SS 06 CV-08 10:50 **(English**

Value of contrast-enhanced MRA in the diagnosis of peripheral arterial occlusive disease at 3T: comparison of meglumine gadoterate- to gadobutrol-enhanced MRA using DSA as a standard of reference <u>Christian Loewe</u>

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PURPOSE: To assess the value of Dotarem[®] and Gadovist[®] - enhanced MRA at 3T for diagnosis and treatment planning in peripheral arterial occlusive disease (pAOD).

MATERIALS AND METHODS: Out of the 189 patients totally included in this international, multicentric randomized, prospective, double-blind, phase IV trial with centralized reading, 156 patients were investigated exactly according to the protocol and could be included in the final evaluation. Patients randomly underwent peripheral MRA at 3T during injection with 0.1 mmol/kg of either Dotarem® or Gadovist®. DSA served as standard of reference in every patient. Additionally to parameters according to stenosis detection and graduation, including degree of agreement to DSA in stenosis detection, stenosis grading, specificity, sensitivity, positive/negative predictive values calculation, even factors important for treatment planning and outcome of the patients were assessed by two independent readers in a centralized reading. These factors include diagnostic confidence, safety, stenosis length, vessel diameter as well as treatment recommendation were assessed.

RESULTS: The agreement in stenosis detection between Dotarem[®]-MRA and DSA was similar to that of Gadovist[®]-MRA for both readers at centralized reading (69.2% \pm 17.6% vs. 69.0% \pm 15.6%, reader 1; and 51.4 \pm 18.3% vs. 49.8% \pm 17.9%, reader 2, respectively), and the 95%CI excluding the non-inferiority limit (-6.5%) demonstrated the non-inferiority. Even the values for sensitivity and specificity for detecting significant stenosis (> 50%), for the PPV, the NPV, and the diagnostic confidence were similar in both groups. Two patients (2.2%) in each group experienced mild adverse events.

CONCLUSION: Peripheral MRA at 3T is possible with high diagnostic accuracy compared to DSA. Dotarem[®]-MRA shows similar diagnostic accuracy as Gadovist[®]-MRA in the diagnosis of PAOD at on site and off site reading.