Diagnostic Performance of Cardiac and Whole-Body ^{124}I-evuzamitide (AT-01) PET/MRI in Systemic Amyloidosis

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Disclosures

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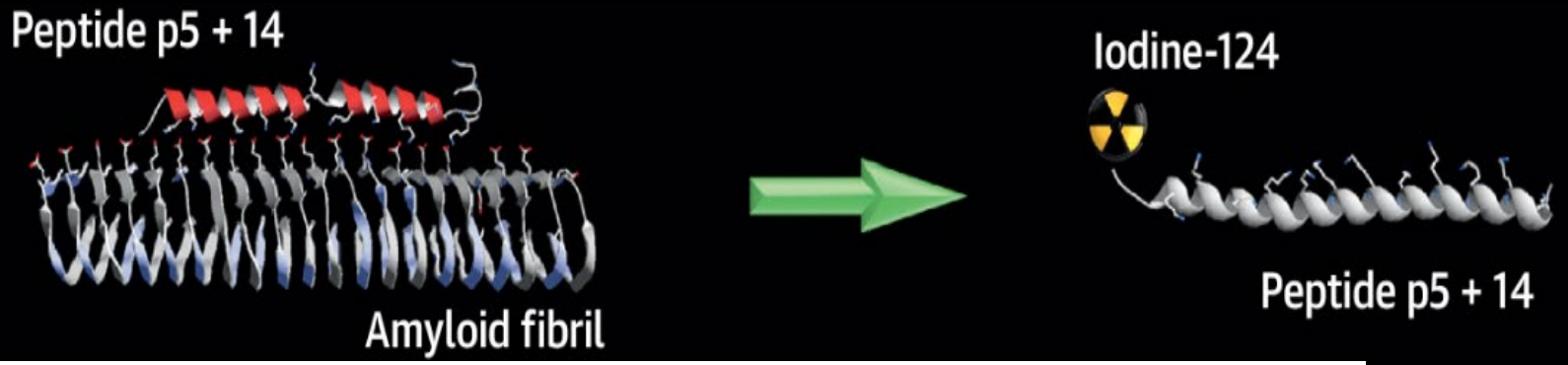
Background

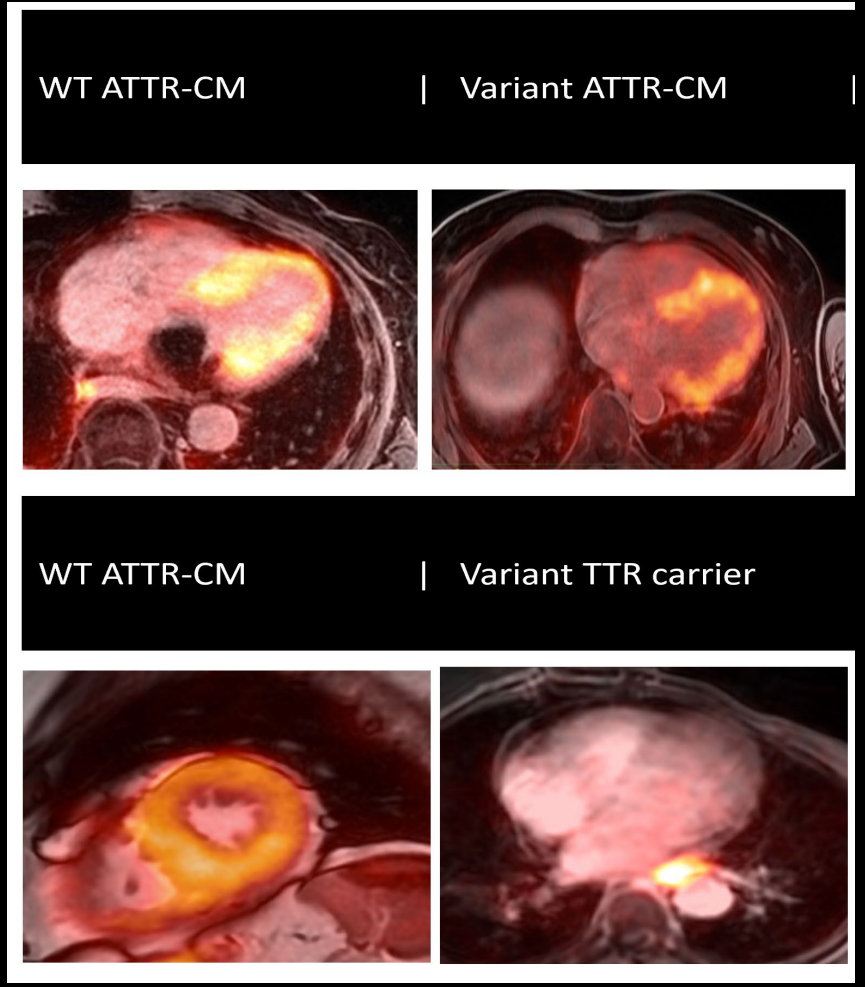
- Cardiac magnetic resonance imaging (CMR) is currently considered the gold standard imaging modality to assess cardiac structure, function, and surrogates of amyloid load.
- ^{124}I-evuzamitide (AT-01) is a novel pan-amyloid PET radiotracer.
- We conducted a prospective study of ^{124}I-evuzamitide cardiac and whole-body PET/MRI to assess the diagnostic accuracy and tracer distribution in patients suspected to have or diagnosed with systemic amyloidosis.



