Incidental Findings in CTLS

Shawn M. Regis, PhD
Rescue Lung Society

Mammography vs CTLS

Mammography	CTLS

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- Dose ≈ 0.4 mSv

CTLS

- Dose ≈ 0.7 mSv

Mammography vs CTLS

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- Dose ≈ 0.4 mSv
- 5-15% false positive rate
  - ~8% overall

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- BI-RADS structured reporting

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Mammography vs CTLS

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- Imaging of the breast

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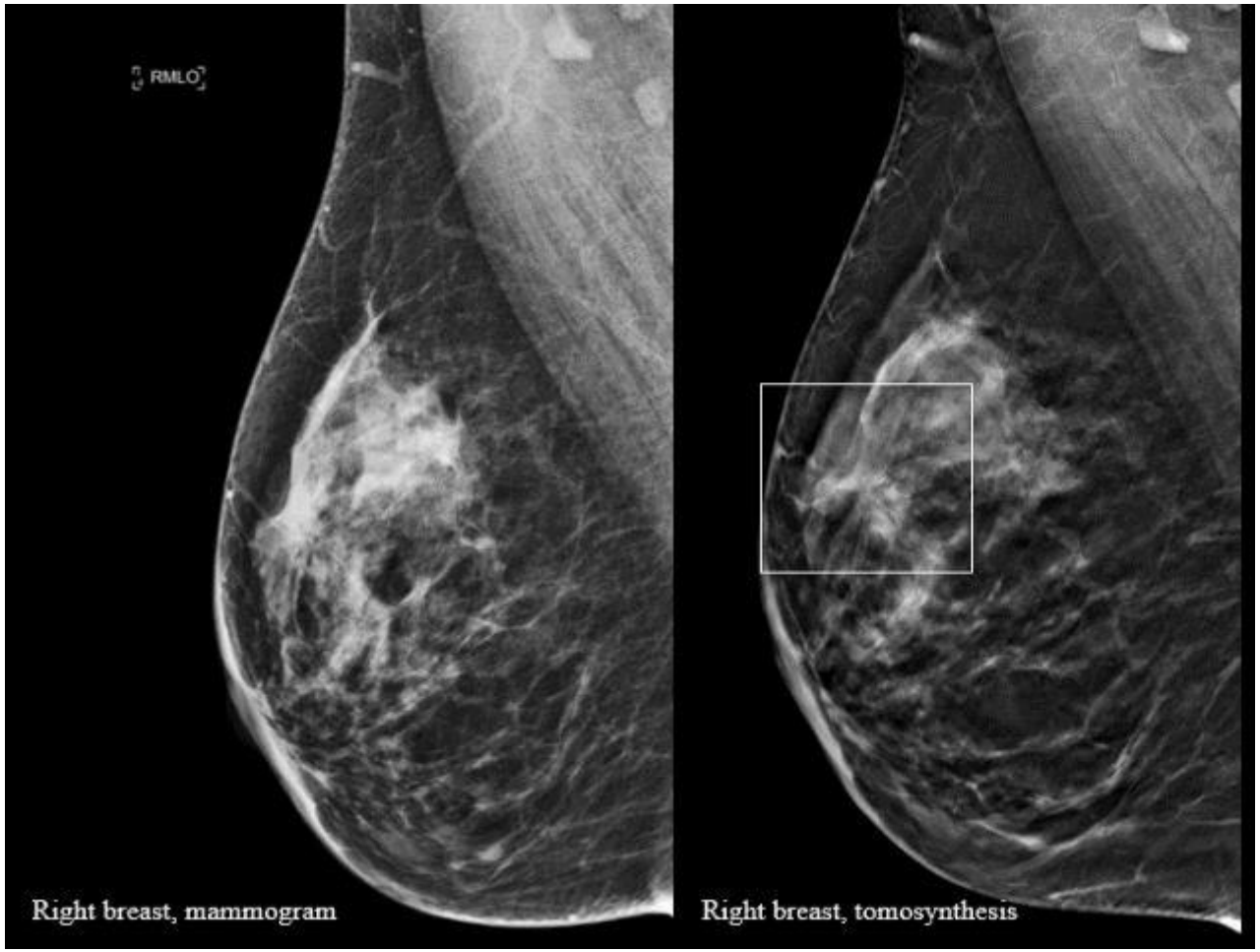
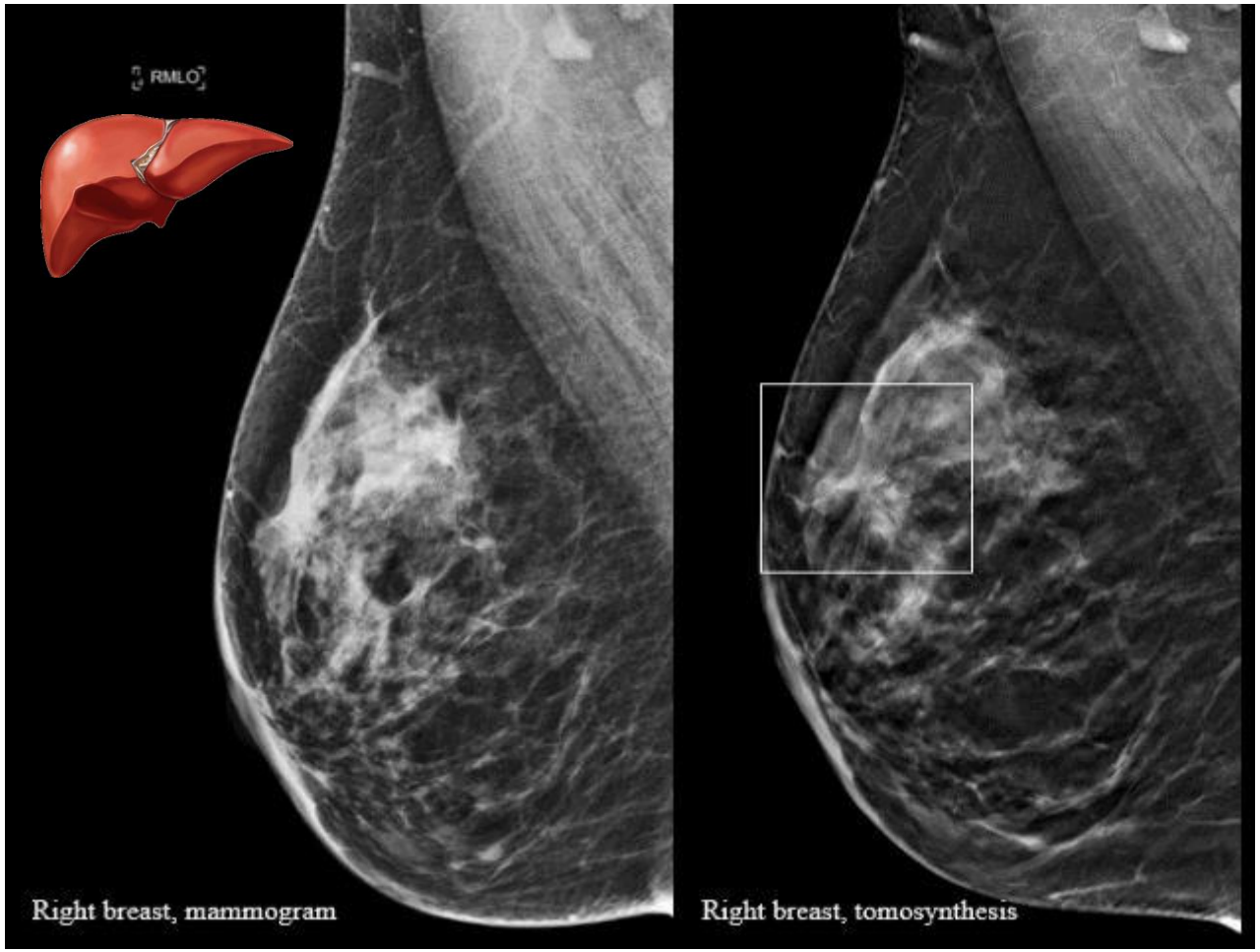
Mammography vs CTLS



