SUNDAY, JAN 15

Coordinating Care to Improve Outcomes in Patients with Psoriatic Arthritis

Bridging Rheumatology and Dermatology

National Doral, Miami, Florida
7:20 AM – 8:20 AM, Ballroom B

Supported by an educational grant from
Novartis Pharmaceuticals Corporation.

CME Outfitters

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Disclosures

- ***Speakers Bureau:*** AbbVie Inc.; Amgen Inc.; Celgene Corporation; Novartis Pharmaceuticals Corporation; Pfizer Inc.; UCB, Inc.
- ***Consultant:*** AbbVie; Amgen Inc.; Celgene Corporation; Novartis Pharmaceuticals Corporation; Pfizer Inc.
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Learning Objective 1

Implement appropriate, guideline-directed screening approaches in patients with psoriasis to facilitate a prompt diagnosis of PsA

Learning Objective 2

Describe current treatment recommendations and emergent therapies

Learning Objective 3

Strategize ways that specialists in rheumatology and dermatology can work together to improve detection and treatment of PsA

Patient-Guided Content

An Innovative Method for Integrating the Voice of Patients

- As part of developing this educational activity, telephone surveys were conducted with patient experts (N = 15) active in the psoriasis/psoriatic arthritis social media community
- This feedback from patient leaders and their social media community represents over 1,200 patients with psoriasis and psoriatic arthritis
- Findings highlight patients' feedback, concerns, and experiences in psoriasis and psoriatic arthritis
- Their feedback was integral in the development of this educational activity to reflect the "patient's voice" in care
- You will hear comments from some of these thought leaders throughout this presentation

CME Outfitters. Survey of Patients with Psoriasis and Psoriatic Arthritis. Data on File. 2016.

Psoriatic Arthritis: Epidemiology

- Estimated prevalence of psoriasis: 5.8 to 7.5 million in U.S. (2%-3% of the general population)
  - PsA occurs in up to 40% of patients with psoriasis
  - Reported incidence of PsA varies from 3.4 to 8 per 100,000 population
- Psoriasis precedes PsA in 75% to 85% of patients
  - Precedes arthritis by 7 to 12 years
- Occurs in about equal numbers in both sexes
- Mean onset of symptoms: between ages 30 & 50

PsA = psoriatic arthritis

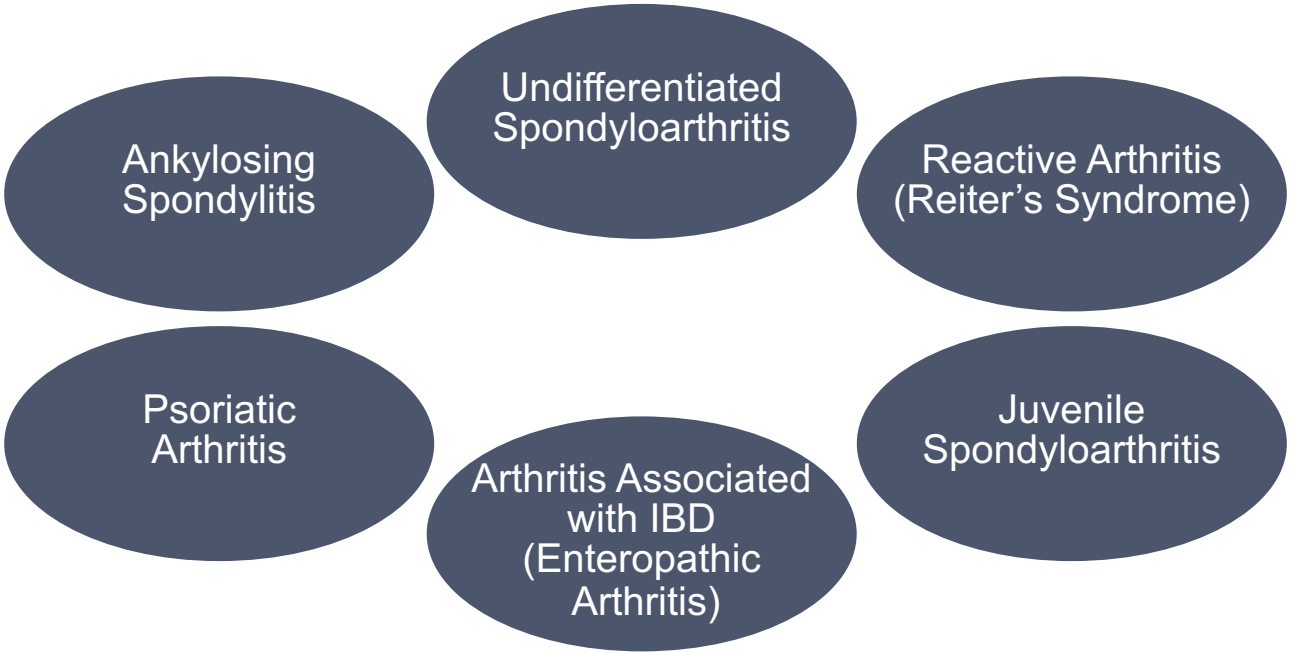
National Psoriasis Foundation. Available at: https://www.psoriasis.org/psoriatic-arthritis/classification-of-psoriatic-arthritis. Accessed January 6, 2017. Gladman DD. *Rheum Dis Clin North* 1998;24:829-44. Mease PJ, et al. *Drug*. 2014;74:423-441.

Psoriatic Arthritis and Rheumatoid Arthritis Differ

- PsA is an inflammatory joint disease with marked phenotypic diversity
  - Rheumatoid arthritis
  - Osteoarthritis
  - Fibromyalgia
- Comorbidities
  - Obesity
  - Type 2 diabetes
  - Hypertension
  - Cardiovascular disease
  - Mortality
  - Depression

Turkiewicz AM, Moreland LW. *Arthritis Rheum*. 2007;56:1051-1066.

Spondylarthritis: A Family of Related Diseases



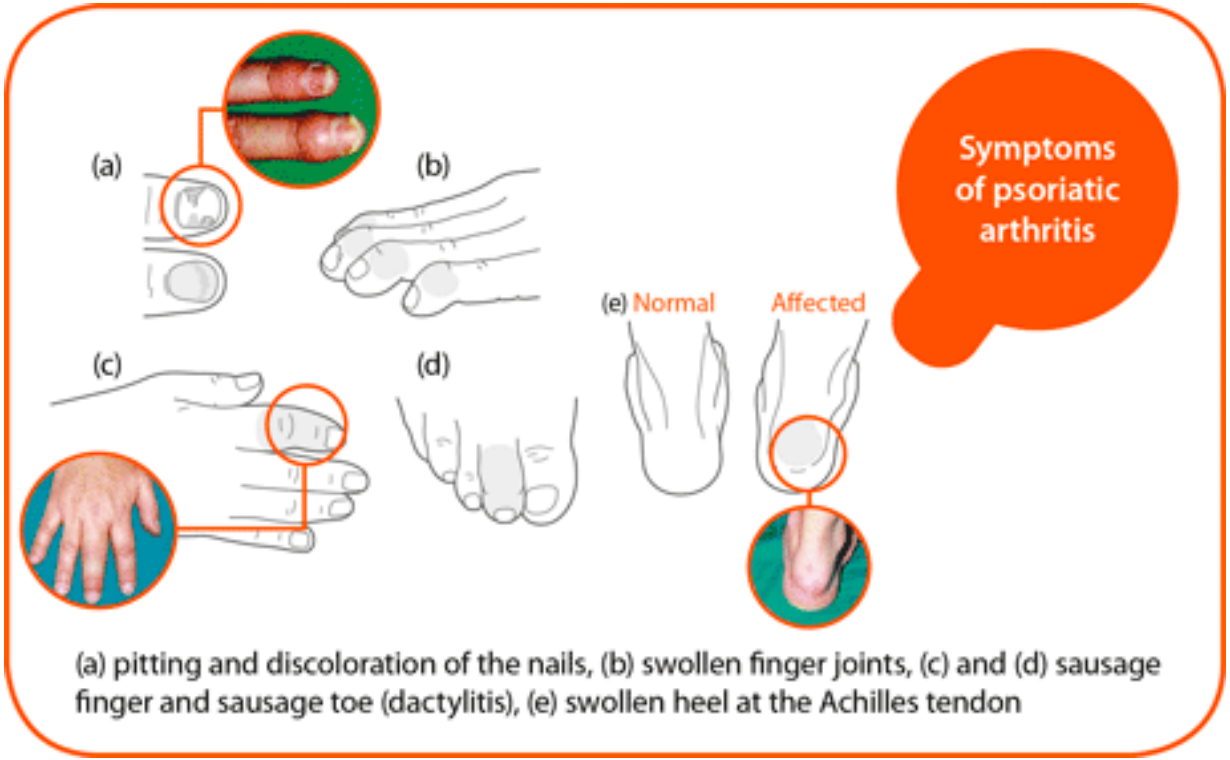
IBD = Inflammatory Bowel Disease.

