HIGHLIGHTS OF
ANNUAL MEETING ACR 2017 (Α΄ ΜΕΡΟΣ)

σπονδυλαρθρίτιδες (axSpA – ΨΑ)

ΣΠΥΡΟΣ Ν ΝΙΚΑΣ
ΡΕΥΜΑΤΟΛΟΓΟΣ
ΙΩΑΝΝΙΝΑ
snnikas@yahoo.com

ΣΥΓΚΡΟΥΣΗ ΣΥΜΦΕΡΟΝΤΩΝ (2 ΕΤΗ)

ΕΛΠΕΝ 1/17

MSD (2/18)

ΕΕΜΜΟ (11/16)

LILLY 4/18

ΕΠΕΜΥ (12/16)

ΕΠΙΤΡΟΠΗ ΕΡΕΥΝΩΝ (11/16)

NOVATRIS 12/17

SANDOZ 4/18

ΚΑΜΙΑ
ΓΙΑ ΤΗΝ ΣΗΜΕΡΙΝΗ ΠΑΡΟΥΣΙΑΣΗ

κυρίως ομιλίες σε δορυφορικά συμπόσια

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Arthritis & Rheumatology

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ABSTRACT SUPPLEMENT

2017 ACR/ARHP Annual Meeting

November 3–8, 2017

San Diego, CA

Κάθε νόσημα – έρευνα


ACR/ARHP
Annual Meeting
San Diego • 2017
San Diego


nr-axSpA
axSpA
AS

top of evidence-based practice hierarchy

Switching bDMARDs στην axSpA

περίπου **30-50%** των ασθ με axSpA υπο τον 1ο bDMARD **δεν ανταποκρίνονται ικανοποιητικά**

- 9 μελέτες
  - Παρατήρησης από εθνικά registries
  - 2 μόνο κλ μελετες
- **1.956** ασθ (91% AS , 9% nr-axSpA) switched σε 2ο bDMARD (97% TNFi and 3% IL-17i) και
- 170 σε 3ο bDMARD (all TNFi)

Efficacy of Switching Biological Dmards in Patients with Axial Spondyloarthritis: Results from a Systematic Literature Review

Victoria Navarro-Compán[1], Chamaida Plasencia-Rodriguez[2], Eugenio De Miguel[3], Petra Diaz del Campo[4], Alejandro Balsa[3] and Jordi Gratacos-Masmitja[5], [1]Rheumatology, Hospital Universitario La Paz, Madrid, Spain,

Baseline χαρακτηριστικά (median -range-) ασθ switched bDMARDs : Ηλικία **43** (38- 46) ετών , 67% (54-80) άνδρες , 77% (62-84) HLA-B27+, BASDAI πριν το switching 6.2 (5.2-7.1)

Κλινική απόκριση (BASDAI50) μετά τον 2ο TNFi :

- **25 56%** Vs
- **50-72%** μετά τον 1ο TNFi

- **47**% switching σε IL-17i -αφού αρχικά αποκρίθηκαν στον 1ο TNFi (ASAS40)
- **66**% όσων έλαβαν IL-17i ως 1ης γραμμής

- Ο λόγος διακοπής του 1ου bDMARD ή
- Ο τύπος του 1ου bDMARD

ΔΕΝ επηρέασαν την απόκριση στον 2ο βιολογικό

Κύριος λόγος διακοπής : **αναποτελεσματικότητα**, μη- ανοχή ή ΑΕ

+ MRI σε κφ

- 47 υγιείς
- 47 age- and gender-matched axSpA
- 47 age- and gender-matched CBP
- 7 γυν με οσφυαλγία λοχείας
- 24 δρομείς

A Positive MRI of the Sacroiliac Joints Is Not Specific for Axial Spondyloarthritis but Frequently Occurs in Healthy Individuals

Janneke de Winter[1], Manouk de Hooge[2], Marleen van de Sande[1], Lonneke van Hoeven[3], Jet de Jong[1], Anoek de Koning[2], Inger Jorid Berg[4], Roberta Ramonda[5], Dominique Baeten[1,6], Désirée van der Heijde[7], Angelique Weel[8] and Robert B.M. Landewé[9], [1]Clinical

Θετική MRI-SI*
23.4%
91.5%
6.4%
57%
12,5%

Υψηλό **SPARCC** scores (≥5) σπάνια φάνηκε σε υγιείς, CBP, δρομείς

Έν τω βάθει (Deep (**extensive => signal ≥1 cm from the articular surface**) βλάβες φάνηκαν αποκλειστικά σε ΙΛ axSpA ασθ.

