First Reported Real-World Use of Pafolacianine and Intraoperative Molecular Imaging for Nodule Localization and Occult Tumor Detection in Malignant Lung Lesions: Results of a Single Institution Pilot

OBJECTIVES
As reported in the ELUCIDATE trial, intraoperative molecular imaging (IMI) with pafolacianine, a fluorescence tagged folate receptor molecule, can improve lung nodule localization and identification of occult tumors. With FDA approval and commercial availability of pafolacianine-IMI for lung cancers, we initiated a pilot study integrating use of this modality into a minimally invasive thoracic surgery practice.
METHODS
Patients with suspicious primary or metastatic cancer in the lung with plans for sublobar pulmonary resection were included. Intravenous pafolacianine infusion was performed the morning of surgery and at least one hour prior to use of IMI. Pre-operative CT scans were used to determine lesion size and lesion depth defined as the shortest distance from lesion edge to pleura. The lung was inspected for fluorescence using a dedicated proprietary fluorescence imaging system.
RESULTS
25 patients (18 female; mean age 67 years) from Jun-Oct 2023 were included. There were no serious adverse events due to drug infusion recorded. Mean lesion size was 14.2 mm (range 6-30 mm) and mean depth was 6.4 mm (range 0-30 mm). MIS (robotic n = 15, VATS n = 10) resection was performed in all patients (segment n=14, wedge n=9, lobe n=2). Pafolacianine-IMI was detected and visualized in 22 of 25 patients (88%). In 7 patients (28%), the primary lesion was detectable with pafolacianine-IMI, but not standard white light. In 2 patients (8%) an occult lesion not visualized on CT was identified with IMI and resected. Final histology included primary lung cancer in 19 patients (76%) (adenocarcinoma n=15, squamous cell carcinoma n=2, carcinoid n=2) and metastatic cancer in 6 patients (24%), including colorectal, renal, urothelial, cervical, and salivary duct carcinoma. All margins were negative for tumor (R0). 3 lesions that were not visualized with IMI were primary lung cancers including 2 adenocarcinoma and 1 squamous cell carcinoma.
CONCLUSIONS
This pilot study reports the first real-world use of pafolacianine intraoperative molecular imaging for cancers of the lung. Pafolacianine-IMI demonstrated a high rate of primary nodule localization across several histologic tumor types, including 28% not detected by standard white light alone. This early experience suggests pafolacianine-IMI may serve as a significant and safe adjunct to MIS resection of the lung, and may further enhance the ability to perform parenchymal sparing operations.

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