

Στοχευμένοι συνθετικοί παράγοντες στην Ψωριασική Αρθρίτιδα



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Conflict of Interest

YES

NO



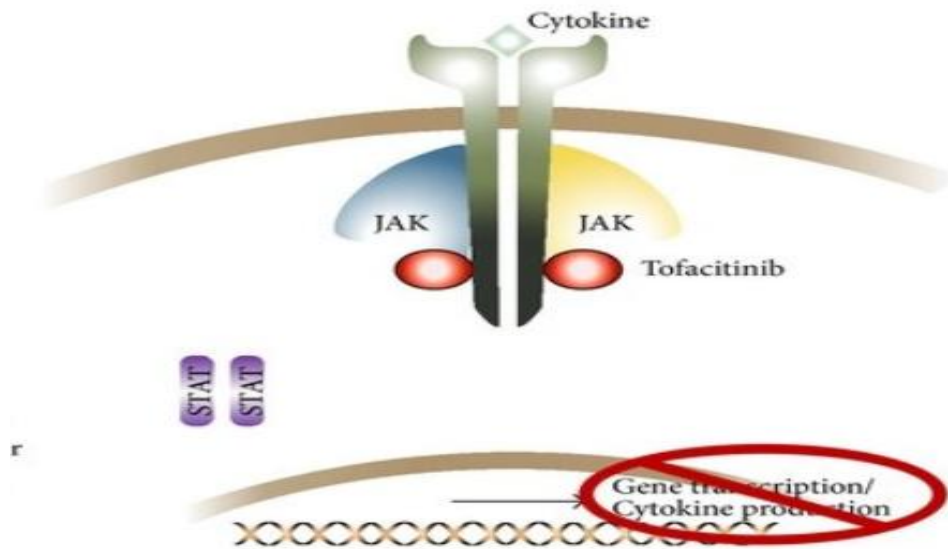
Περίγραμμα ομιλίας

- Στοχευμένα συνθετικά Dmards στην Ψωριασική Αρθρίτιδα ... Που «στοχεύουν» ;
- Το Tofacitinib στην Ψωριασική Αρθρίτιδα.... Μια σύντομη γνωριμία
- Η απρεμιλάστη βάση των Guide lines Έχουν πάντα «δίκιο» οι κατευθυντήριες οδηγίες?
- Υποπληθισμοί της Ψωριασικής Αρθρίτιδας, Real- world data Πού «πραγματικά» ταιριάζει η απρεμιλάστη ?
- Η θέση των στοχευμένων συνθετικών παραγόντων στον θεραπευτικό αλγόριθμο της Ψωριασικής Αρθρίτιδας

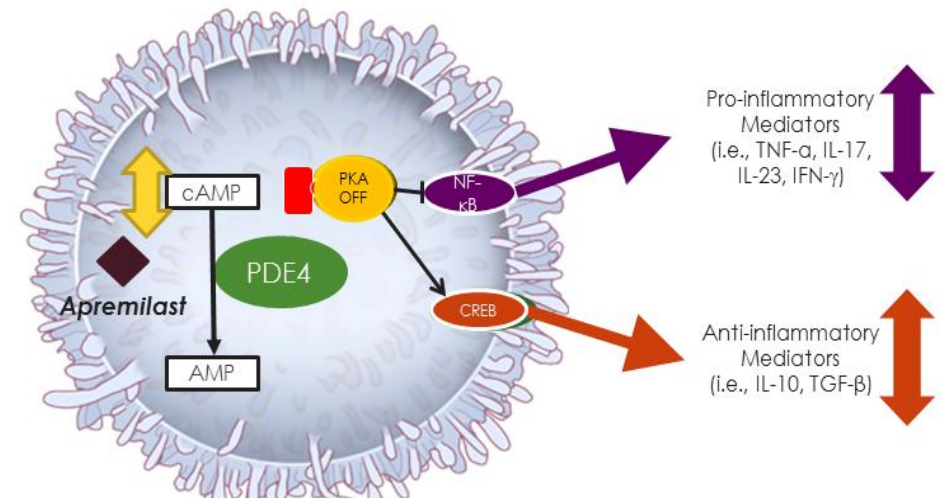
Στοχευμένοι συνθετικοί παράγοντες...που στοχεύουν?

Targeted synthetic Dmards

Tofacitinib



Apremilast



RESEARCH ARTICLE

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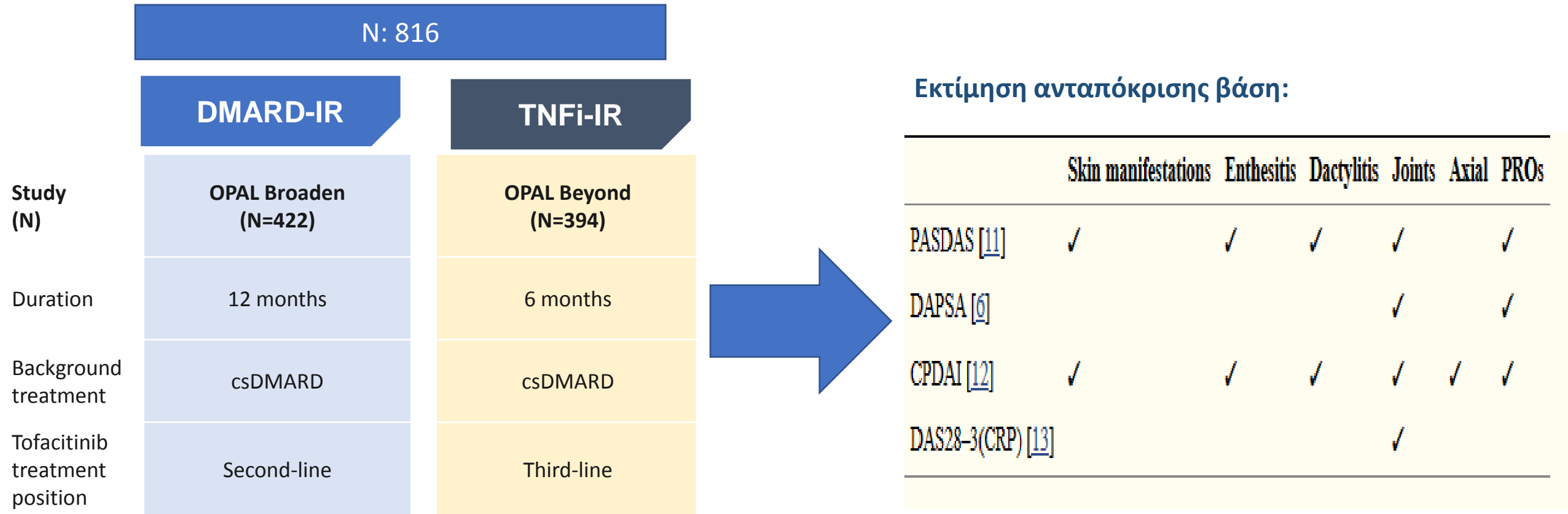


Disease-specific composite measures for psoriatic arthritis are highly responsive to a Janus kinase inhibitor treatment that targets multiple domains of disease

Philip Helliwell¹, Laura C. Coates², Oliver FitzGerald³, Peter Nash⁴, Enrique R. Soriano⁵, M. Elaine Husni⁶, Ming-Ann Hsu⁷, Keith S. Kanik⁷, Thijs Hendrikx⁸, Joseph Wu⁷ and Elizabeth Kudlacz^{7*}

Tofacitinib στην Ψωριασική Αρθρίτιδα... αποτελεσματικότητα

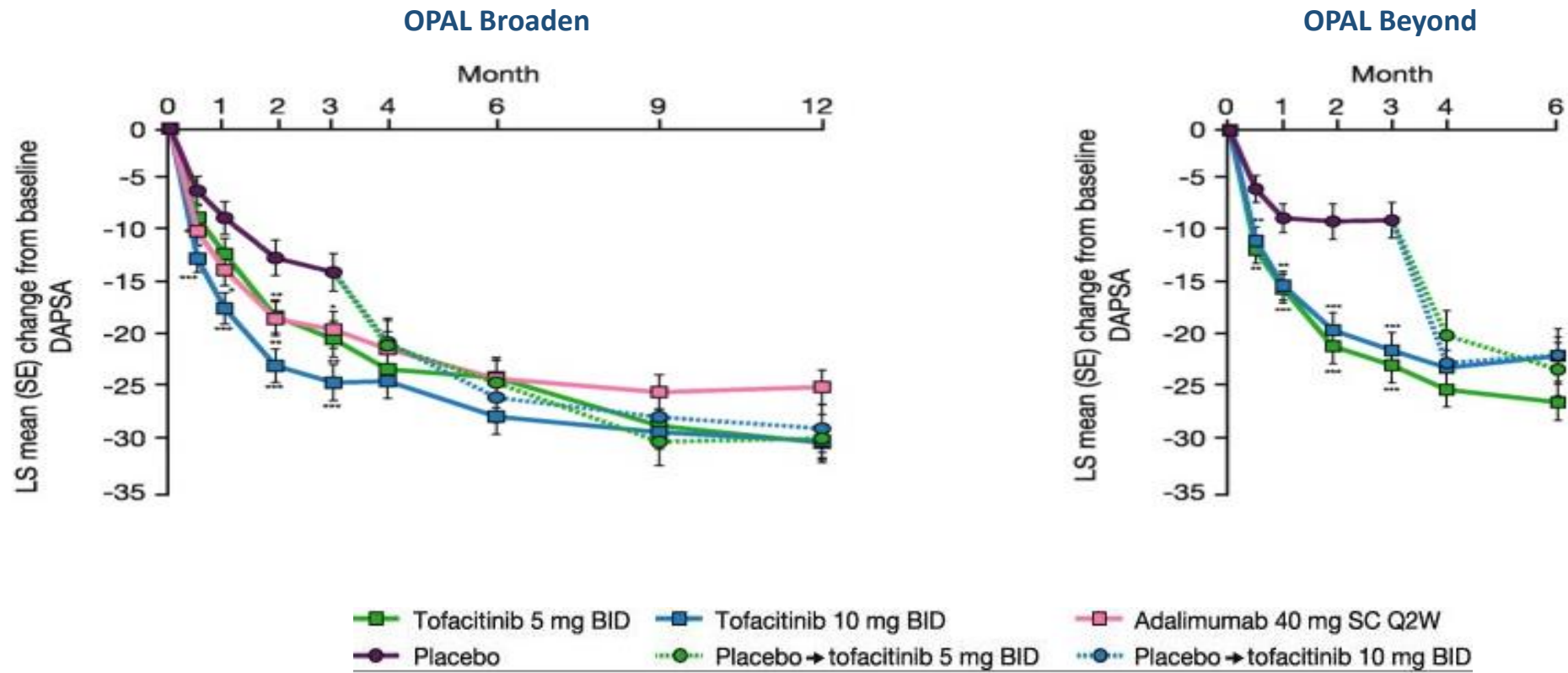
Disease-specific composite measures for psoriatic arthritis are highly responsive to a Janus kinase inhibitor treatment that targets multiple domains of disease



