Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration: Patient Satisfaction under Light Conscious Sedation

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Key Words

Patient satisfaction · Endobronchial ultrasound · Transbronchial needle aspiration · Conscious sedation

Abstract

Background: Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is an increasingly used mediastinal sampling technique. Many centres use conscious sedation in an ambulatory setting to optimise the flow of patients, save costs and shorten recovery time. The only EBUS-TBNA patient satisfaction study published so far used deep conscious sedation with propofol. To our knowledge, ours is the largest prospective study evaluating the experience of patients undergoing EBUS-TBNA using light conscious sedation without propofol. **Objectives:** To evaluate the patient tolerability of EBUS-TBNA under mild conscious sedation. **Methods:** Eighty-two consecutive patients between January 2011 and November 2011 requiring EBUS-TBNA under light conscious sedation for either mediastinal staging of lung cancer or the diagnosis of suspected mediastinal disease due to malignancy or granulomatous disease were invited to complete a questionnaire after the intervention. The collection of data included the diagnostic yield, the number and size of nodes sampled and the dose of sedative medication administered. **Results:** The average dose of sedative agents administered was 59.4 µg fentanyl and 3.2 mg

midazolam. The sensitivity of EBUS-TBNA for the cancer staging, cancer diagnosis and granulomatous disease cohorts was 90.0, 94.1 and 87.5%, respectively. The most commonly reported symptom was a cough in 65 (93%) patients. Of these patients, 46 (71%) described the severity as being mild. All but 9 patients (61/70 or 87%) stated that they would definitely or probably undergo a repeat EBUS-TBNA. **Conclusions:** This single-centre UK study confirms that EBUS-TBNA under light conscious sedation is a well-tolerated procedure maintaining the expected diagnostic performance, with patients reporting a high degree of satisfaction with both the test and the information received beforehand.

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Background

Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is a mediastinal sampling technique recommended by the National Institute of Clinical Excellence [1] for the staging and diagnosis of non-small-cell lung cancer. It is also used to diagnose unexplained accessible mediastinal adenopathy and lesions [2]. The procedure can be carried out under general anaesthesia with the use of airway adjuncts but is commonly performed under light conscious sedation in UK centres in an endoscopy room with a short-recovery area.

Avoidance of a general anaesthetic removes the risks (albeit very small) attending the anaesthesia itself, shortens the post-procedure recovery time and reduces costs by avoiding the need for additional anaesthetic and theatre personnel, drugs and equipment. Accurate coding using the specific EBUS-TBNA tariff is essential, however, as the procedure involves significantly higher costs than conventional bronchoscopy [3]. Patients with multiple medical comorbidities or poor functional Eastern Cooperative Oncology Group performance status [4] may undergo EBUS-TBNA as a minimally invasive alternative to surgical evaluation of the mediastinum via mediastinoscopy when considering the more invasive nature of the latter procedure and the general anaesthesia [5]. EBUS-TBNA performed under light conscious sedation (as opposed to general anaesthesia or deep conscious sedation) may be particularly advantageous in this group of patients. Diagnosis of malignant lesions in such patients is of particular relevance, as recent evidence suggests that patients with a performance status of 2 can benefit from first-line chemotherapy for symptom control and survival [6].

The size of the EBUS-TBNA scope differs from a conventional bronchoscope [7], as the external diameter of <7 mm requires it to be inserted orally [8]. Previous studies assessing patient satisfaction with conventional bronchoscopy have suggested lower scores with this route [9]. Patient satisfaction has increasingly been recognised as an important aspect of health care and also to be associated with the willingness of patients to continue to attend appointments [10]. Procedural and process-of-care factors have been found to affect patient satisfaction. The most important factors to have been identified include the interpersonal skills of the staff, the provision of information and aspects concerning waiting times. These are all areas of particular relevance for patients attending day-case procedures such as EBUS-TBNA [10].

There is only 1 published study, from Australia, that has assessed patient satisfaction during EBUS-TBNA; it used deep conscious sedation with propofol, albeit in only 28/41 patients [11]. In many countries, the use of propofol by non-anaesthetic physicians is not permitted, and the recommendation of the American Society of Anesthesiologists is that another appropriately skilled individual (i.e. other than the operator) should be present in the endoscopy room in order to monitor sedation levels [12]. This is not feasible in most hospital endoscopy units in the UK. Given the extra resources and costs required, light conscious sedation tends to be used so as to avoid

the need for reversal agents, a prolonged recovery period and more advanced monitoring.