CBP: χρόνια οσφυαλγία

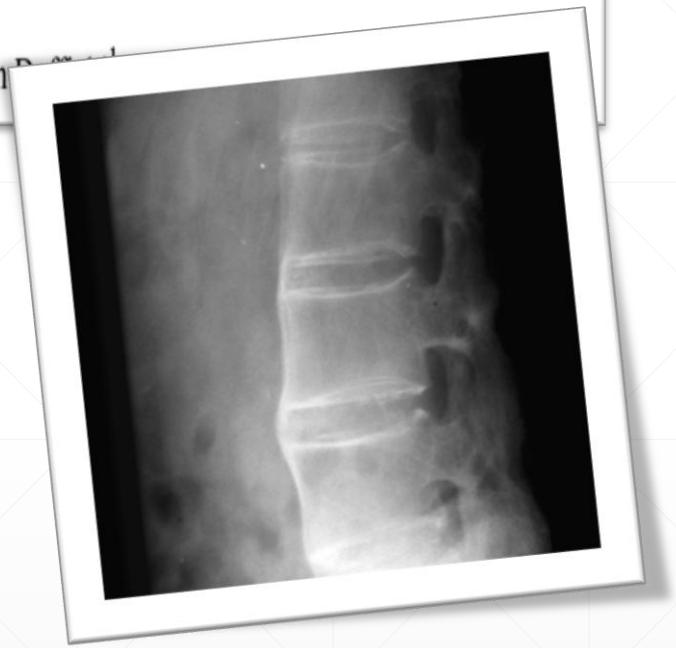
* ASAS/OMERACT definition.

Lateral dexa

Abstract Number: 2514

When Should Lateral Dexa be Used to Measure Spine Bone Mineral Density in Axial Spondyloarthritis Patients: A Cross-Sectional Study

Sizheng Zhao[1,2], Daniel Thong[3], Eleanor Quilliam[2], Stephen



Προσθιοπίθσια (AP) DEXA χρησιμοποιείται συχνά για την BMD, συχνά όμως είναι ανακριβής

-> συνδεσμοφύτων

2015 European League Against Rheumatism (EULAR):

*imaging guidelines highlight the importance of assessing for osteoporosis in axSpA and suggest use of **lateral** DEXA*

259 ασθ με AP DEXA (32 και με lateral DEXA):
Το χρονικό σημείο όπου η **AP-BMD αρχίζει να αυξάνει**

- **AP** -DEXA εκτιμά την κατά την **1η δεκαετία συμπτωμάτων**
- **lateral** DEXA => **μετά τα 13 έτη,** κυρίως σε ασθ με παρουσία συνδεσμοφύτων

TBS

- 215 AS ασθ
- 109 ασθ (50.7%) -> υψηλό mSASSS

The Usefulness of Trabecular Bone Score in Assessing the Bone Strength and Fracture Risk of Patients with Ankylosing Spondylitis

Seoung Wan Nam[1], Yoon-Kyoung Sung[2], Dam Kim[2], Soo-Kyung Cho[3], Yoonah Song[4], Yun Young Choi[5] and Tae-Hwan Kim[2], [1]Department of Rheumatology, Hanyang University Hospital for Rheumatic Diseases, Seoul, Korea,

στην ομάδα **mSASSS group**:

- Ενώ hip και L-spine AP BMD είχαν υψηλότερες τιμές
- L-spine **lateral** BMD και **TBS** είχαν χαμηλότερες τιμές

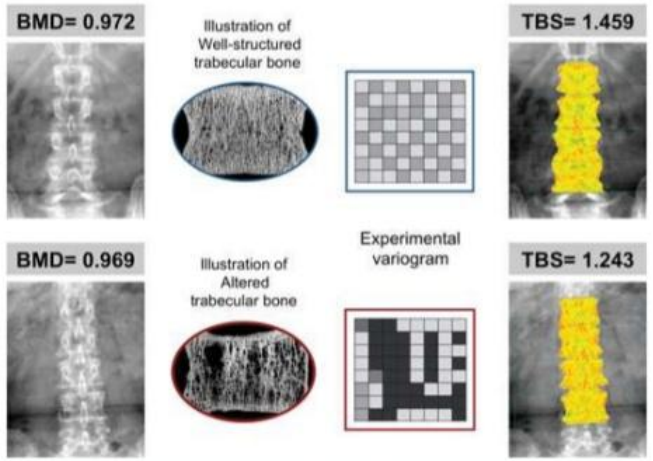
Μετά από προσαρμογή : TBS των **L2-L3** ήταν **σημαντικά** μικρότερο

