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IL PAZIENTE REUMATICO ANZIANO

L'APPROCCIO FARMACOLOGICO

Safety delle terapie utilizzate in reumatologia

Farmaci biotecnologici

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BIOPURE
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EXTENDED REPORT *Ann Rheum Dis* 2014;**73**:1673–1676. doi:10.1136/annrheumdis-2013-203341

Evaluation of the RABBIT Risk Score for serious infections

A Zink,[1,2] B Manger,[3] J Kaufmann,[4] C Eisterhues,[5] A Krause,[6] J Listing,[1] A Strangfeld[1]

Table 1 Calculation of the RABBIT Risk Score

Risk factors		V.1: Number of serious infections per 100 PYs	V.2: Percentage of patients with at least one infection per year
Intercept	Always add	−3.996	−4.191
Age	If age >60 add	0.479	0.470
Function (FFbH)	Add	−0.01014*FFbH	−0.00865*FFbH
Alternatively: HAQ	Add	0.362(HAQ-3.16)	0.309(HAQ-3.16)
Chronic lung disease	If yes add	0.522	0.484
Chronic renal disease	If yes add	0.441	0.415
Previous serious infection	If yes add	0.748	0.992
Number of treatment failures	If >5 add	0.443	0.397
Mean glucocorticoid dose	If 7.5–14 mg/day add	0.756	0.782
Mean glucocorticoid dose	If ≥ 15 mg/day add	1.554	1.355
Treatment with TNF inhibitor	If yes (last 3 months) add	0.593	0.589
Calculate the sum of the corresponding values		Sum1	Sum2
Rabbit Risk Score	Calculate	$100*e^{sum1}$	$100*(1-e^{-e^{sum2}})$

FFbH, Hannover Functional Status Questionnaire, Funktionsfragebogen Hannover; HAQ, Health Assessment Questionnaire; PY, patient-years; RABBIT, Rheumatoid Arthritis Observation of Biologic Therapy; TNF, tumour necrosis factor.

Curtis *et al. Arthritis Research & Therapy* (2017) 19:276
DOI 10.1186/s13075-017-1466-y

RESEARCH ARTICLE Open Access

Use of a baseline risk score to identify the risk of serious infectious events in patients with rheumatoid arthritis during certolizumab pegol treatment

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Relative serious infectious event risk associated with baseline age categories and medically treated comorbidities included in **age-adjusted comorbidity index (AACI)**

Category		HR (95% CI) RCT CZP (n = 1224)	HR (95% CI) All CZP (n = 1506)	Weight in the AACI[a]
Age, years	<50	Reference	Reference	0
	≥50 to <60	1.29 (0.58–2.87)	1.39 (0.99–1.96)	1
	≥60 to <70	1.14 (0.44–2.94)	1.40 (0.92–2.12)	1
	≥70	2.18 (0.70–6.84)	2.93 (1.69–5.09)	3
Diabetes mellitus		1.98 (0.59–6.58)	1.61 (0.90–2.89)	2
COPD/asthma		2.67 (0.77–9.27)	1.29 (0.56–2.97)	2
Cardiac disorder		N/C	1.33 (0.52–3.43)	0
Hypertension		1.34 (0.69–2.63)	0.96 (0.70–1.32)	0
Hyperlipidemia		2.39 (0.82–6.93)	1.47 (0.81–2.67)	2
Thyroid disorder		N/C	0.87 (0.42–1.78)	0
Osteoporosis		2.30 (0.98–5.39)	1.16 (0.73–1.86)	2
Depression		1.00 (0.22–4.51)	1.46 (0.75–2.83)	1

Atzeni F, et al, Long-term anti-TNF therapy and the risk of serious infections in a cohort of patients with rheumatoid arthritis: Comparison of adalimumab, etanercept and infliximab in the GISEA registry, Autoimmun Rev (2012), doi:10.1016/j.autrev.2012.06.008

"serious" (defined as life-threatening, requiring hospitalisation and/or intravenous antibiotic therapy, or leading to significant disability/incapacity or a comparable significant risk)

Baseline demographic and clinical data of the RA patients in the GISEA Register.

	All patients 2769	Infliximab 837 (30.2%)	Adalimumab 802 (29.0%)	Etanercept 1130 (40.8%)	p
Age (years)	53.18 ± 13.35	52.98 ± 12.93	53.84 ± 12.65	52.85 ± 14.14	ns
Females	2277 (82.2%)	673 (80.4%)	672 (83.8%)	932 (82.5%)	ns
Males	492 (17.8%)	164 (19.6%)	130 (16.2%)	198 (17.5%)	ns
Disease duration (years)	9.02 ± 8.34	9.08 ± 8.06	9.07 ± 8.57	8.95 ± 8.40	ns

Univariable and multivariable predictors of serious infections.

	Univariate				Multivariate			
	HR[a]	95% CI[b]		p	AHR[c]	95% CI[b]		p
Age at start of anti-TNF treatment	1.03	1.02	1.04	<.0001	1.036	1.02	1.053	<.0001
Disease duration	1.009	0.99	1.03	0.3	1.004	0.98	1.025	0.709
DAS28	1.055	0.94	1.19	0.381	0.946	0.81	1.107	0.49
DI-HAQ	1.443	1.15	1.81	0.002	1.156	0.85	1.576	0.358
Etanercept	1				1			
Adalimumab	1.942	1.2	3.15	0.0007	2.224	1.12	4.421	0.023
Infliximab	4.291	2.84	6.47	<.0001	4.916	2.71	8.906	<.0001
DMARDs	2.178	1.59	2.98	<.0001	2.145	1.28	3.595	0.004
Corticosteroids	1.849	1.36	2.51	<.0001	1.633	1.01	2.644	0.046
Comorbidity	0.899	0.67	1.21	0.479	1.246	0.87	1.791	0.234

