Μεταβολικά Νοσήματα των Οστών- Βιβλιογραφική ενημέρωση

Βιολογικοί Παράγοντες- Νεότερα δεδομένα

Σουσάνα Γαζή
Ρευματολόγος
ΓΝΑ «ΚΑΤ»

Σύγκρουση συμφερόντων

Καμία για την παρουσίαση

RHEUMATOLOGY

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Original article

The impact of long-term biologics/target therapy on bone mineral density in rheumatoid arthritis: a propensity score-matched analysis

Jia-Feng Chen [1,2], Chung-Yuan Hsu[1,2], Shan-Fu Yu[1,2], Chi-Hua, Ko[1], Wen-Chan Chiu[1], Han-Ming Lai[1], Ying-Chou Chen[1,2], Yu-Jih Su[1,2] and Tien-Tsai Cheng[1,2]

1.support and instruction from Taiwan Bone Muscle Joint Total Care Association (**TBMJ)**.

2. Funding: This work was supported with **grant CMRPG8F1111 from Chang Gung Memorial Hospital** (https://www.cgmh.org.tw/), which sponsored the cost of data collecting, inputting and processing as well as the publication.

TABLE 1 Clinical characteristics of participants before and after propensity score match (PSM)

	Groups (before PSM)			Groups (after PSM)		
	b/tsDMARD + csDMARD *n* = 102	csDMARD *n* = 286	*P*	Group I[c] *n* = 92	Group II[c] *n* = 184	*P*
Age (years)	56.4 (9.4)	59.2 (10.2)	0.02*	56.6 (8.7)	57.2 (9.8)	0.65
Female, *n* (%)	87 (85.3)	247 (86.4)	0.87	78 (84.8)	151 (82.1)	0.57
Menopause, *n* (%)	69 (79.3)	206 (83.4)	0.40	62 (79.5)	120 (79.5)	0.72
Body weight (kg)	60.4 (11.6)	57.4 (11.7)	0.03*	61.0 (11.0)	59.1 (11.1)	0.17
Body height (cm)	158.0 (7.0)	155.9 (7.4)	0.01*	158.2 (6.4)	157.6 (7.1)	0.46
BMI (kg/cm^2)	24.1 (4.0)	23.5 (3.9)	0.23	24.3(4.0)	23.7 (3.9)	0.24
Comorbidity[a]	56 (54.9)	189 (66.1)	0.04*	49 (53.3)	113 (61.4)	0.20
RA related factors						
Disease duration (years)	15.3 (9.5)	14.1 (8.9)	0.25	15.6 (9.6)	13.6 (8.6)	0.07
DAS28-ESR	3.7 (1.3)	3.2 (1.1)	0.001*	3.7 (1.4)	3.2 (1.1)	<0.001*
3-year mean DAS 28-ESR	3.3 (1.0)	3.1 (0.9)	0.03*	3.3 (1.0)	3.1 (0.9)	0.046*
RF, + (%)	79 (77.5)	176 (61.8)	0.005*	72 (78.3)	147 (79.9)	0.75
ACPA, + (%)	78 (76.5)	186 (65.5)	0.05	70 (76.1)	133 (73.1)	0.59
ESR (mm/h)	25.3 (21.2)	22.0 (19.4)	0.15	24.8 (19.9)	22.7 (20.7)	0.44
CRP (mg/l)	7.2 (13.8)	7.5 (15.7)	0.86	7.2 (13.8)	8.3 (17.6)	0.62
HAQ-DI	6.1 (6.1)	4.6 (6.0)	0.04*	6.1 (6.0)	4.0 (5.6)	0.006*
FRAX risk factors[b]						
Previous fracture +, *n* (%)	28 (27.5)	101 (35.3)	0.15	26 (28.3)	59 (32.1)	0.52
2nd Osteoporosis +, *n* (%)	3 (2.9)	14 (4.9)	0.58	3 (3.3)	8 (4.3)	0.66
Glucocorticoid[d]						
Baseline exposure +, *n* (%)	87 (85.3)	251 (87.8)	0.50	78 (84.8)	159 (86.4)	0.71
Dose (mg/day)	4.9 (1.0)	4.5 (1.5)	0.05*	4.9 (1.9)	4.6 (1.6)	0.19
Cumulative exposure +, *n* (%)	97 (95.1)	270 (94.4)	1.00	87 (94.6)	174 (94.6)	1.00
Cumulative dose (mg/day)	4.0 (2.5)	4.2 (2.3)	0.47	3.9 (2.5)	4.3 (2.4)	0.18
Parent fractured hip +, *n* (%)	8/102 (7.8)	27/282 (9.6)	0.60	8 (8.7)	19 (10.3)	0.67
BMD (g/cm^2)						
FN	0.784 (0.144)	0.785 (0.136)	0.92	0.634 (0.117)	0.642 (0.115)	0.54
TH	0.630 (0.115)	0.626 (0.117)	0.81	0.793 (0.146)	0.807 (0.131)	0.35
L1-4	0.901 (0.171)	0.847 (0.161)	0.005*	0.904 (0.168)	0.877 (0.145)	0.20
Current smoking +, *n* (%)	5 (4.9)	18 (6.3)	0.61	5 (5.4)	16 (8.7)	0.34
Alcohol +, *n* (%)	1 (1.0)	4 (1.4)	1.00	1 (1.1)	3 (1.6)	0.72
AOT +, *n* (%)	30 (29.4)	102 (35.7)	0.25	27 (29.3)	56 (30.4)	0.85
Lab[a]						
Calcium (mg/dl)	9.3 (0.3)	9.3 (0.4)	0.90	9.3 (0.3)	9.3 (0.4)	0.77
Vit D25(OH) (ng/ml)	22.1 (7.9)	22.7 (7.4)	0.54	22.1 (8.1)	23.0 (7.3)	0.39
iPTH (pg/ml)	40.9 (19.9)	44.0 (22.8)	0.23	41.5 (19.8)	40.4 (19.2)	0.65

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HAQ-DI	6.1 (6.1)	4.6 (6.0)	0.04*	6.1 (6.0)	4.0 (5.6)	0.006*
FRAX risk factors[b]						

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Group I (N=92)
b/tsDMARD + csDMARD

- **Anti-TNFa (64,1%)**
  - Etanercept
  - Adalimumab
  - Golimumab
  - Certolizumab pegol
- **CTLA4 (12%)**
  - Abatacept
- **Anti IL6r (13%)**
  - Tocilizumab
- **Anti-CD20 (3,3%)**
  - Rituximab
- **JAK inh (7,6%)**
  - Tofacitinib

Group II (N= 184)
csDMARD

- **MTX**
- **Σουλφασαλαζίνη**
- **Υδροξυχλωροκινη**
- **Αζαθειοπρίνη**
- **Λεφλουνομίδη**

