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Comparison of 3D Luminal Ultrasound Visualization (3D LUV) to Carotid Duplex Exam (CDE) and Magnetic Resonance Angiography (MRA) for Evaluation of Carotid Stenosis

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Purpose: To evaluate the clinical relevance of 3D LUV by comparing results with CDE and MRA for proximal internal carotid artery (pICA) studies.

Materials and Methods: Blinded prospective study of 50 consecutive CDE patients (100 pICA segments) ages 25-90, with medical necessity for CDE testing. The data consists of a total of 96 pICA studies (4 segments were excluded due to acquisition concerns). Ultrasound images were acquired using 9 MHz linear probe and stored in DICOM format. Post processed 3D LUV evaluation was performed using Salient Imaging, *Visualize:Vascular* software and includes automatic luminal diameter measurements where the minimum and maximum diameters can lie in any plane 360° about the center of the pICA. MRA was performed for patients qualifying based upon CDE and/or 3D LUV results. The study independently calculated stenosis from CDE, luminal reduction from 3D LUV and MRA.

Results: Correlation between the imaging tests was found to be:
    CDE to 3D LUV 76%, n= 96, $p < .05$
    MRA to 3D LUV 99%, n= 6, $p < .05$
3D LUV results differed from CDE on 7 studies where 3D LUV ranked 1 higher and 6 lower than CDE, affecting patient management and potential surgical intervention. 3D LUV differed from MRA on one study (severe vs. critical) without effect on patient management. The same study was rated "moderate" using CDE. In those studies differing between CDE and 3D LUV, 3D LUV correlated to MRA; considered to be the gold standard for luminal evaluation.

Conclusion: Stroke is the leading cause of morbidity and the third leading cause of death. CDE is the first line diagnostic test used to determine carotid disease. Yet there are conditions when CDE is inhibited by artifacts, impacting results. Sensitivity and specificity of CDE results are statistically improved when used in conjunction with 3D LUV, and may obviate the need for unnecessary additional testing while shunting diseased patients to definite therapy.

 Clinical Relevance Statement: CDE is presently used as a first line diagnostic test in evaluating suspected carotid artery disease. CDE results can vary, based on morphology, calcified plaque and technique. 3D LUV significantly improves diagnostic capability of CDE with results matching those of MRA.