Debulking Of Chronic Total Occlusions With Rotational Atherectomy Before Stenting (DOCTORS): A Prospective Multicenter Pilot Study

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Previous randomized studies have shown that stenting reduces the restenosis and reocclusion rates of successfully recanalized chronic coronary total occlusions (CTO) compared with balloon angioplasty alone, however the restenosis rate after stenting still remains high. Massive plaque burden in CTO is considered to interfere with full stent expansion and be a cause of restenosis. Rotational atherectomy (RA) can be applied for plaque debulking of CTO, however some critical complications such as vessel perforation or no-reflow phenomenon should be concerned. To examine the safety and the impact of pre-stent debulking of CTO on reduction restenosis, we treated 100 patients (male: 81, 64+/−9 yo) with CTO (TIMI flow grade = 0 or 1, estimated occlusive duration >= 1 month) by RA in Japanese 8 centers. RA was performed with max. burr size was 1.86+/−0.22 mm. RA could be performed safely in all lesions without any major complications. Adjunctive ballooning pressure was 7.7+/−2.6 atm, and single or multiple NIR stents were implanted with the max. pressure of 10.5+/−3.4 atm. Max. stent/balloon size was 3.18+/−0.26 mm and total stent length was 27.2+/−13.5 mm. Procedural success was obtained in 99 patients. Vessel rupture was observed in one patient after conventional ballooning at distal non-CTO lesion where RA burr did not pass. Non Q-wave MI was observed in 14 patients, however there were no Q-wave MI or emergent CABG. One patient died of infectious pericarditis after vessel rupture 1 month (M) after the procedure. Two patients died of non-cardiac cause (6M: renal failure, 6M: lung cancer). Angiographic 6M follow-up was performed in 81 patients and repeated PTCA was required in 24 pts (29.6%) because of restenosis. Predictors of repeated PTCA were the total stent length (p=0.004) and the need of stiff conventional wire to cross the CTO lesion (p=0.012). Conclusion: Pre-stent RA of CTO is safe and facilitates subsequent stent implantation, however the impact on reduction restenosis may be limited. To clarify the efficacy of pre-stent debulking of CTO, a randomized study is being conducted which compares stenting alone with pre-stent debulking using RA or directional coronary atherectomy in Japanese 20 multicenters.