TBS είναι **χαμηλότερο** σε ασθ με **εκτεταμένα συνδεσμόφυτα**
Σημαντική συσχέτιση με ΗΧ κατάγματος

TBS σε ασθ με AS -> **χρήσιμο** εργαλείο για την εκτίμηση ->

- Οστική ισχύ
- Πρόγνωση καταγμ κινδύνου

Trabecular Bone Score (TBS)



Reproduced from Silva BC et al. JBMR 2014 [29], 3, 518-530

TBS

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Volume 57, Issue 6
June 2018

Associations between trabecular bone score and vertebral fractures in patients with axial spondyloarthritis

Kwi Young Kang ✉, In Je Kim, Sung-Hwan Park, Yeon Sik Hong

Rheumatology, Volume 57, Issue 6, 1 June 2018, Pages 1033–1040,
https://doi.org/10.1093/rheumatology/key027
Published: 09 March 2018 **Article history** ▾

Αντισώματα ?

Diagnostic Value of Anti-CD74 Antibodies in Early Axial Spondyloarthritis: Data from the Spondyloarthritis Caught Early (SPACE) Cohort

Ann Rheum Dis. 2014 Jun;73(6):1079-82. doi: 10.1136/annrheumdis-2012-202177. Epub 2013 May 3.

High prevalence of anti-CD74 antibodies specific for the HLA class II-associated invariant chain peptide (CLIP) in patients with axial spondyloarthritis.

Baraliakos X[1], Baerlecken N, Witte T, Heldmann F, Braun J.

- **anti-CD74 IgG** και **IgA** serum antibodies σε ασθ με radiographic axSpA (ankylosing spondyloarthritis, (AS)) (n=138) Vs ομάδα ελέγχου – υγιείς (n=57)

- Διαγνωστική αξία => σε early axSpA (n=274) και non-SpA back pain controls (n=319) από την κοόρτη SPondyloArthritis Caught Early (SPACE) cohort

anti-CD74 **IgG** παρουσία
- 79.7% AS ασθ vs.
- 43.9% υγειών (p<0.0001)

anti-CD74 **IgA** antibodies (OD) παρουσία
- 28.5% AS ασθ vs.
- 5.3% υγειών (p<0.0001)

SPACE cohort => anti-CD74 **IgA** antibodies :
- Υψηλότερο τίτλο σε axSpA ασθ Vs non-SpA back pain controls (19.92 vs. 14.02, p<0.0001)
- Παρουσία : 54.7% vs. 37.0% σε axSpA patients vs. nonSpA back pain controls (p<0.0001)

In the SPACE cohort, these differences **disappear** in a multivariate analysis

Nr Vs axSpA

Similarities and Differences between Non-Radiographic and Radiographic Axial Spondyloarthritis

Denis Poddubnyy[1], Robert D Inman[2], Joachim Sieper[1], Servet Akar[3], Santiago Muñoz-Fernández[4] and Maja Hojnik[5], [1]Charité Universitätsmedizin Berlin, Berlin, Germany, [2]Toronto Western Hospital, Toronto, ON, Canada,

JAK i

Effect of Tofacitinib on Reducing Pain in Patients with Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis

Alexis Ogdie[1], Kurt de Vlam[2], Iain B. McInnes[3], Philip J Mease[4], Philip Baer[5], Tatjana Lukic[6], Kenneth Kwok[6], Cunshan Wang[7], Ming-Ann Hsu[7] and Anna Maniccia[6], [1]Division of Rheumatology, Department of Medicine, Perelman School of

JAK ii

Abstract Number: 645

An Oral Tyk2 Inhibitor Effectively Suppresses the Development of Murine Th17 Cells In Vivo and Prevents Joint Damage in Experimental Ankylosing Spondylitis