This study was carried out to investigate the experience of patients undergoing EBUS-TBNA using light conscious sedation (without propofol) and without the use of an artificial airway, airway adjunct or anaesthetic assistance. Patient satisfaction was assessed concerning factors related to the procedure and the process-of-care.

Methods

Study Patients

We prospectively examined the patient satisfaction of 82 consecutive patients referred to the North Bristol Lung Centre for EBUS-TBNA over a 10-month period between January and November 2011 for pre-operative staging of the mediastinum in lung cancer patients ($n = 14$), diagnosis of high-volume mediastinal disease due to suspected malignancy ($n = 50$) and diagnosis of suspected granulomatous disease (i.e. sarcoidosis or tuberculosis, $n = 18$). Patients were referred locally and also from surrounding hospitals within the same Cancer Network. Informed consent was obtained from all patients. Patients were excluded from the study if language barriers or cognitive impairment affected their ability to give informed consent or to complete the paper-based questionnaire. It is the practice in our unit to ensure that all patients are given a written information leaflet prior to attending for the procedure. This study was part of the ongoing standard of care for patients undergoing EBUS-TBNA, and we established that no specific ethical approval was required when we consulted our local research and ethics committee.

Procedure

EBUS-TBNA was performed under local anaesthesia and conscious sedation as previously described, using a dedicated convex-probe ultrasound bronchoscope (Olympus BF-UC260FW, Olympus, Tokyo, Japan) with the patient lying supine [13]. As part of standard practice, all patients underwent conventional fiberoptic bronchoscopy before EBUS-TBNA and any other clinically indicated bronchoscopic procedure (broncho-alveolar lavage, endobronchial biopsy or transbronchial biopsy). Conscious sedation was assessed by verifying and recording purposeful response to a verbal command and/or light tactile stimulation whilst preserving spontaneous ventilation (as confirmed by respiratory rate and pulse oximetry monitoring) and unaffected cardiovascular function (as confirmed by blood pressure and heart rate monitoring). The staff consisted of the proceduralist, an assistant and 2 endoscopy nurses. More specifically, there was no anaesthetist, cytologist or cytotechnician present in the room (rapid on-site evaluation for cytology [14] was not routinely available as samples were analysed by 2 lung histopathologists who double-reported all results). Modest doses of intravenous midazolam and fentanyl were administered at the discretion of the operator for achieving light conscious sedation. All procedures were performed by 1 of 2 physicians in an endoscopy suite with no anaesthetist present. Topical xylocaine (10%) was used to anaesthetise the oropharynx prior to oral intubation through a protective mouth guard. Lidocaine (4%) was applied via the bronchoscope to the vocal cords, trachea and

bronchial tree. Following endobronchial examination of the bronchial tree, the mediastinal nodes were identified under ultrasound. Sampling was carried out using dedicated 21- or 22-gauge EBUS-TBNA sampling needles (NA-201SX-4021 and NA-201SX-4022 Olympus ViziShot Aspiration Needles). The needle size was chosen at the discretion of the operator. A minimum of 2 needle passes were carried out at each sampling station or until the operator was satisfied with the size and nature of the sample obtained (this resulted in 4 passes being performed at most stations to obtain at least 2 tissue cores). Patients were observed in an adjacent recovery area for a minimum of 2 h before they were discharged. The presence of lymphocytes in the EBUS-TBNA sample was regarded as being an adequate sample. EBUS-TBNA samples that were negative for malignancy or granulomatous disease but where there was an ongoing high clinical suspicion were regarded as 'true negative' for the above if there had no progression of lymph nodes (or development of granulomatous disease), no parenchymal disease on clinical follow-up for 12 months on imaging or if subsequent lymph node sampling by mediastinoscopy (or other means) was also negative.

Procedural and Demographic Data

The age and gender of the study participants, the number of previous bronchoscopic tests, the doses of local anaesthetic and sedative medication administered, the average duration of the procedure and procedure-related, predefined complications were recorded. The operator recorded the need for reversal agents and any complications linked to sedative drugs. Patients were monitored for the development of any predefined complications during EBUS-TBNA and during the period (usually 60 min) in the recovery area before discharge. Predefined complications included: desaturation >6% from baseline saturation, systolic blood pressure <70 or >200 mm Hg, heart rate <40 or >130 bpm, respiratory rate <6 or >25 breaths/min, agitation precluding performing EBUS-TBNA, the need for any specific reversal agent (naloxone or flumazenil) or intravenous fluids, ongoing endobronchial bleeding post-biopsy requiring endobronchial adrenaline or cold saline, pneumomediastinum, pneumothorax or haemomediastinum.

