Το Golimumab στην καθημερινή κλινική πρακτική
Πρόσφατα δεδομένα από την Ελλάδα και την Ευρώπη

Νέστορας Αυγουστίδης, Ρευματολόγος

Επιμελητής Α' , Ρευματολογική Κλινική ΠΑΓΝΗ

Δήλωση σύγκρουσης συμφερόντων

- **Οι παρουσιάσεις στοχεύουν σε εκπαιδευτικούς σκοπούς και μόνο και δεν αντικαθιστούν την ανεξάρτητη επιστημονική κρίση**
- **Οι τοποθετήσεις ως προς τα δεδομένα και οι απόψεις που εκφράζονται προέρχονται αποκλειστικά από τους ομιλητές ατομικώς και, εκτός από την περίπτωση που δηλώνεται ρητά το αντίθετο δεν αποτελούν θέση της MSD.**
- **Η MSD δεν υποστηρίζει ή εγκρίνει ούτε αναλαμβάνει καμία ευθύνη για το περιεχόμενο, την ακρίβεια ή την πληρότητα των πληροφοριών που παρουσιάζονται**
- **Χορηγείται τιμητική αμοιβή για τη συγκεκριμένη ομιλία**

- **Ο ομιλητής έχει λάβει την τελευταία διετία αμοιβή για διαλέξεις και υποστήριξη για συμμετοχή σε συνέδρια από τις εταιρείες: AENORASIS, UCB ,MYLAN**

Presentation structure

Patient preferences and correlation with treatment outcomes , the position of golimumab (PANORAMA STUDY)

The impact of golimumab:

- on work productivity
- quality of life
- other patient reported outcomes (PROs)
- (PROs) in patients with failure of previous anti-TNF-a treatment
  Greek studies (GO-UP, GO-Q and GO-BEYOND)

- In socio-economic and health-economic parameters
  in RA, axial SpA and Psoriatic Arthritis patients (GO-NICE)

- Effectiveness of golimumab as first, second and third line biological treatment
  (GO-NICE, POST-HOC)

- long term golimumab retention**(SPANISH BIOBADASER REGISTRY)**

EULAR recommendations for the management of rheumatoid arthritis, psoriatic arthritis & ASAS-EULAR recommendations for the management of axSpA[1,2,3]

Overarching principles

The 2019 updated EULAR RA management recommendations[1]

	Overarching principles	LoE	SoR	LoA
A	Treatment of patients with RA should aim at the best care and must be based on a shared decision between the patient and the rheumatologist.	n.a.	n.a.	9.7
B	Treatment decisions are based on disease activity, safety issues and other patient factors, such as comorbidities and progression of structural damage.	n.a.	n.a.	9.8
E	RA incurs high individual, medical and societal costs, all of which should be considered in its management by the treating rheumatologist.	n.a.	n.a.	9.4

2016 Update of the ASAS-EULAR recommendations for the management of axSpA[2]

2	The primary goal of treating the patient with axSpA is to maximise health-related quality of life through control of symptoms and inflammation, prevention of progressive structural damage, preservation/normalisation of function and social participation	9.8 (0.47) 100% ≥8
3	The optimal management of patients with axSpA requires a combination of non-pharmacological and pharmacological treatment modalities	9.8 (0.45) 100% ≥8
4	Treatment of axSpA should aim at the best care and must be based on a shared decision between the patient and the rheumatologist	9.5 (0.91) 100% ≥8
5	axSpA incurs high individual, medical and societal costs, all of which should be considered in its management by the treating rheumatologist	9.3 (1.17) 97% ≥8

2019 EULAR recommendations for the pharmacological management of psoriatic arthritis

B	Treatment of psoriatic arthritis patients should aim at the best care and must be based on a shared decision between the patient and the rheumatologist, considering efficacy, safety and costs.	9.8 (0.5)
D	The primary goal of treating patients with psoriatic arthritis is to maximise health-related quality of life, through control of symptoms, prevention of structural damage, normalisation of function and social participation; abrogation of inflammation is an important component to achieve these goals.	9.9 (0.4)

Smolen JS, et al. Ann Rheum Dis 2020

CORRELATION OF PATIENT PREFERENCES TO TREATMENT OUTCOMES IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH ANTI-TNF AGENTS IN GREECE: THE PANORAMA STUDY

PANORAMA was a non-interventional, prospective, multicenter (18 centers), cohort study in Greece

The observational period was 12 months and study visits occurred every 3 months

Objective

To study the potential correlations between the level of fulfilment of patient preferences with clinical outcomes and PROs in RA patients

Anti-TNF selection (**adalimumab, certolizumab pegol, etanercept, golimumab and infliximab)** was at physician's discretion independently of patient's participation in the study

Patient demographics and clinical characteristics at baseline

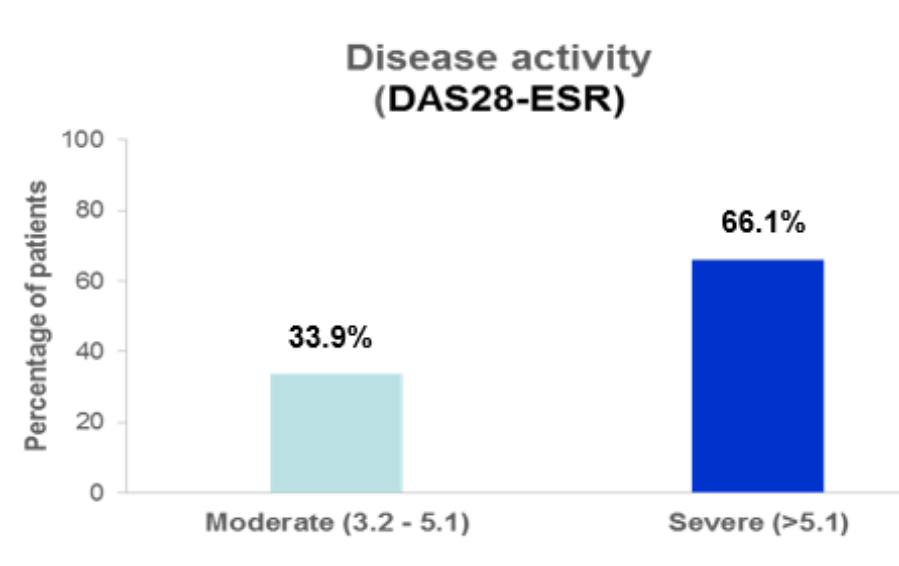
- **254 patients** with moderate-to-severe RA (DAS28-ESR ≥3.2) biologic-naïve (initiating anti-TNF therapy) or biologic-experienced (initiating or switching to an anti-TNF)

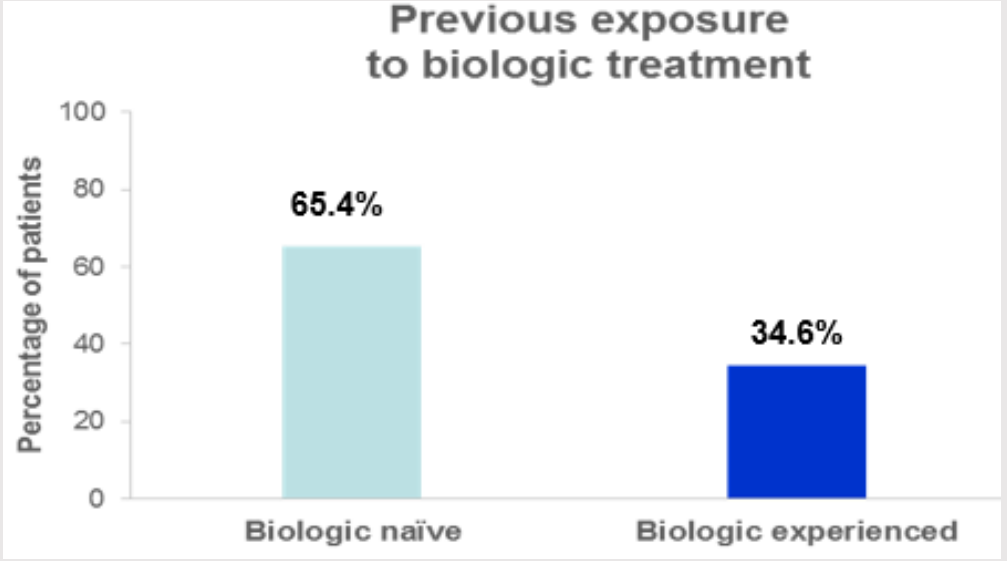
Measure	
n	254[a]
Age, years	58.3 (13.4)
Female, n (%)	210 (82.7)
Pensioners, n (%)	86 (33.9)
Duration of RA, years	6.7 (6.2)
Seropositive (RF and/or anti-CCP), n (%)	133 (53.2)[b]
RF(+), n (%)	122 (49.2)[c]
Anti-CCP(+), n (%)	75 (40.5)[d]
SJC	6.8 (4.3)
TJC	10.0 (5.6)
DAS28-ESR	5.5 (1.1)
HAQ-DI	1.4 (0.6)

Prodromos Sidiropoulos, et al. Clin Rheumatol (2020)

CORRELATION OF PATIENT PREFERENCES TO TREATMENT OUTCOMES IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH ANTI-TNF AGENTS IN GREECE: THE PANORAMA STUDY

Disease activity and previous exposure to biologic treatment at baseline n=244

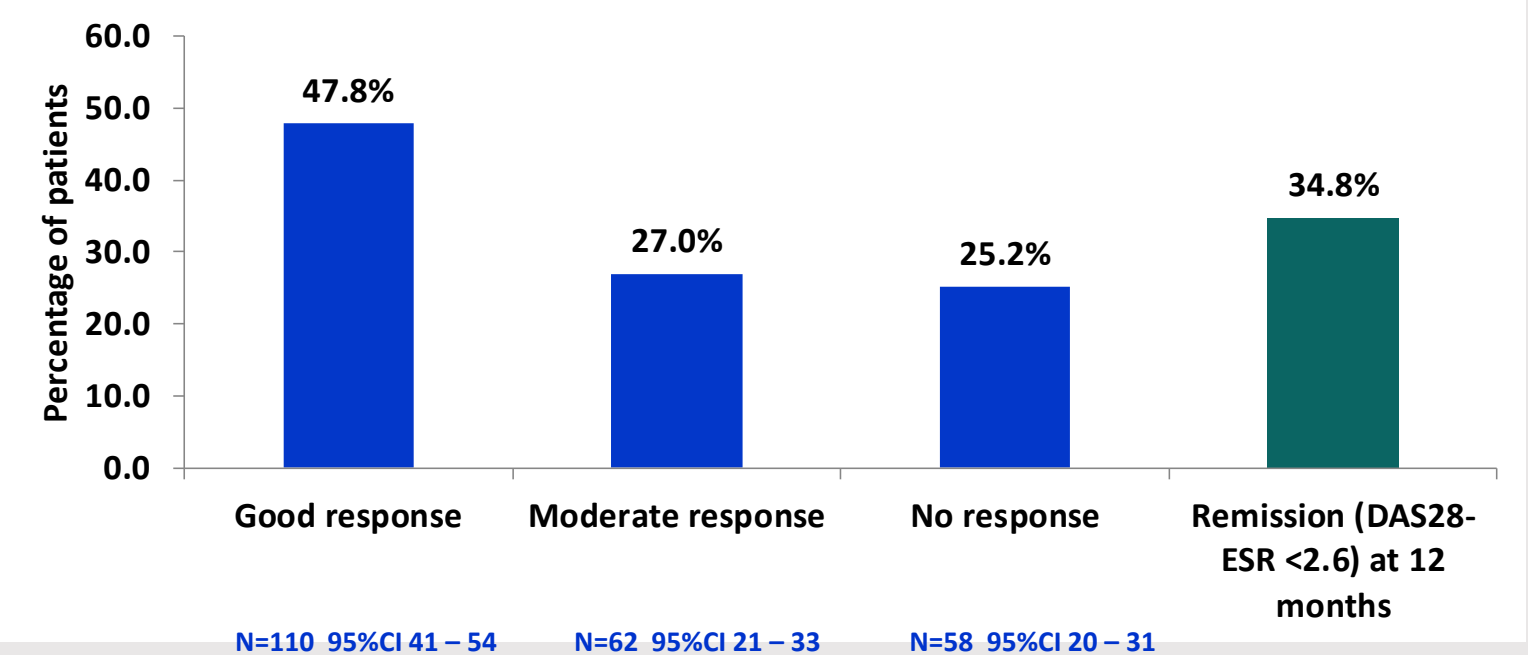




Prodromos Sidiropoulos, et al. Clin Rheumatol (2020)

RESULTS

Response according to EULAR criteria [b] and rate of remission n=230



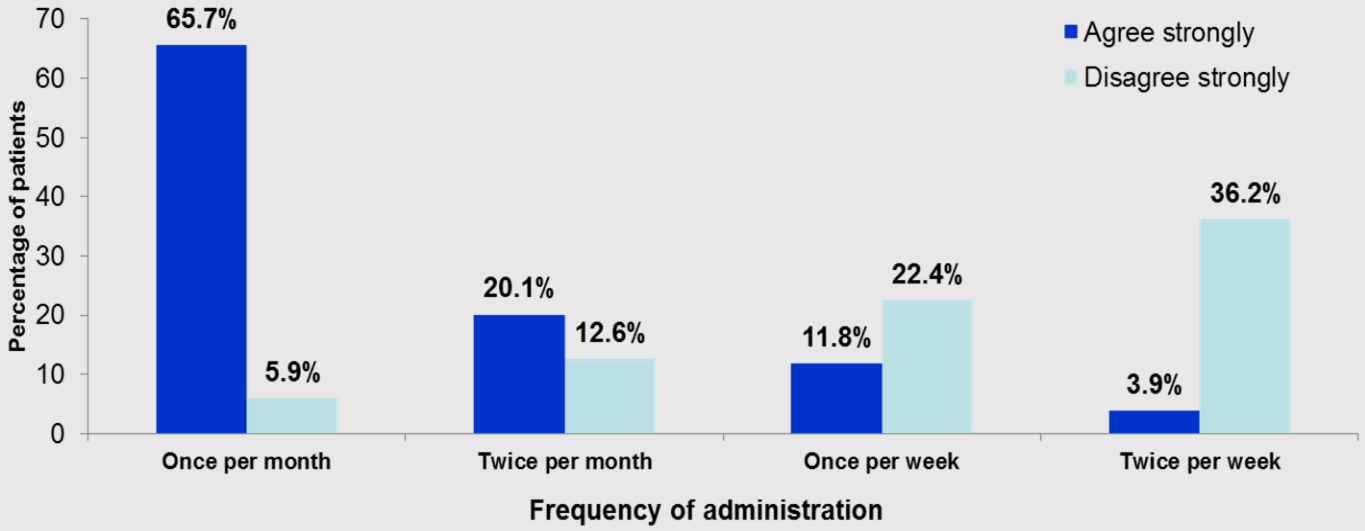
[b]For patients who did not reach 12 month visit, the last observed response was used.
For patients who did reach 12 month visit (n=184), good EULAR response rate was achieved by 56.5% of patients and 40.8% were in DAS-28 remission.

Prodromos Sidiropoulos, et al. Clin Rheumatol (2020)

PATIENTS PREFERENCES

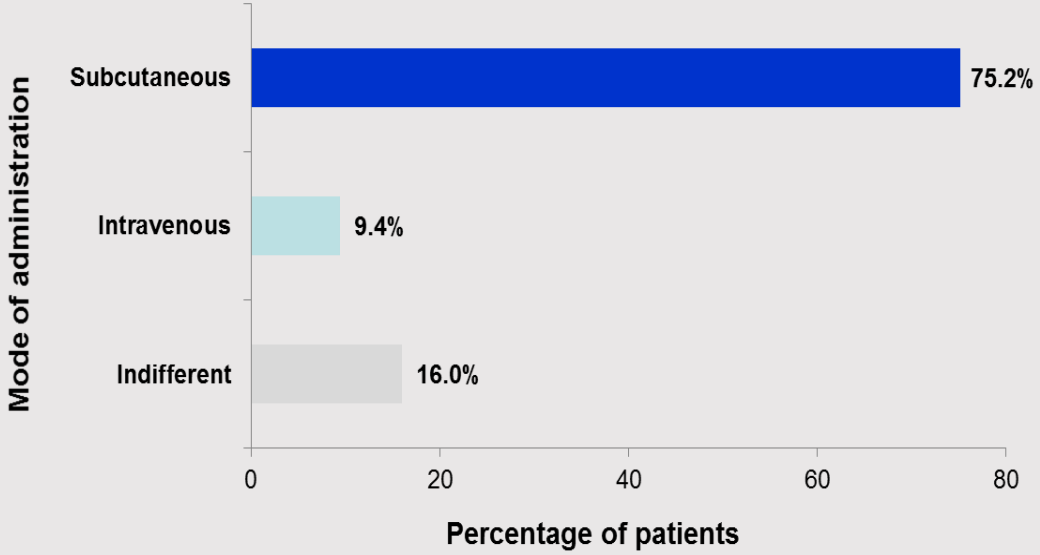
over dosing schedule at baseline[a] n=254

[a]Graph shows patients' responses to the question **'Please indicate to what extent the following dosage schedule is suitable for you'** of the patients' Preference Questionnaire.



over route of administration at baseline[b] n=254

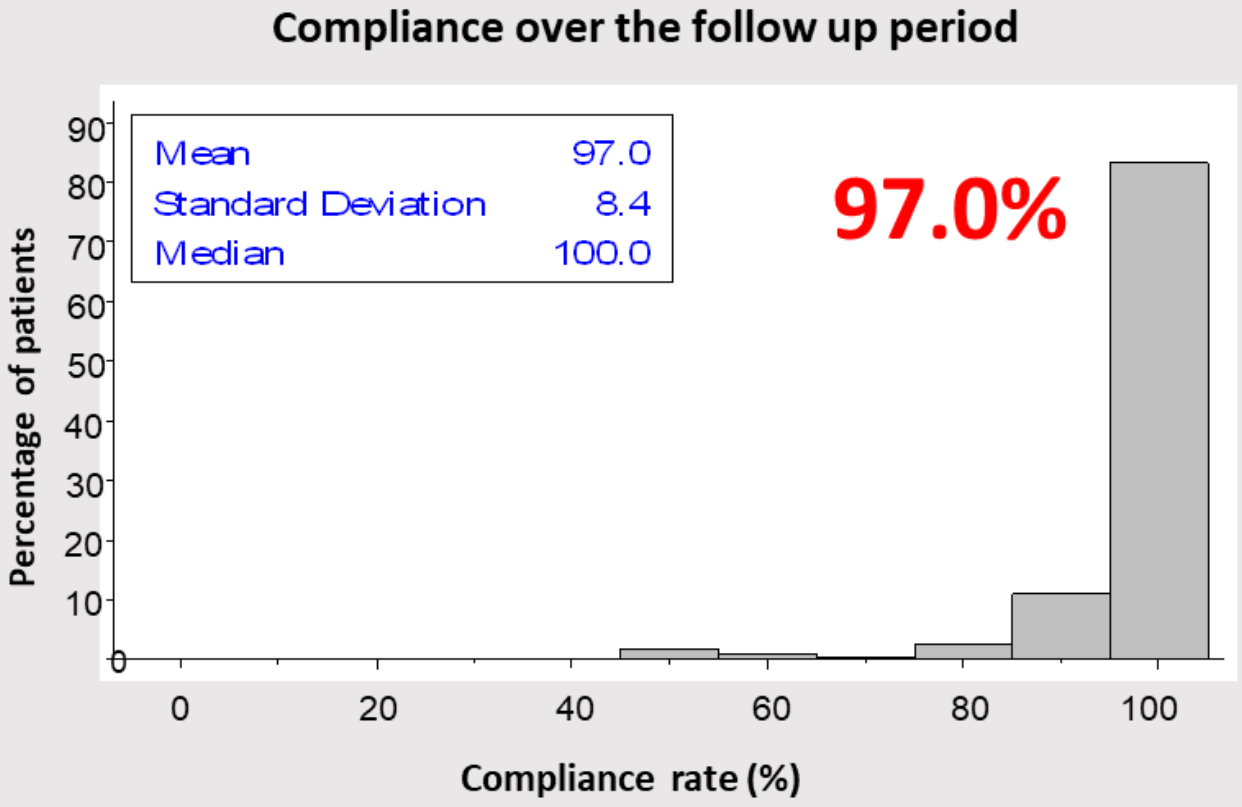
[B] Graph shows patients' responses to the question **'Which mode of administration would you prefer?** Treatment Satisfaction Questionnaire for Medication (TSQM)

