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Session B110 - LUNG CANCER SCREENING AND PULMONARY NODULES: REFINEMENTS AN...

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# A4413 / 107 - Pulmonary Nodule Biomarker Panoptic Study Results at 1 Year Supported by 2-Year Results

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| May 21, 2018, 2:15 PM - 4:15 PM | Room 5 A-B (Upper Level) - San Diego Convention Center |

**Participant**

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**Abstract**

Rationale: The PulmonAry NOdule Plasma proTeomIc Classifier (PANOPTIC) trial evaluated a novel pulmonary nodule classifier integrating two proteins with clinical risk factors in patients with incidentally detected nodules. In nodules with a pretest probability of malignancy (pCA) of ≤ 50%, the classifier correctly identified benign nodules with performance characteristics that included sensitivity 97%, specificity 44%, and NPV 98%. We report on two- year follow-up results.

Methods: The PANOPTIC study is a multicenter, observational study with retrospective evaluation of the performance of the integrated classifier test comprised of the relative abundance of two plasma proteins, LG3BP and C163A, obtained by multiple reaction monitoring mass spectrometry, and 5 clinical risk factors. Patients were ≥ 40 years old with nodules 8-30 mm in diameter. The integrated classifier demonstrated optimal performance for patients with lower risk lung nodules defined as a physician pre-test probability of cancer (pCA) being ≤ 50%. One-year results were categorized as malignant based on histopathologic results and benign based on histopathology or in nodules demonstrating radiographic resolution or stability at one year. The two-year follow-up data are used to assess the one-year analysis.

Results: There were 178 patients with nodule pCA of ≤50% included in the one-year analysis with 29 diagnosed as malignant and 149 as benign. At year two, 10 patients were lost to follow up while 7 had final visits that did not extend to the two-year period leaving 161 patients (90%) with data available for analysis. The 17 excluded patient nodules were previously categorized as benign at the one-year interval reducing the number of benign nodules to 132 at the two-year interval. Participant demographics did not change from year one to two. All means (e.g. age, nodule size, pack years) and counts (e.g. gender, smoking status, nodule location) at year two were within 2 percentage points of the year one values. At the end of two years, none of the previously categorized benign nodules went on to be diagnosed as malignant resulting in maintenance of integrated classifier performance at year two.

Conclusions: The two-year follow-up results in the PANOPTIC trial did not result in a change in nodules previously categorized as benign based on histology, radiographic resolution or stability. These findings support the definition of benign nodules used at 1-year for test validation and integrated classifier performance was therefore maintained at year two.

# Pulmonary Nodule Biomarker PANOPTIC study results at 1-year supported by 2-year results

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## INTRODUCTION

- The PulmonAry NOdule Plasma proTeomIc Classifier (PANOPTIC) trial evaluated a pulmonary nodule classifier integrating two proteins with clinical risk factors
- In nodules with a pretest probability of malignancy (pCA) of ≤50%, the classifier correctly identified benign nodules (sensitivity 97%, specificity 44%, and NPV 98%) at 1-year
- **Aim: Report on trial 2-year results**

## METHODS

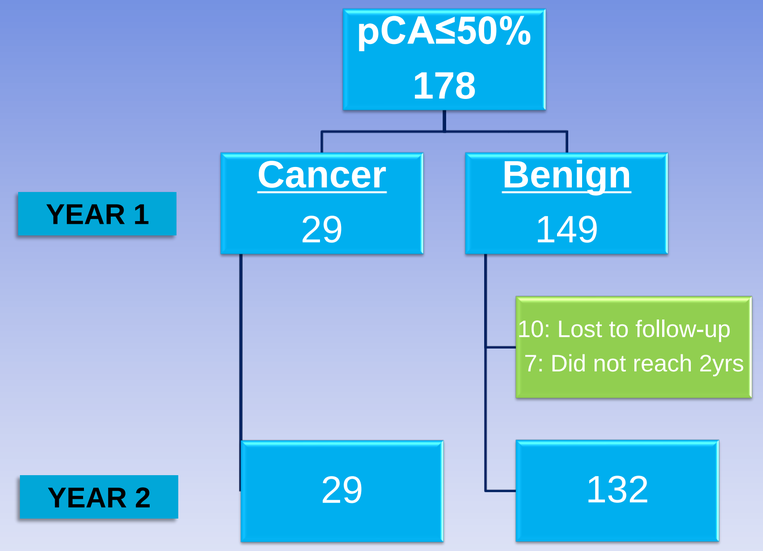
- Design: multicenter, observational trial
- Setting: 33 sites in North America
- Participants: Patients age ≥40 years with nodules 8-30 mm in diameter (n=685)
  - Subgroup of 178 patients with a clinician assessed pCA≤50%
- Diagnoses:
  - *Malignan*t: histopathology
  - *Benign:* histopathology, radiographic resolution or stability at one and two years.
- Integrated Classifier: 2 plasma proteins (LG3BP, C163A), 5 clinical factors (age, smoking status, nodule size, edge and location)
- Analysis: The two-year follow-up data are used to assess one-year analysis

## RESULTS

**Participant demographics and 2-year results**

| | Cancer | Benign |
|---|---|---|
| Patients | 29 | 132 |
| Age | 66(+/- 3) | 65(+/- 2) |
| Gender | | |
| Male | 12 (41%) | 72 (55%) |
| Female | 17 (59%) | 60 (45%) |
| Smoking History | | |
| Never | 6 (21%) | 30 (23%) |
| Former | 16 (55%) | 74 (56%) |
| Current | 7 (24%) | 28 (21) |
| Average Pack Years | 44 (+/- 12) | 44(+/- 7.5) |
| Lung Nodule | | |
| Size* | 16(+/- 2.2) | 13(+/- 0.8) |
| Location | | |
| Upper Lobe | 20 (69%) | 63 (48%) |
| Lower Lobe | 9 (31%) | 69 (52%) |
| Diagnoses | | |
| Benign | | |
| Granuloma | | 9 (6.8%) |
| Hamartoma | | 6 (4.6%) |
| CT Stable/Resolution | | **99 (75.0%)** |
| Other | | 18 (13.6%) |
| Malignant | | |
| Adenocarcinoma | 17 (58.6%) | |
| Squamous Cell | 4 (13.8%) | |
| NSCLC (NOS) | 1 (3.5%) | |
| Small Cell | 2 (6.9%) | |
| Carcinoid | 3 (10.3%) | |
| Other | 2 (6.9%) | |

*p<0.05




## CONCLUSIONS

- The two-year follow-up results in the PANOPTIC trial did not result in a change in nodules previously categorized as benign based on histology, radiographic resolution or stability.
- These findings support the definition of benign nodules used at 1-year for test validation
- Integrated classifier performance characteristics were therefore maintained at year two.

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