dilation	54 (100%)	45 (79%)
Pre-dilation balloon diameter	3.6 ± 0.66	3.5 ± 0.54
Dilation balloon diameter	4.7 ± 0.63	4.5 ± 0.58
Dilation time	151.7 ± 51.6	151.6 ± 47.2
Dilation pressure	8.8 ± 1.7	9.2 ± 2.4
Flow limiting dissection	8 (15%)	13 (23%)
Residual stenosis	20 (37%)	24 (42%)
30%–50%	13	15
50%–70%	3	7
>70%	4	2
Stenting	11 (20%)	13 (23%)
Balloon/vessel ratio	1.012	1.035
Device success	54 (100%)	57 (100%)

implanted for 20% patients in the Paclitaxel group and 23% in the Control group, respectively, according to specific conditions.

During the 6- and 12-month follow-up, 2 patients in the Control group failed in data collection for they did not accept angiography, and 1 patient in Paclitaxel group was lost follow up. The outcomes of diabetics with long lesions were presented in Table 3. The parameter LLL in the Paclitaxel group was highly significantly lower compared to controls at 6 months ($P < .01$). In addition, the Paclitaxel group had consistently lower TLR after 6, 12, and 24 months. The frequency of binary restenosis was similar after 6 months, but significantly lower in the Paclitaxel group at month 12 and 24 ($P < .01$ and .05, respectively). In the mass, the Paclitaxel-coated balloon treated patients exhibited significantly lower degree of restenosis ($P < .01$). In addition, Rutherford classification and ABI were shown in Figure 1A and B. Paclitaxel-coated balloons significantly down-regulated the Rutherford classification at 3 and 6 months. The parameter ABI was much higher at 3 months in the Paclitaxel group ($P < .01$). The primary patency at 12- and 24-month follow-up was 93% vs 63%, and 85% vs 63%, respectively (Paclitaxel vs Control) from the angioplasty. Moreover, there were 21 cases in control group receiving re-intervention; 2 of them received twice in 12 months, and 4 of them had suffered twice TLR in the 24-month follow-up.

Table 3

Outcomes at the lesion level.

	Paclitaxel	Control	*P* value
MLD post procedure	2.4 ± 0.51	2.3 ± 0.57	.5
LLL (6 m)	0.14 ± 0.85	1.13 ± 0.93	<.01
Binary restenosis (6 m)	48 (89%)	51 (93%)	>.05
Degree of restenosis	40.7 ± 20%	63.1 ± 21%	<.01
TLR (6 m)	4 (4/53 = 7%)	21 (21/55 = 37%)	<.01
Binary restenosis (12 m)	13 (13/47 = 28%)	33 (33/51 = 65%)	<.01
TLR (12 m)	4 (7%)	21 (37%)	<.01
Binary restenosis (24 m)	22 (22/44 = 50%)	36 (36/49 = 73%)	.05
TLR (24 m)	8 (15%)	21 (37%)	<.01

Data are presented as mean ± SD or n (%).
MLD = minimal luminal diameter, TLR = target lesion revascularization.

