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Synoptic procedural reporting to improve quality indicators in systematic Staging Endobronchial Ultrasound (EBUS) in Non-small cell lung cancer (NSCLC): protocol for an ambispective multi-centre quality improvement study

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Study protocol

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Abstract

Background:

Accurate mediastinal staging by systematic staging endobronchial ultrasound (EBUS) is essential for prognosticating and guiding management in curative-intent treatment in non-small cell lung cancer (NSCLC). Narrative procedural reports are often incomplete and inconsistent between clinicians, limiting assessment of procedural quality and meaningful audit. Synoptic (structured, check-list style) reporting has improved documentation completeness and procedural quality in other domains of medicine, and a recent Australian multicentre study demonstrated synoptic reporting significantly improved both report and procedural quality in staging EBUS. This ambispective, international, multicentre study aims to evaluate whether synoptic procedural reporting improves quality indicators of systematic staging EBUS, encompassing both process and outcome measures, and will assess acceptability and feasibility to proceduralists.

Methods:

This ambispective multicentre, single-arm interventional study will recruit approximately 15 lung cancer services with substantial EBUS procedural volume. Eligible patients will have known or suspected clinical stage IB-IIIC NSCLC undergoing systematic staging EBUS for treatment planning. Each centre will implement a mandated synoptic report requiring documentation for each of the five mediastinal lymph nodes: examination, size of node and biopsy details. Three months of staging procedures will be contributed prior to and following implementation of this reporting practice.

The primary outcome is the proportion of patients with a complete staging procedure. Secondary outcomes include PET-occult lymph node metastases detection, nodes sampled, radiologically normal node sampling, inter-site variance, and proceduralist feasibility/acceptability.

A sample of 590 patients (295 pre-, 295 post-intervention) provides 80% power to detect an 8% increase in complete staging. Mixed-effects logistic and Poisson regression, with random effect for centre and adjustment for pre-specified baseline case-mix covariates, will be used.

Discussion:

This study will provide the first international multicentre evaluation of whether synoptic reporting improves procedural completeness and clinically meaningful outcomes in systematic staging EBUS. Demonstrating improved complete staging procedures and PET-occult lymph node detection, with proceduralist acceptability, would support widespread adoption of synoptic reporting as a quality improvement tool, strengthen alignment with WABIP quality frameworks, reduce variance in care, and support more accurate multidisciplinary decision-making for NSCLC patients.

Trial registration:

Australian New Zealand Clinical Trials Registry (ANZCTR), ACTRN12625001281482. Registered 18 November 2025. Retrospectively registered.

Background

Accurate staging of the mediastinum is critical in determining prognosis and optimal management in non-small cell lung carcinoma (NSCLC) (1, 2). A systematic staging linear Endobronchial Ultrasound (EBUS) procedure examines and samples the mediastinal and hilar lymph nodes, accurately determining the extent of lymph node metastases.(2)

The extent of metastatic lymph node is of crucial importance, guiding the choice between curative-intent treatment modalities, such as surgical resection, chemoradiotherapy or neoadjuvant therapy followed by resection in M0 disease. (3). Accurate staging is equally important in early stage (T2N0) disease, where detection of PET-occult nodal metastases can redirect patients from upfront resection towards a neoadjuvant treatment paradigm, avoiding post-operative pathologic upstaging. This nodal status is established through systematic staging linear EBUS, with interpretation requiring review of both the procedural report and the pathology report of the samples taken. These combined results are then used by the broader lung cancer multidisciplinary team.

