Optimizing Co-management Best Practices for Psoriatic Diseases

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Disclosure Statement

• Consultant for the following companies, but none of these activities have had an impact on the formulation of this talk or on the content of its presentation:
  - Amgen
  - Genentech
  - UCB
  - Wyeth
  - Bristol Myers Squibbs
  - Pfizer-Executive Team: PRECISION Trial
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• Speaker for the following companies, but none of these activities have had an impact on the formulation of this talk or on the content of its presentation:
  - Abbott Laboratories (AbbVie)

Learning objectives

• Outline the cutaneous and musculoskeletal features of psoriasis and psoriatic arthritis (PsA)

• Describe available classification criteria and methodology to assist in making a diagnosis of PsA

• Highlight complex clinical scenarios:
  — Clinical features and treatment options for patients with TNF-Inhibitor induced psoriasis
  — Early detection of psoriatic arthritis

• Describe the beneficial aspects of optimizing interdisciplinary exchanges in the care of the patient with PsA
Psoriasis Vulgaris

• Chronic immune-mediated skin disease
  – Affects up to 2-3% of the world’s population
  – Th1/Th17 inflammatory disease (TNF-α, IFN-γ, IL-12, IL-17, IL-23)

• Significant Impact on Quality of Life
  – Low self-esteem, stigmatization, depression

• Psoriasis as systemic inflammatory disease
  – Increased risk for CV events
  – Importance of aggressive treatment

Cutaneous Psoriasis

• Clinical subtypes
  – Plaque-type
  – Guttate
  – Inverse
  – Palmoplantar
  – Generalized pustular psoriasis (of Von Zumbusch)
  – Palmoplantar pustulosis
  – Acrodermatitis continua of Hallopeau
  – Erythrodermic
Plaque Psoriasis

- Most common subtype (up to 80-90% of all psoriatic disease)
- Preferentially involves extensor surfaces, scalp

Guttate Psoriasis

- "Rain-drop" shaped scaly papules that typically appear with sudden onset
- Subtype classically associated children/adolescents with streptococcal infection
Palmoplantar Psoriasis

- Can be disabling, even when localized
- Challenging to treat

Palmoplantar Pustulosis

- Sterile pustules of palmoplantar surfaces admixed with yellowish-brown macules
- Can be triggered/aggravated by stress and smoking
- SAPHO- synovitis, acne, pustulosis, hyperostosis, osteitis.
Inverse Psoriasis

- Psoriasis in flexural surfaces
  - Axillary vaults, inframammary, groin, retroauricular, popliteal and antecubital fossae
  - Can occur alone or in combination with other subtypes
- Plaques tend to be moist and without typical thick, silvery scale

Nail Changes in Psoriasis

- Nail pitting
- Onycholysis
Nail Changes in Psoriasis


Nail Changes in Psoriasis

Onychomycosis
Differential Diagnosis of Plaque Psoriasis

- Secondary Syphilis
- Eczema
- Lichen simplex chronicus
- Leprosy
- Sarcoidosis
- Mycosis Fungoides
- Seborrheic Dermatitis
- Hypertrophic lichen planus
- Pityriasis Rosea
- Pityriasis lichenoides chronica
- Subacute cutaneous lupus erythematosus
- Reactive Arthritis

Psoriasis Diagnosis

• Most often a Clinical Diagnosis
  - Clinical history
  - Morphologic characteristics of cutaneous lesions

• Occasionally Biopsy
  - Clinical features unclear
  - Does not respond to treatment
Psoriasis Histology

Normal Skin

Psoriasis Skin

Cleveland Clinic

Psoriasis Histology

Cleveland Clinic
45yo man with psoriasis-like rash on b/l extensor surfaces worsening with topical corticosteroids

Histology
Psoriatic Arthritis

- Up to 30% of patients with psoriasis can develop PsA
- Age of onset for PsA is typically 30–50 years
- Healthcare costs related to psoriasis alone total $11.25 B/yr