Eric Gracey[1,2], Melissa Lim[2], Zoya Qaiyum[1], Yuriy Baglaenko[1,2], Wenyan Miao[3], Craig Masse[3], William Westlin[3] and Robert D Inman[1,4], [1]Department of Immunology, University of Toronto, Toronto, ON, Canada, [2]Toronto Western Hospital, University Health Network, Toronto, ON, Canada, [3]Nimbus Therapeutics, Cambridge, MA, [4]Toronto Western Hospital, University Health Network, toronto, ON, Canada

ΨA

Abstract Number: 497

The JAK1 Selective Inhibitor Filgotinib Regulates Both Enthesis and Colon Inflammation in a Mouse Model of Psoriatic Arthritis

Catherine Robin-Jagerschmidt[1], Stéphanie Lavazais[1], Florence Marsais[1], Maté Ongenaert[2], Alain Monjardet[1], Angélina Cauvin[1], Corinne Saccomani[1], Isabelle Parent[1], Didier Merciris[1], Emilie Chanudet[1], Roland Blanqué[1], Monica Borgonovi[1], Liên Lepescheux[1], Marielle Auberval[1], Sonia Dupont[1], Philippe Clément-Lacroix[1] and **René Galien**[1], [1]Galapagos SASU, Romainville, France, [2]Galapagos NV, Mechelen, Belgium

Tofa & MTX

post hoc ανάλυση από 2 Phase 3, randomized, double-blind, placebo controlled studies

- OPAL Broaden [12 months]
- OPAL Beyond [6 months, IR to ≥1 TNFi]
- 556 ασθ
  - tofacitinib plus MTX ή
  - placebo plus MTX

(tofacitinib 5 mg BID, n=186; tofacitinib 10 mg BID, n=178; placebo, n=192)

Efficacy of Tofacitinib By Background Methotrexate Dose in Patients with Psoriatic Arthritis: A Post Hoc Analysis of Pooled Data from 2 Phase 3 Trials

Alan J. Kivitz[1], Oliver FitzGerald[2], Peter Nash[3], Shirley Pang[4], Valderilio F Azevedo[5], Elizabeth Kudlacz[6], Cunshan Wang[6], Daniela Graham[6] and Liza Takiya[7], [1]Department of Rheumatology, Altoona Center for Clinical Research,

Στον 3ο μηνα => tofacitinib 5 και 10 mg BID => **μεγαλύτερη ACR και HAQ-DI** απόκριση VS placebo

Εν υπήρχαν διαφορές με βάση το background MTX δόση (≤15 vs >15 mg/week)

Tofa & ασφάλεια

- OPAL Broaden [12 μ]
- OPAL Beyond [6 μ , IR to ≥1 TNFi)

➢ 474 υπό tofacitinib- vs 236 PBO

Integrated Safety Summary of Tofacitinib in Psoriatic Arthritis Clinical Studies

Gerd R. Burmester[1], Oliver FitzGerald[2], Kevin Winthrop[3], Valderilio F Azevedo[4], William F C Rigby[5], Keith S Kanik[6], Cunshan Wang[6], Pinaki Biswas[7], Thomas Jones[8], Sujatha Menon[6], Niki Palmetto[7] and Ricardo Rojo[6], [1]Charité -

Ρινοφαρυγγίτιδα (5.9%) και **κεφαλαλγία** (8.5%) τα πιο συχνά (3m)

IRs για **SAEs** => 7.92 (4.09, 13.84) και 8.11 (4.19, 14.17) 12m (**5**-10 mg)

Διακοπή λόγω => 11 (**4.6%**) and 11 (4.7%)

Σοβαρές λοιμώξεις : 11 ασθ (**1.4%**; IR 1.40 [0.70, 2.50])

EZ σε 16 ασθ (**2.0%**; IR 2.05 [1.17, 3.33]) υπό tofacitinib

- **MACE** σε 3 ασθ(0.4%; IR 0.38 [0.08, 1.11])
- **Νεοπλασίες** (εκτός NMSC) σε 5 ασθ (0.6%; IR 0.63 [0.21, 1.48])
- **NMSC** σε 4 ασθ (0.5%; IR 0.51 [0.14, 1.30])

IV Golimumab

- GO-VIBRANT : Phase 3, multicenter, randomized, double-blind, placebo (PBO)-controlled trial.
- 2mg/kg τις εβδ (wk) 0, 4, και κάθε 8 wks vs PBO
- 480 τυχαιοποιήθηκαν (PBO: 239; GLM: 241

Abstract Number: 599

Intravenous Golimumab in Adult Patients with Active Psoriatic Arthritis: Efficacy and Safety through Week 24

