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Diagnostic performance of 64Cu-SARTATE compared to 68Ga-DOTATATE in patients with known or suspected neuroendocrine tumors with focus on liver findings

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BACKGROUND

Diagnostic imaging is critical to theranostic management of neuroendocrine tumors (NETs). ^{64}Cu-SARTATE (SARTATE) may provide advantages over existing imaging agents due to its longer half-life and sarcophagine chelator, potentially improving accurate detection of additional disease in NETs.

METHODS

This multi-center Phase II study compared the diagnostic performance and safety of SARTATE (200 MBq) with ^{68}Ga-DOTATATE (DOTATATE) in gastroenteropancreatic (GEP)-NETs (NCT04438304). Participants with known/suspected GEP-NETs prospectively received SARTATE PET/CT at 4±1 hrs and 20±4 hrs post-injection. The SARTATE scans were compared with DOTATATE PET/CT scans obtained within 35 days prior to SARTATE administration by two independent blinded central readers. All abnormal lesions potentially related to GEP-NET and cannot be accounted for by a benign process were recorded. Discordant lesions (lesions only present on either DOTATATE or SARTATE scan) were subsequently evaluated by an independent assessor against a standard of truth (SOT; biopsy and/or follow-up conventional imaging). Per-lesion sensitivity for discordant lesions was calculated for both SARTATE and DOTATATE (defined as the proportion of true positive lesions / [true positive lesions + false negative lesions]; primary endpoint). Safety was assessed using standard clinical parameters.

RESULTS

Forty-five participants were enrolled and received SARTATE (41 known NETs, 4 suspected NETs), most with stage 3 or 4 disease. The mean number of lesions detected by SARTATE was 441 vs. 227 by DOTATATE. A total of 238 discordant lesions were identified in 34 subjects with scan pairs; 223 of these were detected by SARTATE alone and 15 by DOTATATE alone. For the 122 discordant lesions with evaluable SOT, the difference in sensitivity for SARTATE vs. DOTATATE was statistically significant (94.7% [95% CI 65.1, 99.5]

for SARTATE vs. 5.4% [95% CI 0.5, 34.9] for DOTATATE; p<0.001). The liver had the highest number of lesions detected by both tracers (352 lesions on SARTATE vs. 180 on DOTATATE) among all sites. Seven participants (15.6%) experienced 9 SARTATE-related adverse events; 8 were Grade 1 and 1 was Grade 2, with most resolving within 2 days.

CONCLUSIONS

SARTATE was safe and well-tolerated in patients with GEP-NETs. SARTATE lesion detection was numerically higher than DOTATATE, with the liver having the highest number of lesions identified. SARTATE detected additional true positive lesions compared to DOTATATE. The enhanced diagnostic performance offered by SARTATE, especially in key organs affected by GEP-NETs, may have important clinical implications to inform treatment decisions. A phase III study of SARTATE in GEP-NETs is being planned.

ABSTRACT ID #36508