ΙΠΠΟΚΡΑΤΕΙΟ
ΓΕΝΙΚΟ ΝΟΣΟΚΟΜΕΙΟ
ΘΕΣΣΑΛΟΝΙΚΗΣ

Infliximab στην Αξονική Σπονδυλαρθρίτιδα: Από την ενδοφλέβια εμπειρία στη σύγχρονη υποδόρια θεραπεία

Νικόλαος Κούγκας

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Σύγκρουση συμφερόντων

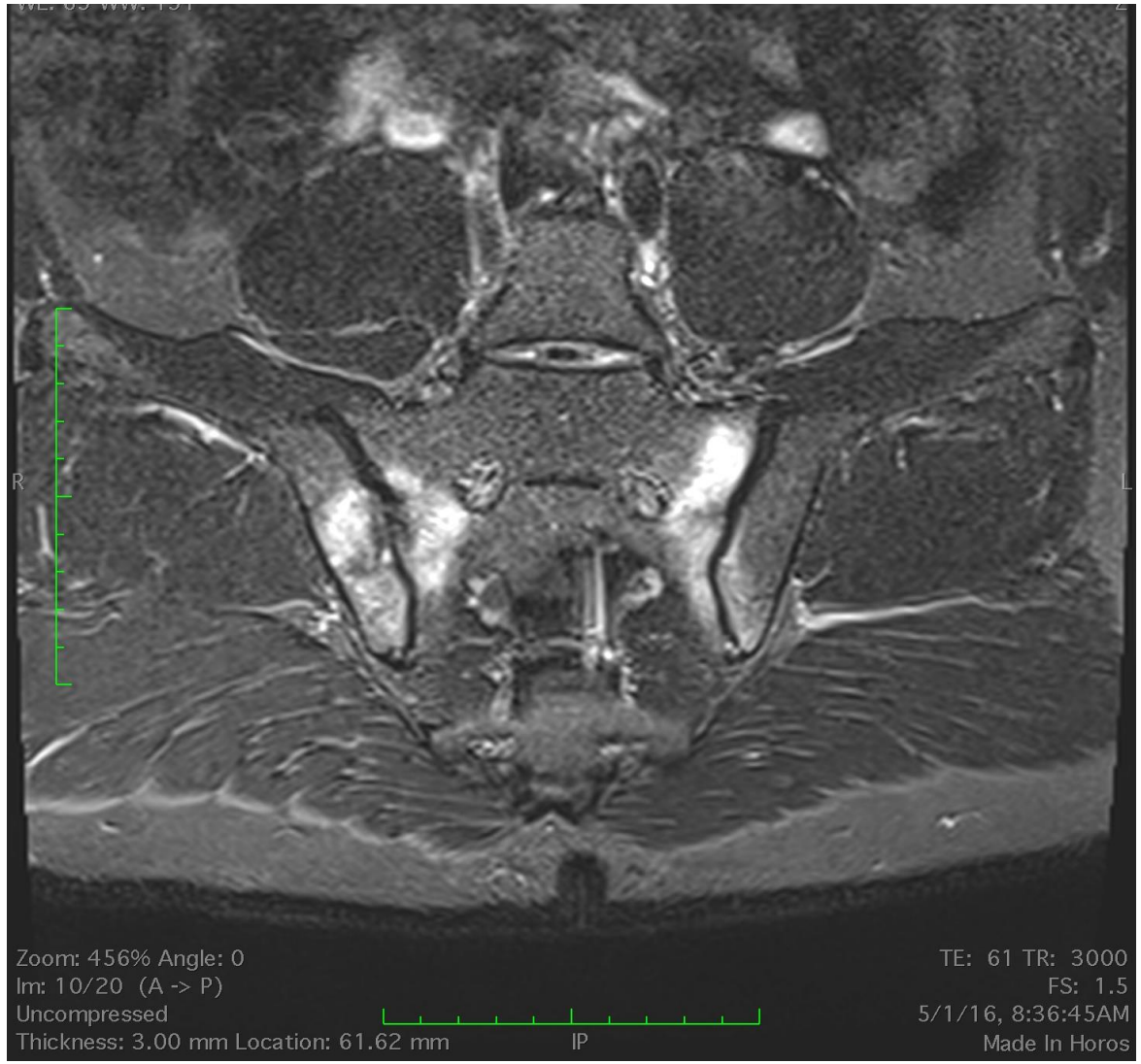
- Τιμητική αμοιβή από την εταιρία Vianex για τη συγκεκριμένη παρουσίαση