Wall JS, et al. J Am Coll Cardiol Img. 2023;16(11):1433-1448.

Methods

- Cardiac amyloidosis was suspected or diagnosed in all patients prior to enrollment.
- Patients were diagnosed by standard clinical, laboratory, biopsy, and imaging criteria. ^{124}I-evuzamitide diagnostic performance was judged against comprehensive clinical evaluation (gold standard).
- All patients underwent hybrid cardiac PET/MRI followed by whole-body (WB) PET/MRI with ^{124}I-evuzamitide (mean administered activity 1.05±0.02 mCi, average 5-6 minutes per bed). All patients received potassium iodide 130 mg for 3 days, first dose at least 30 minutes prior to ^{124}I-evuzamitide administration.
- Ratio of mean LV septum standardized uptake value (SUV) to mean LV blood pool SUV was calculated.



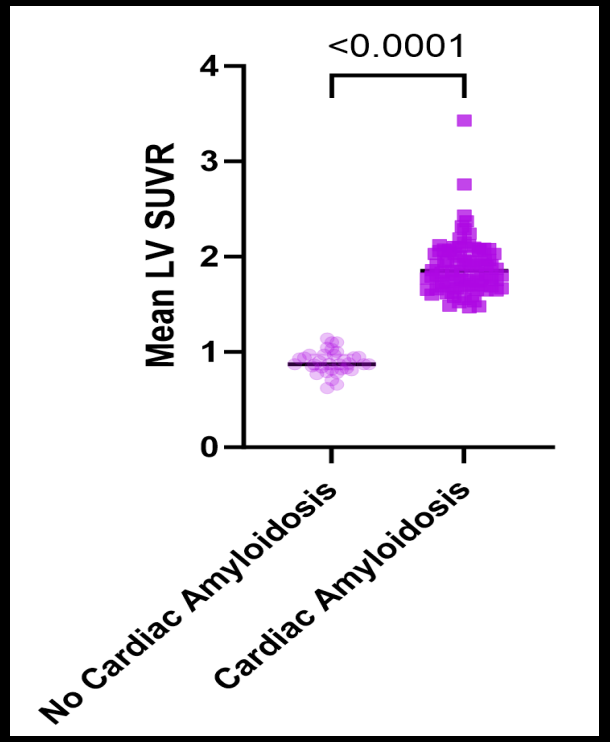
Results

- 111 patients were enrolled from January 2023 through August 2025.
- All subjects underwent the imaging protocol.
  - 77 had cardiac transthyretin amyloidosis
  - 22 had cardiac light chain amyloidosis
  - 3 had ApoA1 or ApoA4
  - 10 had systemic amyloidosis but no cardiac involvement
  - 24 had no evidence of systemic amyloidosis
- ^{124}I-evuzamitide was safe without any serious adverse events.
- Time from ^{124}I-evuzamitide injection to whole-body PET was 3.3 ±0.5 hours.

