Endobronchial Ultrasound: A novel screening test for pulmonary hypertension prior to major pulmonary surgery.

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Endobronchial Ultrasound: A novel screening test for pulmonary hypertension prior to major pulmonary surgery.

Running head: PAP measurement using EBUS

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Endobronchial ultrasound evaluation of the pulmonary artery vascular acceleration time

Central Picture Legend (90char incl spaces)
Endobronchial ultrasound evaluation of the pulmonary artery vascular acceleration time

Central Message (192/200 char incl. spaces)
Endobronchial ultrasound (EBUS) can meaningfully provide insight in relation to pulmonary artery hemodynamics, and may be considered in the screening armamentarium for pulmonary hypertension.

Perspective Statement (357/405 char incl. spaces)
Pulmonary hypertension is an underestimated clinical variable in the preoperative assessment of patients undergoing major pulmonary surgery. EBUS is a simple and promissory method with which to investigate pulmonary hypertension when compared to the gold standard RHC, in patients at high risk of PH and in need for EBUS for staging or diagnostic purposes.

ABSTRACT (250)
**Objectives:** Pulmonary hypertension (PH) is an important physiologic variable in the assessment of patients undergoing major thoracic operations but all too often neglected because of the need for right heart catheterization (RHC) due to the inaccuracy of transthoracic echocardiography (TTE). Patients with lung cancer often require EBUS as part of the staging of the cancer. We sought to investigate whether EBUS can be used to screen these patients for PH.

**Methods:** Patients undergoing a major thoracic operation requiring EBUS for staging were included prospectively in the study. All patients had also a RHC (gold standard). We aimed to compare the pulmonary artery pressure (PAP) measurements by EBUS to the RHC values.

**Results:** A total of 20 patients were enrolled in the study. The prevalence of abnormal pulmonary artery pressure was 65% based on RHC. All patients underwent measurement of the pulmonary vascular acceleration time (PVAT) by EBUS with no adverse events. Linear regression analysis comparing PVAT and RHC showed a correlation (r=-0.059, -0.010 to -0.018, p=0.007). A receiver operator characteristic curve (Area under the curve = 0.736) was used to find the optimal PVAT threshold (140 msec) to predict PH; this was used to calculate a positive and negative likelihood ratio following a positive diagnosis of 2.154 and 0.538 respectively.

**Conclusions:** EBUS interrogation of pulmonary artery hemodynamic is safe and feasible. EBUS may be used as a screening test for PH in high-risk individuals.

**Key Words:** Endobronchial Ultrasound, High Risk Lung Resection, Pre-Operative Screening, Pulmonary Hypertension

**Abbreviations:** EBUS: Endobronchial Ultrasound, PH: Pulmonary Hypertension, RHC: Right Heart Catheterization.
Endobronchial Ultrasound: A novel screening test for pulmonary hypertension prior to major pulmonary surgery

Pulmonary Hypertension (PH) is an important physiologic variable in the assessment of patients undergoing major thoracic operations.

20 patients enrolled to undergo EBUS and RHC to evaluate pulmonary artery pressure.

EBUS interrogation of PAP is safe and feasible. It may be used as a screening test for PH in high-risk individuals.

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Abbreviations: EBUS: endobronchial ultrasound, RHC: right heart catheterization, mPAP: mean pulmonary artery pressure, PVAT: pulmonary vascular acceleration time.
TEXT

Introduction

Proper risk stratification prior to major pulmonary surgery is essential to a smooth post-operative outcome. Cardiac hemodynamics evaluation is indispensable in this patient population, and can predict post-operative mortality and morbidity depending on the extent of resection\(^1\)-\(^3\), however the impact of pulmonary hypertension (PH) is often overlooked and almost never properly evaluated. The National Emphysema Treatment Trial (NETT) highlighted the importance of PH in the mortality and morbidity of patients undergoing lung volume reduction surgery, and going as much as establishing pulmonary hypertension as a contraindication to surgery\(^4\). Furthermore, pulmonary hypertension could be one of the most important neglected physiologic variables leading to post pneumonectomy pulmonary edema\(^5\).