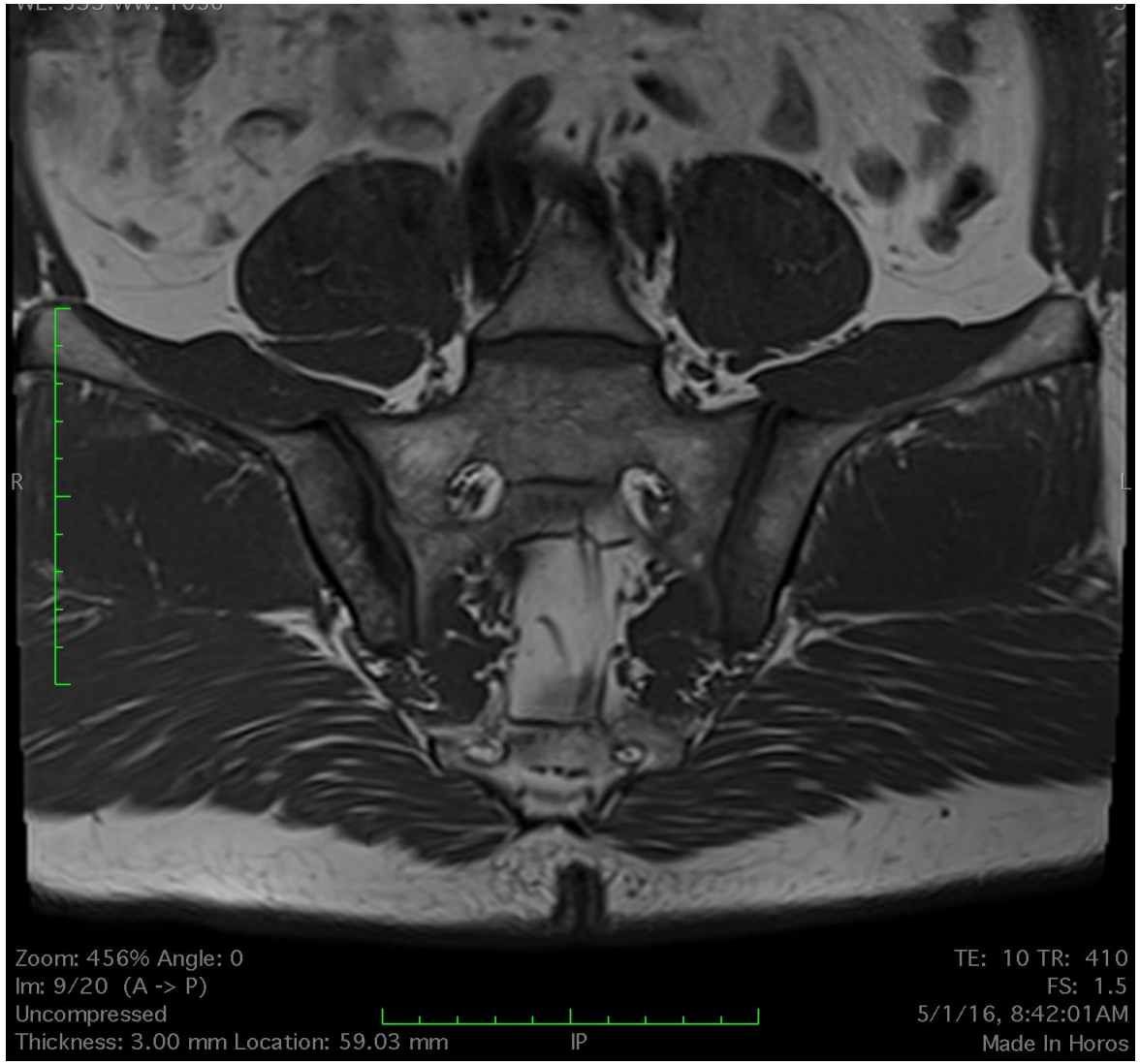
Παρουσίαση περιστατικού

- Άνδρας 28 ετών με ελεύθερο ατομικό ιστορικό
- Πατέρας με IBD related arthritis
- Από 2ετίας χαμηλή οσφυαλγία με εξάρσεις και υφέσεις
- Καλή ανταπόκριση σε ΜΣΑΦ
- Επιδείνωση των συμπτωμάτων από μηνός με ανάγκη καθημερινών μέγιστων δόσεων ΜΣΑΦ
- Παράλληλα αλλαγή των κενώσεων και ήπιο κοιλιακό άλγος
- Παραπομπή σε ρευματολόγο

Παρουσίαση περιστατικού

- Τυπική φλεγμονώδης οσφυαλγία
- Χωρίς περιφερική αρθρίτιδα
- Χωρίς ευρήματα από δέρμα και οφθαλμούς
- CRP x 3, ESR 45, λοιπά εργαστηριακά κφ
- HLA- B27 +
- Ro ιερολαγονίων: ήπια σκλήρυνση ΔΕ





Courtesy of the Speaker

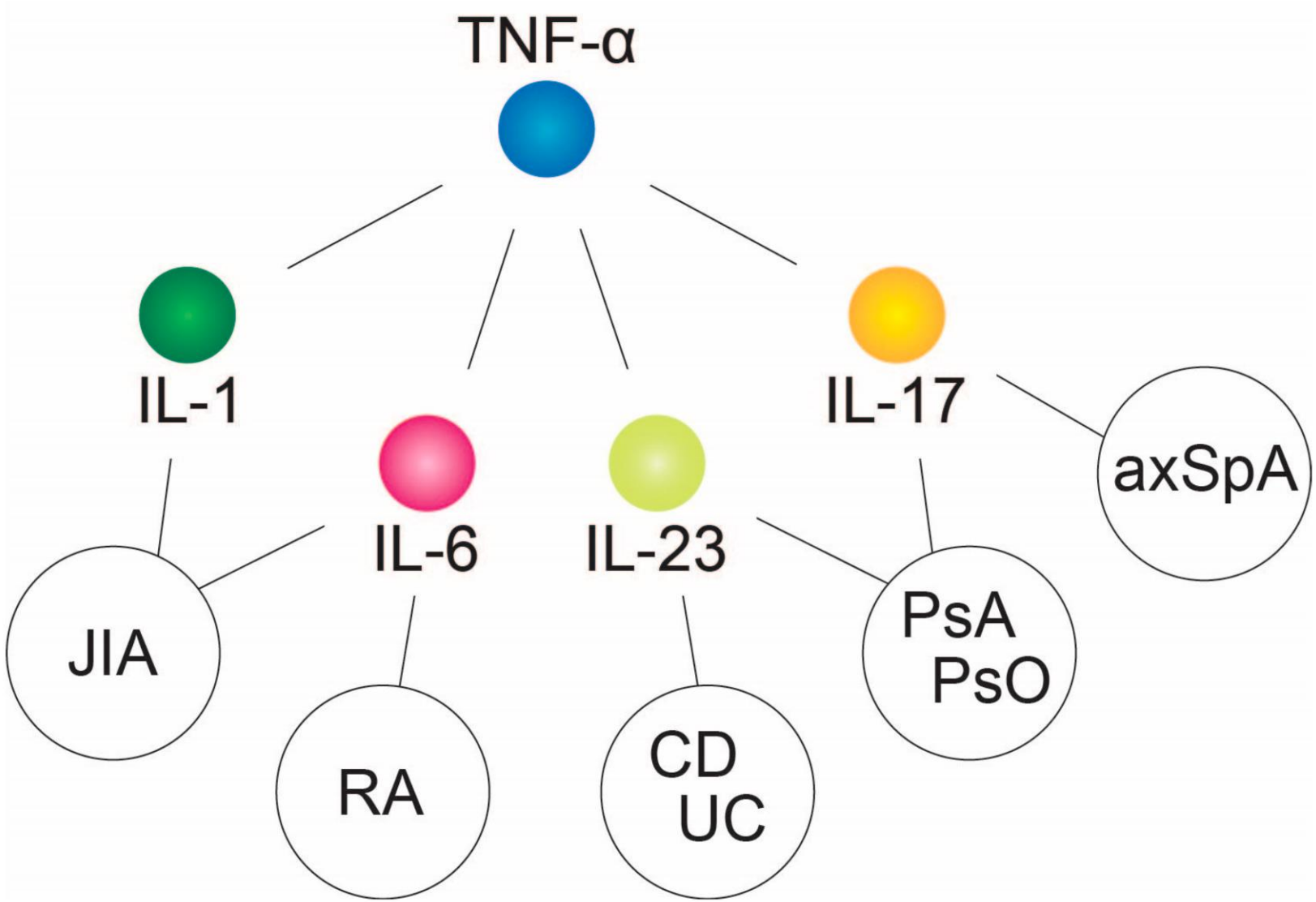
Παρουσίαση περιστατικού

- Κολονοσκόπηση: τελική ειλεΐτιδα
- Έναρξη i.v Infliximab 5 mg/kg ΣΒ
- Άμεση κλινική και εργαστηριακή ανταπόκριση τόσο από το μυοσκελετικό όσο και από το πεπτικό