Spondylitis Association of America. Available at: http://www.spondylitis.org/about/overview.aspx. Accessed January 6, 2017.

Coordinating Care:

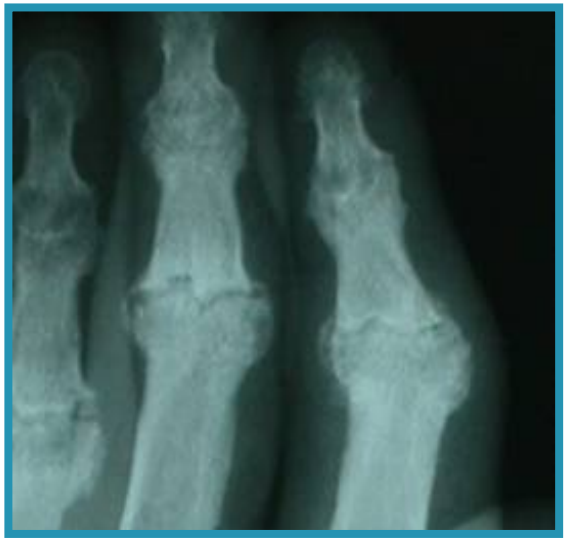
Screening and Recognition of PsA

Symptoms of PsA

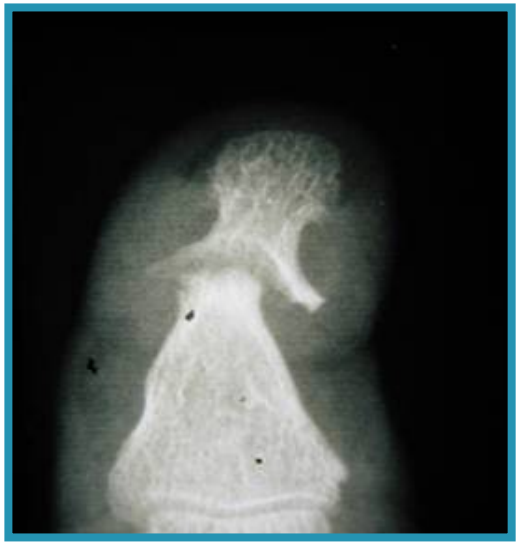


(a) pitting and discoloration of the nails, (b) swollen finger joints, (c) and (d) sausage finger and sausage toe (dactylitis), (e) swollen heel at the Achilles tendon

Recognizing Psoriatic Arthritis: Mild Disease



Joint erosions, joint space narrowing, osteolytis



Pencil in cup deformity

Screening for Psoriatic Arthritis: The Patient Voice

- I know a lot of people have mentioned that psoriatic arthritis didn't come up for them until the pain already began, enough for them to complain about it to their dermatologist.

Risk Factors for Psoriatic Arthritis

- Are there significant risk factors for PsA in psoriasis patients?
  - Family history of PsA, especially in first-degree relatives
- Is it possible to identify a **psoriasis skin phenotype** that is associated with a higher risk of developing PsA?
  - Nails, especially onycholysis
  - Scalp
  - The intergluteal cleft

Richard MA, et al. *J Eur Acad Dermatol Venereol*. 2014;28 Suppl 5:3-12.

Case Presentation

- Jen is a 45-year-old woman
- 10-year history of psoriasis, currently taking methotrexate 15 mg/week
- Presents today for evaluation for her psoriasis
- You see involvement of the nails on the right hand
- Complains of tenderness during the exam

CASPAR Classification Criteria for PsA

- Inflammatory articular disease (joint, spine, or entheseal) with 3 or more points from the following:
  - Evidence of psoriasis (1 of the following):
    - Current psoriasis*
    - Personal history of psoriasis
    - Family history of psoriasis
  - Psoriatic nail dystrophy (may include the following):
    - Onycholysis
    - Pitting
    - Hyperkeratosis
- Negative test for rheumatoid factor
- Dactylitis (1 of the following):
  - Current dactylitis
  - History of dactylitis
- Radiologic evidence of juxta-articular new bone formation
- Specificity 98.7%; sensitivity 91.4%

*Current psoriasis scores 2, whereas all other items score 1

Taylor W, et al. *Arthritis Rheum*. 2006;54(8):2665-73.

Psoriatic Arthritis Screening: Tools of the Trade

Name	Overview	Comments
Current tools		
PASQ	10 items + joint diagram	
	Self-report	
PASE	Self-administered	Threshold score = 47
	15 items	Sensitivity 82 %
	Maximum score: 75	Specificity 73 %
PEST	Self-administered	Threshold score = 3
	5 items + joint diagram	Sensitivity 97 %
	Maximum score: NA	Specificity 79 %
ToPAS	Self-administered	Threshold score = 8
	11 items + pictures/diagram	Sensitivity 86.8 %
	Maximum score: NA	Specificity 93.1 %
		ToPAS II is available online (see http://www.ibridgenetwork.org/uhn/toronto-psoriatic-arthritis-screen-ii-topas-ii)
Tools in development		
ePASQ	10 items + joint diagram	Electronic application is available online (see http://www.nlrt.ca/screenTool.html)
	Self-report	
	Exact match of paper version	
EARP	Self-administered	Sensitivity 85.2 %
	14 questions	Specificity 91.6 %

EARP Early Arthritis for Psoriatic Patients, *ePASQ* Electronic Psoriatic Arthritis Screening Questionnaire, *NA* not applicable, *PASE* Psoriatic Arthritis Screening and Evaluation, *PASQ* Psoriatic Arthritis Screening Questionnaire, *PEST* Psoriasis Epidemiology Screening Tool, *ToPAS* Toronto Psoriatic Arthritis Screening

Olivieri I, et al. *Nat Rev Rheumatol*. 2014;10:531-542; Tinazzi I, et al. *Rheumatology*. 2012;51(11):2058-63.

