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## Abstract FRI0184 - Table 1

		Accepting (n=116)	Ambivalent (n=182)	Indifferent (n=16)	Skeptical (n=7)	р
Mean age (SD)		55.5 (12.6)	54.2 (12.5)	58.8 (13.2)	53.6 (10.2)	0.459
		%	%	%	%	
Sex	Men	19.0	23.1	43.8	43.9	0.090
	Women	81.0	76.9	56.2	57.1	
RA duration	> median	51.8	50.3	43.8	28.6	0.651
	≤ median	48.2	49.7	56.2	71.4	
Satisfaction						
Symptoms control	Very/quite satisfied	93.1	82.9	68.8	85.7	0.009
	Indifferent, quite/very unsatisfied	6.9	17.1	31.2	14.3	
Tolerance/side effects	Very/quite satisfied	79.7	57.0	50.0	57.1	< 0.001
	Indifferent, quite/very unsatisfied	20.3	43.0	50.0	42.9	
Expectations						
Effect of the drug on symptoms	Much/quite greater than expected	69.6	53.3	75.0	57.1	0.031
	+/- As expected	23.5	39.0	12.5	28.6	
	Quite/lower than expected	7.0	7.7	12.5	14.3	
Side effects/discomfort	Much/quite greater than expected	7.0	17.0	12.5	0.0	0.004
	+/- As expected	27.0	39.6	25.0	57.1	
	Quite/lower than expected, or no side effects/discomfort	66.0	43.4	62.5	42.9	

Methods: ARCO was a study carried out on RA Spanish patients who initiated a SC biological drug 11-18 months prior to the study visit. Patients completed the Beliefs About Medication Questionnaire (BMQ). According to the scores obtained in the necessity (N) and concerns (C) sub-scales, patients were classified into 4 groups: accepting (high N [>3]/low C [ $\leq$ 3]), ambivalent (N>3/C>3), indifferent  $(N \le 3/C \le 3)$  and skeptical (low N [ $\le 3$ ]/high C [> 3]). We studied demographic characteristics, expectations and satisfaction with the treatment by group.

Results: 321 patients (77% women) completed the BMQ, 92.8% scored N>3 and 58.9% C>3. A higher % of men than women scored N≤3 (13.5% vs. 5.2%, p=0.031). The % who scored C>3 was higher in those with low satisfaction with symptom control (71.1% vs. 56.7% in satisfied/very satisfied, p=0.098), or side effects (72.1% vs. 52.0%, p<0.001), and in those with lower fulfillment of expectations of efficacy and tolerance (p=0.006 and p<0.001). The combination of N and C scores identified 116 accepting (36.1%), 182 ambivalent (56.7%), 16 indifferent (5.0%) and 7 skeptical patients (2.2%). There were no differences in age, gender, or RA duration among the groups, but differences were seen in the satisfaction with the treatment and in the fulfillment of the expectations (table). Ambivalent patients showed less satisfaction and lower fulfillment of expectations with the treatment received than accepting patients.

Conclusions: Patients with RA have strong beliefs about the need of their biological SC medication, but a high % also expresses concerns. Beliefs, and especially concerns, seem to relate to the satisfaction and fulfillment of expectations of efficacy and tolerability or the drug, rather than to demographics or RA characteristics. Discussing expectations may be important when initiating a biological treatment.

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## FRI0185 A SYSTEMATIC REVIEW AND BIVARIATE META-ANALYSIS OF STUDIES THAT MEASURED ADALIMUMAB DRUG LEVELS BY **ELISA TO DETECT TREATMENT RESPONSE IN RHEUMATOID ARTHRITIS**

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Background: Previous research has demonstrated an association between circulating drug levels and treatment response in patients with rheumatoid arthritis that received the anti-TNF therapy adalimumab. Commercial ELISA assays are now available for use in routine practice to monitor anti-TNF drug levels at regular intervals. However, the ability to detect treatment response by measuring adalimumab drug levels using an ELISA is uncertain.

