ASH® CLINICAL PRACTICE GUIDELINES

Diagnosis of Light Chain Amyloidosis (AL)

An Educational Slide Set

American Society of Hematology 2025 Guidelines for Diagnosis of Light Chain Amyloidosis

Slide set authors:
Shahzad Raza, MD, FACP
Raymond Comenzo, MD
Noel Dasgupta, MD, FACC
Vishal Kukreti, MD, FRCPC, MSc

American Society of Hematology 2025 guidelines for diagnosis of light chain amyloidosis

Vishal Kukreti, Matthew Seftel, Maria Adela Aguirre, Muayad Azzam, Deborah D. Boedicker, Naresh Bumma, Antonia S. Carroll, Raymond Comenzo, Joselle Cook, Noel Dasgupta, Alfredo De La Torre, Angela Dispenzieri, Faizi Jamal, Hassan Kawtharany, Jack Khouri, Nelson Leung, Jamil Nazzal, Maria M. Picken, Shahzad Raza, Vaishali Sanchorawala, Nitasha Sarswat, Hira Shaikh, Daulath Singh, Reem A. Mustafa

How were these guidelines generated?

PANEL FORMATION

Guideline panel was formed following these key criteria:

- Balance of expertise (including disciplines beyond hematology, & inclusive of patients)
- Close attention to minimization & management of conflicts of interest

CLINICAL QUESTIONS

7 clinically-relevant questions generated in **PICO format** (population, intervention, comparison, outcome)

Example: PICO question

"In individuals with clinical suspicion of light chain amyloidosis, should we perform target organ biopsy vs surrogate organ biopsy?

EVIDENCE SYNTHESIS

Evidence summary generated for each PICO question via systematic review of health effects plus:

- Resource use
- Feasibility
- Acceptability
- Equity
- Patient values and preferences

MAKING RECOMMENDATIONS

Recommendations made by guideline panel members based on evidence for all factors.

ASH guidelines are reviewed annually by expert work groups convened by ASH. Resources, such as this slide set, derived from guidelines that require updating are removed from the ASH website.

How patients and clinicians should use these recommendations

	STRONG Recommendation		CONDITIONAL Recommendation	
	"The panel recommends…"	"The panel recommends against…"	"The panel suggests…"	"The panel suggests against…"
				
For patients	Most individuals would want the intervention.		A majority would want the intervention, but many would not.	
For clinicians	Most individuals should receive the intervention.		Different choices will be appropriate for different patients, depending on their values and preferences. Use **shared decision making**.	

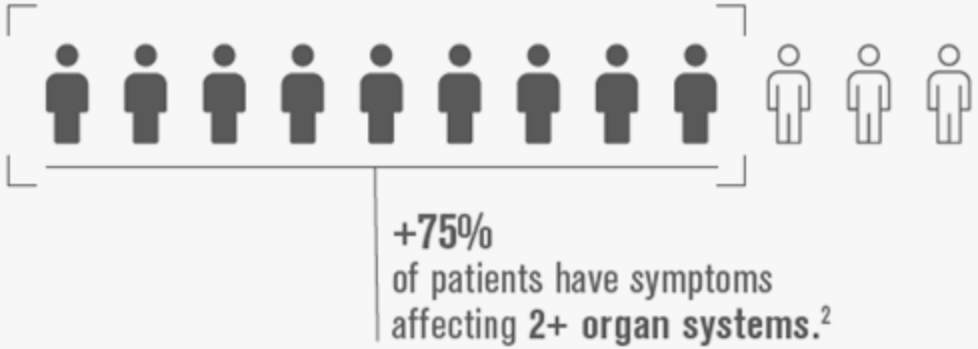
Objectives

By the end of this session, you should be able to

1. Identify signs and symptoms of possible cardiac light chain amyloidosis (AL)
2. Know what lab work should be ordered to evaluate for AL
3. Determine appropriate sites for biopsy in patients with suspected AL

FACTS ABOUT AL AMYLOIDOSIS

AL is an under-recognized disease. Approximately 3,260 people are diagnosed with AL amyloidosis per year in the United States.[1] Patients often experience multiple signs and symptoms for over a year before receiving a diagnosis.