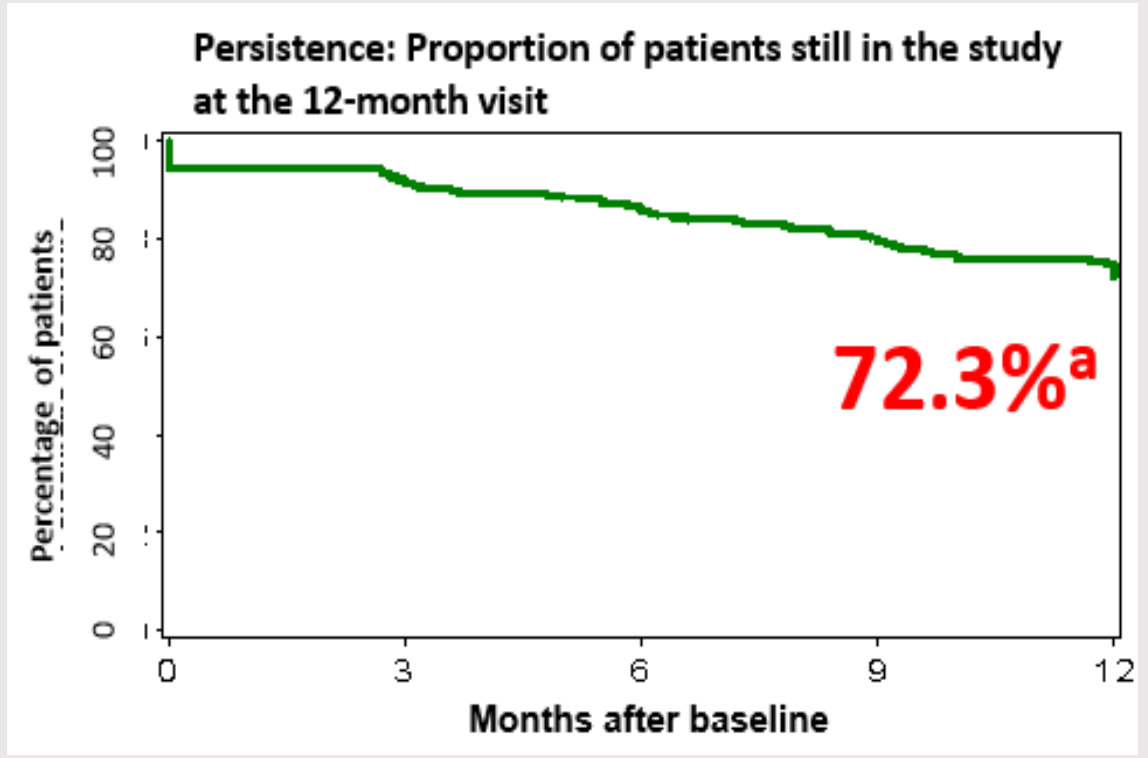


Prodromos Sidiropoulos, et al. Clin Rheumatol (2020)

RESULTS

Compliance and persistence rates at 12 months of anti-TNF treatment n=244





[a] Kaplan-Meier estimate

Prodromos Sidiropoulos, et al. Clin Rheumatol (2020)

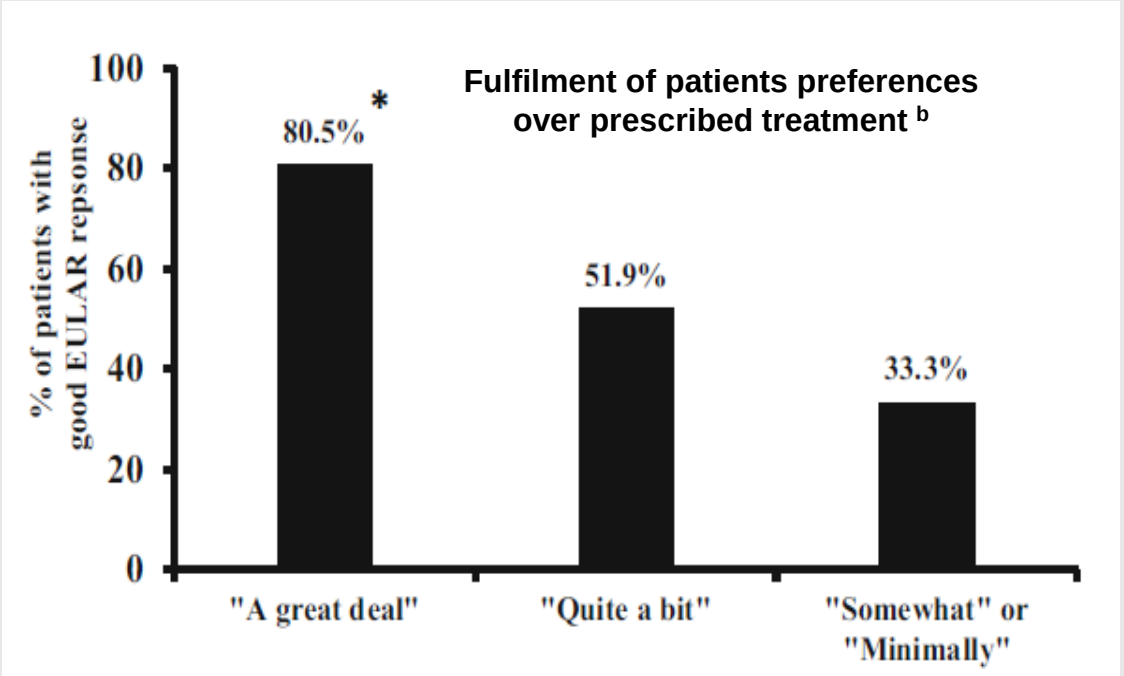
VARIABLES ASSOCIATED WITH

Correlation of good EULAR response to fulfilment of baseline patients preferences over anti-TNF treatment

…a good EULAR response by multivariate analysis **n=194**

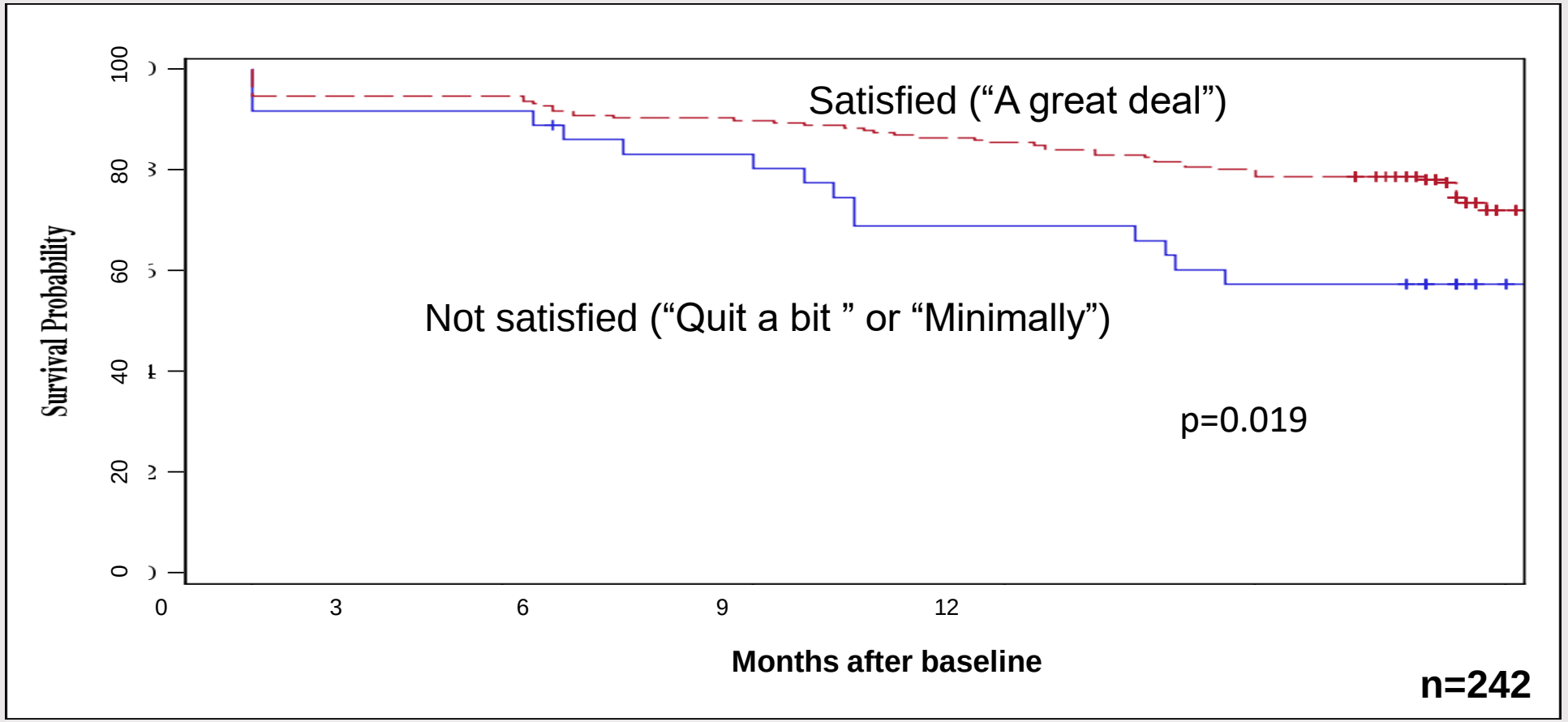
Independent variables	Odds ratio[a]	p-value
Satisfaction of patients preferences over treatment [b]	**5.56**	**<0.001**
At least average general knowledge of the disease [c]	**1.33**	**0.007**
History of comorbidities	**0.41**	**0.014**
Swollen Joint Count	**0.91**	**0.021**

a: Odds of “Good” vs. “Moderate responders” and “Non-responders”
b: Based on answers provided at baseline regarding route of administration and frequency of dosing. Comparison between “A great deal” vs “Quit a bit ” or “Minimally”
c: Based on answers provided at baseline regarding general knowledge of the disease. Answers scale 1 to 7: worst to best)



Prodromos Sidiropoulos, et al. Clin Rheumatol (2020)

ANTI-TNF PERSISTENCE ACCORDING TO FULFILMENT OF PATIENTS PREFERENCES[a] OVER TREATMENT DURING THE 12 MONTH PERIOD AT BASELINE



74.6%

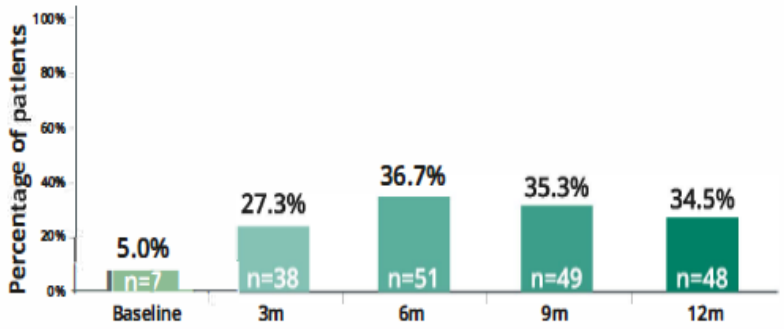
57.4%

a: Based on answers provided at baseline regarding route of administration and frequency of dosing.

Prodromos Sidiropoulos, et al. Clin Rheumatol (2020)

The Effects of Golimumab on Clinical and Patient Reported Outcomes Amongst Rheumatoid Arthritis (RA) Patients in Clinical Practice: a Multicenter Observation Study post-hoc sub-analysis from PANORAMA STUDY

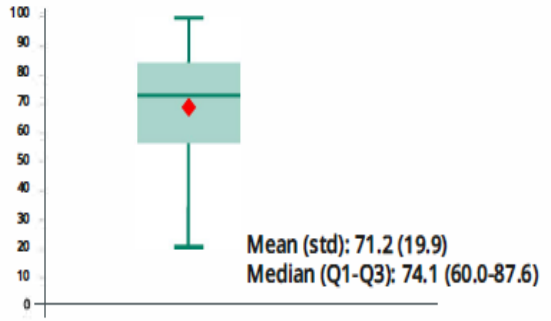
HAQ-DI functional remission rate across the follow up period



Overall, 34.5% of patients treated with GLM were in HAQ-DI functional remission at 12 months.

HAQ-DI functional remission rate was defined as percentage of patients with HAQ-DI score <0.5.

Average global satisfaction at 12 months of follow up[a]



Mean (std): 71.2 (19.9)
Median (Q1-Q3): 74.1 (60.0-87.6)

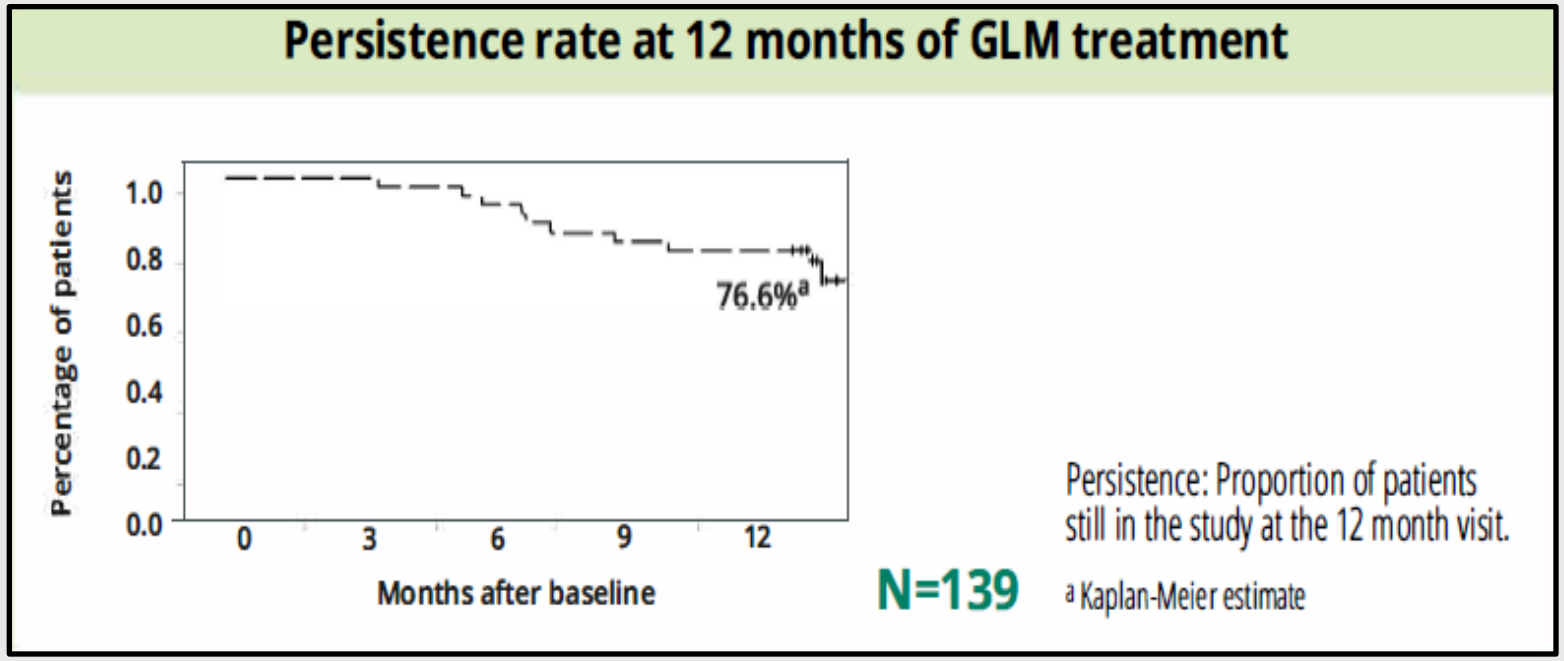
N=127

The overall global satisfaction for patients treated with GLM was 71.2% at 12 months.

[a] Only patients with at least 1 TSQM evaluation were used

P. Sidiropoulos, et al. 11th International Congress of Autoimmunity

The Effects of Golimumab on Clinical and Patient Reported Outcomes Amongst Rheumatoid Arthritis (RA) Patients in Clinical Practice: a Multicenter Observation Study post-hoc sub-analysis from PANORAMA STUDY



P. Sidiropoulos, et al. 11th International Congress of Autoimmunity

ΣΥΜΠΕΡΑΣΜΑΤΑ

- **Στους ασθενείς με PA που επρόκειτο να λάβουν αγωγή με anti-TNFa η εκπλήρωση των επιθυμιών των ασθενών κατά την έναρξη της θεραπείας ήταν ο ισχυρότερος παράγοντας που σχετίστηκε με:**

- καλή ανταπόκριση
- παραμονή στην θεραπεία στους 12 μήνες

- **Αυτά τα δεδομένα από συνθήκες καθημερινής κλινικής πρακτικής στην Ελλάδα αναδεικνύουν την σημασία της συναπόφασης (shared decision making) σε ότι αφορά τα (PROs) αλλά και την παραμονή στην θεραπεία.**

- **Το Golimumab είναι αποτελεσματική θεραπεία σε ασθενείς με ενεργό PA και σχετίστηκε με σημαντική βελτίωση όλων των PROs ενώ τόσο η ικανοποίηση από την αγωγή όσο και η παραμονή στην θεραπεία ήταν σε υψηλά επίπεδα κατά την διάρκεια της δωδεκάμηνης παρακολούθησης**

P. Sidiropoulos, et al. 11th International Congress of Autoimmunity

EFFECTS OF GOLIMUMAB ON WORK PRODUCTIVITY AMONG WORK-ACTIVE ANKYLOSING SPONDYLITIS, NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS AND PSORIATIC ARTHRITIS PATIENTS IN GREECE: THE 'GO-UP' STUDY

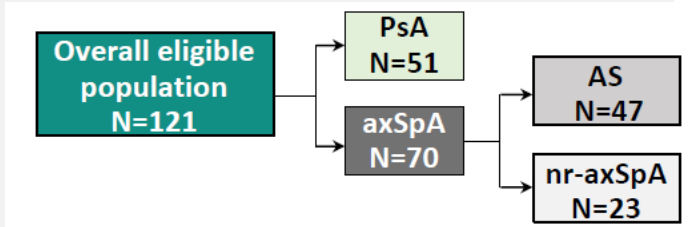
Methods

GO-UP was a non interventional, multicenter, observational prospective study with patients consecutively enrolled by rheumatologists practicing in 15 hospitals and 5 private offices in Greece.

Study Population: 121 eligible Patients

Bio-naïve & bio-experienced working adults **with active axSpA or PsA** newly initiated on Golimumab as per the approved label.

- Patients with prior use of >1 biologic agent or switching from another TNFi due to primary no-response or safety reasons were excluded.



AS: ankylosing spondylitis, axSpA: axial spondyloarthritis, nr-axSpA: non-radiographic axSpA, PsA: psoriatic arthritis

Duration & data collection time

Planned total study duration: 24 months (12 months recruitment +12 months follow-up for each patient).

Data were collected prior to Golimumab initiation and at 3,6 and12 months post treatment onset.

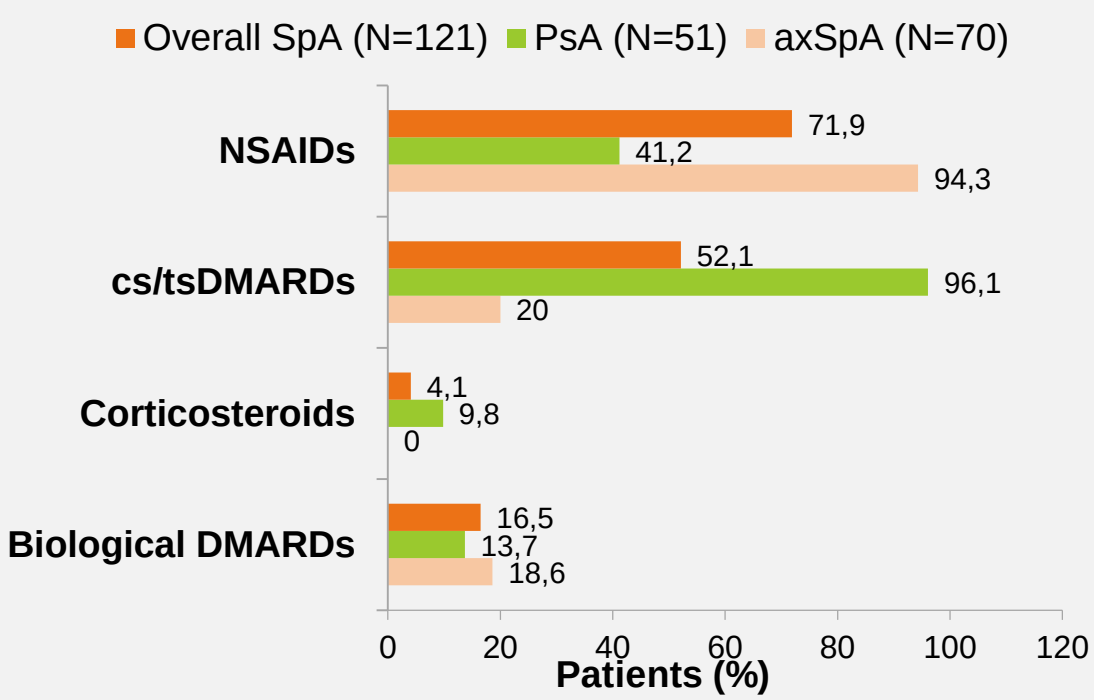
Primary Objective

Assess the impact of Golimumab on **WPAI,** work productivity and activity impairment, over 12 months of treatment in patients with SpA ,overall, and in the axSpA and PsA subpopulations.