- Prevalence - large geographic variation
  - 1 case per 100,000 population in a Japanese study
  - 420 cases per 100,000 population in an Italian study
- Incidence
  - median 6.4, (range 0.1-23.1 cases per 100,000)

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**CASE AH**

- 42 yo aesthetician
- Presents with acute polyarthritis affecting hands, knees, and ankles
- Previous rheumatologist treated with intermittent oral steroids
- Refused DMARDs wanted a “natural treatment regimen”
CASE AH

• PMHx
  – H/o psoriasis in her early teens, no flares x 30 years
  – Guttate type following strep pharyngitis

• Soc Hx
  – Tobacco use disorder (0.5 PPD x 20 years)
  – Social EtOH

Exam

• Healthy appearing, +anxious

• Vitals
  – Normal

• Skin
  – Clear

• Joint inflammatory changes
  – MCP, PIPs, and DIPs
  – Mild knee effusion
  – SJC 12 TJC 16

Labs

  CRP 9.1mg/dL (0-1.0mg/dL); ANA, RF, CCP negative
What is your best diagnosis for this patient at this time?

a) Undifferentiated Inflammatory Arthritis and Psoriasis
b) Seronegative Rheumatoid Arthritis and Psoriasis
c) Reactive Arthritis and Psoriasis
d) Psoriatic arthritis

Classification Criteria

- PsA is poorly understood
  - Clinical diagnosis
  - No definitive serologic markers
  - Heterogeneous presentation

- Classification criteria for PsA
  - Area of intense study
  - Early criteria proposed by Moll and Wright\(^1\)

\(^1\)Moll JM, Wright V. Semin Arthritis. 1973;3:55-78.
PsA is diagnosed when ≥3 points below are assigned in the presence of inflammatory articular disease (joint, spine, or enthesal)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Points</th>
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<tbody>
<tr>
<td>Current psoriasis, or, personal or family history of psoriasis</td>
<td>Psoriatic skin or scalp disease confirmed by dermatologist or rheumatologist; history of psoriasis from patient, family physician, dermatologist, rheumatologist, or other qualified practitioner; patient-reported history of psoriasis in first- or second-degree relative</td>
<td>2</td>
</tr>
<tr>
<td>Psoriatic nail dystrophy on current physical exam</td>
<td>Includes onycholysis, pitting, and hyperkeratosis</td>
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<tr>
<td>Negative for rheumatoid factor (RF)</td>
<td>Enzyme-linked immunosorbent assay or nephelometry preferred (no latex) using local laboratory reference range.</td>
<td>1</td>
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<tr>
<td>Current dactylitis or history of dactylitis documented by a rheumatologist</td>
<td>Swelling of entire digit</td>
<td>1</td>
</tr>
<tr>
<td>Radiographic evidence of juxtaarticular new bone formation</td>
<td>Ill-defined ossification near joint margins excluding osteophyte formation, on plain x-rays of hand or foot</td>
<td>1</td>
</tr>
</tbody>
</table>

*CASPAR=ClaSSification Criteria for Psoriatic ARthritis


Arthritis Mutilans

- Left hand of a patient with arthritis mutilans, demonstrating swelling of the MCP joints and DIP joints as well as telescoping of the third digit that is irreversible. The radiograph shows pencil-cup deformities.
**Dactylitis**

- Patient with dactylitis and mild psoriasis
  - Treatment of choice?
- Local injection difficult to achieve
- Patients may resist systemic therapy for dactylitis
- TNF inhibitors may be effective

**Enthesitis**

- Inflammation of the tendon insertion site
- Often leads to calcification and fibrosis
- Most common sites are plantar fascia (9%), finger flexor tendons (7%), Achilles tendon (7%)\(^1\)
- Seen in 30%-50% of PsA patients\(^2\)
- Treatment of choice?
Spondylitis

