在經皮瘻管成型術中使用Paclitaxel塗層氣球改善橈動脈及頭靜脈接合型瘻管的病灶再阻塞

Percutaneous Angioplasty Using Additional Paclitaxel-Coated Balloon Improves Target Lesion Restenosis on Inflow Lesions of Radiocephalic Fistula

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Background: Neointimal hyperplasia mainly accounts for target lesion restenosis (TLR) particularly in the lesions treated with repeated percutaneous transluminal angioplasty (PTA). Use of paclitaxel-coated balloon (PCB) versus plain balloon (PB) has been proven to be safe and improve vascular restenosis in endovascular intervention. The unique effects of PCB include rapid delivery of the anti-proliferative drug to the local vessel wall and sustained inhibition of neointimal hyperplasia. However, there is little literature available to support the application of PCB in endovascular management of hemodialysis (HD) access vascular stenosis. The study was therefore designed to investigate the impact of PTA using PCB plus PB versus standard PB alone on TLR in patients with recurrent inflow lesions of radiocephalic arteriovenous fistula (RCAVF). The study aims were: (i) to explore the safety of the off-label use of PCB; and (ii) to detect the difference in TLR rate between the two different PTA strategies. Data obtained from the study may be helpful to guide the use of PCB in such patients undergoing repeated PTAs.

Material and Methods: The study is a single-center, prospective, and observational research, which prospectively recruited HD patients who had two separated short (< 2 cm in length estimated using a 2-cm balloon catheter) inflow lesions of RCAVF confirmed by angiography. The upstream and downstream lesions were randomly treated with PTA using PCB plus PB (Group 1) or PB alone (Group 2) at 1:1 ratio. PCB catheters (4.0 x 20 mm; SeQuent Please, B Braun, Berlin, Germany) were used. Excluded patients were those who had another HD access or lesions other than selected lesion types. Dysfunction-driven angiography was performed for confirming TLR after index PTAs. Patients were referred to the center for angiographic examination according to the presence of: (i) abnormal signs for decreased inflow; (ii) blood inflow rate < 250-300 ml/min; or (iii) decreased inflow rate ≥ 25% from baseline. Excluded patients were those who had the other HD access, the different lesion site or lesion number, anyone of lesion lengths exceeding 2 cm, an occluded lesion, or the lesion(s) refractory to balloon pre-dilatation, who did not receive PTA from any cause, who had a history of contrast allergy, or who had severe diseases that the physicians estimated lifespan less than 1 year. Two significant lesions categorized as one downstream lesion and the other upstream lesion in each participant was penetrated using a guide wire (a 0.025 or a 0.035 in. hydrophilic wire, GUIDE WIRE M, Radifocus; Terumo, Tokyo, Japan). Thereafter, the two lesions were randomly treated with one or the other treatment strategy at 1:1 ratio: (i) PCB pretreatment plus PB PTA (Fox plus PTA catheter; Abbott, Illinois, USA or Medtronic, Invatec PTA catheter; Minneapolis, Minnesota, USA) as Group 1; and (ii) PB PTA alone as Group 2. In other words, the

downstream and upstream lesions were exclusively treated with different treatment strategies in each participant. PCB pretreatment had to be guided using a 0.014 in. guide wire system. PCB was inflated to dilate the lesions for 60 seconds. All lesions were subsequently treated with PB PTA in an appropriate balloon size at the inflation pressure of 4 to 30 atmospheres for 30-60 seconds even the lesions had been already treated with PCB. Endovascular stenting was not allowed in the study. The procedure's endpoint was at the individual physician's discretion according to angiographic criteria. A clinical success meant completion of at least one HD session without any dysfunctional sign after the index PTA. The target AVF was assessed monthly using the same clinical and hemodynamic criteria described earlier. The study end point was the event of angiography-confirmed TLR in a need of PTA. When a repeat PTA was done at the target lesion, the follow-up for the lesion ended. PTA on an insignificant target lesion was prohibited. Target lesion PTA-free days were calculated and compared between groups treated with different strategies. Categorical variables were analyzed using either a chi-squared (x2) test or Fisher's exact test. Continuous variables were analyzed using Student's t test. A paired t test was used to compare the continuous variables in the same population.
Results: Dysfunction-driven angiography was performed in all participants during the period of 12-month follow-up. Of 20 lesions collected in 10 patients, the dysfunction-driven PTA-free duration on target lesion in Group 1 was significantly longer than that of Group 2 (251.2 ± 123.0 vs. 103.2 ± 29.3 days; $P < 0.01$). Group 1 compared with Group 2 had the significantly higher patency rate at 6 months ($P < 0.01$), but identical rate at 12 months ($P > 0.05$). A significant increase in the TLR-free rate at 6 months was observed in Group 1 (70 % vs. 0 %; $P < 0.01$) as compared with Group 2. The target lesion PTA-free duration was significantly longer in Group 1 compared with Group 2 (251.2 ± 123.0 vs.103.2 ± 29.3 days; $P < 0.01$). Remarkably, the unassisted patency rates appeared insignificant differences at 3 months (100 % vs. 60 %; $P = 0.09$), at 9 months (40% vs. 0%; $P = 0.09$), and at 12 months (20 % vs. 0 %; $P = 0.47$) between groups.
The short-term patency benefit of additional PCB PTA was also shown in Kaplan-Meier survival analysis indicating significant reduction in a cumulative 6-month incidence of TLR-related PTA as compared with conventional PB PTA alone ($P < 0.01$ by long-rank test).
Conclusion: This study suggests that PCB pretreatment plus PB PTA versus conventional PB PTA alone improves short-term patency and PCB pretreatment may be considered in the management of juxta-anastomotic outflow lesions of RCAVF.