

Company

Olympus America Inc.

Drug or Device Name

BF-UC190F Endobronchial Ultrasound (EBUS) Bronchoscope

Category

Medical Technology

Compound/Technical Name

Procedure Name - Endobronchial Ultrasound with Transbronchial Needle Aspiration (EBUS-TBNA)

Trade Name

BF-UC190F

Date of Approval

09/06/2019

Therapeutic Categories

Diagnosis and Staging of Lung Cancer

Indications

Techniques that allow pathological sampling of mediastinal lymph nodes are critical to effective lung cancer staging and diagnosis. These techniques may include mediastinoscopy, CT-guided transthoracic needle aspiration (TTNA), and bronchoscopy (11). Employing a sampling method with a high diagnostic yield and a low complication rate is imperative. EBUS-TBNA, pioneered by Olympus, is recognized by the American College of Chest Physicians (ACCP) as the “best first test” (12, 13). EBUS-TBNA uses a bronchoscope equipped with ultrasound capability to visualize lymph nodes beyond the bronchial wall and determine their exact location for needle aspiration. As the pioneer for EBUS-TBNA, Olympus has provided a minimally invasive method for pathological staging, providing clinicians with an effective and efficient means to diagnose diseases affecting mediastinal lymph nodes (6, 14-20). With its designation by ACCP as a “first” procedure, EBUS-TBNA is preferred over mediastinoscopy based on numerous studies showing a lower complication rate of EBUS-TBNA than that of mediastinoscopy (17, 21-25).

The diagnostic efficacy, sensitivity, accuracy and specificity of EBUS-TBNA procedures have been reported in several studies (6, 14-19, 20-23, 37-43). Guidelines recommend molecular biomarker testing for several cancer-related genes (44). EBUS-TBNA procedures have provided sufficient material for molecular analysis for biomarkers such as EGFR, ALK, ROS and PD-L1 (45-50). Only pathological diagnosis and sampling, like that performed during EBUS-TBNA, can obtain tissue for analysis using next generation sequencing, thus enabling patients to take advantage of personalized genetically specific therapies, an area which is rapidly evolving with new treatments every year.

Background

Lung cancer is the leading cause of cancer-related death worldwide, largely due to the disease not being detected until it is at an advanced stage when most patients become symptomatic. When detected and diagnosed at a late stage, the disease may be too advanced to have a reasonable chance of being cured (1). Thus, early detection of lung cancer is critical in saving lives.

The lung cancer screening environment has been evolving rapidly in recent years. The National Lung Cancer Screening Trial demonstrated that lung cancer screening for eligible patients can reduce mortality by up to 20% (2). In 2021, the U.S. Preventive Services Task Force (USPSTF) updated the screening recommendations first made in 2013, which increased the number of individuals eligible for lung cancer screening based on the availability of evidence supporting the benefits of screening patients at high risk using low-dose computed tomography.

With increasing focus on early detection through updated screening evidence and guidelines, the need has emerged to provide patients and clinicians with critical diagnostic and staging information to guide patient care. Patients may undergo diagnosis and staging in a variety of ways. Some involve the analysis of clinical images, while others involve pathological staging procedures (3, 4). The use of pathologic staging prior to treatment decisions allows for the most accurate assessment of appropriate therapy and a good prognosis (5-7). Analysis of clinical imaging alone for diagnosis and staging (8) may lead to incorrect over-staging in approximately 19% of patients and under-staging in approximately 13% of patients (9). Meta-analyses evaluating concordance between clinical and pathologic staging have shown that patients who are clinically under-staged have poorer overall survival (10). Further, a study shows that 33% of mediastinum characterizations by PET-CT are inaccurate compared to endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) (5).

Development

In partnership with physicians, the idea for an ultrasound device with real-time lymph node visualization and sampling was proposed in 1997. The BF-UC160, in conjunction with the ViziShot™ EBUS-TBNA needle, marked the initial introduction of the EBUS-TBNA procedure worldwide. Subsequent generations, such as the BF-UC180F and the recently launched BF-UC190F in the US (representing the latest Olympus EBUS-TBNA innovation), have been introduced. A significant study performed using animal and cadaver models preceded the first in-human clinical trial, which was completed in 2004 by Dr Kazuhiro Yasufuku (51) at Chiba University (now of Toronto General Hospital). Since that time, a breadth of clinical evidence has underscored the important modality of Olympus' EBUS-TBNA in the field of interventional pulmonology and thoracic surgery and has outlined Olympus' contribution to promote significant advances in lung cancer diagnosis and treatment.

Innovation

Control, accessibility, and reliability are critical factors to a successful EBUS-TBNA procedure. Now, with the feedback from physicians and staff, Olympus has launched the next generation of EBUS bronchoscopes to meet each of these needs. The BF-UC190F scope has a slimmer distal end and a decreased forward oblique angle than the previous EBUS scope, making insertion of the bronchoscope easier. The compact distal tip and increased scope angulation enhances maneuverability, allowing better access to difficult-to-reach lymph node stations in the mediastinum (4L) and hilum (10R) regions of the lung. The BF-UC190F also offers an improved endoscopic image with higher resolution that provides better visualization in the airway designed to assist in the identification of anatomical landmarks and detection of abnormalities.* Used with the Olympus EBUS-TBNA needle portfolio, the BF-UC190F provides physicians better access to difficult-to-reach lymph nodes and lesions, samples of which may improve diagnosis and staging of lung cancer. Olympus

offers a needle selection with the largest inner lumen currently available in the United States, supporting improved sample acquisition for advanced molecular testing and enabling physicians to obtain ample quantities of the high-quality specimens needed for a comprehensive histological analysis, a benefit for patients who may be undergoing genetic testing as part of their cancer journey (52, 53, 54). The breadth of clinical evidence underscores an important modality of Olympus' EBUS-TBNA in the field of interventional pulmonology and thoracic surgery. It also outlines Olympus' contribution to promote significant advances in lung cancer diagnosis, hence the introduction of the BF-UC190F. A recent publication has highlighted how the BF-UC190F allows deeper access into segmental bronchi, therefore improving lymph node staging and the diagnosis of lesions. (55) * Data on file with Olympus as of 09/06/2019

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Attachments