

	No serious infections after vaccination N=470	Serious infections after vaccination N=27
serotype 6B		
Pre-vaccination antibody titers (mg/L) GML; 95%CI	1.8 (1.6-2.1)	1.1 (0.6-1.9)
Post-vaccination antibody titers (mg/L) GML; 95%CI	4.1 (3.5-4.8)	2.2 (1.3-3.8)
Post/pre-vaccination ratio	2.2 (2.0-2.5)	2.0 (1.3-3.1)
serotype 23F		
Pre-vaccination antibody titers (mg/L) GML; 95%CI	0.8 (0.7-0.9)	0.4 (0.2-0.7)
Post-vaccination antibody titers (mg/L) GML; 95%CI	2.6 (2.2-3.0)	1.5 (0.9-2.3)
Post/pre-vaccination ratio	3.4 (3.0-3.8)	3.8 (2.2-6.4)
% responders for 6B	39%	30%
% responders for 23F	59%	65%
% responders for 6B +23F	33%	30%

Conclusions: Patients with a history of a serious infection after vaccination had lower antibody levels compared to those without such infections. Cut-off levels of post-vaccination antibody titers associated with protection for serious infections corresponded to those of ≥ 1 mg/L being generally considered as protective at our laboratory. Frequency of positive antibody response to vaccination did not differ between patients with and without serious infections.

Disclosure of Interest: None declared

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FRI0214 EULAR PROJECT: SPONDYLOARTHRITIS PREVALENCE IN SERBIA

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Background: There is a need to enable comparable spondyloarthropathy (SpA) prevalence estimates in Europe, which was made possible by the unique European EULAR project methodology

Objectives: to estimate the SpA prevalence in Serbia, as part of the EULAR study

Methods: In a detection phase, a previously translated and validated telephone Questionnaire comprising of signs, symptoms and self-reported diagnosis (1) was used by 30 lay interviewers on a representative sample of 6213 randomly selected telephone numbers (every 100-th), from urban Serbian population: Belgrade (north) and Cacak, Uzice and Krusevac (south). Suspected cases have received a second call by a rheumatologist. In a confirmation phase, for patients with self-reported diagnosis and positive symptoms patient's rheumatologist was contacted to confirm diagnosis; a complete rheumatologist examination was arranged for those with positive symptoms only. Prevalence estimates were standardised for age and sex with relation to Serbian population (census 2002).

Results: The response rate was 63.6% (3950 respondents). Second call was received by 571 people, among whom 16 SpA cases were confirmed (11 diagnosed previously and 5 newly-diagnosed during the rheumatology examination). The Serbian standardized SpA prevalence was 0.32% (95% confidence interval-CI: 0.14-0.50), it was 0.34% (95% CI 0.04-0.64) for men and 0.31% (95% CI: 0.09-0.53) for women. The prevalence for ankylosing spondylitis was 0.08% (95% CI 0.03-0.13), for psoriatic arthritis 0.09% (95% CI 0.03-0.15), for reactive arthritis (morbus Reiter) 0.10% (95% CI 0.04-0.16), for enteropathic arthritis (associated with inflammatory bowel diseases) 0.03% (95% CI 0.00-0.06) and for undifferentiated spondyloarthropathy 0.02% (95% CI 0.00-0.05).

Conclusions: Compared to prevalence studies using the same methodology and design, SpA prevalence estimates in Serbia are close to France (2), but lower than those reported from Lithuania (3).

References:

- [1] Zlatkovic-Svenda MI, Stojanovic RM, Milenkovic MP, Vlajinac HD, Le Bihan E, Guillemin F. Adaptation and validation of a telephone questionnaire – Serbian version for case detection of rheumatoid arthritis and spondyloarthropathy (multicentric Eular study). *Clin Exp Rheumatol*. 2007; 25 (1): 75-84.
- [2] Saraux A, Guillemin F, Guggenbuhl P, Roux CH, Fardellone P, Le Bihan E, et al. Prevalence of spondyloarthropathies in France: 2001. *Ann Rheum Dis*. 2005 Oct;64(10):1431–35.
- [3] Adomaviciute D, Pileckyte M, Baranauskaitė A, Morvan J, Dadoniene J, Guillemin F. Prevalence survey of rheumatoid arthritis and spondyloarthropathy in Lithuania. *Scand J Rheumatol*. 2008 Mar-Apr;37(2):113–9.

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FRI0215 FATIGUE IN EGYPTIAN PATIENTS WITH RHEUMATIC DISEASES; A DIFFICULT CONCEPT BUT A MAJOR IMPACT: A QUALITATIVE STUDY

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Background: Patients with rheumatic diseases commonly experience fatigue and

this fatigue has a substantial impact on patients' self-care activities and overall quality of life. Fatigue levels and the expression of fatigue may be modified by cultural differences as has been demonstrated for pain (1). However qualitative studies of fatigue in non-European cultures are lacking.