Patient Questionnaire

All patients who were able to give their informed consent were invited to complete a paper-based anonymised questionnaire. They were assured that the questionnaire responses would not affect their current or future care. Patients were specifically instructed to complete and return the questionnaires within 48 h after discharge from hospital, in order to allow sufficient time for the sedation to wear off but soon enough to recall the experience.

The questionnaire was used to assess the process and the procedure-related factors (table 1).

Statistics

The diagnostic utility of EBUS-TBNA was calculated for each cohort separately to evaluate performance in all of the cohorts, i.e. staging, non-staging suspected cancer and suspected granulomatous mediastinal disease. A contingency table analysis was performed using GraphPad Prism Software v5 (San Diego, Calif., USA) using the Fisher exact test to derive sensitivity, negative predictive value, accuracy and prevalence.

Table 1. Patient questionnaire

Age		
Gender	Male/Female	
Is this the first time you have had a bronchoscopy?	Yes/No	
Were you given adequate written information before the day of your test?	Yes/No	
Were you given adequate verbal information before the day of your test?	Yes/No	
Did you have the opportunity to ask any questions before the test?	Yes/No	
Were the risks of the test explained to you?	Yes/No	
I felt comfortable throughout the test.	Strongly disagree/Disagree/Neutral/Agree/Strongly agree	
I was given enough time for recovery.	Strongly disagree/Disagree/Neutral/Agree/Strongly agree	
I was treated with dignity and respect before, during and after the test.	Strongly disagree/Disagree/Neutral/Agree/Strongly agree	
How much of the following symptoms did you experience during the test?	Chest discomfort	None Small amount A lot
	Shortness of breath	None Small amount A lot
	Throat discomfort	None Small amount A lot
	Cough	None Small amount A lot
Have you received details of who to contact if you need to ask anything further?	Yes/No	
Is there anything that we could have done better?	Please comment	
Was there anything that we did particularly well?	Please comment	
Would you be willing to have the test done again (if necessary)?	Definitely not/Probably not/Unsure/Probably would/Definitely would	

Table 2. Diagnostic performance of EBUS-TBNA**a** For staging cohort (n = 14)

Stage (PET)	Total	Number	EBUS-TBNA diagnosis	Final diagnosis (method, if not EBUS-TBNA)	EBUS-TBNA performance
2A	2	2	reactive	reactive (MEDI)	True -ve
3A	10	2	reactive	reactive (MEDI)	True -ve
		1	reactive	adNSCLC (MEDI)	False -ve
		3	sqNSCLC	sqNSCLC	True +ve
		2	adNSCLC	adNSCLC	True +ve
		1	NSCLC-NOS	NSCLC-NOS	True +ve
3B	2	1	MM	MM	True +ve
		2	adNSCLC	adNSCLC	True +ve

b For high-volume mediastinal disease (n = 50)

Diagnosis	Total	Number	EBUS-TBNA diagnosis	Final diagnosis (method, if not EBUS-TBNA)	EBUS-TBNA performance
Malignancy	34	11	adNSCLC	adNSCLC	True +ve
		8	sqNSCLC	sqNSCLC	True +ve
		5	SCLC	SCLC	True +ve
		2	NSCLC-NOS	NSCLC-NOS	True +ve
		2	BCL	BCL	True +ve
		2	RCC	RCC	True +ve
		1	BC	BC	True +ve
		1	CRC	CRC	True +ve
		1	reactive	adNSCLC (bone)	False -ve
		1	reactive	adNSCLC (CTBx)	False -ve
Benign	16	9	reactive	reactive (interval CT)	True -ve
		6	reactive	reactive (MEDI)	True -ve
		1	cyst	cyst (MRI)	True -ve

c For suspected granulomatous mediastinal disease (n = 18)

Diagnosis	Total	Number	EBUS-TBNA diagnosis	Final diagnosis (method, if not EBUS-TBNA)	EBUS-TBNA performance
Sarcoidosis	15	13	sarcoidosis	sarcoidosis	True +ve
		2	reactive	sarcoidosis (MEDI)	False -ve
TB	1	1	TB	TB	True +ve
Reactive	2	2	reactive	reactive (MEDI)	True -ve

d Summary according to the cohorts (n = 82)