Table 1 Baseline characteristics of elderly RA patients

Characteristic	Biologics ($n = 64$)	Non-Biologics ($n = 119$)	P
Age (years, mean ± SD)	73.7 ± 5.1	73.7 ± 5.8	0.92
Female, *n* (%)	50 (78.1%)	83 (69.7%)	0.22
Disease duration (years, mean ± SD)	12.7 ± 9.7	10.9 ± 13.3	0.34
RF positive, *n* (%)	57 (89.1%)	97 (81.5%)	0.18
ESR 60 (mm, mean ± SD)	60.6 ± 33.0	36.7 ± 28.7	<0.001
CRP (mg/L, mean ± SD)	27.9 ± 34.4	13.7 ± 35.6	0.011
Steinbrocker stage (I + II/III + IV)	32/32	71/48	0.23
Comorbidities, *n* (%)			
Coexisting lung disease	21 (32.8%)	31 (26.1%)	0.33
Diabetes mellitus	3 (4.7%)	8 (6.7%)	0.58
Medications, *n* (%)			
Methotrexate	51 (79.7%)	95 (79.8%)	0.98
Other DMARDs	21 (32.8%)	61 (51.3%)	0.016
PSL (mg/day)	1.8 ± 2.5	1.9 ± 3.1	0.78
PSL, any dose (%)	28 (43.7%)	44 (37.0%)	0.37
PSL ≧5 mg/day	12 (18.7%)	27 (22.7%)	0.39
Biologics, *n* (%)			
TNF inhibitors	36 (56.2%)		
Tocilizumab	6 (9.4%)		
Switch of biologics	22 (34.4%)		

RF rheumatoid factor, *DAS* disease activity score, *DMARDs* disease-modifying antirheumatic drugs, *PSL* prednisolone

Rheumatol Int (2017) 37:369–376 DOI 10.1007/s00296-016-3631-z

Table 2 Incidence of serious infections that required hospitalization in elderly RA patients

Serious infections	Biologics ($n = 64$)	Non-biologics ($n = 119$)	P
Number of events	13	21	
Number of patients with ≧1 events	10	16	0.68
Biologics, OR (95% CI)	1.2 (0.5–2.8)	1.0 (ref.)	0.74
Observation period (months), median (IQR)	36 (26–36)	36 (31–36)	0.007
Rate, per 100 Person-years (95% CI)	8.0 (4.7–13.5)	6.3 (4.1–9.5)	0.78
Bacterial pneumonia, *n*	6	12	
Cellulitis, *n*	3	2	
Pyelonephritis, *n*	1	3	
Pneumocystis pneumonia, *n*	1	0	
Gastroenteritis, *n*	1	1	
Bacterial arthritis, *n*	1	1	
Viral infection, *n*	0	2	

IQR interquartile range, *ref.* reference

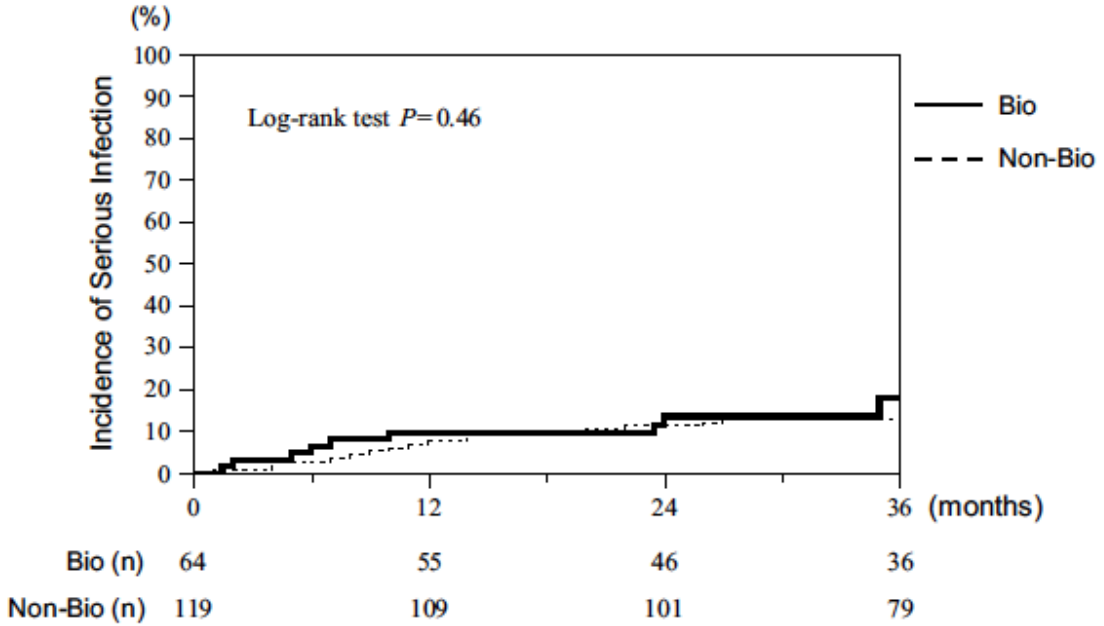

Fig. 1 Kaplan–Meier curves of incidence of serious infections between biologics and non-biologics groups in elderly RA patients. Time to the first serious infection that required hospitalization was analyzed using the Kaplan–Meier method. Incidence of serious infections is not significantly different between biologics and non-biologics groups in elderly RA patients (log-rank test $P = 0.46$)

Multiple regression analysis of risk factors for serious infections in biologics and non-biologics group of elderly RA patients