With an increased understanding of the effect of PH on intra-operative hemodynamics and outcomes, non-invasive screening approaches using echocardiography have been investigated generating a plethora of formulas\(^6\)-\(^11\). Unfortunately, these models remain inaccurate\(^12\), lack validation\(^13,14\), and fail to predict patients who might require the gold-standard diagnostic right heart catheterization (RHC), and therefore, pre-operative medical optimization, or intra-operative interventions\(^15\). These limitations in non-invasive testing are further accentuated in patients with obstructive sleep apnea (OSA), and those with underlying lung disease such as COPD with barrel chest deformities\(^16\).

Multiple societies across the world recently addressed an epidemiologic discrepancy in the diagnosis of abnormal pulmonary artery pressures by decreasing the diagnostic threshold from 25mmHg to 20mmHg\(^17\)-\(^19\) mean pressure. This led to an increased incidence of PH\(^20\), which increased the positive predictive value of existing screening strategies and decreased the negative predictive value\(^12\).

Considering that patients undergoing major thoracic operations routinely undergo bronchoscopic staging with endobronchial ultrasound (EBUS)\(^21,22\), we sought to investigate the feasibility, value, and accuracy of an endobronchial ultrasound-based method to evaluate pulmonary artery hemodynamics in patients scheduled for major pulmonary resection. We hypothesized that endobronchial evaluation of the
pulmonary artery acceleration time (PVAT) by doppler would feasibly and accurately provide insight regarding pulmonary vascular outflow physiology and hemodynamics.

Methods

Following approval by the internal review board (PA: 2018-0500), twenty patients were prospectively recruited. All patients were scheduled to undergo a major thoracic operations and suffered from a clinical condition that could affect their pulmonary artery physiology, such as a diagnosis or suspicion of OSA, a diagnosis of COPD or the need of a pneumonectomy. All patients required a staging EBUS preoperatively.

Endobronchial Ultrasonography

Following consent, patient underwent a staging endobronchial procedure under general anesthesia, with laryngeal mask airway (LMA), and with additional local analgesia obtained with 6mL of 2% Lidocaine applied to the tracheobronchial tree. First, a slim video diagnostic bronchoscope (Olympus BF-Q190) was introduced through the LMA to examine the tracheobronchial tree of both lungs. Following this, a convex probe EBUS bronchoscope (Olympus UC180F, Olympus Surgical Technologies, Westborough, Massachusetts) was introduced through the LMA, and further evaluated the peri-bronchial anatomy. During the procedure, peri-bronchial lymph nodes were evaluated and tissue samples were obtained when appropriate. The endobronchial evaluation of pulmonary artery pressure was via doppler interrogation of the pulmonary artery through the right mainstem bronchus, in order to generate a pulmonary vascular acceleration time (PVAT) in milliseconds, across three time points, regardless of heart rate. The two measurements with the least variance were used in this analysis. The PVAT was defined as the time required for the pulmonary artery vascular flow to accelerate from minimal velocity to maximal velocity (V1 and V2, respectively, as calculated in Figure 1). This was performed using the EVIS EXERA III ultrasound processor (Olympus Surgical Technologies, Westborough, Massachusetts). Historically, a transthoracic echocardiogram (TTE) doppler generated PVAT of less than 105 msec was characterized as being abnormal, in accordance with the British Society of Echocardiography (BSE) guidelines, where the pulmonary arterial systolic pressure has been estimated
on echo by utilizing the simplified Bernoulli equation from the peak tricuspid regurgitant velocity in
patient with cardiac disease\textsuperscript{23}. All measurements were performed by the same interventional
pulmonologists (GAP, RFC).

\textbf{Right Heart Catheterization}

All patients underwent cardiac catheterization under intravenous sedation. RHC generated
measurements of mean PAP, systolic PAP, and diastolic PAP using a standard fluid filled catheter. All
measurements were performed by the same interventional cardiologist (JBD). A mean PAP of 20mmHg
or greater was considered abnormal\textsuperscript{17-19}.

