



BTS National Audit Report:

Adult Bronchoscopy Audit 2017

National Audit Period: 1 April – 31 May 2017

Dr Jonathan Bennett and Dr Raman Verma

Number of participating institutions and records submitted:

Part 1 (Flexible Bronchoscopy): 3594 records from 139 hospitals (115 trusts)

Part 2 (Endobronchial Ultrasound): 1606 records from 82 hospitals (80 trusts)

Part 3 (Organisation): 120 records/hospitals (105 trusts)

Introduction

This was the largest audit assessing bronchoscopy services and outcomes undertaken globally with 3594 flexible bronchoscopy (FB) procedures and 1606 Endobronchial Ultrasound (EBUS) procedures entered for patients with possible lung cancer in the UK. The audit found areas of good practice, but, as with all services and audits there was room for improvement.

National Improvement Objectives

- 1) Annual Reporting of Bronchoscopic Outcome Data to include biopsy hit rate for histology, immunological and genetic mutation markers for both FB and EBUS at each institution.
- 2) Improve FB diagnostic biopsy rate to at least 85% for visible presumed tumour.
- 3) At least 95% of patients referred for bronchoscopy (FB and EBUS) for possible lung cancer have the procedure within 3 working days of the request.
- 4) Improve pre-procedure processes:
 - a) At least 95% of patients receive a bronchoscopy patient information document, with a standard list of risks explained.
 - b) At least 98% of patients have a patient safety checklist completed.
 - c) 100% of patients are consented by a trained bronchoscopist (Respiratory consultant, HST or nurse bronchoscopist) or reason consent is not taken is documented.

Timeframe: to be achieved by time of re-audit in 3 years

Key Findings

1. The median number of working days (IQR) from request to procedure for FB was 5 (2-9) and for EBUS was 6 (3-9). However, 15% of patients had a FB more than 14 working days following request. This is too long for patients with possible lung cancer.
2. We have demonstrated some excellent standards of care with greater than 95% of patients having evidence of documented consent, use of a safety checklist, monitoring of vital signs and CT prior to FB and EBUS.
3. The rates for FB and EBUS patients receiving a documented standard list of risks and patient information leaflet were unacceptably low at 70-76%.

4. For FB, the diagnostic pathological confirmation rate when a potential malignant lesion was seen was 76% (BTS Guidelines/Quality Standards target is 85%) and only 20% of patients undergoing FB had a histological diagnosis of cancer made at the procedure.
5. EBUS lesions were identified in 97% of cases which were biopsied in 96% of patients. For samples that were sent for molecular analysis there was a greater than 90% success rate.
6. There was variability in the number of medical and non-medical staff supporting each procedure, in the time allocated to each procedure, in the number of trained bronchoscopists and the number of sessions allocated to bronchoscopy between organisations.

Evidence Base

The audit was based upon the BTS Quality Standards for Diagnostic Flexible Bronchoscopy in Adults (2014)¹ (the 'BTS Quality Standards'), which were derived from the BTS Guideline for Advanced Diagnostic and Therapeutic Flexible Bronchoscopy in Adults (2011)² and the BTS Guideline for Diagnostic Flexible Bronchoscopy in Adults (2013)³ (the '2013 BTS Guidelines').

Background

Bronchoscopy is a key diagnostic tool in the investigation of patients with respiratory disease but the configuration, processes and outcomes of bronchoscopy services vary between organisations. BTS has published Guidelines and Quality Standards to ensure equity of service and outcomes for all patients undergoing bronchoscopy.

Aims and Objectives

The aim of the audit was to examine the provision of care and the outcomes of patients having a diagnostic FB (including EBUS) for suspected lung cancer to determine to what extent national standards are being met. The audit questions cover organisational provision of service, pre and peri-procedure care and diagnostic outcomes.

In order to be able to assess outcomes as well as processes the audit was confined to patients having a diagnostic bronchoscopy for suspected lung cancer and thus bronchoscopies for research, those performed on ITU or for non-cancer related indications were excluded.