+75%
of patients have symptoms affecting **2+ organ systems.**[2]

Two-thirds
of patients see **3 or more providers** before receiving a diagnosis.[1]

DELAYED DIAGNOSIS

2.7 years
Median time from symptom onset to diagnosis.[3]

Up to 72% of patients experience their first symptom more than a year prior to diagnosis.[4]

Symptoms may include:

- Difficulty breathing
- Low blood pressure
- Severe fatigue
- Diarrhea/Constipation
- Proteinuria
- Numbness and tingling in extremities
- Bruised looking eyes
- Tongue swelling
- Difficulty swallowing
- Carpal tunnel
- Swelling of legs or abdomen

Kumar N, Zhang NJ, Cherepanov D, Romanus D, Hughes M, Faller DV. Global epidemiology of amyloid light-chain amyloidosis. Orphanet J Rare Dis. 2022;17(1):278.; 2. Szor RS, Fernandes F, Lino AMM, et al. Systemic amyloidosis journey from diagnosis to outcomes: a twelve-year real-world experience of a single center in a middle-income country. Orphanet Journal of Rare Diseases. 2022;17(1):425; 3. Hester LL, Gifkins DM, Bellew KM, et al. Diagnostic delay and characterization of the clinical prodrome in AL amyloidosis among 1523 US adults diagnosed between 2001 and 2019. Eur J Haematol. 2021; 107: 428–435. https://doi.org/10.1111/ejh.13679

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

- A 54-year-old male presented with complaints of difficulty going up the hill with his colleagues during lunch breaks for the past 1.5 years.
- Symptoms included:
  - Dizziness
  - Headache
  - Fatigue
  - Mild dyspnea on exertion
- Routine tests including complete blood count (CBC), comprehensive metabolic profile (CMP), and chest x-ray (CXR) were normal.
- The patient was encouraged to exercise and make lifestyle modifications.
- Over the next 12 months, he developed progressively worsening leg swelling, significant fatigue, and worsening dyspnea.
- He was then referred to cardiology for further evaluation.

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

Investigations:

- **EKG:** Sinus rhythm, low voltage QRS complexes, prolonged QTc (493 msec)
- **Echocardiogram:** Left ventricular posterior wall thickness 1.4 cm (Normal range: 0.6-1.1 cm), interventricular septal thickness 1.3 cm (Normal range: 0.6-1.1 cm), EF 52%, Global peak longitudinal strain reduced with apical sparing (abnormal)
- **Cardiac biomarkers:** NT-proBNP 7050 pg/mL (AL threshold >332 pg/mL), High sensitivity Troponin T 137 ng/L (AL threshold >35 ng/L)
- **Labs**: WBC 7.02 (4-11 k/µL), hemoglobin 12.1 (13-17 g/dL), platelet 89 (150 –400 K/µL), creatinine 1.0 (0.73-1.22 mg/dL), total protein 5.1 (6.3-8 g/dL), calcium 8.1 (8.5-10.2 mg/dL), albumin 2.7 (3.9-4.9 g/dL), liver chemistries are normal

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

Which of the following increase suspicion for cardiac AL?

A. Low voltage on EKG, left ventricular hypertrophy on echo that is discordant to the QRS voltage on EKG, echocardiographic reduced longitudinal strain with an apical sparing pattern, elevated NT-proBNP, elevated troponin
B. High voltage of EKG, normal wall thickness on echocardiography, normal diastolic function, elevated NT-proBNP, elevated troponin
C. High voltage on EKG, echocardiographic longitudinal strain with a basal sparing pattern, elevated NT-proBNP, elevated troponin

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

Which of the following increase suspicion for cardiac AL?

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B. High voltage of EKG, normal wall thickness on echocardiography, normal diastolic function, elevated NT-proBNP, elevated troponin

C. High voltage on EKG, echocardiographic longitudinal strain with a basal sparing pattern, elevated NT-proBNP, elevated troponin

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

What labs should be ordered to evaluate for AL?

A. Serum protein electrophoresis
B. Serum free light chains with ratio, Serum Immunofixation, and Urine Immunofixation
C. Urine free light chains
D. Serum free light chains with ratio and urine free light chains

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

What labs should be ordered to evaluate for AL?