Ο ρόλος του TNF στην παθογένεση της axSpA

- Ο TNF-α αποτελεί κεντρικό ρυθμιστή της φλεγμονώδους αντίδρασης
- Λειτουργεί ως κύριος κόμβος στο δίκτυο των κυτταροκινών
- Ενεργοποιεί προ-φλεγμονώδεις μηχανισμούς, όπως:
  - IL-1, IL-6, IL-17/23, IFN-γ
- Προάγει τη διαφοροποίηση Τ-βοηθητικών λεμφοκυττάρων τύπου 1 και 17
- Διατηρεί ένα χρόνιο προ-φλεγμονώδες περιβάλλον
- Ενισχύει τη μετανάστευση και συσσώρευση φλεγμονωδών κυττάρων στους ιστούς
- Συνδέεται με συστηματικές εκδηλώσεις και προσβολή πολλαπλών οργάνων

Muth K.N et al J. Clin. Med. 2023



Muth K.N et al J. Clin. Med. 2023

Κλινική σημασία της αναστολής του TNF στις ΣπΑ

- Η αναστολή του TNF οδηγεί σε βελτίωση όλων των εκφάνσεων της νόσου
- Αποτελεσματικότητα σε:
  - αξονική προσβολή
  - περιφερική αρθρίτιδα
  - ενθεσίτιδα, δακτυλίτιδα
- Σημαντική δράση στις εξωαρθρικές εκδηλώσεις:
  - φλεγμονώδης νόσος εντέρου
  - ραγοειδίτιδα
  - ψωρίαση
- Βελτιώνει:
  - λειτουργικότητα
  - ποιότητα ζωής
  - εργασιακή ικανότητα
- Συμβάλλει στον έλεγχο της συστηματικής φλεγμονής

Ramiro S et al. Ann Rheum Dis 2023

Infliximab: μηχανισμός δράσης και ιδιαίτερα χαρακτηριστικά

- Χιμαιρικό μονοκλωνικό αντίσωμα έναντι του TNF-α
- Υψηλή συγγένεια και ισχυρή αναστολή του TNF
- Δρα τόσο σε:
  - διαλυτό TNF
  - μεμβρανικό TNF
- Μπορεί να προκαλέσει απόπτωση ενεργοποιημένων Τ-λεμφοκυττάρων
- Δοσολογία με βάση το σωματικό βάρος → εξατομίκευση θεραπείας
- Ταχεία έναρξη δράσης, ιδιαίτερα σε ασθενείς με υψηλή ενεργότητα

Tracey D et al Pharmacol Ther. 2008

Expert Opinion on Biological Therapy

ISSN: 1471-2598 (Print) 1744-7682 (Online) Journal homepage: www.tandfonline.com/journals/iebt20

Efficacy of intravenous infliximab in axial spondyloarthritis: impact on disease activity, quality of life, and productivity in subgroups with psoriasis and inflammatory bowel disease

Nikolaos Kougkas, Elpida Skouvaklidou, Dimitrios Deligeorgakis, Konstantinos Tsafis, Afroditi Mpitouli, Vasiliki Dimitriadou, Vasileios Skepastianos, Maria Boutel, Paraskevi Avgerou, Christina Adamichou & Theodoros Dimitroulas

Table 1. Baseline characteristics.

Characteristic	All patients (n = 39)	Psoriasis (n = 10)	IBD (n = 13)
Age (years), mean ± SD	33.5 ± 8.4	36.5 ± 7.5	30.5 ± 6.5
Disease duration (years), mean ± SD	3.15 ± 1.9	3.6 ± 2.0	2.7 ± 1.5
Male sex, n (%)	22 (56%)	6 (60%)	6 (46%)
Body Mass Index (kg/m^2), mean ± SD	26.3 ± 3.2	27.5 ± 3.4	25.5 ± 2.8
Employed, n (%)	31 (80%)	9 (90%)	10 (76.9%)
Psoriasis, n (%)	10 (26%)	–	–
IBD, n (%)	13 (33%)	–	–
Prior biologics, n (%)	11 (28%)	3 (30%)	2 (15%)
One prior biologic, n (%)	8 (21%)	2 (20%)	2 (15%)
Two prior biologics, n (%)	3 (8%)	1 (10%)	0

IBD: Inflammatory bowel disease, SD: standard deviation.

Table 2. Measures of disease activity, quality of life, and work productivity.

Outcome	Baseline*	6 months*	12 months*	Δ (0→6 m)	95% CI	p† (0→6 m)	Δ (0→12 m)	95% CI	p† (0→12 m)
ASDAS	3.41 ± 1.20	1.69 ± 1.10	1.73 ± 1.10	1.72	0.67, 2.77	0,002	1.68	0.61, 2.75	0,003
BASDAI	5.50 ± 1.40	2.34 ± 1.30	2.38 ± 1.30	3.16	1.49, 4.83	0,017	3.12	1.47, 4.77	0,02
EQ-VAS	0.56 ± 0.20	0.85 ± 0.20	0.83 ± 0.20	−0.29	−0.55, −0.03	0,03	−0.27	−0.52, −0.03	0,027
HAQ	0.93 ± 0.30	0.37 ± 0.20	0.40 ± 0.20	0.56	0.03, 1.09	0,04	0.53	0.01, 1.05	0,042
Absenteeism %	11.20 ± 5.00	6.90 ± 4.20	7.10 ± 4.40	4.30	2.25, 6.35	<0.001	4.10	2.05, 6.15	<0.001
Presenteeism %	43.50 ± 12.00	22.40 ± 10.00	19.70 ± 9.50	21.10	14.89, 27.31	<0.001	23.80	17.93, 29.67	<0.001
Activity Impairment %	43.80 ± 15.20	22.00 ± 14.30	21.30 ± 14.70	21.80	1.93, 41.67	0,032	22.50	7.10, 37.90	0,003
Work Productivity Loss %	35.60 ± 13.40	15.10 ± 9.90	14.50 ± 9.90	20.50	9.61, 31.39	0,028	21.10	10.86, 31.34	0,025
CDAI (IBD) ($n = 9$)	268 ± 52	172 ± 44	166 ± 42	96.00	18.57, 173.43	0,017	102.00	23.81, 180.19	0,015
Mayo Score (UC) ($n = 4$)	7.0 ± 1.2	1.75 ± 0.9	2.0 ± 1.0	5.25	−1.55, 12.05	0,25	5.00	−1.78, 11.78	0,32
BSA (psoriasis) ($n = 10$)	4.33 ± 1.1	1.40 ± 0.7	1.20 ± 0.6	2.93	0.13, 5.73	0,042	3.13	0.22, 6.04	0,038

