



SLE-key[®] Case Studies

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Case Study #1 (Dr. Field)



- 28 year old female
- Referred with diagnosis of SLE and positive ANA (1:80) speckled
- Pertinent history
- Hypothyroidism
- Fibromyalgia
- Positive thyroid antibodies
- Positive sicca and Raynauds

- Initial clinical impression: likely secondary Sjogren's from autoimmune thyroid disease
- SLE-key: SLE Not Ruled Out – but just above threshold
 - Based on experience with SLE-key test, this was as expected
 - Positive ANA likely due to autoimmune thyroid disease

- Conclusion: Secondary Sjogren's from autoimmune thyroid disease?

Case Study #2 (Dr. Field)

- 35 year old female
- Referred for positive ANA (1:160) homogenous; suspicion of SLE
- Pertinent history
- Polyarthralgias
- Sleep disturbance
- Positive Raynaud's
- Exam negative
- Positive Family History - autoimmune thyroid disease
- Other serology ordered but negative
- Repeat ANA: positive (1:40)

- Initial clinical impression: fibromyalgia; initiate treatment with Cymbalta
- SLE-key: SLE Ruled Out

- **Conclusion: Fibromyalgia**

Case Study #3 (Dr. Field)



- 48 year old female
- Positive ANA (1:40) homogenous
 - Negative dsDNA
 - Normal C3, C4
 - Positive RNP
 - Negative Sm
 - Negative Sjogren's
- Mild synovitis and arthralgias
- DVT / PE while on OCP
 - On chronic coumadin so no anti-phospholipid work up
- ROS Positive Raynauds, sicca, arthralgias

- Initial clinical impression: VT and PE unusual in a young woman. Probably APS. Suspected SLE
- SLE-key: SLE Not Ruled Out; value on curve with greatest number of SLE patients

- Conclusion: SLE. Manage patient accordingly
 - Later on ANA and dsDNA became positive and she became more symptomatic

Case Study #4 (Dr. Thomas)



- 45 year old caucasian female
- History of type II diabetes and bipolar disorder
- 2 years prior positive ANA (1:80) speckled at PCP
- Referred to rheumatologist
 - Diagnosed with lupus like syndrome; Joint pain, nonspecific rash, mouth sores, numbness & mild Raynauds
 - Plaquenil and prednisone did not improve physical symptoms
- Referred to 2nd rheumatologist
 - ENA (all negative), CBC, urinalysis, APL antibodies all normal
 - Diagnosed with SLE; tender joints, morning stiffness, oral ulcers, Raynauds, low positive ANA
 - Treated with Plaquenil, steroids, and pain relievers; no improvement in physical symptoms
- Initial clinical impression (of 3rd Rheumatologist) post extensive chart review, physical exam and labs: fibromyalgia syndrome + diabetic neuropathy + clinically unrelated positive ANA
- SLE-key: SLE Ruled Out
- Conclusion: Fibromyalgia, diabetic neuropathy and unrelated abscess ulcers and primary Raynauds
 - Treatment tailored to diabetes
 - Refer to dermatologist next time rash appears

Case Study #5 (Dr. Thomas)



- 54 year old South Asian Indian female
- Primary Care Physician Evaluation
 - Gradual onset of polyarticular arthralgias of the elbows, proximal interphalangeal joints, and feet along with intermittent fatigue and red facial rash
 - ANA positive (1:320; speckled)
- Referred to rheumatologist at major tertiary care center
 - ENA/complements/dsDNA/Coombs/APLAs negative
 - Positive ANA confirmed (1:160; speckled)
 - Patient reported subjective loss of hair & 45 minutes of morning stiffness
 - Physical exam: tender elbows, malar erythema; no alopecia
 - Diagnosed with early mild SLE; physician prescribed Hydroxychloroquine/Plaquenil
- Patient requested 2nd opinion (Dr. Thomas); did not want to take hydroxychloroquine
 - Physical exam: rosacea, tender lateral epicondyles with normal PROM, no joint line tenderness; Small Heberden's nodes present. Doppler US showed no inflammatory synovitis of the UEs
- Clinical impression: Lateral epicondylitis, osteoarthritis + rosacea (confirmed by dermatologist as opposed to malar lupus rash)
- SLE-key: SLE Ruled Out
- Conclusion: Target therapy to lateral epicondylitis, OA & Rosacea; patient improved without hydroxychloroquine

General Lessons & Conclusions



- **SLE-key test may help overcome patient anxiety following confounding or mis-diagnosis**
- **Definitive RuleOut result may**
 - Reduce the incidence of a diagnosis of SLE based solely on 'soft' clinical findings
 - Allow the patient therapy to be directed by the primary care physician; thereby saving the HC system significant dollars on specialist physician time and testing that would have been otherwise ordered given clinical presentation
 - Patient #1: PCP able to treat and manage thyroid condition
 - Aid the physician in earlier diagnosis and initiation of targeted therapy
 - Lead to reduction in unnecessary exposure to toxic medications and serious side effects including organ damage
 - Some of these patients were already being treated with steroids even though they didn't really have lupus
 - Patient #4: Steroids probably made her diabetes worse!!
 - Patient #5: Avoided exposure to hydroxychloroquine by seeking out 2nd opinion
- **In cases of diffuse undifferentiated symptoms, test can be used to RuleOut SLE**

General Lessons & Conclusions (cont)



- **The more you use the test, the more you develop an understanding of how to use the test in the context of individual patients**
- **Looking at the curve eg.**
 - Autoimmune thyroid disease often scores as Not Ruled Out but usually just above the threshold with a relatively low score
 - Overlap patients and those developing connective tissue disease may fall more towards the middle of the curve
- **Keep in mind that the curve is a probability distribution. SLE-key® RO test statistics (94% sensitivity, 75% specificity) were validated based on the classification threshold less than 0.18.**