Tofacitinib στην Ψωριασική Αρθρίτιδα ...αποτελεσματικότητα

Disease-specific composite measures for psoriatic arthritis are highly responsive to a Janus kinase inhibitor treatment that targets multiple domains of disease

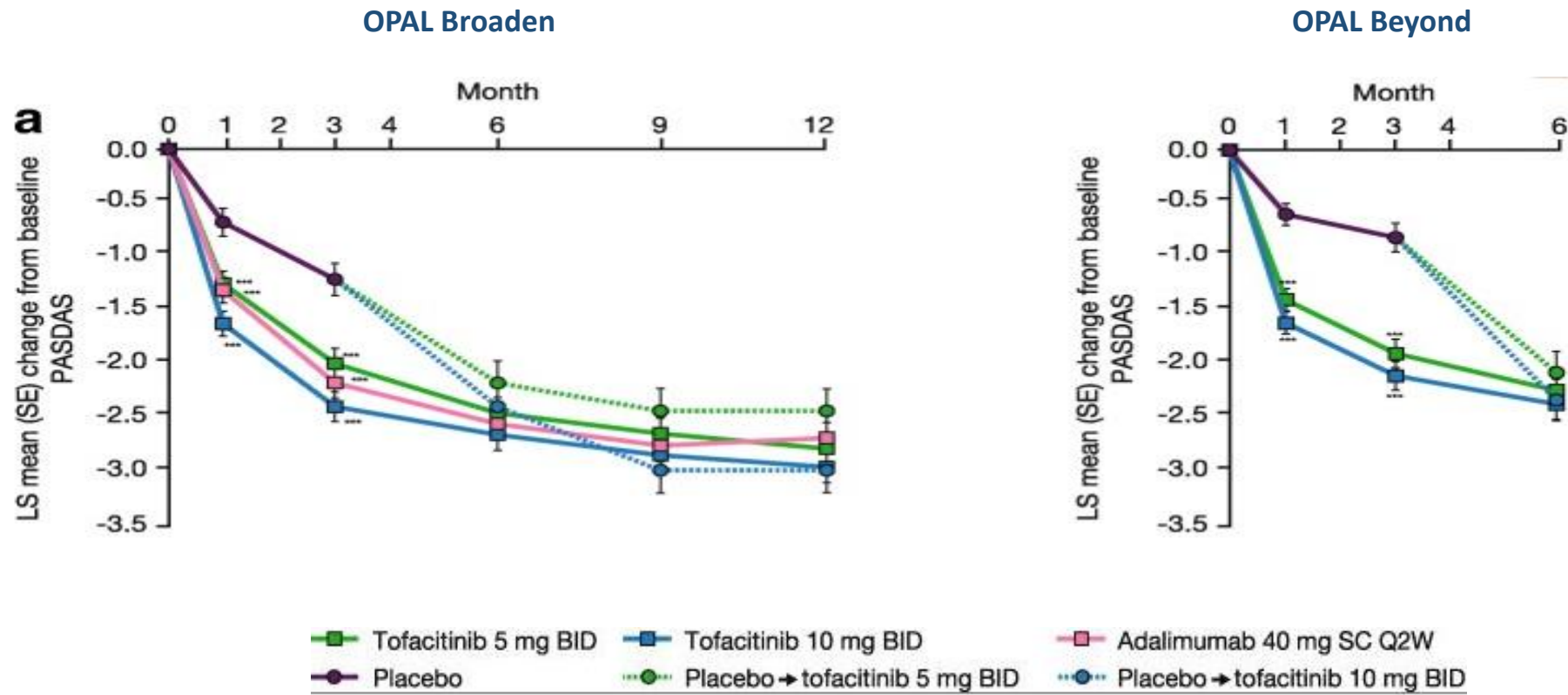
Ανταπόκριση βάση DAPSA



Tofacitinib στην Ψωριασική Αρθρίτιδα... αποτελεσματικότητα

Disease-specific composite measures for psoriatic arthritis are highly responsive to a Janus kinase inhibitor treatment that targets multiple domains of disease

Ανταπόκριση βάση PASDAS



Rheumatol Ther (2018) 5:567–582
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ORIGINAL RESEARCH

Efficacy of Tofacitinib for the Treatment of Psoriatic Arthritis: Pooled Analysis of Two Phase 3 Studies

Peter Nash · Laura C. Coates · Roy Fleischmann · Kim A. Papp ·
Juan Jesus Gomez-Reino · Keith S. Kanik · Cunshan Wang ·
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Efficacy of Tofacitinib for the Treatment of Psoriatic Arthritis: Pooled Analysis of Two Phase 3 Studies

	Tofacitinib 5 mg BID (N= 238)	Tofacitinib 10 mg BID (N= 236)	Placebo (N= 236)	Total (N= 710)
Age (years), mean (SD)	49.5 (12.4)	49.4 (11.7)	48.4 (12.5)	49.1 (12.2)
Female, n (%)	121 (50.8)	136 (57.6)	136 (57.6)	393 (55.4)
BMI (kg/m ²), mean (SD)	29.8 (6.3)	30.2 (6.3)	29.2 (5.6)	29.7 (6.1)
Race, Caucasian ^a , n (%)	226 (95.0)	221 (93.6)	222 (94.1)	669 (94.2)
PsA duration (years), mean (SD)	8.6 (7.9)	7.5 (6.6)	8.1 (7.5)	8.0 (7.4)
Tender JC^b, mean (SD)	20.5 (12.8)	23.2 (15.8)	20.2 (14.6)	21.3 (14.5)
Swollen JC ^c , mean (SD)	12.5 (10.3)	12.3 (9.8)	10.9 (8.9)	11.9 (9.7)
hsCRP > 2.87 mg/l, n (%)	153 (64.3)	148 (62.7)	143 (60.6)	444 (62.5)
Polyarticular disease^d, n (%)	236 (99.2)	231 (97.9)	229 (97.0)	696 (98.0)
Screening distal interphalangeal joints involvement, n (%)	153 (64.3)	151 (64.0)	134 (56.8)	438 (61.7)
Arthritis mutilans, n (%)	16 (6.7)	18 (7.6)	23 (9.7)	57 (8.0)
Spondylitis ^e , n (%)	50 (21.0)	47 (19.9)	44 (18.6)	141 (19.9)
Psoriatic BSA ≥ 3%, n (%)	162 (68.1)	151 (64.0)	168 (71.2)	481 (67.7)
PASI ^f , mean (SD)	NI = 162 9.0 (7.8)	NI = 151 10.1 (7.9)	NI = 168 10.3 (9.9)	NI = 481 9.8 (8.6)
Enthesitis assessed by LEI ^g , n (%)	158 (66.4)	163 (69.1)	158 (66.9)	479 (67.5)

Tofacitinib στην Ψωριασική Αρθρίτιδα...αποτελεσματικότητα

Efficacy of Tofacitinib for the Treatment of Psoriatic Arthritis: Pooled Analysis of Two Phase 3 Studies

Physical function, enthesitis, dactylitis, and BASDAI endpoints at month 3 and month 6; pooled data from OPAL Broaden and OPAL Beyond (NRI)