	All ($n = 183$)		Biologics ($n = 64$)		Non-biologics ($n = 119$)	
	OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*
Aging ≧75 years	0.8 (0.3–2.1)	0.65	1.1 (0.2–5.3)	0.91	0.7 (0.2–2.4)	0.59
Biologics	1.1 (0.4–3.2)	0.78	–	–	–	–
PSL none	1.0 (ref.)		1.0 (ref.)		1.0 (ref.)	
1–4 mg/day	5.7 (1.5–24.2)	0.012	11.7 (1.5–257.1)	0.02	3.6 (0.4–24.5)	0.21
≧5 mg/day	21.5 (6.8–84.2)	<0.001	29.3 (3.6–652.2)	<0.001	19.2 (4.9–101.0)	<0.001
DMARDs	0.7 (0.1–6.3)	0.70	0.2 (0.01–2.7)	0.21	–	–
Coexisting lung disease	0.9 (0.3–2.5)	0.89	0.4 (0.03–2.5)	0.33	1.2 (0.3–4.3)	0.83

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Safety of Biologic Agents in Elderly Patients with Rheumatoid Arthritis

Atsuko Murota, Yuko Kaneko, Kunihiro Yamaoka, and Tsutomu Takeuchi

ABSTRACT. ***Objective.*** To clarify the safety of biologics in elderly patients with rheumatoid arthritis.

Methods. Biologics were analyzed for safety in relation to age in 309 patients.

Results. Young (< 65 yrs old, n = 174), elderly (65–74 yrs old, n = 86), and older elderly patients (≥ 75 yrs old, n = 49) were enrolled. Although the incidence of adverse events causing treatment withdrawal was significantly higher in elderly and old elderly compared with young patients, no difference was found between elderly and older elderly patients. Pulmonary complications were independent risk factors.

Conclusion. Old patients require special attention, although the safety of biologics in those ≥ 75 years old and 65–74 was comparable. (J Rheumatol First Release September 1 2016; doi:10.3899/jrheum.160012)

Characteristics	Total, n = 309	Young, n = 174	Elderly n = 86	Older Elderly, n = 49	ANOVA p	Student t Test		
						< 65 vs 65–74 y/o	< 65 vs ≥ 75 y/o	65–74 vs ≥ 75 y/o
Age, yrs, mean ± SD	59.7 ± 14.9	49.4 ± 11.5	69.7 ± 2.9	78.3 ± 3.1				
Disease duration, weeks, mean ± SD	398.9 ± 527.2	298.0 ± 382.3	422.8 ± 558.4	715.2 ± 751.1				
Female, %	82.8	86.8	79.1	83.7				
DAS28-ESR, mean ± SD	4.9 ± 4.9	4.7 ± 1.4	5.2 ± 1.3	5.2 ± 1.5	**< 0.01**	**0.02**	**< 0.01**	0.41
Stage 1/2/3/4, (n)	104/114/18/71	76/63/9/26	19/40/5/20	9/11/4/25				
Class 1/2/3/4, (n)	71/188/33/0	59/98/10/0	7/62/10/0	5/28/13/0				
HAQ-DI	1.07	0.86	1.18	1.63	**< 0.01**	**< 0.01**	**< 0.01**	**< 0.01**
Current smoking, n (%)	74 (24.1)	40 (23.3)	29 (33.7)	5 (10.2)	**0.03**	0.17	0.26	**0.02**
Brinkman index	131.0	82.3	237.2	115.7	**< 0.01**	**< 0.01**	**0.03**	**0.02**
MTX usage, n (%)	262 (84.8)	155 (89.1)	71 (82.6)	36 (73.5)				
Dose, mg/week	8.7	9.6	7.4	7.1	**< 0.01**	**< 0.01**	**< 0.01**	0.60
Total amount, mg	999.2	920.7	876.6	1575.8	0.11			
PSL usage, n (%)	98 (31.7)	50 (28.7)	30 (34.9)	18 (36.7)				
Dose, mg/day	4.8	4.9	4.8	4.4	0.88			
Total amount, mg	12666.0	17102.5	5236.0	11733.9	0.09			
Biologics, n (%)								
TNFi	166 (53.7)	108 (62.1)	42 (48.8)	16 (32.7)				
TCZ	92 (29.8)	58 (33.3)	25 (29.1)	9 (18.4)	**< 0.01**	**< 0.01**	**< 0.01**	**< 0.01**
ABA	51 (16.5)	8 (4.6)	19 (22.1)	24 (49.0)				
Complications, n (%)								
Pulmonary diseases	56 (18.1)	23 (13.2)	19 (22.1)	14 (28.6)	**< 0.05**	0.08	**0.02**	0.41
Cardiovascular diseases	22 (7.1)	5 (2.9)	12 (14.0)	5 (10.2)	**< 0.01**	**< 0.01**	**0.04**	0.60
Lifestyle diseases	75 (24.3)	26 (14.9)	29 (33.7)	20 (40.8)	**< 0.01**	**< 0.01**	**< 0.01**	0.46
Diabetes mellitus	16 (5.2)	6 (3.4)	6 (7.0)	4 (8.2)				
Hypertension	53 (17.2)	18 (10.3)	18 (20.9)	17 (34.7)				
Hyperlipidemia	23 (7.4)	7 (4.0)	10 (11.6)	6 (12.2)				
Renal function eGFR	80.8 ± 22.3	88.2 ± 19.9	73.5 ± 23.4	67.1 ± 17.9	**< 0.01**	**< 0.01**	**< 0.01**	0.0977