Source: National Breast Cancer Foundation

Mammography vs CTLS



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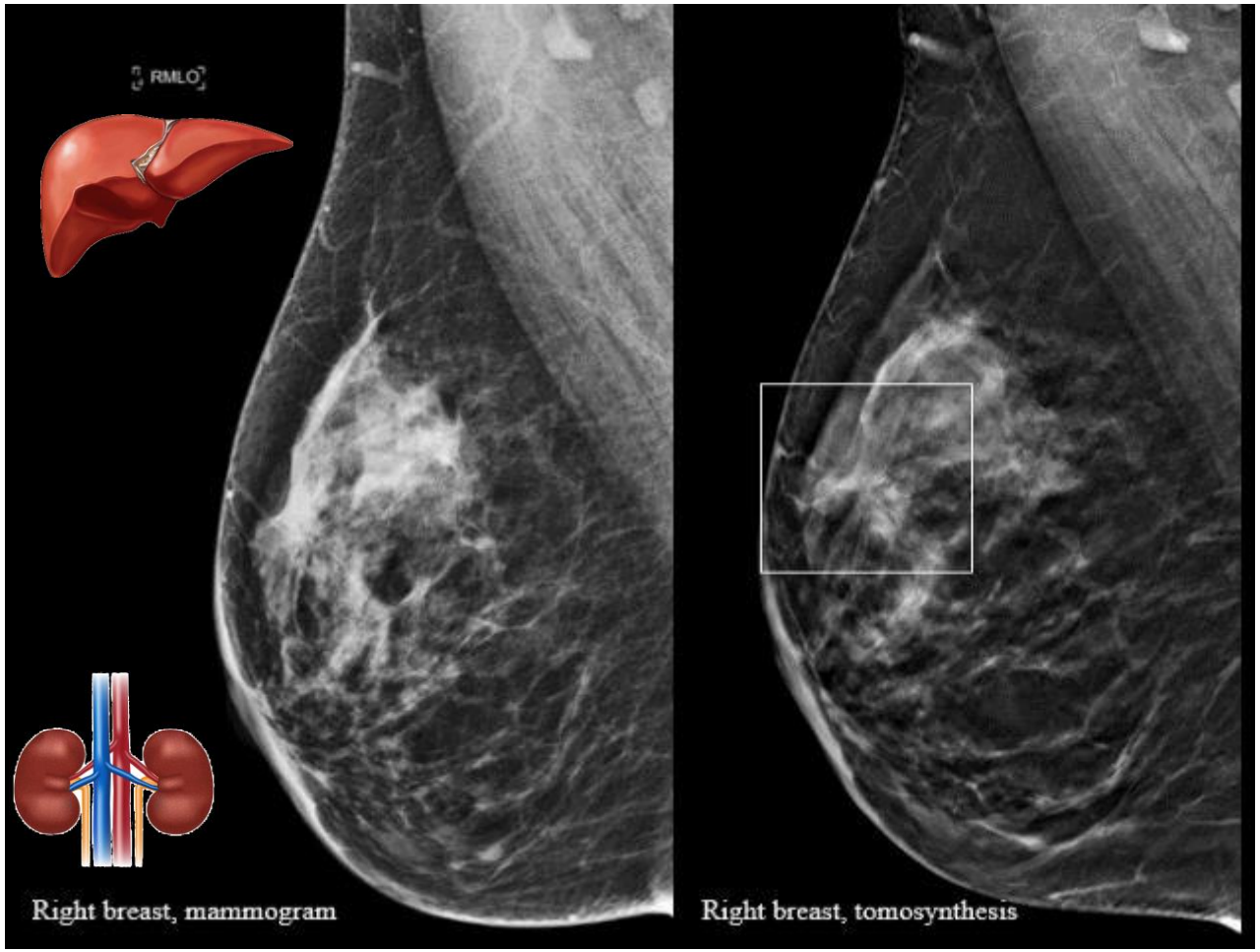

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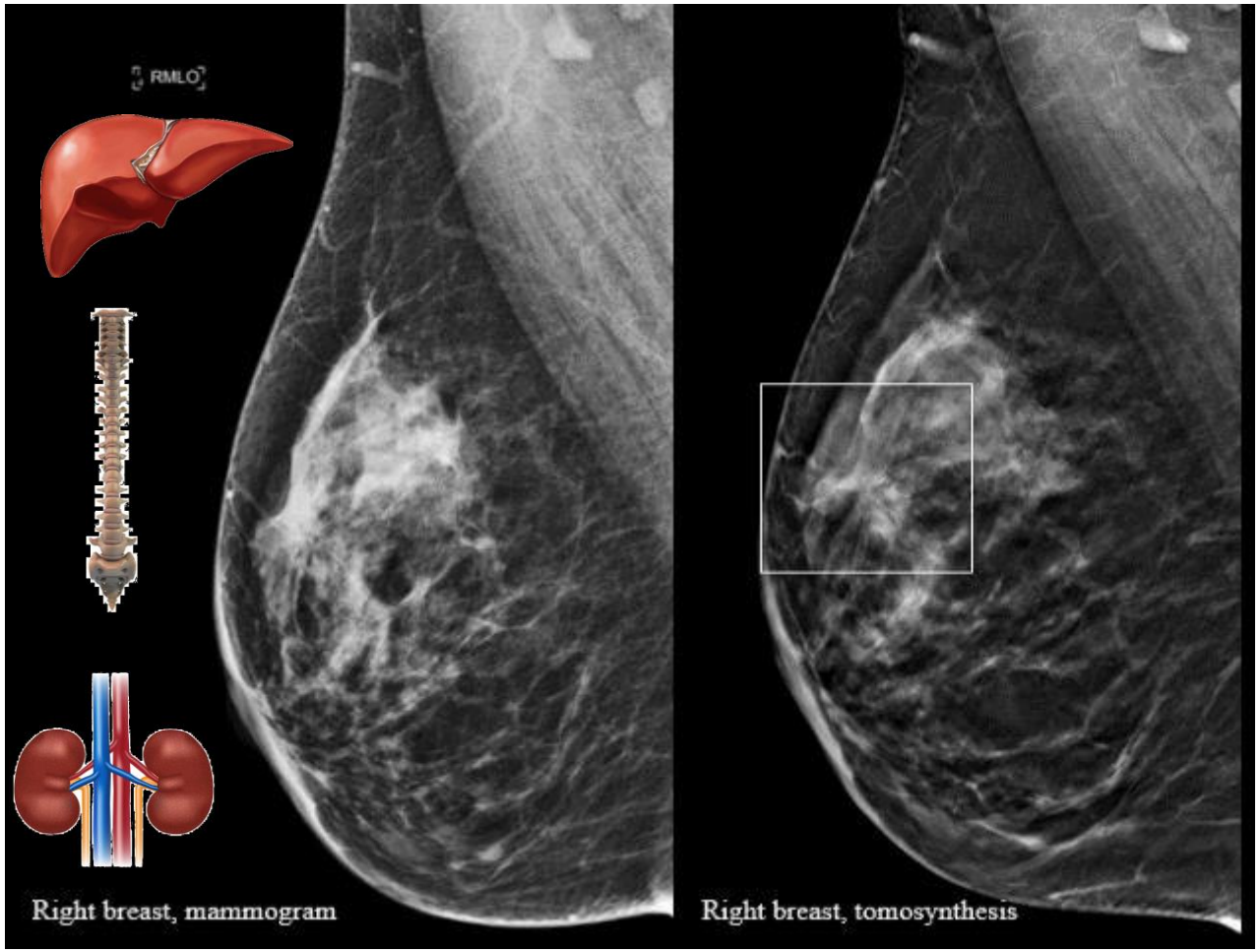