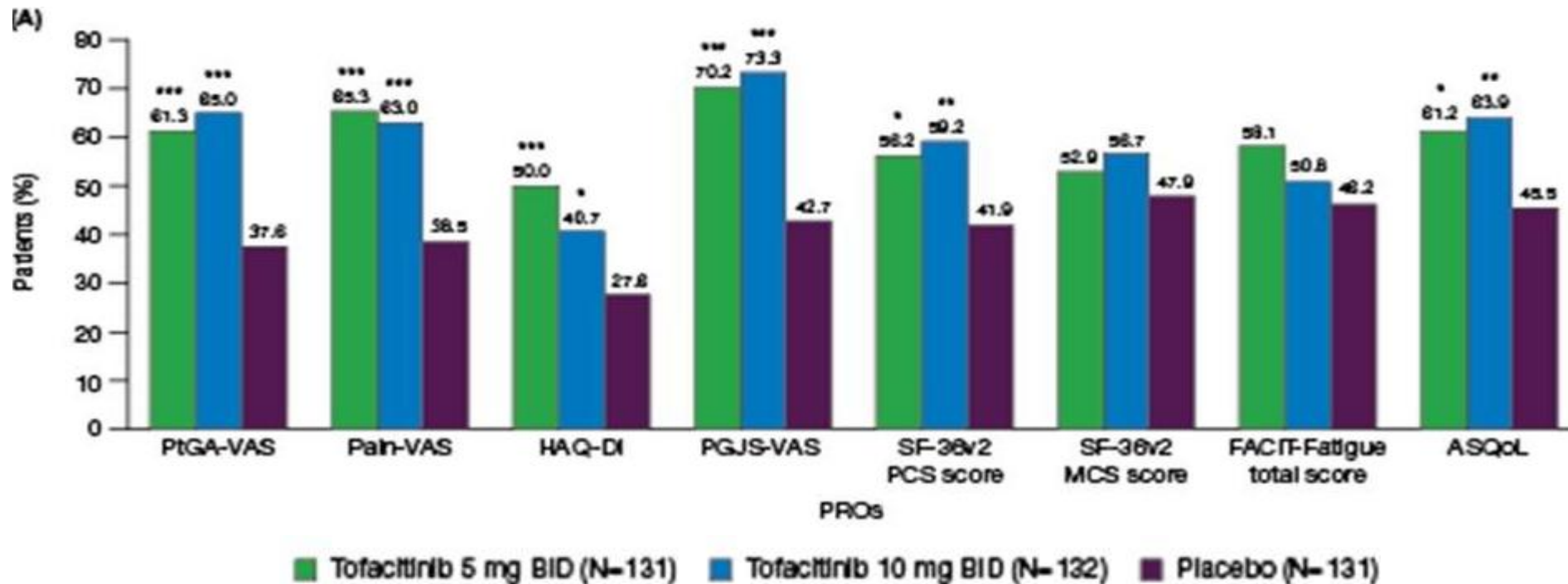
	Month 3		Placebo	Month 6	
	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID		Tofacitinib 5 mg BID	Tofacitinib 10 mg BID
HAQ-DI response rate ^a , <i>n/N</i> (%)	109/212*** (51.4)	101/215*** (47.0)	61/210 (29.1)	119/212 (56.1)	96/215 (44.7)
Enthesitis resolution rate (LEI) ^b , <i>n/N</i> (%)	58/158** (36.7)	58/163** (35.6)	34/158 (21.5)	75/158 (47.5)	71/163 (43.6)
Enthesitis resolution rate (SPARCC Enthesitis Index) ^b , <i>n/N</i> (%)	52/177 (29.4)	66/189* (34.9)	42/179 (23.5)	69/177 (39.0)	76/189 (40.2)
Dactylitis resolution rate (DSS) ^b , <i>n/N</i> (%)	55/127* (43.3)	69/125*** (55.2)	37/121 (30.6)	71/127 (55.9)	76/125 (60.8)
BASDAI response rate ^c , <i>n/N</i> (%)	16/43* (37.2)	12/41 (29.3)	6/38 (15.8)	16/43 (37.2)	10/41 (24.4)

Conclusions

In a pooled analysis of csDMARD-IR/TNFi-naïve and TNFi-IR patients, **tofacitinib was superior** to placebo at month 3 across four PsA domains: **peripheral arthritis, psoriasis, enthesitis and dactylitis.**

Tofacitinib στην Ψωριασική Αρθρίτιδα...PROs

Effect of tofacitinib on patient-reported outcomes in patients with active psoriatic arthritis and an inadequate response to tumour necrosis factor inhibitors in the phase III, randomised controlled trial: OPAL Beyond.



Conclusion:

TNFi-IR patients with PsA receiving tofacitinib reported statistically and clinically meaningful improvements in PROs versus placebo over 3 months, which were maintained to month 6. Despite lower baseline scores, these improvements were similar to the csDMARD-IR TNFi-naive OPAL Broaden trial.

Tofacitinib στην Ψωριασική Αρθρίτιδα... Ασφάλεια

ABSTRACT NUMBER: 617

Comparing Tofacitinib Safety Profile in Patients with Psoriatic Arthritis in Clinical Studies with Real-World Data

Meeting: [2017 ACR/ARHP Annual Meeting](#)

Date of first publication: September 18, 2017

Table. Incidence rates (95% CI)* [PY exposure] for adverse events of special interest

	SIEs ^b	HZ	Malignancies ^c	NMSC	MACE
Tofacitinib cohort^d					
Tofacitinib 5 mg BID (N=238)	1.30 (0.16, 4.69) [154]	1.96 (0.41, 5.74) [153]	NR	NR	NR
Tofacitinib 10 mg BID (N=236)	2.00 (0.41, 5.83) [150]	2.66 (0.73, 6.81) [150]	NR	NR	NR
Tofacitinib all doses (N=783)	NR	NR	0.63 (0.21, 1.48) [791]	0.51 (0.14, 1.30) [789]	0.38 (0.08, 1.11) [791]
Comparison cohort					
Any bDMARD (N=5,075)	5.02 (4.19, 5.97) [2,569]	1.26 (0.91, 1.70) [3,343]	0.51 (0.34, 0.74) [5,499]	1.40 (1.10, 1.75) [5,448]	0.38 (0.22, 0.61) [4,468]
Any bDMARD + csDMARD (N=2,542)	5.10 (3.83, 6.66) [1,058]	1.53 (0.94, 2.37) [1,303]	0.40 (0.16, 0.82) [1,751]	1.79 (1.21, 2.53) [1,736]	0.25 (0.07, 0.64) [1,591]
Any TNFi (N=4,617)	5.13 (4.26, 6.11) [2,419]	1.26 (0.90, 1.71) [3,181]	0.51 (0.33, 0.74) [5,144]	1.39 (1.09, 1.76) [5,098]	0.41 (0.24, 0.65) [4,183]
Any TNFi + csDMARD (N=2,383)	5.12 (3.83, 6.72) [1,015]	1.51 (0.91, 2.36) [1,257]	0.42 (0.17, 0.86) [1,670]	1.75 (1.17, 2.52) [1,656]	0.26 (0.07, 0.67) [1,520]
Adalimumab (N=1,934)	4.16 (3.00, 5.63) [1,009]	1.16 (0.65, 1.91) [1,297]	0.48 (0.23, 0.88) [2,095]	1.40 (0.94, 2.01) [2,070]	0.41 (0.16, 0.84) [1,724]
Etanercept (N=1,412)	4.82 (3.37, 6.67) [747]	1.10 (0.55, 1.97) [1,000]	0.41 (0.16, 0.84) [1,720]	1.46 (0.95, 2.16) [1,709]	0.30 (0.08, 0.76) [1,343]
Infliximab (N=615)	8.91 (6.09, 12.57) [359]	1.94 (0.93, 3.57) [516]	1.21 (0.55, 2.30) [743]	1.35 (0.65, 2.48) [741]	0.47 (0.10, 1.37) [638]
Golimumab (N=389)	3.49 (1.40, 7.19) [201]	1.16 (0.24, 3.39) [258]	0.00 (0.00, 0.90) [410]	0.99 (0.27, 2.53) [404]	0.91 (0.19, 2.67) [328]
Certolizumab (N=267)	6.80 (2.74, 14.02) [103]	0.91 (0.02, 5.06) [110]	0.00 (0.00, 2.09) [176]	1.72 (0.35, 5.02) [175]	0.00 (0.00, 2.44) [151]
Apremilast (N=617)	5.34 (2.56, 9.82) [187]	2.62 (0.85, 6.13) [191]	1.14 (0.24, 3.35) [262]	3.45 (1.58, 6.56) [261]	0.00 (0.00, 1.60) [231]

Conclusion: IRs of AEs of special interest reported in tofacitinib PsA Phase 3 studies were generally comparable to those in a general PsA population comprising pts receiving a range of biologic agents, **except HZ, which was higher for tofacitinib-treated pts but similar to the incidence observed with tofacitinib treatment in other indications.**

Tofacitinib στην Ψωριασική Αρθρίτιδα ...ναί μεν αλλά..



