It Is Recommended For Operable Patients With SPN To Go To Surgery

Every year thousands of patients are identified with small pulmonary nodules as a consequence of the increased utilization of chest CT scans. As a result, numerous asymptomatic indeterminate pulmonary nodules (IPN) are being discovered. The ACCP Guidelines recommend the following: In surgical candidates with an indeterminate small pulmonary nodule (SPN) that measures at least 8 to 10 mm in diameter, surgical diagnosis is preferred in most circumstances. In patients with an indeterminate SPN in the peripheral third of the lung who chose surgery, it is recommended that thoracoscopy be performed to obtain a diagnostic wedge resection. For patients with clinical stage I and II NSCLC and no medical contraindication to operative intervention, surgical resection is recommended. In a patient who chooses surgery with an indeterminate SPN that is not accessible by thoracoscopy, bronchoscopy, or transthoracic needle aspiration (TTNA), it is recommended that a diagnostic thoracotomy should be performed.

Surgery Has High Risk

Surgical resection of lung masses has solid clinical evidence and is linked with higher survival rate for malignant lesions. However, it is a high risk, highly invasive procedure associated with higher morbidity and mortality than the other alternatives. Video Assisted Thoracoscopy Surgery (VATS) is a minimally invasive surgery that allows the thoracic surgeon to accomplish the same goal as the comparable open chest procedure but with less trauma (three 1 cm cuts vs. one 10 cm cut), less pain, less morbidity and a shorter hospital stay for the patient. VATS can be used for diagnostic purposes by resection of lung tissue for excisional biopsy or for curative attempts. For curative or therapeutic purposes (depending on the patient’s condition and the extent of the cancer), a segment, lobe or entire lung can be removed.

Not All Small Nodules Are Malignant

The goals in diagnosis and management of small IPN depend on the importance of its setting. Is it a solitary nodule? Is there a prior or current malignancy? Is there a prevalence of benign disease in community? Not all small nodules are malignant; in fact, the majority of nodules found incidentally on screening CTs are benign. Therefore, considering the ACCP Guidelines clearly recommending surgery, the goal should be to obtain accurate diagnosis in the least invasive means possible as quickly as possible.

Less Invasive Surgery Is Challenging When Lesions Are Very Small

Less invasive surgery is limited by the ability to visualize and palpate the small nodule. Inability to visualize or palpate the nodule was reported in 63% to 82% of cases when nodules were ≤10 mm in size and ≥5 mm in distance from the pleural surface. The conversion rate of a diagnostic VATS to a thoracotomy in small SPNs (<10 mm) varies from 46% to 54%. Furthermore non-therapeutic thoracotomy has been reported in 20% to 45% of cases. In order to overcome these limitations, surgical enhancements to pinpoint the lesion as a preparation for surgery have been explored: CT guided bronchoscopy, CT guided percutaneous dye
injection, placement of external wire transthoracically, injecting liquids that solidify and radiopaque markers such as barium. Essentially all of these approaches necessitate an incision and some require valuable CT time.

Achieving New Synergies — Enhancing Communication Between Medical Specialties

To achieve the best results for physicians and their patients through best practice integration of advanced technology, superDimension now offers the opportunity to use its inReach™ System to obtain a tissue sample for diagnosis and to place pre-operative dye markers — both performed transbronchially during the same procedure. This procedure provides enhanced visual localization of a lesion and directs the depth of resection for ‘true’ excisional biopsy with VATS, thus, avoiding confusion in lesion identification that could result in more aggressive surgery.

Now, Bronchoscopists Inject Pre-Op Dye Markers

The inReach System uses Electromagnetic Navigation Bronchoscopy to provide a minimally invasive pathway to peripheral lung lesions — even for patients with procedure restricting conditions. The inReach System enables physicians to locate, diagnose and plan treatment for lung tumors that are otherwise difficult to access safely or precisely with traditional procedures. The inReach System has revolutionized the way physicians think and manage peripheral lung lesions. Now, bronchoscopists can inject pre-op dye markers in peripheral lung lesions and near the pleura surface — providing thoracic surgeons with accurate guidance during VATS.

Tattooing The Lungs — Reaching The Smallest Nondiagnostic, Inconclusive Nodules

During the planning phase, two target points are marked; one target point is marked at the lung lesion center, as small as it is, for biopsy, and another target is marked just beneath the closest overlying pleural surface to facilitate the dye marking while keeping in mind that this will serve as the ‘entry point’ for the surgeon. During the procedure phase, the inReach System is used to navigate to the target location in attempt to diagnose the suspicious lung lesion(s). Biopsies are taken and submitted for pathologic examination. After successful collection of tissue samples, the steerable navigation catheter (LG) is placed back into the guide catheter (EWC) and navigation to the second target point beneath the pleural surface is performed. The EWC is locked into position and the LG is replaced by a 25g sclerotherapy needle. With fluoroscopic guidance, indigo carmine dye is injected adjacent to the pleural surface. The needle is then withdrawn in 5mm increments with repeat injections in each stop with the last injection site being 5mm proximal to the target lesion. Up to 5cc of dye is typically used in this procedure.

Obtain Accurate Diagnosis and Provide Potentially Curative Attempt in the Least Invasive Means Possible as Safely and Quickly as Possible

Accurate

• 3-D visualization and steerable navigation enable access to dye mark locations within the lungs
• Electromagnetic Navigation Bronchoscopy with dye placement provides a means for visual identification of lung nodules that are not visible or palpable at the time of surgery for ‘true’ excisional biopsy
• Optimal visualization allows surgeons to accurately direct the depth of resection

Less Invasive

• Transbronchial inReach procedure reduces risk of damage to healthy lung tissue
• Successful identification of nodule enable surgeons to preserve the VATS approach
• Potential to prevent non-therapeutic thoracotomy
• May allow inoperable patients to be surgical candidates

Potential For Better Outcomes

• Preserves healthy lung tissue
• Reduced complications
• Get a definitive diagnosis and/or treatment solutions in a less invasive manner
• Minimized time between diagnosis and treatment
• Lower morbidity, stress, pain
• Shorter hospital length of stay
Dye Marking May Be Able To Reduce The Time Between Diagnosis And Treatment

Depending on the pathology results, dye marking is followed by a minimally invasive surgical approach in 24–72 hours. The surgeon is able to identify the dye immediately and will cut and stitch around the dye allowing adequate margins while sparing healthy lung tissue.

inReach™ System Expands The Boundaries

The inReach System enables physicians to expand the boundaries of their practice and bridge medical specialties for better outcomes for patients and for the advancement of the medical profession. By using the inReach System for transbronchial injection of dye markers, physicians provide enhanced visual localization of the tumor and guide accurate minimally invasive surgery, thus, offering the potential of reducing their patients’ complication rate and length of stay in the hospital.

Technique at a Glance

Planning Phase
- Two target points are selected with the inReach Planning Software
- One target on lesion
- One target adjacent to the pleural surface

Localization
- Using the inReach steerable navigation catheter (LG) and guide catheter (EWC) under electromagnetic guidance

Marker Placement
- 25g sclerotherapy catheter
- Indigo carmine placed adjacent to the pleural surface and at ~5mm increments until proximal to lesion

VATS
- All patients begin with thoracoscopic approach (VATS)

Tissue Sample Results Obtained by the inReach System are Back in 12 To 24 Hours (Depends On Pathology)
- If diagnostic of non-malignant disease, of metastatic disease, or if inoperable patient then surgery is avoided but other treatment may proceed
- If positive for NSCLC & operable — then proceeds to surgery
- If ‘non-diagnostic’ & operable — then proceeds to surgery
References