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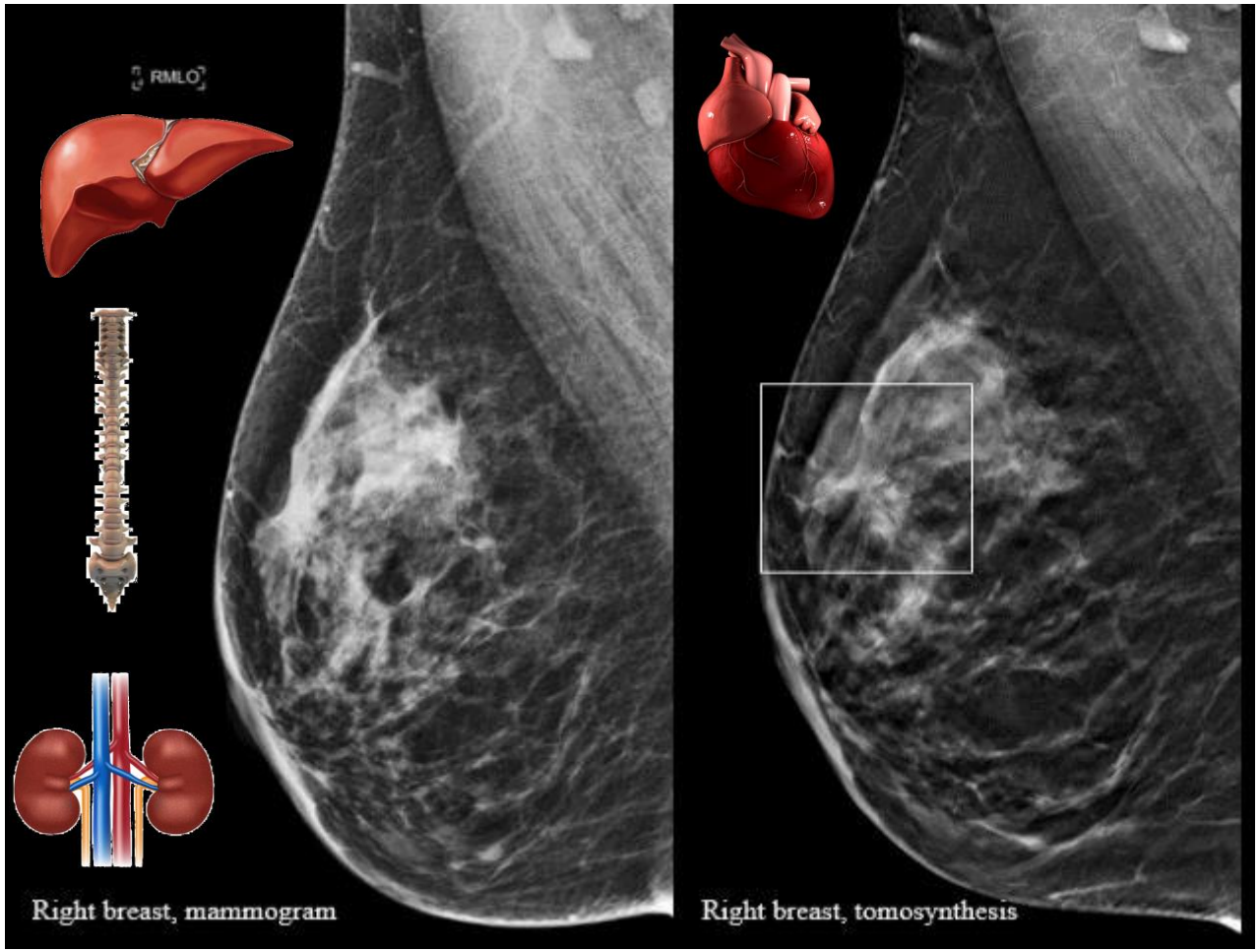

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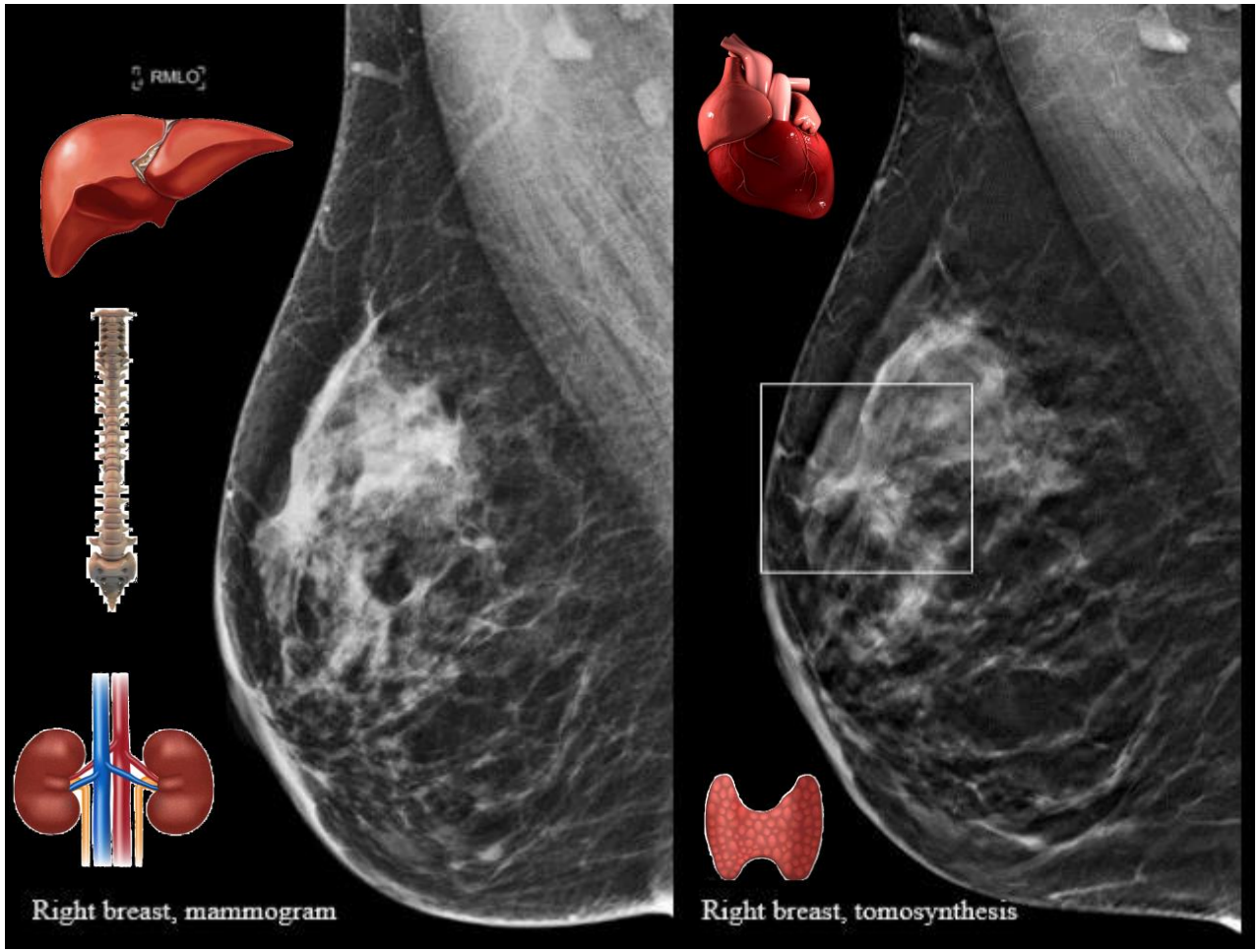