\textbf{Statistical Methods}

The primary analysis aimed to evaluate if the EBUS generated PVAT measurements correlated
with PAP measurements originating from the RHC procedure. The study was powered (n=20) to provide
a 95% confidence interval (95\%CI) of 0.56 should an estimated correlation of 0.7 be discovered. The
analysis used the mean of the two EBUS PVAT measurements and the RHC mean PAP values. We
evaluated the measurements from both modalities and their association with a Spearman correlation
analysis and a univariate linear regression model in order to measure the strength and direction of the
monotonic relationship. Using the equation generated from our regression model, the difference in
measurement was evaluated using the Bland-Altman method. An area under the curve analysis of a
receiver operator characteristic curve was performed. Data distribution was assessed using the Shapiro-
Wilkes test. Lastly, a comparison of varying thresholds according to previously determined diagnostic
criteria was also performed. All statistical analyses were performed using GraphPad Prism (version 9.3.1
for Windows, GraphPad Software, San Diego, California USA).

\textbf{Results}

\textbf{Patient Population}

All twenty patients were recruited between 11/2018 and 04/2023. Patients had a mean age of 69
years (standard deviation: 9), were predominantly female (n=11, 55\%), and usually had a smoking history
(n=11, 55\%). Patients underwent surgical evaluation for bronchogenic carcinoma, thymoma requiring en-
bloc resection with lung, mesothelioma and one case for obstructing broncholithiasis (no cancer on final pathology). Many patients had risk factors for PH due to a previous diagnosis or suspicion of OSA (heavy snoring), cardiac disease or COPD (Table 1). Measurements of PAP occurred at an average of 6 days between one another (range: 1-20).

**Endobronchial Ultrasound**

All patients underwent endobronchial evaluation of PVAT, with a total of 3 measurements each. The median PVAT calculated using the aforementioned methodology in this cohort was 147.0 msec (Interquartile Range [IQR]: 107.0-183.0), and ranged from 82.5 to 250.0 msec (Table 2). Based on BSE criteria (<105 msec), 5 (25%) patients had abnormal readings that were suggestive of PH. There were no adverse events due to the endobronchial procedure in any of the patients included.

**Right Heart Catheterization**

All patients also underwent RHC, with mean PAP (mPAP<sub>RHC</sub>) measurement. The median mPAP<sub>RHC</sub> in this cohort was 20.0 (IQR: 18.0-23.0), and ranged from 12.0 to 32.0. Based on the 6th World Symposium on PH criteria (≥20 mmHg), 13 (65.0%) patients had abnormal readings. In this cohort, the median pulmonary vascular resistance was 1.77 (IQR: 1.30-3.18), and the median pulmonary capillary wedge pressure was 11.5 (IQR 10.0-14.3) (Table 2). There were no adverse events due to the cardiac catheterization procedure in any of the patients included.

**Correlation Between Modalities**

Considering the five patients with abnormal EBUS readings based on a threshold of 105 msec, four also had abnormal RHC readings. Given a parametric distribution in our PVAT and mPAP<sub>RHC</sub> data, a Spearman correlation analysis was performed and revealed a coefficient of -0.56 (95% confidence interval [95%CI]: -0.80 to -0.16, *p* value = 0.010). The univariate linear regression analysis between mPAP<sub>RHC</sub> and PVAT (EBUS) revealed a weak but significant correlation (slope= -0.059 (95% CI: -0.010 to -0.018, *p* value = 0.007, Figure 2). The univariate linear regression produced the following equation to generate a calculated mPAP from PVAT (mPAP<sub>EBUS</sub>):

\[
mPAP_{EBUS} = -0.059 \times PVAT + 30.46
\]
The difference between $\text{mPAP}_{\text{EBUS}}$ and the $\text{mPAP}_{\text{RHC}}$ was analyzed using the Bland-Altman method, which showed limits of agreement with a mean value of -0.003 and standard deviation of 4.439 (Figure 3).

Next, an area under the receiver-operating characteristic curve analysis was performed, and found to be 0.736, when using a PVAT threshold of <140 msec leading to a sensitivity of 61.5% and specificity of 85.7% and accuracy of 65% (supplemental figure 1). Using this new threshold in our cohort, the prevalence of patients with pulmonary hypertension was found to be 45% based on EBUS measurements. This led to a positive likelihood ratio of 2.154 and negative likelihood ratio of 0.538 (Figure 4).