n = 39, otherwise stated after each variable, * mean ± SD, † Holm-Bonferonni adjusted p-values, Δ: change from baseline, ASDAS: Ankylosing Spondylitis Disease Activity Score, BASDAI: Bath Ankylosing Spondylitis Disease Activity Index, EQ VAS: Euroquol Visual Analog Scale, HAQ: Health Assessment Questionnaire, CDAI: Crohn's Disease Activity Index, UC: Ulcerative Colitis, BSA: Body Surface Area.

Παρουσίαση περιστατικού

- 1 χρόνο μετά την έναρξη του i.v Infliximab σε πλήρη εργαστηριακή και κλινική ύφεση
- Νέα κολονοσκόπηση χωρίς ενεργότητα
- Ποιο θα ήταν το επόμενο βήμα
  - Συνέχιση i.v σχήματος;
  - Αλλαγή σε sc χορήγηση του φαρμάκου;

Baraliakos *et al. BMC Rheumatology* (2025) 9:139
https://doi.org/10.1186/s41927-025-00594-9

BMC Rheumatology

RESEARCH Open Access

A retrospective, multinational, cross-sectional survey of real-world outcomes for patients with axial spondyloarthritis receiving subcutaneous infliximab

Xenofon Baraliakos[1], Ye Eun Lee[2], Soyeon Park[2], Young Nam Lee[2], Isabel Truman[3], Molly Edwards[3], Emily Quiñones[3] and Raj Sengupta[4,5,6*]

Table 1 Baseline characteristics of patients with axSpA treated with SC IFX

	Patients with axSpA (*N* = 191)
Age, years, mean (SD)	44.5 (11.2)
Sex, male, *n* (%)	117 (61.3)
BMI, kg/m^2, mean (SD)	25.8 (3.8)
Country, *n* (%)	
France	50 (26.2)
Germany	31 (16.2)
Italy	30 (15.7)
Spain	30 (15.7)
UK	50 (26.2)
Smoking status, *n* (%)	
Current smoker	35 (18.3)
Ex-smoker	54 (28.3)
Never smoked	92 (48.2)
Unknown	10 (5.2)
Disease subtype, *n* (%)	
r-axSpA	116 (60.7)
nr-axSpA	75 (39.3)
Patients with concomitant condition, *n* (%)	68 (35.6)
Patients with autoimmune conditions, *n*/*N* (%)	27/61 (44.3)
Concomitant medication, *n* (%)	
csDMARD	17 (8.9)
NSAID-COX inhibitor	35 (18.3)
Corticosteroid	4 (2.1)
Total number of lines of advanced therapy, mean (SD)	1.4 (0.6)
Current line of therapy, *n* (%)	*n* = 183
1	130 (71.0)
2	41 (22.4)
3	12 (6.6)
Previous advanced therapy ever prescribed, *n* (%)	*n* = 53
Adalimumab	34 (64.2)
Infliximab	13 (24.5)
Etanercept	9 (17.0)
Secukinumab	2 (3.8)
Upadacitinib	2 (3.8)
Tofacitinib	1 (1.9)
Guselkumab	1 (1.9)
Ixekizumab	1 (1.9)
Duration of SC IFX therapy, months	*n* = 169
Mean (SD)	15.7 (15.2)
ESR at initiation, mm/hour	*n* = 159
Mean (SD)	62.4 (48.0)
CRP at initiation, mm/hour	*n* = 180
Mean (SD)	49.0 (65.8)