Arrows: inflammation

MSK Ultrasound

- Diagnosis vs therapeutic
- Prevalence of subclinical entheseal involvement in patients with psoriasis
  - 45 patients with psoriasis were evaluated
  - 32.9% (148/450)
  - Mean GUESS score was significantly higher in patients with psoriasis as compared with controls: 7.9 (0.6) vs 2.9 (0.3); p<0.0001
- Enthesopathy was more frequent in patients with psoriasis
Audience Response Question

Which of the following clinical features of psoriasis correlates best with risk of progression to psoriatic arthritis?

a) Palmoplantar pustulosis
b) Older age at onset of psoriasis
c) Nail involvement
d) Erythroderma (>90% BSA)

Audience Response Question

Which of the following clinical features of psoriasis correlates best with risk of progression to psoriatic arthritis?

• A) Palmoplantar pustulosis
• B) Older age at onset of psoriasis
• C) Nail involvement
• D) Erythroderma (>90% BSA)
Skin vs Joint Disease

• Cutaneous predictors of psoriatic arthritis
  – Scalp lesions, intergluteal/perianal lesions
  – Psoriatic nail dystrophy
    – Found in multiple studies
  – Involvement of ≥ 3 sites
  – Younger age of psoriasis onset
  – Greater BSA involvement affected by psoriasis
    – Association or subset with genetic predisposition?
  – Family history of psoriatic arthritis

• All studies had limitations
  – Case-control studies, recall bias, possible misclassification bias (OA)

Soltani-Arabshani R et al. Arch Dermatol 2010; 146: 721-726
Tey HL et al. J Dermatol 2010; 37: 426-430

Treatment Options For PsA by Cutaneous or Musculoskeletal Manifestation

<table>
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<tr>
<th>Intervention</th>
<th>Psoriatic Arthritis Manifestation</th>
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<td>Peripheral Arthritis</td>
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<tr>
<td>NSAIDs</td>
<td>✓</td>
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<td>Intra-articular steroids</td>
<td>✓</td>
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<tr>
<td>Topical therapies</td>
<td>✓</td>
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<tr>
<td>Physiotherapy</td>
<td>✓</td>
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<tr>
<td>Psoralen UVA/UVB</td>
<td>✓</td>
</tr>
<tr>
<td>DMARDs (MTX, CsA, SSZ, LEF)</td>
<td>✓</td>
</tr>
<tr>
<td>Biologic DMARDs (TNF inhibitors)</td>
<td>✓</td>
</tr>
</tbody>
</table>

• NSAIDs=non-steroidal antiinflammatory drugs, UV=ultraviolet, DMARDs=disease-modifying antiinflammatory drugs, MTX=methotrexate, CsA=cyclosporine, SSZ=sulfasalazine, LEF=leflunomide, TNF=tumor necrosis factor

Current Issues with NSAIDs

- Efficacy comparisons
- Adverse Events
  - GI events
  - CV events
- Balancing risks and benefits in your patient
  - Blackbox warning
PRECISION Trial

- Many arthritis patients require NSAIDs for pain relief and/or to maintain quality of life - withholding pain relievers in these patients is not an option
- The relative cardiovascular safety of Coxibs vs. NSAIDs is unknown - no previous trials have adequately assessed the relative safety of these two classes of agents in these high risk patients
- Only a large, prospective comparative trial in patients at high CV risk can resolve this question

CASE AH

- Treatment
  - Initiated on methotrexate 20mg weekly and prednisone 10mg daily
  - Improved, but still active tenosynovitis after 3 months
  - Expresses desire to discontinue methotrexate
    - “bad for my liver”
Methotrexate In Psoriatic Arthritis Trial

- Is Methotrexate effective for treating Psoriatic Arthritis?
  - 6-month double-blind RCT compared MTX (15 mg/week) vs PBO
  - Primary outcome measure was the PsA response criteria (PsARC)
  - Secondary outcome assessments comprised ACR 20% improvement criteria (ACR20) and DAS for 28 joints (DAS-28)

- Found no significant treatment effects on tender and swollen joint counts, ESR, CRP, HAQ and pain
  - Effective for skin