Quality of Peripheral Joint Pain

- Predominantly nocturnal, especially during the second half of the night
- Associated with significant morning stiffness (> 30-45 min) alleviated or improved with activity and/or physical exercise
- Worsens with prolonged rest
- Usually improves with nonsteroidal anti-inflammatory treatment

Cañete JD, et al. *Actas Dermosifiliogr*. 2014;105(3):216-32.

Characteristics of PsA Axial Pain

- Onset age < 45-years-old
- Symptoms > 3 months
  - Insidious onset
- Morning stiffness > 30 min
  - Limitation of motion of cervical, thoracic, or lumbar spine in sagittal and frontal planes
- Improved with exercise
- Alternating buttock pain

American College of Rheumatology. Available at: https://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Spondylarthritis_%28Spondylarthropathy%29/. Accessed January 13, 2017; Thorn N, et al. *Arthritis Care Res* (Hoboken). 2015;67(6)829-835.

Coordinating Care

In Treatment of PsA

Discussing Treatments: Patient Point of View

- Patients with psoriasis and psoriatic arthritis seem to get their information about new agents and drugs in the pipeline from TV commercials and from online resources such as bloggers who are staying up to date on what is coming down the pipeline in potential new treatments. It seems that doctors are not forthcoming with this information, perhaps at the risk of patients just wanting to drug hop instead of sticking with something that might be working well.

GRAPPA PsA 2015 Treatment Recommendations

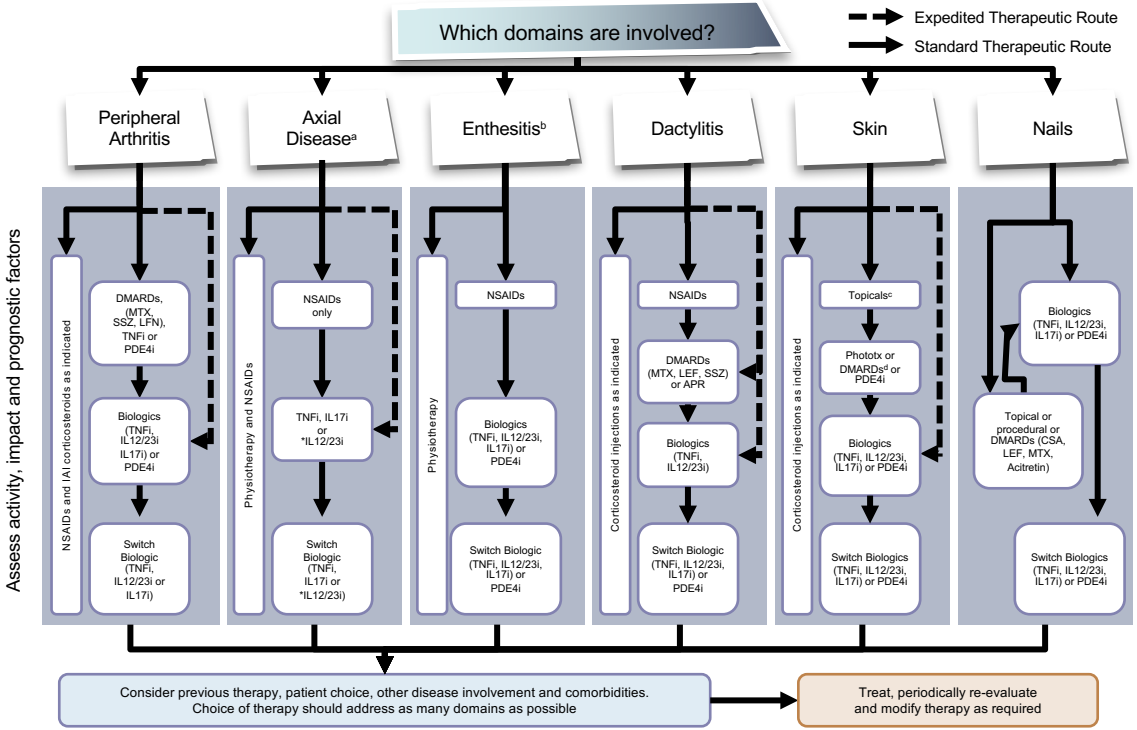
Methods

- 10 overarching principles
- Updated systematic literature reviews performed based on data publicly available through November 2014
- Six separate literature reviews completed covering treatment for key PsA clinical domains: arthritis, spondylitis, enthesitis, dactylitis, skin and nail disease
- Evidence assessed from the published literature reviews and formally evaluated with the GRADE system to provide treatment recommendations
- Differs from EULAR recommendations: analyzed five domains and comorbidities, published manuscripts on each domain, applied GRADE method and obtained consensus from rheumatologists, dermatologists and patient research partners

GRAPPA, Group for Research and Assessment of Psoriasis and Psoriatic Arthritis

Coates LC, et al. *Arthritis Rheum*. 2016;68:1060-1176.

GRAPPA 2015: Treatment Recommendations



IAI = intra-articular injection.

Coates LC, et al. *Arthritis Rheum*. 2016;68:1060-11076.

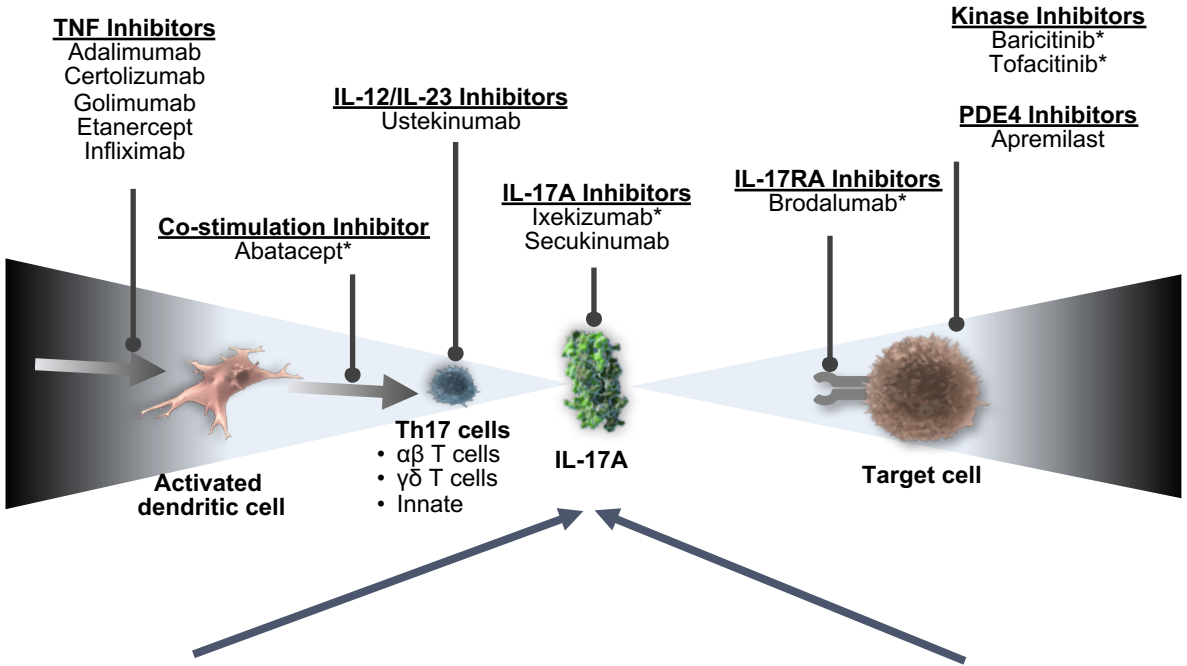
GRAPPA PsA 2015 Treatment Recommendations

Comorbidity	NSAIDs	Glucocorticoids	HCQ	Sulfasalazine	Methotrexate	Leflunomide	Cyclosporine	Etanercept	Adalimumab	Infliximab	Certolizumab	Golimumab	Ustekinumab	Apremilast
CV disease	C	?											?	
Congestive heart failure	C	C						C	C	C	C	C	?	
Obesity					C									
Metabolic syndrome		C			C									
Diabetes		C			C									
Ulcerative colitis	?			A			OL		A	A		A		
Crohn's disease	?			A	OL				A	A	A			
Uveitis		p#						?	P	P				
Osteoporosis		C												
Malignancy								C	C	C	C	C	?	
Fatty liver disease	C			C	C	C								
Chronic kidney disease	C				C	?	SM							
Depression														?
Chonic Hep B*	C				C	C		SM	SM	SM	SM	SM	?	
Chronic Hep C*	C				C	C		?/P	?	?	?	?	?	
HIV								SM	SM	SM	SM	SM	?	