Key Objectives

- 1) To determine the timeliness of bronchoscopy from initial request
- 2) To determine whether units have safe and informative pre-procedure processes
- 3) To determine the staffing of bronchoscopy units
- 4) To assess the diagnostic accuracy of bronchoscopic biopsies
- 5) To examine whether units have a process for reporting local bronchoscopic procedural outcomes

Having mapped the audit to the BTS Quality Standards the audit comprised three parts:

- 1) Diagnostic Flexible Bronchoscopy (FB)
- 2) Endobronchial Ultrasound (EBUS)
- 3) Organisation of Bronchoscopy Services at each site

Methodology

Instructions and data collection questionnaires were made available on the BTS audit website before the start of the audit, and data entry was via the secure online BTS audit tool.

We asked all UK organisations to enter data for procedures falling during the audit period 1 April to 31 May 2017, with the final deadline for data entry being 31 August 2017. Organisations were asked to enter all eligible cases, or if this was not possible e.g. due to large numbers, then care should be taken to avoid bias, e.g. by entering consecutive cases.

RESULTS

139 hospitals participated in the audit and 5200 bronchoscopy records were entered (3594 flexible bronchoscopies and 1606 endobronchial ultrasound procedures).

For some categories, data were missing or fell outwith the expected range, possibly as a result of transcription error or misunderstanding of requirements. These data points were censored.

Patient Characteristics

The median (mean) age for patients undergoing FB was 67 (65) years and 68 (65) years for EBUS with age ranges from 16 to 98.

The median age for lung cancer patients at diagnosis in the UK is 72 years (National Lung Cancer Audit (NLCA) data 2015⁴).

13% of patients having FB and 11% of patients having EBUS were aged 80 years or more.

There was a male predominance; 57% for FB and 60% for EBUS compared to the NLCA figures which show a slight male predominance of 53%, with males more likely to have higher stage disease.

Pre-Procedural Assessment

In 70% of patients about to undergo FB a patient information leaflet was documented as having been provided compared to 73% of patients about to undergo EBUS.

A standard list of potential risks was provided to 70% of FB and 76% of EBUS patients.

98.7% and 99.4% of patients had documented evidence of written consent for FB and EBUS respectively.

87% of patients had FB consent taken by a consultant, respiratory higher specialist trainee or nurse bronchoscopist compared with 95% of patients undergoing EBUS.

A high proportion of patients had a World Health Organisation⁵ or equivalent safety checklist completed (95% FB, 96% EBUS).

Nearly all patients had a CT chest performed prior to the procedure (95% for FB, 99% for EBUS) although for 14-15% of patients this occurred more than 6 weeks prior to the date of the procedure.

38% of patients having EBUS had a PET scan prior to the procedure.

Sedation

For FB procedures:

87% of patients had sedation.

The majority of these patients (58%) received a single sedative.

The most common single agent sedative used was midazolam (96.3%).

If another sedative was used, there was a preference for fentanyl (58.2%) or alfentanil (33.9%) in these cases.

The mean doses used were:

Midazolam	2.39mg
Fentanyl	55.0mcg
Alfentanil	160mcg

Propofol was used in 105 patients, most commonly in combination with remifentanyl.

A reversal agent was used in 39 patients (1.3%).

For EBUS procedures:

98.5% of patients having EBUS had sedation.

94% of these patients had a combination of sedatives used.

The most common sedative used was midazolam (96.1%), usually in combination with fentanyl (69.7%) or alfentanil (21.7%).

The mean doses used were:

Midazolam	3.15mg
Fentanyl	61.5mcg
Alfentanil	440mcg

Propofol was used in 55 patients, most commonly in combination with remifentanyl.

A reversal agent was used in 28 patients (1.8%).

Procedural Processes

98% of patients having FB and 99% of EBUS patients had documented monitoring of vital signs during the procedure.

For FB procedures:

23% of patients had an endobronchial lesion identified.

90% of endobronchial lesions identified had at least one biopsy performed.

76% of lesions biopsied had a positive malignant diagnosis.

95 additional patients had a malignant diagnosis made from cytological sampling only i.e. brush or wash cytology.

51% of malignant samples were sent for molecular testing with a 91% success rate.

The overall malignancy “hit rate” was 20% i.e. 1 in 5 patients had a cytopathological diagnosis made at FB.