Historically, procedure reports in medicine consisted of narrated telephone or computer dictations by the proceduralist,(4–6), transitioning to typed narrative reports with the digitisation of healthcare. Narrative reports often lack key information (6) and due to the personalised nature are inconsistent between clinicians. (4, 6). When procedural reports do not contain adequate information, the ability to analyse whether the procedure was of adequate quality is significantly impaired. In a retrospective review of procedural reports at our institution, systematic staging reporting was of particularly poor quality, with a large proportion of incompletely documented mediastinal staging procedures. (7)

Synoptic reporting – a structured report with a check-list style manner - is a potential solution to the challenges of narrative reporting and has been adopted by other procedural/surgical craft groups (6, 8, 9). Synoptic reports capture the items critical for patient care and audit.(6, 8, 9). In surgery, for example, synoptic reporting for laparoscopic cholecystectomy and pancreaticoduodenectomy found synoptic reports were 98.5%-99.7% complete compared with 70–76% for matched dictated reports, with the missing items in dictated reports disproportionately being essential outcomes such as resection margin status. (10)

A recent Australian multicentre pilot study (11) evaluating synoptic reporting in systematic staging EBUS, demonstrated that the introduction of synoptic reporting significantly improves both the quality of procedural documentation, and quality of the procedure. Report completeness, defined *a priori* as fidelity to six mandated reporting domains, increased significantly across four of these domains. Procedural quality was assessed using both process and outcome measures. The process measures, namely the number of lymph nodes sampled per procedure and the proportion of patients with sampling from radiologically normal lymph node, showed marked increases, while the outcome measure of PET-occult

lymph node disease also increased significantly, from 3.1% to 11.7%. These findings support synoptic reporting as a quality improvement intervention with potential for impact beyond documentation to improve procedural thoroughness and clinically meaningful outcomes in lung cancer staging.

This ambispective international multi-centre study will examine the use of synoptic procedural reporting in patients with clinical stage Ib to IIIC NSCLC planned for curative intent. We hypothesise that use of synoptic procedural reporting improves quality indicators of systematic staging EBUS procedures, encompassing both process measures (e.g. nodes sampled) and outcome measures (e.g. detection of PET-occult nodal metastases).

Aims of the study include:

1. To evaluate whether the implementation of a synoptic procedural report for EBUS results in improved patient outcome metrics, specifically
2. To evaluate variance in care of systematic mediastinal staging with EBUS
3. To assess the acceptability and feasibility of completing synoptic reporting as a standard component of multidisciplinary care from the perspective of proceduralists.

Methods/Design

Study design: This is an ambispective international multi-centre single arm interventional study.

Setting: International lung cancer services

Intervention: Implementation of a synoptic procedural report for systematic staging EBUS procedures.
Patient Population: Patients with known or suspected clinical stage Ib to IIIC non-small cell lung cancer. Inclusion and exclusion criteria are recorded in Table 1. All consecutive eligible patients within the three-month window will be included in both phases, with a screening log of all systematic staging EBUS procedures recorded at each site. Patients subsequently found to have benign disease, small cell histology or M1 disease will be retained in all analyses.

Institutional Criteria: Centres must routinely perform systematic staging EBUS and be of substantial volume to contribute a minimum of 20 cases to both phases of the ambispective design.

Table 1: Inclusion and exclusion criteria	
Inclusion criteria	Exclusion criteria
Hospital level: - Able to nominate a lead EBUS proceduralist - Systematic staging EBUS routinely performed at institution for stage IB-IIIC NSCLC - Institution volume such that the site expects to be able to contribute a minimum of 20 cases - Willingness of proceduralists to complete synoptic reports with standardised reporting for all 5 mediastinal lymph node stations with patients undergoing systematic staging	**Hospital level:** - Insufficient number of procedures conducted at pre- or post-test stages of the study
Patient level: - Known/suspected NSCLC, clinical stage IB to IIIC undergoing systematic staging EBUS for evaluation of curative-intent treatment	**Patient level:** - Medical co-morbidities preclude bronchoscopy - Medical co-morbidities or known pathologic extent of disease preclude consideration of curative-intent therapy - Age <18 years

Data collection

Patient demographic data including age, gender and smoking status will be collected.

