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Mini Review

Current Challenges of Coronary Paclitaxel-Coated Balloon Angioplasty

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ABSTRACT

In this mini-review, current challenges of coronary Paclitaxel-Coated Balloon (PCB) angioplasty are summarized. Since the outcomes of PCB angioplasty had to be non-inferior to those of Drug-Eluting Stents (DESs), the indications, the optimal endpoints, and the clinical and angiographic outcomes of PCB angioplasty should be re-evaluated by comparing with the advances in the DESs outcomes. In our recent reports used the Propensity-Score Matched (PSM) analysis to adjust the baselines, PCB angioplasty demonstrated a similar efficacy to DESs in both of elective and emergent cases of patients with Chronic Coronary Syndromes and Acute Coronary Syndromes (CCS and ACS). PSM analysis showed the considering factors such as non-calcified lesions, lesions with a total PCB length of approximately 20 mm (non-diffuse lesion), and a maximum PCB size of approximately 3.0 mm (non-small vessels). Since all of the recent PCB angioplasty was conducted under the guidance of intravascular assessments, the mechanism of Late Lumen Enlargement (LLE) after PCB angioplasty was almost resolved. The predictor of LLE related to the residual dissection was consistent, the insignificant dissection, either the type A or B. In a daily practice, as raising the PCB angioplasty experiences in the cases of in-stent restenosis inside DES and stenotic lesions in small vessels, the indications of PCB angioplasty would gradually spread for various conditions including complex lesions and any clinical presentations. The value of post procedural % Diameter Stenosis (DS) <30, so called "stent like result," has persisted as the optimal surrogate procedural endpoint of PCB angioplasty. However, this concept of primary Plain Old Balloon Angioplasty (POBA) for patients with acute myocardial infarction was inferior to the outcomes of routine primary stenting using bare-metal stents. Thus, the relationships between the pre procedural parameters, post procedural %DS, and the cumulative clinical outcomes after PCB angioplasty have to be newly re-evaluated with the recent PCB angioplasty procedures under the intravascular assessments. PCB angioplasty would be further spread with the understanding of suitable indication, the re-evaluation of the optimal endpoint, and the long-term better outcomes with the increase in the LLE frequency along with the advances of PCI technique in comparison to DESs placement.

Keywords: Coronary angioplasty; Drug-coated balloon; Drug-eluting stents; Late lumen enlargement

INTRODUCTION

Coronary Drug-Coated Balloons (DCB) have emerged as a valid alternative for Drug-Eluting Stents (DESs), as one of the devices of DES-less coronary angioplasty [1,2]. Paclitaxel-Coated Balloon (PCB: SeQuent Please, B. Braun, Melsungen, Germany) angioplasty has been widely used as one of DCB devices. On the basis of the consistent efficacies of PCB angioplasty for in-DES restenosis Drug-Eluting Stents-Stent Restenosis (DES-ISR) and *de novo* stenotic lesions in small coronary vessels, there have made significant efforts to investigate the roles of PCB angioplasty for large vessels and for the complex lesions, such as bifurcations, chronic total occlusions, severely calcified lesions using rot ablator, ostial lesions, and diffuse long lesions.

In our institute, PCB angioplasty was conducted in approximately 40%-45% of all PCI without restriction of vessel size and clinical presentation under the doctor's discretion. In this mini-review, we briefly summarized the several current challenges of PCB

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angioplasty for coronary revascularization, by referring recent reports including our report showing the clinical safety and angiographic efficacy of elective PCB angioplasty for patients with stable Chronic Coronary Syndrome (CCS) with the possible mechanism of Late Lumen Enlargement (LLE) [3].