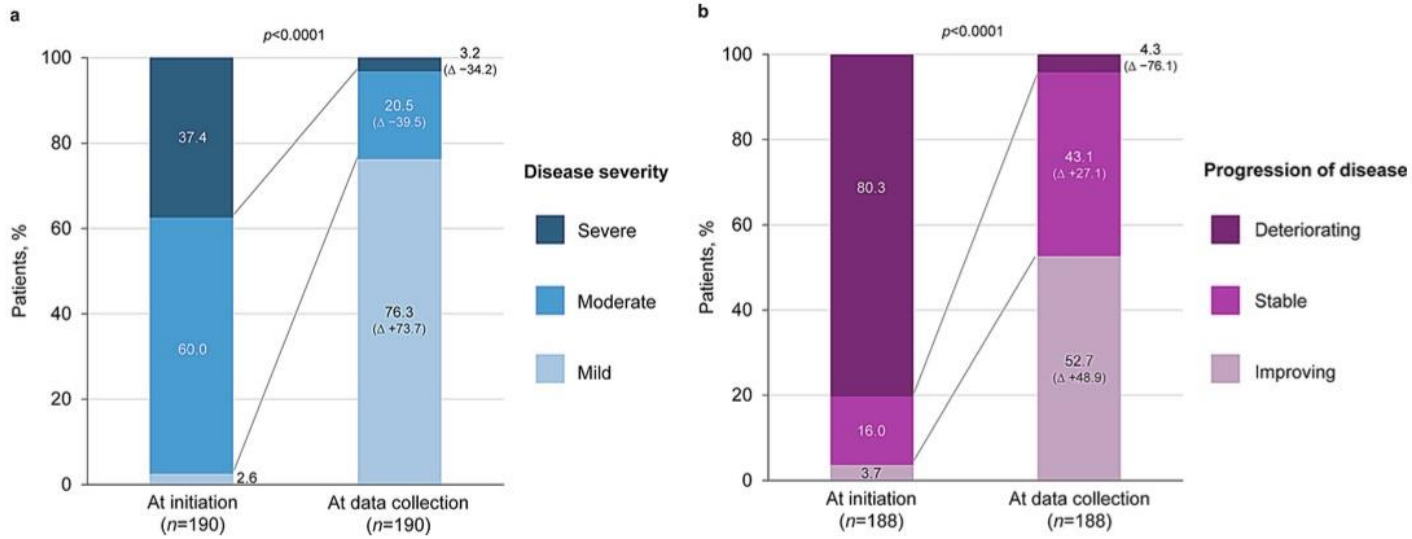
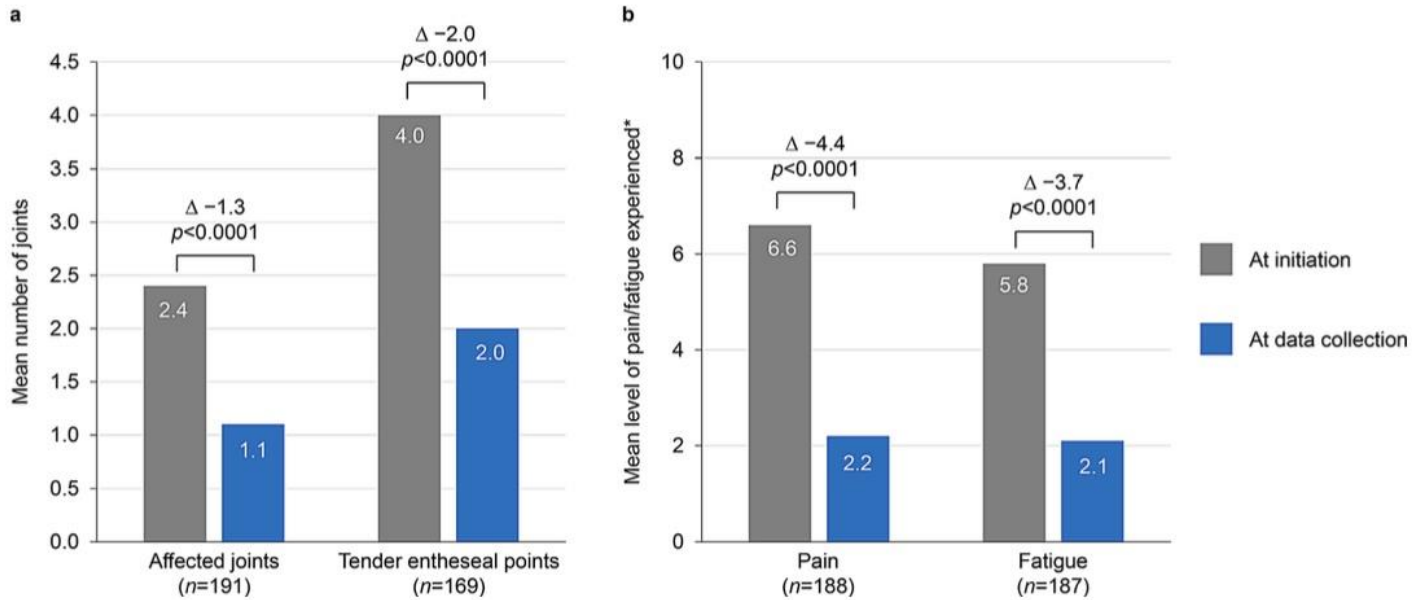
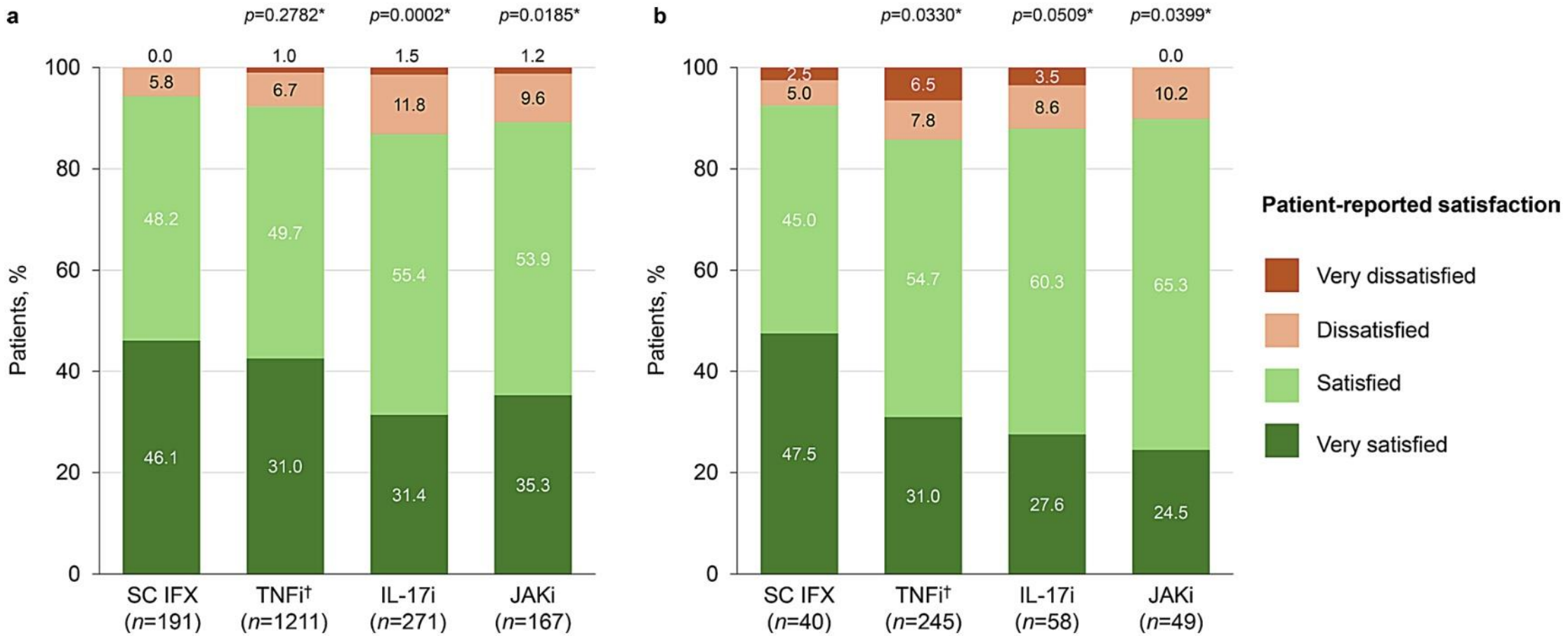