A. Serum protein electrophoresis

B. Serum free light chains with ratio, Serum Immunofixation, and Urine Immunofixation

C. Urine free light chains

D. Serum free light chains with ratio and urine free light chains

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

Sensitivity to diagnose light chain amyloidosis increases if all of the following labs are ordered:

- serum free light chains with ratio
- serum immunofixation, and
- urine immunofixation

For this patient:

- **Serum free light chains with ratio:**
  - Kappa (k) FLC 18.0 mg/L
  - Lambda (λ) FLC 245.7 mg/L
  - kλ ratio 13.65
- **Serum immunofixation:**
  - SPEP+ IFE showed monoclonal lambda protein band
- **Urine immunofixation:**
  - UPEP+ IFE : No evidence of monoclonal protein

Recommendation

For individuals with suspected cardiac amyloidosis, the ASH Guideline Panel ***recommends*** the use of serum and urine immunofixation (SIFE/UIFE) and serum free light chains with ratio to increase clinical suspicion of cardiac light chain amyloidosis. (Strong recommendation based on moderate certainty in the evidence about effects)

- The panel judged the diagnostic performance of these tests to be very accurate as these tests have high sensitivity (99%) and hence an optimal screening tool for increasing suspicion of AL amyloidosis.

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

Part A - What would you suggest as the next step to establish diagnosis?

A. Cardiac MRI
B. Renal Ultrasound
C. Fat pad sampling and Bone Marrow Biopsy
D. Bone scintigraphy using Tc99m-PYP, Tc99-DPD or Tc99m-HMDP

- PYP – Pyrophosphate; HMDP – Hydroxymethylene Diphosphonate; DPD – 3,3-diphosphono-1,2-propanodicarboxylic acid

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Part A - What would you suggest as the next step to establish diagnosis?

A. Cardiac MRI

B. Renal Ultrasound

C. Fat pad sampling and Bone Marrow Biopsy

D. Bone scintigraphy using Tc99m-PYP, Tc99-DPD or Tc99m-HMDP

Recommendations

For individuals with positivity in any of the following studies: SIFE, UIFE, or sFLC, abnormal cardiac biomarkers, and echocardiography consistent with amyloidosis, the ASH Guideline Panel ***suggests against*** performing cardiac magnetic resonance (CMR) (conditional recommendation based on a very low certainty in the evidence about effects).*

**Note that this recommendation solely applies to diagnosis, not staging.*

For individuals with a suspicion of light chain amyloidosis, the ASH Guideline Panel ***recommends against*** the use of bone scintigraphy (PYP, DPD, HMDP) for the diagnosis of AL cardiac amyloidosis (strong recommendation based on moderate certainty in the evidence about effects).

For individuals with suspected AL cardiac amyloidosis and positive cardiac biomarkers, echocardiogram, and positivity in any of the following studies: SIFE, UIFE, or sFLC, the ASH Guideline Panel ***suggests either*** both fat pad sampling and bone marrow biopsy or endomyocardial biopsy. (conditional recommendation based on low certainty in the evidence about effects)

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

Part B - Fat pad sampling showed no evidence of amyloidosis (negative Congo red staining). Bone marrow biopsy showed 5% lambda clonal plasma cells and negative Congo red stain. What should be done next to establish the diagnosis?

A. Cardiac MRI
B. No additional tests are needed; starting systemic treatment for light chain amyloidosis
C. Endomyocardial Biopsy
D. Repeat Bone Marrow Biopsy

Case 1: Suspected Cardiac Light Chain Amyloidosis (AL)

Part B - Fat pad biopsy showed no evidence of amyloidosis (negative Congo red staining). Bone marrow biopsy showed 5% lambda clonal plasma cells and negative Congo red stain. What should be done next to establish the diagnosis?

A. Cardiac MRI

B. No additional tests are needed; starting systemic treatment for light chain amyloidosis

C. Endomyocardial Biopsy

D. Repeat Bone Marrow Biopsy

Case 1: Conclusion

Part A

In this case, the patient has suspected cardiac light chain amyloidosis (AL). He has positive cardiac biomarkers, an abnormal echocardiogram and abnormal free light chains levels. Fat pad sampling and bone marrow or endomyocardial biopsy should be performed first to establish the diagnosis.