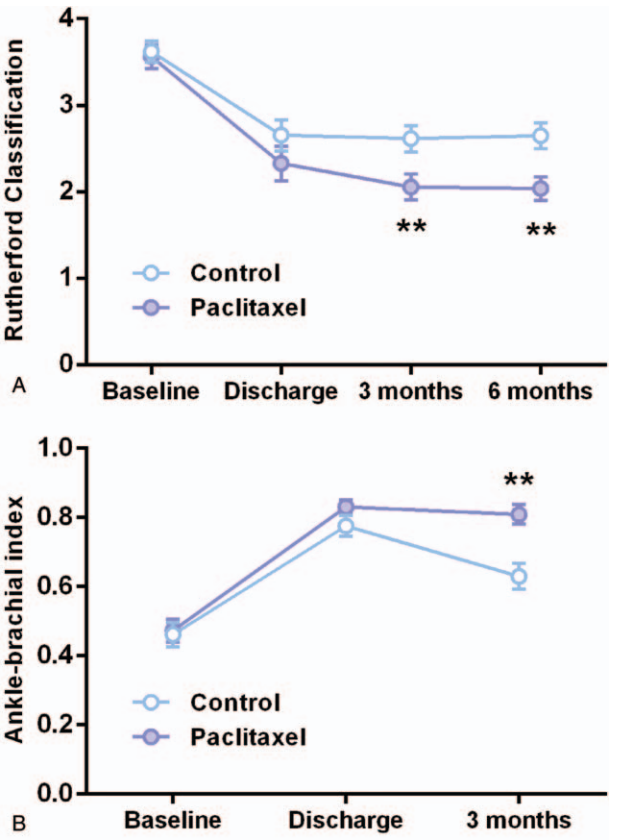

Figure 1. The paclitaxel-coated balloon group exhibited lower Rutherford classification grade and higher ABI compared to controls. (A) The Rutherford classification grades before treatment, at the discharge time, 3 months after treatment and 6 months after treatment. (B) The ABI before treatment, at the discharge time, and 3 months after treatment. The bar represents SEM. $^{**}P < .01$ Paclitaxel vs Control. ABI = ankle-brachial index.

Next, we analyzed clinical factors that may influence the outcomes in the whole cohort. As Figure 2 shown, part of patients received the fasting blood glucose examination after admission, and the blood glucose may be referential for ABI prediction 3 months later, that these two indexes exhibited a significant negative linear relationship (Fig. 2A). Accordingly, a more serious diabetic situation implies a poor prognosis. Moreover, the

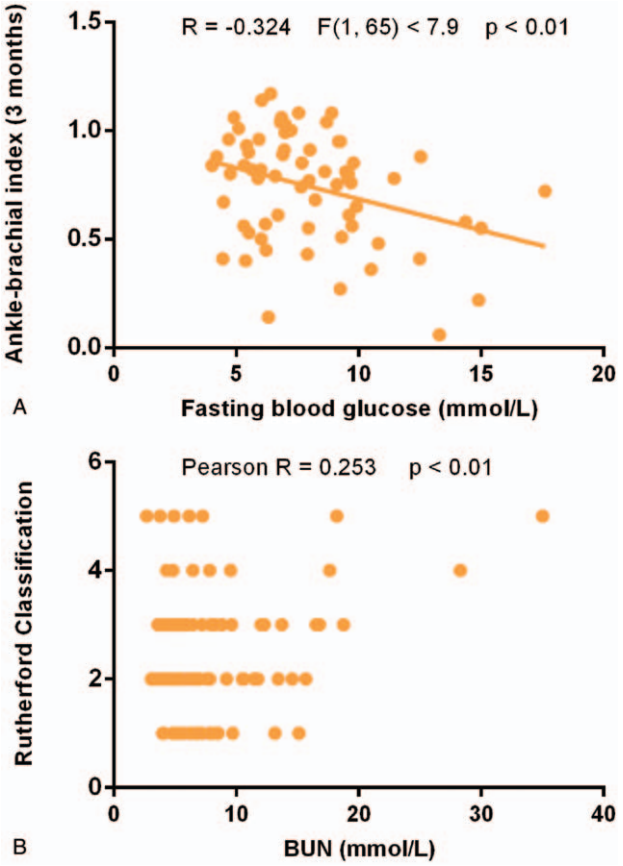

Figure 2. The basal fasting blood glucose and BUN were correlated with prognosis. (A) The ABI after treatment was negatively correlated with the basal fasting blood glucose; (B) Rutherford classification 3 months after treatment was positively correlated with the basal BUN level. BUN = blood urea nitrogen.

Rutherford classification at 3 or 6 months after treatment had a positive correlation with the basal BUN level (Fig. 2B at 3 months, the data at 6 months was highly similar to 3 months and not shown). In addition, the state of CHD may partially decide whether residual stenosis would happen (Pearson $R = 0.287$, $P < .01$); residual stenosis also had a relationship with smoking history (Pearson $R = 0.247$, $P = .026$). Together, those patients with a smoking or CHD history, or a higher level of BUN and glucose, are more likely to have a poorer outcome.

4. Discussion

In the present post-hoc study, we confirmed that paclitaxel-coated balloon angioplasty yielded more favorable results, with no recognizable adverse effects. Besides, blood glucose, BUN, CHD, and smoking could be predictors of poorer curative effects of PTA.