Radiologic features from Positron Emission Tomography (PET)/Computed Tomography (CT) scans will include location of primary tumour, presence of enlarged and/or PET avid lymph nodes at each station. Whether PET/CT was performed prior to EBUS will be recorded, and the number of radiologically abnormal mediastinal nodes (enlarged ³10mm short axis on CT and/or FDG avid) will be derived. Clinical TNM stage prior to EBUS will be documented.

Procedural data will be extracted from the EBUS procedural report by participating centres, corresponding to the mandated synoptic reporting fields outlined below. In addition, the total number of nodes sampled per procedure and whether at least one radiologically normal node was sampled will be documented.

Only pseudonymised data will leave participating sites, entered directly into REDCap. The re-identification key will remain at each site. Data transfer will comply with local data protection regulations and the conditions of each site's institutional ethics and governance approval.

Synoptic Reporting Procedure

Proceduralists at participating sites will be asked that all procedural reports for systematic staging EBUS procedures contain the following information

1. Indication specified as 'Systematic Staging EBUS'

2. Clinical stage of patients lung cancer (prior to bronchoscopy being performed)

3. For each of the 5 mediastinal lymph node stations, comment on whether

1. The lymph node station was examined (Y/N), where examined denotes ultrasonographic interrogation of the expected nodal station location, coded as Y irrespective of whether a lymph node was visualised.

2. Size of the lymph node (mm)

3. Whether the lymph node was biopsied (Y/N) and if so, how many needle passes

Other parameters of the report will not be mandated in this study, and physicians will use the reporting software already in use at their site. The synoptic procedure report will be used for all patients undergoing a systematic staging EBUS procedure as part of their routine clinical care. There will be no changes to patient care.

Pathological data collected will be the cytopathology result from each of the mediastinal lymph nodes sampled and final histopathological diagnosis. The number of distinct nodal stations from which samples are received will be recorded from the pathology report rather than the procedural report. Station-level pathological positivity will additionally be used to derive, for patients with N2 disease, whether nodal involvement can be classified as N2a (single-station), or N2b (multi-station) under the IASLC 9th edition TNM classification.

Acceptability, usability, and feasibility

To assess the acceptability, usability and feasibility of synoptic reporting from the perspective of the proceduralists, participating proceduralists will be asked to complete an online survey prior to the implementation of synoptic reporting and following the completion of study period. Both surveys will assess the proceduralists perceptions of the acceptability, usability and feasibility of incorporating synoptic reporting into routine practice. Survey responses will be summarised descriptively, and numerical values will be assigned to the likert scale values to describe changes between pre- and post-implementation, with chnages between pre- and post- implementation surveys assessed with Wilcoxon signed rank tests for paired ordinal responses.

Outcomes

The primary outcome is the proportion of patients with suspected or confirmed non-small cell lung cancer (NSCLC) undergoing systematic staging who have a complete procedure. A complete procedure is defined as examination of all five mediastinal lymph node stations (7, 2R, 2L, 4R, 4L) with sampling of

any nodes sonographically >5mm in short axis, or meeting any criteria for suspicious morphology as per Fujiwara classification (round shape, distinct margin, heterogeneous echogenicity, presence of central necrosis sign and absence of a central hilar structure)(12). An incomplete procedure is defined as a procedure where not all 5 lymph node stations are examined and/or failure to sample any lymph node per the above criteria.
Hilar stations (10 and 11) are excluded from the completeness definition, as these five stations form the systematic staging standard in the proposed quality indicators(13), and previous studies suggest a very low rate of up-staging from N0 to N1 following hilar examination. (14)

Secondary outcomes include:

1. Proportion of patients with PET-occult lymph node metastases detected, defined as histologically confirmed malignancy in a station that was neither FBG-avid nor ³ 10mm on short axis on CT.
PET-occult lymph node metastasis detection is designated as the key secondary outcome because it is the study end point least susceptible to documentation-artefact bias. Unlike procedural completeness, which is ascertained from the procedural report that is itself the object of the intervention, a pathological result in a radiologically normal node cannot be produced by improved documentation alone, since it requires an actual biopsy of a node which would not have otherwise been sampled. If PET is unavailable at the time of procedure, radiologically abnormal nodes will be defined on CT size criteria only.