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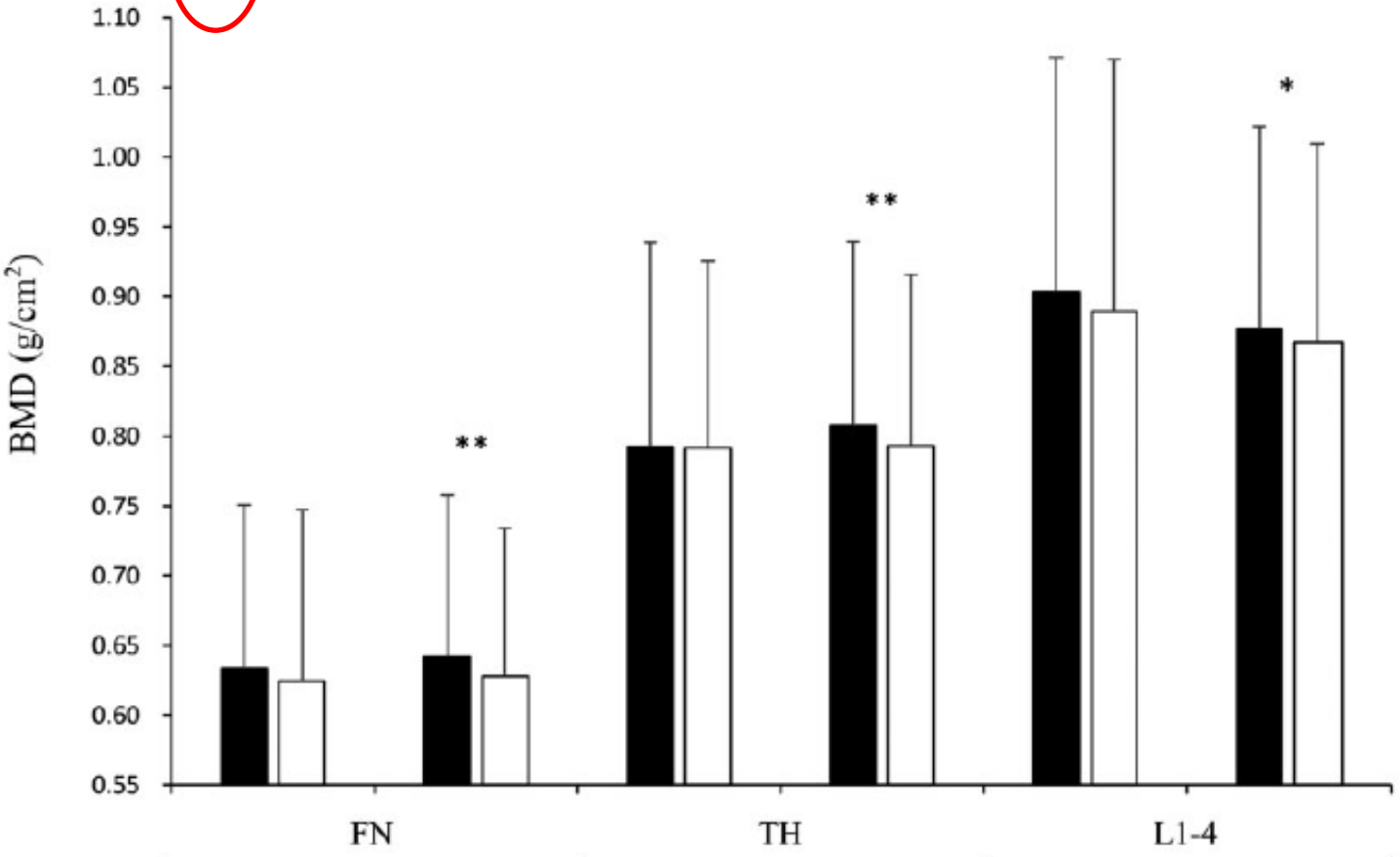
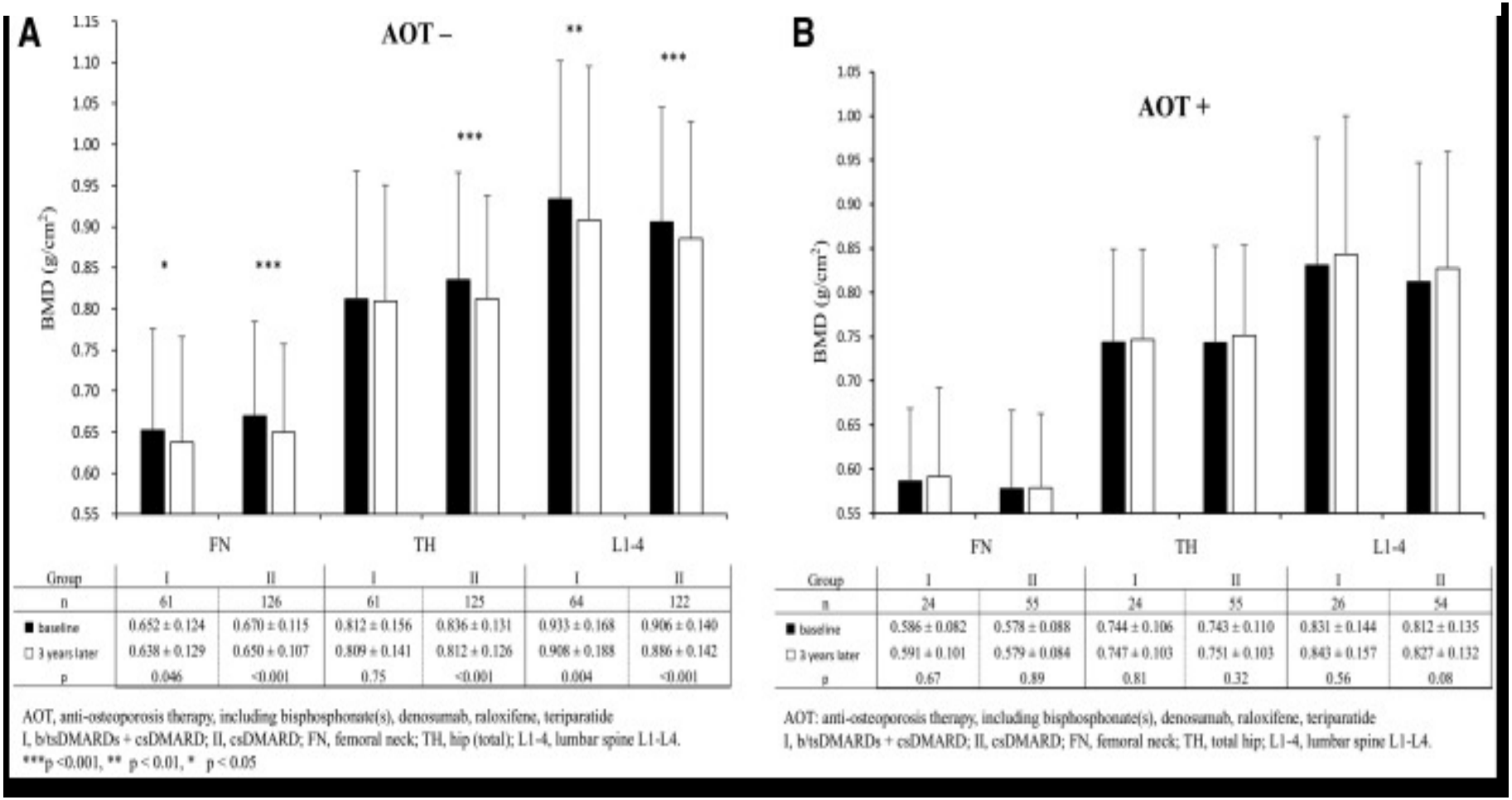
FIG. 2 Comparison of BMD at baseline and 3 years later at FN, TH and L1-4 in Group I and II participants



Group	I	II	I	II	I	II
■ baseline	0.634 ± 0.117	0.642 ± 0.116	0.793 ± 0.146	0.808 ± 0.132	0.904 ± 0.168	0.877 ± 0.145
□ 3 years later	0.625 ± 0.123	0.628 ± 0.106	0.792 ± 0.134	0.793 ± 0.123	0.889 ± 0.181	0.868 ± 0.142
p	0.15	<0.001	0.87	0.004	0.09	0.04

FIG. 3 Difference of BMD between baseline and 3 years later in patients receiving csDMARDs or adding on b/tsDMARDs, combined AOT use or not



Group	I	II	I	II	I	II
n	61	126	61	125	64	122
■ baseline	0.652 ± 0.124	0.670 ± 0.115	0.812 ± 0.156	0.836 ± 0.131	0.933 ± 0.168	0.906 ± 0.140
□ 3 years later	0.638 ± 0.129	0.650 ± 0.107	0.809 ± 0.141	0.812 ± 0.126	0.908 ± 0.188	0.886 ± 0.142
p	0.046	<0.001	0.75	<0.001	0.004	<0.001

AOT, anti-osteoporosis therapy, including bisphosphonate(s), denosumab, raloxifene, teriparatide
I, b/tsDMARDs + csDMARD; II, csDMARD; FN, femoral neck; TH, hip (total); L1-4, lumbar spine L1-L4.
***p <0.001, ** p < 0.01, * p < 0.05

Group	I	II	I	II	I	II
n	24	55	24	55	26	54
■ baseline	0.586 ± 0.082	0.578 ± 0.088	0.744 ± 0.106	0.743 ± 0.110	0.831 ± 0.144	0.812 ± 0.135
□ 3 years later	0.591 ± 0.101	0.579 ± 0.084	0.747 ± 0.103	0.751 ± 0.103	0.843 ± 0.157	0.827 ± 0.132
p	0.67	0.89	0.81	0.32	0.56	0.08

AOT: anti-osteoporosis therapy, including bisphosphonate(s), denosumab, raloxifene, teriparatide
I, b/tsDMARDs + csDMARD; II, csDMARD; FN, femoral neck; TH, total hip; L1-4, lumbar spine L1-L4.

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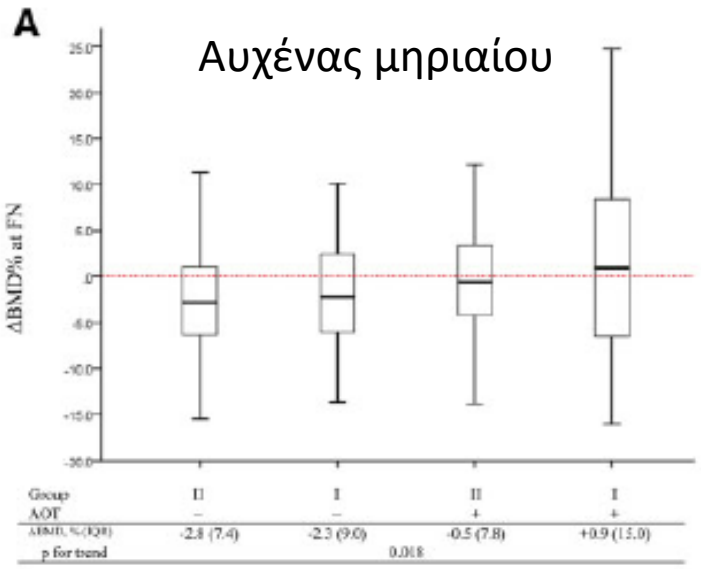
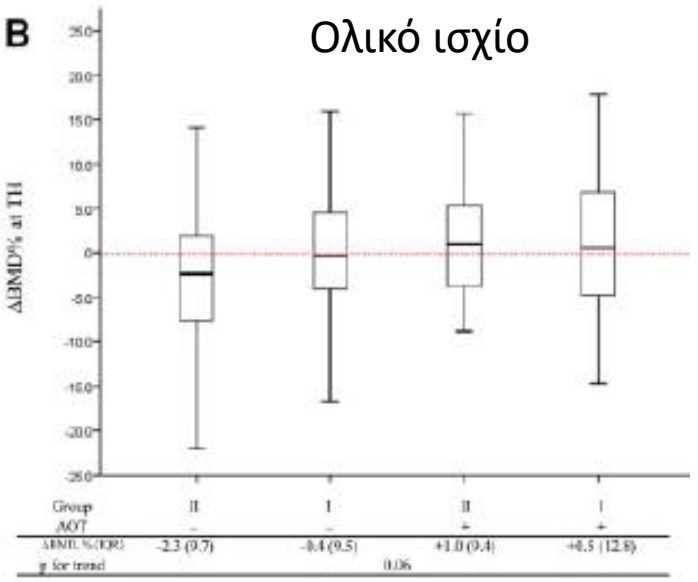
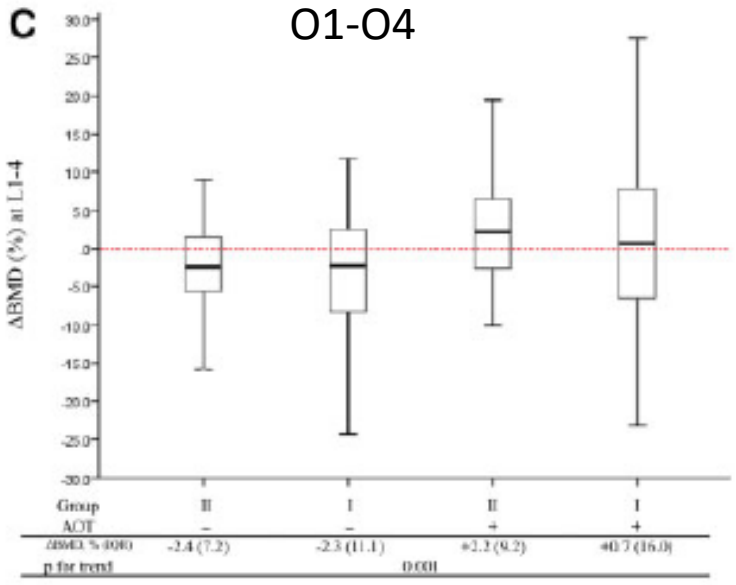
Fig. 4 BMD change from baseline at different measured sites in group I and II, with or without use of AOT (**A**) BMD change from baseline at different measured sites in group I and II, with or







