Electromagnetic navigation bronchoscopy
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Record Status
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Citation

Authors’ conclusions
Electromagnetic navigational bronchoscopy (ENB) is an emerging technology used to improve the clinical utility of fiberoptic bronchoscopy (FB) in the management of lung cancer. Early studies identified in horizon scanning reports from CEDIT (2005) and Avalia-t (2007) proposed using ENB as a means of avoiding more invasive and higher risk biopsy procedures. Since publication of the Avalia-t (2007) report, new data have emerged that show ENB is a safe technology in the hands of a skilled bronchoscopist without fluoroscopic guidance and without significantly prolonging procedure time.

Two manufacturers market ENB devices for clinical use: superDimension® Ltd, Plymouth, MN and Northern Digital, Inc., Waterloo, Canada. Information on FDA approval could be found only for the superDimension® system. Two studies used the Aurora® system by Northern Digital, Inc., but neither met criteria for inclusion in this VATAP review: Hautmann (2005)8 was reviewed previously by Avalia-t (2007) and Deguchi (2006)9 used a phantom model. New data using the superDimension® system have emerged on the diagnostic performance in patients with CT-evidence of peripheral lung lesions or solitary pulmonary nodules. These data comprise different patient populations either who were candidates for elective FB (Eberhardt 2007a and 2007b), who had lesions that were inaccessible with FB (Wilson 2007), or who were medically inoperable (Makris 2007). One study conducted a prospective head-to-head comparison of two new emerging technologies ENB vs. EBUS vs. EBUS+ENB (Eberhardt 2007b). Rapid on-site cytologic evaluation (ROSE) was used on all patients in one study (Wilson 2007), which may have enhanced the immediate diagnostic yield, but ROSE is not routinely used in clinical practice.

The growing body of literature suggests that many factors may affect the diagnostic performance of ENB such as: prevalence of malignancy in the population studied, definition of ENB success, % of upper lobe PLL in study (sharper bronchial angle may make navigation even with ENB difficult), diaphragmatic movement, an absent or occluded bronchus leading to the lesion, and procedural differences (number of passes/biopsy specimens, biopsy instrument used, use of fluoroscopy, method of confirmation, use of ROSE or EBUS, and CT-to-body divergence).

The diagnostic yield for ENB ranged from 59% to 68% and was slightly higher when used with EBUS (88%) or ROSE (70%). The sensitivity of ENB ranged from 55%-68%, and both its specificity and positive predictive value were 100%. The negative predictive value across studies ranged from 35%-44%, indicating that ENB can be helpful in ruling in disease but it would not be useful in ruling out malignancy and further workup would be required. Fryback and Thornbury Level 3 and 4 studies would be needed to determine if use of ENB in diagnosing PLLs would reduce the number of surgical biopsy procedures. New data have emerged for the use of ENB with transbronchial needle aspiration (TBNA) in mediastinal staging and in the placement of fiducial markers used in external beam radiation therapy (EBRT), but this latter application has not yet been FDA-approved. ENB for these indications appears safe and technically feasible, but further data are needed to confirm these findings. Problems with ENB that may lower diagnostic yield include respiratory variations that cause larger than anticipated navigation errors and dislodgement of the extending working channel when biopsy instruments are introduced. For mediastinal staging, TBNA with and without ENB needs further study with attention paid to the reduction in false negative results and to the need for further invasive work up (Fryback and Thornbury Level 3 and 4 studies).

In conclusion, the data are insufficient to determine whether use of ENB will avoid surgical biopsy procedures in surgical candidates because of its low negative predictive value. ACCP (2007) recommends that “…Until further progress is made in guidance of bronchoscopy, peripheral nodules that do not have a CT-bronchus sign should be pursued with TTNA.” If done by a skilled bronchoscopist, ENB appears to offer promise for:

- patients in whom a diagnostic bronchoscopy has failed and in whom more invasive procedures pose a significant
risk, such as those with poor pulmonary function and emphysematous changes, or;
• patients who are medically inoperable or those with nonresectable disease.
Ultimately, head-to-head comparisons of FB with and without ENB are needed to determine the true clinical value of
ENB in patients with lung cancer, as indicated not only by diagnostic performance, but also by the impact of the
diagnostic information on patient management decisions and outcomes.

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