Association of Provisional Stenting with Long-Term All-Cause Mortality: A Further Analysis of 5-Year outcome of the ACOART I Study

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Abstract

Background and objectives: Paclitaxel-based device associated with increased mortality was controversial. Five years results of the ACOART I Study didn’t show significant higher all-cause mortality in the DCB group. The aim of this study was to investigate the association of provisional stenting with all-cause mortality in the ACOART I Study.

Methods: A total of 200 Chinese patients with FPAD were prospectively randomized into treatment with DCB or with PTA. The primary endpoints were all-cause mortality, freedom from clinically driven target
lesion revascularization, and improved Rutherford class at 5 years. The primary safety endpoint was the rate of major adverse events. The associations between provisional stenting with all-cause mortality were examined by multivariate Cox regression. Interaction and stratified analyses were conducted according to intervention, sex, BMI, smoking status, Rutherford class and histories of chronic disease.

**Results:** All-cause death occurred 14(35%) in the provisional stenting group and 27(16.88%) in the control group (p=0.01). Correspondingly, the rates of target lesion revascularization were 27.5% and 31.25% (p = 0.645) in the provisional stenting group versus the control group. The multivariate logistic regression analyses revealed that provisional stenting was significantly associated with higher risk of all-cause mortality (HR=2.26, 95% CI 1.11 to 4.57, p=0.02). In the further stratified analyses, the results stayed robust in all subgroups. The interaction analysis showed that paclitaxel-coated balloons played an interactive role between the association of provisional stenting and all-cause mortality. (p for interaction = 0.047).

**Conclusions:** Provisional stenting was independently associated with an elevated risk of all-cause mortality. Further studies are needed to confirm the results and revealed the mechanism.