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Συμπέρασμα

- **Η επί μακρόν θεραπεία με b/tsDMARDs σε PA ασθενείς είχε προστατευτικό ρόλο στην BMD σε όλες τις θέσεις.**
- **Με τα cDMARD παρατηρήθηκε σημαντική πτώση της BMD.**
- **Η αντι-ΟΠ αγωγή έπαιξε προστατευτικό ρόλο στην BMD και στις 2 ομάδες**
- **ΔBMD% → b/tsDMARD+AOT> csDMARD+AOT> b/tsDMARD>csDMARD (FN-p=0.018, TH-p=0.06, Li-L4-p=0.001)**

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Published online 2021 Dec 20. doi: 10.3389/fimmu.2021.783030 PMID: 34987510

Different Effects of Biologics on Systemic Bone Loss Protection in Rheumatoid Arthritis: An Interim Analysis of a Three-Year Longitudinal Cohort Study

Ming-Han Chen,[1,2,†] Shan-Fu Yu,[3,4,†] Jia-Feng Chen,[3,4] Wei-Sheng Chen,[1,2] The-Ling Liou,[1] Chung-Tei Chou,[1] Chung-Yuan Hsu,[3,4] Han-Ming Lai,[3,4] Ying-Chou Chen,[3,4] Chang-Youh Tsai,[1,2] and Tien-Tsai Cheng[3,4,*]

This work was **supported by grants CMRPG8F1111 and CMRPG8K0441 from Chang Gung Memorial Hospital** (https://www.cgmh.org.tw/), which sponsored the cost of data collection, gathering, processing, and publication.

Ασθενείς 182

- Ομάδα Α (N=104) → cDMARDs
- Ομάδα Β (N= 52) → αντι-TNFa : Infliximab
  Adalimumab
  Etanercept)
- Ομάδα C (N =26)→ Abatacept

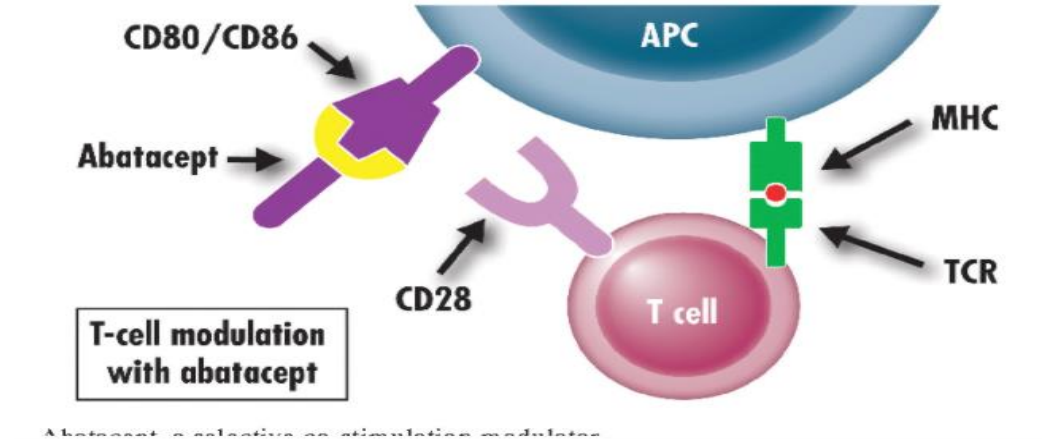


Fig. 3. Abatacept, a selective co-stimulation modulator. APC: antigen presenting cell; MHC: major histocompatibility complex; TCR: T-cell receptor.

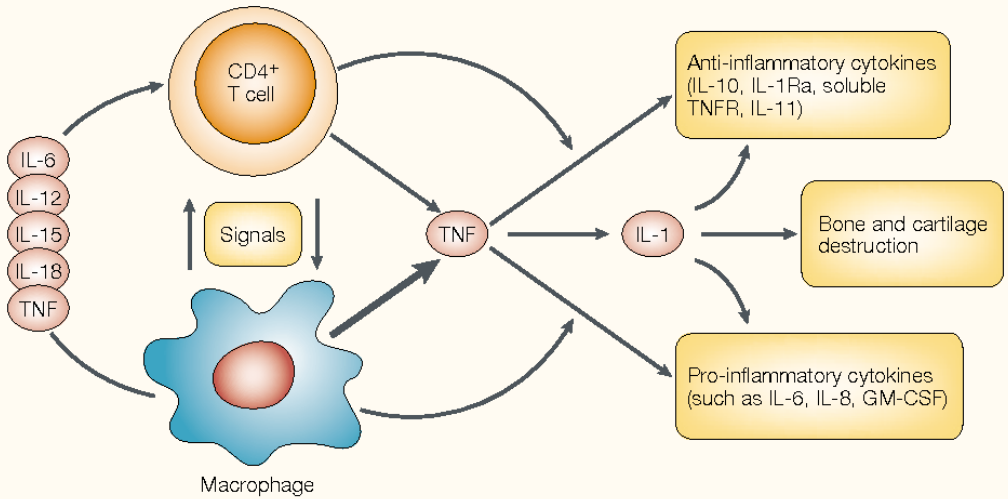


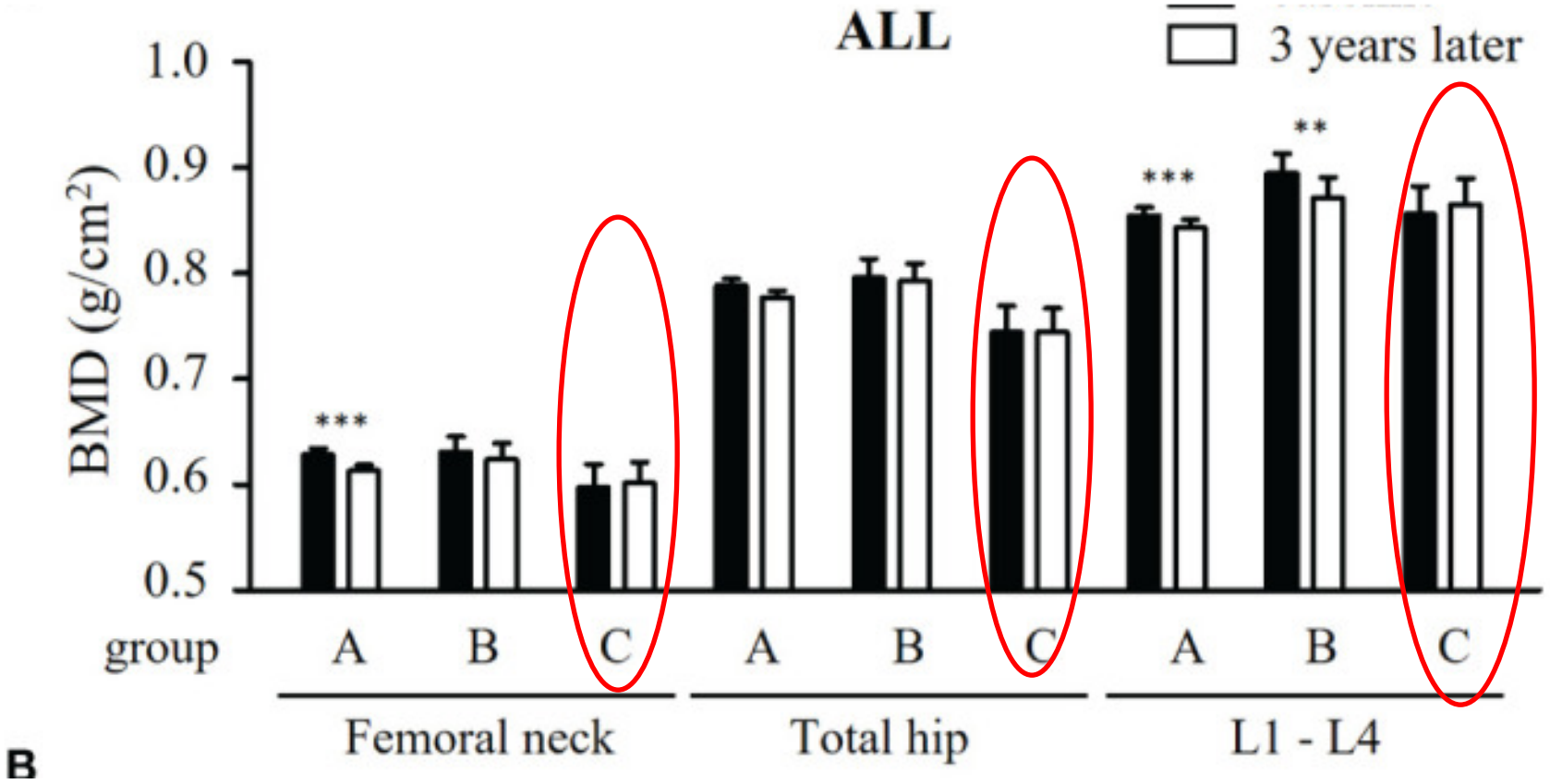
Figure 1 | **The cytokine network in rheumatoid arthritis.** A schematic representation of some of the

Table 2

Demographics and clinical characteristics of participants, after matching.

