INTER-CORE LAB VARIABILITY IN ANALYZING QUANTITATIVE CORONARY ANGIOGRAPHY FOR BIFURCATION LESIONS: A POST-HOC ANALYSIS OF A RANDOMIZED TRIAL

Poster Contributions
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Authors: Maik J. Grundeken, Yuki Ishibashi, Philippe Genereux, Laura Lasalle, Joanna Wykrzykowska, Marie-angèle Morel, Jan Tijssen, Robbert de Winter, Chrysafios Girasis, Hector García Garcia, Yoshi Onuma, Martin Leon, Patrick W.J.C. Serruys, Cardialysis, Rotterdam, The Netherlands, Cardiovascular Research Foundation, New York, NY, USA

Background: Data on inter-core lab variability in quantitative coronary angiography (QCA) of bifurcation lesions is lacking.

Methods: We used the 9-month angiographic follow-up data (n=326) from a randomized trial on bifurcation treatment to evaluate the inter-core lab variability between 2 core labs before and after alignment of QCA methodology (i.e. single vessel vs bifurcation software, manual vs automatic segmentation etc).

Results: Before alignment, the mean difference (bias) was large for all QCA parameters with wide 95% limits of agreement (±1.96* the standard deviation of the bias), indicating marked variability. The bias of 1 of the key endpoints, in-segment percentage diameter stenosis (%DS) of the side branch (SB), was 5.5% (95% limits of agreement: -26.7; 37.8%, left panels of figure). After alignment, this bias was reduced to 1.8% (95% limits of agreement -16.7; 20.4%, right panels of figure). Importantly, after aligning the methodology, the differences between treatment groups with regard to the %DS of the SB were no longer significant (treatment A vs B: 31.6% vs 38.6%, p=0.002 before alignment; 34.4±19.4% vs. 32.4±16.1%, p=0.34 after alignment).

Conclusion: A marked inter-core lab variability of bifurcation QCA analysis was found due to differences in methodology. After alignment of methodology, variability decreased considerably and affected the QCA results. This latter finding emphasizes the importance of using the same methodology among different core labs world-wide.