Drug-coated balloons have been demonstrated superior effectiveness and similar safety for the treatment of femoropopliteal lesions in different cohorts.[8,9,12,13] Anti-inflammatory and anticoagulant drugs may induce excellent patency and decrease the low CD-TLR rates. Independent studies have proved that drug-coated balloons resulted in higher primary patency and lower rate of vessel thrombosis.[14,15] Paclitaxel is regarded as a mitotic inhibitor and has an activity of inhibiting neointimal hyperplasia.[16–19] The clinical application of paclitaxel coated balloon was first reported in 2010, and gradually widely applied

Table 4

Reasons for stenting.

	Paclitaxel	Control
Flow limiting dissection	4	8
Residual stenosis (RS)		
30%–50%	1	0
50%–70%	2	1
>70%	2	2
Flow limiting dissection & 30%–50% RS	0	1
Flow limiting dissection & 50%–70% RS	0	1
Flow limiting dissection >70% RS	2	0

in angioplasty for treatment of thrombolysis, coronary lesions, and peripheral artery diseases.[20–23] In 2015, Rosenfield et al reported a paclitaxel-coated balloon for femoropopliteal artery disease for the first time[24,25]. It is more challenging for diabetics with long and occlusive lesions. So far, it has not been fully addressed the problem of vessel recoil, with bailout stenting rates due to dissection. Acute recoil and residual stenosis account for 10% incidence rate [11]; and we noticed that approximately 20% cases in our study received stenting post balloon angioplasty, and the reasons were summarized in Table 4. The placement of stents can reduce occurrence of some early complications, such as elastic recoil, residual stenosis, and flow-limiting dissections. Interestingly, although coating paclitaxel provided significant benefits, the post-stenting rate of the paclitaxel group was similar to the uncoated group, which indicates that stenting is still a necessary reserved solution for treatment of femoropopliteal long lesions.

Our results showed that the accumulated TLR in the Control group reached 37% at the 6th month and this level lasted to the 24th month, but this index gradually increased from 7% (at the 6th month) to 15% (at the 24th month) in the Paclitaxel group. This result implied that the causative factors lie in the circulatory system and induce the atherosclerotic diseases rapidly in 6 to 12 months when levels of some factors have reached the threshold. Further studies are needed to explore the mechanisms of restenosis after PTA therapy, and it is promising to probe the above factors that influence the prognosis (blood glucose, BUN, CHD, and smoking).

This study has some limitations. First, limited by sample number, our patients were not stratified by diabetes status, and more specific studies are merited to improve our conclusion. Another limitation in diabetics is the lack of data on calcification status, which is known to affect restenosis occurrence. Also, there may be bias regarding the decision to perform TLR, and TLR did not fully match the binary restenosis rate. Finally, our study involved only Chinese patients and other populations remain to be assessed.

5. Conclusion

The paclitaxel-coated balloon angioplasty can yield more favorable angiographic and clinical outcomes than normal uncoated balloon angioplasty, even in the more challenging long and occlusive femoropopliteal lesions in diabetics, when it had a similar safety profile to the traditional balloon. Blood glucose, BUN, CHD, and smoking may play a predictive role in poor curative effects.

Author contributions

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Writing – original draft: Xin Du, Feng Wang.
Writing – review & editing: Wei Guo, Shen-Ming Wang.