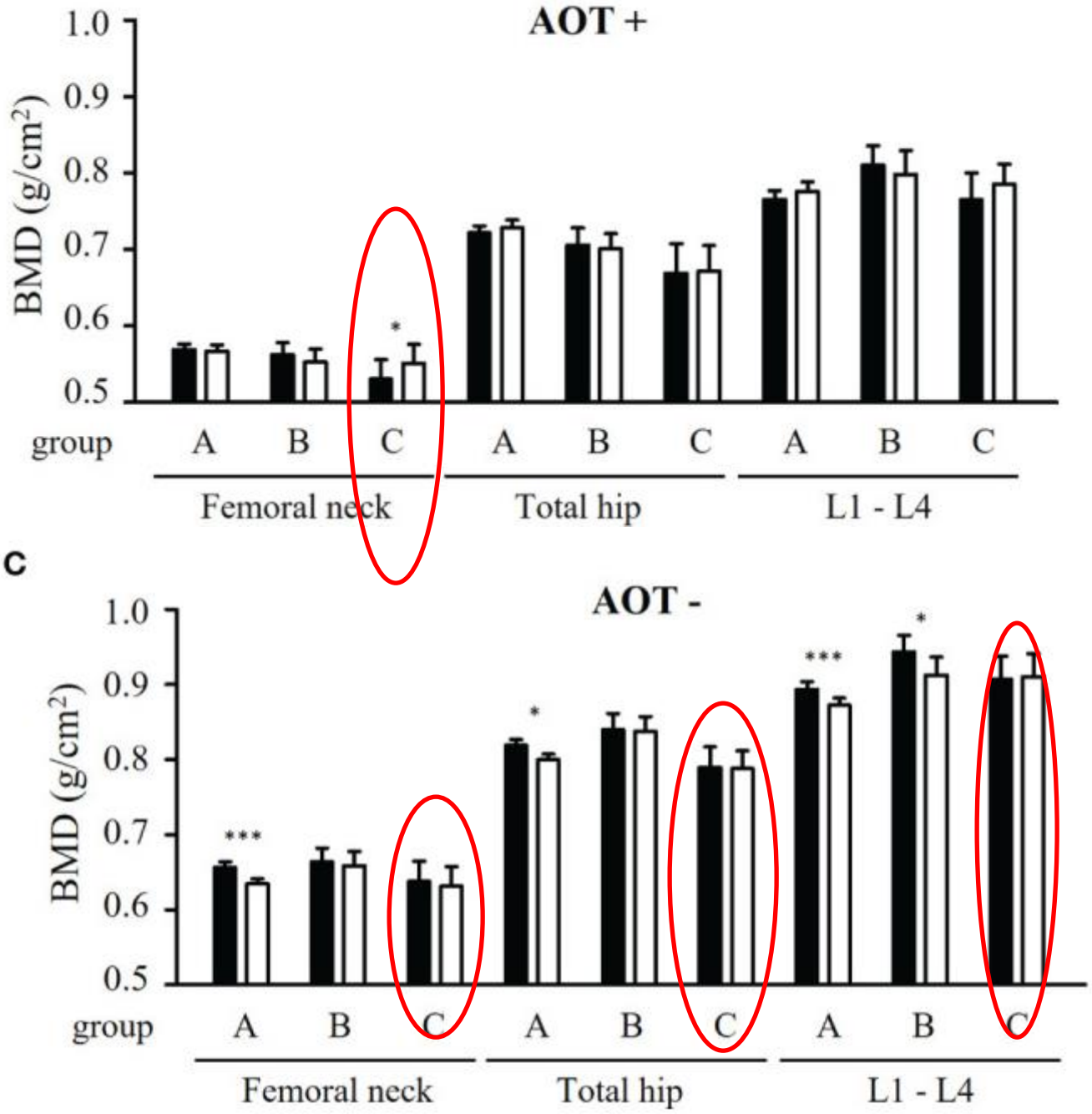
Group	All N = 182	A n = 104	B n = 52	C n = 26	P [f]
Age (years)	57.5 ± 10.7	57.7 ± 10.5	58.1 ± 10.2	55.3 ± 12.8	0.531
Female, n (%)	159 (87.4)	93 (89.4)	43 (82.7)	23 (88.5)	0.500
Body weight (kg)	58.2 ± 10.6	56.8 ± 9.6	61.8 ± 12.6	56.7 ± 8.5	0.016*
Body height (cm)	157.4 ± 6.5	156.8 ± 6.8	158.1 ± 5.6	158.2 ± 6.9	0.425
BMI (kg/cm^2)	23.5 ± 3.7	23.0 ± 3.3	24.7 ± 4.6	22.8 ± 2.9	0.023*
Factors associated with RA					
Disease duration (years)	10 (11.5)	10 (9)	11 (14.7)	7.5 (10.8)	0.170
Baseline DAS28-ESR	3.7 ± 1.5	3.1 ± 1.1	4.2 ± 1.5	4.9 ± 1.6	<0.001*
3-year mean DAS 28-ESR	3.0 ± 0.9	2.9 ± 0.8	3.4 ± 1.0	3.2 ± 1.0	0.004*
Rheumatoid factors, + (%)	142 (78.0)	78 (75.0)	43 (82.7)	21 (80.8)	0.508
ACPA, + (%)	133/179 (74.3)	69/104 (66.3)	42/49 (85.7)	22/26 (84.6)	0.013*
FRAX risk factors[a]					
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Comparison of BMD at baseline and 3 years later in all patients

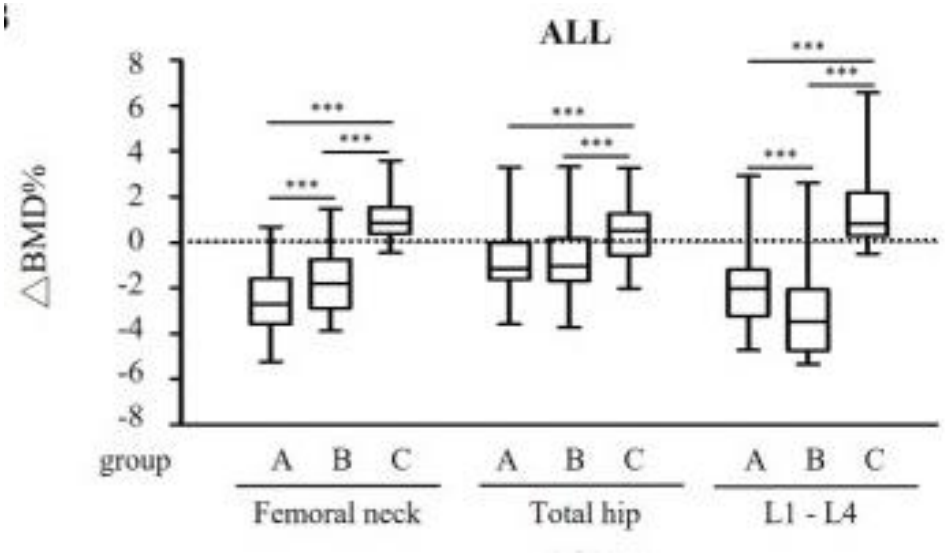


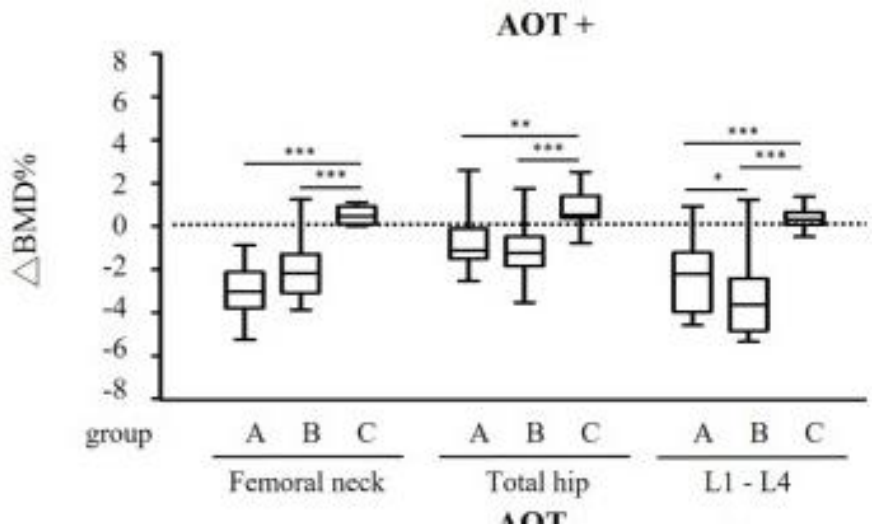
B

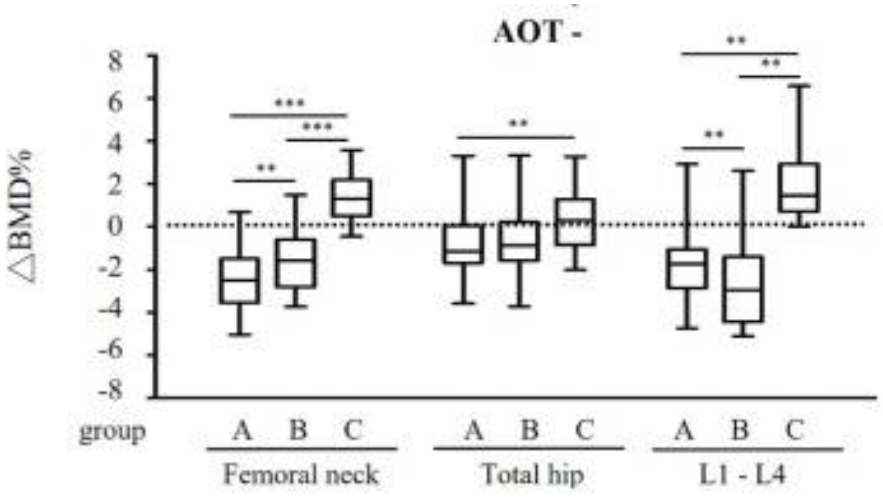
BMD at baseline and 3 years later in patients with and without anti-osteoporosis therapy



percentage change in BMD from baseline in all participants and participants with or without anti-osteoporosis therapy.