Arthur Kavanaugh[1], M. Elaine Husni[2], Diane D. Harrison[3], Lilianne Kim[3], Kim Hung Lo[3] and Elizabeth C. Hsia[4], [1]Medicine, University of California, San Diego, La Jolla, CA, [2]Rheumatology, Cleveland Clinic, Cleveland, OH, [3]Janssen Research & Development, LLC, Spring House, PA, [4]Janssen Research & Development, LLC/University of Pennsylvania, Spring House/Philadelphia, PA

wk14, **ACR20 απόκριση (75.1%** vs. 21.8%)

- HAQ-DI score (-0.60 vs. -0.12)
- ACR50 (43.6% vs. 6.3%)
- PASI 75 (59.2% vs. 13.6%)
- ACR70 (24.5% vs. 2.1%)
- Βελτίωση σε enthesitis / dactylitis scores *(-1.8 vs. -0.8 and -7.8 vs. -2.8, respectively) (all p<0.001) at wk14.*

Η πιο συχνή AE => **λοιμώξεις** (20.0% of GLM pts vs. 13.8% of PBO pts)
Αντιδράσεις στην **έγχυση** με GLM <2%

Ixekizumab

monoclonal με στόχο **IL-17A**

- The SPIRIT phase 3 trials consist of patients with active PsA who were bDMARD-naive (SPIRIT-P1)
- were inadequate responders to TNF-inhibitors (SPIRIT-P2)

80 mg IXE, after a 160 mg starting dose or PBO, every

- 4 weeks (Q4W, N=229) or
- 2 weeks (Q2W, N=225)

Ixekizumab Exhibits a Favorable Safety Profile during 24 Weeks of Treatment in Subjects with Active Psoriatic Arthritis: Integrated Safety Analysis of Two Randomized, Placebo Controlled, Phase III Clinical Trials

Philip J Mease[1], Gerd R. Burmester[2], Susan Moriarty[3], Olivier Benichou[3], Wen Xu[3] and Peter Nash[4], [1]Swedish Medical Center and University of Washington, Seattle, WA, [2]Department of Rheumatology and Clinical Immunology, Charité -

Ασθ με ≥1 **TEAE** σημαντικά πιο συχνά με IXE

Δεν υπήρχε σημαντική διαφορά
- Με ≥ 1 SAE
- Διακοπή

Λοιμώξεις- πιο συχνά με of IXE **Q2W**

Οι πιο **συχνές** λοιμώξεις : ανώτ αναπνευστικού, ρινοφαρυγγίτδα, κολπίτιδα

1PBO, 4 IXE Q4W, και 8 IXE Q2W-treated => ≥1 **Candida infection**

Αλλεργικές αντιδράσεις /υπερευαισθησία=> πιο συχνά με IXE Q2W vs PBO

Ixekizumab
αποτελεσματικότητα

Ixekizumab Provides Sustained Improvement in Signs and Symptoms in Patients with Active Psoriatic Arthritis: Two Year Results from a Phase 3 Trial

Abstract Number: 2969

Efficacy and Safety of Ixekizumab in Patients with Active Psoriatic Arthritis and Previous Inadequate Response to TNF Inhibitors: 52-Week Results from a Phase 3 Study

SPIRIT-P2

Mark C. Genovese[1], Bernard Combe[2], Joel Kremer[3], David Adams[4], Chin Lee[4], Lisa Kerr[4] and Peter Nash[5], [1]Stanford University Medical Center, Palo Alto, CA, [2]Rheumatology, CHU Lapeyronie and Montpellier University, Montpellier, France, [3]St. Peter's

patients who were initially randomized to IXE **Q4W** or **Q2W** during the DBTP, ACR20 responses at Week 52 were **68%** and **59%**

patients treated with PBO during the DBTP and re-randomized to IXE **Q4W** or **Q2W** during the EP, ACR20 responses at Week 52 were **61%** and **50%**

Μικροβίωμα εντέρου

The Effect of Biologic Therapies on the Gut Microbial Composition in Psoriatic Arthritis

Julia Manasson[1], Carles Ubeda[2], Lu Yang[3], Melania Fanok[4], Gary E. Solomon[1], Soumya M. Reddy[5], Sergei Koralov[6], Jose C. Clemente[7] and Jose U. Scher[1,4], [1]Department of Medicine, Division of Rheumatology, New York University