Fig. 1 Change in (**a**) disease severity and (**b**) progression of disease with SC IFX. Wilcoxon signed-rank test used for statistical analysis. Physicians were asked to provide their own perception of the severity and progression of their patient's condition at initiation of treatment and at the time of data collection. Δ indicates change from initiation to data collection. *Abbreviations: IFX* infliximab, *SC* subcutaneous




a
p=0.2782*
p=0.0002*
p=0.0185*
0.0
1.0
1.5
1.2
5.8
6.7
11.8
9.6
48.2
49.7
55.4
53.9
46.1
31.0
31.4
35.3
Patients, %
100
80
60
40
20
0
SC IFX (n=191)
TNFi† (n=1211)
IL-17i (n=271)
JAKi (n=167)
b
p=0.0330*
p=0.0509*
p=0.0399*
2.5
5.0
6.5
7.8
3.5
8.6
0.0
10.2
45.0
54.7
60.3
65.3
47.5
31.0
27.6
24.5
SC IFX (n=40)
TNFi† (n=245)
IL-17i (n=58)
JAKi (n=49)
Patient-reported satisfaction
Very dissatisfied
Dissatisfied
Satisfied
Very satisfied

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Advance access publication 19 December 2022
Concise report

British Society for Rheumatology
RHEUMATOLOGY
OXFORD

Clinical science

Efficacy of subcutaneous *vs* intravenous infliximab in rheumatoid arthritis: a post-hoc analysis of a randomized phase III trial

Arnaud Constantin[1], Roberto Caporali [2], Christopher J. Edwards [3], João Eurico Fonseca[4], Florenzo Iannone [5], Edward Keystone [6], Hendrik Schulze-Koops[7], Taek Kwon[8], Seungmin Kim[8], SangWook Yoon[9], Dong-Hyeon Kim[9], Gahee Park[10], Dae Hyun Yoo [11]*

Aim

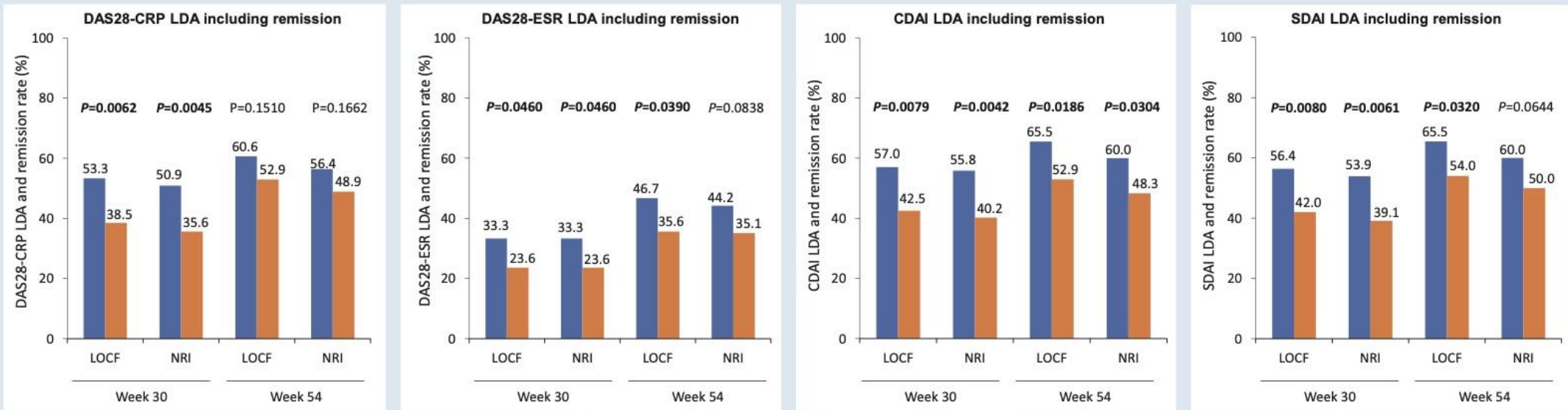
Post-hoc analysis of a phase III randomised study to investigate whether differences in efficacy outcomes in RA patients were statistically significant between IFX s.c. vs IFX i.v. (pre- and post-switch) when using conservative imputation methods* for missing data

Design

Results

At Week 30, significant efficacy improvements were observed with IFX s.c. vs IFX i.v.

At Week 54, between-group efficacy differences were reduced, with numerical advantages for the IFX s.c. group across outcomes



Conclusion

Findings suggests benefits of IFX s.c. compared the IFX i.v. at W30.

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Expert Review of Clinical Immunology

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Efficacy and safety of subcutaneous infliximab versus adalimumab, etanercept and intravenous infliximab in patients with rheumatoid arthritis: a systematic literature review and meta-analysis

Roberto Caporali, Yannick Allanore, Rieke Alten, Bernard Combe, Patrick Durez, Florenzo Iannone, Mike T. Nurmohamed, Sang Joon Lee, Taek Sang Kwon, Jean Soo Choi, Gahee Park & Dae Hyun Yoo