References

[1] Werner M, et al. Treatment of complex atherosclerotic femoropopliteal artery disease with a self-expanding interwoven nitinol stent: midterm results from the Leipzig SUPERA 500 registry. EuroIntervention 2014;10:861–8.
[2] Park UJ, Kim HT, Roh YN. Impact of tibial runoff on outcomes of endovascular treatment for 1 femoropopliteal atherosclerotic lesions. Vasc Endovascular Surg 2018;1538574418779466.
[3] Kim W, et al. Effects of percutaneous transluminal angioplasty on diastolic function in patients with chronic occlusion of lower-extremity artery. J Invasive Cardiol 2016;28:498–504.
[4] Bozic-Mijovski M, et al. Nurr1 haplotypes are associated with femoropopliteal restenosis/re-occlusion after percutaneous transluminal angioplasty. Eur J Vasc Endovasc Surg 2012;43:337–8.
[5] Gahlen J, Koeppel T, Prosst RL. Vascular occlusion by ruptured balloon after percutaneous transluminal angioplasty. J Endovasc Ther 2003;10:1117–9.
[6] Y E, et al. Percutaneous transluminal angioplasty (PTA) alone versus PTA with balloon-expandable stent placement for short-segment femoropopliteal artery disease: a metaanalysis of randomized trials. J Vasc Interv Radiol 2008;19:499–503.
[7] Inoue T, Node K. Molecular basis of restenosis and novel issues of drug-eluting stents. Circ J 2009;73:615–21.
[8] Iida O, et al. Drug-coated balloon vs standard percutaneous transluminal angioplasty for the treatment of atherosclerotic lesions in the superficial femoral and proximal popliteal arteries: one-year results of the MDT-2113 SFA Japan randomized trial. J Endovasc Ther 2018;25:109–17.
[9] Tepe G, 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.
[10] Mehrotra S, Paramasivam G, Mishra S. Paclitaxel-coated balloon for femoropopliteal artery disease. Curr Cardiol Rep 2017;19:10.
[11] Jia X, et al. Acotec drug-coated balloon catheter: randomized, multicenter, controlled clinical study in femoropopliteal arteries: evidence from the AcoArt I trial. JACC Cardiovasc Interv 2016;9: 1941–9.
[12] Pepe C, et al. Budget impact analysis of drug coated balloon vs. percutaneous transluminal balloon angioplasty in the treatment of peripheral arterial disease in lower limbs in Brazil. Value Health 2015;18:A858.
[13] Pepe C, et al. Cost effectiveness of drug coated balloon versus percutaneous transluminal balloon angioplasty in the treatment of peripheral arterial disease in lower limbs in Brazil. Value Health 2015;18:A807–8.
[14] Cassese S, et al. Drug-coated balloon angioplasty for in-stent restenosis of femoropopliteal arteries: a meta-analysis. EuroIntervention 2017;13: 483–9.
[15] Albashaireh D, et al. Drug coated balloon angioplasty for subclavian artery stenosis: a potential novel indication. Cardiovasc Revasc Med 2017;18(6S1):45–7.
[16] Yasuhira S, et al. Paclitaxel-induced aberrant mitosis and mitotic slippage efficiently lead to proliferative death irrespective of canonical apoptosis and p53. Cell Cycle 2016;15:3268–77.
[17] Berndtsson M, et al. Phosphorylation of BAD at Ser-128 during mitosis and paclitaxel-induced apoptosis. FEBS Lett 2005;579:3090–4.
[18] Schachner T, et al. Paclitaxel treatment reduces neointimal hyperplasia in cultured human saphenous veins. Eur J Cardiothorac Surg 2007;32:906–11.
[19] Masaki T, et al. Inhibition of neointimal hyperplasia in vascular grafts by sustained perivascular delivery of paclitaxel. Kidney Int 2004;66: 2061–9.
[20] Mayor S. Angioplasty with paclitaxel coated balloon reduces restenosis in peripheral artery disease. BMJ 2015;350:h3451.
[21] Ikenaga H, et al. Slow-flow phenomenon after paclitaxel-coated balloon angioplasty: findings from optical coherence tomography and coronary angioscopy. JACC Cardiovasc Interv 2015;8:e59–62.
[22] Brenot P, et al. First experience with paclitaxel-coated balloon angioplasty in patients with adult transplant coronary artery disease: is it an alternative to drug-eluting stents? J Heart Lung Transplant 2015;34:264–6.
[23] Her AY, et al. Comparison of paclitaxel-coated balloon treatment and plain old balloon angioplasty for de novo coronary lesions. Yonsei Med J 2016;57:337–41.
[24] Rosenfield K, Metzger DC, Scheinert D. A paclitaxel-coated balloon for femoropopliteal artery disease. N Engl J Med 2015;373:1785–6.
[25] Rosenfield K, et al. Trial of a paclitaxel-coated balloon for femoropopliteal artery disease. N Engl J Med 2015;373:145–53.