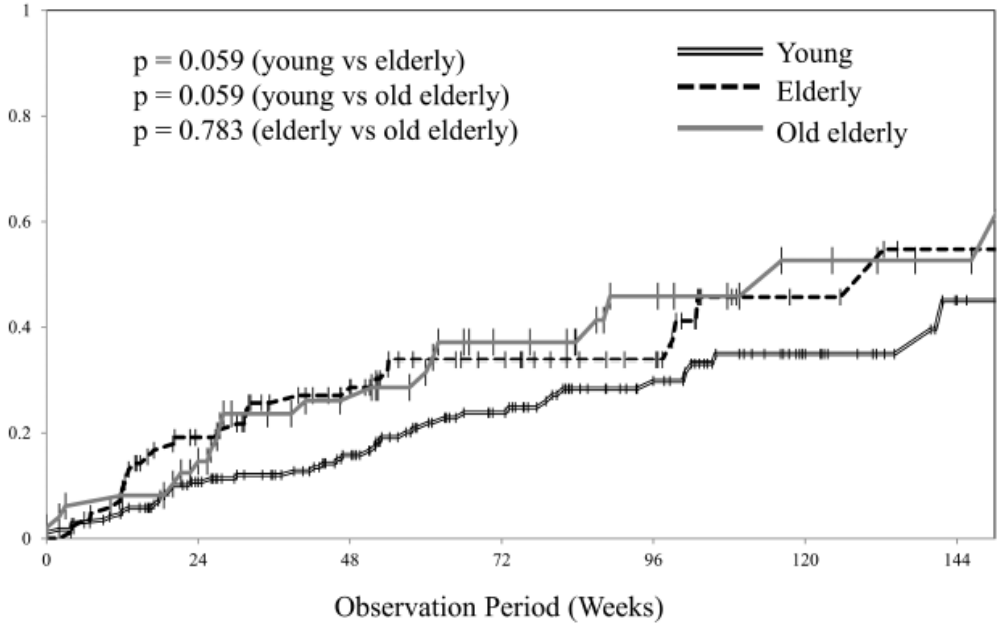


Figure 1. Discontinuation rate of biologic agents in the young group, the elderly, and the older elderly.

Table 2. Risk factors associated with adverse events leading to withdrawal of biologic agents.

Variables	OR	95% CI	p	Multiple Regression p, stepwise method
Age, yrs				
< 65 yrs vs ≥ 65 yrs	2.68	1.31–5.48	< 0.01	**0.015**
Disease duration, weeks	—	—	0.08	0.617
Sex	1.55	0.66–3.64	0.34	
DAS28-ESR	—	—	0.86	
HAQ-DI	—	—	0.12	0.090
Current smoking	1.31	0.61–2.80	0.54	
Brinkman index	—		0.39	
Concomitant use of MTX	0.49	0.22–1.13	0.14	0.151
mg/weeks	—	—	0.22	
Amount, mg	—	—	0.22	
Concomitant use of PSL	1.48	0.73–2.97	0.27	
mg/day	—	—	0.91	
Amount, mg	—	—	0.71	
Biologics				
TNFi	—	—		
TCZ	—	—	0.26	
ABA	—	—		
Pulmonary diseases	2.76	1.31–5.81	0.01	**< 0.01**
Cardiovascular diseases	2.26	0.78–6.54	0.17	0.086
Lifestyle diseases	1.32	0.62–2.80	0.54	
Renal function				
eGFR	—		0.103	0.151

Table 1 Comparison of demographic and clinical characteristics in elderly and younger patients treated with TNF inhibitors

	Total ($n = 429$)	Elderly patients ($n = 107$)	Younger patients ($n = 322$)	p-value
Age, year	**49.5 ± 13.6**	**66.1 ± 5.4**	**44.0 ± 10.6**	**<0.01**
Sex, male	**60 (14.0)**	**24 (22.4)**	**36 (11.2)**	**0.01**
Disease duration, years	**8.6 ± 6.8**	**10.0 ± 7.9**	**8.2 ± 6.4**	**0.03**
First use of TNF inhibitor	329 (76.7)	83 (77.6)	246 (76.4)	0.91
Number of previous non-biologic DMARDs used	**4.1 ± 1.5**	**4.4 ± 1.7**	**3.9 ± 1.5**	**0.01**
Concomitant MTX use	311 (72.5)	79 (73.8)	232 (72.1)	0.75
Concomitant MTX dosage, mg/week	14.0 ± 3.8	13.6 ± 3.5	14.2 ± 3.6	0.20
Concomitant glucocorticoid use	331 (77.2)	83 (77.6)	248 (77.0)	1.00
Concomitant glucocorticoid dosage, mg/day	6.0 ± 4.1	6.5 ± 5.8	5.8 ± 3.4	0.34
RF positivity	327 (76.2)	84 (78.5)	243 (75.5)	0.59
DAS28-ESR*	6.0 ± 0.9	6.0 ± 0.8	6.0 ± 0.9	0.46
Comorbid conditions				
Cardiovascular disease	**12 (2.8)**	**8 (7.5)**	**4 (1.2)**	**<0.01**
Pulmonary disease[a]	**23 (5.4)**	**17 (15.9)**	**6 (1.9)**	**<0.01**
Previous history of pulmonary tuberculosis	41 (9.6)	14 (13.1)	27 (8.4)	0.21
Gastrointestinal disease	138 (32.2)	41 (38.3)	97 (30.1)	0.15
Hepatobiliary disease[b]	46 (10.7)	13 (12.2)	33 (10.3)	0.71
Diabetes mellitus	**41 (9.6)**	**20 (18.7)**	**21 (6.5)**	**<0.01**
Malignancy	18 (4.2)	7 (6.5)	11 (3.4)	0.17
Hypertension	**95 (22.1)**	**50 (46.7)**	**45 (14.0)**	**<0.01**
Thyroid disease	26 (6.1)	7 (6.5)	19 (5.9)	0.99
Renal disease[c]	10 (2.3)	1 (0.9)	9 (2.8)	0.46
Biologic agents				
Etanercept	264 (61.5)	72 (67.3)	192 (59.6)	0.34
Adalimumab	113 (26.3)	25 (23.4)	88 (27.3)	
Infliximab	52 (12.1)	10 (9.4)	42 (13.0)	