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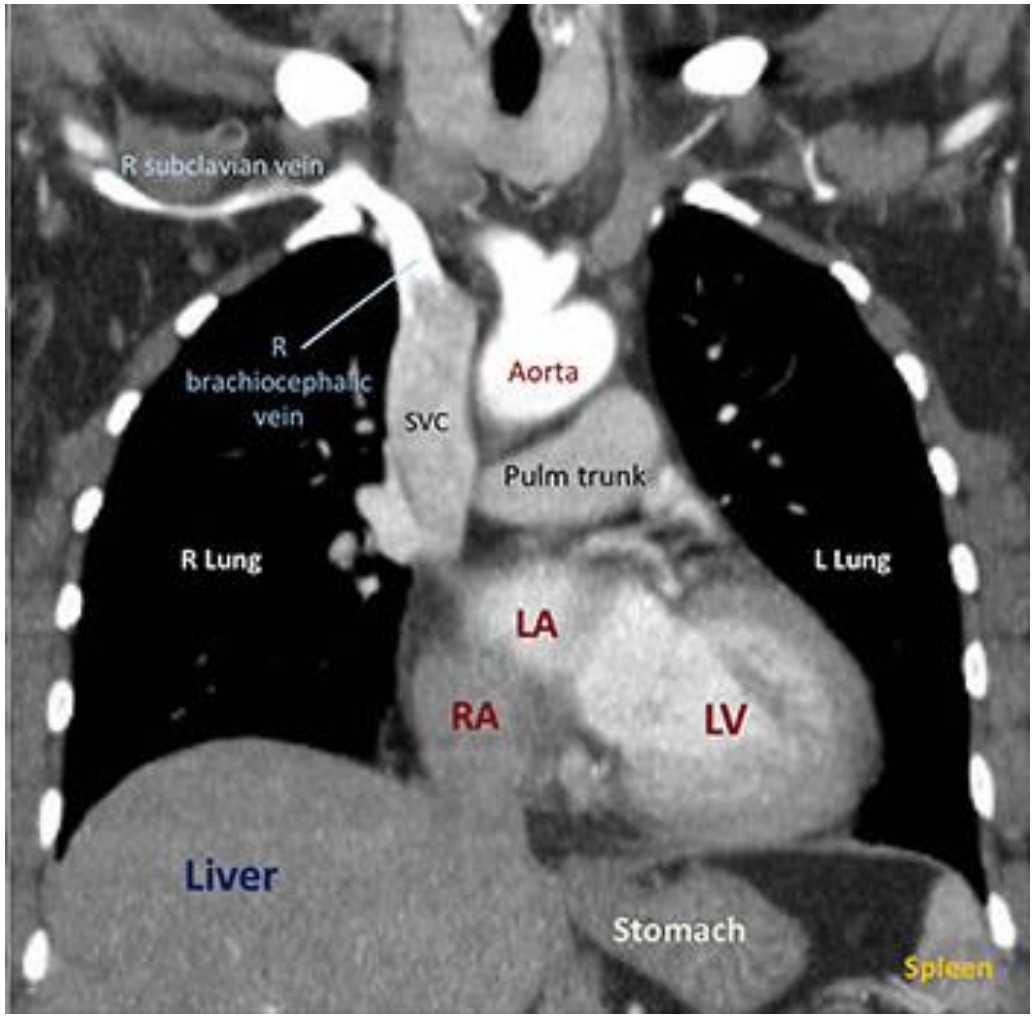

Source: Radiology Cafe

Category Descriptor	Lung-RADS Score	Findings	Management	Risk of Malignancy	Est. Population Prevalence
Incomplete	0	Prior chest CT examination(s) being located for comparison Part or all of lungs cannot be evaluated	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed	n/a	1%
Negative No nodules and definitely benign nodules	1	No lung nodules Nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules	Continue annual screening with LDCT in 12 months	< 1%	90%
Benign Appearance or Behavior Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	**Perifissural nodule(s)** *(See Footnote 11)* < 10 mm (524 mm^3) **Solid nodule(s):** < 6 mm (< 113 mm^3) new < 4 mm (< 34 mm^3) **Part solid nodule(s):** < 6 mm total diameter (< 113 mm^3) on baseline screening **Non solid nodule(s) (GGN):** <30 mm (<14137 mm^3) OR ≥ 30 mm (≥ 14137 mm^3) and unchanged or slowly growing **Category 3 or 4 nodules unchanged for ≥ 3 months**			
Probably Benign Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	**Solid nodule(s):** ≥ 6 to < 8 mm (≥ 113 to < 268 mm^3) at baseline OR new 4 mm to < 6 mm (34 to < 113 mm^3) **Part solid nodule(s)** ≥ 6 mm total diameter (≥ 113 mm^3) with solid component < 6 mm (< 113 mm^3) OR new < 6 mm total diameter (< 113 mm^3) **Non solid nodule(s)** (GGN) ≥ 30 mm (≥ 14137 mm^3) on baseline CT or new	6 month LDCT	1-2%	5%
Suspicious Findings for which additional diagnostic testing is recommended	4A	**Solid nodule(s):** ≥ 8 to < 15 mm (≥ 268 to < 1767 mm^3) at baseline OR growing < 8 mm (< 268 mm^3) OR new 6 to < 8 mm (113 to < 268 mm^3) **Part solid nodule(s):** ≥ 6 mm (≥ 113 mm^3) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm^3) OR with a new or growing < 4 mm (< 34 mm^3) solid component **Endobronchial nodule**	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm^3) solid component	5-15%	2%
Very Suspicious Findings for which additional diagnostic testing and/or tissue sampling is recommended	4B	**Solid nodule(s)** ≥ 15 mm (≥ 1767 mm^3) OR new or growing, and ≥ 8 mm (≥ 268 mm^3) **Part solid nodule(s) with:** a solid component ≥ 8 mm (≥ 268 mm^3) OR a new or growing ≥ 4 mm (≥ 34 mm^3) solid component	Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm^3) solid component. *For new large nodules that develop on an annual repeat screening CT, a 1 month LDCT may be recommended to address potentially infectious or inflammatory conditions*	> 15%	2%
	4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			

	Category	Recommended Action
0	Incomplete	Need additional views / imaging to further evaluate
1	Negative	Continue routine annual screening
2	Benign	Continue routine annual screening
3	Probably Benign	Short interval follow-up suggested (6 months)
4	Suspicious for malignancy	Biopsy should be considered
5	Highly suggestive of malignancy	Biopsy required
6	Known biopsy-proven malignancy	Confirmed biopsy and treatment planning

Rescue Lung Rescue Life

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	4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			
Other Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)	S	**Modifier - may add on to category 0-4 coding**	As appropriate to the specific finding	n/a	10%

	Category	Recommended Action
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1	Negative	Continue routine annual screening
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Other Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)	**S**	**Modifier - may add on to category 0-4 coding**

Rescue Lung Rescue Life

Incidental Findings – What Should Be Reported?