- Conclusions: no evidence for MTX improving synovitis in PsA

Liver Biopsy in Psoriasis Patients on MTX

- Recommendations based on assumption that hepatotoxicity risk is increased compared to RA patients
  - Increased incidence of obesity, alcohol use, diabetes
  - Obesity and diabetes shown to be associated with worse liver histology at all cumulative MTX doses (Berends)

- Liver biopsy vs. other methods of monitoring
  - Ultrasound and other radiologic techniques so far unsuccessful
  - Amino-terminal peptide of Pro-collagen III (PIIINP)
    - If stable appears to reflect minimal risk for hepatotoxicity
    - Used by majority of dermatologists in UK to monitor for hepatic fibrosis
    - No FDA-approved or commercially available test in U.S. presently
Liver Biopsy in Psoriasis Patients on MTX

Table II. Risk factors for hepatic toxicity from methotrexate

- History of or current alcohol consumption*  
- Persistent abnormal liver chemistry studies  
- History of liver disease, including chronic hepatitis B or C  
- Family history of inheritable liver disease  
- Diabetes mellitus  
- Obesity  
- History of significant exposure to hepatotoxic drugs or chemicals  
- Lack of folate supplementation  
- Hyperlipidemia

* Methotrexate toxicity is associated with a history of total lifetime alcohol intake before methotrexate therapy. The exact amount of alcohol that confers risk is unknown and differs among persons.

• Patients should be organized in 2 categories:
  • None of above risk factors: use ACR criteria for monitoring MTX in RA patients  
  • 1 or more of above risk factors: use previous stringent guidelines

Liver Biopsy in Psoriasis Patients on MTX

• Dermatology guidelines for monitoring MTX in low-risk patients
  – (ACR) Persistent elevations in 5/9-6/12 AST levels over 12 mo OR if decline in serum albumin with normal nutritional status below normal range in setting of well-controlled disease, liver bx should be performed.  
  – After 3.5-4.0g total MTX, consider following with above guidelines, liver biopsy, or switching to another agent.

• Dermatology guidelines for monitoring MTX in high-risk patients
  – Consider feasibility of using MTX vs. different agent  
  – Consider delayed baseline liver biopsy (after 2-6 mo therapy to establish medication efficacy and tolerability)  
  – Repeat liver biopsies after approximately 1.0-1.5g of therapy

The RESPOND study

**Objective:** To compare the efficacy and safety of infliximab plus methotrexate with methotrexate alone in methotrexate-naive patients with active psoriatic arthritis (PsA).

**Study design:** This was a phase IIIB, randomized, prospective, open-label study conducted in 25 centers in Europe, the Middle East, South Africa and Turkey.

**Methods** 115 patients 18 years and older with active PsA (naive to MTX) were randomized to:
- infliximab (5 mg/kg) at weeks 0, 2, 6 and 14 plus methotrexate (15 mg/week)
- methotrexate (15 mg/week) alone

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**Proportion of patients (%) achieving ACR20 response**

- **IFX + MTX (n=56):** 86.3%
- **MTX (n=54):** 66.7%

![Graph showing proportion of patients achieving ACR20 response over visits](image-url)
Proportion of patients (%) achieving ACR50 response

![Graph showing proportion of patients achieving ACR50 response over time.]

- IFX + MTX (n=56)
- MTX (n=54)

Proportion of patients (%) achieving ACR70 response

![Graph showing proportion of patients achieving ACR70 response over time.]

- IFX + MTX (n=56)
- MTX (n=54)
Conclusions from the RESPOND study

- Combination Infliximab plus methotrexate group demonstrated significantly greater ACR20 response rates and PASI75 improvement compared with methotrexate alone.

- The use of infliximab plus methotrexate in methotrexate-naïve patients with PsA achieved greater improvements in all clinical outcomes measured than the use of methotrexate alone.