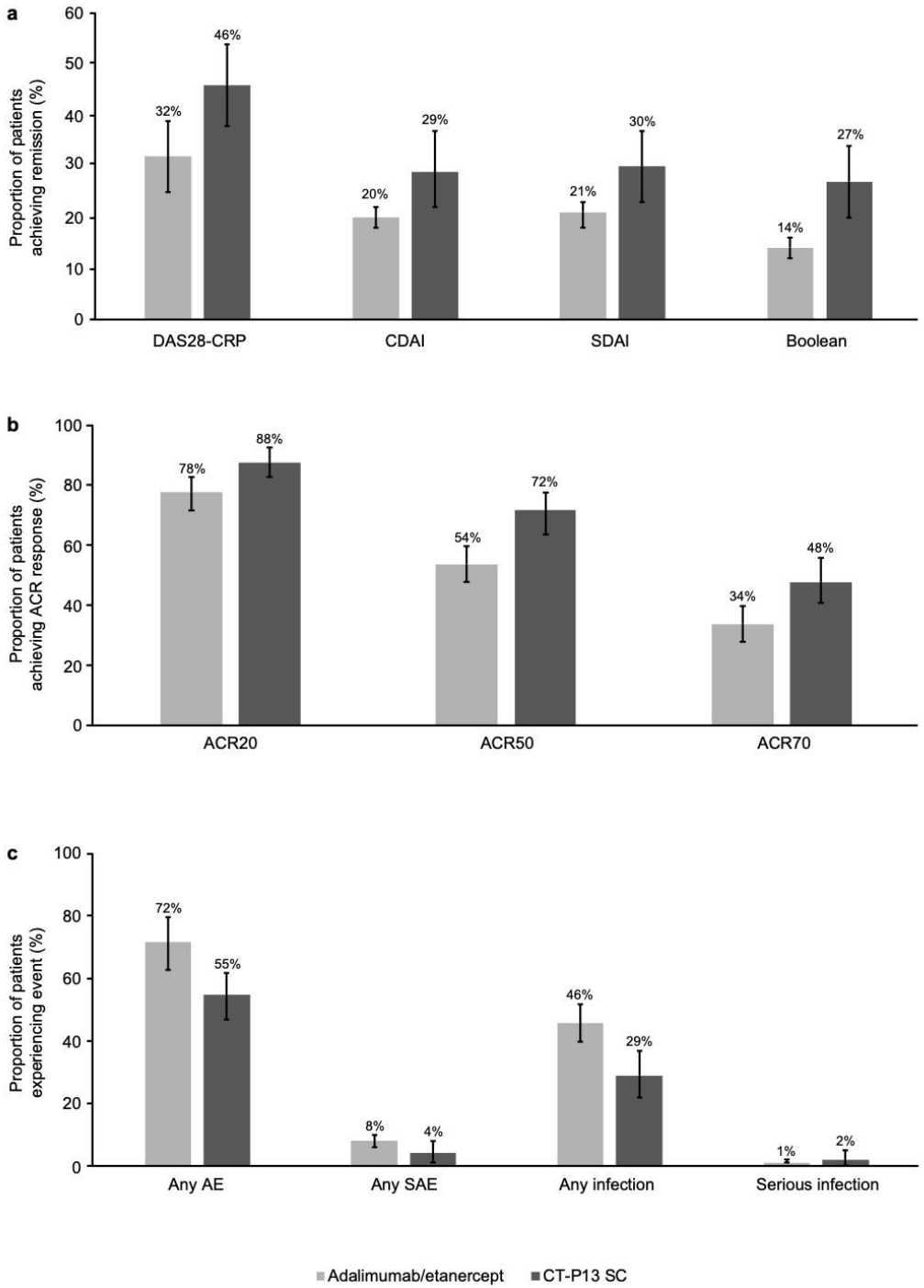
ABSTRACT

Objectives: There are few comparative data for tumor necrosis factor inhibitors in patients with rheumatoid arthritis (RA).

Methods: Historical data for reference product/biosimilar intravenous infliximab, or adalimumab and etanercept, were pooled and compared with phase 3 study results for a subcutaneous (SC) formulation of the infliximab biosimilar CT-P13, in a systematic review and meta-analysis (PROSPERO: CRD42019149621).

Results: The authors identified 13 eligible controlled trials that randomized over 5400 participants to prespecified treatments of interest. Comparison with pooled historical data suggested a numerical advantage for CT-P13 SC over intravenous infliximab for almost every prespecified efficacy outcome evaluated, including Disease Activity Score in 28 joints (C-reactive protein/erythrocyte sedimentation rate), Clinical/Simplified Disease Activity Index scores, American College of Rheumatology responses, and multiple measures of disease remission and low disease activity; for the majority of outcomes, there was no overlap in 95% confidence intervals between groups. A numerical advantage for CT-P13 SC was also observed for safety outcomes (adverse events, infections, and discontinuations). Similar, but less marked, trends were observed for comparison with historical efficacy and safety data for adalimumab/etanercept.

Conclusion: CT-P13 SC offers an improved or similar benefit-to-harm ratio compared with infliximab (intravenous) and adalimumab/etanercept, for the treatment of moderate-to-severe RA.


a
Proportion of patients achieving remission (%)
60
50
40
30
20
10
0
32%
46%
20%
29%
21%
30%
14%
27%
DAS28-CRP
CDAI
SDAI
Boolean
b
Proportion of patients achieving ACR response (%)
100
80
60
40
20
0
78%
88%
54%
72%
34%
48%
ACR20
ACR50
ACR70
c
Proportion of patients experiencing event (%)
100
80
60
40
20
0
72%
55%
8%
4%
46%
29%
1%
2%
Any AE
Any SAE
Any infection
Serious infection
Adalimumab/etanercept
CT-P13 SC

frontiers | Frontiers in Medicine

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Check for updates

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Switching from intravenous to subcutaneous infliximab in patients with immune mediated diseases in clinical remission

Nikos Viazis[1]*, Anastasios Karamanakos[2], Konstantinos Mousourakis[1], Angeliki Christidou[1], Fotios Fousekis[3], Konstantinos Mpakogiannis[3], Anastasios Koukoudis[3], Konstantinos Katsanos[3], Dimitrios Christodoulou[3], Myrto Cheila[2], Maria Tzouvala[4], Eirini Zacharopoulou[4], Maria Palatianou[4], Olga Giouleme[5,6], Anastasia Katsoula[5,6], Christos Liatsos[7], Nikolaos Kyriakos[7], Evi Zampeli[8], Evgenia Papathanasiou[8], Angeliki Theodoropoulou[9], Konstantinos Karmiris[9], Ioannis Psaroudakis[9], George Tribonias[10], Souzanna Gazi[11], Evangelia Mole[11], Theodoros Dimitroulas[12], Christos Koutsianas[13], Dimitris Vassilopoulos[13], George E. Fragoulis[14], Nikos Michalakeas[14], Charalampos Papagoras[15], Pantelis Panagakis[16], Marina Papoutsaki[16], Vasiliki Chasapi[16], Alexandros Stratigos[16] and George Katsikas[2]

Results: Between April 2023 and April 2024, a total of 344 patients (CD = 136, UC = 62, SpA = 52, PsA = 38, RA = 7, PsO = 44, co-existence of more than one disease = 5) were switched from IFX-IV to IFX-SC. After a mean±SD follow up period of 8 ± 4 months, 12 patients (3.5%) discontinued treatment with IFX-SC. Five of them (1.5%) because of disease worsening and the remaining 7 (2.0%) because of the occurrence of side effects. All 332 other patients (96.5%) showed favorable response, none of them requested an unscheduled visit, or developed an adverse event (clinical or laboratory) or needed escalation of treatment.