Cohort	Number	Sensitivity, %	NPV, %	Accuracy, %	Prevalence, %
Suspected malignancy, staging EBUS-TBNA	14	90.0	80.0	92.9	71.4
Suspected malignancy, diagnostic EBUS-TBNA (high-volume mediastinal disease)	50	94.1	88.9	96.0	68.0
Suspected granulomatous mediastinal disease	18	87.5	50.0	88.9	83.3

adNSCLC = Lung adenocarcinoma; BC = metastatic breast cancer; BCL = B cell lymphoma; CRC = metastatic colorectal cancer; CTBx = CT-guided lung biopsy; MEDI = mediastinoscopy; MM = metastatic melanoma; MRI = magnetic resonance imaging; NPV = negative predictive value; NSCLC-NOS = non-small cell lung cancer, not otherwise specified; PET = positron emission tomography; RCC = metastatic renal cell carcinoma; SCLC = small-cell lung cancer; sqNSCLC = squamous cell carcinoma; TB = tuberculosis.

Results

A total of 70/82 (85%) patients responded to the questionnaire. Three patients who consented via an interpreter for EBUS-TBNA were subsequently unable to complete the questionnaire due to language difficulties and were excluded from the analysis. The average age of the patients who completed the questionnaire was 61.6 years and 36/58 (62%) were male. The mean (SD) number of nodes sampled was 1.7 (0.9), range 1–5, equating to 5.0 (2.6) needle punctures per patient. The mean size of the sampled nodes was 2.0 cm (0.8), range 0.5–4 cm.

The final diagnosis and diagnostic performance for each of the 3 groups are shown in table 2 with regard to sensitivity, NPV, diagnostic accuracy and prevalence of suspected disease in each cohort. Thirteen patients underwent additional diagnostic or staging investigations: 10 mediastinoscopies (5 for staging and 5 for diagnosis), 1 bone biopsy, 1 CT-guided lung biopsy and 1 MRI thorax. In the non-staging suspected malignancy cohort, 9 patients also underwent interval CT scanning to monitor mediastinal nodes when reactive nodes were detected on EBUS-TBNA but mediastinoscopy was not suitable. No patients underwent repeat EBUS-TBNA.

The adequacy for genotyping for EGFR mutations in those with lung adenocarcinoma was 91.7% (11/12 adenocarcinoma EBUS-TBNA samples were successfully tested with only 1 failure due to inadequate material; 10 patients were negative for EGFR mutation and 1 was positive). It is our local practice not to test for EGFR in other non-small cell lung cancer types.

The average dose of sedative agents administered was 59.4 µg fentanyl and 3.2 mg midazolam. The average dose of 4% topical lidocaine used was 560 mg. All but 1 patient felt that they had been provided with adequate written and verbal information, had been given adequate opportunity to ask questions and had had all potential risks explained to them prior to undergoing the test. In addition, 62/66 patients (94%) stated that they had been provided with details of who to contact if they required further information regarding the test prior to attending for the procedure. The most commonly reported symptom was cough in 65 patients (93%); 46 (71%) of them described this as mild (table 3). The mean duration of the procedure was 34 min (range 19–49; this included the initial conventional bronchoscopy and 18 broncho-alveolar lavage, 11 endobronchial biopsy and 2 transbronchial biopsy procedures). All but 1 patient agreed that adequate time had been given for recovery following the procedure. All but 9 patients (i.e. 61/70 or 87%) stated that they

Table 3. Frequency and severity of symptoms reported during EBUS-TBNA

Symptom	Frequency and severity of symptoms during procedure, n (%)		
	None	Mild	Significant
Shortness of breath	47 (67)	18 (26)	5 (7)
Throat discomfort	32 (46)	37 (53)	1 (1)
Chest discomfort	50 (71)	18 (26)	2 (3)
Cough	5 (7)	46 (66)	19 (27)

would definitely/probably undergo a repeat EBUS-TBNA. Five (7%) stated that they would definitely/probably not undergo the procedure again if required and 4 (6%) were unsure. There were no procedure-related complications reported. No patients required administration of reversal agents and there were no sedation-related complications.

Discussion

This large, single-centre UK study confirms that EBUS-TBNA performed under light conscious sedation in an endoscopy suite is associated with high levels of patient satisfaction whilst maintaining expected diagnostic performance in cancer staging, cancer diagnosis and diagnosis of granulomatous mediastinal disease [5, 15]. Previous studies have reported lower levels of patient satisfaction with oral intubation than with nasal intubation in patients undergoing conventional bronchoscopy [9]. Our study does not support this finding. Since the EBUS-TBNA bronchoscope has a larger external diameter, all procedures were carried out via the oral route. Despite this, we can report high levels of satisfaction using equivalent doses of sedative agents and topical anaesthetic.