A, approved for primary therapy; C, reason for caution; OL, off-label use; P, preferred therapy; SM, requires special monitoring; ?, data insufficient, concerns raised; *When treating patients with chronic infections that can affect the liver, consider consultation with providers having expertise in the area; #corticosteroids used as preferred therapy for uveitis are most commonly given as topical and/or intraocular injections in preference to oral steroids.

Coates LC, et al. *Arthritis Rheum*. 2016;68:1060-1176.

Current and Novel Treatment Options for PsA



*Not FDA-approved for PsA.

PDE4 = phosphodiesterase type 4; Th17 = T helper 17 cell.

Adapted from Nestle F et al. *N Engl J Med*. 2009;361:496-509; Garber K. *Nat Biotechnol*. 2011;29:563-566.

Case Presentation

- Jen is a 45-year-old woman
- 10-yr history of psoriasis, currently taking MTX 15 mg/week
- Referred to rheumatologist for assessment of suspected PsA
  - Patient presents with pain in both hands
  - RF-
  - X-rays reveal joint erosions and joint space narrowing in the interphalangeal joints of both hands
- Patient is diagnosed with mild to moderate PsA
- Rheumatologist sends note to dermatologist regarding treatment plan to treat her with…….

MTX = methotrexate; RF = rheumatoid factor.

Management of PsA:

When First Line Therapies No Longer Work

Case Presentation

- Jen returns three months later and her PsA has worsened
- Joint pain has increased and her morning stiffness is impacting her quality of life
- What other options are available for Jen?

Coordinating Care:

Bridging Dermatology and Rheumatology

Coordination of Care: The Patient Voice

- In my communities it does not appear that dermatologists and rheumatologists are really speaking with one another. Also primary care physicians should be moved in, and it doesn't appear that they're all that involved.

Coordination of Care

- What can we do to improve screening, diagnosis, and treatment of PsA?
- Network with local rheumatologists
  - Develop relationships and agree to “fast track” mutual patients who need to be seen quickly

High Priority Referrals to Rheumatologist

- Active PsA, not well controlled on current psoriasis therapy
- Joint pain or morning stiffness in a patient with psoriasis
- Family history of PsA

Coordination of Care

- When to consult with rheumatologist?
  - Patient has joint pain

Recommendations for the Coordinated Management of PsA: A Delphi Study

- Guidelines for the coordinated management of psoriatic arthritis by rheumatologists and dermatologists
  - 6 rheumatologists, 6 dermatologists, and 2 epidemiologists
- 100% agreement dermatology and rheumatology:
  - Treatment plan for PsA should be devised jointly by the rheumatologist and dermatologist taking into account skin lesions as well as involvement of peripheral and axial joints and entheses
  - Both specialists should be involved in assessing the effectiveness of treatment
  - Any decision to modify or continue treatment should be agreed by both specialists

Cañete JD, et al. *Actas Dermosifiliogr*. 2014;105(3):216-32.

GRAPPA 2013 Comorbidity Monitoring

- No question there is a connection between psoriasis and other medical conditions
- Current recommendations:
  - Define who is caring for patient
    - Primary care physician, dermatologist, rheumatologist
  - Screen for other medical comorbidities regularly
  - Lab abnormalities while monitoring patients should be dealt with and appropriate treatment provided

Boehncke WH. *J Rheumatol*. 2014;41(6):1224-6.

Monitoring for Comorbidities

US National Psoriasis Foundation Checklist	Checklist as Modified in Recent Publication
Heart rate	Heart rate
Blood pressure	Blood pressure
Body mass index	Waist circumference • Limit 102 cm (men), 88 cm (women)
Fasting blood lipids	Fasting blood lipids
Fasting blood glucose	Blood glucose • Not necessarily fasting

Kimball AB, et al. *J Am Acad Dermatol*. 2008;58(6):1031-42.
Boehncke WH, Boehncke S. *Curr Rheumatol Rep.* 2012;14(4):343-8.

SMART Goal

- Integrate one strategy into your clinical practice to optimize the overall care of your patients with psoriasis
  - Regularly assess for PsA
  - Document assessment and referral to rheumatology
  - Monitor regularly for medical comorbidities
  - Discuss any changes to treatment plan with all providers involved and document

Questions?

How to Collect Credit for This Activity

Complete the Credit Request Form and Evaluation Form found on your seat at the beginning of the presentation.

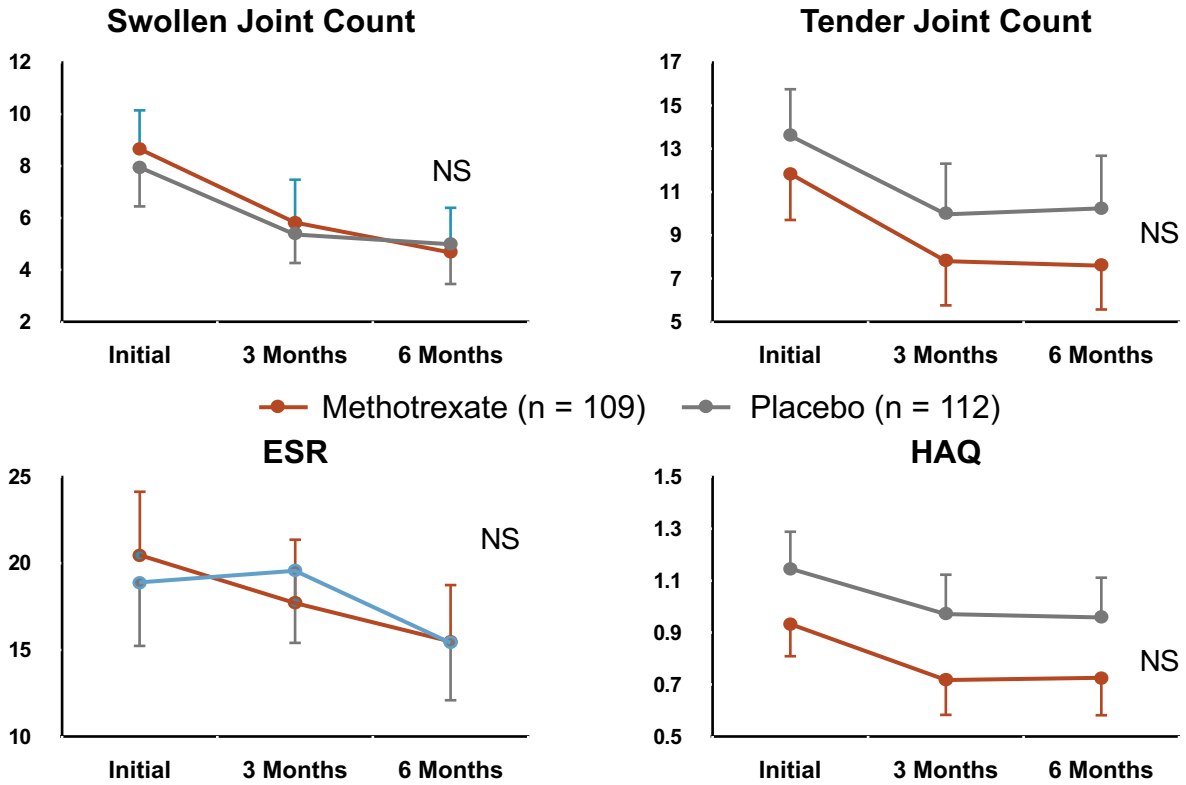
Please submit your completed forms to conference staff before you leave in order to receive your credit.