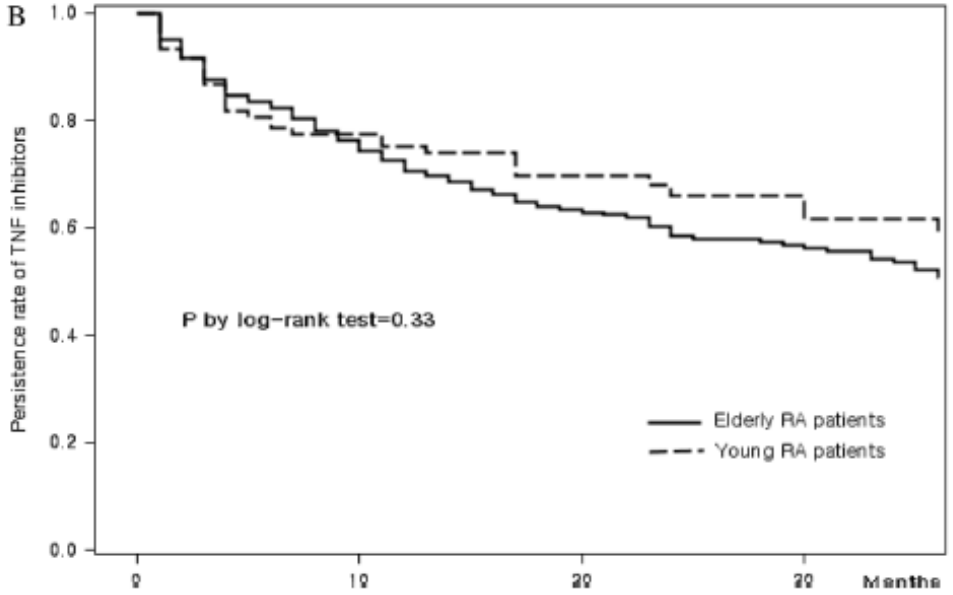


Fig. 1 Persistence rate of TNF inhibitors. **a** Persistence rate of TNF inhibitors in total patients. **b** Comparison of TNF inhibitor persistence rate between elderly patients and younger patients

Table 2 Reasons for discontinuation of TNF inhibitors, N (%)

	Total ($n = 429$)	Elderly patients ($n = 107$)	Younger patients ($n = 322$)	p value
Number of discontinuations	167 (38.9)	35 (32.7)	132 (41.0)	0.16
Reason for discontinuation				0.43
Adverse effect	**44 (26.4)**	**12 (34.3)**	**32 (24.2)**	
Ineffectiveness	**64 (38.3)**	**9 (25.7)**	**55 (41.7)**	
Patient need	37 (22.2)	9 (25.7)	28 (21.2)	
Good effectiveness	7 (4.2)	2 (5.7)	5 (3.8)	
Economic problem	3 (1.8)	1 (2.9)	2 (1.5)	
Operation or hospitalization	4 (2.4)	1 (2.9)	3 (2.3)	
Other[a]	3 (1.8)	1 (2.9)	2 (1.5)	
Unknown	5 (3.0)	-	5 (3.8)	

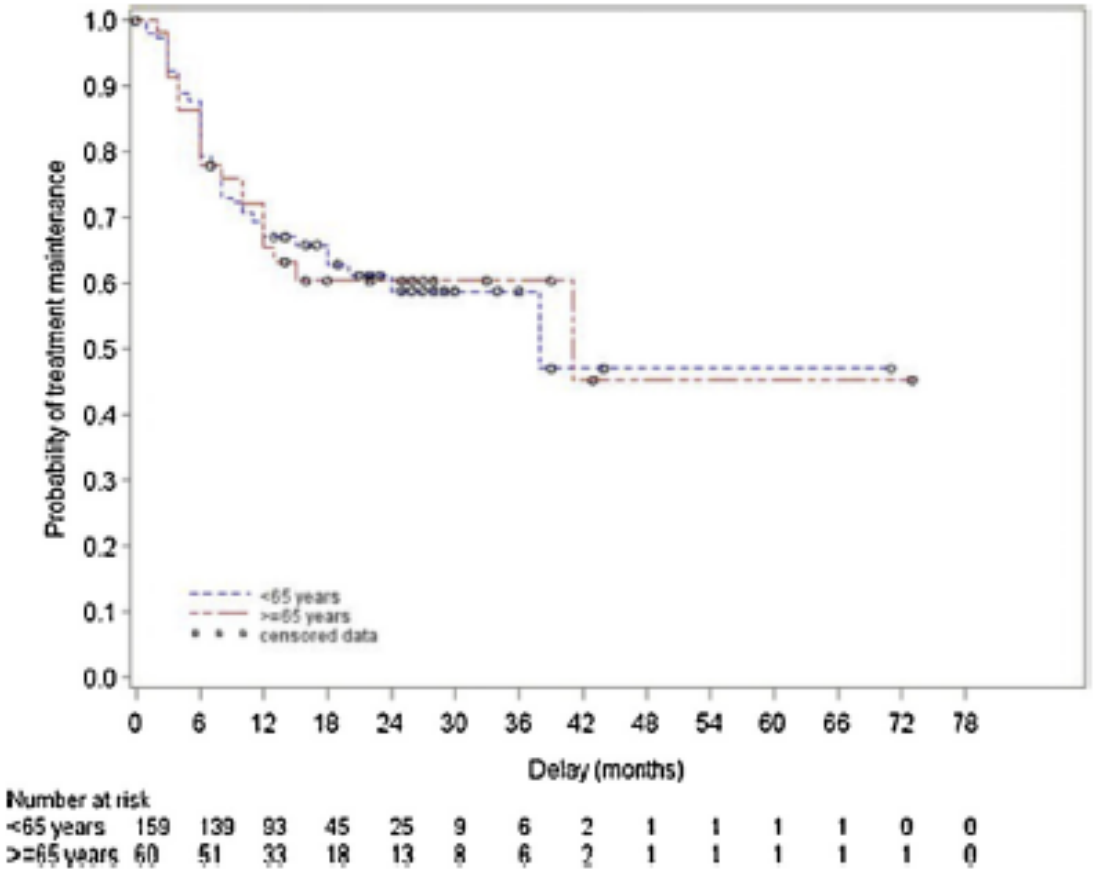
[a]Other reasons include mobility impaired, preparation for pregnancy, and dental treatment
Bold means statistical significant at the $p < 0.05$