"The review of the scan reveals that an abnormality is present and requires further evaluation, but is not suggestive of lung malignancy. It is up to the radiologist to determine whether an abnormality is clinically significant."	*N Engl J Med 2011; 365:395-409*
"Radiologists and coordinators were asked to record only incidental findings that would likely require follow up or further evaluation. Overall, 857 patients (40.7%) had 1 or more incidental findings reported (site range, 89 of 444 [20.0%] to 135 of 213 [63.4%])"	*JAMA Intern Med. 2017;177(3):399-406*
"In the present study, extrapulmonary findings were defined as incidentally discovered masses or lesions included on the CT scan not referable to lung, bronchial tree, or pleura. Each radiologist assessed whether the extrapulmonary finding was a PS-IF. An extrapulmonary finding was classified as potentially significant if it required further diagnostic and/or clinical examination."	*Radiology: Volume 261: Number 1—October 2011*
"Unexpected findings which are either new or unknown and require some form of clinical or imaging investigation before the next recommended CTLS exam"	*J Natl Compr Canc Netw 2018;16(4):444–449*

Incidental Findings – What Should Be Reported?

Table 2. Results of Three Rounds of Screening.*

Screening Round	Low-Dose CT			
	Total No. Screened	Positive Result	Clinically Significant Abnormality Not Suspicious for Lung Cancer	No or Minor Abnormality
			no. (% of screened)	
T0	26,309	7191 (27.3)	2695 (10.2)	16,423 (62.4)
T1	24,715	6901 (27.9)	1519 (6.1)	16,295 (65.9)
T2	24,102	4054 (16.8)	1408 (5.8)	18,640 (77.3)

N Engl J Med 2011; 365:395-409

Table 1. Summary Results for the Initial Ro

Characteristic	No. (%) All Sites
Patients who met all screening criteria	4246
Patients who agreed to be screened[b]	2452 (57.7)
Patients screened	2106 (85.9)
Patients with nodular findings on scans[c]	1257 (59.7)
Patients with nodules to be tracked[d]	1184 (56.2)
Patients with suspicious findings not confirmed to be lung cancer[e]	42 (2.0)
Patients with confirmed lung cancer	31 (1.5)
Patients with incidental, non-nodule findings on scans	857 (40.7)
Total LDCT scans completed[f]	2694

JAMA Intern Med. 2017;177(3):399-406

Four hundred thirty-six PS-IFs were identified in 402 of the initial 5201 subjects from the COSMOS study (7.7%; 95% confidence interval [CI]: 7.0%, 8.5%) by the end of the 5th year of screening. The mean age (±standard

Radiology: Volume 261: Number 1—October 2011

Table 5

Screening Round	Significant Incidental Findings						
	Overall		Group 1		Group 2		*P* Value
T0	188	6.4%	150	6.7%	38	5.4%	.23
T1	45	2.5%	40	3.0%	5	1.2%	.03
T2	23	2.1%	20	2.4%	3	1.1%	.32
≥T3	13	1.9%	10	1.9%	3	1.9%	1
Total	269	4.1%	220	4.5%	49	3.2%	.02

J Natl Compr Canc Netw 2018;16(4):444–449

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eTable. Incidental Findings

Type of Incidental Finding	**# Findings (%)**
Abdominal abnormalities (i.e., mass, cyst, or other finding)	146 (14.0%)
Abdominal or thoracic aortic dilation or aneurysm	87 (8.3%)
Infectious, inflammatory, or interstitial process	265 (25.4%)
Thyroid nodule	25 (2.4%)
Other incidental findings (e.g., emphysema, coronary artery calcifications, hernias, etc.)	521 (49.9%)
Total Number of Findings	**1,044**

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Incidental Findings – Emphysema and Coronary Calcifications

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6A15. *Other clinically significant or potentially significant abnormalities – CT exam result modifier S:	O No O Yes If yes, what were the other findings? (Select all that apply.) ☐ Aortic aneurysm ☐ Coronary arterial calcification, moderate or severe ☐ Pulmonary fibrosis ☐ Mass, please specify, e.g., neck, mediastinum, liver, kidneys: _____ ☐ Other interstitial lung disease, select type if known: O UIP/IPF O ILD, other, please specify: _____ O ILD, unknown

https://nrdrsupport.acr.org/support/solutions/articles/11000041249-lcsr-exam-form

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Table 1. Prevalence/Extent of CAC and Emphysema

	CACs				Emphysema			
Qualitative Radiology Assessment	Overall	Group 1	Group 2	*P* Value	Overall	Group 1	Group 2	*P* Value
None	23.9%	21.8%	29.4%	.004	43.3%	39.7%	53.1%	<.001
Mild	28.9%	27.9%	31.7%	.17	38.6%	39.4%	36.4%	.3
Moderate	25.4%	27.2%	20.6%	.01	14.3%	16.6%	8.1%	<.001
Marked	21.9%	23.2%	18.3%	.06	3.8%	4.3%	2.5%	.1

	Overall	Group 1	Group 2	*P* Value
At least mild CAC and/or emphysema	88.3%	90.1%	83.6%	.001
Marked CAC and/or marked emphysema	24.7%	26.3%	20.3%	.02

Abbreviations: CAC, coronary artery calcifications; CTLS, CT lung screening.