Presentation Slides

Downloadable resources will be available online at **CMEOutfitters.com/PsAresources**

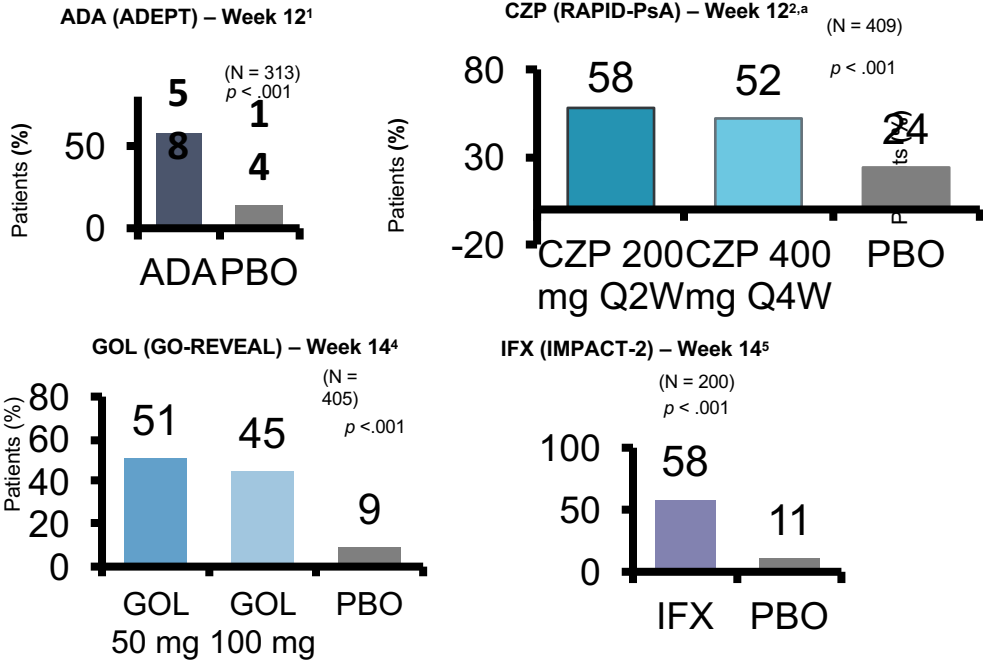
Reference Slides

Methotrexate in Psoriatic Arthritis (MIPA) Trial Results: Joint Counts, ESR and HAQ



Kingsley GH, et al. *Rheumatology*. 2012;51:1368. PMID: 22344575.

Primary Outcome ACR20 Responses in PsA Patients Who Received Anti-TNF Therapy



Different studies: Not head-to-head comparison. Results of individual studies cannot be directly compared

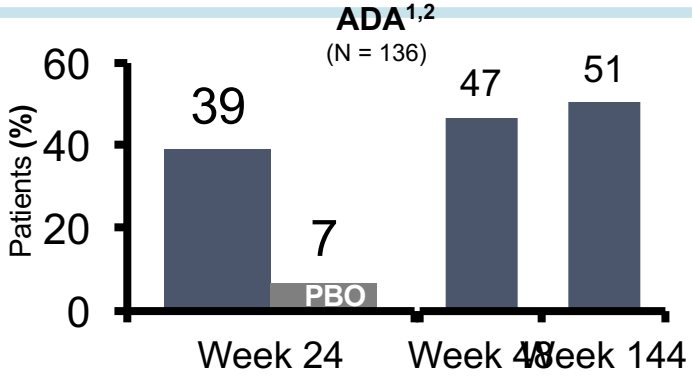
[a]The CZP population included anti-TNF-naïve and anti-TNF-experienced patients.

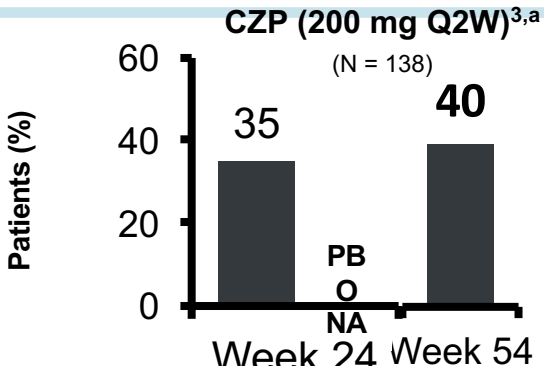
ADA; adalimumab, CZP; certolizumab pegol, ETN; etanercept, GOL; golimumab, IFX; infliximab

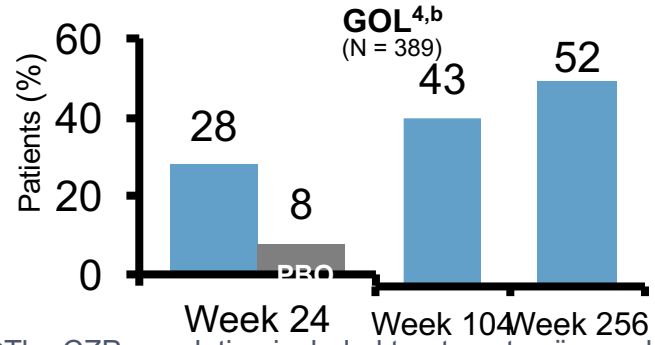
1. Mease PJ, et al. *Arthritis Rheum*. 2005;52:3279-3289; 2. Mease PJ, et al. *Ann Rheum Dis.* 2014;73:48-55; 3. Mease PJ, et al. *Arthritis Rheum.* 2004;50:2264-2272;

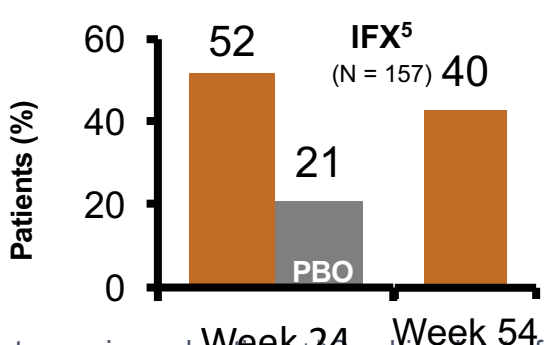
4. Kavanaugh A, et al. *Arthritis Rheum.* 2009;60:976-986; 5. Antoni C, et al. *Ann Rheum Dis.* 2005;64:1150-1157.