For EBUS procedures:

1561 (97.2%) patients had paratracheal or parabranchial lesions identified of whom 1541 (96%) patients had EBUS-Transbronchial Needle Aspiration (TBNA) performed.

Details of the number of lesions sampled per patient are set out at Table 1.

Number of lesions	1	2	3	4	>4
Number of patients	770	487	199	58	27

Table 1. Number of paratracheal/parabranchial lesions sampled at EBUS

The number of transbronchial needle aspirates was also assessed (see Table 2).

Lesion	1	2	3	4
Samples per lesion (mean)	3.3	2.8	2.5	2.2

Table 2. Number of Aspirates per paratracheal/parabranchial lesion at EBUS

47.4% of patients having EBUS for suspected lung cancer had a malignant diagnosis.

Benign lymphoid tissue was the next most common diagnosis (26%).

10.2% of patients had granulomatous inflammation seen on cytopathology.

10% of patients undergoing EBUS had inadequate or non-diagnostic samples.

Further details of cytopathological diagnoses are set out at Figure 1.

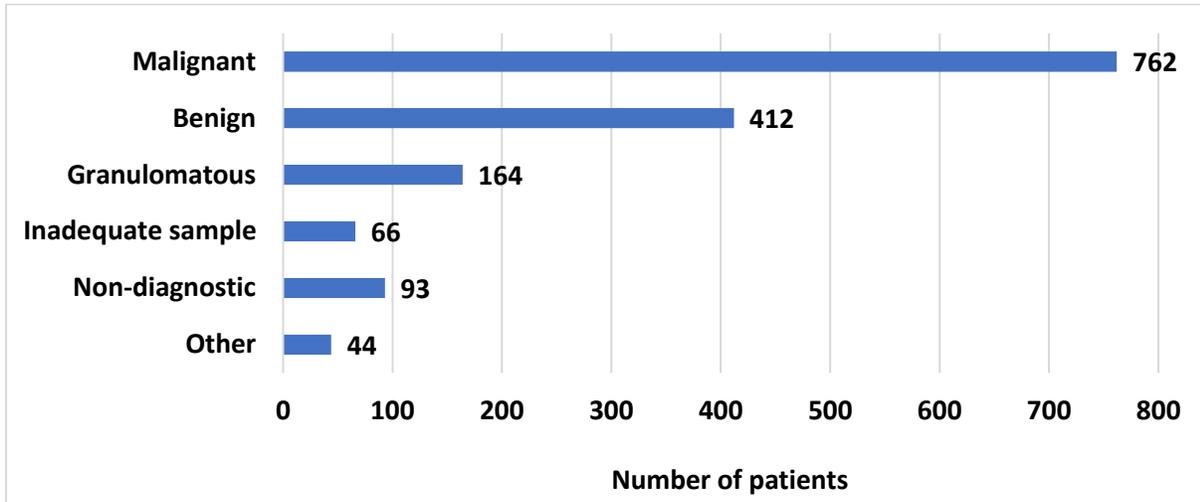


Figure 1. EBUS cytopathological diagnoses

501 (66%) of patients with a positive EBUS-TBNA malignant diagnosis had samples assessed for molecular profiling, of which 461 (92%) were of diagnostic standard.

In 88% of patients undergoing EBUS, it was the first diagnostic pathological procedure with diagnosis being the most common clinical indication for the procedure with combined staging and pathological diagnosis being the next most common (see Figure 2).

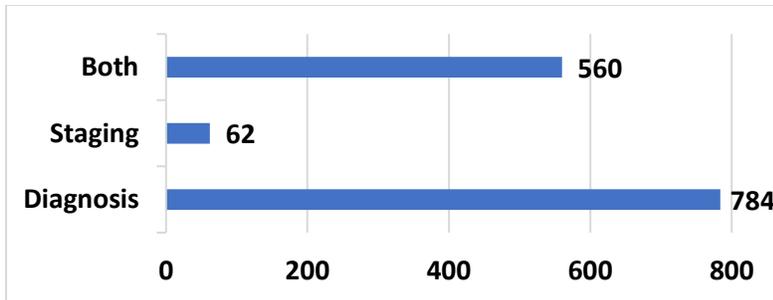


Figure 2. Indication for EBUS

PET-CT is an important diagnostic imaging modality used in the investigation of lung cancer and its staging. We assessed EBUS performance with or without the use of PET-CT. PET-CT was performed in 38% of patients undergoing EBUS with no difference in malignant diagnostic rate (see Table 3).