γρήγορη ανταπόκριση

Βελτίωση σε πολλές παράμετρους

Και μετά από bdmard



Διατήρηση αποτελέσματος

Αξονική προσβολή

Συννοσηρότητες



Ελλειψη (real-world) data

European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update

Ann Rheum Dis 2016;**75**:499–510

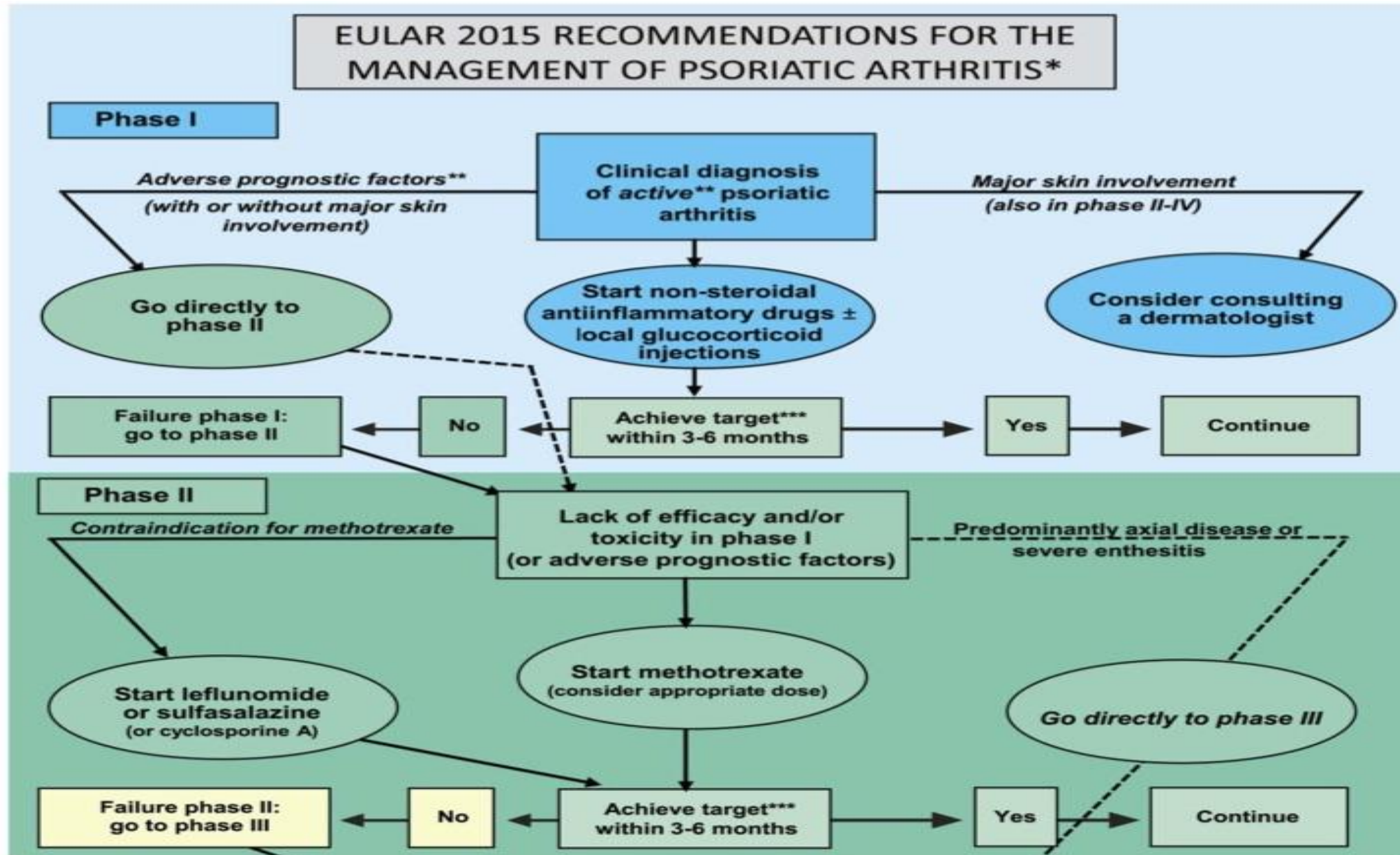
ARTHRITIS & RHEUMATOLOGY
Vol. 68, No. 5, May 2016, pp 1060–1071
DOI 10.1002/art.39573
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SPECIAL ARTICLE

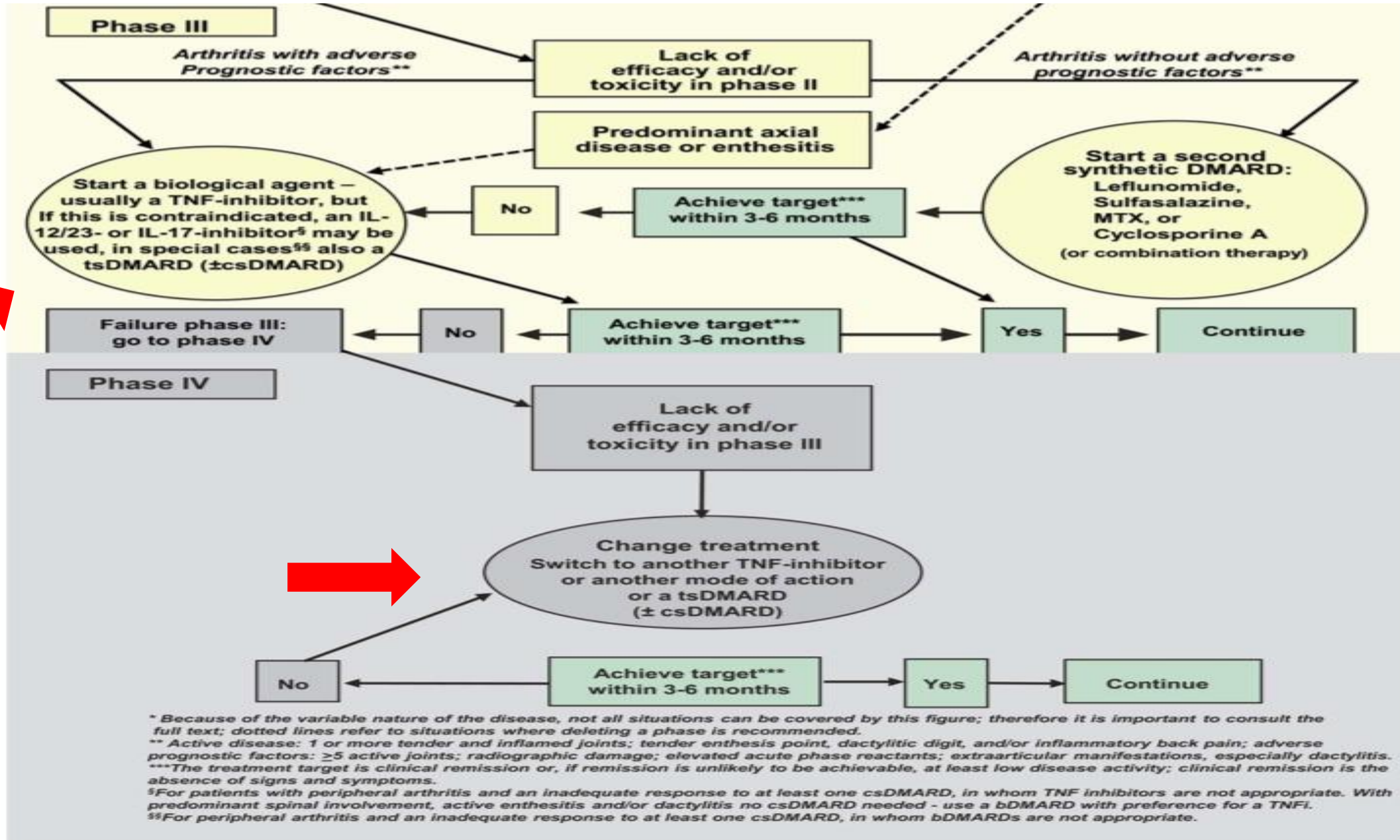
Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis

Laura C. Coates,¹ Arthur Kavanaugh,² Philip J. Mease,³ Enrique R. Soriano,⁴
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Wolf-Henning Boehncke,⁷ Willemina Campbell,⁸ Alberto Cauli,⁹ Luis R. Espinoza,¹⁰
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Η Απρεμιλάστη στην Ψωριασική Αρθρίτιδα – EULAR guide lines

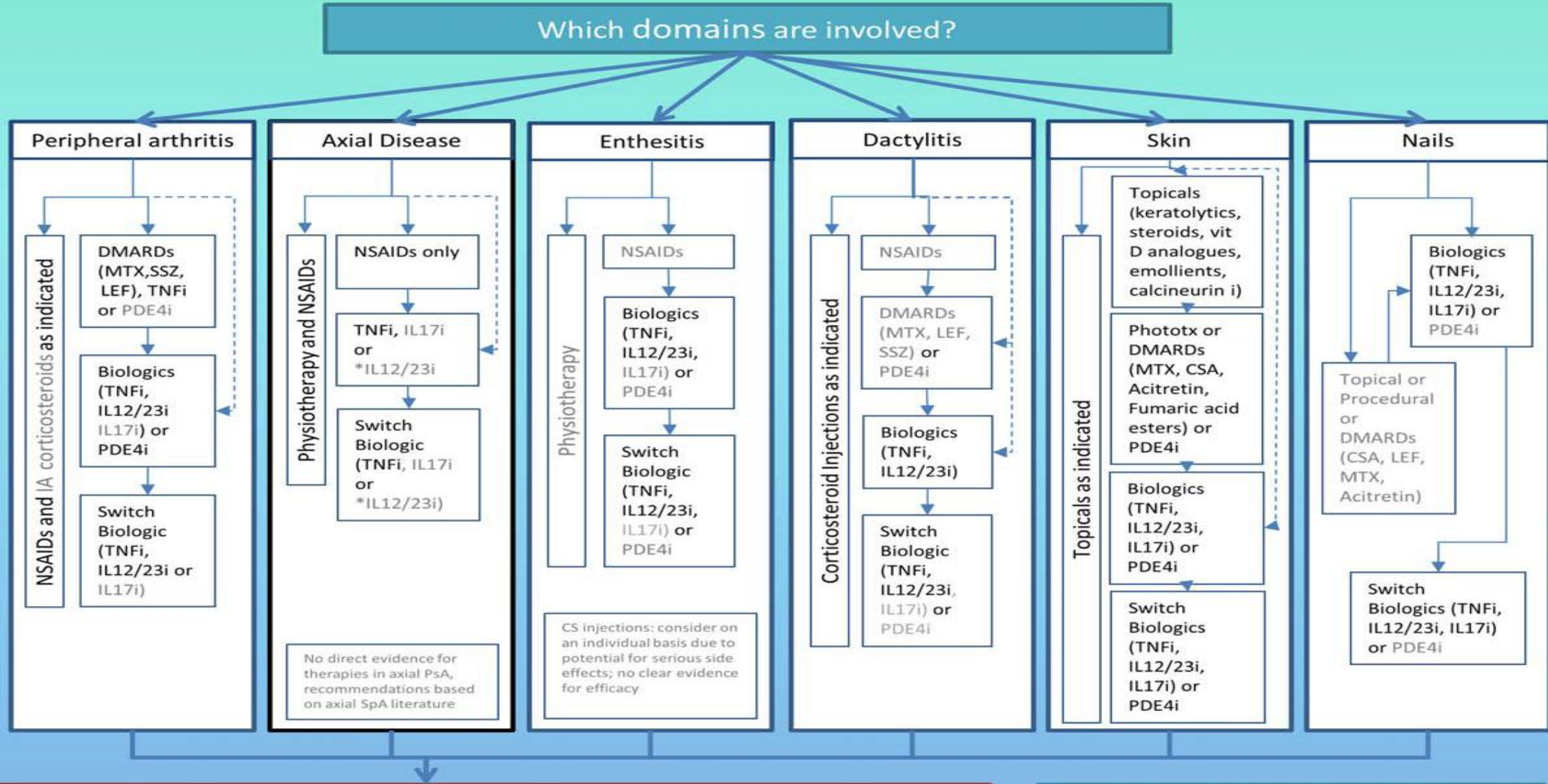


Η Απρεμιλάστη στην Ψωριασική Αρθρίτιδα – EULAR guide lines



Η Απρεμιλάστη στην Ψωριασική Αρθρίτιδα – GRAPPA guide lines

Assess activity, impact and prognostic factors



Consider previous therapy, patient choice, other disease involvement and comorbidities. Choice of therapy should address as many domains as possible