Steinfort and Irving [11] also report high levels of patient satisfaction with EBUS-TBNA with staging for lung cancer being performed on 28/41 patients. However, in their study, combinations of midazolam, fentanyl and propofol were used with an additional skilled person, not the operator, assessing sedation during the procedure. The sub-group that received fentanyl and midazolam only (as in our study) received, on average, higher doses of these agents compared with our study (midazolam 3.8 ± 1.4 mg, fentanyl 75 ± 28 µg). The average duration of their procedures was 31 min, which is slightly shorter than the 34 min in our study. We acknowledge that a higher pro-

portion of staging EBUS-TBNA procedures was performed in their series (28/41 or 68% vs. 14/82 or 17% in our series). With no significant difference in patient satisfaction being noted in this sub-group, we feel that a comparison with this study is valid. We also used a higher-gauge EBUS-TBNA needle (21-gauge) in a significant proportion of our patients, and this was well tolerated (there are no published data on needle gauge tolerability). This suggests that high levels of patient satisfaction can still be achieved using more frugal doses of sedation and despite a slightly longer procedure time, irrespective of needle gauge. This is important in the context of lung cancer, where increasingly complex cases with patients of more advanced age, comorbidities and higher disease stages are referred for the consideration of treatment. Such patients may be particularly susceptible to sedation-related complications if high doses are administered.

This study also demonstrates that light conscious sedation can be achieved safely without the assistance of an additional anaesthetist in the room; we report no sedation-related complications, no patients required the administration of reversal agents and the findings from our patient tolerability data are positive. We report a high degree of satisfaction with both procedural and process-of-care-related factors; almost all patients were satisfied with respect to the adequacy of verbal and written information prior to the procedure. This is very important, with it increasingly being recognised that patient satisfaction and willingness to return for future treatments is associated with the adequacy of information provided. We consider adequate information and other process-of-care-related factors to be parameters of paramount importance to patient satisfaction. In our institution, patients are provided with a written leaflet as well as an opportunity to discuss the procedure with a specialist nurse, either face-to-face or by telephone prior to attendance for the test. Our study supports the continued use of this approach.

There were some limitations to our study. We accept that there was a 15% failure to return information and we cannot exclude the possibility that the reason for this failure was due to reduced patient satisfaction; however, we feel that an 85% return compares favourably with many other patient surveys. The generally consistent, positive results (especially with regard to the provision of information) meant that our study was not significantly diminished in this respect. It was a single-centre study, but is relevant to UK practice and contains more results than the existing published study with regard to both the needle gauges and with assessment over a longer procedure time. No control group was used, but this was because it

is good practice to assess patient satisfaction for all patients as a standard of care. This also reflects current practice in specialist centres nationally. We excluded 3 patients who were unable to complete the questionnaire as a result of language barriers. They represent an important group of patients, who report lower levels of satisfaction with health care and a reduced willingness to return for treatment [16] because of the difficulty in obtaining adequate information regarding procedures. The impact of this in other centres with more diverse populations (i.e. more patients in this situation) should be considered. All the EBUS-TBNA procedures were performed by two operators at our institution (A.J. and A.R.L.M.), who also administered the sedation. It could be argued that the learning curve for the development of skills in EBUS-TBNA may affect patient satisfaction, but the primary operators were fully trained prior to the initiation of the study, so this was not relevant. Any such effect is also likely to adversely affect patient satisfaction, but this topic requires independent study [17–19]. We did not specifically investigate the impact of performance status or semi-recumbent positioning on patient satisfaction. It could be postulated that patients with more advanced disease or multiple comorbidities may report lower levels of satisfaction, which may be also position-dependent. In addition, there is no specific evidence on the effect of pre-test diagnosis of probable malignancy on patient satisfaction and willingness to return for treatment. We assessed patients for up to 48 h after the procedure to reduce the chances of attenuated patient recall impacting on our results. However, Maguire et al. [20] assessed patient experience for up to 1 month following bronchoscopy and found no difference in patient recall.

In conclusion, EBUS-TBNA carried out under light conscious sedation with adequate information provision is associated with a high level of patient satisfaction and maintains expected diagnostic performance. This study supports the use of EBUS-TBNA under light conscious sedation, which also reduces costs and allows quick recovery. It would be of interest to conduct more prospective studies to examine the effect on patient satisfaction of suspected malignant diagnosis, performance status, rapid on-site evaluation for cytology, stage of training, positioning and the number of samples taken.

Financial Disclosure and Conflicts of Interest

The authors have no conflict of interest or funding to declare.

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