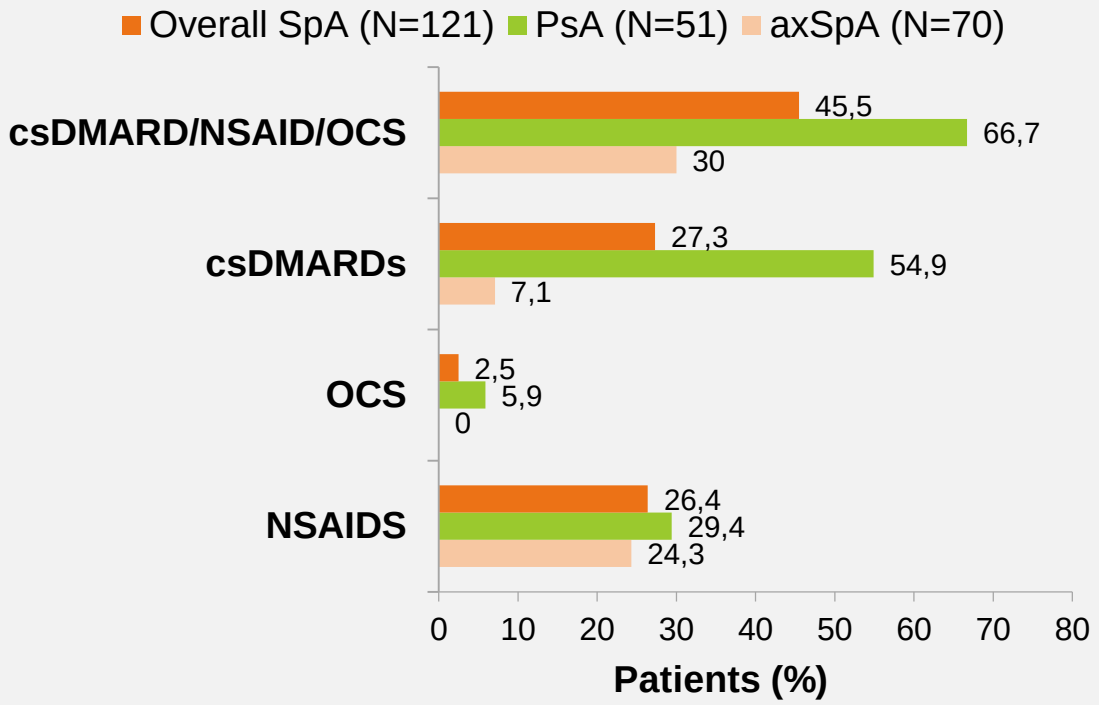
P. Athanassiou et al. Ann Rheum Dis. 2020;79(suppl 1):1275.

TREATMENT HISTORY AND CHARACTERISTICS

Prior Medications for SpA



Concomitant Medications for SpA at Baseline



cs/ts DMARD, conventional synthetic/targeted synthetic DMARD; DMARD, disease-modifying antirheumatic drug; GLM, golimumab; IQR, interquartile range; NSAID, nonsteroidal anti-inflammatory drugs; OCS, oral corticosteroid; PsA, psoriatic arthritis; SpA, spondyloarthritis.

P. Athanassiou et al. Ann Rheum Dis. 2020;79(suppl 1):1275.

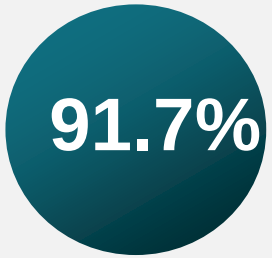
TREATMENT HISTORY AND CHARACTERISTICS

Other GLM Treatment Characteristics

Median (IQR) duration of study participation=11.9 (11.4–12.1) months

Median (IQR) GLM injections received=12 (11–13)

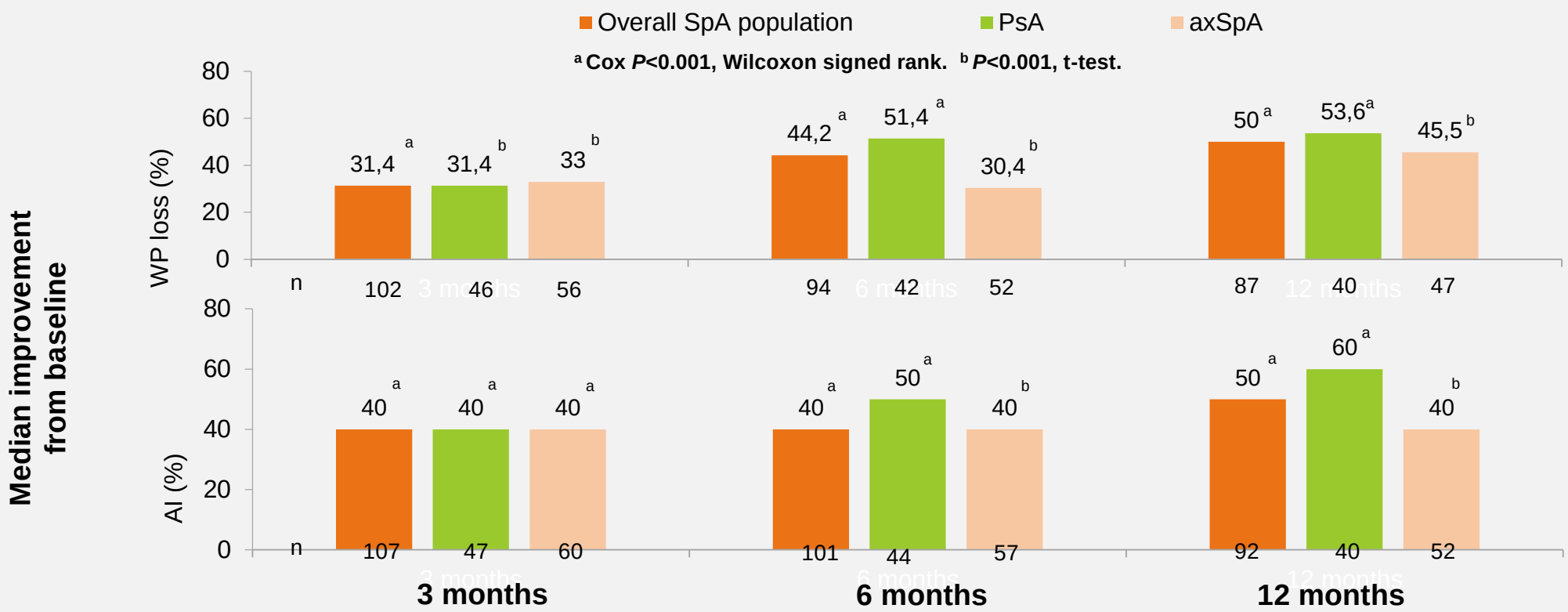
12-month GLM retention rate



P. Athanassiou et al. Ann Rheum Dis. 2020;79 (suppl. 1):1275.

RESULTS: GLM-INDUCED IMPROVEMENTS IN WPAI MEASURES

Improvement in WPAI from baseline: Overall SpA, PsA, and axSpA subpopulation

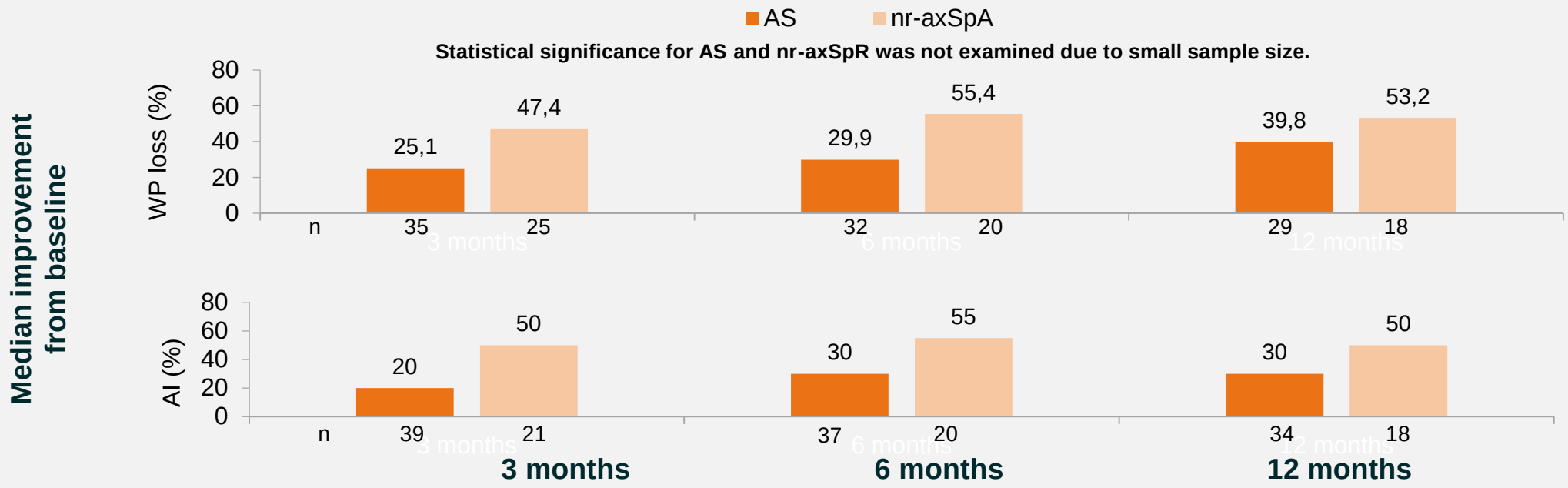


- **In the overall SpA, PsA and axSpA subpopulations, median baseline WP was 70.0%, 70.8%, and 63.5%; AI was 65.0%, 70.0%, and 60.0%, respectively**
- **These values decreased significantly at all post-baseline time points after treatment with GLM**

P. Athanassiou et al. Ann Rheum Dis. 2020;79(suppl 1):1275.

RESULTS: GLM-INDUCED IMPROVEMENTS IN WPAI MEASURES

Improvement in WPAI from baseline: AS and nr-axSpA subpopulations



P. Athanassiou et al. Ann Rheum Dis. 2020;79 (suppl 1):1275.

ΣΥΜΠΕΡΑΣΜΑΤΑ

Στην καθημερινή κλινική πρακτική στην Ελλάδα σε ασθενείς με Σπονδυλοαρθροπάθειες που έλαβαν αγωγή με Golimumab υπήρξε σημαντική αύξηση της παραγωγικότητας στην εργασία ενώ βελτιώθηκαν σημαντικά και οι δείκτες λειτουργικότητας στους 3, 6 και 12 μήνες μετά την έναρξη της θεραπείας.

Κατά την έναρξη της θεραπείας σε σχέση με 3 μήνες μετά:

- **(Απουσία από την εργασία) - Absenteeism: 69.7% vs 46.1%**
- **(Εργασία με συμπτώματα από το υποκείμενο νόσημα)- Presenteeism: 92.3% vs 87.9%**
- **(Απώλεια της παραγωγικότητας στην εργασία)-Work productivity loss: 94.1% vs 87.3%**
- **(Μείωση χρόνου και ποιότητας των καθημερινών δραστηριοτήτων)-Activity impairment: 96.7% vs 88.0%**

P. Athanassiou et al. Ann Rheum Dis. 2020;79 (suppl 1):1275.

GOLIMUMAB IMPROVES QUALITY OF LIFE AND OTHER PATIENT-REPORTED OUTCOMES IN PATIENTS WITH RHEUMATOID ARTHRITIS, IN REAL-WORLD CONDITIONS, THE GO-Q STUDY

Methods

GO-Q was an observational, prospective study conducted in Rheumatology sites throughout Greece

Study Population: 145 patients were enrolled

Adults patients **with moderate to severe active RA** naïve to golimumab.

- Patients previously treated with >1 biologic (b)DMARDs or switching anti-TNFs were excluded.

Duration & data collection time

12 months study.
Data were collected at 3,6 and12 months post Golimumab treatment onset.

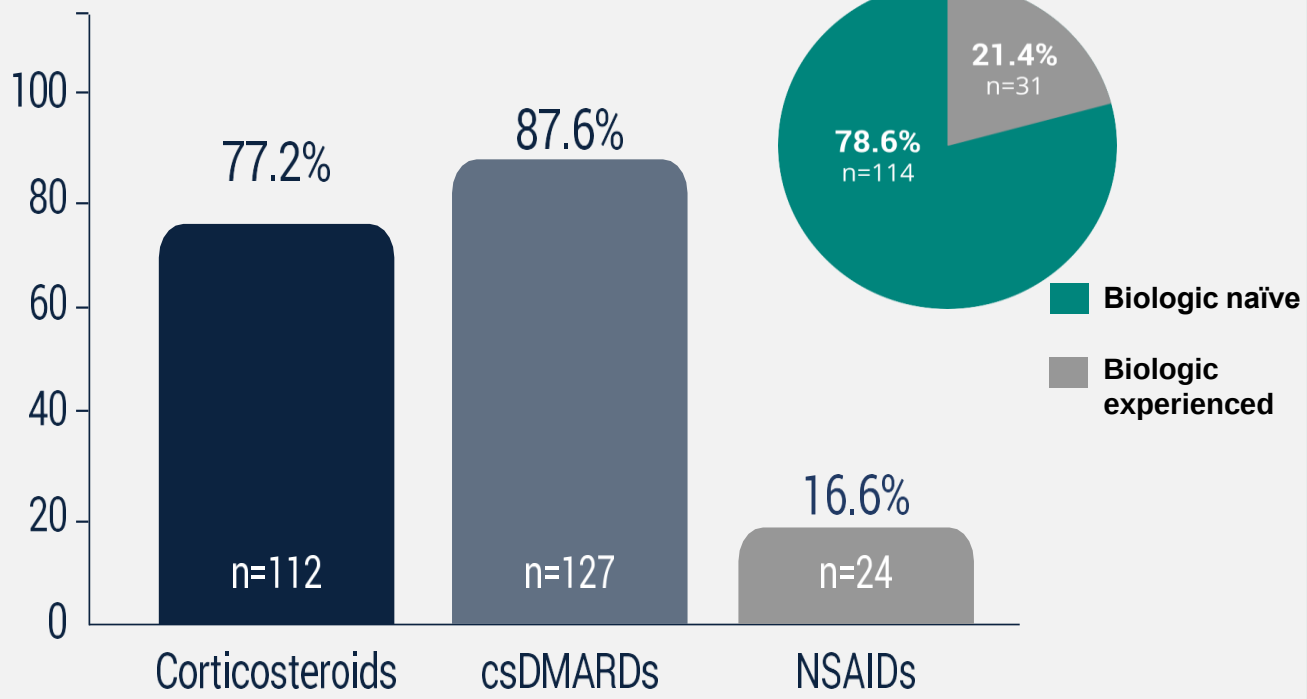
Primary Objective

The impact of golimumab on QoL at 3/6/12 months, by the EQ-5D-3L questionnaire. Non-parametric tests were used for all comparisons.

D. Psaltis, et al . ISPOR Europe 2019

TREATMENT AND PATIENT CHARACTERISTICS AT BASELINE

Treatment at baseline

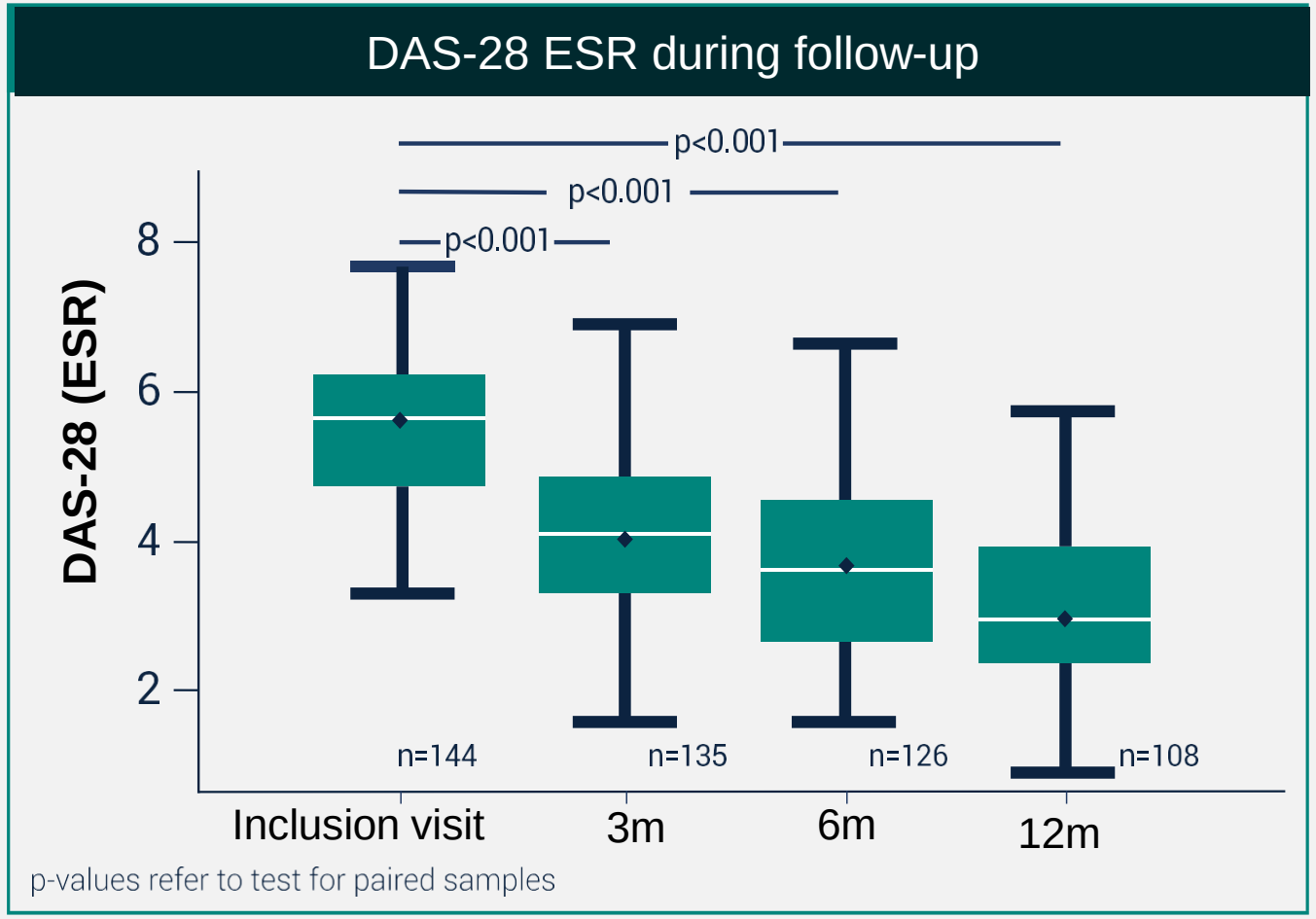


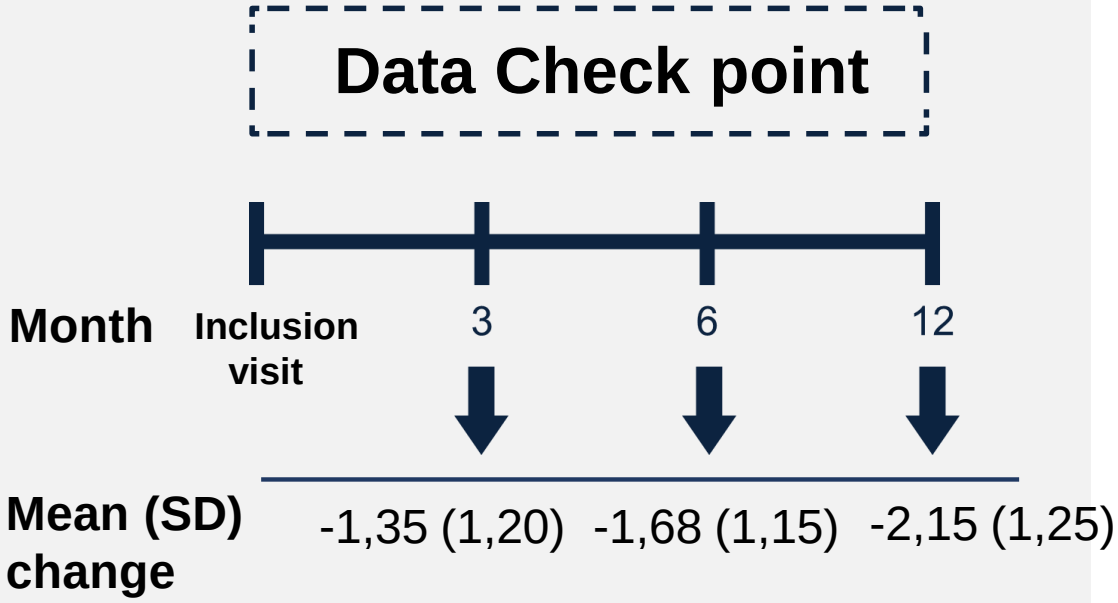
Other Baseline Patient Characteristics

	N	Mean (± sd)
Age (Years)	145	54,6 (12,2)
Disease duration (years)	145	4,6 (5,1)
Gender Female N (%)	116 (80%)	
Duration of previous biologic treatment (in Months)	31	301,2 (40,4)