Patients With PsA Treated With Anti-TNF Therapy Achieving Minimal Disease Activity (MDA)*









*Different studies: Not head-to-head comparison. Results of individual studies cannot be directly compared

[a]The CZP population included treatment-naïve and treatment-experienced patients; [b]Combined data from 50 and 100 mg dose groups; data for individual doses were not presented

[1]Mease P, et al. *J Rheumatol.* 2013;40:647-652; [2]Abbvie Data on file; [3]Mease P, et al. ACR 2013: Abstract 312; [4]Kavanagh A, et al. ACR 2013: Abstract 341; [5]Coates L and Helliwell PS. *Arthritis Care Res.* 2010;62:965–969

RESPOND Trial: IFX + MTX MTX-Naïve Early PsA Patients

- Purpose
  - IFX + MTX vs MTX in MTX-naïve pts with active, polyarticular PsA
- Method
  - Pts randomized (1:1) to IFX (5 mg/kg) IV at week 0, 2, 6, and 14 + MTX (15 mg/week) or MTX (15 mg/week) alone
  - Primary endpoint: wk 16 ACR20
- Conclusion
  - Significantly greater remission rates with IFX + MTX at every time point in the study
  - MTX monotherapy response impressive

Response at Week 16

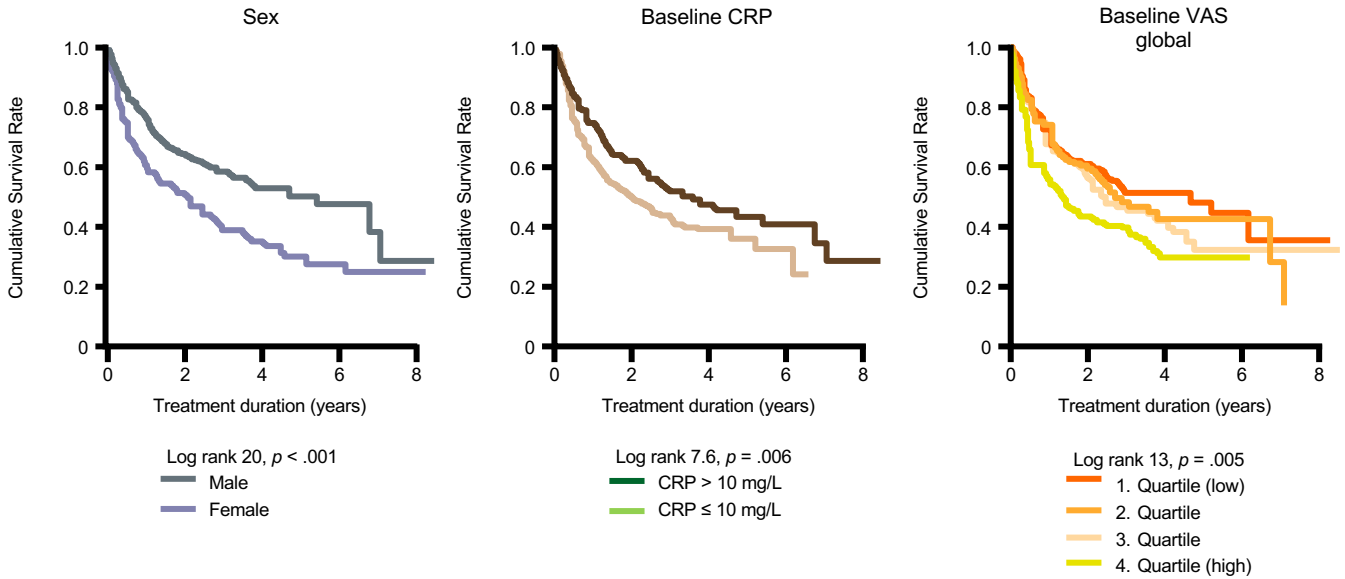
Outcome	IFX + MTX (%)	MTX (%)	*p* Value
ACR20	86.3	66.7	.021
ACR50	72.5	39.6	.009
ACR70	49.0	18.8	.0015
Good EULAR response	82.4	33.3	<.0001
Moderate EULAR response	15.7	39.6	<.0001
DAS28 remission	68.6	29.2	<.0001
PASI 50	100	80.0	.0059
PASI 75	97.1	54.3	<.0001
PASI 90	70.6	28.6	<.01

Intent-to-treat analysis

Antoni CE, et al. *J Rheumatol*. 2008;35(5):869-76.

Drug Survival Rates of Anti-TNF Therapy in PsA

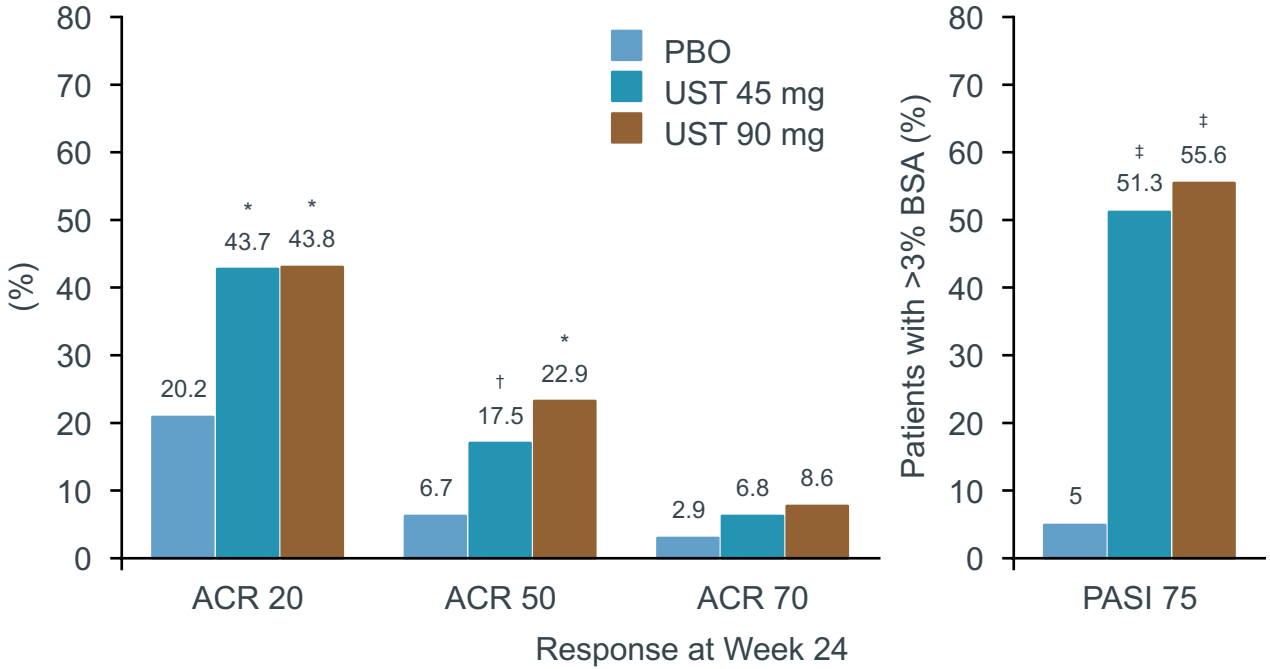
Results From the DANBIO Registry: Drug Survival in 764 Patients with PsA Treated With Anti-TNF Therapy



CRP = C-reactive protein; VAS = Visual analog scale.

Glintborg B, et al. *Arthritis Rheum*. 2011;63:382–390.