LITERATURE REVIEW

Clinical efficacies of PCI-related devices have been established in order by comparing those angiographic outcomes from balloon angioplasty, bare-metal stent, 3 generations of DESs, and PCB. The clinical outcomes of DESs have become better from the first-generation DES to the current third-generation DES with the reductions of the frequencies of DES-ISR, definite stent thrombosis, and stent fractures. PCB angioplasty should be promoted concomitantly with the advances in DES's outcomes. One of the consistent advantages of PCB angioplasty was observed in the followed-up angiographic outcomes at chronic phase. The mean values of late luminal loss in PCB angioplasty lesions were ranging from 0 to approximately 0.10 mm [2-5]. LLE, defined as minus late luminal loss, was occurred in approximately half or more than half of angiographic followed-up lesions [1-6]. The precise mechanism of this unique LLE phenomenon has been under investigation [1-6]. We reported that the final residual type-A dissection after DCB angioplasty was the predictor of LLE studied in 201 angiographic followed-up lesions [3]. We speculated the following 4 factors as the mechanism of LLE: 1) balloon angioplasty enlarged the lumen and vessel areas (vessel enlargement), 2) distribution of paclitaxel suppresses the plaque and induces the plaque regression, 3) the minor dissections formed at any steps further allow the diffusion of paclitaxel into the plaques, and 4) almost all of the minor dissections formed at the procedure were sealed at chronic phase without late lumen loss (Figure 1).

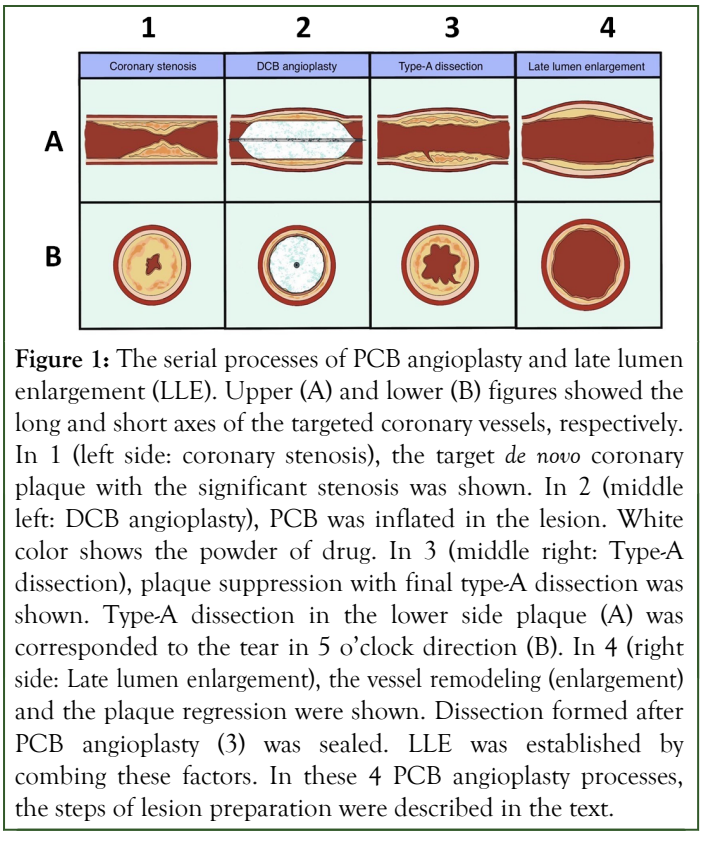

Figure 1: The serial processes of PCB angioplasty and late lumen enlargement (LLE). Upper (A) and lower (B) figures showed the long and short axes of the targeted coronary vessels, respectively. In 1 (left side: coronary stenosis), the target *de novo* coronary plaque with the significant stenosis was shown. In 2 (middle left: DCB angioplasty), PCB was inflated in the lesion. White color shows the powder of drug. In 3 (middle right: Type-A dissection), plaque suppression with final type-A dissection was shown. Type-A dissection in the lower side plaque (A) was corresponded to the tear in 5 o'clock direction (B). In 4 (right side: Late lumen enlargement), the vessel remodeling (enlargement) and the plaque regression were shown. Dissection formed after PCB angioplasty (3) was sealed. LLE was established by combing these factors. In these 4 PCB angioplasty processes, the steps of lesion preparation were described in the text.

Taken into the results of other reports under the guidance of intravascular assessments, the predictor of LLE related to the residual dissections was consistently reported to be the insignificant dissections, either type A or B without epicardial coronary flow limitation [4,5]. It is very difficult to intentionally establish type-A or type-B dissections, but when the type-C dissection was established, coronary flow was limited and ST-segments would be raised with chest symptom, resulted in the bailout procedure to place DESs. Thus, the strategy of PCB angioplasty has been almost unified, and the mechanism of LLE after PCB angioplasty has been considered to be almost resolved.