J Natl Compr Canc Netw 2018;16(4):444–449

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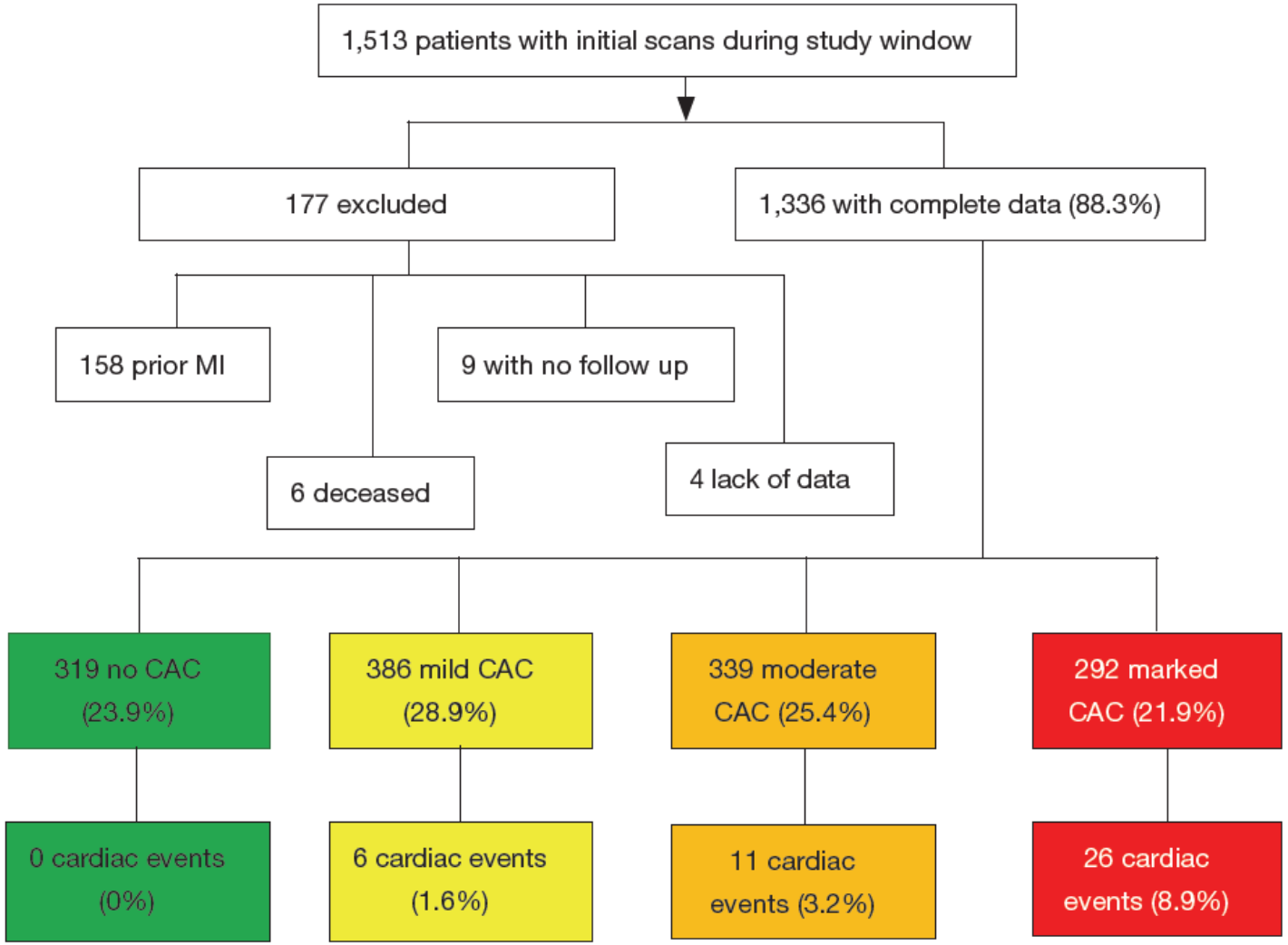
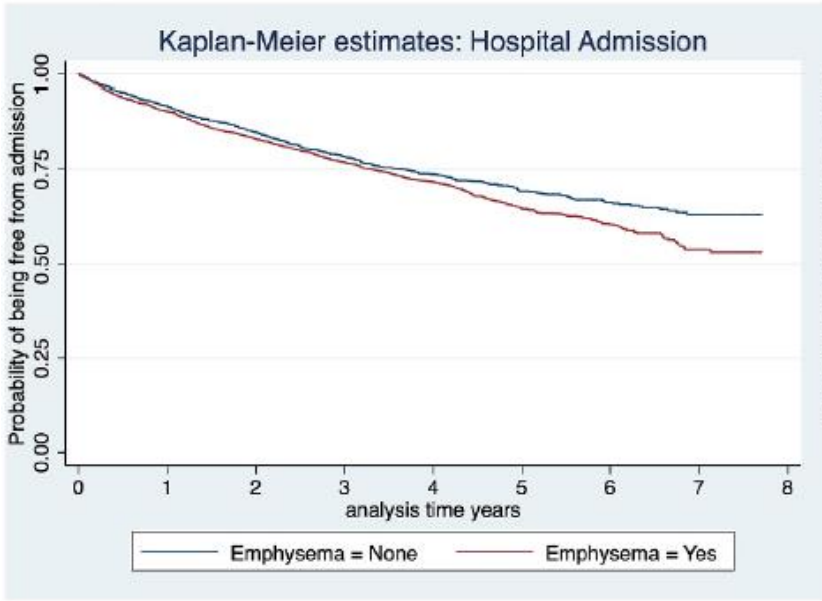


"Compared to individuals with no CAC the increased odds of an initial cardiac event was 2.56 (95% CI, 1.76–3.92, P<0.001) for mild CAC, 6.57 (95% CI, 3.10–15.4, P<0.0001) for moderate CAC, and 16.8 (95% CI, 5.46–60.3, P<0.001) for marked CAC."

J Thorac Dis 2018;10(5):2740-2751

Incidental Findings – Emphysema and Coronary Calcifications

A) LHMC



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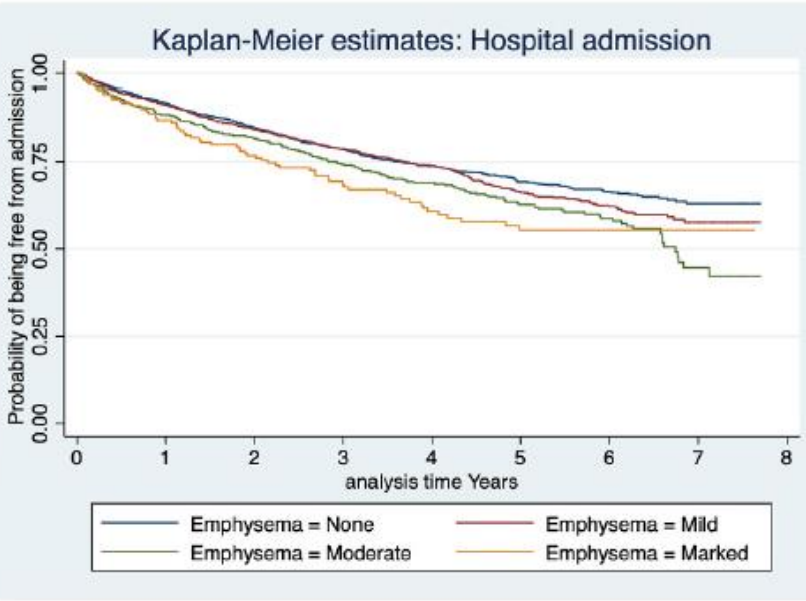
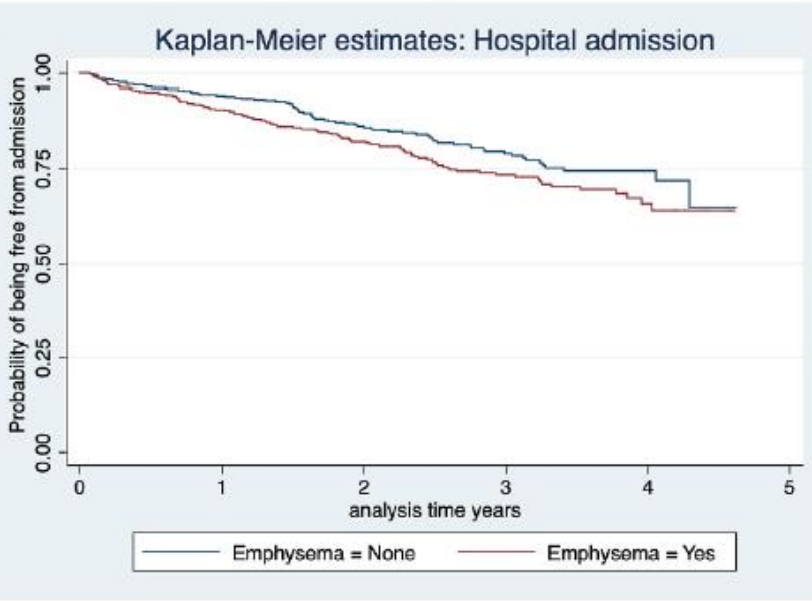


C) MAH Cohort



"These results also suggest that qualitative emphysema is associated with all cause and pneumonia related hospital admission. However, all cause and pneumonia related hospital admission was not replicated in our smaller replication cohort. These results did demonstrate that qualitative assessments of emphysema are associated with an increased risk for COPD admission in both cohorts."