Conclusion: Elective switching from IFX-IV to IFX-SC seems to be an effective and safe approach in real-world every day clinical practice to maintain long-term clinical remission, inactive disease or low disease activity in patients with immune-mediated diseases.

Κλινικά ερωτήματα στην καθημερινή πράξη

- Τι κάνουμε με τον ασθενή που ανταποκρίνεται στην infliximab;
- Διατηρούμε την ενδοφλέβια θεραπεία;
- Μεταβαίνουμε σε υποδόρια μορφή;
- Ξεκινάμε εξαρχής με υποδόρια θεραπεία;
- Ποιος ασθενής είναι κατάλληλος για κάθε στρατηγική;
- Ποιος είναι ο βέλτιστος χρόνος μετάβασης;

Stydy protocol

- **Comparative Real-World Effectiveness, Drug Survival, and Patient-Reported Outcomes of Subcutaneous Infliximab Strategies in Axial Spondyloarthritis: A Prospective Cohort Study**
- **Objective**: To compare treatment persistence, effectiveness, safety, and patient-reported outcomes between patients switching from IV to SC infliximab and patients managed with SC infliximab who are in low disease activity or remission at a comparable index date.
- **Methods**: Approximately 50 patients with axSpA treated with SC infliximab will be included in this prospective observational cohort study. The primary outcome will be 12-month drug survival. Secondary outcomes include disease activity, patient-reported outcomes, treatment satisfaction, healthcare utilization, and safety.

Baseline and disease characteristics of patients initiating subcutaneous infliximab (SC IFX) or switching from intravenous

Variables	SC start (n=22)	Switch to SC (n=31)	p-value
Age[a]	39.45 (11.95)	44.42 (13.57)	0.18[b]
Disease duration[a]	5.95 (3.59)	7.87 (5.41)	0.16[b]
Sex (Male)	14 (64%)	15 (48%)	0.27[c]
HLA-B27	12 (55%)	9 (29%)	0.06[c]
r- axSpA	11 (50%)	18 (58%)	0.56[c]
Psoriasis	7 (32%)	13 (42%)	0.45[c]
IBD	5 (23%)	10 (32%)	0.45[c]
Prior bDMARD	11 (50%)	19 (61%)	0.41[c]
NSAID	6 (27%)	8 (26%)	0.90[c]
cDMARD	5 (23%)	8 (26%)	0.79[c]
Adverse events	4 (18%)	6 (19%)	0.59[c]
Leading to drug discontinuation	4 (18%)	3 (10%)	0.70[d]
Injection site reaction	0	3 (10%)	0.29[d]
Preference			
Yes	15 (68%)	23 (74%)	0.64[d]
No	1 (5%)	5 (16%)	
No preference	6 (27%)	3 (10%)	

[a] mean (SD), [b] student's t-test, [c] chi squared, [d] Fisher's exact test, HLA-B27: human leukocyte antigen B27, r-axSpA: radiographic axial spondyloarthritis, IBD: inflammatory bowel disease, bDMARD: biologic disease-modifying antirheumatic drug, cDMARD: conventional disease-modifying antirheumatic drug, NSAID: nonsteroidal anti-inflammatory drug.

Unpublished data

Comparison of longitudinal clinical and patient-reported outcomes between treatment groups

	Baseline		3 months		6 months		12 months		p-values	
Variables	SC start	Switch to SC	SC start	Switch to SC	SC start	Switch to SC	SC start	Switch to SC	between group	time * group
ASDAS[a]	1.57 (0.25)	1.66 (0.28)	1.47 (0.32)	1.48 (0.35)	1.41 (0.33)	1.17 (0.34)	1.31 (0.34)	0.87 (0.33)	0.37	0.003
BASDAI[a]	1.74 (0.66)	2.16 (0.68)	1.57 (0.46)	2.13 (0.43)	1.50 (0.53)	1.60 (0.49)	1.32 (0.75)	0.99 (0.70)	<0.001	<0.001
CRP[a]	0.62 (0.34)	0.54 (0.32)	0.51 (0.29)	0.47 (0.23)	0.44 (0.22)	0.39 (0.22)	0.49 (0.3)	0.31 (0.20)	0.11	0.36
EQ-VAS[a]	73.41 (11.38)	70 (8.76)	75.91 (10.19)	72.58 (7.17)	77.73 (9.6)	76.77 (8.02)	82.11 (8.05)	82.07 (7.62)	0.40	0.17
HAQ[a]	0.36 (0.14)	0.38 (0.18)	0.28 (0.15)	0.38 (0.23)	0.29 (0.19)	0.32 (0.19)	0.24 (0.19)	0.24 (0.21)	0.47	0.046
Absenteism	3.34 (2.47)	3.98 (3.23)	1.86 (2.74)	2.69 (3.54)	1.6 (2.79)	1.54 (2.60)	1.26 (2.50)	0.60 (1.27)	0.81	0.10
Presenteism	14 (11.88)	20.43 (13.47)	12 (10.05)	13.57 (8.26)	9 (9.12)	9.64 (9.99)	3.53 (4.93)	4.62 (7.06)	0.31	0.17
Work Impairement	16.34 (12.72)	23.16 (13.73)	13.24 (11.17)	15.74 (8.27)	9.93 (9.66)	10.47 (11.1)	4.18 (5.01)	5.16 (7.54)	0.30	0.13
Activity Impairement	13.18 (16.44)	18.39 (12.93)	10 (12.72)	14.52 (12.34)	10.45 (13.62)	9.68 (10.16)	3.33 (5.94)	5.17 (7.85)	0.51	0.02

Unpublished data

Take home message

- Ο TNF αποτελεί κεντρικό στόχο στην παθογένεση της αξονικής σπονδυλαρθρίτιδας
- Το infliximab προσφέρει ισχυρό και ευρύ έλεγχο της νόσου σε πολλαπλές εκφάνσεις
- Η υποδόρια μορφή διατηρεί την αποτελεσματικότητα, με βελτιωμένη ευκολία και αυτονομία για τον ασθενή
- Τα δεδομένα πραγματικής ζωής υποστηρίζουν την ασφαλή και αποτελεσματική χρήση, καθώς και τη μετάβαση από ενδοφλέβια σε υποδόρια χορήγηση
- Η επιλογή θεραπευτικής στρατηγικής πρέπει να είναι εξατομικευμένη, με βάση τα χαρακτηριστικά και τις ανάγκες του ασθενούς