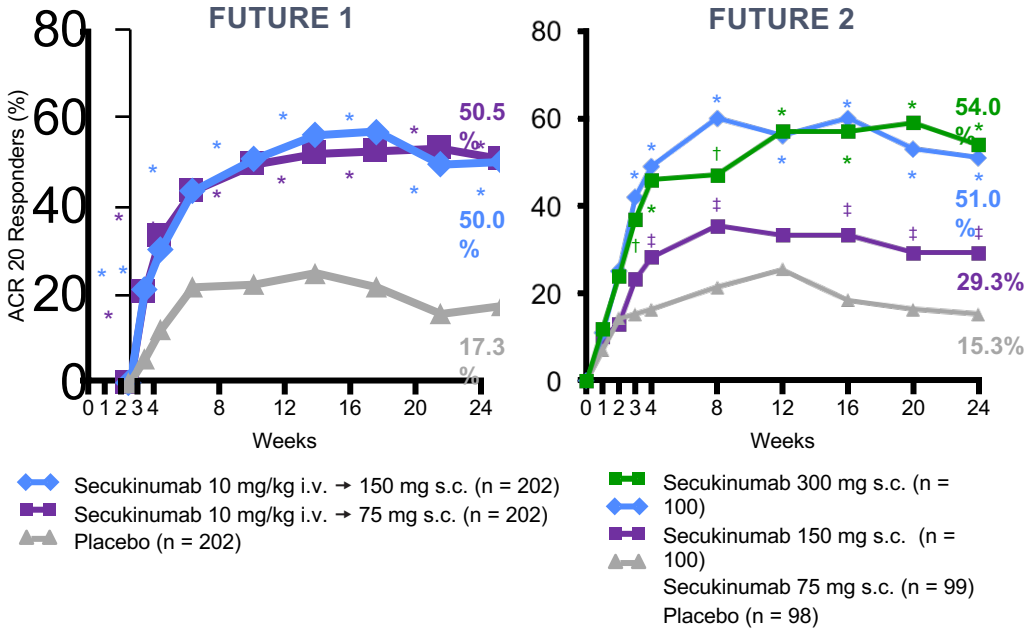
PSUMMIT 2: Ustekinumab Response at Week 24



*$p \leq .001$ vs. placebo; †$p < .05$ vs. placebo.

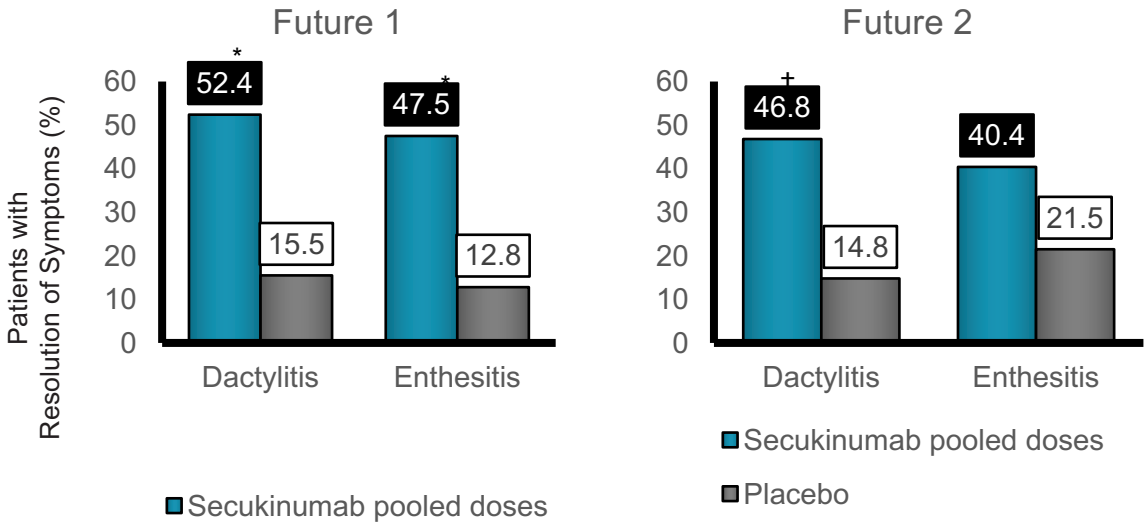
Ritchlin C, et al. *Ann Rheum Dis*. 2014 Jun;73(6):990-9.

Secukinumab in PsA: Primary Outcome Measure



*p < .0001; †p < .001; ‡p < .05 vs. placebo (p-values at Week 24 adjusted for multiplicity).
Missing values imputed as nonresponse (nonresponder imputation).
Mease P, et al. *Rheumatol Ther*. 2016;3(1):5-29.

Secukinumab in PsA: Secondary Outcome Measures: Resolution of Dactylitis and Enthesitis at Week 24



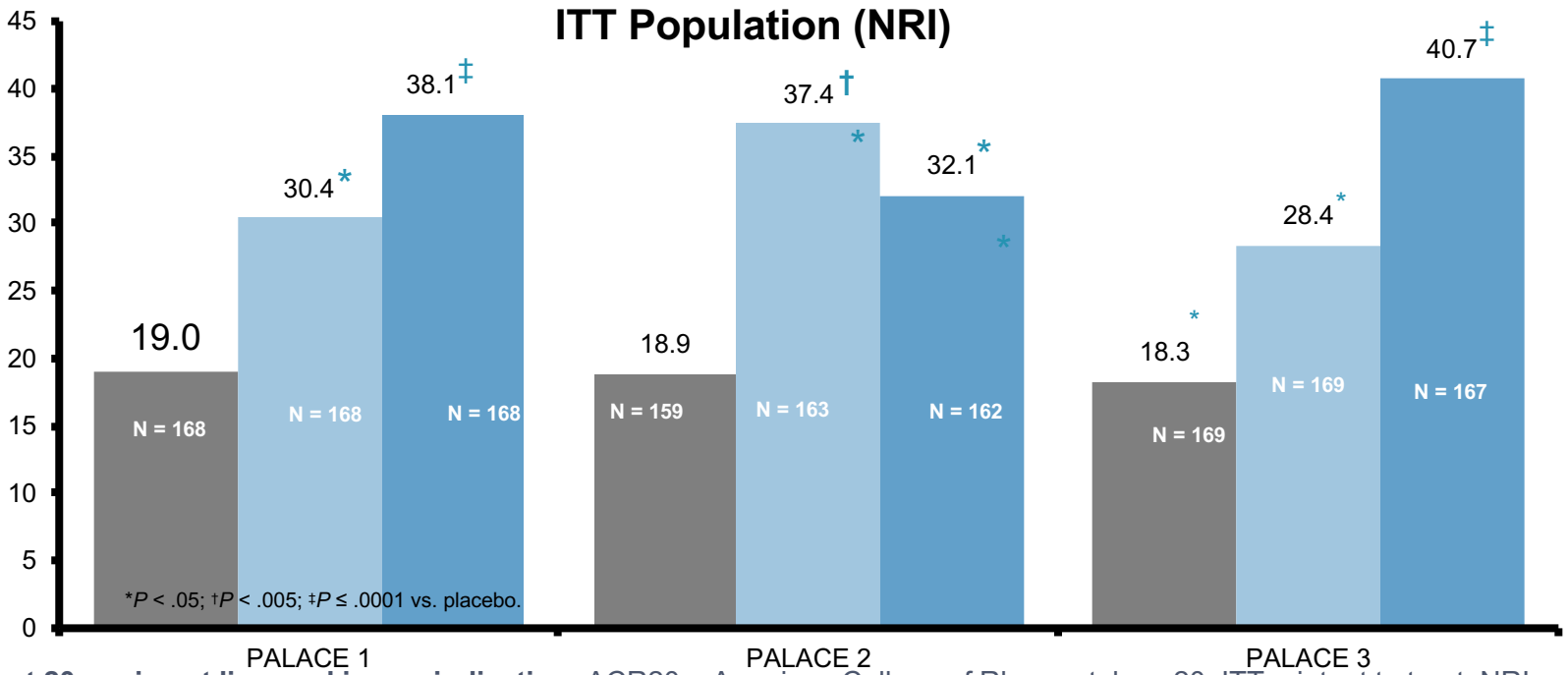
*p < .05 vs. placebo (P-values at Week 24 adjusted for multiplicity)

Resolution of dactylitis and enthesitis amongst those patients with these symptoms at baseline

Missing values were imputed as nonresponse (nonresponder imputation) at Week 24.