Συμπέρασμα

- **Οι PA ασθενείς σε abatacept είχαν καλύτερη προστασία της BMD σε σχέση με τους αντι-TNF και τα cDMARD.**
- **Η αντι-ΟΠ αγωγή είχε σημαντική προστασία της BMD άσχετα με την βασική θεραπεία των PA ασθενών**
- **Περαιτέρω μελέτες θα διευκρινίσουν αν το abatacept ή άλλοι βιολογικοί μπορούν να προλαμβάνουν τα κατάγματα ευθραυστότητας σε PA ασθενείς.**
- **Δεν μπορούμε να πούμε ποιος βιολογικός είναι καλύτερος για την πρόληψη της οστικής απώλειας σε PA ασθενείς .**
- **Δεν προσδιορίστηκε η επίδραση στα κατάγματα λόγω μικρού χρονικού διαστήματος και μικρού δείγματος ασθενών.**

European Review for Medical and Pharmacological Sciences 2021; 25: 3416-3424

Impact of biologic disease-modifying antirheumatic drugs on fracture risk in patients with rheumatoid arthritis: a systematic review and meta-analysis

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[1]Department of Rheumatology, The Third People's Hospital of Huzhou city, Huzhou, Zhejiang Province, P.R. China
[2]Zhejiang Chinese Medical University, Hangzhou, Zhejiang Province, P.R. China
[3]Department of Nephrology, Huzhou Traditional Chinese Medicine Hospital Affiliated to Zhejiang Chinese Medical University, Zhejiang Province, P.R. China

Συστηματική ανασκόπηση και μετανάλυση

- 9 μελέτες δημοσιευμένες 2012-2019
  - 4 από Βόρεια Αμερική
  - 3 από Ασία
  - 2 από Ευρώπη
- Η πλειονότητα αναδρομικές

- Ασθενείς 193.160
  - Χρήση bDMARD 2.4% - 51.2%

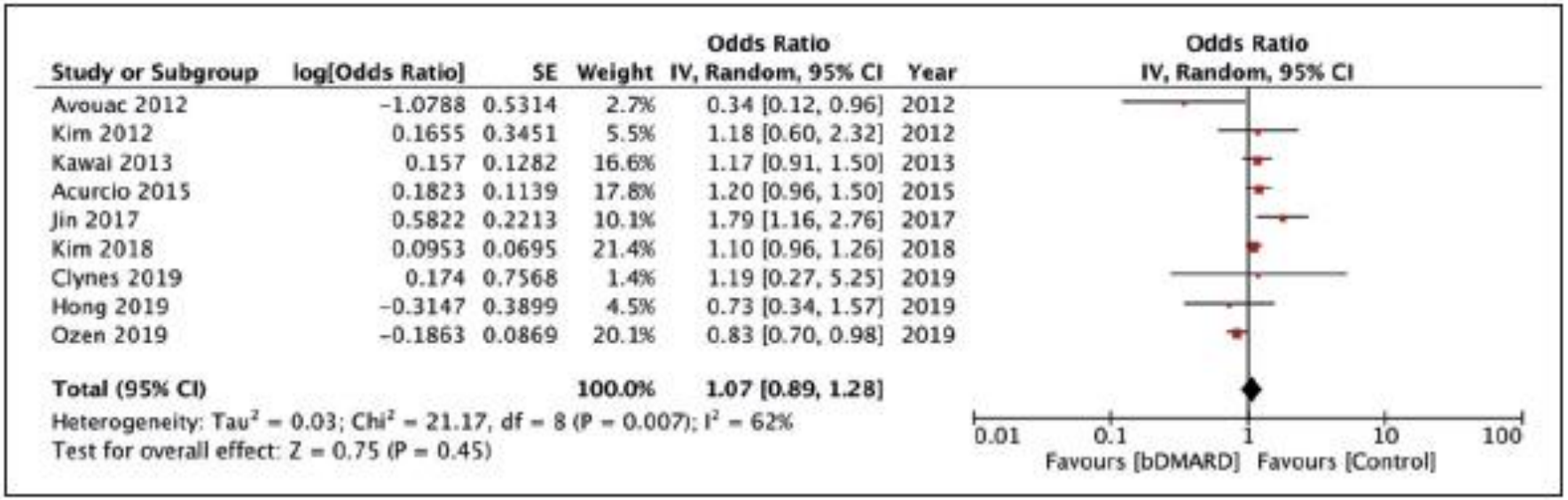

Figure 2. Meta-analysis of fracture risk in bDMARDS users *vs.* non-users.

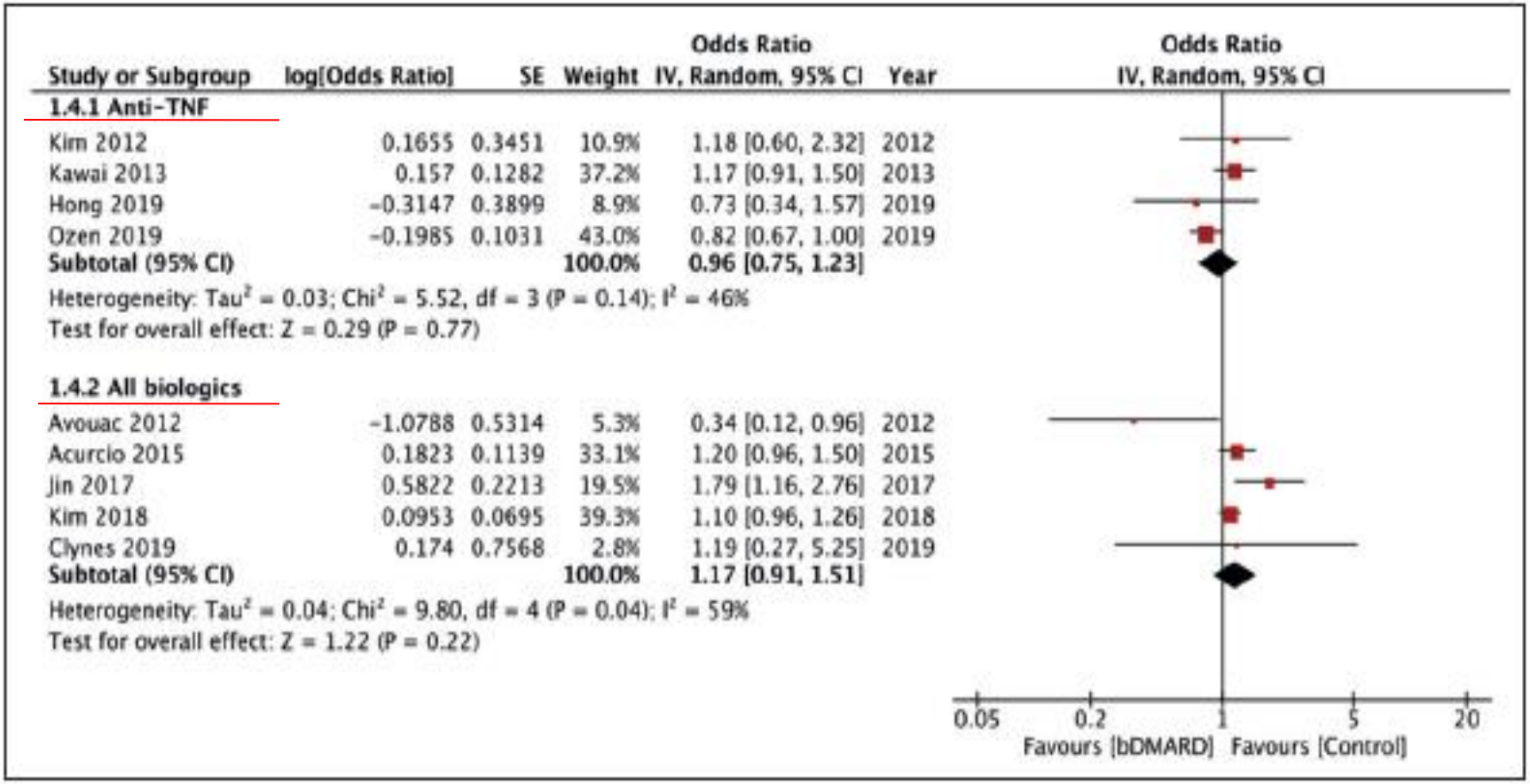

Figure 3. Meta-analysis of fracture risk in bDMARDS users *vs.* non-users based on the type of bDMARDS used.