Additionally, we compared the previously published threshold of 105msec to the old RHC threshold of 25mmHg. Using these two values (105msec and 25mmHg), we found that EBUS achieved a sensitivity of 50.0%, specificity of 81.3%, and accuracy of 75.0%.

Comment

The medical optimization of patients with comorbidities prior to surgery is vital to the practice of surgery. Pulmonary hypertension may be a significant factor associated with perioperative morbidity and it is often neglected in the preoperative assessment. Current echocardiographic screening approaches are lacking in efficacy and accuracy, relying on right heart catheterization for accurate diagnosis, which is a step many thoracic surgeons prefer to avoid. The reported models based on TTE measurements continue to be inaccurate and there is real need for a reliable screening or diagnostic test to stratify the perioperative risks based on the PAP.

We present here a feasible test that would not use resources that are not already allocated to preoperative planning in patient population undergoing lung resection. We sought to investigate the feasibility and accuracy of evaluating the hemodynamics of the pulmonary outflow tract during routine pre-operative endobronchial ultrasonographical staging. The method developed involved interrogating the acceleration time in the pulmonary artery, by monitoring the velocity curves of the flow of blood and measuring the time between lowest and maximal velocity. Interestingly, using a PVAT threshold of
<140msec had better sensitivity for predicting pulmonary hypertension than the current BSE guidelines of <105 msec, which is used for TTE.

A screening test in medicine should possess qualities such as a good sensitivity, specificity, and safety. The higher the sensitivity and specificity the more effective is the screening test. While there is no universally agreed upon threshold for what constitutes a good sensitivity and specificity, in general higher values are preferred. Commonly, a sensitivity and specificity of at least 80% or higher are considered reasonable for a screening test\textsuperscript{24}.

In comparing the performance of our methodology, with that of other established screening modalities, such as low-dose computed tomography (LDCT) or breast mammography, our approach may be appropriate in patients with a high pre-test probability based on clinical characteristics\textsuperscript{27}. For example, sensitivity of LDCT in detecting lung cancer ranged between 59% and 100% with a specificity ranging from 26.4% and 99.7% \textsuperscript{28}. Breast digital mammography achieved a sensitivity of 97% and specificity of 64.5% in the detection of breast cancer\textsuperscript{27}.

TTE and doppler echocardiography have been reported to have a reasonable sensitivity and specificity in detecting PH. Pooled sensitivity values in the range of 85% and specificity of 74%, with a PLR of 3.2 and NLR of 0.2 have been reported in some studies but only in patients in whom the PAP could be calculated. In patients with underlying lung disease, TTE can be unreliable to measure PAP\textsuperscript{16}.

Based on the present data, the measurement of PAP by EBUS in patients in need of EBUS for staging or diagnostic purposes may be more suitable in individuals considered to be at high risk of suffering from PH than TTE. High risk individuals include those with OSA, diagnosed or suspected based on sleep behavior, obesity, and the magnitude of the surgery to reduce the vascular bed of the right heart such as in individuals requiring pneumonectomy. In the future, EBUS may play a role in screening all patients who undergo an extensive intra-thoracic operation and who are categorized as being high risk, in order to physiologically optimize patients prior to resection.

Those with PH on EBUS can then be guided to have a RHC (still the gold standard), or potentially to measurement of the PAP by direct puncture of the PA, which has been shown to be safe in
human and animal models with normal pulmonary pressures\textsuperscript{28,29}. Ideally, in the context of patients undergoing EBUS for oncologic staging, pulmonary artery puncture and direct measurement of pulmonary artery pressure may be performed during the pre-operative assessment period. This could provide additional data to surgeons that might inform which patients would benefit most from ongoing perioperative physiologic optimization, however, the safety of pulmonary artery puncture and direct measurement of pulmonary artery pressure in patients with significant pulmonary hypertension requires additional study. In patients with a confirmation of PH, pharmacological (pulmonary vasodilators) or physiological intervention (CPAP) to reduce the PAP prior to surgery may be helpful to reduce the morbidity and the mortality of the planned surgery.