A. Cardiac MRI should not be performed: The patient already has suspected light chain amyloidosis with abnormal serum free light chains with ratio and serum immunofixation and an echocardiogram consistent with possible cardiac amyloidosis (left ventricular hypertrophy, reduced left ventricular global longitudinal strain with an apical sparing pattern). Cardiac MRI would delay the diagnosis.
B. Renal Ultrasound provides information on kidney morphology, and helpful for ruling out other causes of renal dysfunction.
C. Tc99m-PYP scan: This test is performed if there is a high suspicion for ATTR Amyloidosis

Case 1: Conclusion

Part B

In this case, we emphasize need for an accurate diagnosis, avoiding delays by choosing the right investigation and identifying common errors.

A. Cardiac MRI is incorrect: The patient already has suspected light chain amyloidosis. His echocardiogram has features concerning for cardiac amyloidosis. Cardiac MRI would delay the diagnosis.

B. No additional tests; starting systemic treatment for light chain amyloidosis is incorrect. Detecting clonal plasma cells alone without amyloidosis does not establish the diagnosis.

C. Endomyocardial Biopsy: If surrogate biopsy is negative for amyloidosis, clinicians should evaluate target site for biopsy. This will prevent delays in making a diagnosis.

D. Repeat bone marrow biopsy: The patient has a bone marrow biopsy with clonal plasma cells but without evidence of amyloidosis (negative Congo red stain). To avoid delays, the patient should get a target organ biopsy, in this case, an endomyocardial biopsy.

Case 1: Summary

- Lab work to evaluate for suspected cardiac light chain amyloidosis (AL) should include serum free light chains with ratio, serum immunofixation, urine immunofixation, NT-proBNP, and troponin.
- Diagnostic tests that may increase clinical suspicion of light chain amyloidosis include low voltage on EKG, echocardiography showing increased left ventricular wall thickness, diastolic dysfunction, reduced global longitudinal strain with an apical sparing pattern, and a cardiac MRI with diffuse subendocardial late gadolinium enhancement.
- Diagnosis of cardiac AL includes a bone marrow biopsy demonstrating a plasma cell disorder and a tissue sample showing amyloid deposition with amyloid typing using a verified method. If a surrogate site is negative for amyloid deposition, the next highest yield site is typically the affected organ.

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

- A 65-year-old female presents to the clinic as a referral from her nephrologist. She reports symptoms of unexplained generalized fatigue, weight gain (20 pounds) and significant bilateral leg swelling to the extent that her shoes do not fit anymore over the last 2 months. She has also noticed foamy urine over the past month.
- Her medical history includes hypertension but no prior renal disease. Her surgical history is notable for bilateral carpal tunnel release surgery which she had done 10 years ago. She denies smoking history or use of any illicit drugs.
- Physical examination reveals bilateral lower extremity pitting edema 3+, macroglossia, dark bruises around the eye. Rest of the exam was unremarkable.

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

On presentation, her laboratory findings include:

- **Urine Protein** (24-hour collection): 5.5 g/day (normal is less than 150 mg/day)
- **Serum Albumin**: 2.8 g/dL (normal range: 3.4-5.4 g/dL)
- **Creatinine**: 1.3 mg/dL (previously 1.0 mg/dL)
- **NT-proBNP:** 350 pg/mL (AL threshold >332 pg/mL)
- **Echocardiogram findings:**
    - Normal left ventricular size, with an interventricular septal thickness of 0.9 cm (normal values range between 0.6 - 1.1 cm) and an ejection fraction of 60-65%. No evidence of diastolic dysfunction.

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part A: Based on the clinical presentation and laboratory findings, what is the first diagnostic test to consider evaluating for suspected renal AL?

A) Serum protein electrophoresis (SPEP) with Immunofixation (IFE) alone (SPEP/IFE)
B) Urine protein electrophoresis (UPEP) with Immunofixation (IFE) alone (UPEP/IFE)
C) Serum Immunoglobulin Free Light Chains with ratio (sFLC)
D) Combination of SPEP/IFE, UPEP/IFE, and sFLC
E) Renal biopsy

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Question 1 (Part A): Based on the clinical presentation and laboratory findings, what is the first diagnostic test to consider evaluating for suspected renal AL?