	Malignant	Benign	Granulomatous	Other
PET-CT done	47%	33%	4%	16%
PET-CT not done	48%	21%	14%	17%

Table 3. Diagnostic outcomes for EBUS related to PET-CT scanning

312 patients (19.4%) of patients undergoing EBUS also had diagnostic FB performed at the same time. For 9 institutions all patients undergoing EBUS had FB.

Organisational Data

- All hospitals provided a FB service (120)
- 76 hospitals provided an EBUS service (63%)
- 27 hospitals provided Therapeutic FB (23%)

Time to procedure may have an impact on the timely diagnosis and subsequent management of patients with lung cancer. For FB, 85% of patients had the procedure within 14 working days of request.

The number of dedicated bronchoscopy sessions and trained bronchoscopists may influence timely access to the procedure and we asked organisations how many bronchoscopy sessions they provided per week.

The median number of dedicated bronchoscopy sessions per week was 2 (mean 2.95). There was a median of 5 (mean 6.15) clinically independent flexible bronchoscopists per organisation.

The median number of trained EBUS operators was 3 (mean 3.33) per institution.

However, there was a wide range of both number of dedicated bronchoscopy sessions, trained bronchoscopists and number of bronchoscopic procedures performed between organisations (see also Table 4 for details of variation in volume of the types of procedures performed).

Staffing of bronchoscopy sessions was variable with qualified nurses, health care assistants, and allied health professionals all caring for patients in the bronchoscopy room.

The median (mean) number of bronchoscopists present at each FB procedure was 1 (1.57) and 2 (1.92) for EBUS.

The median (mean) number of non-medical staff present at FB was 2 (2.69) and at EBUS was 3 (2.89) (most commonly 2 trained nursing staff and one health care assistant).

Procedure	Annual mean (range)	Number of institutions
Flexible Bronchoscopy	270.9 (3-908)	116
EBUS linear	169.3 (11-655)	68
EBUS radial	51.1 (1-175)	14
Therapeutic – stents	7.1 (1-25)	14
Therapeutic – LVRS	11.9 (1-70)	11
Therapeutic – laser	15.3 (4-35)	4
Therapeutic – diathermy	11.75 (3-28)	8
Therapeutic – cryotherapy	22.8 (2-75)	9
Therapeutic – photodynamic	3.7 (2-6)	3

Table 4. Number of procedures performed annually at hospitals in the UK

65% of services had a dedicated bronchoscopy coordinator.

85% of services use an electronic data reporting system.

Reporting of outcome data is viewed as best practice in the UK and is formalised in several surgical specialties (e.g. Cardio-thoracic surgery) and for Colonoscopy via the Joint Advisory Group on GI Endoscopy.

Table 5 sets out details of whether bronchoscopy units and individuals reported their outcomes annually:

Outcomes reporting and feedback	Yes	No	%
Does your institution prepare a report detailing FB performance outcomes annually?			
Institutional level	32	88	26.7
Individual level	27	93	22.5
Has a report on outcomes been discussed at a clinical governance meeting in the last 12 months?	30	90	25
Is information on adverse events during bronchoscopy formally collated and reported each year?	53	67	44.2
Does your institution collect regular (at least annual) bronchoscopy patient feedback?	34	86	28.3

Table 5. Formalised outcome reporting of bronchoscopy services

Conclusions

The BTS bronchoscopy audit was the largest audit assessing bronchoscopy services and outcomes undertaken globally.

We had an excellent response rate with 139 organisations providing data for a total of 3594 FB procedures and 82 organisations contributing data on 1606 EBUS procedures. 120 organisations provided data on the organisation of their services.

Our patient cohort was slightly younger than the National Lung Cancer Audit data for the UK which may reflect that patients undergoing a bronchoscopic procedure will often have an anti-cancer treatment intent and thus have a better performance status than the overall UK lung cancer population. Although 11-13% of patients undergoing bronchoscopy were aged 80 or above, there may be a reluctance to perform the procedure in older patients who may not be suitable for anti-cancer treatment such as radical treatments or systemic chemotherapy.