Treat, periodically re-evaluate and modify therapy as required

Η Απρεμιλάστη στην Ψωριασική Αρθρίτιδα..GRAPPA vs EULAR

ΧΑΡΑΚΤΗΡΙΣΤΙΚΑ	EULAR	GRAPPA
Μεθοτρεξάτη	Συστήνεται ως το csDMARD 1 ^{ης} επιλογής	Στην ίδια θέση με τα υπόλοιπα csDMARDs, χωρίς ειδική προτίμηση
Αναστολείς TNF	<ol style="list-style-type: none"> 1. Συστήνονται μετά την αποτυχία csDMARDs στην περίπτωση κυρίαρχης περιφερικής νόσου, ή πιο πρώιμα σε δεσπόζουσα αξονική νόσο ή ενθεσίτιδα 2. Η χρήση τους συστήνεται μετά την αποτυχία csDMARDs 3. Ξεκάθαρη προτεραιότητα στους αναστολείς TNF, σαν 1^{ης} γραμμής bDMARD 	<ol style="list-style-type: none"> 2. Δυνατότητα χρήσης στην 1^η γραμμή, πριν τα csDMARDs, σε ασθενείς με σοβαρή ενεργότητα της νόσου 3. Δε δίδεται προτίμηση στην 1^η γραμμή θεραπείας
Secukinumab και Ustekinumab	Συστήνονται μετά την αποτυχία της MXT, προτιμώνται οι TNFi σαν 1 ^{ης} γραμμής bDMARD	Συστήνονται στην ίδια θέση με τους αναστολείς TNF
Apremilast	Συστήνεται για χρήση μετά τη MXT, στην περίπτωση που αντενδείκνυνται τα bDMARDs	<ol style="list-style-type: none"> 1. Συστήνεται για χρήση μετά την αποτυχία csDMARDs ή στην περίπτωση που τα csDMARDs αντενδείκνυνται 2. Συστήνεται υπό όρους πριν από τα csDMARDs, σε συγκεκριμένες περιπτώσεις

Η Απρεμιλάστη στην Ψωριασική Αρθρίτιδα..GRAPPA vs EULAR

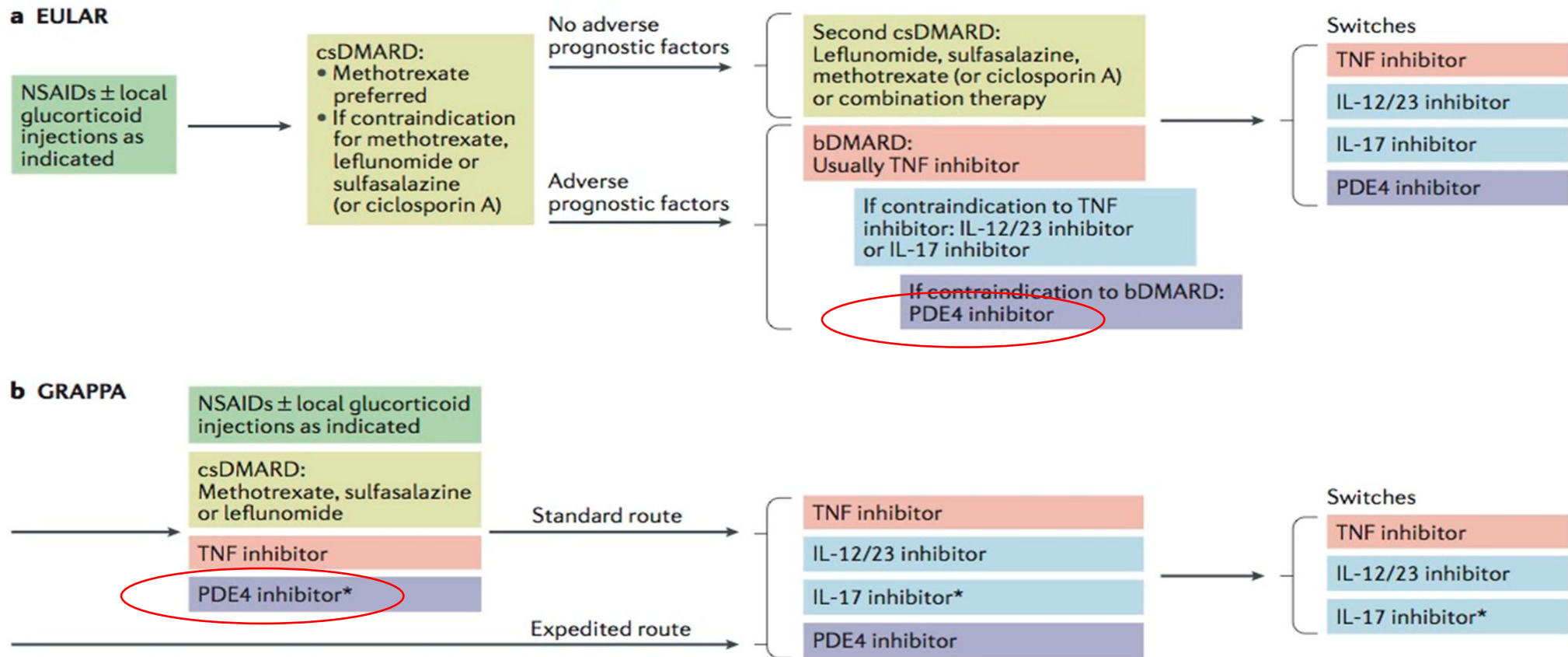


Figure 1 | Simplified EULAR and GRAPPA treatment algorithms for predominant peripheral psoriatic arthritis^{5,6}. The order of drug use proposed for patients with psoriatic arthritis (PsA) and predominant peripheral joint involvement, with a step-up approach (indicated by staggered boxes) in case of inefficacy or toxicity. *Conditional recommendation in the

GRAPPA) guidelines for drugs without current regulatory approval or where recommendations are based on abstract data only. bDMARD, biologic DMARD; csDMARD, conventional synthetic DMARD; EULAR, European League Against Rheumatism; GRAPPA, Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; PDE4, phosphodiesterase 4.

Abstract Number: 2570

Meeting: [2018 ACR/ARHP Annual Meeting](#)

Probability of Achieving Low Disease Activity or Remission in Subjects with Active Psa Treated with Apremilast

Philip J. Mease¹; Frank Behrens²; Dafna D. Gladman³; Arthur Kavanaugh⁴;
Michele Brunori⁵; Lichen Teng⁵; Benoit Guerette⁵; Rubén Queiro⁶; Alexis Ogdie⁷

¹Swedish Medical Center and University of Washington School of Medicine, Seattle, WA; ²Division of Rheumatology, Goethe University and Fraunhofer IME-TMP, Frankfurt, Germany; ³Krembil Research Institute, Toronto Western Hospital, Toronto, ON, Canada; ⁴University of California, San Diego, School of Medicine, La Jolla, CA; ⁵Celgene Corporation, Summit, NJ; ⁶Rheum-Derm Unit, Hospital Universitario Central de Asturias, Oviedo, Spain; ⁷Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Probability of Achieving Low Disease Activity or Remission in Subjects with Active Psa Treated with Apremilast

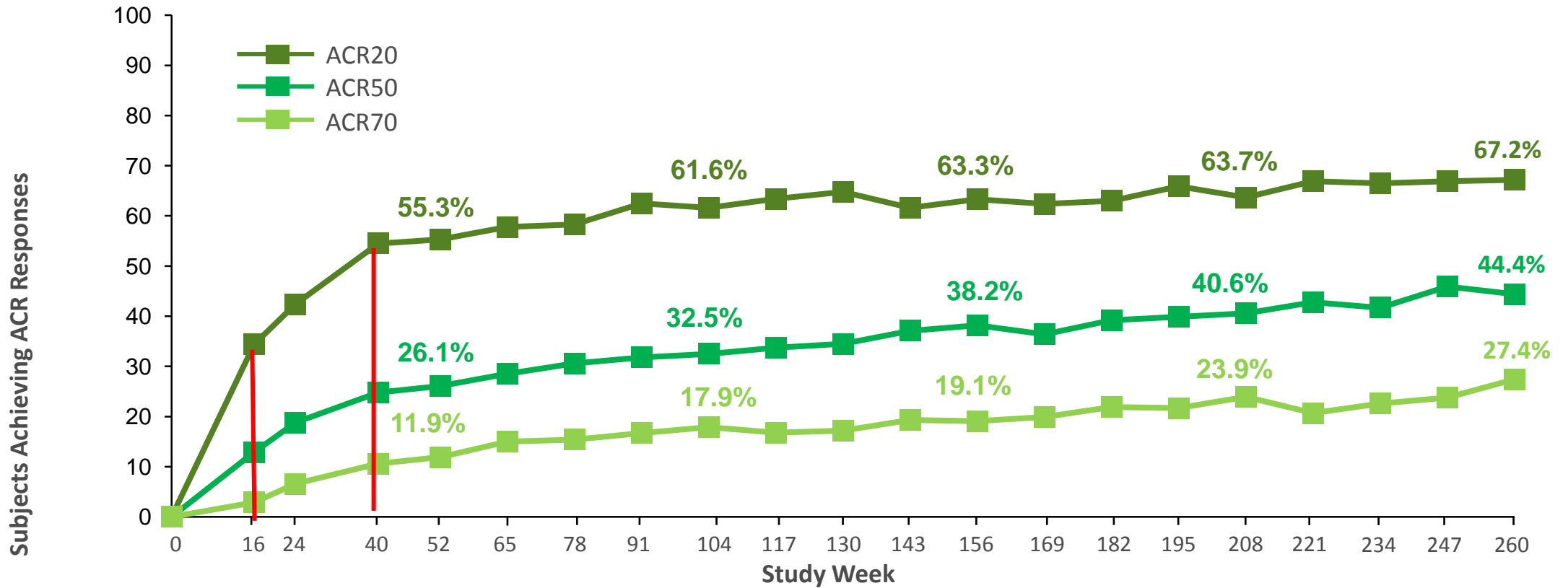
Πιθανότητα επίτευξης στόχων θεραπείας cDAPSA την εβδομάδα 52