Table 1
Baseline characteristics of rheumatoid arthritis patients treated with tocilizumab, and comparisons according to their age group.

Characteristics	Global population (n = 222)	< 65 years (n = 161)	≥ 65 years (n = 61)	P
Age, median (IQR), years	56 (47-66)	–	–	–
Female, n (%)	183 (82.4)	133 (82.6)	50 (82)	0.911
Disease duration, median (IQR), years	14 (8–22)	12 (7–20)	18.5 (11.5–28.5)	< 0.001
Active smokers, n (%)	40 (23.7)	37 (30.6)	3 (6.3)	< 0.001
Prior cardiovascular diseases, n (%)	50 (22.5)	29 (18)	21 (34.4)	< 0.001
Prior cancer diseases, n (%)	8 (3.6)	4 (2.5)	4 (6.7)	0.217
Erosive status, n (%)	173 (79)	117 (74.2)	55 (91.7)	0.005
RF positive, n (%)	154 (71)	111 (69.8)	43 (74.1)	0.534
ACPA positive, n (%)	140 (65.7)	103 (66)	37 (64.9)	0.880
Naïve to biologics, n (%)	29 (13.1)	18 (11.2)	11 (18)	0.176
Previous biologics use, median (min–max)	3 (1–6)	3 (1–6)	2 (1–6)	0.188
Previous DMARDs use, median (min–max)	3 (1–10)	3 (1–7)	4 (1–10)	< 0.001
Concomitant therapy				
MTX, n (%)	105 (47.3)	82 (50.9)	23 (37.7)	0.078
MTX dose, median (IQR), mg/week	15 (10–15)	15 (10–17.5)	15 (12.5–15)	0.933
Other DMARDs, n (%)	24 (10.8)	15 (9.4)	9 (14.8)	0.294
Steroid, n (%)	143 (64.7)	99 (61.9)	44 (72.1)	0.154
Steroid dose, median (IQR), mg/day	10 (5–10)	10 (5–15)	8 (5–10)	0.042
TCZ dose, median (min–max), mg/kg	8 (4–8)	8 (4–8)	8 (8–8)	0.539
Baseline disease activity measures				
ESR, median (IQR), mm	27 (11–44)	22.5 (10–36)	36 (18–52)	0.002
CRP, median (IQR), mg/L	8 (3–24)	8 (3–20)	11.8 (3–60.6)	0.077
DAS28-ESR, mean (SD)	5.1 (1.3)	5.0 (1.3)	5.3 (1.3)	0.152
Follow-up duration, median (IQR), months	12 (6–20)	12 (7–20)	18.5 (11.5–28.5)	< 0.001

IQR: interquartile range; n: number; RF: rheumatoid factor; ACPA: anti-citrullinated peptide antibodies; DMARDs: disease modifying anti-rheumatic drugs (leflunomide, sulfasalazine, hydroxychloroquine or azathioprine); MTX: methotrexate; TCZ: tocilizumab; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; DAS28: Disease Activity Score in 28 joints; EULAR: European League Against Rheumatism

Drug maintenance for TCZ was similar between elderly and younger RA patients: 75% of patients were still taking TCZ at 8 months (95% CI [6–12]). At 6 months, 77 patients (34.7%) withdrew TCZ. Among them, reasons identified were inefficiency (31.2%), secondary failure (24.7%) and AE (40.3%).



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Rheumatic & Musculoskeletal Diseases

SHORT REPORT

Safety and efficacy of baricitinib in elderly patients with rheumatoid arthritis

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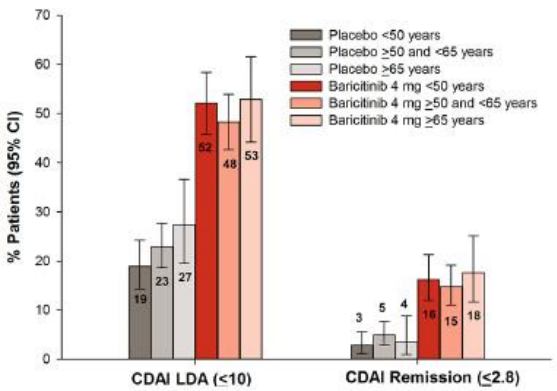
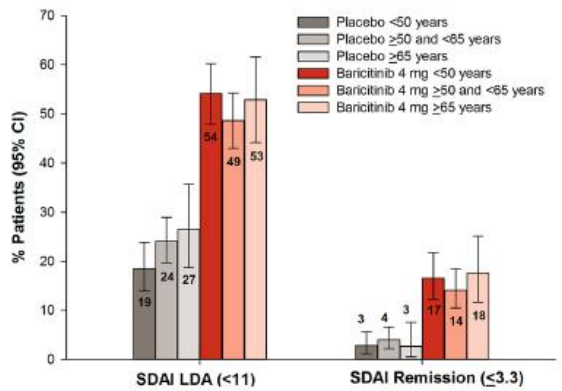
Table 2 Safety at week 24