Objectives: The objectives of this research were to identify and synthesise all published studies that investigated the accuracy of measuring adalimumab drug levels by ELISA to detect treatment response in patients with rheumatoid arthritis. Methods: A systematic review identified all published studies that performed a receiver operating characteristic (ROC) analysis to detect treatment response in patients with rheumatoid arthritis by measuring adalimumab drug levels using an ELISA. Medline and Embase were searched electronically from inception to August 2016. Two researchers independently identified studies for the review using a pre-defined inclusion criteria. Assay results were classified as positive if adalimumab drug levels exceeded the cut-point reported in each study. Study design characteristics, sample characteristics, and test outcomes from 2x2 tables (true-positive; false-positive; true-negative; false-negative) were extracted from each study. The quality of each study was assessed using the QUADAS-2. A hierarchical bivariate meta-analysis synthesised the findings of the ROC analyses to account for between-study heterogeneity and correlation between assay sensitivity and specificity.

Results: The search strategy identified 4,006 abstracts and four studies met the

inclusion criteria of the systematic review. Patients received 40mg adalimumab every two weeks in all studies. Studies varied in their design and sample characteristics, but had low risk of bias and low concern of applicability to the research objective. The hierarchical bivariate meta-analysis estimated that measuring high adalimumab drug levels by ELISA detected treatment response with an average sensitivity of 0.95 (95% CI: 0.85-0.98) and specificity of 0.68 (95% CI: 0.28-0.92).

Conclusions: Measuring high adalimumab drug levels by ELISA in patients with rheumatoid arthritis appeared to be predictive of treatment response. However, the measurement of low adalimumab drug levels was less predictive of no response to treatment. In practice, test accuracy may be improved by measuring anti-drug antibodies alongside adalimumab drug levels. Given the imperfect accuracy of ELISA assays, the relative cost-effectiveness of drug level monitoring should be evaluated before being recommended for use in routine practice.

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## FRI0186 INFLUENCE OF IMMUNOGENICITY TO THE FIRST TNF-I THERAPY ON RESPONSE TO THE SECOND BIOLOGIC AGENT IN RA PATIENTS

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Background: There is currently no consensus on selecting a therapeutic target in patients (pts) non-responsive to their first TNF-inhibitors (TNF-i). The development of anti-drug antibodies (ADA) is a frequent cause of secondary inefficacy in our pts with TNF-i and there is evidence that those who develop ADA at their 1st TNF-i achieve a higher degree of response to the second one, compared to ADApts. Thus ADA measurement can help in choosing a therapeutic target in pts who failed to respond to their 1st TNF-i

Objectives: To assess if development of ADA to the 1st TNF-i determines better response when switching to a 2nd TNF-i versus a nonTNF-i. As secondary objective, analyze whether the presence or absence of ADA to a 1st TNF-i influences the efficacy of a 2nd TNF-i

Methods: Of a total of 144 pts that switched from infliximab or Adalimumab to a 2nd biologic agent (Etanercept, Rituximab, Tocilizumab, Adalimumab, Abatacept, Certolizumab and Infliximab), only 60, who had measured drug levels (DL)/ADA at discontinuation of the 1st TNF-I, were included. Clinical response was evaluated with DAS28, Delta-DAS28 (ΔDAS28) and EULAR response (E-resp) at 6 (v-6) and 12 (v-12) months after initiating 2nd biologic agent and at the last visit prior to drug discontinuation or ending of the study for those who did not interrupt the biological therapy (v-end). DL/ADA levels were measured by ELISA. Statistical analysis was performed using SPSS version 20.0

Results: Within the 60 pts who had measured DL/ADA at suspension of the 1st TNF-i, 26 (43%) were ADA- (i.e. DL +). In this ADA- subpopulation, 50% changed to a 2nd TNF-i; at v-6 there were no differences between switchers to a 2nd TNF-i and switchers to a nonTNF-i in DAS28 (3.7±2.1 TNF-i vs 4.2±1.1 nonTNF-i, p=0.286),  $\Delta DAS28$  (1,4±2 TNF-i, 1±1,2 nonTNF-i, p=0,374) and resp-E (75% good/moderate resp in TNF-I, 40% in nonTNF-i, p=0,064). At v-12, switchers to a 2nd TNF-i showed a lower DAS28 (2.5±0.6 TNF-i, 3.9±0.9 nonTNF-i, p=0.009) and a higher good E-resp rate with a marginally significant difference (80% in TNF-i, 22% in nonTNF-i, p=0.071). However, at v-end, pts with a 2nd nonTNF-i had better response (DAS28 > 5,1 in 50% of TNF-i pts, 0% of nonTNF-i, p=0.044). Likewise  $\Delta DAS28$  at v-end was higher in the nonTNF-i group with trend to significance (0,7±1,7 TNF-i, 1,7±0,8 nonTNF-i, p=0,06). Along these lines, the