Respiratory Medicine 176 (2021) 106245

Incidental Findings – Emphysema and Coronary Calcifications

- Correlate with downstream health-related outcomes
- Should be reported on every CTLS exam
- Expected in this population, therefore not significant incidental findings

FINDINGS:
Lung Screening Specific (LungRADS): Negative

Potentially Significant Incidentals (LungRADS category S): None.

Pulmonary Incidentals: Diffuse mild bronchial wall thickening sparing the posterior membrane with cartilage calcification, unchanged. Mild upper lung predominant centrilobular emphysema. Areas of linear atelectasis/ scarring in the inferior lingula not appreciably changed.

Other Incidentals: Status post CABG with marked native coronary artery calcifications. Small hiatal hernia.

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FINDINGS:
Lung Screening Specific (LungRADS): Negative

Potentially Significant Incidentals (LungRADS category S): None.

Pulmonary Incidentals: Diffuse mild bronchial wall thickening sparing the posterior membrane with cartilage calcification, unchanged. Mild upper lung predominant centrilobular emphysema. Areas of linear atelectasis/ scarring in the inferior lingula not appreciably changed.

Other Incidentals: Status post CABG with marked native coronary artery calcifications. Small hiatal hernia.

Incidental Findings – What Should Be Reported?

Table 1. Summary Results for the Initial Rou

Characteristic	No. (%) All Sites
Patients who met all screening criteria	4246
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JAMA Intern Med. 2017;177(3):399-406

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Incidental Findings – Infectious/Inflammatory Findings

Table 5. CTLS Metrics by Screening Round: Other Results

Screening Round	False Negatives							Significant Incidental Findings							Infectious/Inflammatory Findings						
	Overall		Group 1		Group 2		*P* Value	Overall		Group 1		Group 2		*P* Value	Overall		Group 1		Group 2		*P* Value
T0	3	0.1%	1	0%	2	0.3%	.14	188	6.4%	150	6.7%	38	5.4%	.23	219	7.5%	170	7.6%	49	7.0%	.59
T1	2	0.1%	2	0.1%	0	0%	1	45	2.5%	40	3.0%	5	1.2%	.03	120	6.8%	92	6.9%	28	6.5%	.76
T2	1	0.1%	0	0%	1	0.4%	.24	23	2.1%	20	2.4%	3	1.1%	.32	72	6.6%	53	6.4%	19	7.3%	.6
≥T3	0	0%	0	0%	0	0%	1	13	1.9%	10	1.9%	3	1.9%	1	45	6.5%	33	6.3%	12	7.4%	.61
Total	6	0.1%	3	0.1%	3	0.2%	.15	269	4.1%	220	4.5%	49	3.2%	.02	456	7.0%	348	7.1%	108	6.9%	.87

Abbreviation: CTLS, CT lung screening.

J Natl Compr Canc Netw 2018;16(4):444–449

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Very Suspicious Findings for which additional diagnostic testing and/or tissue sampling is recommended	4B	**Solid nodule(s)** ≥ 15 mm (≥ 1767 mm^3) **OR** new or growing, and ≥ 8 mm (≥ 268 mm^3)	Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm^3) solid component. *For new large nodules that develop on an annual repeat screening CT, a 1 month LDCT may be recommended to address potentially infectious or inflammatory conditions*	> 15%	2%
		Part solid nodule(s) with: a solid component ≥ 8 mm (≥ 268 mm^3) **OR** a new or growing ≥ 4 mm (≥ 34 mm^3) solid component			
	4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			

Lung-RADS® Version 1.1

Incidental Findings – Infectious/Inflammatory Findings

- Correlate with downstream health-related outcomes
- Should be reported when seen on CTLS exam
- Lung screening specific, therefore not significant incidental findings

FINDINGS:
Lung Screening Specific (LungRADS): Benign
Ill-defined ground-glass density in the left CP angle suggesting an infectious or inflammatory process.

Potentially Significant Incidentals (LungRADS category S): None.

Pulmonary Incidentals: Stable scattered areas of scarring bilaterally. Calcified pulmonary granuloma.

Other Incidentals: Small hiatal hernia. Mild coronary artery calcifications. Stable mildly prominent right axillary lymph node.

IMPRESSION:

1. ACR LungRADS category 2i: Negative - Benign appearing findings suspicious for infection/inflammation.
Ill-defined ground-glass attenuation in the left lung base.

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Incidental Findings – What Should Be Reported?

Table 2. Results of Three Rounds of Screening.*

Screening Round	Low-Dose CT			
	Total No. Screened	Positive Result	Clinically Significant Abnormality Not Suspicious for Lung Cancer	No or Minor Abnormality
			no. (% of screened)	
T0	26,309	7191 (27.3)	2695 (10.2)	16,423 (62.4)
T1	24,715	6901 (27.9)	1519 (6.1)	16,295 (65.9)
T2	24,102	4054 (16.8)	1408 (5.8)	18,640 (77.3)

N Engl J Med 2011; 365:395-409

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Four hundred thirty-six PS-IFs were identified in 402 of the initial 5201 subjects from the COSMOS study (7.7%; 95% confidence interval [CI]: 7.0%, 8.5%) by the end of the 5th year of screening. The mean age (±standard

Radiology: Volume 261: Number 1—October 2011

Table 5

Screening Round	Significant Incidental Findings						
	Overall		Group 1		Group 2		*P* Value
T0	188	6.4%	150	6.7%	38	5.4%	.23
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≥T3	13	1.9%	10	1.9%	3	1.9%	1
Total	269	4.1%	220	4.5%	49	3.2%	.02

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Incidental Findings – What is Significant?