F. Shao, H.-C. Li, M.-J. Wang, C.-M. Cui

Σπονδυλικά #

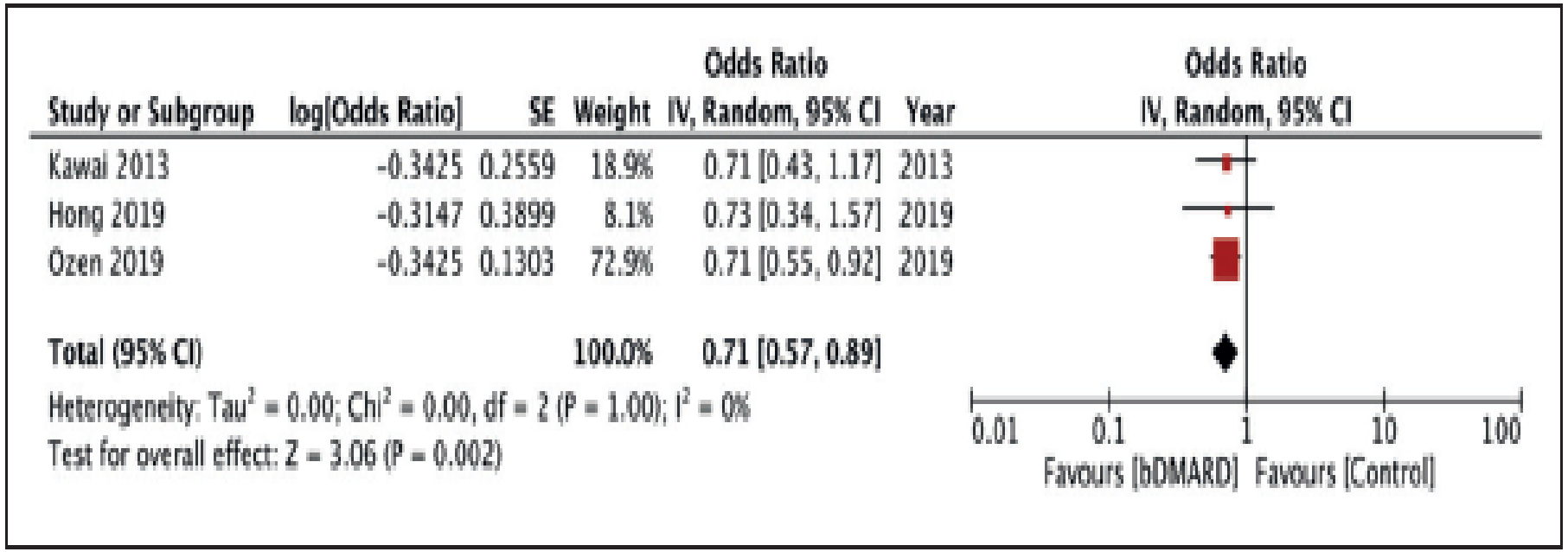

Figure 4. Meta-analysis of vertebral fracture risk in bDMARDS users *vs.* non-users.

Συμπέρασμα

- **Αντίθεση της μελέτης με αυτές που δείχνουν επίδραση των bDMARD στην BMD & τους βιοχημικούς δείκτες**
  - **Πολιτική των κρατών στη χορήγηση βιολογικών**
  - **? ΚΣ, είδος βιολογικού, αρχικό # κίνδυνο**

- **Σε 3 μελέτες → Σημαντική μείωση των σπονδυλικών καταγμάτων με bDMARD vs cDMARD**

- **Περισσότερες μελέτες**

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ORIGINAL ARTICLE

Effects of one-year tofacitinib therapy on bone metabolism in rheumatoid arthritis