		Κατηγορίες cDAPSA την εβδομάδα 52				
		HDA	Mod	LDA	REM	LDA/REM
Κατηγορίες cDAPSA κατά την έναρξη*	LDA	1.7%	27.2%	52.2%	18.9%	71.1%
	Mod	13.8%	39.3%	36.2%	10.7%	46.9%
	HDA	36.3%	38.8%	20.7%	4.2%	24.9%

*Μεγαλύτερα ποσοστά ανταπόκρισης
οι «εχοντες» μέτρια ενεργότητα νόσου*

Η Απρεμιλάστη στην Ψωριασική Αρθρίτιδα... «η υπομονή είναι αρετή»

ACR ανταποκρίσεις σε ασθενείς που έλαβαν Apremilast 30 mg BID για 5 έτη



ACR20, n	561	509	492	469	450	435	429	419	406	394	384	367	364	357	343	335	320
ACR50, n	563	515	496	472	452	433	429	418	408	396	388	373	367	355	343	338	324
ACR70, n	564	519	499	473	452	441	435	420	408	397	388	373	368	357	349	340	325

Data as observed. Analyses include all subject data, including the placebo-controlled period, regardless of when subjects started taking apremilast (baseline, Week 16, or Week 24). The n represents the number of subjects with evaluable data at the time point; it may vary slightly for each outcome.

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Letters to the Editor

Rheumatology 2018;57:578–580

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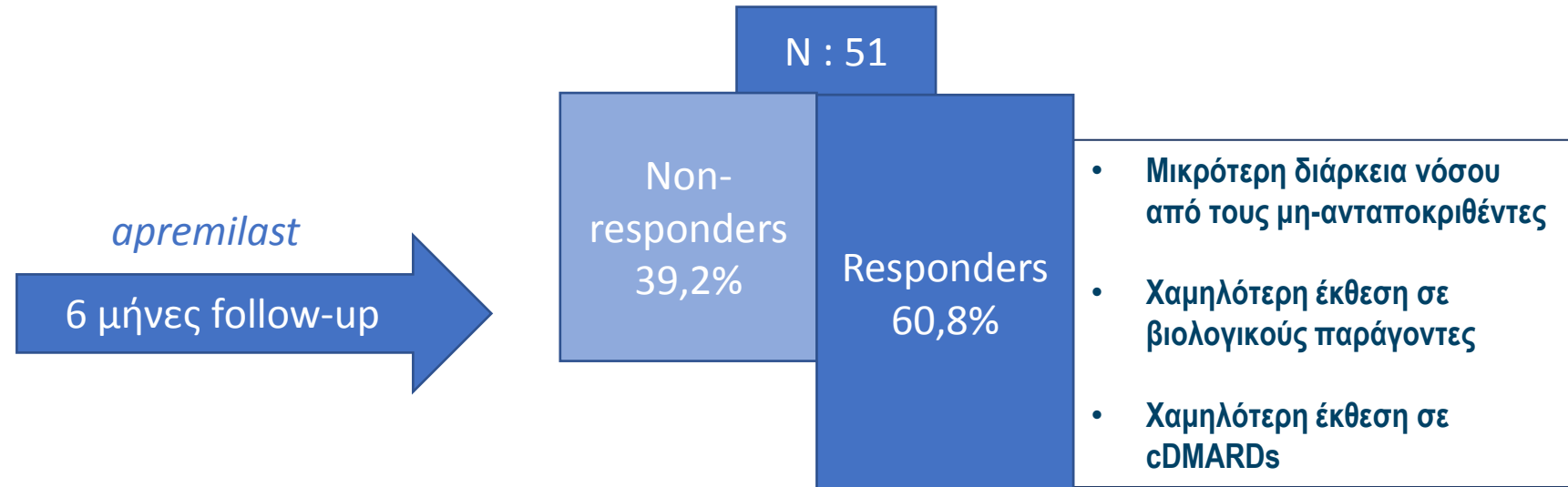
Advance Access publication 20 December 2017

Apremilast for the treatment of active psoriatic arthritis: a single-centre real-life experience

Apremilast for the treatment of active psoriatic arthritis: a single-centre real-life experience

TABLE 1 Baseline clinical characteristics of 71 PsA patients treated with apremilast

Male, <i>n</i> (%)	33 (46.5)
Age, mean (s.d.), years	51 (13.2)
PsA disease duration, mean (s.d.), years	7.7 (6.4)
Peripheral involvement (all polyarticular), <i>n</i> (%)	71 (100)
Axial involvement, <i>n</i> (%)	22 (31)
Psoriasis, <i>n</i> (%)	59 (83.1)
Nail involvement, <i>n</i> (%)	20 (44.4)
Enthesal/dactylitis involvement, <i>n</i> (%)	38 (60.3)
CRP baseline, median (range), mg/l	7.1 (5–115)
Tender joint count, median (range)	7 (0–40)
Swollen joint count, median (range)	3 (0–16)
Patient's disease activity (1–5), median (range)	4 (1–5)
Physician's disease activity (1–5),	3 (1–5)
Previous cDMARDS, <i>n</i> (%)	67 (94.4)
Previous bDMARDS, <i>n</i> (%)	40 (56.3)



Rheumatology key message

- Real-life experience of apremilast in PsA suggests enhanced efficacy in early disease.

Real-world effectiveness and safety of apremilast in german patients with psoriatic arthritis: analysis of an ongoing multicentre, prospective, non-interventional study

Objectives To assess effectiveness and safety of APR in pts with active PsA from routine clinical practice settings in Germany.

Results The first **202 of a planned 500 German pts** receiving APR for ≥ 4 month (≥ 1 month [V1], ≥ 4 month [V2]) **and 127** pts receiving APR **for ≥ 7 months (V3)** were evaluated.A sub-analysis suggests that APR was associated with greater benefits in biologic-naïve pts compared with pts who previously received biologic therapies. The observed safety and tolerability after V3 was consistent with the known overall safety profile of APR. Common AEs in clinical trials were similar, with a lower incidence: diarrhoea (10.4%), nausea (5.6%), headache (4.0%), and respiratory tract infection (1.2%).

Conclusions The first results from this real-world PsA study reinforce findings from previous clinical trials of APR. In pts with ≥ 4 and ≥ 7 months of follow-up, APR was associated with improvements in both physician-assessed and patient-reported outcomes **with possibly a greater benefit in biologic-naïve compared with biologic-experienced pts**. Safety and tolerability were similar to the known profile of APR.

Δεδομένα από την κοόρτη ασθενών με Ψωριασική Αρθρίτιδα στο «ΑΤΤΙΚΟΝ»



Μονάδα Ρευματολογίας και Κλινικής Ανοσολογίας
Δ' Πανεπιστημιακή Παθολογική Κλινική
Πανεπιστημιακό Γενικό Νοσοκομείο «Αττικόν»