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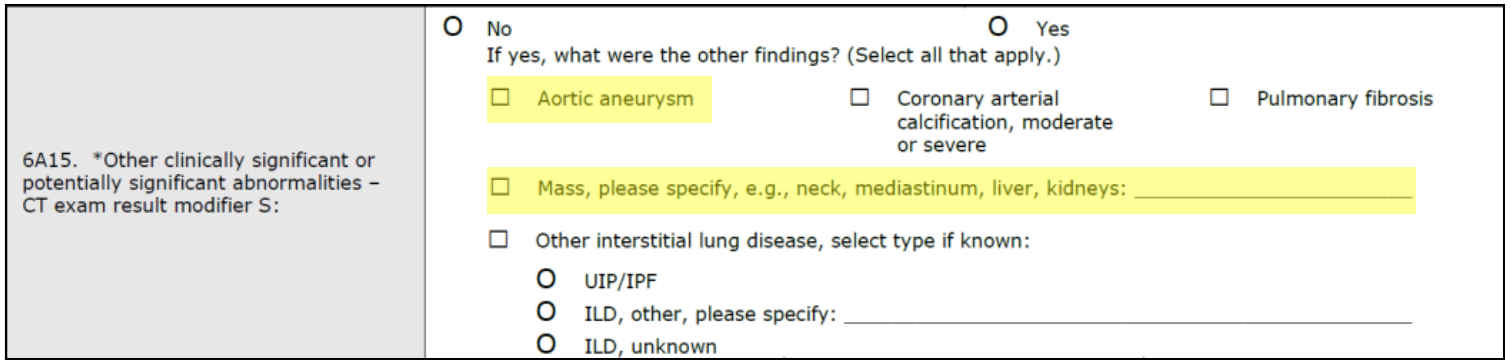


6A15. *Other clinically significant or potentially significant abnormalities – CT exam result modifier S:

O No O Yes

If yes, what were the other findings? (Select all that apply.)

☐ Aortic aneurysm ☐ Coronary arterial calcification, moderate or severe ☐ Pulmonary fibrosis

☐ Mass, please specify, e.g., neck, mediastinum, liver, kidneys: _____

☐ Other interstitial lung disease, select type if known:

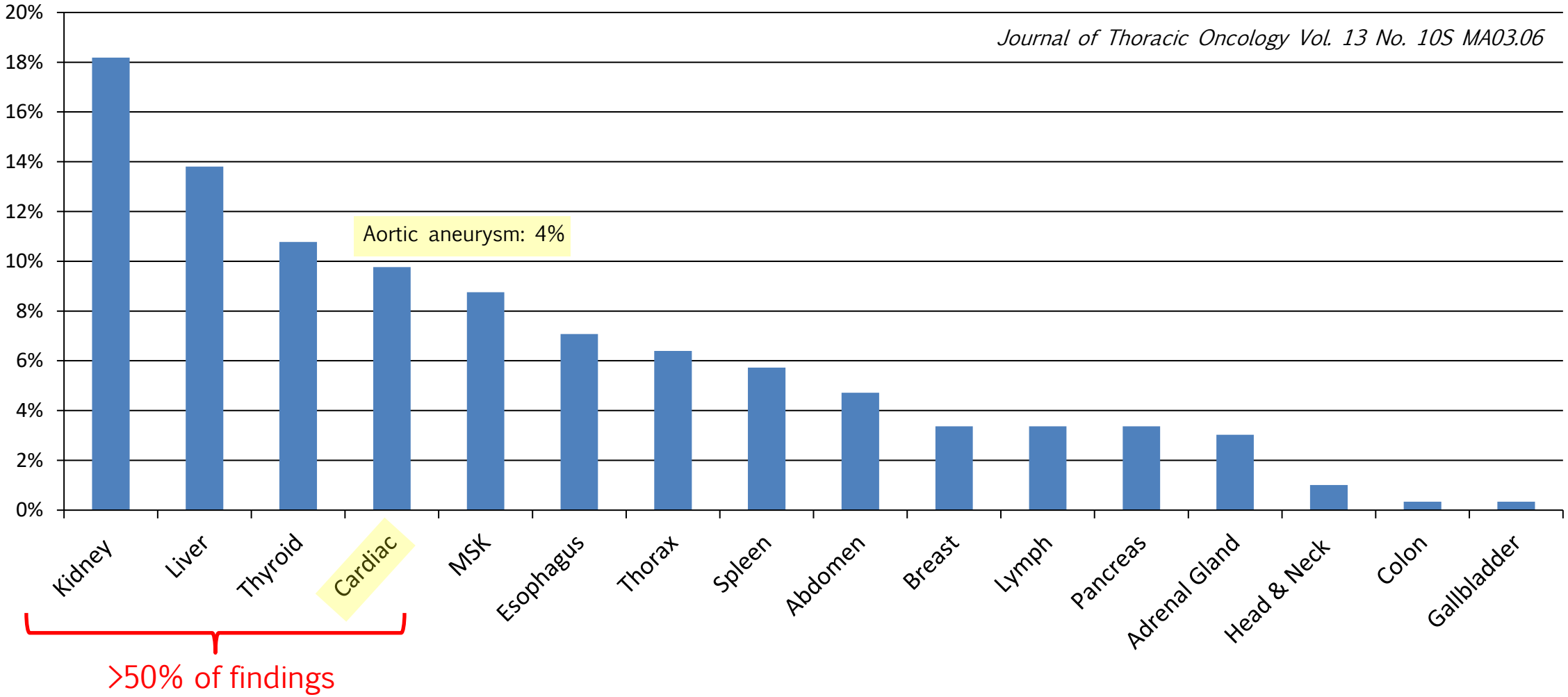
O UIP/IPF

O ILD, other, please specify: _____

O ILD, unknown

https://nrdrsupport.acr.org/support/solutions/articles/11000041249-lcsr-exam-form

Incidental Findings – What is Significant?



Incidental Findings – What is Significant?

IMPRESSION:

1. Lung-RADS category 2: Negative, benign appearance/behavior.

2. Lung-RADS category S: Positive.
> Intermediate density lesion at the posterior aspect of the right kidney, probable hemorrhagic or proteinaceous cyst, however ultrasound warranted as initial next step in characterization.

IMPRESSION:
1. ACR LungRADS category 1: Negative, no evidence of primary lung cancer.

2. ACR LungRADS category S: Positive.
Splenomegaly.

IMPRESSION:

1. ACR LungRADS category 2i: Negative - Benign appearing findings suspicious for infection/inflammation.
> Tree-in-bud nodular opacities in the right upper lobe as noted above.
> Asymmetric nodular biapical scarring.

2. ACR LungRADS category S: Positive.
> Large left thyroid nodule measuring up to 3 cm.

Incidental Findings – Recommendations

RECOMMENDATIONS:
1. Continued routine annual LDCT lung screening.
2. Evaluation of the right kidney with renal ultrasound.

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1. Continued routine annual LDCT lung screening.
2. Clinical and laboratory evaluation for splenomegaly.

RECOMMENDATIONS:
1. Suggest clinical evaluation and repeat LDCT chest in 3 months following antimicrobial therapy as appropriate to evaluate for stability and resolution.
2. Thyroid ultrasound.

Incidental Findings – Results

	LHMC	COSMOS
Patients in study	2927	5201
Study duration	5 years	5 years
Mean follow up interval	35.7 months	51.1 months
Patients with significant incidental finding(s)	9.4%	7.7%
Significant incidental CDR	6.2%	6.2%
Significant incidental cancer : lung cancer ratio	1 : 7.5	1 : 7
Significant incidental cancer rate	1 per 195 patients screened	1 per 200 patients screened

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Incidental Findings – Summary

- Coronary artery calcifications and emphysema are highly prevalent in the CTLS eligible population; should be graded on every exam
- Findings associated with pulmonary infection/inflammation can overlap with lung cancer findings
  - Not reliably incidental; should be characterized with the Lung-RADS number but uniquely coded to allow for downstream QA
- Significant incidentals: new/unknown, unexpected findings warranting some form of clinical or imaging evaluation prior the next CTLS exam
  - Closely approximates what was observed in the NLST (which formed the foundation of USPSTF and CMS approval)
  - Higher at baseline
  - Recommended next step by reading radiologist ideally per established industry/institutional standards

Thank You!

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