Δείγματα κοπράνων

- Πριν και μετα τη αγωγή με **secukinumab** (n=9), - antiIL-17A monoclonal antibody
- **adalimumab** (n=10), a TNFi, ομάδα ελέγχου
- wild type **ποντίκια** πριν και μετα την έκθεση σε **anti-IL-17**

IL-17i => δεν φάνηκαν διαφορές συνολικά σε μικροβιακό alpha ή beta diversity πριν και μετα τη θεραπεία

Σημαντική αλλαγή (shift) **Firmicutes /Bacteroidetes ratio** 5 εβδ μετά

Σχετική αύξηση **Clostridiales** (Firmicutes) συσχετίστηκε με επίπεδα SCFA acetate (r=0.4, p=0.09) και MCFA hexanoate

Οι μεταβολές αυτές δεν φάνηκαν σε ασθ υπό **TNFi**

Παρόμοιες ήταν και οι μεταβολές στα ποντίκια που εκτέθηκαν σε antiI-L17

Treatment with **IL-17i leads to a gut microbial dysbiosis** not seen with TNFi

TNFi & MTX

- RCTs με δεδομένα συνδυασμού MTX & TNFi versus TNFi monotherapy
- 1.055 ασθ

Abstract Number: 636

Effect of Adding MTX to TNF Inhibitors on Joint Severity Indices and Skin Scores in Psoriatic Arthritis: A Post-Hoc Meta-Analysis of Randomized, Controlled Trials

Rochelle Castillo[1], Khushboo Sheth[2] and Santhanam Lakshminarayanan[3], [1]University of Connecticut, Farmington, CT,

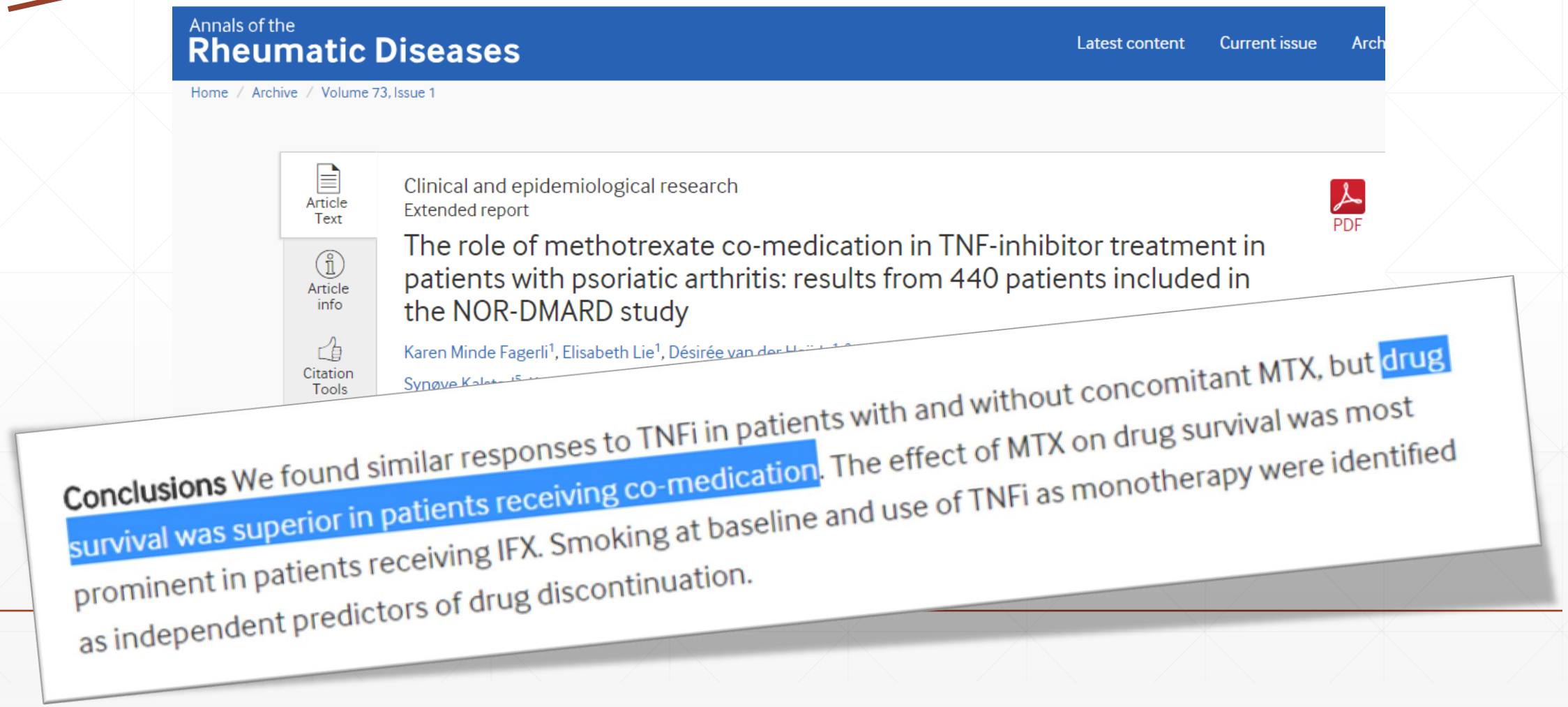
ACR 20/50/70 at Week 12, **ΔΕΝ υπήρχε στατιστικά σημαντική διαφορά** μεταξύ συνδυασμού TNFi & MTX vs. TNFi mono