D. Psaltis, et al . ISPOR Europe 2019

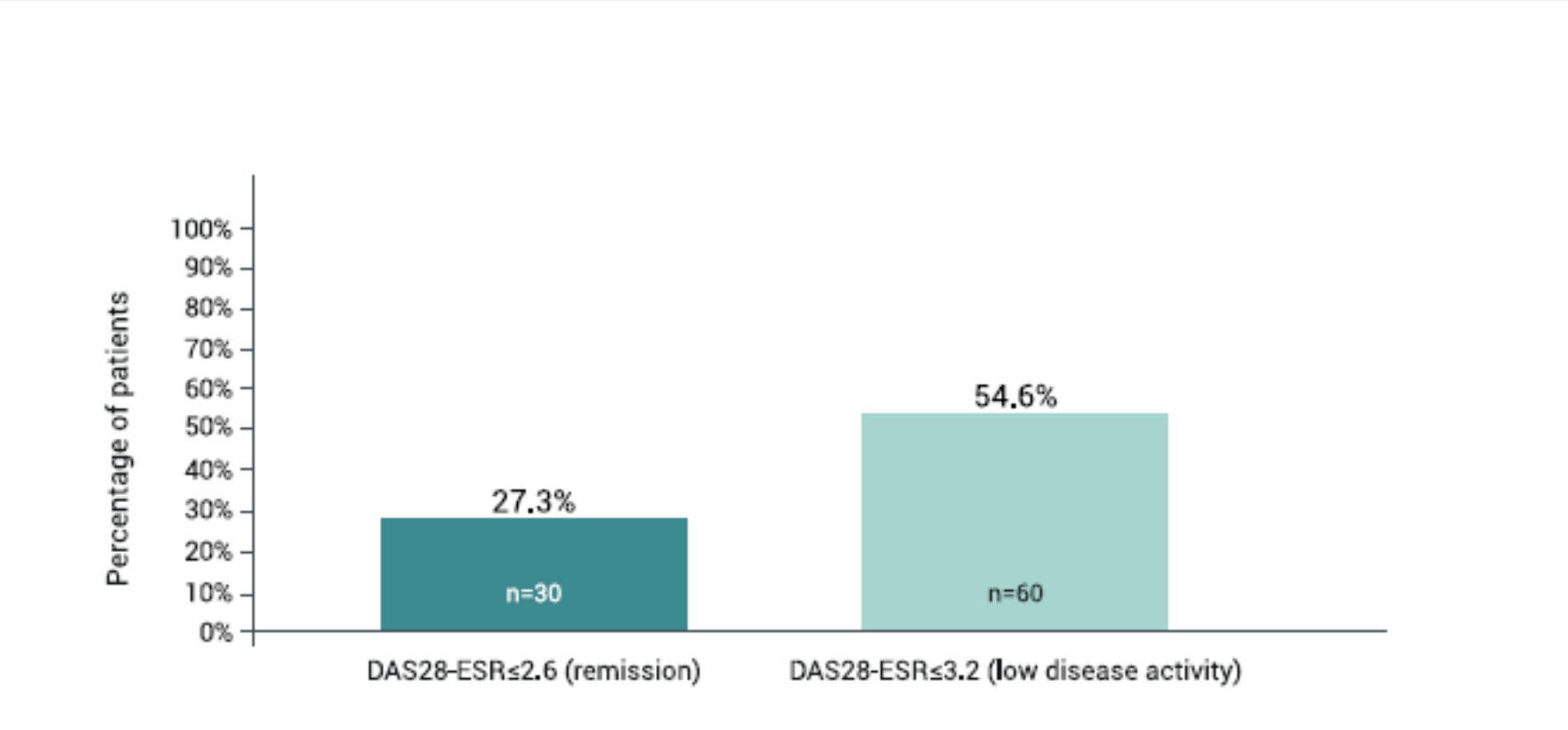
RESULTS: SIGNIFICANT REDUCTIONS IN DISEASE ACTIVITY (DAS-28-ESR)





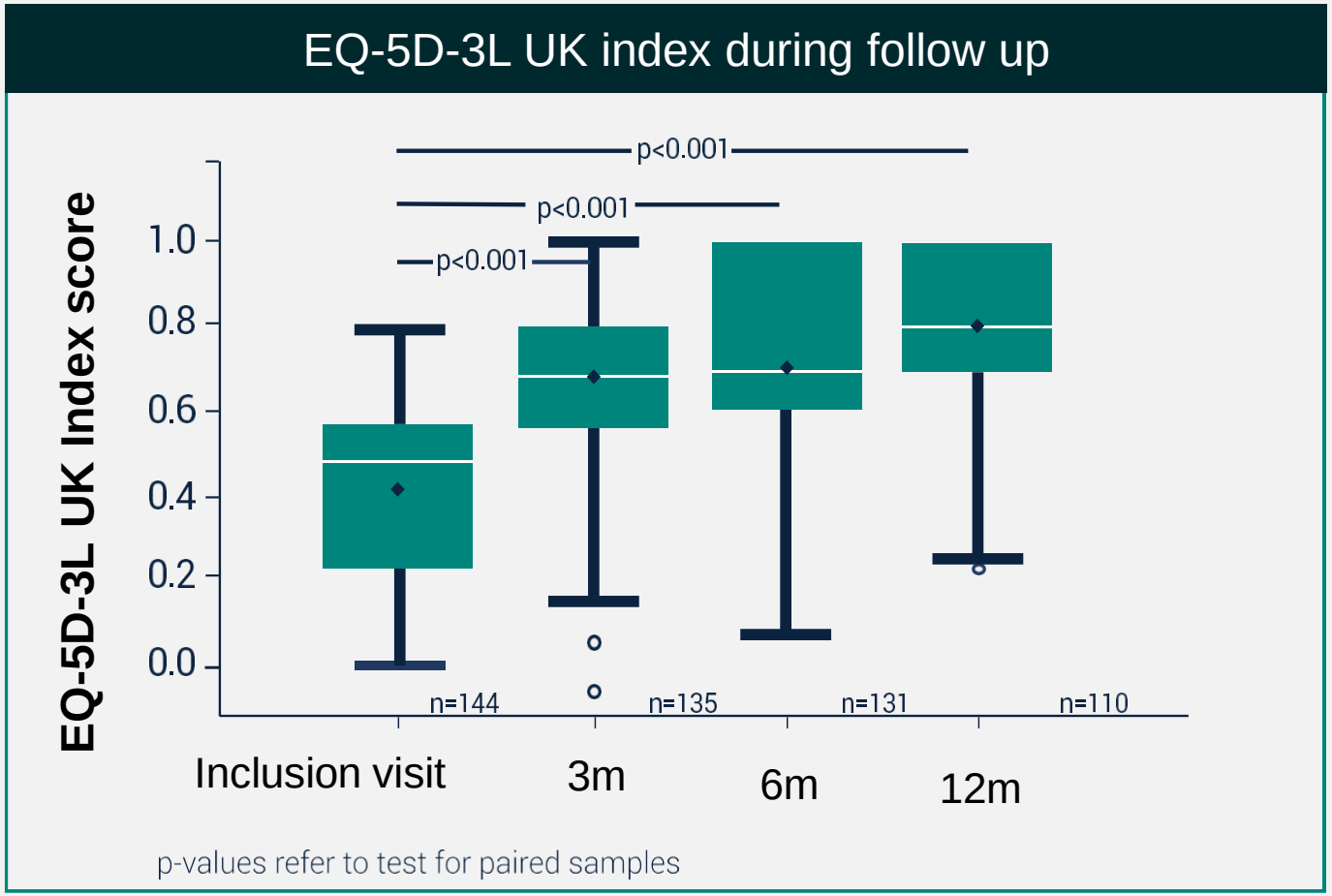
D. Psaltis, et al . ISPOR Europe 2019

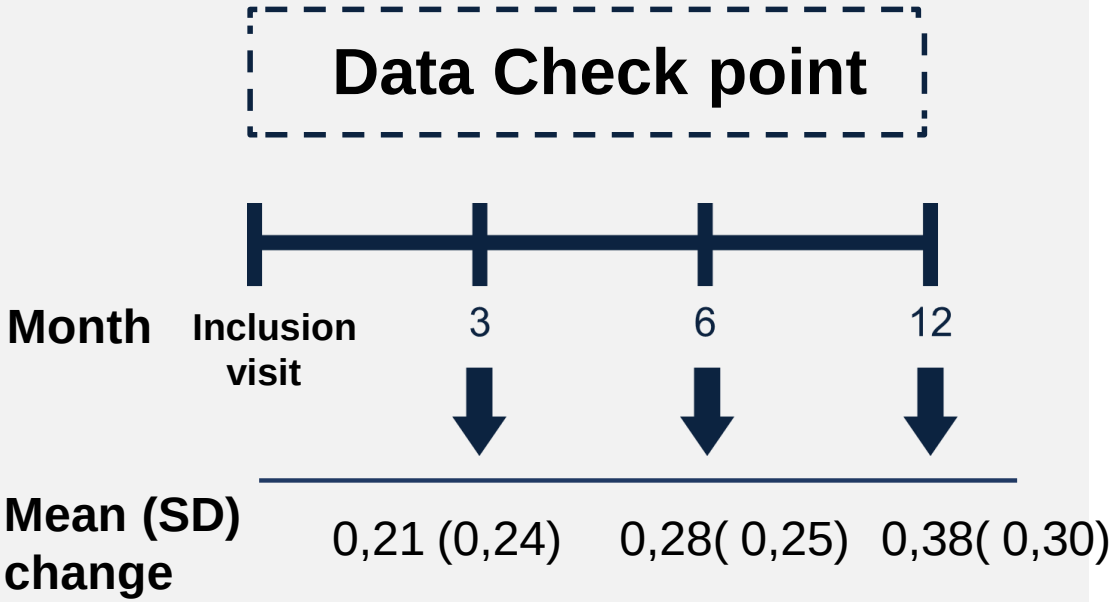
RESULTS: DAS-28 ESR REMISSION & LOW DISEASE ACTIVITY RATE 12 MONTHS AFTER GOLIMUMAB INITIATION (N=108)



D. Psaltis, et al . ISPOR Europe 2019

RESULTS: SIGNIFICANT IMPROVEMENTS IN EQ-5D-3L UK INDEX SCORES

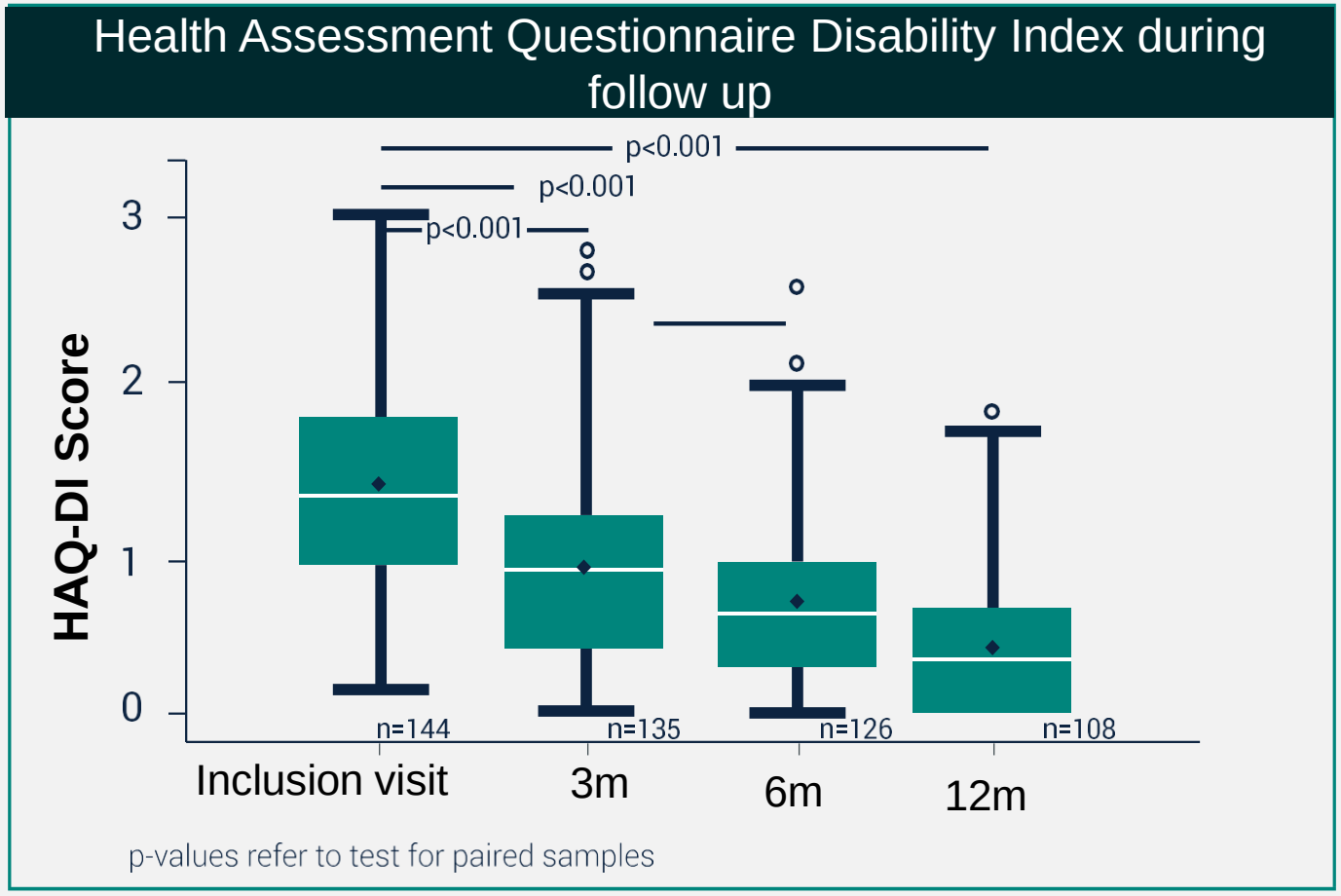


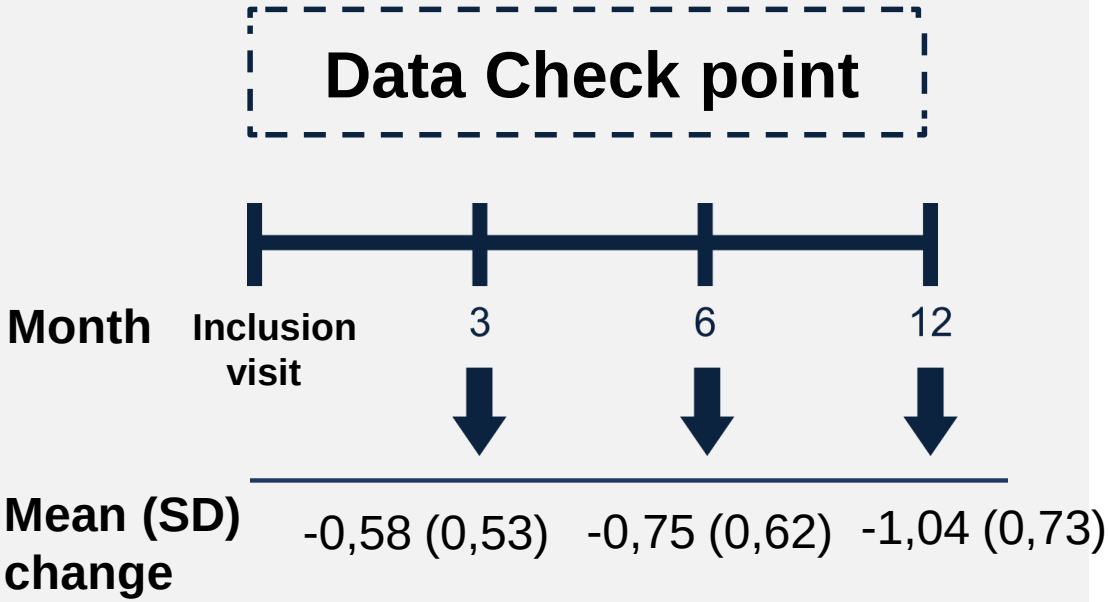


QoL: Quality of life
SD: Standard Deviation

D. Psaltis, et al . ISPOR Europe 2019

RESULTS: SIGNIFICANT REDUCTIONS ON THE BURDEN OF THE DISEASE (HAQ-DI)





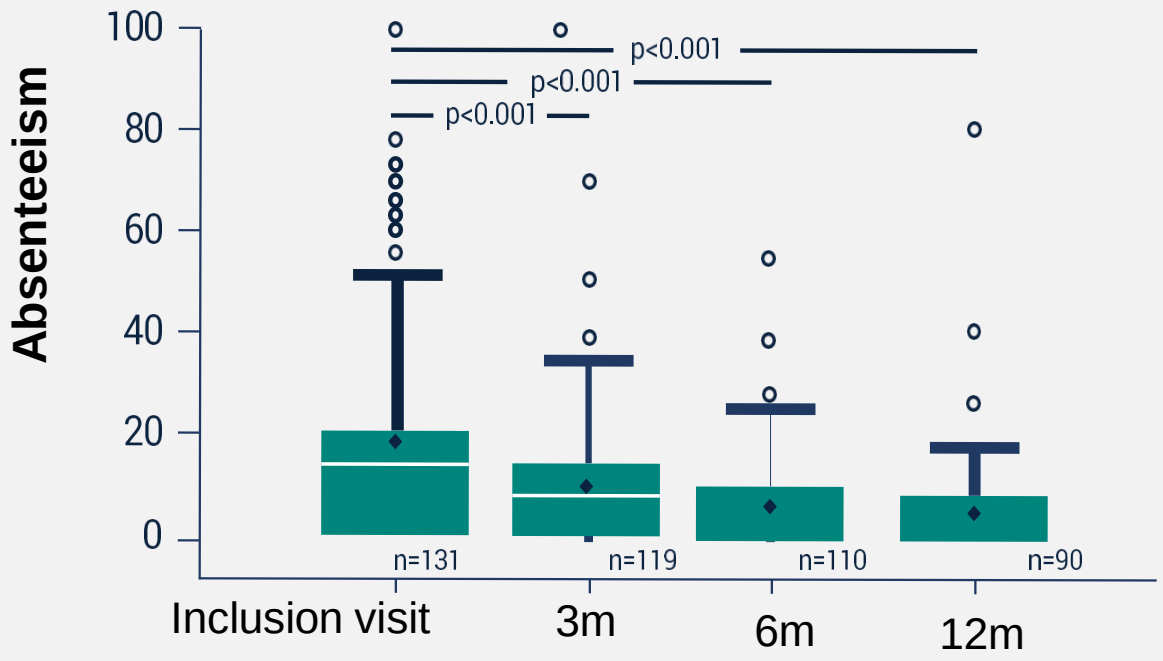
HAQ-DI: Health Assessment Questionnaire-Disability Index
SD: Standard Deviation

D. Psaltis, et al . ISPOR Europe 2019

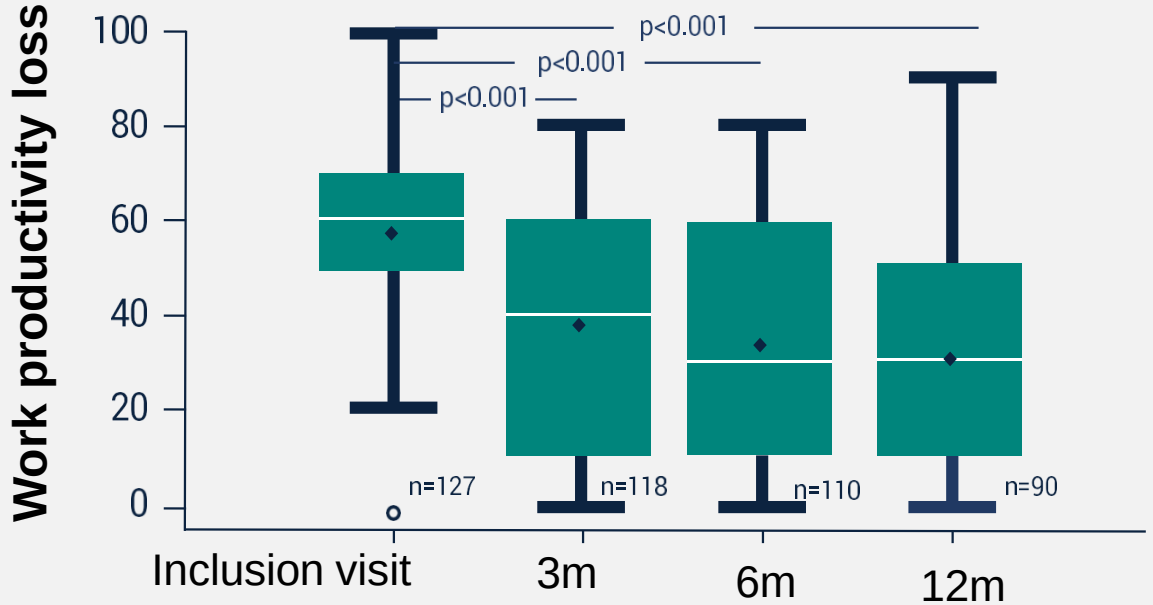
RESULTS: SIGNIFICANT REDUCTIONS IN THE TIME OF ABSENCE FROM WORK (ABSENTEEISM, WPAI) AND WORK PRODUCTIVITY LOSS (OVERALL WORK IMPAIRMENT / ABSENTEEISM PLUS PRESENTEEISM)