	<50 years		≥50 and <65 years		≥65 years	
	Placebo (n=254)	Baricitinib 4 mg (n=259)	Placebo (n=349)	Baricitinib 4 mg (n=319)	Placebo (n=113)	Baricitinib 4 mg (n=136)
Patients with ≥1 adverse event	212 (83.5)	229 (88.4)	326 (93.4)	296 (92.8)	111 (98.2)	135 (99.3)
Discontinuation from study due to adverse event or death*	6 (2.4)	6 (2.3)	14 (4.0)	18 (5.6)	7 (6.2)	12 (8.8)
Discontinuation from study for any reason	21 (8.3)	14 (5.4)	31 (8.9)	28 (8.8)	19 (6.8)	17 (12.5)
Death†	0	0	2 (0.6)	1 (0.3)	0	1 (0.7)
Serious adverse event‡	10 (3.9)	8 (3.1)	11 (3.2)	15 (4.7)	12 (10.6)	12 (8.8)
Serious infections	4 (1.6)	3 (1.2)	5 (1.4)	2 (0.6)	2 (1.8)	4 (2.9)
Cardiac disorders	1 (0.4)	0	1 (0.3)	2 (0.6)	2 (1.8)	2 (1.5)
Patients with ≥1 infection	89 (35.0)	99 (38.2)	86 (24.6)	125 (39.2)	38 (33.6)	48 (35.3)
Herpes zoster	0	2 (0.8)	2 (0.6)	5 (1.6)	0	3 (2.2)

C CDAI Low Disease Activity/Remission at Week 24



D SDAI Low Disease Activity/Remission at Week 24



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Characteristics	All (nr. 225)	<45 years old (nr. 47)	45-64 years old (nr. 133)	≥65 years old (nr. 45)
Female. nr (%)	181 (80.4)	44 (93.6)°	104 (78.2)	**33 (73.3)°**
Disease duration, months.	40.5 (14.5-102)	30.5 (10-84)	48 (15-120)	36 (21-78)
BMI	25.6 (4,9)	22.9 (3.3)°*	25.8 (4.5)*#	**27.8 (5.8)°#**
Comorbidities. nr (%)	62 (27.6)	4 (8.5)°	26 (19.5)#	**32 (71.1)°#**
Lung disease. nr (%)	33 (14.7)	1 (2.1)°	14 (10.5)#	**18 (40)°#**
Diabetes. nr (%)	20	2 (4.3)°	8 (6)#	**10 (22.2)°#**
Heart disease. nr (%)	28 (12.4)	1 (2.1)°	10 (7.5)#	**17 (37.8)°#**
Smoking. nr (%)	65 (28.9)	12 (25.5)	44 (33.1)	9 (20)
ESR-DAS28	4.7 (1.4)	4.5 (1.5)	4.6 (1.5)	4.9 (1.2)
CDAI	20.5 (12.9)	20 (12.6)	20.7 (13.5)	20.6 (11.7)
HAQ-DI	1.17 (0.87)	0.7 (0.74)°*	1.14(0.84)*#	**1.7 (0.89)°#**
RF/ACPA nr (%)	190 (84.4)	38 (80.9)	113 (85)	39 (86.7)
Etanercept nr (%)	61 (27.1)	12 (25.5)	39 (29.3)	10 (22.2)
TNFa mAb nr (%)	54 (24)	12 (25.5)	33 (24.8)	9 (20)
Tocilizumab nr (%)	45 (20)	11 (23.4)	25 (18.8)	9 (20)
Abatacept nr (%)	65 (28.9)	12 (25.5)	36 (27.1)	**17 (37.8)**
Glucocorticoids nr (%)	166 (74.1)	33 (70.2)	96 (72.2)	37 (84.1)
csDMARDs. nr (%)	198 (88)	38 (80.9)	122 (91.7)	38 (84.4)
Suspension for ineffectiveness	75 (33.3)	16 (34)	48 (36.1)	11 (24.4)
Suspension for infective AE, nr (%)	4 (1.8)	0	1 (0.8)	3 (6.7)
Suspension for others AE	17 (7.6)	2 (4.3)	14 (10.5)	1 (2.2

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Infective Adverse Event (AE)

Infective AE, nr (%)	20 (8.9)
Suspension for AE, nr (%)	4 (1.8)
Data of 20 patients with AE during follow-up	
Follow-up time, median-months (IQR)	32 (24-48)
First AE, median-months (IQR)	21 (5-46)
Concomitant csDMARDs, nr. (%)	17 (89.5)
Glucocorticoids, mean (SD)	11 (59.7)
Type of biologics	5 TCZ, 4 ETN, 8 ABA, 3 anti-TNFmAb
Low respiratory tract, nr (%)	3 (15)
Upper respiratory tract, nr (%)	6 (30)
Skin infections, nr (%)	7 (35)
Urinary tract infection, nr (%)	4 (20)
Infective AE resolved, nr (%)	20 (100)