Baseline Characteristics

Variable	Cardiac Amyloidosis (N=77)	Controls (N=34)	p-value
Age (years)	73±9.3	66±8.3	<0.001
Female sex	11 (14%)	18 (53%)	<0.001
Controls Underlying Phenotype:			
LVH/HCM		4 (11.7%)	
Extracardiac AL amyloidosis		8 (24%)	
Transthyretin variant carrier		11 (32%)	
Orthopedic amyloid deposit		5 (14.7%)	
Systemic amyloidosis without cardiac involvement	0%	10 (29%)	—
Pathogenic transthyretin variant	9 (12.5%)	11 (32%)	0.25
Mean myocardial SUV	7.3 (1.8)	3.2 (0.7)	<0.001
Mean LV blood pool SUV	3.9 (1.1)	3.5 (0.8)	0.001
SUVR (myocardium over LV blood)	1.9 (0.3)	0.9 (0.1)	<0.001
^{124}I-evuzamitide distribution			—
Cardiac	77 (100%)	0 (0%)	
Spleen	15 (19.4%)	2 (8.0%)	
Liver	14 (18.2%)	2 (8.0%)	
Renal	15 (19.4%)	9 (36.0%)	
Lungs	9 (11.6%)	1 (4.0%)	
Orthopedic	32 (41.6%)	10 (40%)	

^{124}I-evuzamitide PET/MRI had 100% sensitivity and specificity in detecting cardiac amyloidosis. No false positive or false negative cases were observed

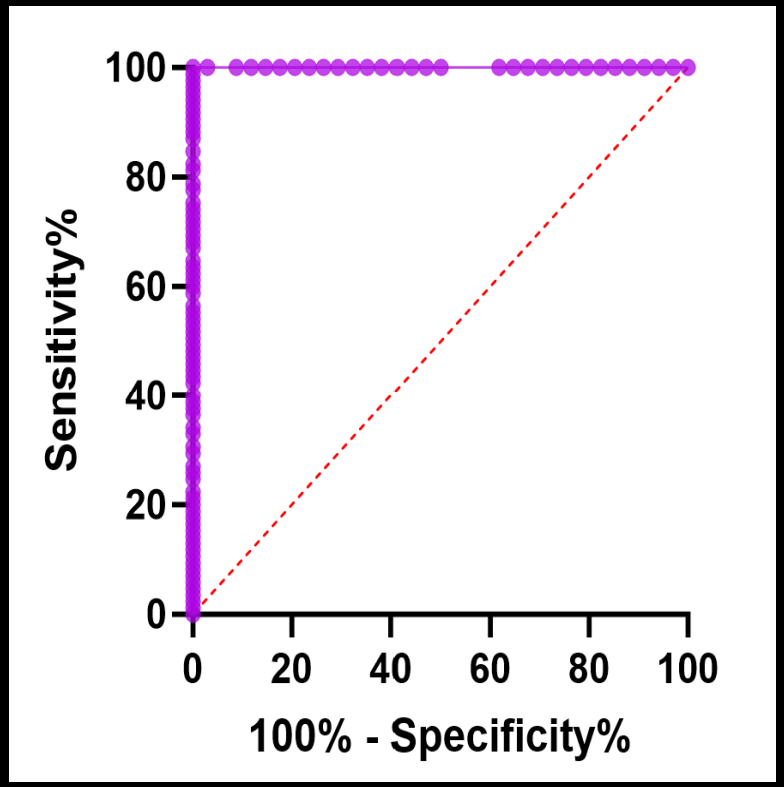


A mean myocardial/LV blood SUV ratio cut-off of 1.31 yielded:

Sensitivity of 100% (95% CI 96%, 100%)