Τάση (trend) - **no added benefit** to combination therapy φάνηκε και :

- ACR 20/50/70 at Week 24
- ACR 20 at Week 48

PASI 75 => **non-significant trend** για αυξημένη απόκριση στις Weeks 24 και 48 με τον συνδυασμό Vs TNFi monotherapy

TNFi & MTX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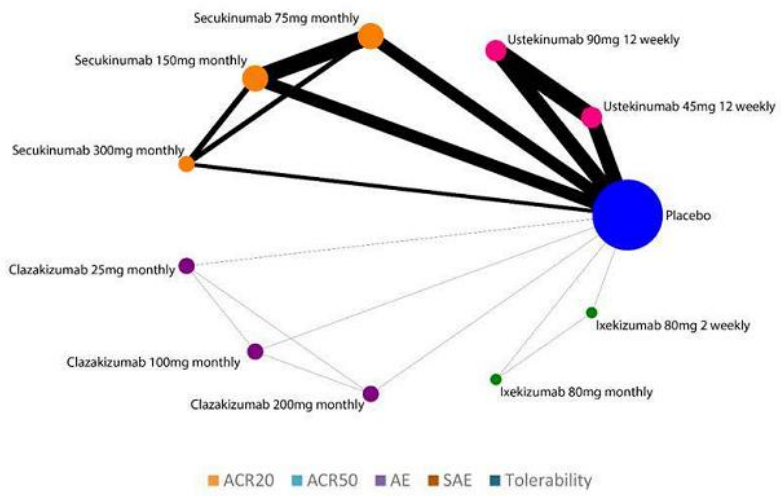
The role of methotrexate co-medication in TNF-inhibitor treatment in patients with psoriatic arthritis: results from 440 patients included in the NOR-DMARD study
Karen Minde Fagerli[1], Elisabeth Lie[1],
Conclusions We found similar responses to TNFi in patients with and without concomitant MTX, but drug survival was superior in patients receiving co-medication. The effect of MTX on drug survival was most prominent in patients receiving IFX. Smoking at baseline and use of TNFi as monotherapy were identified as independent predictors of drug discontinuation.

Νεότεροι βιολογικοί

Abstract Number: 635

Short-Term Efficacy and Safety of New Biological Agents Targeting the IL-6, IL-12/23 and IL-17 Pathways for Active Psoriatic Arthritis: A Network Meta-Analysis of Randomised Controlled Trials

- 6 trials were identified which included
- 2.411 participants
- 11 treatments.



secukinumab, ustekinumab and ixekizumab demonstrated superior efficacy over **placebo**

Ixekizumab has a higher incidence of adverse events (AE) than placebo

ustekinumab has a higher tolerability (less likely to be discontinued due to AE) than placebo

- **secukinumab** (300mg monthly) had the **highest efficacy** in achieving ACR20 and ACR50
- clazakizumab (anti-IL6 , 200mg monthly), ustekinumab (45mg 12 weekly), secukinumab (150mg monthly) had the **lowest probability of having AE**, serious AE, and intolerability respectively