- Response was more rapid with combination therapy, and it accomplished profound disease suppression in a significantly larger proportion of patients by week 16 compared with methotrexate monotherapy.
Which of the following therapies would you initiate next in this patient?

a) Continue Methotrexate alone  
b) Methotrexate plus steroid taper  
c) Combination Methotrexate plus anti TNF therapy  
d) Anti TNF therapy

CASE AH

• Treatment
  – Started on Etanercept 50mg weekly
  – Stopped methotrexate (patient request) and prednisone

• 3 months later
  – Complains of progressively worsening rash on hands/feet
  – Area of injection site reaction on thigh "turned into psoriasis"
Which would the best option at this time?

a) Stop anti TNF inhibitor
b) Consult Dermatology and continue anti TNF inhibitor
c) Consult Dermatology and stop anti TNF inhibitor
TNF Inhibitor-induced Psoriasis

• Psoriasiform dermatitis precipitated by TNF-α inhibitor therapy
  – Incidence rate 1-3 per 1000 person years
  – Up to 5% of patients treated with TNF-α inhibitors
  – Female predominance; Avg age in 40s
  – Essentially all TNF-α inhibitors implicated
    – Etanercept, Infliximab, Adalimumab, Certolizumab pegol

• Typically occurs in patients treated for other conditions
  – Usually no previous history of psoriasis
  – Occurs at any time during course of TNF-inhibitor therapy
    – Mean time is approximately 9-15 months

• No known risk factors

Collamer AN, Battafarano DF. Semin Arth Rheum 2010
Tilack C et al. Gut 2013

TNF Inhibitor-induced Psoriasis

• Psoriatic lesions with variety of morphologies can occur
  – Plaque-type and Palmoplantar pustulosis most common
    – Particularly high percentage PPP in TNF Inhibitor-induced psoriasis
  – Scalp psoriasis with alopecia

• Patients with known psoriasis
  – Tend to develop lesions in new anatomic locations and with new morphologic characteristics

• No correlation between morphology of lesions and underlying disease being treated
  – Appearance has no relation to response of underlying disease to the TNF-inhibitor
Histologic Characteristics

- Various histologic patterns observed
  - Psoriasis
    - Plaque-type, Guttate
    - Lichenoid
    - Pustular

- Eosinophils and plasma cells typically present
  - May serve as clue to diagnosis

- Clinical impression is usually psoriasis

Collamer AN, Battafarano DF. Semin Arth Rheum 2010
Laga AC et al. Am J Dermatopathol 2010
Histologic Characteristics

Pathogenesis

• Unknown

• Disruption of cytokine balance by TNF-α blockade
  – TNF-α inhibits generation and speeds maturation of Plasmacytoid dendritic cells, both of which inhibit IFN-α production
  – TNF-α blockade leads to:
    – Unopposed IFN-α production by Plasmacytoid dendritic cells
    – Increased expression of CXCR3 ligands, which facilitate homing of reactive T-cells to skin

• MxA expression higher in TNF inhibitor-induced psoriasis than typical psoriasis
TNF induced Psoriasis

• Variable
  – Resolve without interruption of TNF inhibitor in minority
  – Controlled with variety of interventions
  – Resolve only after discontinuation of TNF inhibitor
  – Persist despite discontinuation of TNF inhibitor in minority

• No predictive factors in terms of severity, morphologic subtype, or anatomic distribution

• Reaction often recurs with switch to another TNF-α inhibitor

Audience Response Question

Concomitant treatment with which of the following at time of initiating TNF-α inhibition can effectively prevent TNF-induced Psoriasis?

a) Phototherapy  
b) Cyclosporine  
c) Topical Vitamin D analogs  
d) Methotrexate  
e) None of the above
Audience Response Question

Concomitant treatment with which of the following at time of initiating TNF-α inhibition can effectively prevent TNF-induced Psoriasis?