The psoriatic arthritis cohort at Attikon

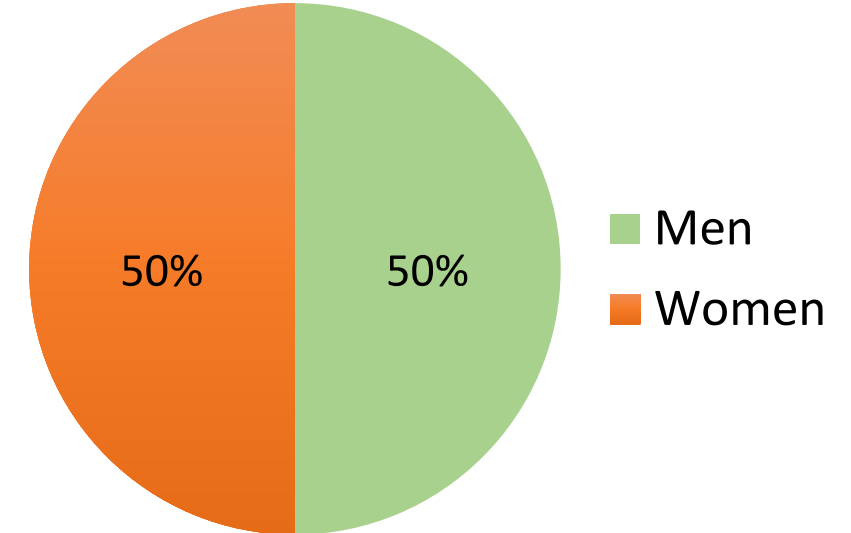
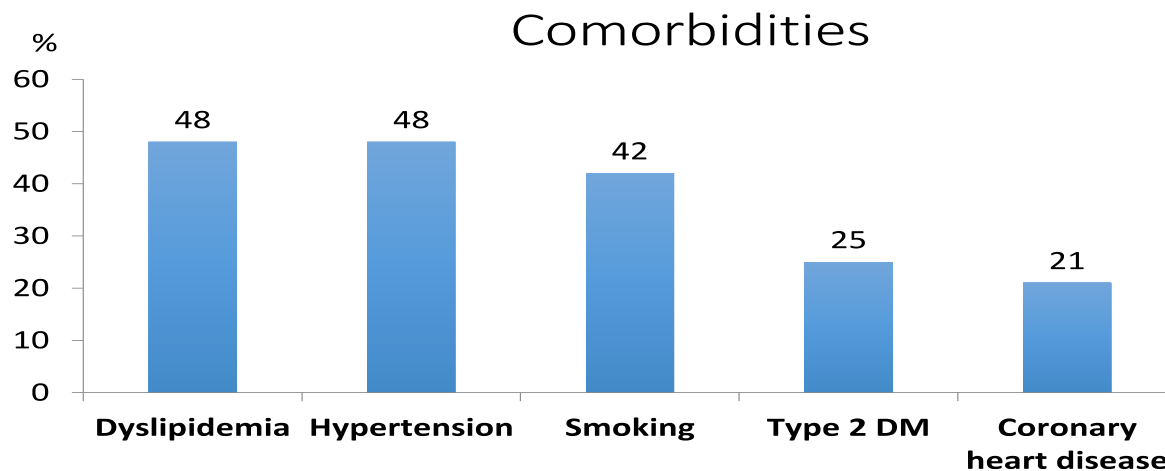
- 478 patients: 47% male and 53% female. Median age 47 with median psoriasis presenting age of 29 years.
- Type of psoriasis, 86% with plaque psoriasis, 4% palms and soles
- Peripheral arthritis 94%, axial disease 13%., mixed 27%
- Polyarthritis 38%. Oligoarthritis 27% (Patients at referral centers tend to present later when disease becomes polyarticular plus discovery of more less symptomatic joints)
- Enthesitis 26%, Dactylitis 13%
- High disease activity 43%
- csDMARDs 62%, biologics 29%, **Apremilast 9%**
- Comorbidities 24%

Η Απρεμιλαστή στην Ψωριασική Αρθρίτιδα..Real-life data

Η Απρεμιλάστη στο «Αττικόν»

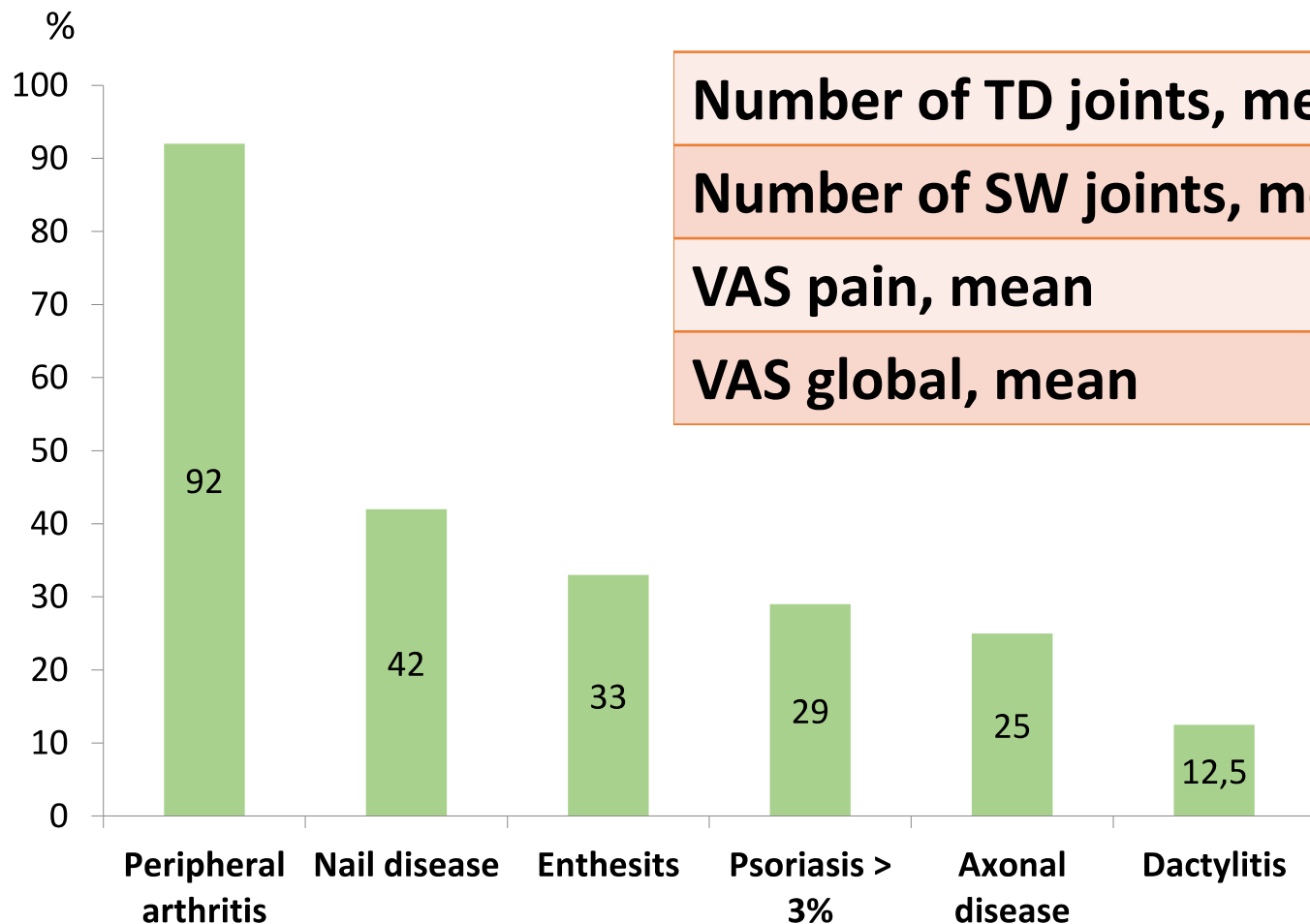
- Baseline demographics: 25 out of at least 40 patients with at least 1 year follow up
- All patients MTX/LEF IR, 27% IR or discontinuation of biologics

Total number of pts with at least 1 year follow up	N=25
Duration of psoriasis, mean (range)	13yrs (0-60)
Duration of PsA, mean (range)	5yrs (0-14yrs)



Η Απρεμιλάστη στο «Αττικών»

Patient characteristics at baseline

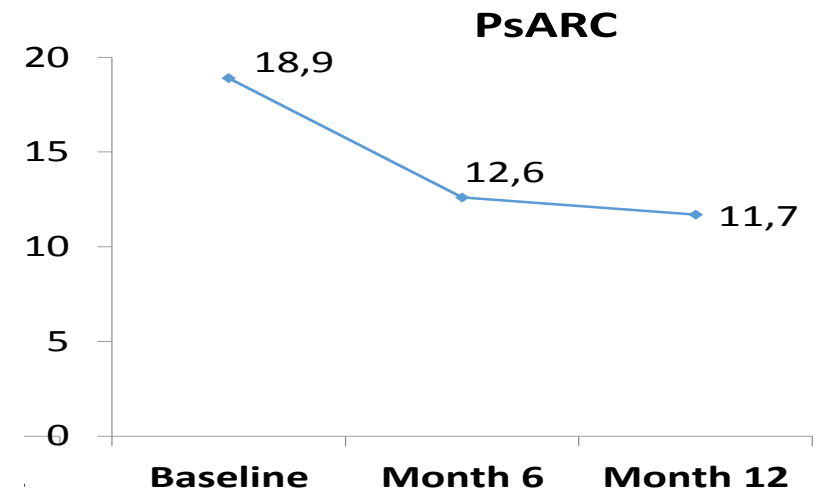
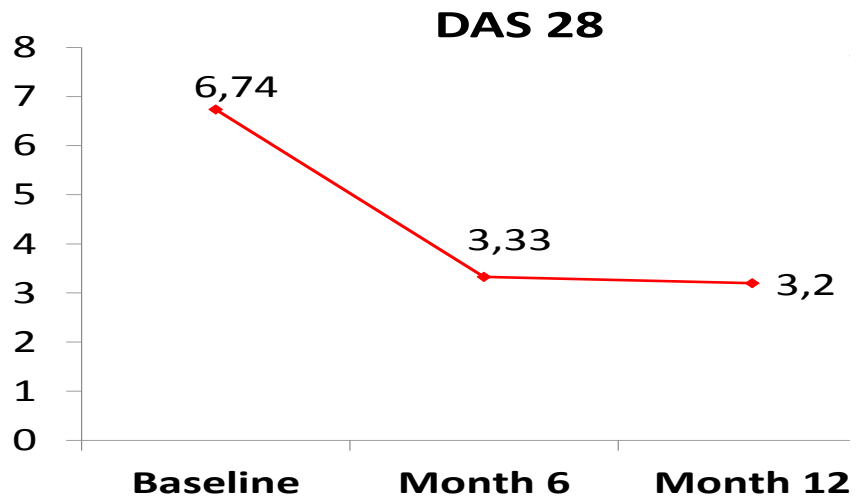
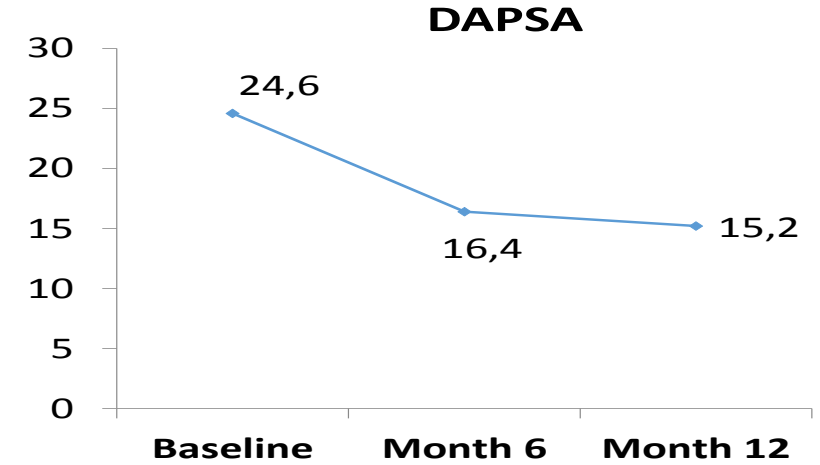
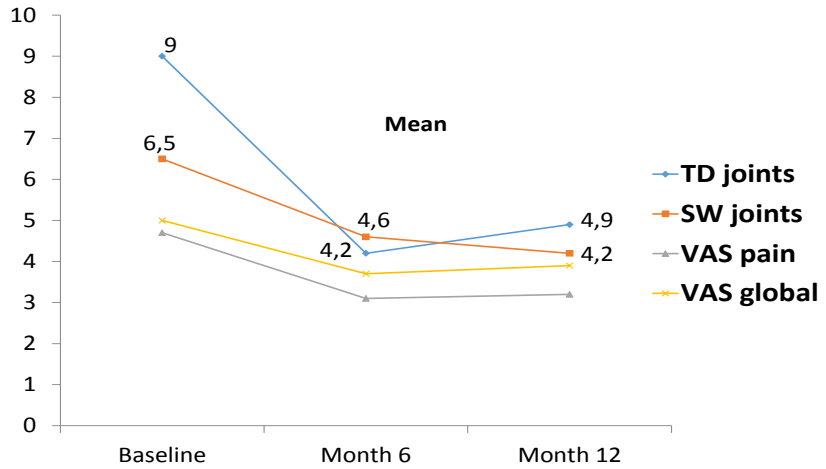