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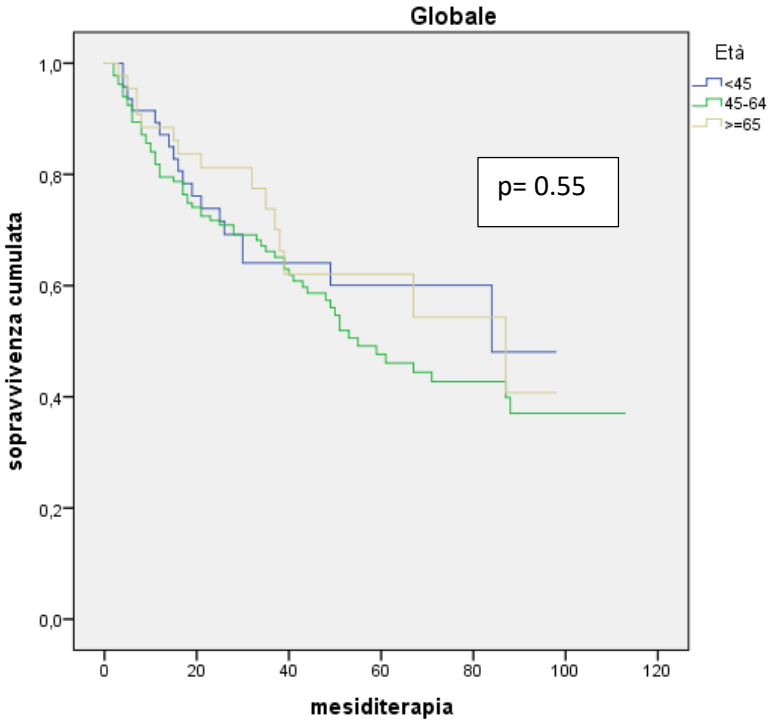
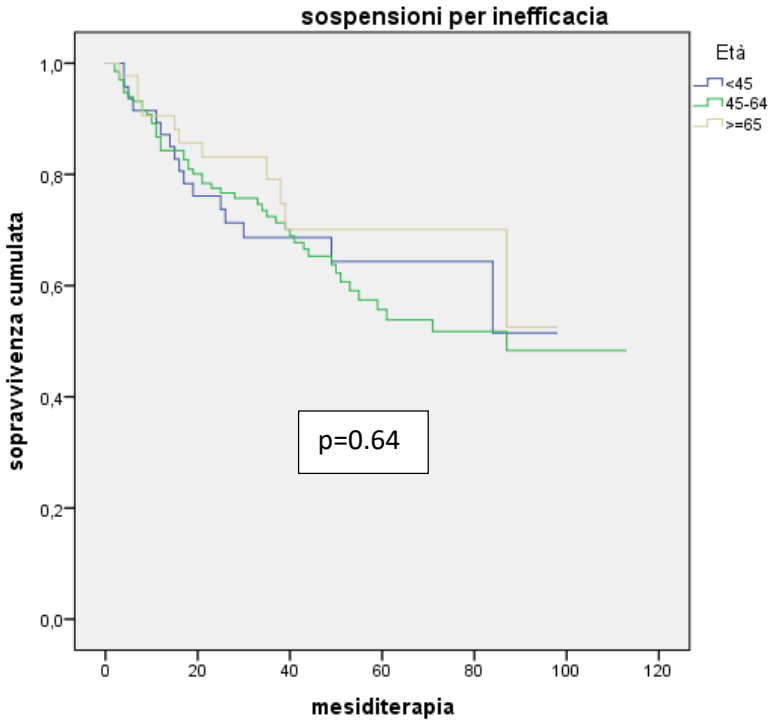
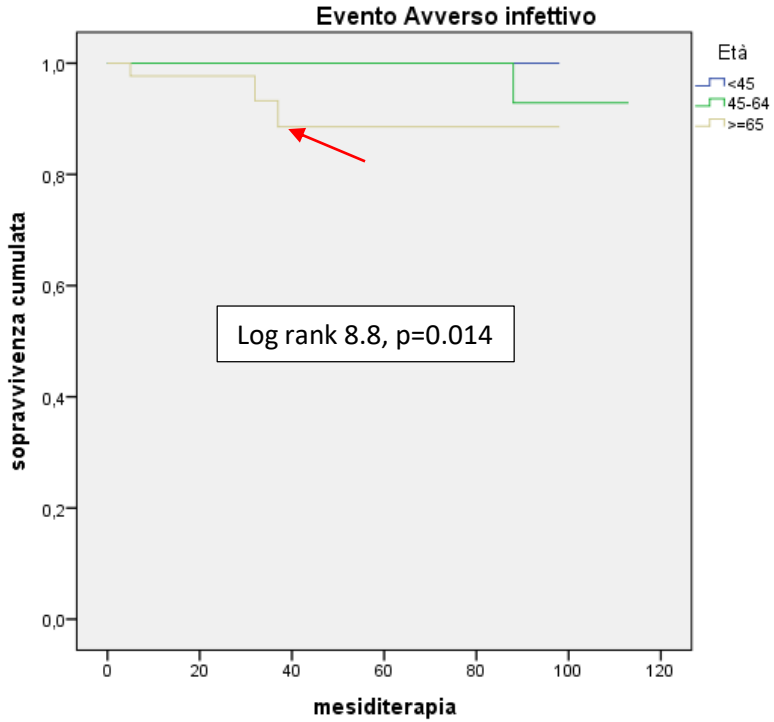
Drug survival







Farmaci biotecnologici nell'anziano: caveats

"safety" globale: buona

"Tight control"

Effetto vaccinazioni ?

BIOPURE
BIOlogic aPUlian REgistry

A.R.R.
ASSOCIAZIONE PER LA
RICERCA IN REUMATOLOGIA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