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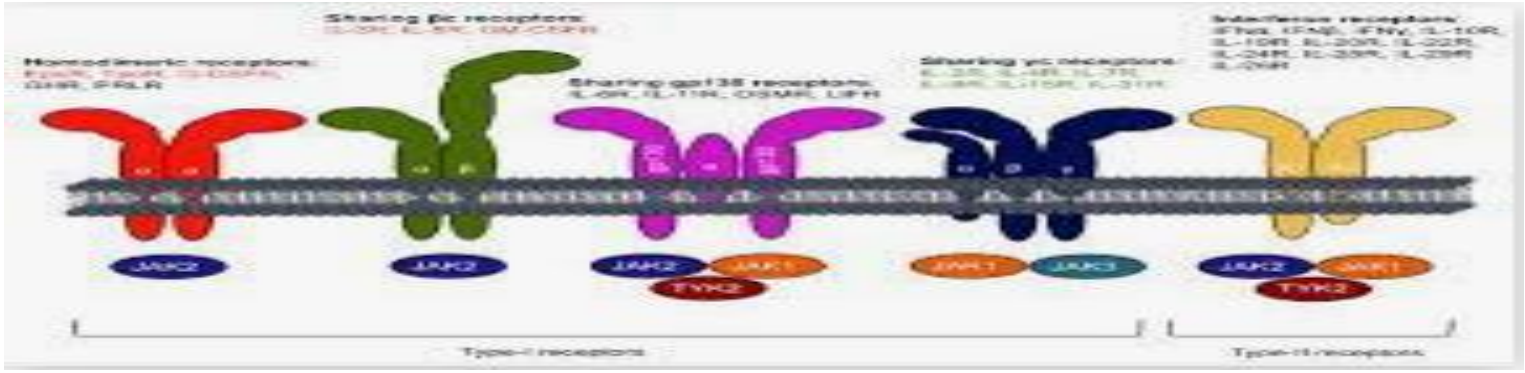
JAK2
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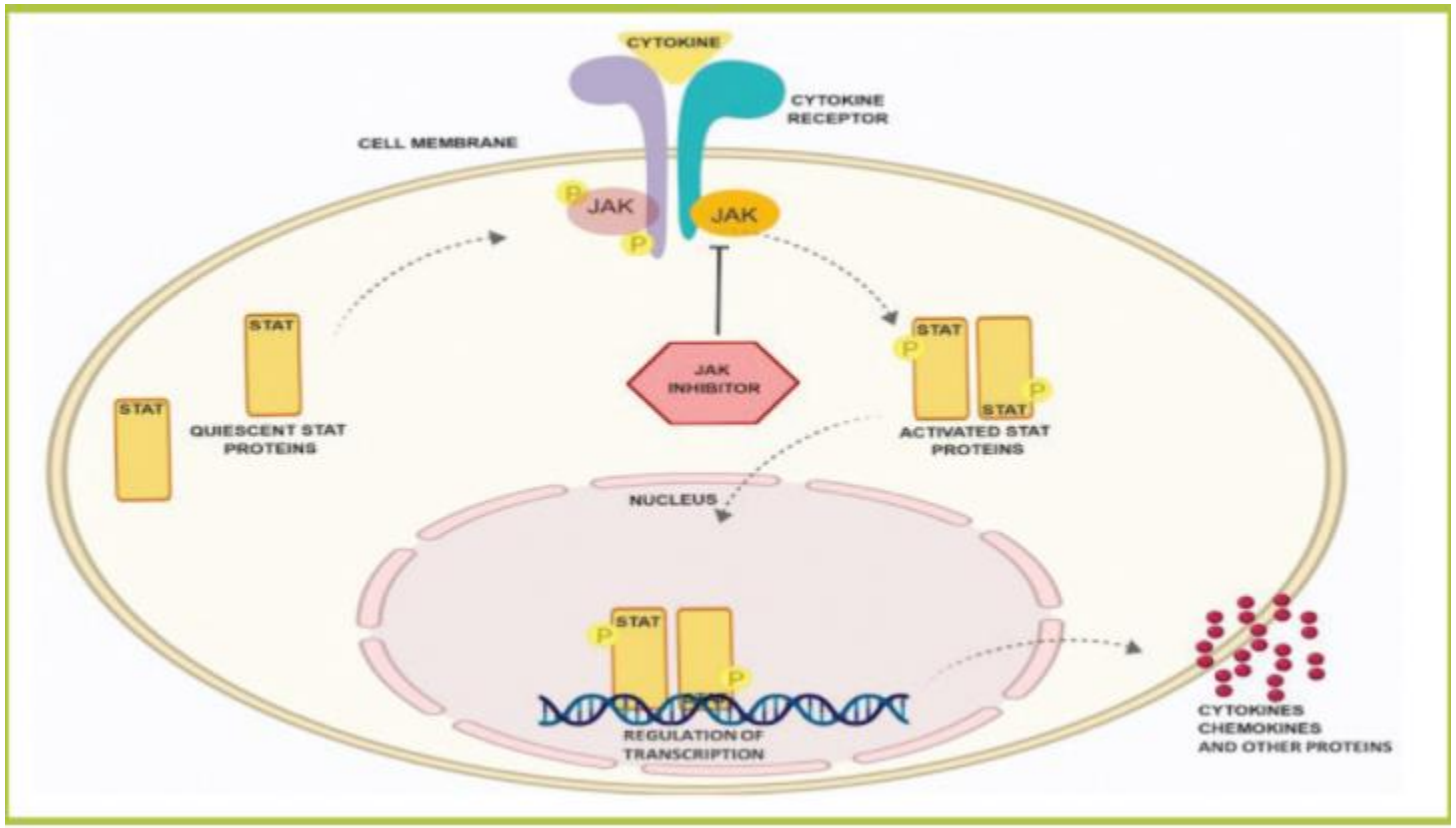
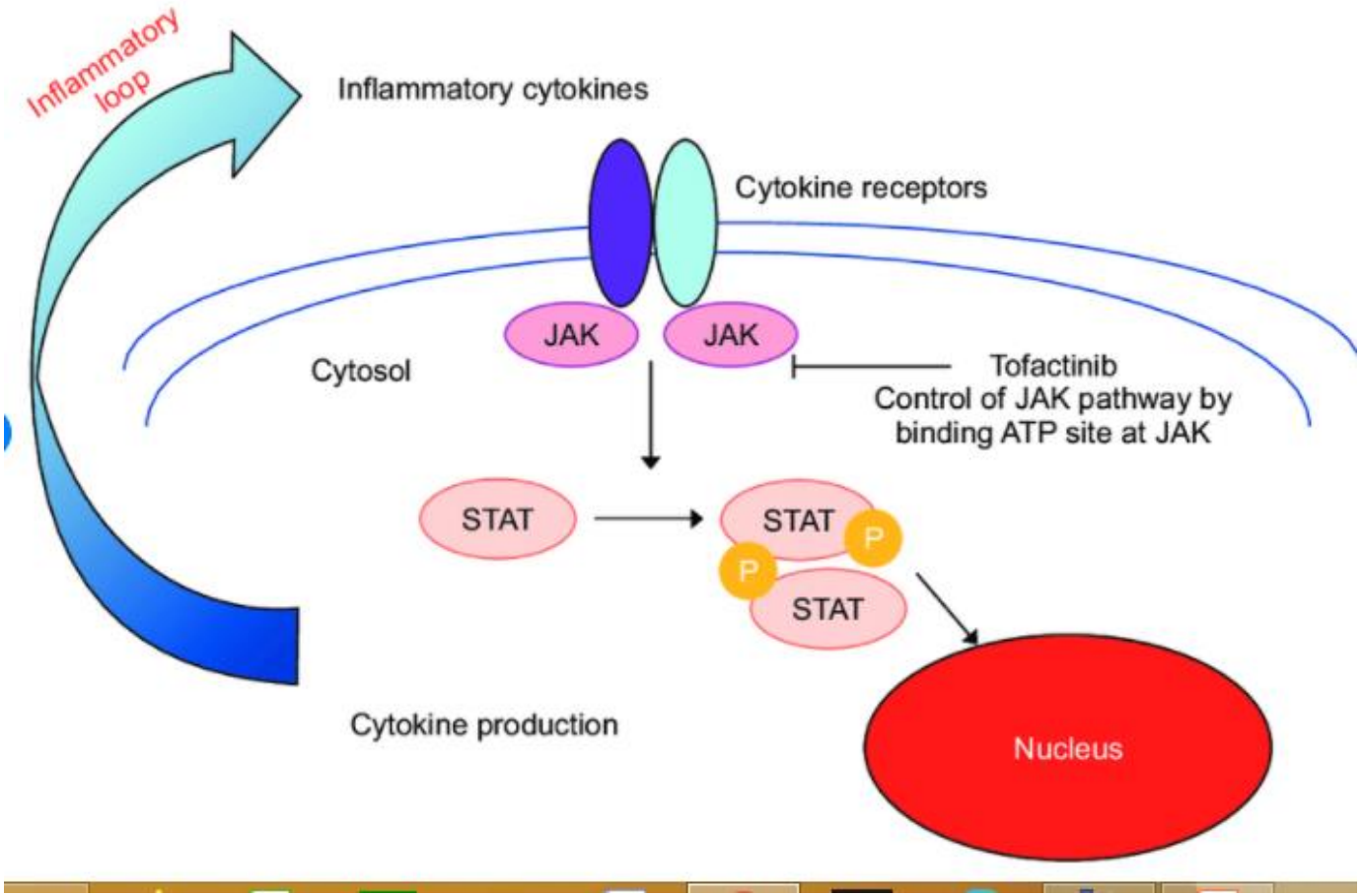
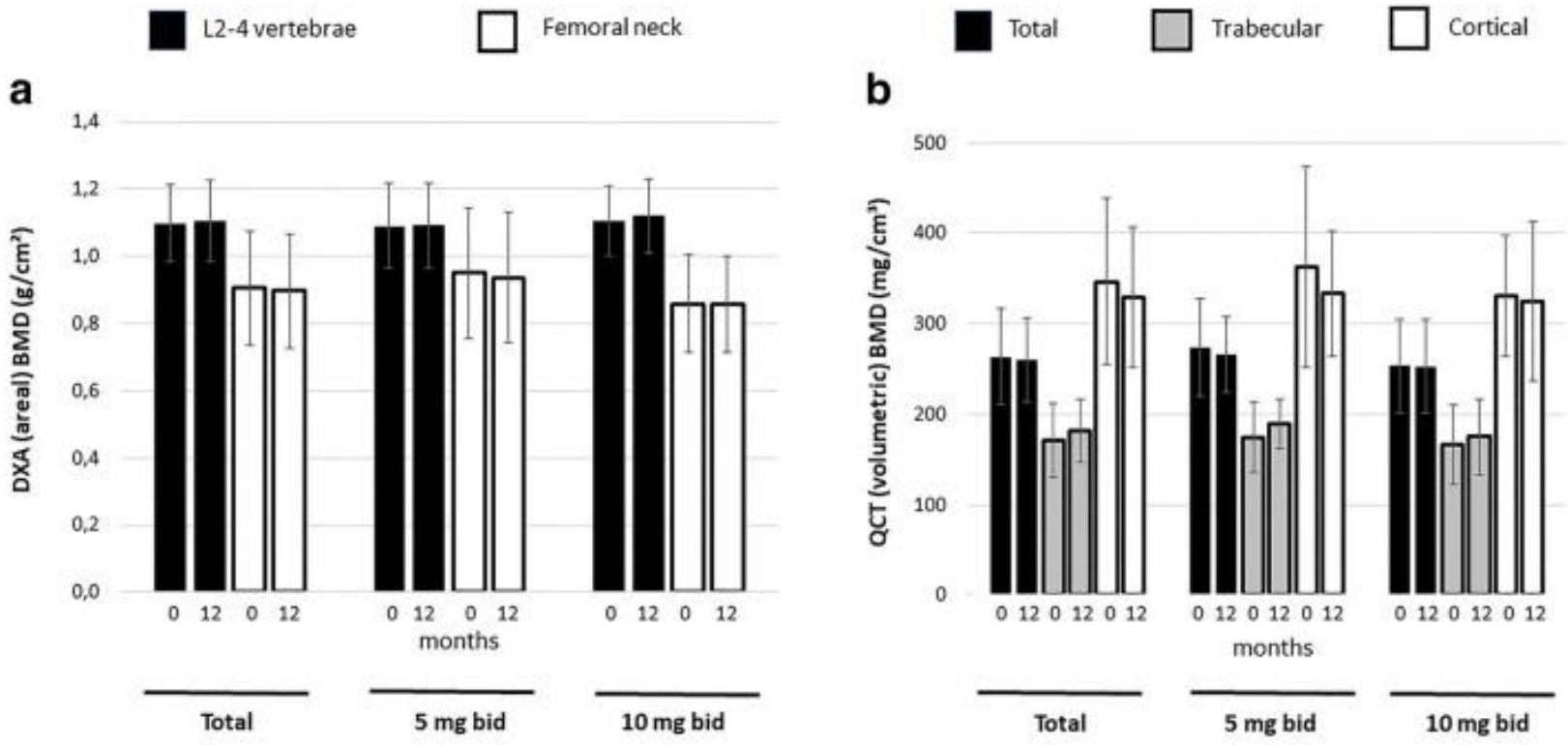

CYTOKINE
CYTOKINE RECEPTOR
CELL MEMBRANE
JAK
JAK
STAT
STAT
QUIESCENT STAT PROTEINS
JAK INHIBITOR
STAT
STAT
ACTIVATED STAT PROTEINS
NUCLEUS
STAT
REGULATION OF TRANSCRIPTION
CYTOKINES CHEMOKINES AND OTHER PROTEINS


Inflammatory loop
Inflammatory cytokines
Cytokine receptors
JAK
JAK
Cytosol
Tofactinib
Control of JAK pathway by binding ATP site at JAK
STAT
STAT
P
P
STAT
Cytokine production
Nucleus

	Tofacitinib 5-mg bid	Tofacitinib 10-mg bid	Total
Number of recruited patients (*n*)	15	15	30
Female/male ratio	14:1	13:2	27:3
Age (mean ± SD) (range), years	52.3 ± 11.4 (27–69)	53.3 ± 8.8 (34–69)	52.8 ± 10.0 (27–69)
Disease duration (mean ± SD) (range), years	6.3 ± 4.7 (1–15)	7.1 ± 4.9 (2–21)	7.7 ± 5.0 (1–21)
RF positivity, *n* (%)	12 (80)	12 (80)	24 (80)
Anti-CCP positivity, *n* (%)	13 (87)	11 (73)	24 (80)
DAS28 (baseline) (mean ± SD)	4.80 ± 0.69	5.29 ± 0.79	5.05 ± 0.77
Fragility fracture history	2	0	2
DXA L2-4 osteoporosis (T-score < − 2.5)	0	0	0
DXA L2-4 osteopenia (T-score < − 1)	7	3	10
DXA femoral neck osteoporosis (T-score < − 2.5)	1	2	3
DXA femoral neck osteopenia (T-score < − 1	4	4	8

Effects of 1-year tofacitinib therapy on areal and volumetric BMD, total, 5-mg bid, and 10-mg bid subsets. (A) Baseline and 12-month L2–4 vertebral and femoral neck BMD as determined by DXA. (B) Total, trabecular, and cortical volumetric BMD changes as determined by QCT



Effects of 1-year tofacitinib therapy on (A) osteocalcin, (B) CTX, (C) osteoprotegerin, and (D) 25-hydroxy-vitamin D3 levels. Total, 5-mg bid, and 10-mg bid subsets. $^{*}p < 0.05$