WPAI score from baseline to 12m visit

Absenteeism (Work time missed)



Work productivity loss (overall work impairment / absenteeism plus presenteeism)



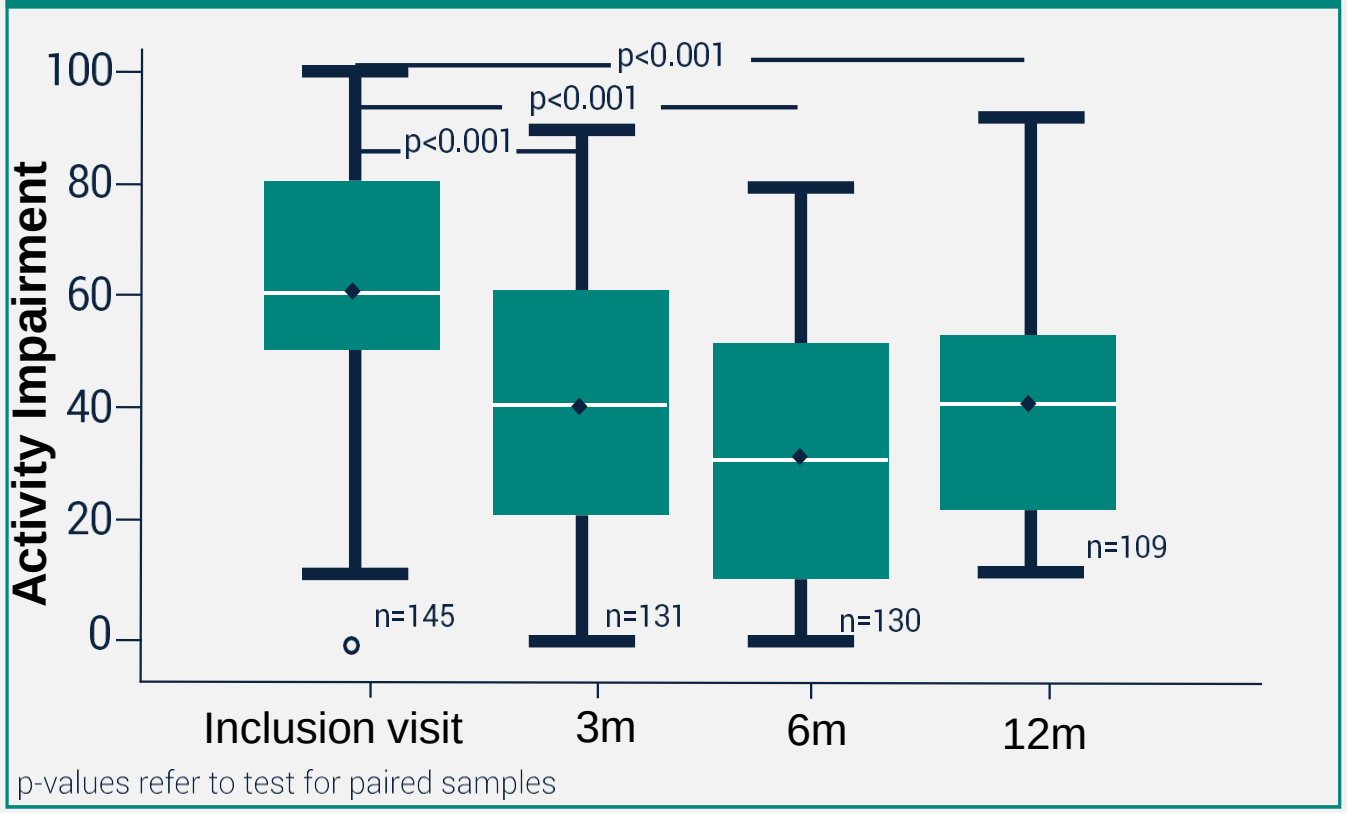
p-values refer to test for paired samples

D. Psaltis, et al . ISPOR Europe 2019

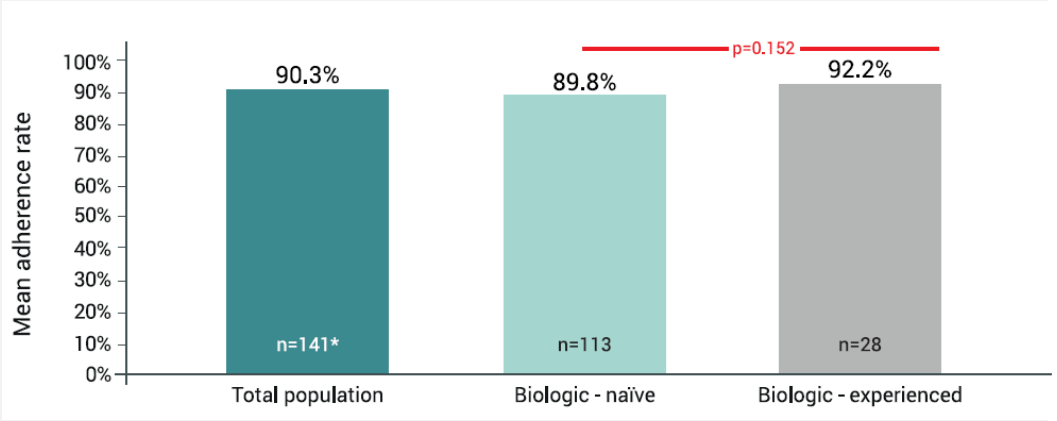
WPAI: Work productivity/activity impairment (Work Productivity and Activity Impairment questionnaire)

RESULTS: SIGNIFICANT REDUCTIONS ON ACTIVITY IMPAIRMENT MEAN ADHERENCE RATE TO GOLIMUMAB OVERALL (N=141*)

WPAI score from baseline to 12m visit - Activity Impairment



Mean adherence rate to golimumab overall (n=141*) and by biologic treatment



*A total of 4 patients were lost to follow-up after the baseline visit and were excluded from this analysis; adherence rate= Total number of injections dispended over the study period/scheduled number of injections

WPAI: Work productivity/activity impairment (Work Productivity and Activity Impairment questionnaire)

D. Psaltis, et al . ISPOR Europe 2019

ΣΥΜΠΕΡΑΣΜΑΤΑ

- **Σε πραγματικές συνθήκες καθημερινής κλινικής πρακτικής στην Ελλάδα οι ασθενείς με Ρευματοειδή Αρθρίτιδα που έλαβαν θεραπεία με Golimumab κατά την περίοδο 12 μηνών παρακολούθησης παρουσίασαν σημαντική βελτίωση στους δείκτες ποιότητας ζωής, λειτουργικότητας ενώ αυξήθηκε και η παραγωγικότητα στην εργασία.**

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- **Η μείωση της ενεργότητας και του συνολικού φορτίου της νόσου παρατηρήθηκε ήδη κατά τους τρείς πρώτους μήνες από την έναρξη της θεραπείας με Golimumab και διατηρήθηκε σε όλη την δωδεκάμηνη διάρκεια παρακολούθησης .**

D. Psaltis, et al . ISPOR Europe 2019

REAL-WORLD GOLIMUMAB EFFECTIVENESS AND IMPACT ON PATIENT-REPORTED OUTCOMES IN PATIENTS WITH RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS OR AXIAL SPONDYLARTHRITIS AND A TREATMENT FAILURE TO PREVIOUS TNFA INHIBITOR THERAPY: THE 'GO-BEYOND' STUDY

Methods

GO-BEYOND was a non-interventional prospective study

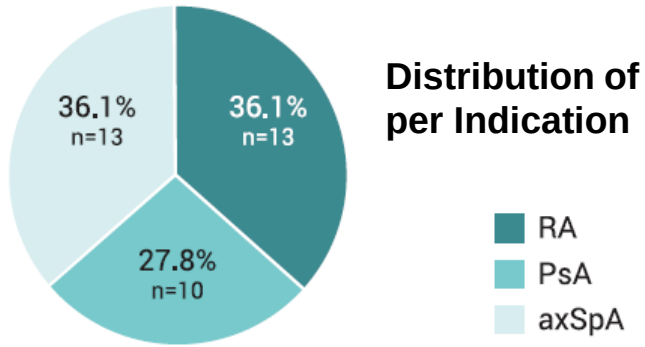
Duration & data collection time

18-month study Data were collected at 3,6 and12 months post Golimumab treatment onset.

INTERIM ANALYSIS presents results for patients who participated in the **study for 6 months** (cut-off date:28/02/2019). Per-indication statistical comparisons were not performed due to small sample size.

Study Population: 36 Patients (RA:13; PsA:10; axSpA:13)

Adult patients with **active RA, PsA or axSpA** and an **inadequate response/intolerability to 1 TNFa inhibitor**, who are considered for golimumab treatment.



Distribution of Patients per Indication

Primary Objective

The proportion of patients attaining:

- low disease activity (LDA) in RA (by Disease Activity Score for 28 joints with C-reactive protein [DAS28-CRP]),
- minimal disease activity (MDA) in PsA (by MDA criteria) and
- moderate disease activity in axSpA (by Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] and inactive disease by Ankylosing Spondylitis Disease Activity Score [ASDAS]), at 6 months.
- **Other objectives include:** Assessment of work productivity/activity impairment and quality of life at 3/6/12/18 months and changes from baseline

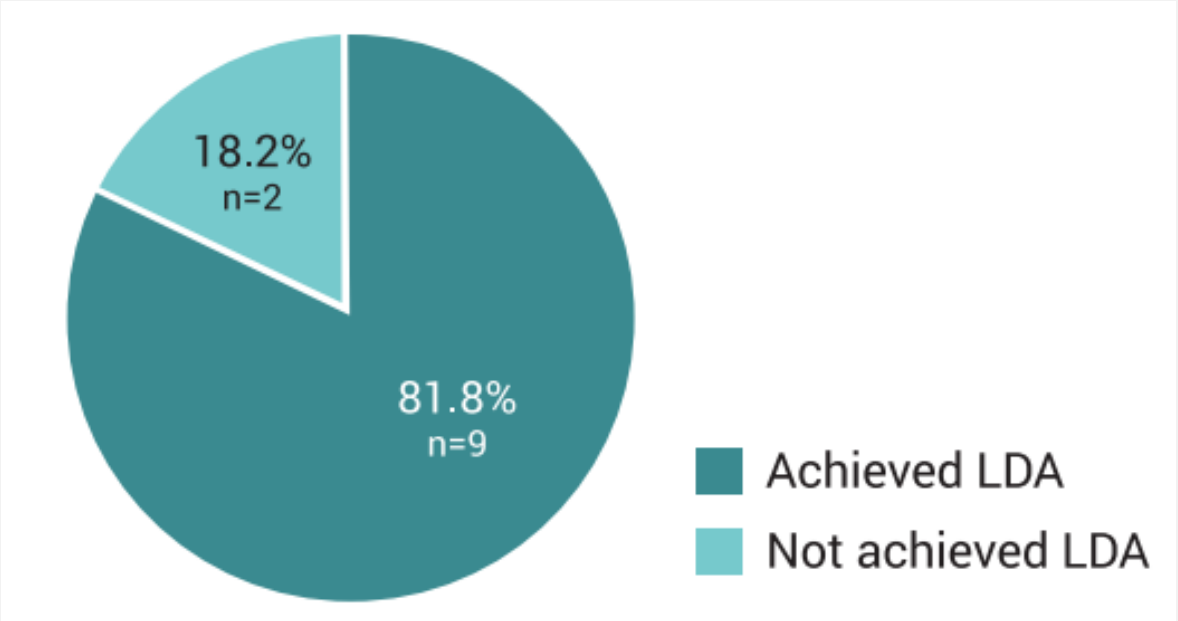
Georgiadis A , et al . ISPOR Europe 2019

RESULTS: MAJORITY OF PATIENTS WITH RA ACHIEVED LDA

RA

~82% of RA patients achieved low disease activity

INTERIM ANALYSIS presents results for patients who participated in the **study for 6 months** (cut-off date:28/02/2019). Per-indication statistical comparisons were not performed due to small sample size.



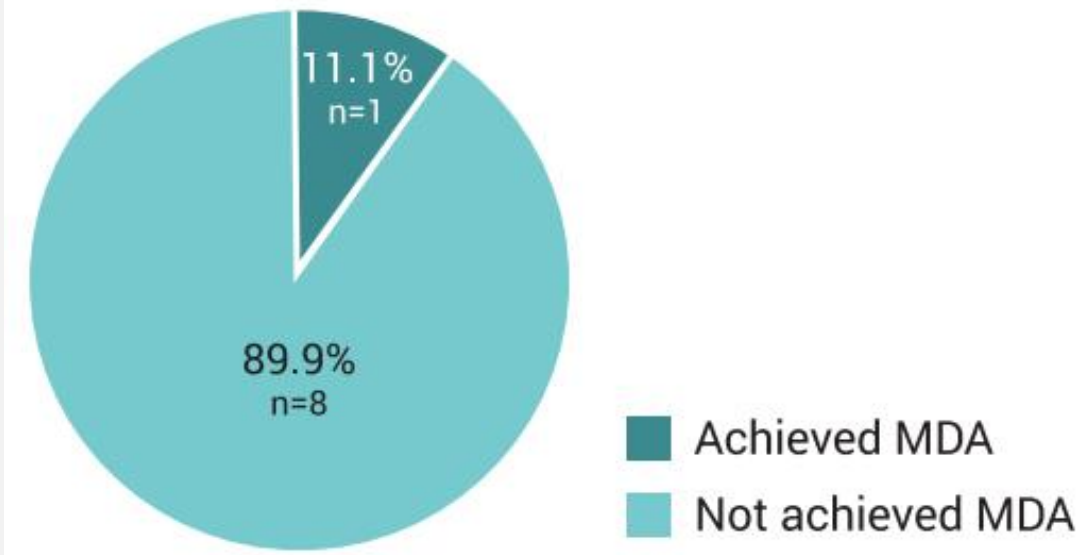
LDA: DAS28-CRP<3.2 after 6 months of treatment
(Baseline: N=13, 6m: N=11)

RESULTS: MORE THAN 10% OF PATIENTS WITH PsA ACHIEVED MDA

INTERIM ANALYSIS presents results for patients who participated in the **study for 6 months** (cut-off date:28/02/2019). Per-indication statistical comparisons were not performed due to small sample size.

PsA

~11 % of PsA patients achieved minimal disease activity



MDA: as per MDA criteria, after 6 months of treatment (Baseline: N=10, 6m: N=9)

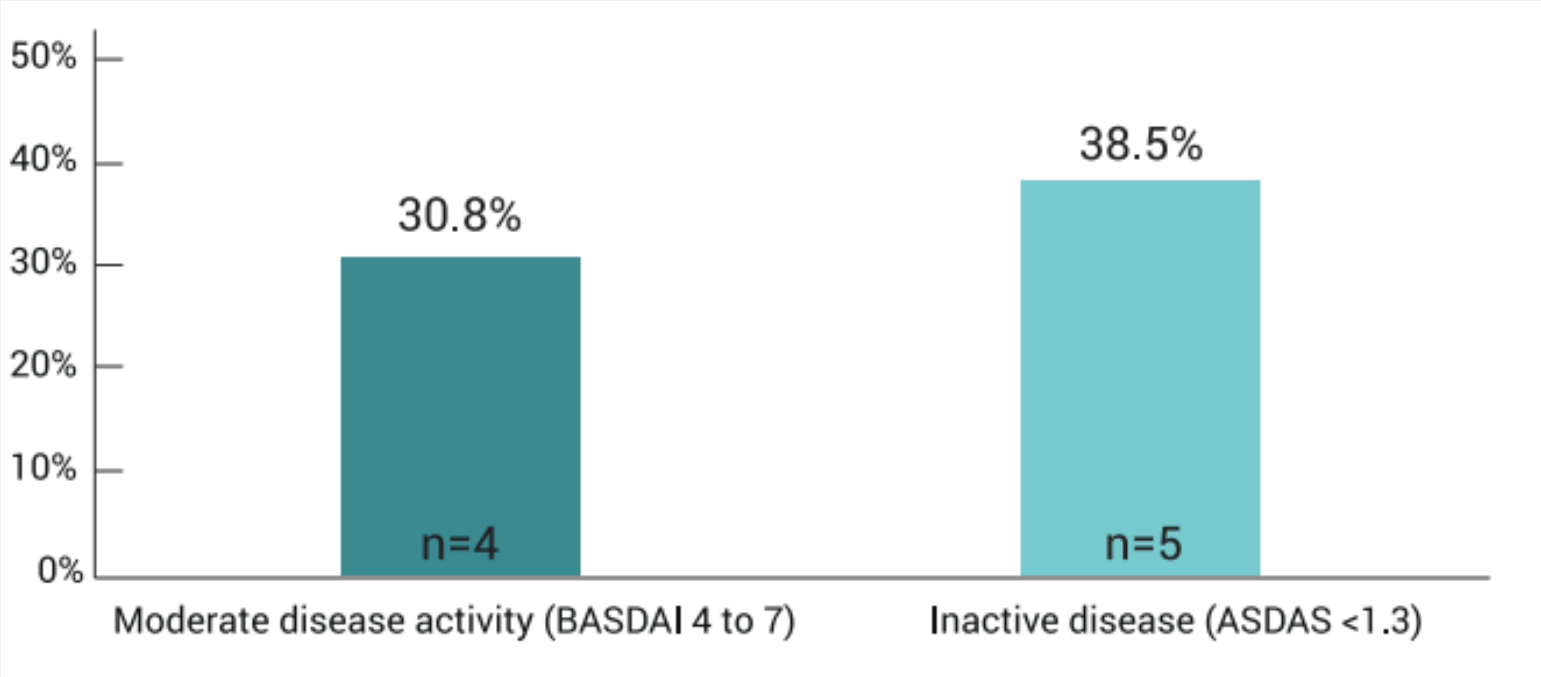
Georgiadis A , et al . ISPOR Europe 2019

RESULTS: MORE THAN 1/3 OF PATIENTS WITH axSpA ACHIEVED MODERATE DISEASE ACTIVITY BY BASDAI AND 38.5% INACTIVE DISEASE BY ASDAS.

axSpA

- ~31 % of axSpA patients achieved moderate disease activity by BASDAI and
- ~39% inactive disease by ASDAS, respectively

INTERIM ANALYSIS presents results for patients who participated in the **study for 6 months** (cut-off date:28/02/2019). Per-indication statistical comparisons were not performed due to small sample size.