• A) Phototherapy
• B) Cyclosporine
• C) Topical Vitamin D analogs
• D) Methotrexate
• E) None of the above

Treatment

• Psoriasis significantly affects quality of life and/or is severe AND TNF-inhibitor is not optimally treating underlying disease
  — Stop the TNF-inhibitor

• Psoriasis significantly affects quality of life and/or is severe BUT TNF-inhibitor is effectively treating underlying disease
  — Can attempt to treat psoriasiform eruption WITHOUT stopping the TNF inhibitor
Treatment while maintaining TNF Inhibitor (NEW)

- Topical medications
  - Corticosteroids, Vit D analogs

- Phototherapy
  - Narrowband UVB, PUVA

- Steroid-sparing Immunosuppressants
  - Methotrexate, Azathioprine, Cyclosporine, MMF

- Oral or topical Retinoids
  - Acitretin, Tazorac

- No treatment modality associated with superior results

CASE AH

- Dermatology was consulted
- Clobetasol and urea cream were started
- Phototherapy not covered by insurance

- The rash persisted and the patient continued to note discomfort with activities of daily living.
Audience Response Question

What is the next best possible step?

a) Switch to another TNF inhibitor
b) Ask your dermatology colleague to help start Ustekinumab
c) Consider alternate biologic or non biologic DMARD
d) Consider a clinical trial on IL-17, JAKi

Treatment

• Unable to continue current TNF-inhibitor OR significant involvement continues after discontinuation
  – Treatment with Ustekinumab may be useful
    – IL-12/23 monoclonal antibody
    – Unclear whether Ustekinumab has utility in treating inflammatory conditions other than psoriasis.
      – Pilot trials suggest some efficacy in Crohn’s disease
  – New agents?
    – IL-17 inhibitors
    – JAK inhibitors
  – Switch TNF-α Inhibitors?
    – Effective only in minority of cases

Tilack C et al. Gut 2013
Sanso SA et al. Gastroent Hep 2011
Diagnosis of patients presenting with musculoskeletal pain and psoriasis

PsA: 41%
PsA + OA: 15%
OA: 27%
Gout: 2%
PsA + Gout: 1%
OA + Gout: 1%
Indeterminate: 13%
Psoriatic Arthritis Screening and Evaluation (PASE) Questionnaire

Psoriatic Arthritis Screening and Evaluation (PASE) Questionnaire

Please circle or mark only ONE of the answers to the following questions. The answers to these questions will help us determine if you may have psoriatic arthritis. We should take your full medical history. You don’t have to fill out the blanks in each section if you don’t want to. We can add them for you. Thank you for your time.

**HAVE YOU EVER BEEN DIAGNOSED WITH PSORIATIC ARTHRITIS BY A RHEUMATOLOGIST?**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
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<tbody>
<tr>
<td>Your symptoms</td>
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<tr>
<td>1. I feel joint pain most of the day.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2. My joints hurt.</td>
<td>1</td>
<td>2</td>
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<tr>
<td>3. My feet hurt.</td>
<td>1</td>
<td>2</td>
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<tr>
<td>4. My joints become swollen.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>5. My joints feel stiff.</td>
<td>1</td>
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**DO YOU NOTICELY, YOUR FINGERS OR TOE BONES...**

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<tbody>
<tr>
<td>Your ability to do daily activities</td>
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<tr>
<td>1. I feel that my joint problems have affected my ability to live daily life.</td>
<td>1</td>
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<tr>
<td>2. I have trouble fitting into or out of a car.</td>
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<td>2</td>
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<tr>
<td>3. I am unable to be as active as I used to be.</td>
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<td>2</td>
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<tr>
<td>4. I feel stiff for more than 2 hours after waking up and before leaving.</td>
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**TOTAL SYMPTOM SCORE**

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**TOTAL FUNCTION SCORE**

**PASE Score**

PASE translated in over 15 languages

Korean

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Dermatology and Rheumatology Co-Management

• Optimizes care for patients with complex inflammatory diseases
  – Patients appreciate cooperation

• Fosters collaboration that helps all involved clinicians to gain insight into different aspects of diseases

• Creates an environment that fosters research opportunities
  – May lead to better understanding of complex chronic inflammatory diseases

Cleveland Clinic

Thank You!