We have demonstrated some excellent standards of care with greater than 95% of patients having evidence of documented consent, use of a safety checklist, monitoring of vital signs and CT prior to FB and EBUS.

For EBUS, in nearly all patients, lesions were identified (97%) which were biopsied (96%) with confirmation of lymph node sampling in approximately 90% of cases. This was consistent with the BTS Quality Standard 5a target of 88% diagnostic sensitivity for EBUS-TBNA procedures. For those with a malignant diagnosis, greater than 90% of samples assessed had successful molecular sampling which is reassuring given the increasing requirement for genetic and immunological profiling in lung cancer patients.

There was a wide range in the number of bronchoscopic procedures, bronchoscopic sessions and trained bronchoscopists across organisations in the UK. Most centres have 2 or 3 non-medical staff supporting the patients and medical staff in bronchoscopy. Whilst not formally characterised, most services have at least one non-medical staff member supporting and monitoring the patients and one supporting the bronchoscopist.

The median number of working days (IQR) from request to procedure for FB was 5 (2-9) and for EBUS was 6 (3-9). Only 37% of patients had FB within 3 working days or less of request which diminished to 28% for those patients having EBUS. In order to provide a responsive service for patients with suspected lung cancer and to deliver the Lung Cancer Optimum Pathway, the median time from request to performing both procedures needs to be greatly reduced.

For FB, the diagnostic pathological confirmation rate for potential malignant lesion seen was 76%, which is below the 2013 BTS Guideline and BTS Quality Standard 3a target of 85%, and only one in five patients undergoing FB had a histological diagnosis of cancer made at the procedure. Thus four out of five patients had a procedure with associated harm with no cytopathological confirmation of lung cancer. For many patients this will be appropriate as an alternative diagnosis may have been evident from the procedure e.g. pulmonary infection, mucus plug obstruction, and granulomatous disease. However, whilst debatable, an 80% non cytopathological cancer diagnostic rate would seem high and each organisation should assess their diagnostic rate and also the clinical indications for performing bronchoscopy to ensure that patient care is optimised.

Several institutions performed FB in all patients undergoing EBUS. The additional information, if any, produced by such an approach should be assessed more formally, given the increased resource required and potential of increased risk to the patient.

Not surprisingly, EBUS was associated with use of sedation, usually a benzodiazepine (Midazolam) in combination with a short acting opioid (Fentanyl or Alfentanyl). FB was more commonly associated with single agent benzodiazepine (Midazolam). The median doses used are in line with those recommended by the safe sedation guidelines⁶ although there was evidence of very high dose utilisation in occasional patients.

Reversing agents were used sparingly but all events should be assessed and used to guide future practice.

Whilst there was evidence of good practice being delivered, the reporting of bronchoscopic practice and outcomes at formal fora, both for individuals and at institutional level was limited. Given the number of procedures performed, this should become part of routine annual practice.

References

1. BTS Quality Standards for Diagnostic Flexible Bronchoscopy in Adults (2014) <https://www.brit-thoracic.org.uk/document-library/clinical-information/bronchoscopy/bts-quality-standards-for-flexible-bronchoscopy-2014/>
2. BTS Guideline for Advanced Diagnostic and Therapeutic Flexible Bronchoscopy in Adults (2011) <https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guideline-for-advanced-diagnostic-and-therapeutic-flexible-bronchoscopy-in-adults/> (archived)
3. BTS Guideline for Diagnostic Flexible Bronchoscopy in Adults (2013) <https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guideline-for-diagnostic-flexible-bronchoscopy-in-adults/>
4. Royal College of Physicians National Lung Cancer Audit annual report 2015 <https://www.rcplondon.ac.uk/projects/outputs/nlca-annual-report-2015>
5. World Health Organisation Surgical Safety Checklist <http://www.who.int/patientsafety/safesurgery/checklist/en/>
6. Academy of Medical Royal Colleges Safe Sedation Practice for Healthcare Procedures Standards and Guidance (2013) <https://www.rcoa.ac.uk/system/files/PUB-SafeSedPrac2013.pdf>

28 June 2018