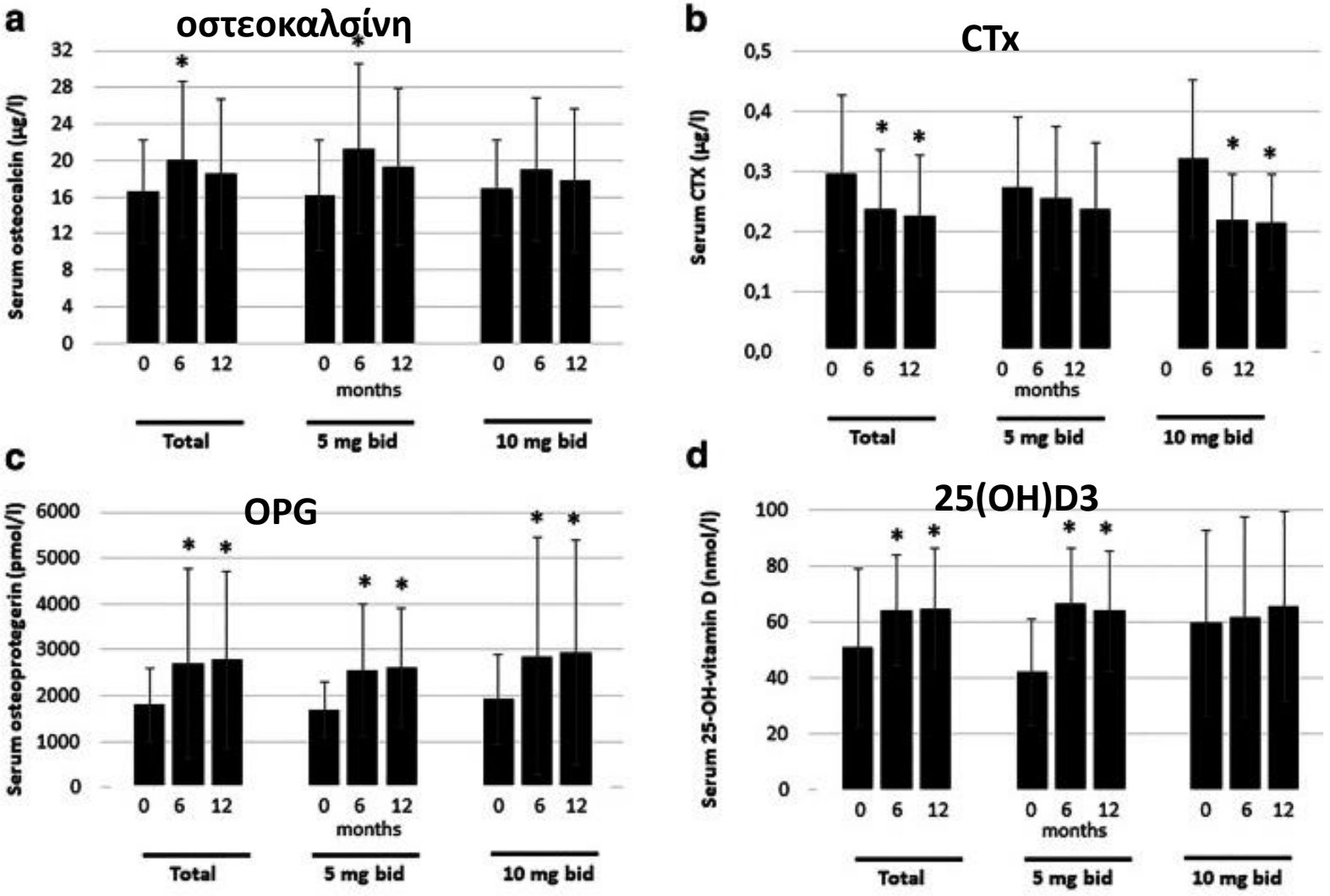


Table 2 Univariable and multivariable analysis of determinants of DXA and QCT parameters

Dependent variable	Independent variable	Univariable regression analysis				Multivariable regression analysis			
		β	*p*	B	95% CI	β	*p*	B	95% CI
DXAL24BMD-0	*CTX-0*	−0.463	0.015	−0.414	−0.741- -0.088				
DXAL24BMD-12	*CTX-0*	−0.474	0.013	−0.432	−0.763- -0.101	−0.474	0.013	−0.432	−0.763- -0.101
	CTX-12	−0.484	0.043	−0.392	−0.952- -0.016				
	P1NP-12	−0.457	0.017	−0.003	−0.006- -0.001				
	RANKL-0	−0.390	0.045	0	−0.001-0				
DXAFNBMD-0	*Age*	−0.531	0.004	−0.009	−0.025- -0.003	−0.522	0.001	−0.009	−0.012- -0.004
	OC-0	−0.558	0.002	−0.017	−0.027- -0.007	−0.550	< 0.001	−0.017	−0.025- -0.008
	CTX-0	−0.555	0.003	−0.751	−1.215- -0.288				
DXAFNBMD-12	*Age*	−0.568	0.002	−0.010	−0.015- -0.004	−0.543	< 0.001	−0.009	−0.013- -0.005
	OC-0	−0.536	0.004	−0.016	−0.027- -0.006	−0.345	0.030	−0.010	−0.020- -0.001
	OC-12	−0.482	0.011	−0.010	−0.017- -0.003				
	CTX-0	−0.549	0.003	−0.739	−1.202- -0.275	−0.312	0.048	−0.420	−0.836-0.005
	P1NP-12	−0.382	0.049	−0.004	−0.008-0				

Univariable and multivariable analysis of determinants of DXA and QCT parameters

Dependent variable	Independent variable	Univariable regression analysis				Multivariable regression analysis			
		β	*p*	B	95% CI	β	*p*	B	95% CI
QCTTOTBMD-0	-								
QCTTOTBMD-12	*CRP-12*	−0.389	0.033	−2.359	−4.519--0.199				
QCTTRABBMD-0	*DAS28-0*	−0.389	0.034	−20.730	−39.730--1.72				
QCTTRABBMD-12	-								
QCTCORTBMD-0	-								
QCTCORTBMD-12	*RANKL-0*	−0.398	0.029	−0.217	−0.410--0.023	−0.364	0.031	−0.198	−0.377--0.019
	CRP-12	−0.424	0.020	−4.305	−7.867--0.743	−0.392	0.021	−3.983	−7.325--0.641

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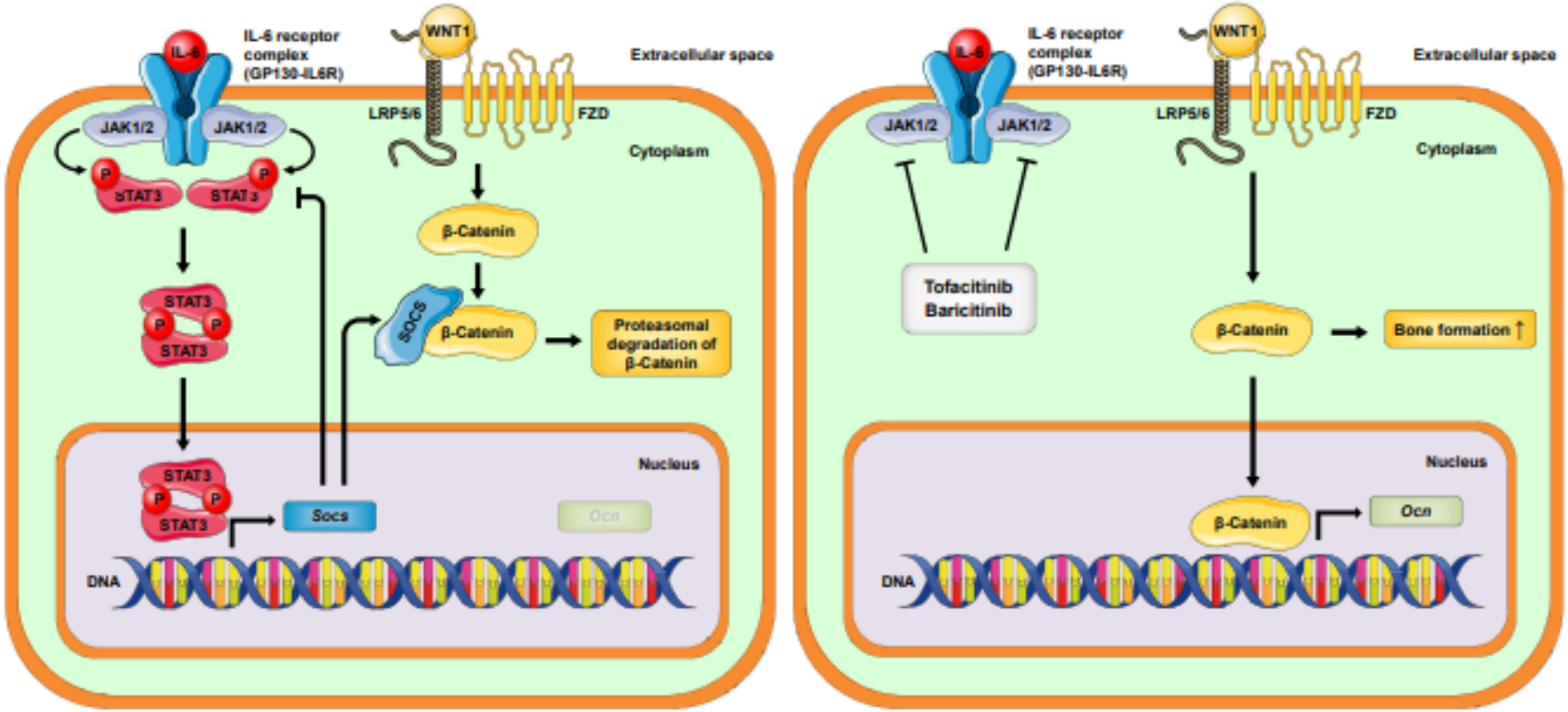
Journal of Cellular Immunology Commentary

Prospects of JAK Inhibition in the Framework of Bone Loss

Susanne Adam[1,2], Georg Schett[1,2], Silke Frey[1,2*]



Συμπέρασμα

- **Το Tofacitinib έδειξε μείωση στην οστική απώλεια σε PA ασθενείς και στις 2 δόσεις**
- **Η DXABMD έδειξε συσχέτιση με την ηλικία, OC, CTX**
- **Η QCTBMD συσχέτιση με CRP, RANKL**
- **Περισσότερες μελέτες**

Ευχαριστώ