From the point of view of possible mechanism of LLE regarding the coronary dissections, it is important to define the endpoint of PCB angioplasty. In addition, as described above, it is important to decide the timing of bailout by placing DESs at any steps during the PCB angioplasty procedures. Coronary dissection occurs and extends in any steps from the lesion preparation using smaller semi-compliant balloons and/or scoring balloons to the final PCB dilation procedures. The definition of the optimal endpoint of PCB angioplasty was proposed as not only the good coronary epicardial flow allowing the residual insignificant (type A or B) dissection, but also the value of post procedural percent Diameter Stenosis (%DS) less than 30 [2]. The value of post procedural %DS<30, was so called "stent like result," and has persisted as the optimal surrogate procedural endpoint of PCB angioplasty for more a decade [6]. This post procedural %DS<30 was same with the endpoint of reperfusion with primary Plain Old Balloon Angioplasty (POBA) for patients with Acute Myocardial Infarction (AMI) [7]. However, this "stent like result" with POBA was proven to be inferior to primary stenting strategy using bare-metal stents for patients with AMI [7]. On the other hand, it was reported that the clinical outcomes of the cases implicated in DES placement by bailout procedures in the PCB angioplasty procedure were inferior to those of cases without need to bailout [8]. Thus, the relationships between the pre procedural parameters, post procedural %DS, and the cumulative clinical outcomes after PCB angioplasty have to be re-evaluated with the recent advances in PCB angioplasty under the guidance of intravascular findings by comparing with those of DES placement.

DISCUSSION

PCB angioplasty has been spreading in the field of PCI, and the statements by summarizing the growing observational data were published [1,2]. However, at present in a daily practice, PCB angioplasty is applied for less complex lesions compared to DES placement [3,8]. Thus, as raising the doctor's experiences of PCB angioplasty for stable cases with the elective procedures, PCB angioplasty could be gradually implemented for the emergent procedures in patients with Acute Coronary Syndrome (ACS) [8]. Thus, in order to find the benefits of PCB angioplasty in various PCI categories, it is essential to compare the outcomes of PCB angioplasty with those of DESs placement in the real practices. For this purpose, either prospectively randomized studies, meta-analysis with a systematic review, or the estimation with statistical adjustment were necessary [3-11].

In our reports regarding about CCS and ACS, PCB angioplasty demonstrated similar efficacies to DESs in the propensity-score matched adjusted baselines [3,8]. The considered factors were lesions with no calcified, with a total PCB length of approximately 20 mm (non-diffuse lesion), and with a maximum PCB size of approximately 3.0 mm (non-small vessels). This PCB-efficacious length-dependent baseline was also supported by our recent report which examined the impact of the elective PCB angioplasty for large (reference vessel diameter>2.75 mm) vessel size [11]. In addition, these PCB-efficacious non-diffuse baselines overlapped with the conditions in which PCB angioplasty was statistically similar to DES placement for DES-ISR (10, DAEDALUS study). The benefit of PCB angioplasty for DES-ISR was limited in non-diffuse (<20 mm) DES-ISR, could not find in diffuse (≥ 20 mm) ISR compared to recurrent DES placement (DES-in-DES strategy). Thus, we proposed the lesion-length dependent PCB angioplasty with the use of 3.0 mm size with 20 mm length PCB for non-calcified lesion. This would be the most evidence based, and robust PCB angioplasty. Thus, it needed to be clarified in any conditions where PCB angioplasty showed the non-inferior outcomes to DES placement.

CONCLUSION

In summary, the outcomes of PCB angioplasty had to be concomitantly revised as with the advances in the clinical outcomes of DESs. According to the observational preliminary data of PCB angioplasty, PCB angioplasty for complex lesions and for patients with any clinical presentations has been gradually spread. The mechanism of LLE, the most advantageous effect of PCB angioplasty, has been almost resolved as the insignificant residual dissections by the recent reports. PCB-length dependent efficacy was statistically robust as shown by DAEDALUS study and unrestrictive uses for both of CCS and ACS. The indications and the endpoints leading the non-inferior outcomes of PCB angioplasty compared to the update DES outcomes should be always examined in various baselines.

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