2. Number of lymph nodes sampled per procedure

3. Proportion of patients with at least one radiologically normal lymph node sampled ("endoscopic R0 procedure")(15)

4. Proportion of patients in whom N2a (single station) versus N2b (multi-station) nodal disease can be assigned from the procedural and pathology record

5. Variance in care of systematic mediastinal staging with EBUS across sites

6. Acceptability and feasibility of synoptic reporting as a standard component of multidisciplinary care, from the perspective of the proceduralist

Sample size calculation

Based on prior observations at the study sites, we estimate that 10% of patients with suspected or confirmed non-small cell lung cancer (NSCLC) undergo complete systematic staging, and 5% have PET-occult lymph node metastases detected retrospectively. Assuming a two-sided alpha of 0.05, a minimum total sample size of 590 patients (295 pre- and 295 post- intervention) is required to achieve 80% power to detect a 8% increase in the proportion of patients with suspected or confirmed NSCLC undergoing complete systematic staging (i.e. at least 18% in the post-intervention phase). This sample size will provide 80% power to detect an 7% increase (from 5% pre- to 12% post-intervention) in the key secondary outcome, the proportion of patients with PET-occult lymph node metastases detected. As each centre

contributes patients to both phases with no change in staffing, the intervention effect is estimated within centres and no design-effect inflation is required.

To achieve this sample size, we aim to recruit 15 participating centres, each submitting retrospective data for three months (approximately 20 patients) in the pre-intervention phase and three months (approximately a further 20 patients) in the post-intervention phase.

Pilot data from the participating sites indicate consistent baseline characteristics over multiple years, and no systematic difference between the pre- and post-intervention cohorts is anticipated. Nonetheless, because case mix may differ between cohorts recruited six months apart, and plausibly influences both the number of stations warranting sampling and the opportunity to detect PET-occult disease, the primary and secondary analysis will adjust for a pre-specified set of baseline covariates (see Data Analysis). The sample size calculation is based on an unadjusted comparison. Adjustment for prognostic covariates is not expected to reduce power.

Data analysis

Descriptive statistics will be reported for patient characteristics and study outcomes by pre-intervention (retrospective collection of patient data) and post-intervention phases (prospective collection of patient data). Continuous variables will be summarised using means and standard deviations (SD) or medians and interquartile ranges (IQR), as appropriate. Categorical variables will be summarised using frequencies and percentages.

To assess whether the implementation of a synoptic report for EBUS (intervention) results in improvements in complete systematic staging (primary outcome) and detection of PET-occult lymph node metastases (key secondary outcome), logistic mixed-effects regression models will be fitted with a binary variable for the pre- and the post-intervention phases, with a random effect for study centre. Models will additionally adjust for the following pre-specified baseline covariates, chosen on clinical grounds because each plausibly influences both the number of nodal stations warranting sampling and likelihood of detecting PET-occult disease: (i) clinical stage prior to EBUS (I-II vs ³III or higher); (ii) number of radiologically abnormal mediastinal nodal stations (0,1, ³2); (iii) whether PET/CT was performed prior to EBUS (yes/no). Adjusted and unadjusted (sensitivity) odds ratios for post- versus pre-intervention will be reported with 95% confidence intervals and p-values. Firth penalised estimation will be used if the key secondary outcome model fails to converge or shows separation. Multiple imputation will be used if more than 5% of patients have missing covariate data.

A similar analysis will be conducted to evaluate whether the implementation of the synoptic report leads to improvements in the proportion of patients with at least one radiologically normal lymph node sampled, and the proportion of patients in whom N2a versus N2b disease can be determined.