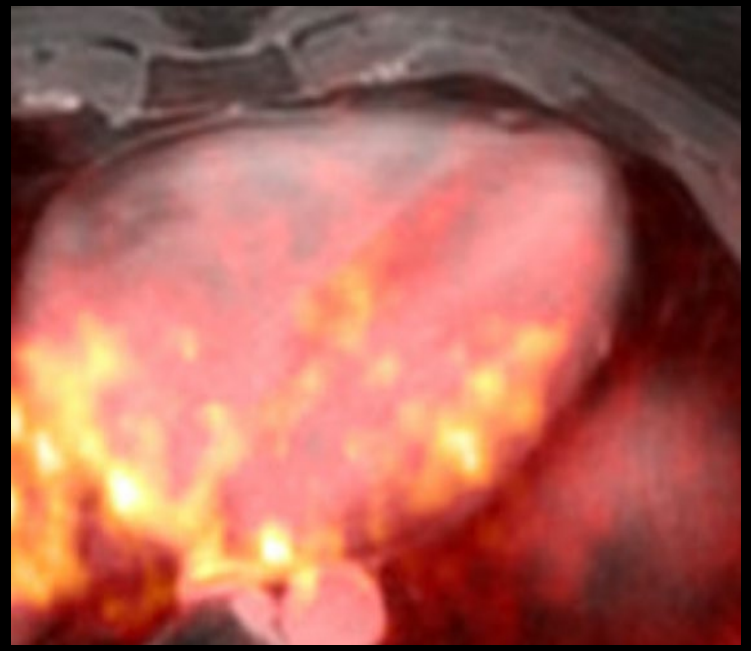
Specificity of 100% (95% CI 90%, 100%)

AUC 1.00, p<0.0001

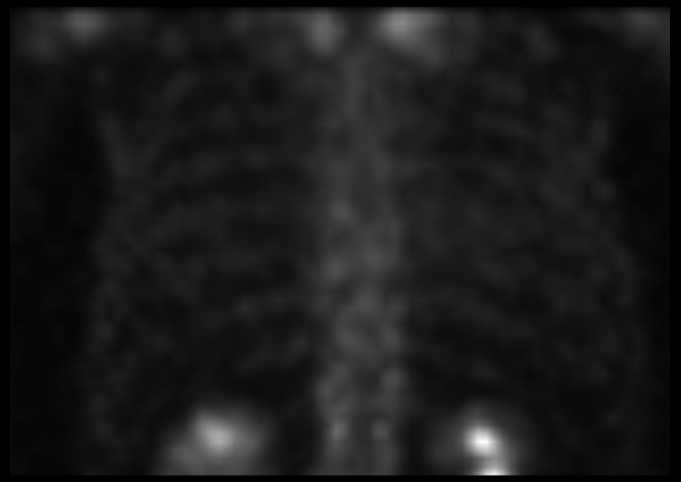


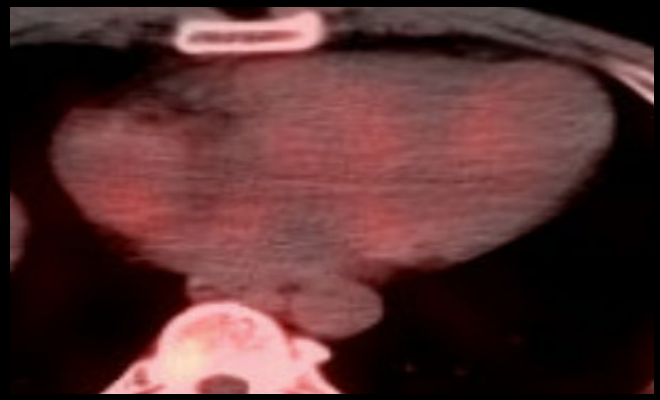
Representative Examples of ^{124}I-evuzamitide uptake in a patients with biopsy-proven wild type ATTR-CM while bone scintigraphy and CMR were not suggestive.

^{124}I-evuzamitide PET/MRI



^{99m}Tc-PYP Scintigraphy





Conclusions

- ^{124}I-evuzamitide PET/MRI is a powerful diagnostic tool for cardiac amyloidosis, and provides comprehensive diagnostic evaluation and organ survey of patients suspected to have or diagnosed with systemic amyloidosis.
- In this population of patients diagnosed with or suspected to have cardiac amyloidosis, there were no false positive or negatives with ^{124}I-evuzamitide PET/MRI imaging for the diagnosis of cardiac amyloidosis.
- A simple measure of mean myocardial to LV blood pool SUV ≥1.31 yielded a 100% sensitivity and specificity for the diagnosis of cardiac amyloidosis.
- Some of our participants were already diagnosed with systemic amyloidosis. The ongoing REVEAL study will define the diagnostic performance in a population with suspected cardiac amyloidosis referred for evaluation.