A) Serum protein electrophoresis (SPEP) with Immunofixation (IFE) alone (SPEP/IFE)
B) Urine protein electrophoresis (UPEP) with Immunofixation (IFE) alone (UPEP/IFE)
C) Serum Free Light Chains with ratio (sFLC)
D) Combination of SPEP/IFE, UPEP/IFE, and sFLC
E) Renal biopsy

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

For patients with unexplained proteinuria, the ASH Guideline Panel suggests performing paraprotein testing (IFE/UIFE/FLC) to increase clinical suspicion of light chain amyloidosis (conditional recommendation based on low certainty in the evidence about effects ⊕⊕◯◯).

- Renal biopsy is not indicated as initial diagnostic test.

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Free Light Chains showed the following:

- Kappa (k): 10 mg/L (reference range: 3.3-19.4 mg/L)
- Lambda (λ): 140 mg/L (reference range: 5.7-26.3 mg/L)
- kλ Ratio: 0.07 (reference range: 0.26-1.65)
- SPEP+IFE showed no monoclonal spike in the serum
- UPEP+ IFE showed minimal detected monoclonal spike (0.02 g/dL) in the urine

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part B: Based on the clinical presentation and laboratory findings, what is the next diagnostic test to consider?

A. Kidney ultrasound
B. Renal biopsy
C. Abdominal fat pad sampling and bone marrow biopsy
D. Cardiac MRI

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part B: Based on the clinical presentation and laboratory findings, what is the next diagnostic test to consider?

A. Kidney ultrasound
B. Renal biopsy
C. Abdominal fat pad biopsy and bone marrow biopsy
D. Cardiac MRI

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part B: Based on the clinical presentation and laboratory findings, what is the next diagnostic test to consider?

A. Kidney ultrasound

B. Renal biopsy

C. Abdominal fat pad biopsy and bone marrow biopsy

D. Cardiac MRI

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part C: The abdominal fat pad sampling was positive for amyloid with Congo red staining, but mass spectrometry results were inconclusive. Bone marrow biopsy revealed 10% plasma cells with negative Congo red stain. What is the next best step in management of this patient?

A. Repeat fat pad biopsy
B. Perform a renal biopsy
C. Perform endomyocardial biopsy
D. Perform Bone Scintigraphy (Tc-99 m-PYP, Tc-99m-DPD, or Tc-99m-HMDP)
E. Monitor renal function and proteinuria in 6 months

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part C: The abdominal fat pad sampling was positive for amyloid with Congo red staining, but mass spectrometry results were inconclusive. Bone marrow biopsy revealed 10% plasma cells with negative Congo red stain. What is the next best step in management of this patient?

A. Repeat fat pad biopsy
B. Perform a renal biopsy
C. Perform endomyocardial biopsy
D. Perform Bone Scintigraphy (Tc-99 m-PYP, Tc-99m-DPD, or Tc-99m-HMDP)
E. Monitor renal function and proteinuria in 6 months

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part D: The patient's renal biopsy confirms AL with a lambda light chain. Echo was normal. What lab tests could be performed to evaluate for cardiac involvement?

A. C reactive protein, Erythrocyte sedimentation rate
B. NT-proBNP and high sensitivity troponin
C. Bone scintigraphy using Tc99m-PYP, Tc99-DPD or Tc99m-HMDP

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part D: The patient's renal biopsy confirms AL with a lambda light chain. Echo was normal. What lab tests could be performed to evaluate for cardiac involvement?

A. C reactive protein, Erythrocyte sedimentation rate

B. NT-pro BNP and high sensitivity troponin

C. Bone scintigraphy using Tc99m-PYP, Tc99-DPD or Tc99m-HMDP

Recommendation

For individuals with proven light chain amyloidosis and no cardiac symptoms and the ASH Guideline Panel ***recommends*** performing cardiac biomarkers (high sensitivity troponin T and NT-proBNP) and cardiac imaging rather than not performing these tests to define the presence and extent of cardiac involvement. (Strong recommendation based on moderate certainty in the evidence about effects)

For individuals with a suspicion of light chain amyloidosis, the ASH Guideline Panel ***recommends against*** the use of bone scintigraphy (PYP, DPD, HMDP) for the diagnosis of AL cardiac amyloidosis. (Strong recommendation based on moderate certainty in the evidence about effects)