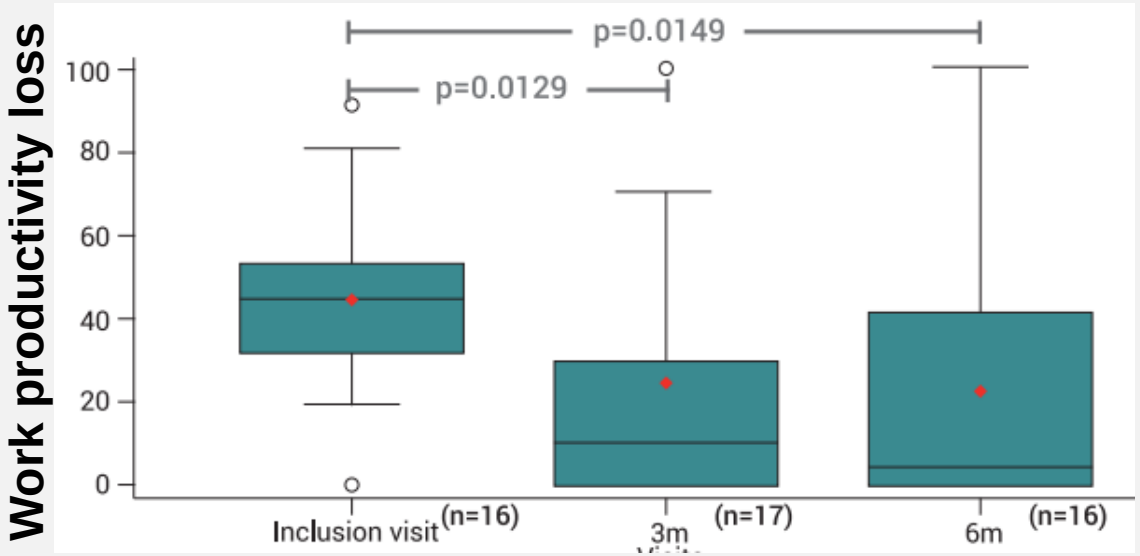


Baseline, 6m: N=13

Georgiadis A , et al . ISPOR Europe 2019

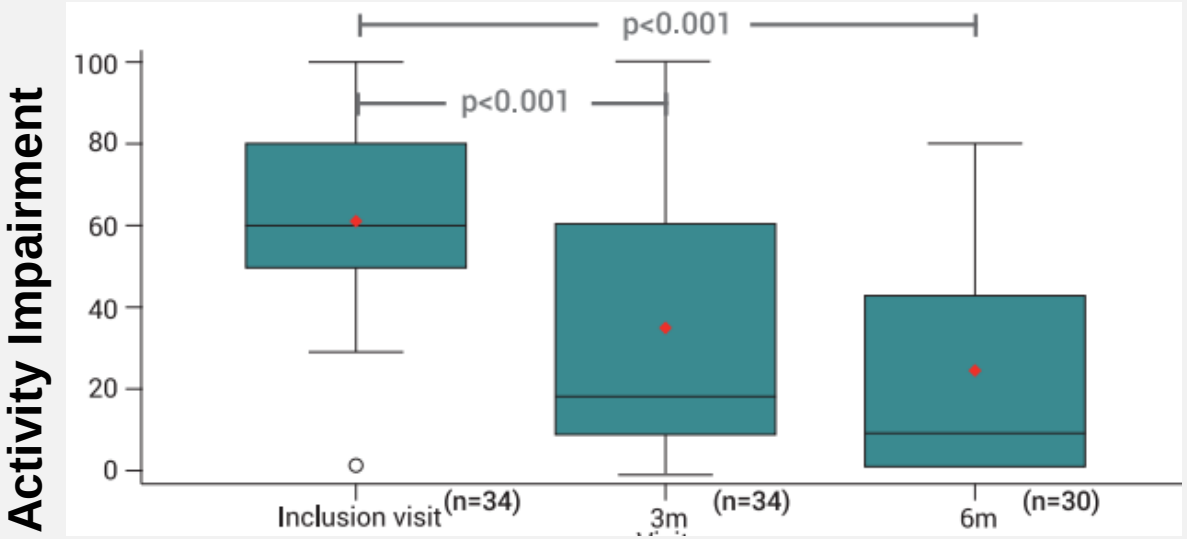
RESULTS: WORK PRODUCTIVITY, ACTIVITY IMPAIRMENT AFTER 6 MONTHS OF GOLIMUMAB TREATMENT

Notable reduction in work productivity loss after 3 and 6 months of treatment compared to baseline



p-values refer to test for paired samples

Notable reduction in activity impairment after 3 and 6 months of treatment compared to baseline

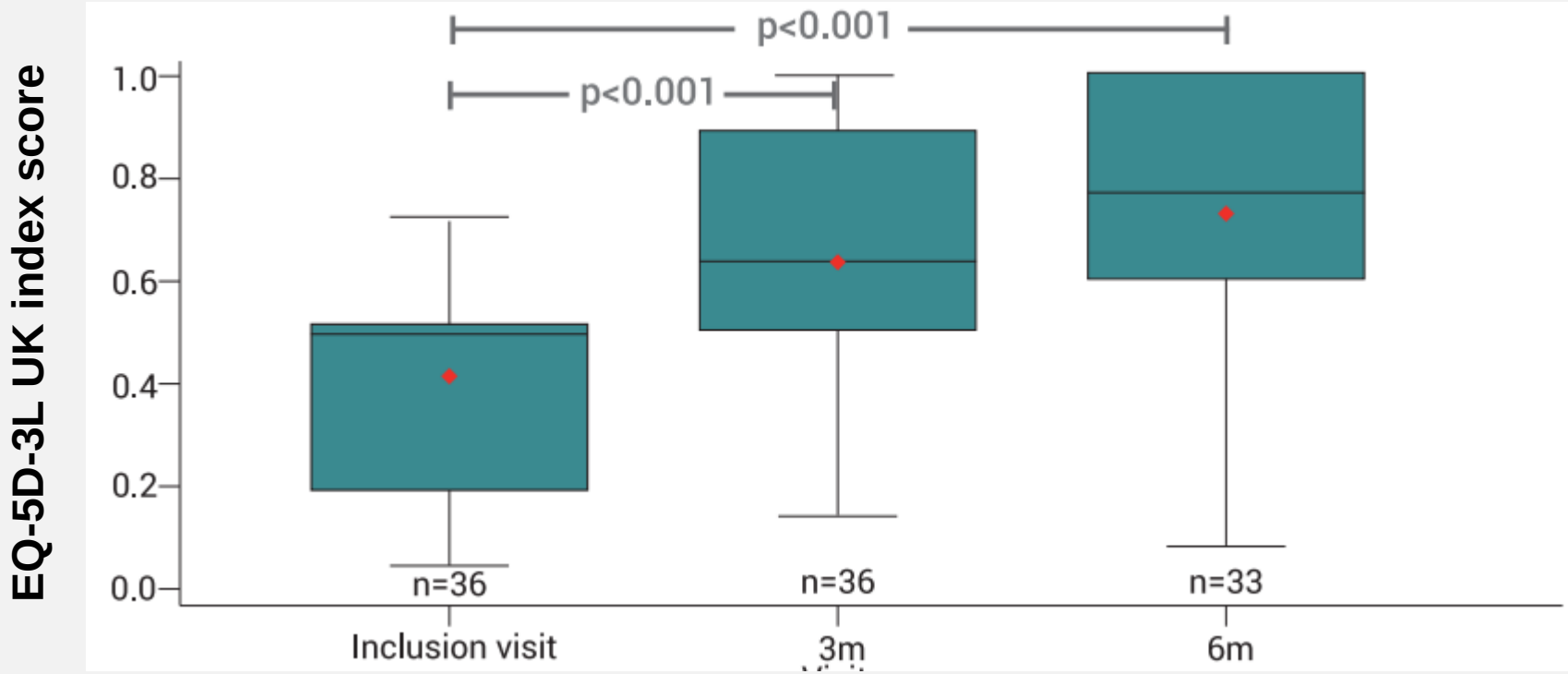


p-values refer to test for paired samples

Georgiadis A , et al . ISPOR Europe 2019

RESULTS: QUALITY OF LIFE AFTER 6 MONTHS OF GOLIMUMAB TREATMENT

Notable improvements in Quality of life by EQ-5D-3L UK index scores after 3 and 6 months of treatment compared to baseline



p-values refer to test for paired samples

Georgiadis A , et al . ISPOR Europe 2019

ΣΥΜΠΕΡΑΣΜΑΤΑ

Στην εσωτερική ανάλυση της μελέτης οι Έλληνες ασθενείς με PA, ΨΑ και Αξονική Σπονδυλοαρθροπάθεια πέτυχαν σημαντική βελτίωση στους δείκτες ποιότητας ζωής και παραγωγικότητας στην εργασία ενώ βελτιώθηκε και η λειτουργικότητα στην καθημερινότητα τους

Η ενεργότητα της νόσου 6 μήνες μετά την έναρξη θεραπείας με Golimumab:

- ~82% από τους ασθενείς με PA πέτυχαν χαμηλή ενεργότητα νόσου
- ~11 % από τους ασθενείς με Ψ.Α πέτυχαν ελάχιστη ενεργότητα νόσου
- ~31 % και ~39% των ασθενών με Αξονική Σπονδυλοαρθροπάθεια πέτυχαν μέτρια ενεργότητα νόσου με τον δείκτη BASDAI και ανενεργή νόσο σύμφωνα με τον δείκτη ASDAS αντίστοιχα.

Τα ευρήματα τις μελέτης υπόκεινται σε περιορισμούς λόγω του μικρού αριθμού ασθενών

Georgiadis A , et al . ISPOR Europe 2019

GOLIMUMAB IMPROVES SOCIO ECONOMIC AND HEALTH ECONOMIC PARAMETERS IN PATIENTS WITH RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, AND ANKYLOSING SPONDYLITIS: THE 'GO-NICE' STUDY

Methods

GO-NICE was a non-interventional prospective study

Duration & data collection time

24-month study Data were collected at 6,12, 18, and 24 months post Golimumab treatment onset.

Study Population: 1458 Patients (RA:474; PsA:501; AS:483)

Parameter	RA ($n=474$)	PsA ($n=501$)	AS ($n=483$)
Demographics			
Age, years	54.9 ± 13.4	50.5 ± 12.1	43.6 ± 12.3
Range	19–82	18–83	18–73
Males, *n* (%)	129 (27.2)	230 (45.9)	321 (66.5)
Body mass index, kg/m^2	26.5 ± 4.9	28.1 ± 5.4	26.7 ± 5.5
Disease characteristics			
Time since first diagnosis, years	10.4 ± 8.9	13.0 ± 11.5	9.8 ± 9.4
At least one concomitant disease, *n* (%)	264 (55.7)	258 (51.5)	203 (42.0)
Patients with extra-articular manifestations, *n* (%)	73 (15.4)	439 (87.8)	163 (33.9)
(Pre-)treatment status			
Biologic-naïve, *n* (%)	305 (64.3)	286 (57.1)	292 (60.5)
Patients currently on NSAIDs, coxibs, analgesics, *n* (%)	258 (54.4)	333 (66.5)	416 (86.2)
Patients currently on basic therapy or immunosuppressants, *n* (%)	407 (85.8)	322 (64.3)	133 (27.6)
Patients currently on syst. Glucocorticoids, *n* (%)	360 (75.9)	206 (41.1)	22 (4.6)

Objective

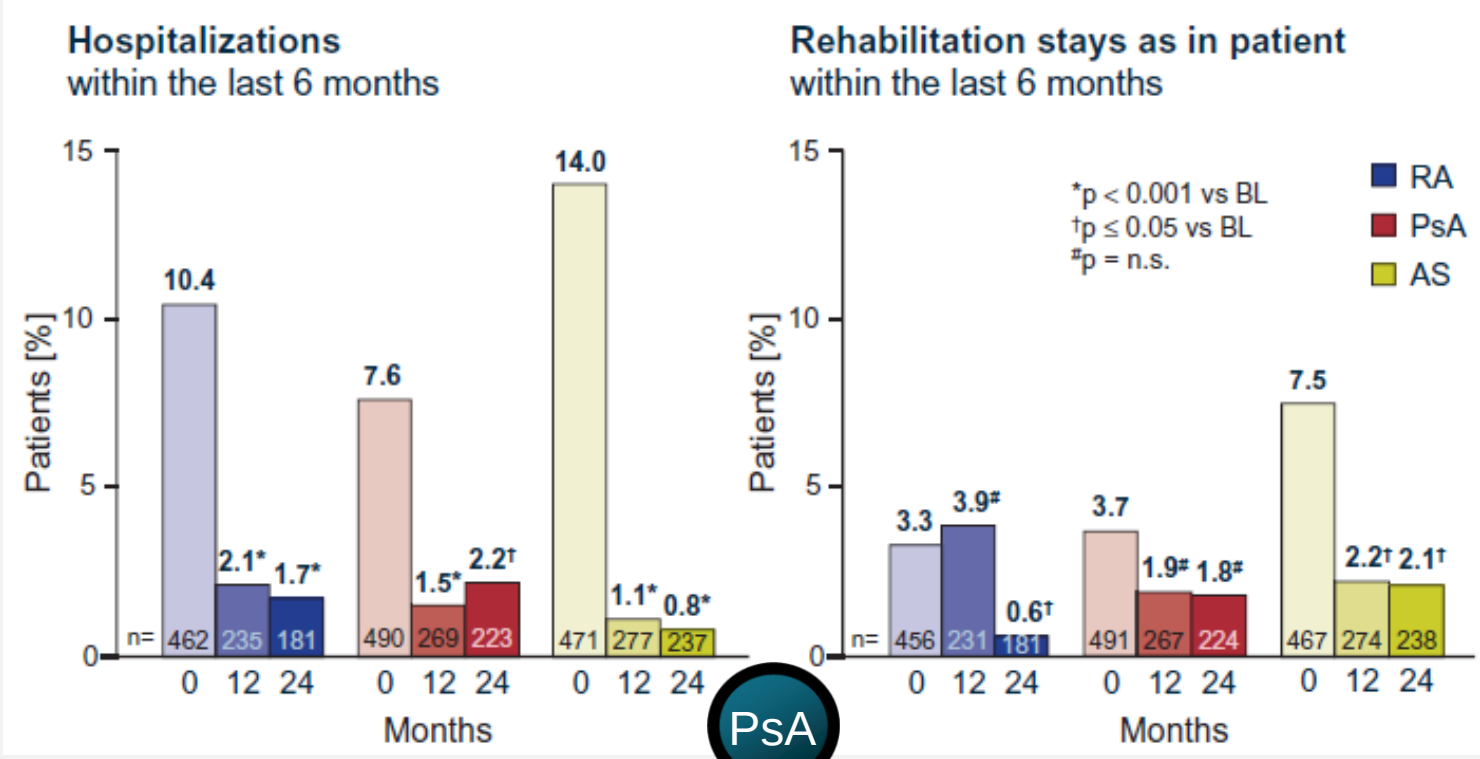
The present analysis based on the data of a prospective observational study assesses the effects of GLM treatment on socio economic and health economic parameters in patients with RA, PsA and AS seen in daily clinical practice.

Klaus Kruger et al Current Medical Research and Opinion (2020).

RESULTS: REDUCTION IN HOSPITALIZATION AND REHABILITATION RATES FOR RA, PSA, AND AS

Klaus Kruger et al Current Medical Research and Opinion (2020).

Proportion of patients undergoing hospitalizations and rehabilitation stays within the last 6 months due to rheumatic diseases in patients with RA, PsA or AS



RA

Hospitalization decreased significantly from 10.4% to 1.7%

Rehabilitation decreased significantly from 3.3% to 0.6%

PsA

Hospitalization decreased significantly from 7.6% to 2.2%

Rehabilitation decreased from 3.7% to 1.8%

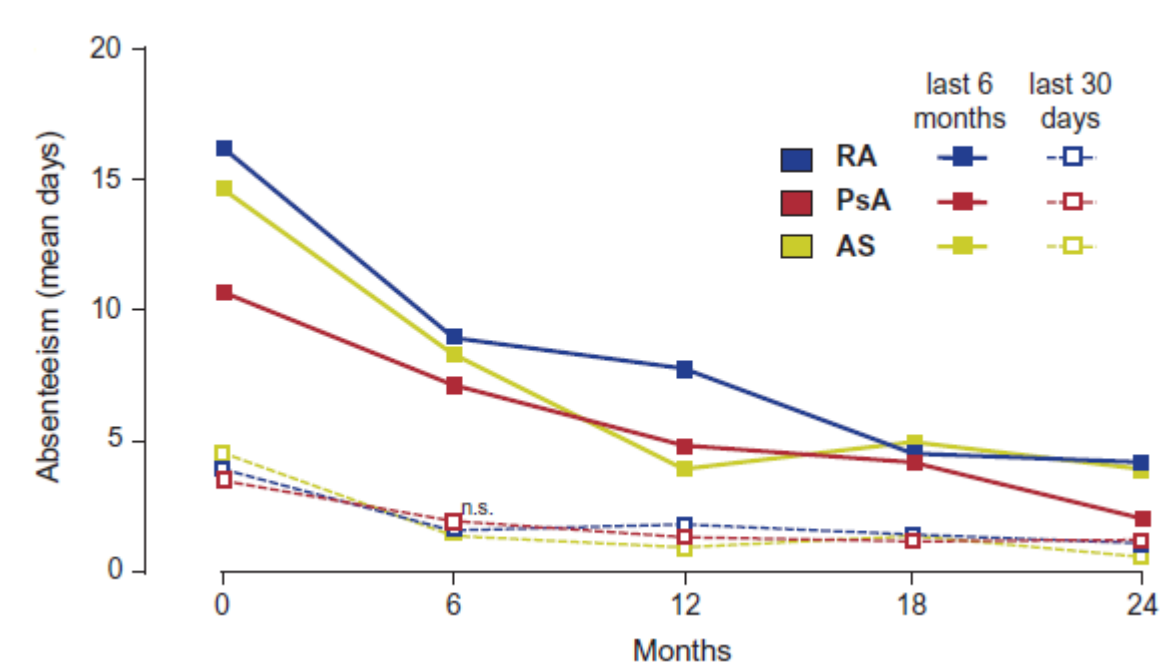
AS

Hospitalization decreased significantly from 14% to 0.8%

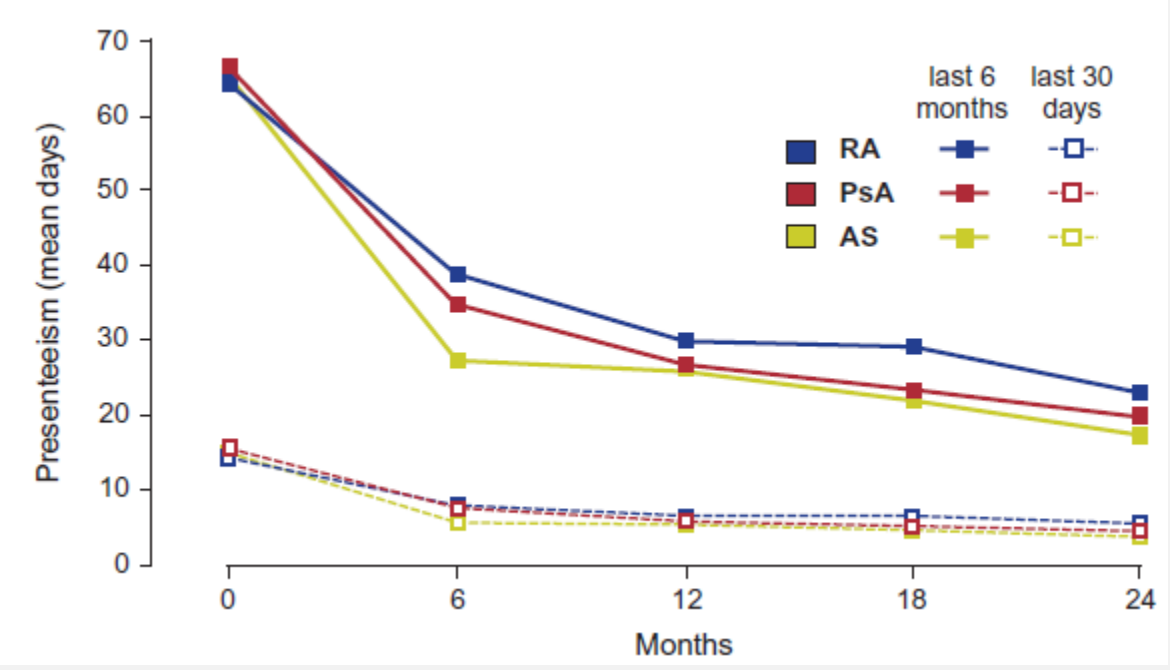
Rehabilitation decreased significantly from 7.5% to 2.1%

RESULTS: ABSENTEEISM AND PRESENTEEISM POST-TREATMENT WITH GOLIMUMAB

Notable reduction in absenteeism post-treatment compared to baseline



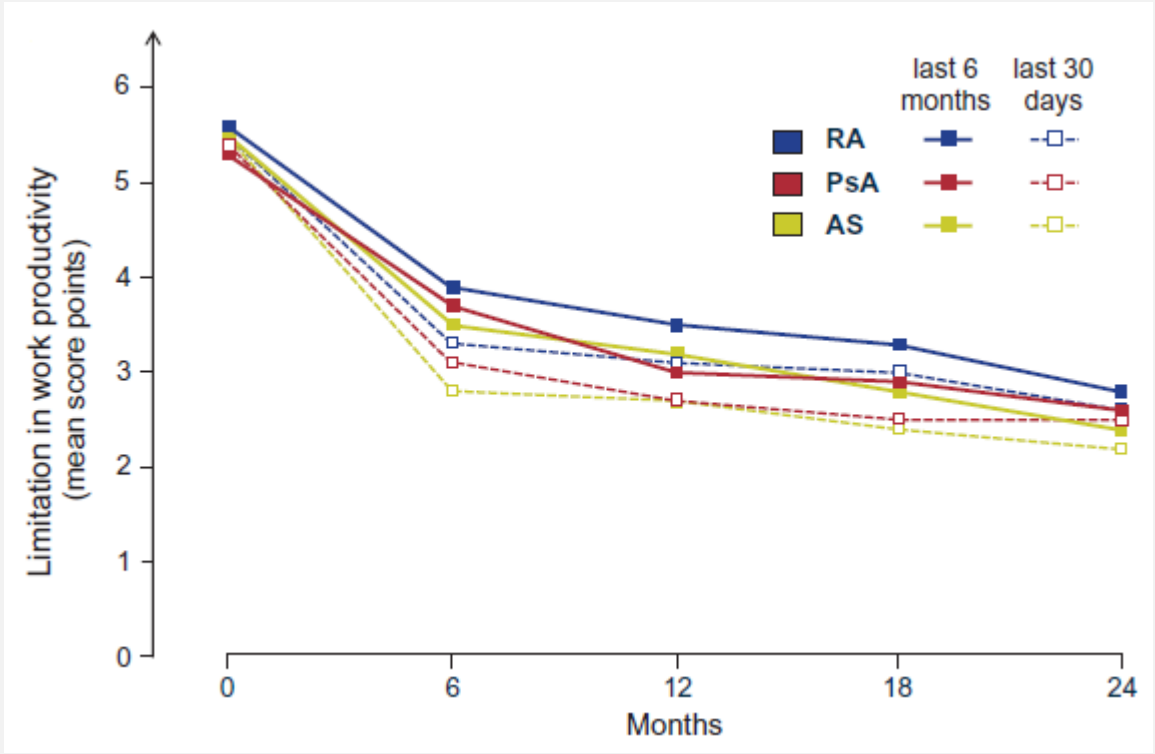
Notable reduction in presenteeism post-treatment compared to baseline



