Multicenter Prospective Study of Novel Biopsy Assessment System for the Intraprocedural Evaluation of Lung Biopsies by Robotic Assisted Bronchoscopy

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RATIONALE: Minimally invasive methods of diagnosing and staging pulmonary malignancy by robotic-assisted bronchoscopy (RAB) rely on small biopsy specimens. However, there is significant variability in assessing the adequacy of biopsy specimens intra-procedurally. This study employed a novel Biopsy Assessment System (CelTivity, Aquyre Biosciences) utilizing full field optical coherence tomography with dynamic cell imaging (FFOCT-DCI). These combined technologies capture metabolic activity of a biopsy sample at a cellular level to enable a proceduralist to perform interpretations in similar fashion to cytologic rapid on-site evaluation (ROSE). We aim to assess feasibility of this Biopsy Assessment System in determining accurate FNA and forceps sampling of lesional tissue.METHODS: A multicenter prospective study was conducted in which patients with lesions suspicious for lung malignancy based on CT and/or PET/CT scan underwent RAB (MONARCH^{TM} Platform, Ethicon Inc.). At the discretion of the operator, 2D fluoroscopy and radial EBUS were also used. After biopsy of each peripheral lung lesion, samples were analyzed by ROSE per standard of care. Additional samples were also placed on glass slides and imaged with the Biopsy Assessment System, which were then rinsed into cytology buffer solution or placed in formalin for cytology and pathology review. RESULTS: A total of 54 patients were enrolled and 43 patients were considered evaluable with a total of 43 peripheral lung lesions (43 TBNA and 41 TBBx forceps biopsy were included in the final analysis, with 49% cancer prevalence). Mean peripheral lesion size was 22 mm. Biopsy Assessment System in-room interpretation was compared to ROSE as well as final cytology and final pathology. Compared to final diagnosis, the proceduralist interpretation of Biopsy Assessment System images (FNA and forceps biopsies in aggregate) yielded sensitivity and specificity of 90% and 77%, respectively, while sensitivity and specificity for ROSE (FNA and touch preparation when available) was 44% and 100%, respectively. On average, time spent preparing images was 1 minute 46 seconds. All tissue imaged was recaptured for final evaluation by cytology and pathology. No tissue was lost or destroyed during this study. CONCLUSIONS: In conclusion, use of the Biopsy Assessment System for intraprocedural biopsy evaluation is feasible in assessing lung biopsy adequacy within 2 minutes. Continued development and refinement of diagnostic criteria for malignancy may improve specificity of the technology.

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