Mease P, et al. *Rheumatol Ther*. 2016;3:5-29; Mease P, et al. *ACR* (Boston 2014).

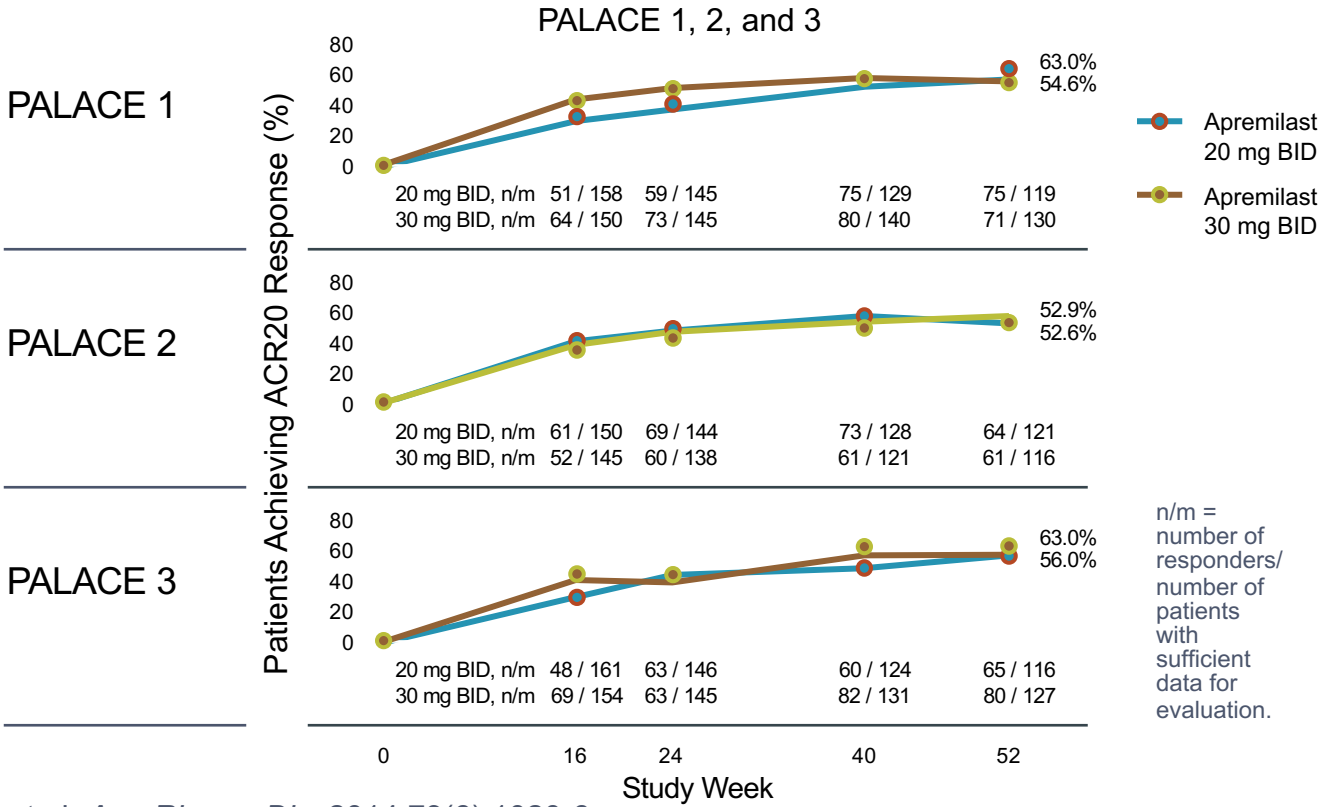
Apremilast in PsA: Primary End Point Across Studies: ACR20 Response at Week 16



Apremilast 20 mg is not licensed in any indication; ACR20 = American College of Rheumatology 20; ITT = intent to treat; NRI = non-responder imputation.

Kavanaugh A, et al. ACR 2014. Abstract 548. Kavanaugh A. et al. *Ann Rheum Dis*. 2014;73:1020-1026. Cutolo M, et al. *J Rheumatol.* 2016;43;1724-1734.

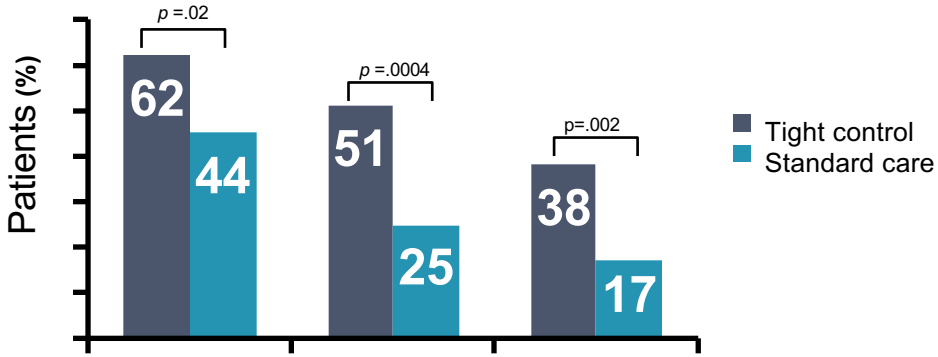
ACR20 Response over 52 Weeks Patients Receiving Apremilast from Baseline (Data as Observed)



Kavanaugh A, et al. *Ann Rheum Dis*. 2014;73(6):1020-6.

Tight Control Was Associated With Significantly Greater Improvements in Signs and Symptoms of Disease at Week 48

Primary Outcome: Complete Case Analysis



	Tight Control	Standard Care
Deaths	0	0
SAE	25	8
SAE related to drug	8	2

SAE = serious adverse event.

Coates LC, et al. *Lancet*. 2015;386(10012):2489-2498.

Emerging Agents for Psoriatic Arthritis

- Ixekizumab (IL-17A Inhibitor)
- Brodalumab
- Baricitinib
- Tofacitinib (Kinase Inhibitor)

Coordination of Care

- When to consult with cardiologist or primary care physician?
  - Patients at risk for cardiovascular disease- obesity, diabetes mellitus, hypertension, hyperlipidemia, smokers
- When to consult with psychiatrist?
  - Patients who are depressed, dysphoric, express suicidal ideation

Reference Guide

- Coates LC, et al. *Arthritis Rheum*. 2016;68:1060-11076.
  - [a] No direct evidence for therapies in axial PsA, recommendations based on axial SpA literature;
  - [b] Corticosteroid injections: consider on an individual basis due to potential for serious side effects; no clear evidence for efficacy; cKeratolytics, steroids, vitamin D analogues, emollients calcineurini; dMTX, CSA Acitretin, Fumaric acid esters.