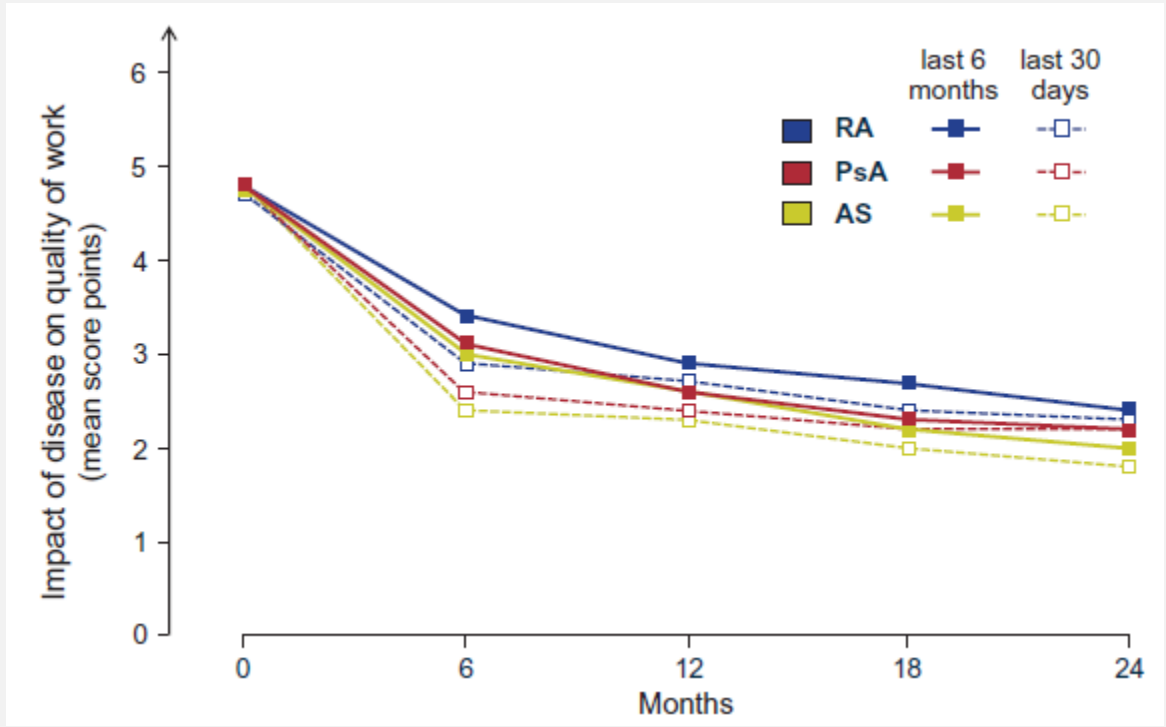
Klaus Kruger et al Current Medical Research and Opinion (2020).

RESULTS: WORK PRODUCTIVITY AND QUALITY OF WORK POST-TREATMENT WITH GOLIMUMAB

Notable reduction in the limitation in work productivity post-treatment compared to baseline



Notable reduction on the impact of disease on quality of work post-treatment compared to baseline



Klaus Kruger et al Current Medical Research and Opinion (2020).

ΣΥΜΠΕΡΑΣΜΑΤΑ

Σε αυτή την ανάλυση οι ασθενείς με ενεργο PA, Ψ.Α και ΑΣ που έλαβαν θεραπεία με Golimumab παρουσίασαν σημαντική μείωση του ποσοστού των νοσηλειών και των εισαγωγών σε τμήματα αποκατάστασης

Στην καθημερινή κλινική πρακτική ασθενείς με PA, ΨΑ και ΑΣ που έλαβαν θεραπεία με Golimumab για 24 μήνες βελτίωσαν σημαντικά την παραγωγικότητα τους στην εργασία, (work productivity) μείωσαν τον χρόνο απουσίας από την εργασία τους (absenteeism) και μείωσαν τον χρόνο παραμονής στην εργασία με συμπτώματα από την υποκείμενη νόσο (presenteeism).

Klaus Kruger et al Current Medical Research and Opinion (2020).

GOLIMUMAB AS THE FIRST-, SECOND-, OR AT LEAST THIRD-LINE BIOLOGIC AGENT IN PATIENTS WITH RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, OR ANKYLOSING SPONDYLITIS: POST HOC ANALYSIS OF A NON INTERVENTIONAL STUDY IN GERMANY THE 'GO-NICE' STUDY

Methods

GO-NICE was a non-interventional prospective study

Duration & data collection time

24-month study Data were collected every 3 months post Golimumab treatment onset.

Objective

The aim of this post hoc analysis was to assess the effectiveness of GLM used as a first-, second-, or at least third-line biologic agent in RA, PsA, and AS in a real-world setting.

Baseline characteristics of the RA, PsA, and AS patients by line of treatment

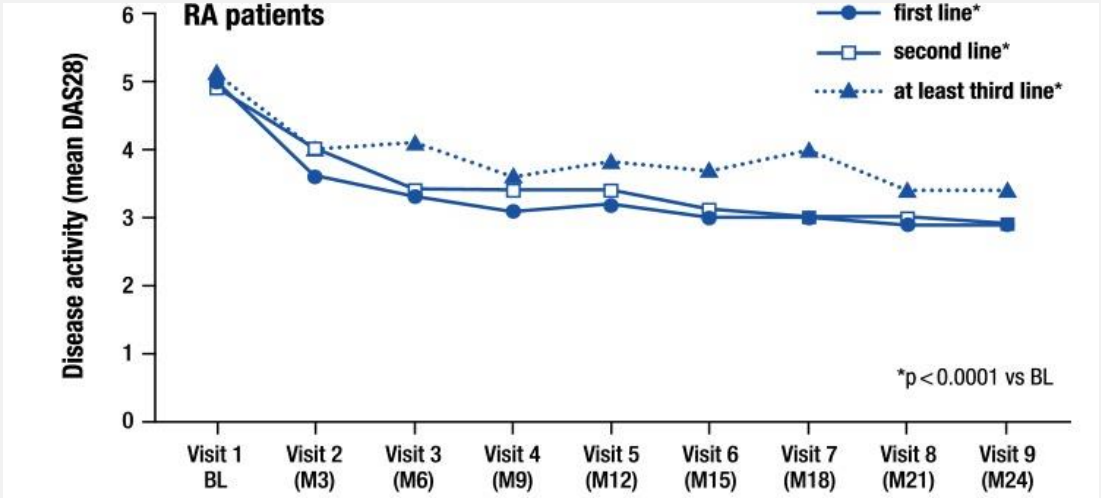
Characteristic	Line of treatment	RA n = 473 (100.0%)	PsA n = 501 (100.0%)	AS n = 480 (100.0%)
Number of patients	1st line	305 (64.5%)	286 (57.0%)	292 (60.8%)
	2nd line	104 (22.0%)	136 (27.1%)	130 (27.1%)
	At least 3rd line	64 (13.5%)	79 (15.8%)	58 (85.3%)
Completers (24 months of treatment, 9 visits)	1st line	131 (40.6%)	152 (50.3%)	157 (49.1%)
	2nd line	32 (27.8%)	52 (35.4%)	64 (44.8%)
	At least 3rd line	25 (34.2%)	27 (30.3%)	24 (35.3%)
Mean age, years (range)	1st line	55.0 ± 13.6 (20–82)	50.0 ± 12.4	42.5 ± 12.4
	2nd line	55.7 ± 13.1 (20–81)	50.7 ± 11.9	45.3 ± 12.3
	At least 3rd line	53.4 ± 13.0 (19–79)	50.7 ± 11.5	44.8 ± 11.2
Proportion of males	1st line	86 (28.2%)	131 (45.8%)	207 (70.9%)
	2nd line	30 (28.8%)	70 (51.5%)	82 (63.1%)
	At least 3rd line	13 (20.3%)	29 (36.7%)	31 (53.4%)
Mean body mass index, kg/m^2 (range)	1st line	26.3 ± 4.7 (17.0–61.3)	27.8 ± 5.3 (16.7–48.5)	26.7 ± 5.0 (18.2–56.1)
	2nd line	27.3 ± 5.4 (20.3–53.1)	28.6 ± 5.7 (15.6–55.4)	26.6 ± 4.6 (18.0–42.6)
	At least 3rd line	26.3 ± 4.8 (17.6–39.6)	28.3 ± 5.4 (17.6–42.9)	27.2 ± 6.0 (16.4–48.4)
Employed full-time or part-time	1st line	142 (46.7%)	172 (61.4%)	219 (75.3%)
	2nd line	48 (46.1%)	66 (48.9%)	78 (60.0%)
	At least 3rd line	26 (40.6%)	40 (50.7%)	37 (63.8%)
Time since first diagnosis, years (range)	1st line	9.7 ± 8.7 (0.3–59.3)	12.4 ± 12.0 (0.1–62.0)	9.4 ± 9.7 (0.0–49.2)
	2nd line	10.1 ± 8.4 (0.7–48.6)	13.7 ± 11.0 (0.3–56.9)	9.8 ± 8.6 (0.5–47.1)
	At least 3rd line	14.3 ± 10.0 (1.5–43.6)	13.8 ± 10.3 (0.1–43.8)	12.4 ± 9.3 (1.2–48.7)
Rheumatoid factor positive (RF +)	1st line	233 (76.9%)		
	2nd line	73 (70.2%)		
	At least 3rd line	38 (59.4%)		
CCP antibody positive (ccp +)	1st line	230 (76.2%)		
	2nd line	80 (78.4%)		
	At least 3rd line	36 (59.0%)		

Study Population: 1454 Patients
(RA:473; PsA:501; AS:480)

Klaus Kruger,et al .Rheumatol Ther (2020).

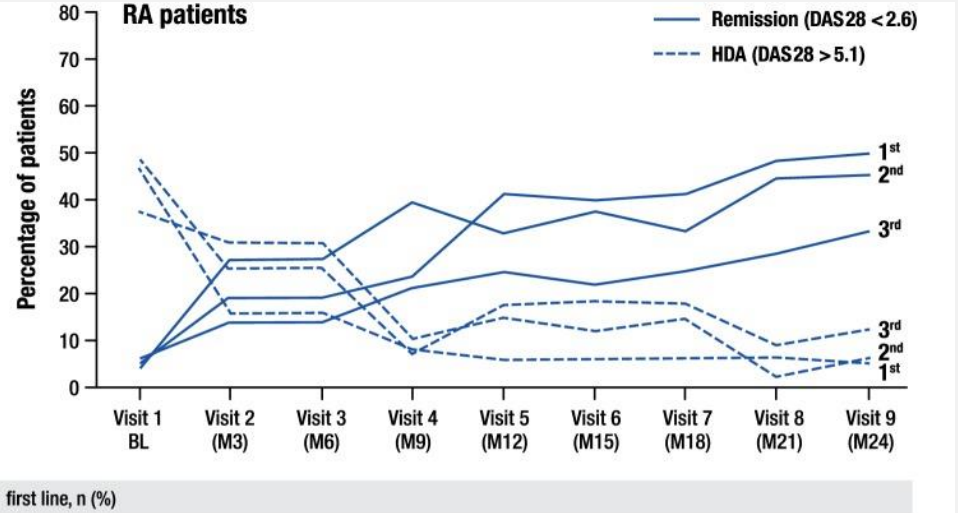
RESULTS: DISEASE ACTIVITY POST-TREATMENT WITH GOLIMUMAB ACROSS ALL LINES IN RA

Notable reduction in disease activity post-treatment across all lines compared to baseline in RA



	Visit 1 BL	Visit 2 (M3)	Visit 3 (M6)	Visit 4 (M9)	Visit 5 (M12)	Visit 6 (M15)	Visit 7 (M18)	Visit 8 (M21)	Visit 9 (M24)
first line									
mean DAS28 ± SD	5.0±1.3	3.6±1.5	3.3*±1.4	3.1±1.3	3.2±1.3	3.0±1.3	3.0±1.3	2.9±1.3	2.9±1.3
n	303	255	206	179	168	148	130	130	128
second line									
mean DAS28 ± SD	4.9±1.3	4.0±1.5	3.4±1.5	3.4±1.2	3.4±1.6	3.1±1.3	3.0±1.3	3.0±1.2	2.9±1.3
n	104	87	57	46	46	40	32	35	32
at least third line									
mean DAS28 ± SD	5.1±1.5	4.0±1.7	4.1±1.7	3.6±1.3	3.8±1.4	3.7±1.7	4.0±1.6	3.4±1.5	3.4±1.5
n	64	55	46	37	28	27	23	21	24

Notable reduction in HDA post-treatment across all lines compared to baseline in RA

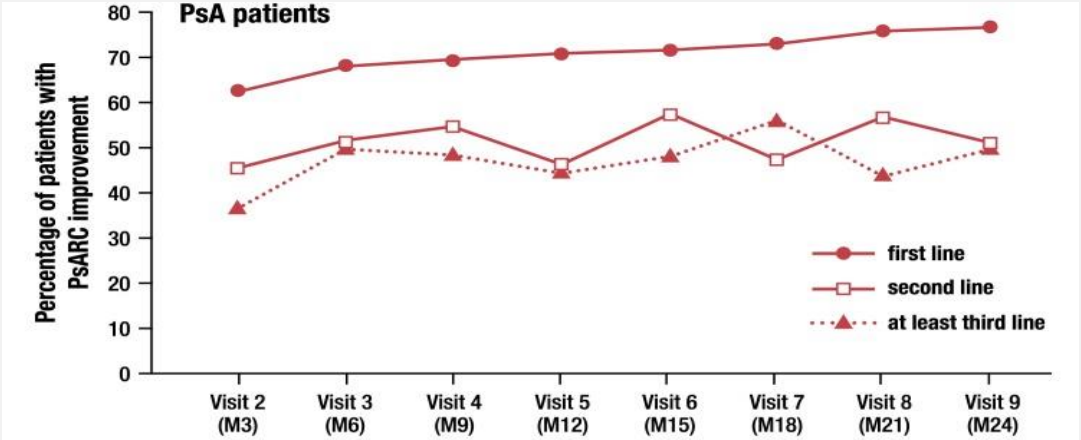


	Visit 1 BL	Visit 2 (M3)	Visit 3 (M6)	Visit 4 (M9)	Visit 5 (M12)	Visit 6 (M15)	Visit 7 (M18)	Visit 8 (M21)	Visit 9 (M24)
first line, n (%)									
HDA	142 (46.9%)	41 (16.1%)	41 (16.1%)	15 (8.4%)	11 (6.5%)	10 (6.8%)	11 (6.5%)	9 (6.9%)	7 (5.5%)
Remission	14 (4.6%)	70 (27.5%)	70 (27.5%)	71 (39.7%)	56 (33.3%)	56 (37.8%)	56 (33.3%)	58 (44.6%)	58 (45.3%)
second line, n (%)									
HDA	39 (37.5%)	27 (31.0%)	27 (31.0%)	5 (10.9%)	7 (15.2%)	5 (12.5%)	7 (15.2%)	1 (2.9%)	2 (6.3%)
Remission	5 (4.8%)	17 (19.5%)	17 (19.5%)	11 (23.9%)	19 (41.3%)	16 (40.0%)	19 (41.3%)	17 (48.6%)	16 (50.0%)
at least third line, n (%)									
HDA	31 (48.4%)	14 (25.5%)	14 (25.5%)	3 (8.1%)	5 (17.9%)	5 (18.5%)	5 (17.9%)	2 (9.5%)	3 (12.5%)
Remission	4 (6.3%)	8 (14.5%)	8 (14.5%)	8 (21.6%)	7 (25.0%)	6 (22.2%)	7 (25.0%)	6 (28.6%)	8 (33.3%)

Klaus Kruger,et al .Rheumatol Ther (2020).

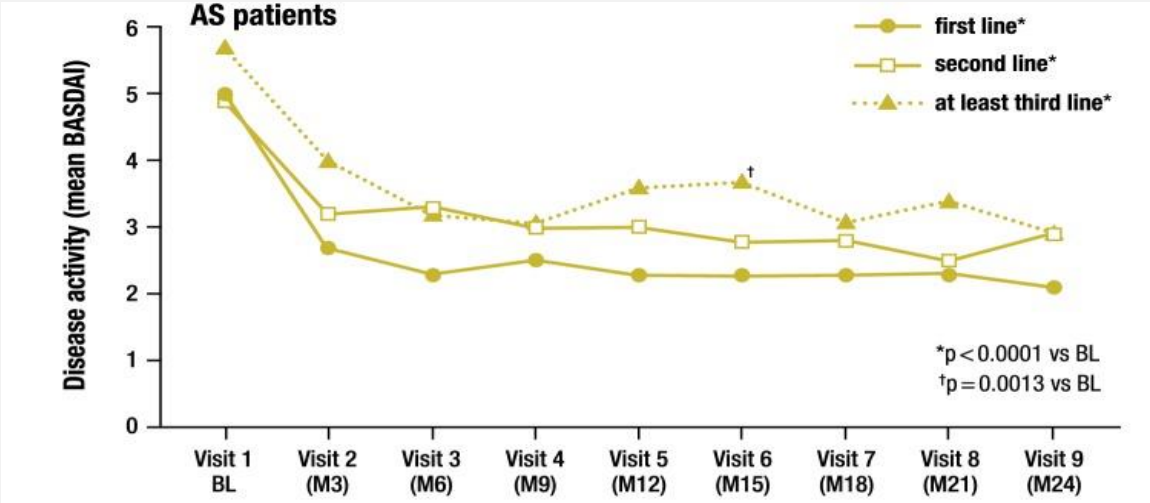
RESULTS: DISEASE ACTIVITY POST-TREATMENT WITH GOLIMUMAB ACROSS ALL LINES IN PSA AND AS

Notable increase in the % of PsA patients who responded post-treatment across all lines



	Visit 2 (M3)	Visit 3 (M6)	Visit 4 (M9)	Visit 5 (M12)	Visit 6 (M15)	Visit 7 (M18)	Visit 8 (M21)	Visit 9 (M24)
first line								
n	230	194	175	162	152	156	149	148
PsARC improvement yes, n (%)	144 (62.6%)	132 (68.0%)	121 (69.1%)	115 (71.0%)	109 (71.7%)	114 (73.1%)	113 (75.8%)	113 (76.4%)
second line								
n	99	82	73	67	56	55	44	49
PsARC improvement yes, n (%)	45 (45.5%)	42 (51.2%)	40 (54.8%)	31 (46.3%)	32 (57.1%)	26 (47.3%)	25 (56.8%)	25 (51.0%)
at least third line								
n	65	50	43	36	33	25	25	24
PsARC improvement yes, n (%)	24 (36.9%)	25 (50.0%)	21 (48.8%)	16 (44.4%)	16 (48.5%)	14 (56.0%)	11 (44.0%)	12 (50.0%)

Notable reduction in disease activity post-treatment across all lines compared to baseline in AS



	Visit 1 BL	Visit 2 (M3)	Visit 3 (M6)	Visit 4 (M9)	Visit 5 (M12)	Visit 6 (M15)	Visit 7 (M18)	Visit 8 (M21)	Visit 9 (M24)
first line									
mean BASDAI ± SD	5.0 ± 2.0	2.7 ± 2.0	2.3 ± 2.9	2.5 ± 1.9	2.3 ± 1.9	2.3 ± 1.9	2.3 ± 1.8	2.3 ± 1.8	2.1 ± 1.8
n	290	261	216	183	187	173	154	151	157
second line									
mean BASDAI ± SD	4.9 ± 2.0	3.2 ± 2.0	3.3 ± 2.2	3.0 ± 2.1	3.0 ± 2.2	2.8 ± 2.1	2.8 ± 2.1	2.5 ± 1.9	2.9 ± 2.4
n	130	107	94	87	73	72	66	58	64
at least third line									
mean BASDAI ± SD	5.7 ± 2.0	4.0 ± 2.2	3.2 ± 2.1	3.1 ± 2.0	3.6 ± 2.2	3.7 ± 2.3†	3.1 ± 2.2	3.4 ± 2.4	2.9 ± 2.0
n	58	46	32	26	29	22	22	23	24

Klaus Kruger,et al .Rheumatol Ther (2020).