Number of TD joints, mean	9
Number of SW joints, mean	6.5
VAS pain, mean	4.7
VAS global, mean	5

Η Απρεμιλαστή στην Ψωριασική Αρθρίτιδα..Real-life data

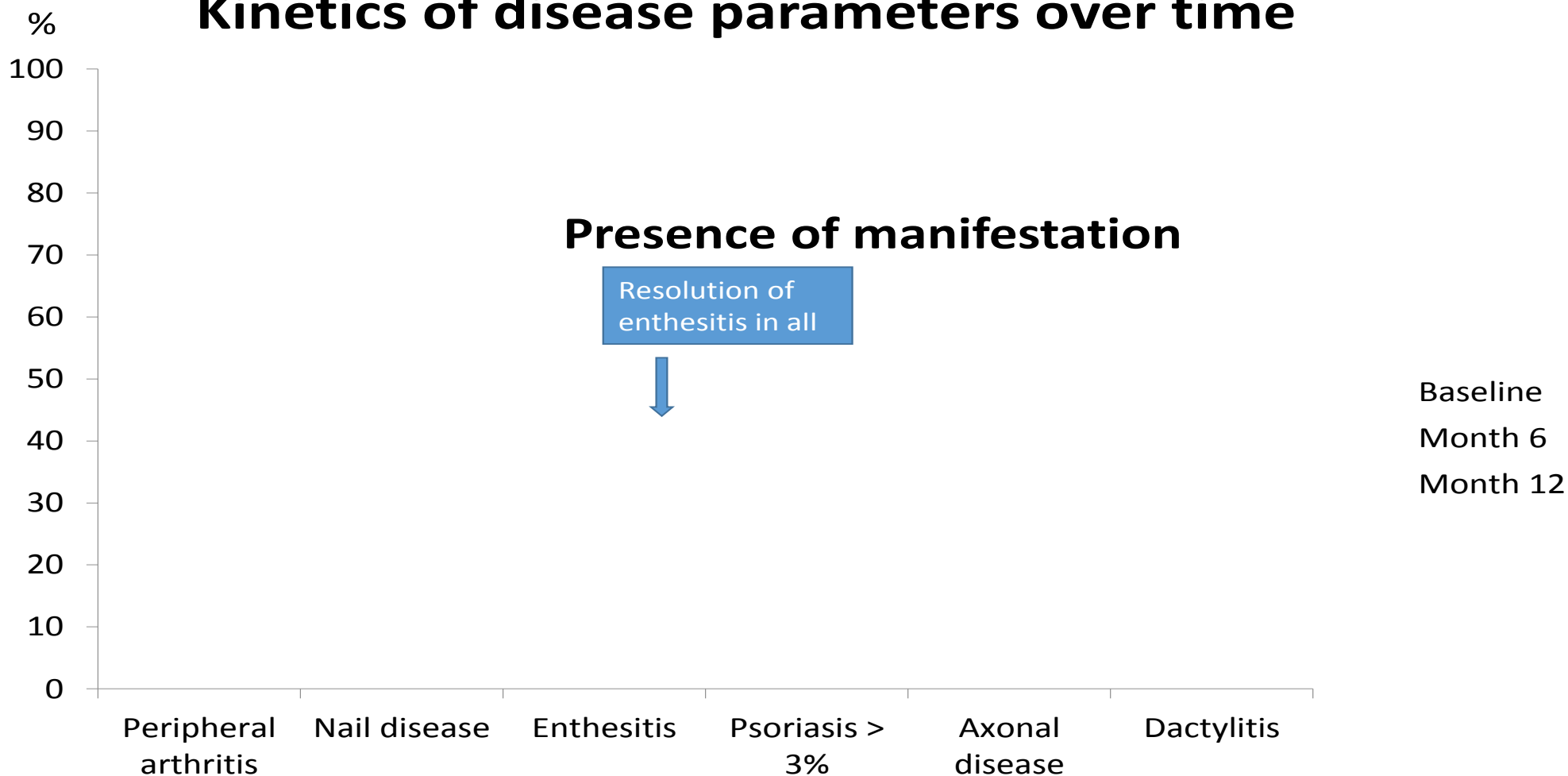
Η Απρεμιλάστη στο «Αττικόν»

25-ασθενείς 12 μήνες follow-up



Η Απρεμιλάστη στο «Αττικών»

Kinetics of disease parameters over time



9/24 patients (**37.5%**) discontinued before achieving 12 months treatment

Η Απρεμιλαστή στην Ψωριασική Αρθρίτιδα.. Που τελικά «ταιριάζει» ?



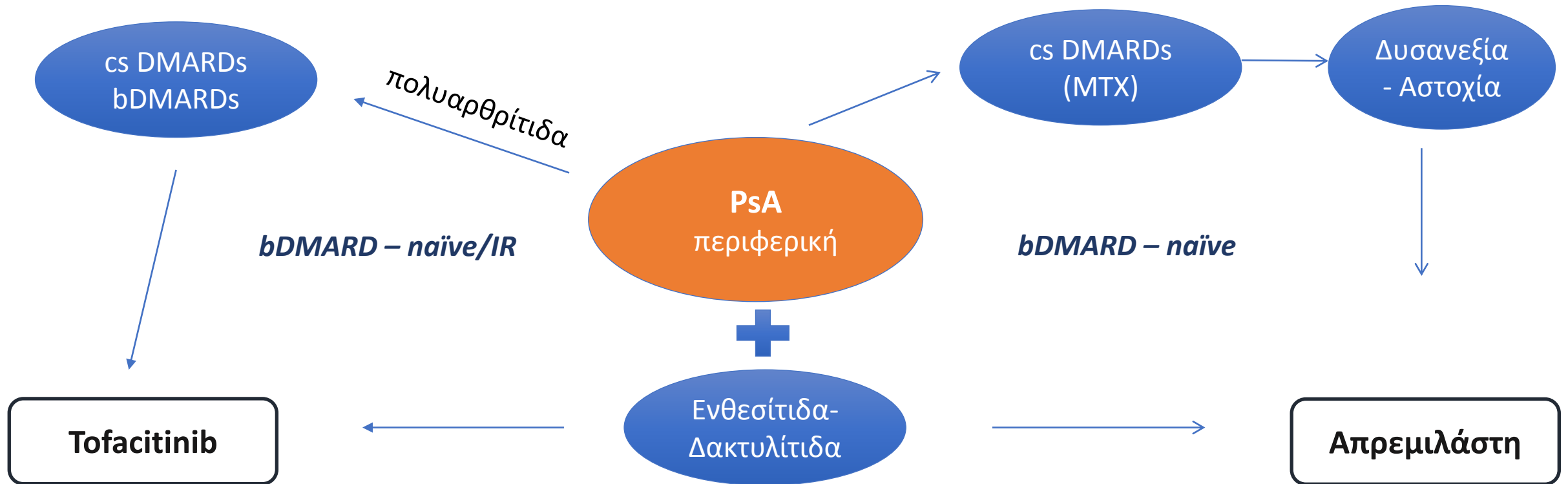
- Μέτριας ενεργότητας νόσος, (περιφερική),
- Πρώιμη νόσος
- Περιφερική SpA (ενθεσιτιδά, δακτυλίτιδα)
- Μετα την Μεθοτρεξάτη, πριν bdmards
- Συννοσηρότητες



- Υψηλής ενεργότητας
- εγκατεστημένη νόσος
- Αμιγως αξονική προσβολη
- μετά από αποτυχία πολλών θεραπειών
- όταν απαιτείται γρήγορη ανταπόκριση



Στοχευμένοι συνθετικοί παραγοντες: Θέση στον θεραπευτικό αλγόριθμο της ΨΑ



That's all Folks!



Thank you