The number of lymph nodes sampled per procedure will be compared between the pre- and post-intervention phases using Poisson mixed-effects regression, with random effect for centre and

adjustment for pre-specified baseline case-mix covariates. Adjusted rate ratios for post- versus pre-intervention, corresponding 95% confidence intervals and p-values, will be reported. The ICC for each outcome will be reported, and models with centre as a fixed effect will be fitted as a sensitivity analysis.

Assessment of Variance

Funnel plots will be created for both the pre-intervention and post-intervention periods to assess whether synoptic reporting reduces geographic disparities and variance in care of systematic mediastinal staging with EBUS. The x-axis will represent the number of patients at each study site, and the y-axis will represent the percentage of patients who undergo complete systematic staging. Control limits of 95% and 99.8% arounds the overall proportion for each period will be shown.

Discussion

Accurate mediastinal staging is fundamental to determining prognosis and optimal treatment for patients with non-small cell lung cancer (NSCLC). Despite the central role of systematic staging EBUS in current lung cancer pathways, substantial variance in care persists in both procedural performance and the quality of procedural reporting. (7, 16)

Incomplete and inconsistent narrative procedural reports limit the ability to reliably assess adherence to quality standards and to conduct meaningful audit of staging practice. Separately, and more directly, incomplete procedures, such as under-examination or under-sampling of mediastinal lymph node stations, risk failing to detect nodal disease, which may compromise decision-making regarding suitability for curative intent treatment. Synoptic reporting has been proposed as a potential intervention to reduce this variance in care, (15) both by encouraging more thorough procedural technique and by improving reliability of documentation for audit and quality monitoring.

Synoptic reporting has been shown in other procedural specialities to improve report completeness, standardisation between clinicians and auditability of clinical documentation.(6, 8, 9) The findings from a multi-centre pilot study suggested improved procedural quality and diagnostic performance in interventional pulmonology (11). A *post hoc* analysis of the international SEISMIC trial further supports the value of synoptic reporting in this setting, as synoptic data enabled reporting of quality metrics and staging outcomes, particularly delineation of N2A and N2B disease. (17).

This study is designed to examining whether implementation of a synoptic procedural report in an international setting, improves key quality indicators in systematic staging EBUS, spanning both process measures indicative of procedural thoroughness and the clinically meaningful outcome of PET-occult lymph node detection. By collecting pre and post intervention data across diverse international centres, the study will evaluate changes in staging completeness, detection of PET-occult lymph node metastases and sampling thoroughness. Assessment of acceptability and feasibility will provide insight into the practical considerations of adopting structured reporting in routine practice.

The World Association of Bronchology and Interventional Pulmonology (WABIP) consensus statement recommended a set of standard reporting items for inclusion in EBUS procedural reports.(13). These items were developed alongside the twelve proposed quality indicators, with the specific intent of ensuring that the data required to calculate and interpret these indicators is consistently captured in clinical practice. Standard reporting items serve two functions, they allow collection of the data points required to report each quality indicator, and provide additional contextual details that allow interpretation if there is underperformance or unexpected variance in a quality indicator.

Both WABIP and the NHS Lung Cancer Clinical Expert Group have provided quality standards for staging EBUS that are aligned and consistent, providing a framework for quality assurance.(13, 18). Quality metrics specific to systematic staging have subsequently been proposed to address variance in care and support people whose performance monitoring demonstrates suboptimal outcomes.(15). These include the number of lymph nodes sampled per procedure and the proportion of patients who have at least one radiologically normal lymph node sampled- referred to as an “endoscopic R0” procedure- alongside the rate of PET-occult lymph node detection as a key outcome measure. Such metrics can only be measured through consistent recording of standard reporting items, as is achieved through synoptic reporting.(15). Widespread use of synoptic reporting therefore has the potential to not only improve completeness of individual procedural reports, but also validate the utility of these proposed quality metrics, including the concept of endoscopic R0, as tools for performance monitoring in systematic staging EBUS.

