Abstract

Background: A higher rate of bioresorbable vascular scaffold (BVS) thrombosis has been observed after device implantation compared to implantation of permanent metallic stents in recently published studies. The mechanism of BVS thrombosis is currently under debate.

Aim: To assess whether the immune-inflammatory response after BVS implantation is a potential trigger of BVS thrombosis.

Methods and results: The PRAGUE-19 study was an academic study that enrolled consecutive patients with ST-segment elevation myocardial infarction (STEMI) with the intention to implant a BVS. A laboratory sub-study included 49 patients with an implanted BVS (of which 38 underwent the complete 2-year follow-up and 44 5-year telephone follow-up) and 52 patients as the control group having an implanted permanent metallic stent (of which 30 underwent the complete 2-year follow-up and 44 5-year telephone follow-up). Samples for inflammatory markers (high sensitivity C-reactive protein [hs-CRP], interleukin-6 [IL-6] and tumor necrosis factor-alpha [TNF-α]) were taken before BVS or stent implantation, on days 1 and 2 after device implantation and at 1 month and 2 years of a clinical control. The primary combined clinical endpoint of the sub-study (death, reinfarction or target vessel revascularization) occurred in 14.29 % of the BVS group and 9.62% of the control group ($p = 0.01$) during the 5-year follow-up period, with overall mortality of 8.16 % in the BVS group and 3.85 % in the control group ($p = 0.001$).

Definite BVS thrombosis occurred in one patient in the subacute phase and in one patient in very late phase; one patient had probable very late ST. Two definite stent thromboses were observed in the control group: one the subacute phase and the other the late phase. Baseline inflammatory marker levels did not differ between the groups. Lower levels of IL-6 and hs-CRP were observed in the BVS group compared to the control group (12.02 ± 5.94 vs. 15.21 ± 5.33 pg/ml; $p < 0.01$; 3,952.9 ± 1,704.75 ng/ml vs. 4,507.49 ± 1,190.01 ng/ml; $p = 0.037$, respectively) on days 1 and 2 (12.01 ± 6.31 vs. 13.85 ± 6.01 pg/ml; $p = 0.089$; 4,447.92 ± 1,325.31 ng/ml vs. 4,637.03 ± 1,290.99 ng/ml; $p = 0.255$, respectively). No differences in IL-6 or hs-CRP were observed after 1 month or 2 years in the clinical control. Levels of TNF-α did not differ between the groups in the early period after BVS or metallic stent implantation, nor during follow-up.

Conclusion: The immune-inflammatory response is lower during the early phase after BVS implantation compared to that after metallic stent implantation, but the responses did not differ in the long term.