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Title: Validation of CALIPER (Computer-aided lung informatics for pathology evaluation and rating) for the non-invasive assessment of pulmonary nodules of the adenocarcinoma spectrum

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Body: Rationale: The growing utilization of high-resolution computed tomography (HRCT) for clinical diagnosis and lung cancer screening results in identification of pulmonary nodules of unknown clinical significance. Non-invasive strategies for the individualized management of these lesions are required. In a pilot study we have demonstrated the consistent classification of pulmonary nodules of the adenocarcinoma spectrum using CALIPER. Methods: Two pumonary patholgists independently assessed histopathologic tissue invasion in 72 surgically resected pulmonary nodules (≤ 3cm) of adenocarcinoma spectrum from 68 patients. Based on consensus, all lesions were categorized as either NINV-“non-invasive” (≤5mm invasion), n=6 or INV-“invasive” (>5mm invasion), n=66. CALIPER mapped the individual HRCT voxels (pre-operative HRCT) within all the nodules to one of the previously identified 9 unique radiological patterns. The nodules were categorized as INV or NINV based on the relative distribution of the patterns. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for CALIPER-based detection of tissue invasion were calculated. Results: Sensitivity, specificity, NPV and PPV were respectively 98.5%[90.7-99.9%], 66.7%[24.1-94%], 97%[88.7-99.4%] and 80%[30-98%]. Only one case was identified as NINV by CALIPER and as INV by the pulmonary pathologists. Conclusion: CALIPER represents a promising tool for non-invasive risk stratification of pulmonary nodules of the adenocarcinoma spectrum. Further prospective and retrospective validation of our data is currently ongoing.