Limitations and Considerations

Several limitations warrant consideration. As a single-arm study, there is no concurrent control group against which outcomes can be compared over the same period. However, given the short time frame, it is unlikely that there would be impact from trends in staging practice and changes in procedure volume or experience.

A pre-post design within an implementation science framework was adopted as a pragmatic method for evaluating the impact of implementation and quality improvement interventions, particularly given randomisation is not feasible within clinical care. To account for potential differences between the pre- and post- intervention cohorts, mixed-effects regression with a random effect for study centre will be used to account for clustering; as no confounding covariates were identified a priori, no covariate adjustment is planned.

A further limitation relates to ascertainment of the primary outcome. Because procedural completeness is determined from the synoptic report, and the synoptic report is itself the object of the intervention, part of any measured improvement in completeness could reflect more thorough documentation of an unchanged procedure, rather than more thorough procedural conduct. Two features of the study design mitigate this risk. First, the nodal pathology metrics are taken from the pathology report not the procedural report. Second, PET-occult lymph node detection is the outcome most resistant to a pure

documentation effect, since a positive result requires demonstrable sampling of a node that imaging had classified as negative, and therefore cannot be generated by improved reporting alone.

Despite these limitations, this study is the first evaluation of synoptic reporting in EBUS bronchoscopy. Demonstrating improvements in staging outcomes for both process and outcome measures and a reduction in variance in care would provide strong justification for widespread adoption of synoptic reporting to support consistent, high-quality lung cancer care globally.

Conclusion

This study will address a critical gap in the interventional pulmonology literature by evaluating for the first time in an international, multicentre setting, whether synoptic procedural reporting improves both the completeness of procedural reporting and the quality of systematic staging EBUS procedures. By standardising key elements of procedural documentation, synoptic reporting has the potential to improve completeness of systematic mediastinal staging, increase detection of clinically significant PET-occult nodal disease and reduce variation of care across participating institutions.

If successful, this international trial will provide robust evidence to support widespread adoption of synoptic reporting as a quality improvement tool in systematic staging EBUS. This has the potential to improve multidisciplinary decision-making, support more accurate and consistent nodal staging under 9th edition TNM classification, and ultimately optimise outcomes for patients with non-small cell lung cancer.

Abbreviations

EBUS
Endobronchial ultrasound
TBNA
Transbronchial needle aspiration
NSCLC
Non-small cell lung cancer
PET
Positron emission tomography
TNM
Tumour, Node, Metastases
LN
Lymph node
WABIP
World Association for Bronchology and Interventional Pulmonology
HREC
Human Research Ethics Committee

ANZCTR
Australian New Zealand Clinical Trials Registry
CI
Confidence Interval, IRB:Institutional Review Board
SD
Standard Deviation
IQR
Interquartile Range
OR
Odds Ratio
RR
Relative Risk

Declarations

Ethics approval and consent to participate

This study was approved by the Melbourne Health Human Research Ethics Committee on 21 January 2025 (Ref: HREC/114677/MH-2024) and has received IRB approval at individual centres. Most sites granted a waiver of patient consent, as the intervention involves no change to clinical care; one site required individual patient consent in accordance with local requirements.

Consent for publication

Not applicable

Availability of data and materials

Data sharing is not applicable to this article as non datasets were generated or analysed during the current study.

Competing Interests

The authors declare that they have no competing interests

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Authors' Contributions

Study conception and protocol development: AW, NMR, DPS, SS. Project administration: AW. DPS. Investigation including performance of procedures, data collection/management: AW, ME, DM, FK, DW, NN, DF, AF, KY, PN, DO, CT, CG, PP, AL, DPS. Manuscript preparations: AW, NMR, SEC, DPS. Manuscript revision: All authors. All authors read and approved the final manuscript.

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