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part E: The patient's NT-proBNP is 350 pg/mL (AL threshold >332 pg/mL) and high-sensitivity Troponin: 10 ng/L (reference: <14 ng/L). Serum creatinine is 1.3 mg/dL. How do you interpret these results:

A. Definite cardiac amyloidosis
B. Possible cardiac amyloidosis
C. No evidence of cardiac amyloidosis

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part E: The patient's NT-proBNP is 350 pg/mL (AL threshold >332 pg/mL) and high-sensitivity Troponin: 10 ng/L (reference: <14 ng/L). Serum creatinine is 1.3 mg/dL. How do you interpret these results:

A. Definite cardiac amyloidosis

B. Possible cardiac amyloidosis

C. No evidence of cardiac amyloidosis

The patient's high sensitivity troponin T is normal. Her NT-pro BNP is slightly over the proposed screening value of 332 pg/dL but may be affected by her renal impairment, so it is not clear if she has cardiac involvement with her amyloidosis based on the available data.

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part F: What additional imaging tests could be considered to screen for cardiac involvement in this patient with renal AL, no definite cardiac symptoms, and equivocal labs?

A. Bone scintigraphy with Tc-99m-PYP looking for grade 1 uptake consistent with cardiac AL amyloidosis
B. Cardiac MRI looking for diffuse late gadolinium enhancement
C. Exercise stress test

Case 2: Suspected Renal Light Chain Amyloidosis (AL)

Part F: What additional imaging tests could be considered to screen for cardiac involvement in this patient with renal AL, no definite cardiac symptoms, and equivocal labs?

A. Bone scintigraphy with Tc99m-PYP, Tc99-DPD or Tc99m-HMDP looking for grade 1 uptake consistent with cardiac AL amyloidosis

B. Cardiac MRI looking for diffuse late gadolinium enhancement

C. Exercise stress test

Recommendation

For individuals with suspected light chain amyloidosis, abnormal biomarkers and nondiagnostic echocardiography, the ASH Guideline Panel ***suggests*** performing cardiac CMR rather than not performing CMR to increase clinical suspicion of cardiac amyloidosis. (conditional recommendation based on a moderate certainty in the evidence about effects)

Case 2: Summary

- In patients with suspected renal light chain amyloidosis (AL) the panel recommends performing serum free light chains with ratio (sFLC), serum immunofixation (sIFE) and urine immunofixation (uIFE)
- Fat pad biopsy and bone marrow biopsy are recommended initially rather than target organ biopsy (renal) initially due the combined sensitivity of 89% to lower associated patient risks and accessibility. A positive abdominal fat pad sampling or bone marrow biopsy with subtyping makes renal biopsy unnecessary.
- In patients where subtyping of the abdominal fat is not feasible, the patient should be referred for a kidney biopsy

Case 2: Summary

- When fat pad biopsy is positive for Congo red stain but mass spectrometry cannot subtype the amyloid, a biopsy of the symptomatic organ (the kidneys in this case) can provide tissue for further amyloid subtyping. This is crucial for identifying the specific type of amyloidosis and guiding appropriate treatment.
- In patients with AL and no cardiac symptoms, cardiac imaging (echo/MRI) and cardiac biomarkers (NT-pro BNP, troponin) can be performed to evaluate for the presence and extent of cardiac involvement.
- In patients with evidence of AL and nondiagnostic echocardiograms, cardiac MRI has higher sensitivity to detect cardiac amyloidosis and could be performed if available and not cost prohibitive to evaluate for cardiac involvement.

Future Priorities for Research

- Earlier detection of amyloidosis/enhancing clinical suspicion
- Predictive Models for likelihood of light chain amyloidosis or of organ involvement
- Disease heterogeneity
- Optimizing Diagnostic pathways

In Summary: Back to our Objectives

1. Identify signs and symptoms of possible cardiac light chain amyloidosis (AL)
2. Know what lab work should be ordered to evaluate for AL
3. Determine appropriate sites for biopsy in patients with suspected AL

Acknowledgements

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See more about the **ASH Amyloidosis guidelines** at
https://www.hematology.org/amyloidosis-guidelines