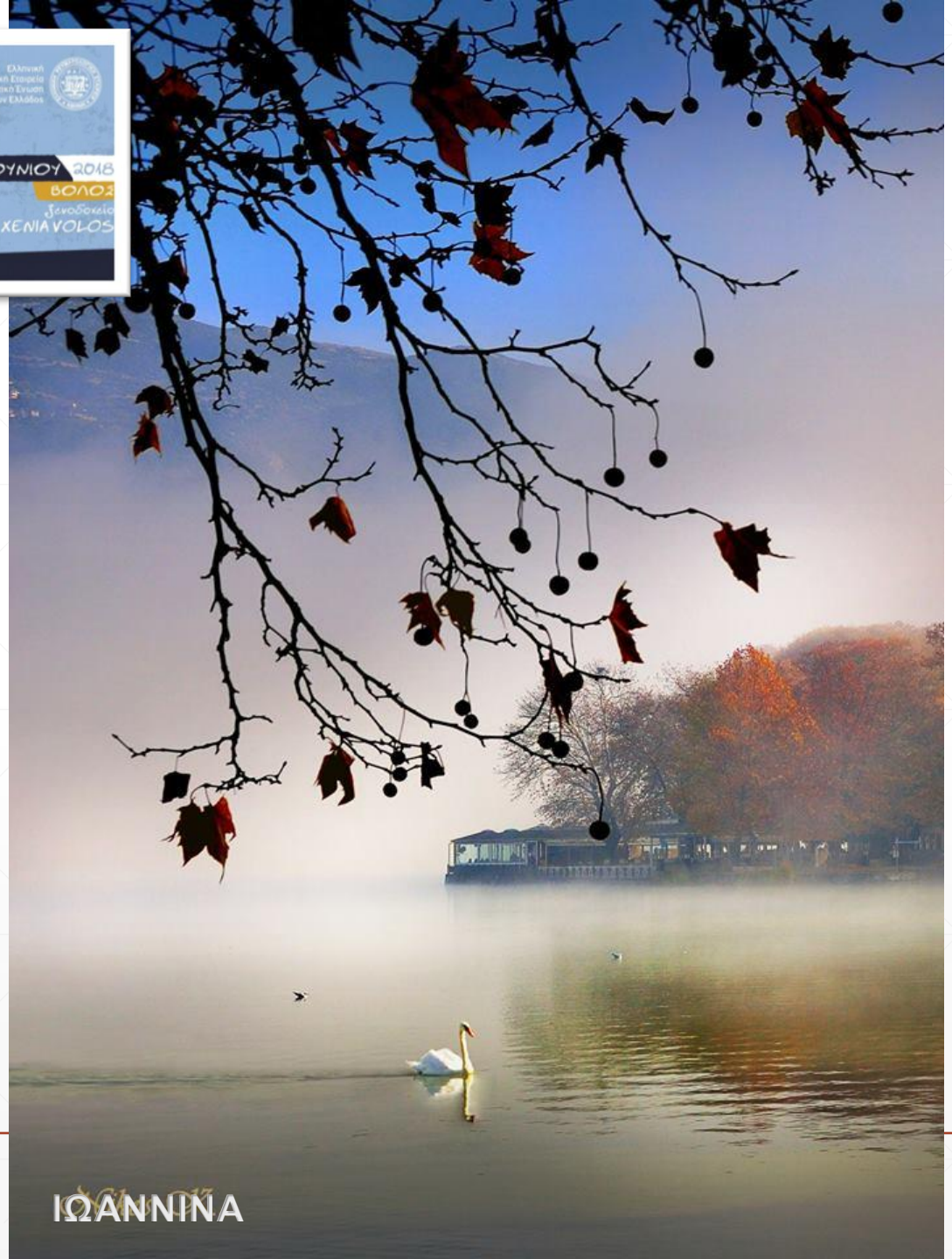
Considering overall risk-benefit profile, **secukinumab (150mg monthly)** may offer an optimal balance for active PsA patients

Στο μέλλον…

Abstract Number: 2878

Efficacy and Safety Results of Guselkumab in Patients with Active Psoriatic Arthritis over 56 Weeks from a Phase 2a, Randomized, Double-Blind, Placebo-Controlled Study

Atul A. Deodhar[1], Alice B Gottlieb[2], Wolf-Henning Boehncke[3], Bin Dong[4], Yuhua Wang[4], Yanli Zhuang[4], William Barchuk[5], Xie L. Xu[5] and Elizabeth Hsia[4], [1]Division of Arthritis & Rheumatic Diseases OP09, Oregon Health & Science University, Portland, OR,



Σας ευχαριστώ…