ΣΥΜΠΕΡΑΣΜΑΤΑ

Το Golimumab είναι αποτελεσματική θεραπεία σε ασθενείς με ενεργό Ρευματοειδή Αρθρίτιδα ανεξάρτητα από την προηγούμενη βιολογική θεραπεία

Σε συνθήκες καθημερινής κλινικής πρακτικής οι ασθενείς με ΡΑ, ΨΑ, ΑΣ που έλαβαν θεραπεία με Golimumab πέτυχαν σημαντική μείωση της ενεργότητας της νόσου σε όλη την διάρκεια των 24 μηνών της μελέτης

Klaus Kruger,et al .Rheumatol Ther (2020).

FACTORS ASSOCIATED WITH LONG-TERM RETENTION OF TREATMENT WITH GOLIMUMAB IN A REAL-WORLD SETTING: AN ANALYSIS OF THE SPANISH BIOBADASER REGISTRY

Methods

A retrospective, noninterventional study involving an analysis of the BIOBADASER database was carried out to estimate the probability of long-term retention **(up to 5 years)** with Golimumab as any line of anti-TNFα therapy in AxSpA, RA, and PsA patients, and to identify factors associated with a greater retention rate.

Table 1 General characteristics of patients at golimumab initiation

	All ($N=353$)	Rheumatoid arthritis ($N=105$)	Axial spondyloarthritis ($N=147$)	Psoriatic arthritis ($N=101$)
Age				
Years, mean (SD)	52.2 (11.0)	57.2 (11.2)	49.8 (11.5)	50.4 (11.8)
Gender				
Male, *n* (%)	162 (45.9)	23 (21.9)	98 (66.7)	41 (40.6)
Female, *n* (%)	191 (54.1)	82 (78.1)	49 (33.3)	60 (59.4)
Duration of disease				
Years, median (IQR)	8.0 (2.8–15.0)	7.1 (2.7–12.9)	8.9 (3.2–19.4)	7.1 (2.8–11.6)
Smoking habit				
Never, *n* (%)	194 (55.0)	49 (46.7)	76 (51.7)	69 (68.3)
Current, *n* (%)	81 (23.0)	21 (20.0)	46 (31.3)	14 (13.9)
Past, *n* (%)	37 (10.5)	18 (17.1)	10 (6.8)	9 (8.9)
Not available, *n* (%)	41 (11.6)	17 (16.2)	15 (10.2)	9 (8.9)
Body mass index				
Normal weight	75 (21.2)	28 (26.7)	27 (18.4)	20 (19.8)
Overweight	120 (34.0)	24 (22.9)	61 (41.5)	35 (34.7)
Obesity	74 (21.0)	23 (21.9)	30 (20.4)	21 (20.8)
Not available, *n* (%)	84 (23.8)	30 (28.6)	29 (19.7)	25 (24.7)
Order of golimumab treatment[a]				
First biological, *n* (%)	145 (40.1)	57 (52.8)	47 (31.3)	41 (39.4)
Second, *n* (%)	109 (30.1)	24 (22.2)	52 (34.7)	33 (31.7)
Third or later, *n* (%)	108 (29.8)	27 (25.0)	51 (34.0)	30 (28.9)
Concomitant medication				
Steroids, *n* (%)	94 (26.0)	54 (50.0)	19 (12.7)	21 (20.2)
Methotrexate, *n* (%)	122 (33.7)	59 (54.6)	22 (14.7)	41 (39.4)
Sulfasalazine, *n* (%)	22 (6.1)	2 (1.9)	15 (10.0)	5 (4.8)
Leflunomide, *n* (%)	46 (12.7)	27 (25.0)	4 (2.7)	15 (14.4)

IQR interquartile range, *SD* standard deviation

[a]Nine patients received two different golimumab treatments during follow-up

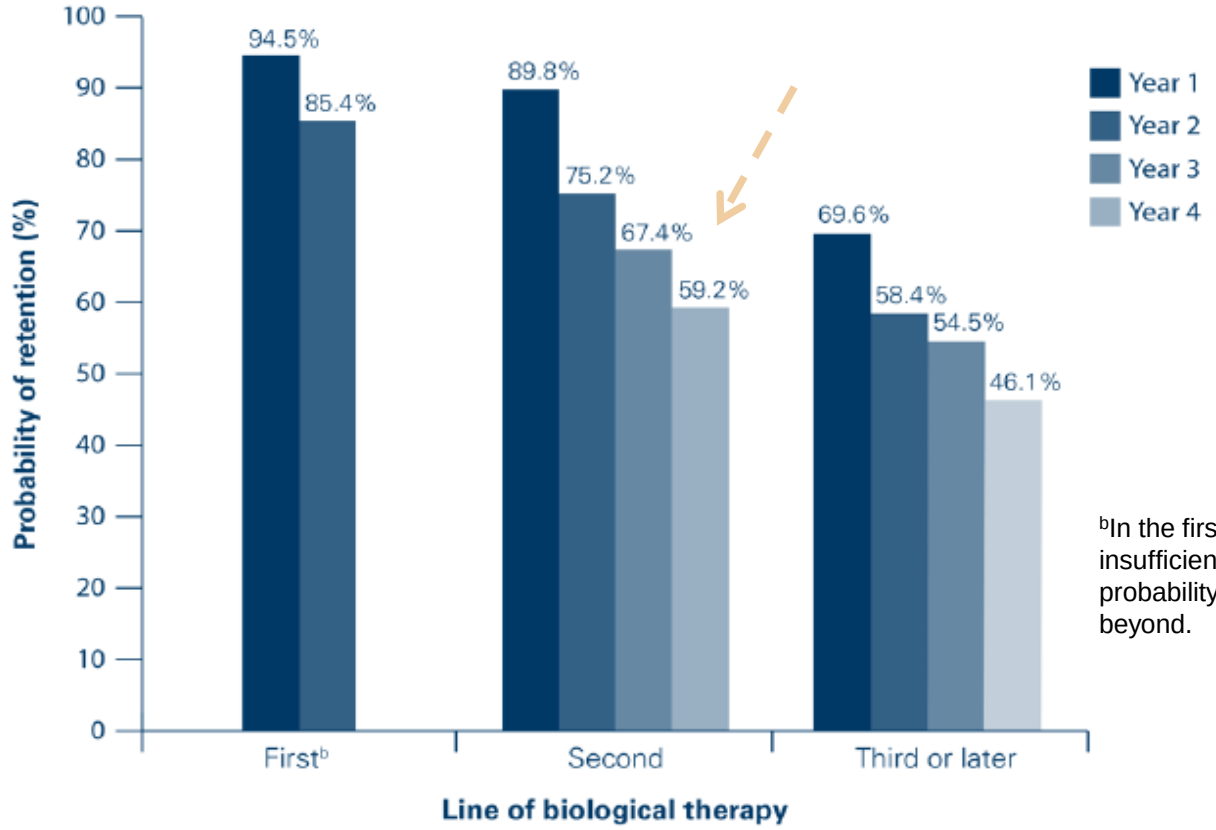
[a]Nine of the AxSpA, RA, and PsA patients received 2 different Golimumab treatments during follow-up.

Hernandez MV ,et al .Rheumatol Int. 2019;.

RESULTS: OVERALL PROBABILITY OF RETENTION

The highest probability of retention was seen when Golimumab was given as first-line biological therapy

Probability of retention with Golimumab by line of biological therapy in PsA, RA, and AxSpA patients (combined) from year 1 to year 4



[b]In the first-line group, there were insufficient cases for estimation of the probability of retention at year 3 or beyond.

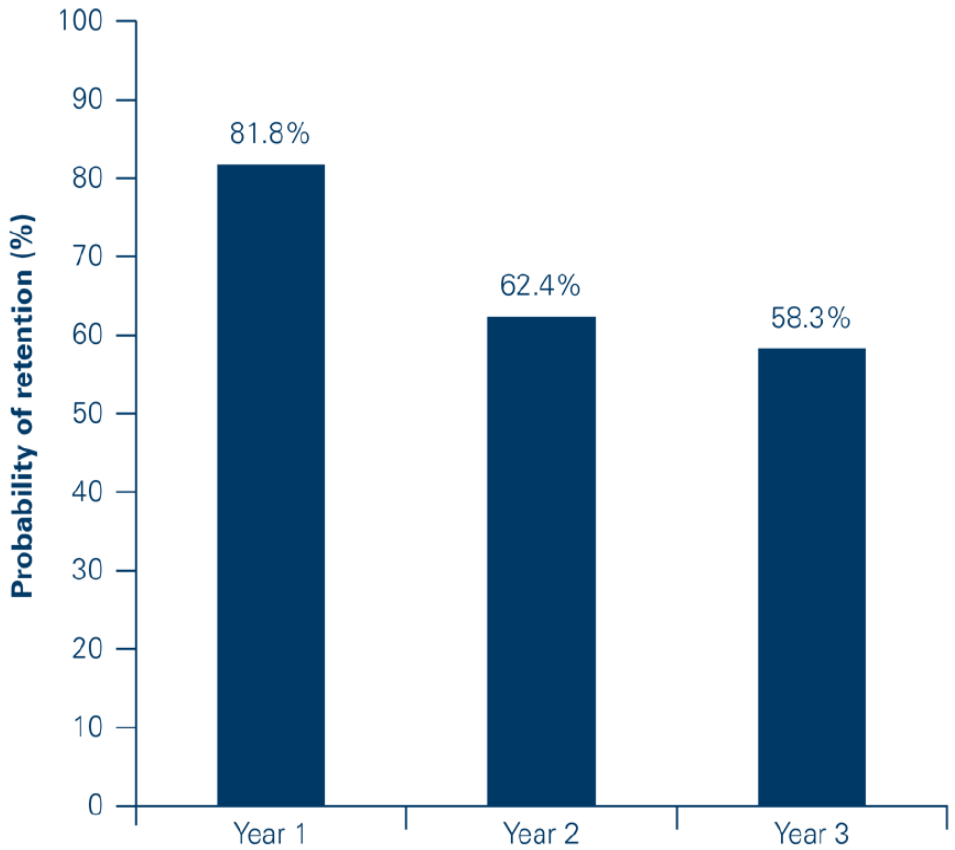
Hernandez MV ,et al .Rheumatol Int. 2019;.

RESULTS: PROBABILITY OF RETENTION IN RA

The highest probability of retention with Golimumab in RA patients was seen in the short term

- **81.8%** of RA patients were estimated to still be on treatment with Golimumab 1 year after initiation, and
- **58.3%** were estimated to sustain treatment through 3 years.

Probability of retention with SIMPONI in RA patients from year 1 to year 3[1]



Patient numbers at year 4 or later were too small to estimate probability of retention

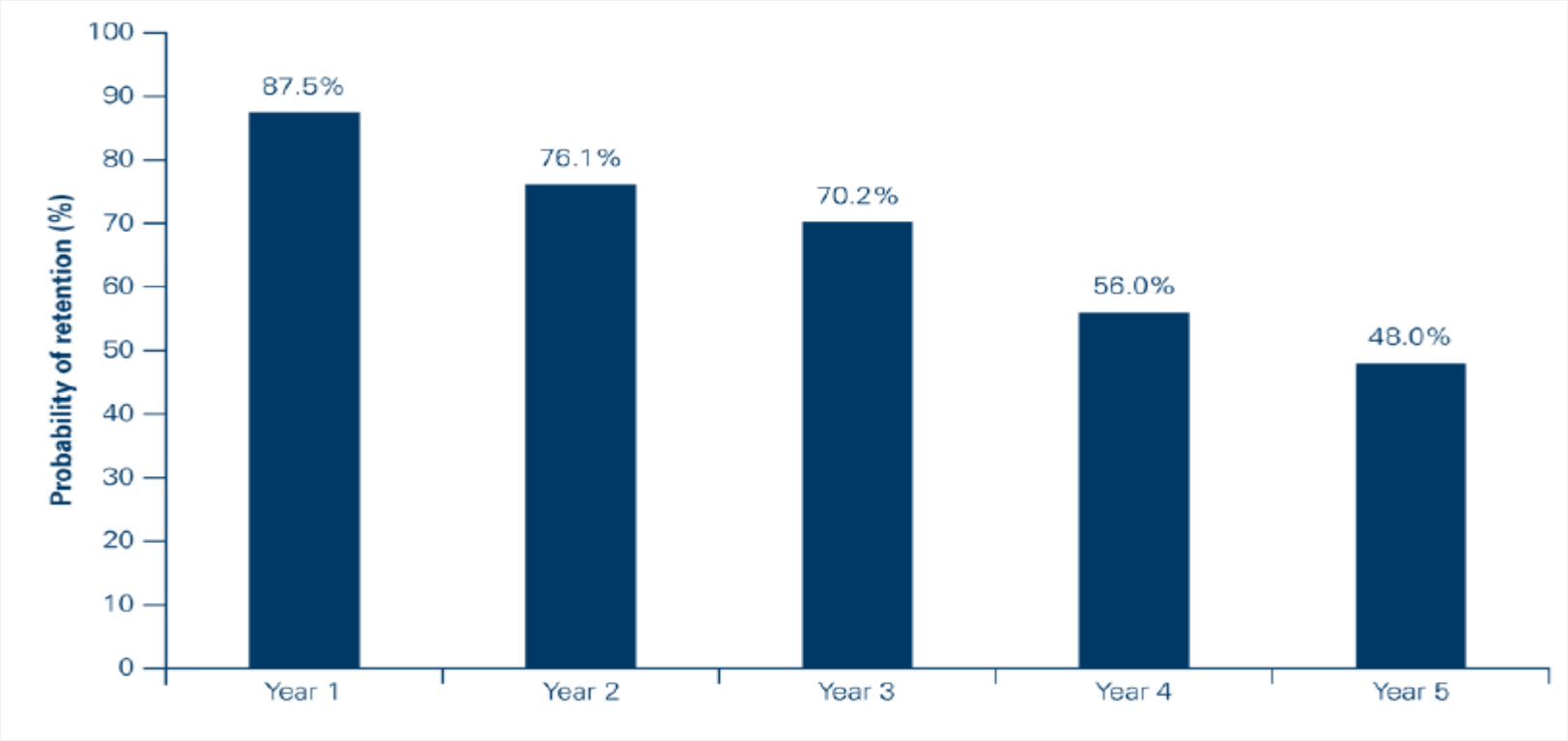
Hernandez MV ,et al .Rheumatol Int. 2019;.

RESULTS: PROBABILITY OF RETENTION IN AXIAL SPA

The highest probability of retention with Golimumab in AxSpA patients was seen in the short term

- **87.5%** of AxSpA patients were estimated to still be on treatment with Golimumab 1 year after initiation, and
- **48.0%** were estimated to sustain treatment through 5 years.

Probability of retention with Golimumab in AxSpA patients from year 1 to year 5

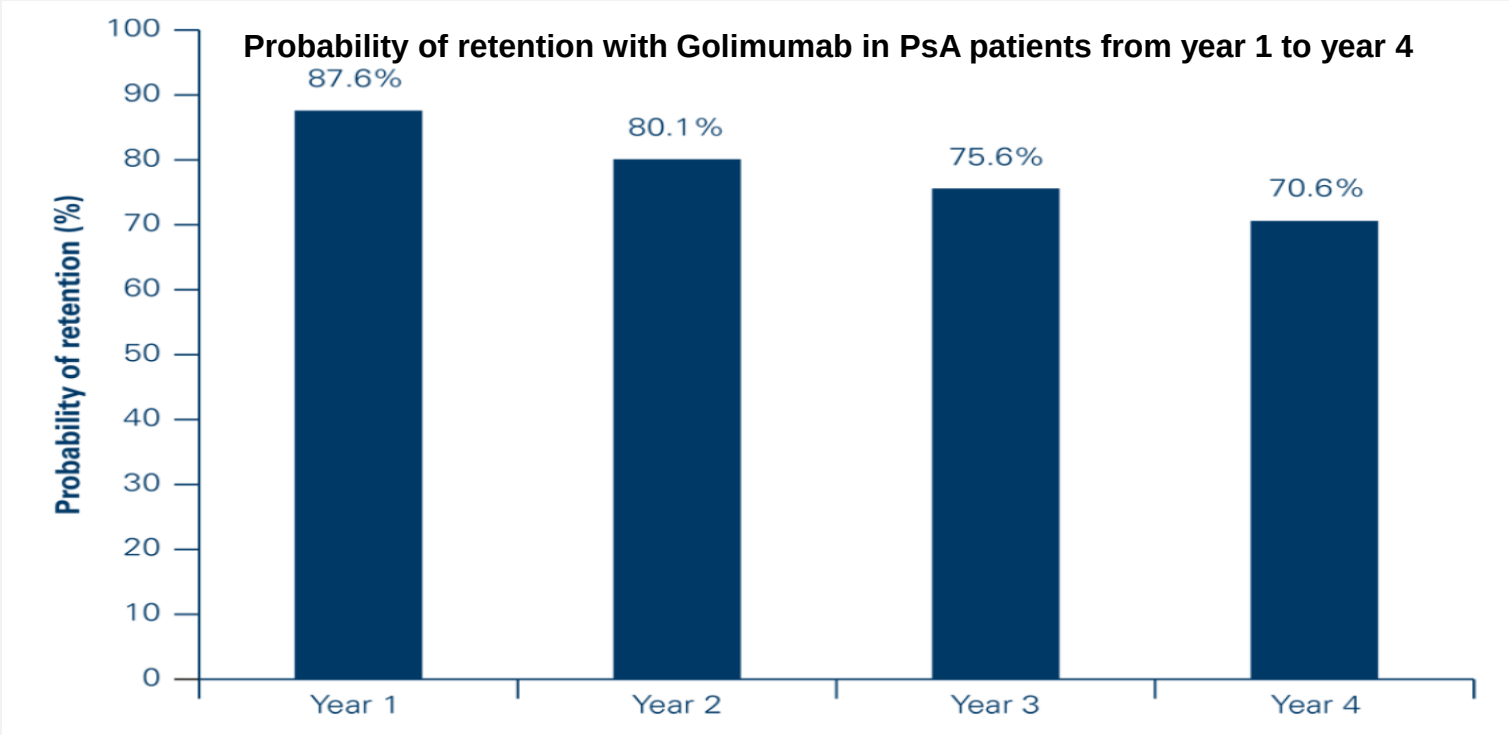


Hernandez MV ,et al .Rheumatol Int. 2019;.

RESULTS: PROBABILITY OF RETENTION IN PSA

The highest probability of retention with Golimumab in PsA patients was seen in the short term

- **87.6%** of PsA patients were estimated to still be on treatment with Golimumab 1 year after initiation, and
- **70.6%** were estimated to sustain treatment through 4 years.



Patient numbers at year 5 were too small to estimate the probability of retention

Hernandez MV ,et al .Rheumatol Int. 2019;.

ΣΥΜΠΕΡΑΣΜΑΤΑ

- **Σε συνθήκες καθημερινής κλινικής πρακτικής οι ασθενείς με PA,ΨΑ και Αξονική Σπονδυλοαρθροπάθεια που έλαβαν θεραπεία με Golimumab πέτυχαν μεγαλό ποσοστό παραμονής στην θεραπεία που φτάνει μέχρι και την πενταετία.**

- **Οι παράγοντες που συσχετίστηκαν με μεγαλύτερη παραμονή στην θεραπεία ήταν:**

1. **Η χρήση του Golimumab ως πρώτης γραμμής βιολογική θεραπεία**

2. **Η συνχορήγηση μεθοτρεξάτης-methotrexate**

- **Ενώ η αυξημένη ανάγκη για χρήση στεροιδών συσχετίστηκε με μειωμένη παραμονή στην θεραπεία.**

Table 2 Factors associated with the retention of treatment with golimumab: hazard ratios for risk of discontinuation of golimumab (Cox regression analysis)

	Hazard ratio	95% confidence interval	*p*
Initial model			
Gender (women vs men)	1.23	0.62–2.44	0.56
Age at golimumab initiation	1.01	0.99–1.04	0.25
Disease duration	0.99	0.96–1.02	0.38
Smoking habit (vs non-smoker)	1.67	0.85–3.26	0.13
Overweight (vs normal)	1.61	0.74–3.52	0.23
Obesity (vs normal)	1.53	0.64–3.66	0.33
Second vs first biological drug	3.06	1.28–7.32	0.01
Third vs first biological drug	5.22	2.18–12.49	< 0.01
Axial SpA vs RA	0.79	0.36–1.73	0.55
PsA vs RA	0.59	0.27–1.29	0.19
Methotrexate	0.41	0.21–0.80	0.01
Steroids	4.26	2.26–8.04	< 0.01
Final model			
Gender (women vs men)	1.38	0.84–2.27	0.21
Age at golimumab initiation	1.01	1.00–1.03	0.14
Second vs first biological drug	2.30	1.16–4.55	0.02
Third vs first biological drug	3.92	2.07–7.39	< 0.01
Methotrexate	0.55	0.33–0.91	0.02
Steroids	2.83	1.72–4.66	< 0.01

PsA psoriatic arthritis, *RA* rheumatoid arthritis, *SpA* spondyloarthritis

We cannot rule out the influence of other factors, this aspect requires a larger study to be conducted.

Hernandez MV ,et al .Rheumatol Int. 2019;.