In this clinical trial, despite consistency in approach and methodology, and with paired comparison with the current gold standard for pulmonary hypertension diagnosis, a few limitations were encountered. First, while we aimed to develop a robust model, able to reliably predict PH with high sensitivity and specificity, our sample size limited our ability to do so and thus the correlation obtained is weak. Slow accrual may have been secondary to the number of patients requiring RHC as a part of their pre-operative workup. We felt that confirmation of our results with a gold standard was mandatory in order to generate meaningful results. Second, this trial was performed in a single-center, and thus, may have limited dissemination to other patient populations who present at other centers. Lastly, while we identified a cutoff PVAT value that is relevant in the current cohort, a larger multi-institutional study may reveal a different cutoff that may be more sensitive and or specific. In conclusion the use of EBUS, an already routine test to stage patients with pulmonary malignancies, may be a useful tool to screen for pulmonary hypertension in high-risk patients undergoing major pulmonary surgery.

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Financial/Nonfinancial Disclosure: RRC has received research grants from Siemens and Olympus, and he is paid consultant for Intuitive Surgical, Siemens and Olympus. The other authors declare no potential conflicts of interest.

Funding Information: The Authors would like to acknowledge the philanthropic support from the Mason Family Fund.

References


Figure 1: Olympus (EVIS EXERA III) generated endobronchial ultrasound investigation of the pulmonary artery, with velocities graphically represented on an x-y axis. V1 representing velocity of 0 cm/s, and V2 representing maximal velocity. AcT representing acceleration time taken between V1 and V2.
Figure 2: Linear Regression model with 95% confidence intervals, comparing endobronchial ultrasound generated pulmonary vascular acceleration time (EBUS PVAT) with right heart catheterization generated median pulmonary artery pressure (RHC mPAP).

Figure 3: Limits of agreement between right heart catheterization (RHC) generated mean pulmonary artery pressure ($mPAP_{RHC}$) and calculated mean pulmonary artery pressure from endobronchial ultrasound.
(EBUS) generated pulmonary vascular acceleration time (mPAP_{EBUS}) originating from the Bland-Altman analysis. (Solid line: Median = 0.000, pointed lines: 95% Confidence Interval)
Figure 4: Fagan Nomogram with pulmonary vascular acceleration time threshold set at 140 msec, revealing a positive likelihood ratio (PLR) and negative likelihood ratio (NLR) of 2.154 and 0.538, respectively, in our sample of patients with a pulmonary hypertension prevalence of 65% (prior prob). The positive probability (blue line) and negative probability (red line) are 80% and 50%, respectively.
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Abbreviations: PAP: pulmonary artery pressure; TN: tumor and nodal; Hx: history; Dx: diagnosis; OSA: obstructive sleep apnea; PA: pulmonary artery; n/a: not available

**Table 1**: Clinicopathologic variables of patients who met inclusion criteria and indication for endobronchial pulmonary artery pressure (PAP) evaluation.
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Abbreviations: PVAT: pulmonary vascular acceleration time; mPAP: mean pulmonary artery pressure; PVR: pulmonary vascular resistance; PWP: pulmonary wedge pressure

Table 2: Pulmonary artery hemodynamic readings of all patients.
Supp Fig 1: Receiver Operator Curve, with 2x2 table representing the results of right heart catheterization (threshold of 20mmHG), as well as endobronchial ultrasound (threshold of 140msec). Abbreviations: EBUS: endobronchial ultrasound, RHC: right heart catheterization.
Prevalence = 65%
PLR = 2.154, NLR = 0.538
Posterior Positive Probability = 80%
Posterior Negative Probability = 50%
Endobronchial Ultrasound: A novel screening test for pulmonary hypertension prior to major pulmonary surgery

Pulmonary Hypertension (PH) is an important physiologic variable in the assessment of patients undergoing major thoracic operations.

20 patients enrolled to undergo EBUS and RHC to evaluate pulmonary artery pressure.

EBUS interrogation of PAP is safe and feasible. It may be used as a screening test for PH in high-risk individuals.

Abbreviations: EBUS: endobronchial ultrasound, RHC: right heart catheterization, mPAP: median pulmonary artery pressure, PVAT: pulmonary vascular acceleration time.