Objectives: The objective of this qualitative study was to increase the understanding of the fatigue experience and characteristics among Egyptian patients with rheumatic diseases: rheumatoid arthritis (RA), fibromyalgia (FM) and axial spondyloarthritis (AxSpA).

Prospective monocentric qualitative study based on conventional qualitative content analysis, inductive reasoning, grounded theory. Consecutive patients with definite disease (either RA, FM or AxSpA) were invited to participate in 30-min interviews. Patients were asked about fatigue, its patterns, consequences and self-management. Interviews were recorded by audiotape, transcribed verbatim and all phrases were systematically coded until overarching themes appeared.

Methods: Prospective monocentric qualitative study based on conventional qualitative content analysis, inductive reasoning, grounded theory. Consecutive patients with definite disease (either RA, FM or AxSpA) were invited to participate in 30-min interviews. Patients were asked about fatigue, its patterns, consequences and self-management. Interviews were recorded by audiotape, transcribed verbatim and all phrases were systematically coded until overarching themes appeared.

Results: Of the 60 patients interviewed, 20 patients had each disease (RA, FM and AxSpA). Patients were mainly male (N=40, 66%), had 3 to 7 years (mean) of disease duration and had moderate disease activity. Fatigue was high with median fatigue visual analog scales (0-10) of 50 in RA, 70 in FM and 40 in AxSpA. *Concept of fatigue:* Fatigue was a difficult concept for patients; when clarified, RA and FM patients described fatigue as the need to rest more whereas AxSpA patients described fatigue as a freezing of the body. *Consequences of fatigue:* In all diseases, the participants stated that fatigue influenced and affected physical activity and work, whereas fatigue had a major impact on social and leisure activities only for RA and FM patients (AxSpA patients not stating such a limitation). Fatigue affected sexual activity markedly in all disease groups and this was a major concern of most of the participants. *Self-management of fatigue:* Patients felt their fatigue was ignored from medical staff and from families alike; however RA patients expressed getting more help from their family.

Conclusions: This study gives insights into fatigue in rheumatic diseases in an Arabic and Muslim culture. We found that the characteristics of fatigue and its consequences had some differences from previously reported European studies; these differences may be attributed mainly to cultural reasons.

References:

- [1] Yazici Y, Kautiainen H, Sokka T. *Journal of Rheumatology*.2007; 34(2):311–315

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FRI0216 THERAPEUTIC EDUCATION AND FUNCTIONAL READAPTATION IN OBESE PATIENTS ON A WAITING LIST FOR TOTAL KNEE REPLACEMENT. A CASE-CONTROL STUDY

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Background: Studies show patients with knee osteoarthritis (OA) on waiting list for total knee replacement (TKR) underused conservative treatment, did not adhere to clinical guidelines on knee OA management, and potentially had earlier surgery and a higher risk of revisions. Therapeutic education and functional readaptation (TEFR) plus conventional therapy in waiting list patients improved function and adherence. TKR patients are often obese, negatively influencing TKR results, many patients are dissatisfied after TKR, and around 14% of TKR are inappropriate.

Objectives: To compare whether TEFR plus conventional therapy improves health outcomes in obese patients (body mass index [BMI] ≥ 35) with knee OA and a control group receiving conventional therapy only at entry to a TKR waiting list and after 12 months.

Methods: Case-control study with 18 months follow-up. TERF patients received conventional medical and surgical treatment plus TEFR (n=59). TERF combined individualized and group visits (4 months before TKR) based on cognitive learning theories, social change approaches and active teaching strategies. Controls were matched for age, sex, BMI and total WOMAC score (n=59). Sociodemographic, clinical and intra- and postoperative surgical data were collected. The health status was measured using the disease-specific WOMAC questionnaire. Evaluations: baseline, 12 months post TKR, and 4 months post baseline in the TEFR group.

Results: *TEFR group:* 56 female, mean age 68.8 (SD 7.8) years, BMI 40.1 (SD 3.8) WOMAC total index 60.5 (17.2). At 4 months there were significant improvements in all WOMAC dimensions (p<0.001). At 4 months, 10 patients refused surgery due to improvement. At 12 months after TKR (n=49) there was a significant improvement compared with scores at 4 months (p<0.001) and baseline with a mean reduction of 34.95 (95%CI 29.8–40.1) points in total WOMAC score. *Control group:* 56 female, mean age 70.2 (SD 6.6) years, BMI 40.2 (SD 3.6) and total WOMAC score 63.3 (SD 17.3). At 12 months, there was a significant improvement in all dimensions (p<0.001) with a reduction in total WOMAC score of 32.7 (95%CI 26.5-38.8). *Between-group* comparison showed no

significant differences at baseline. 12 months after TKR, no significant differences were found except for the WOMAC function dimension (mean score 19.5 (SD 10.4) in the TEFR group and 30.98 (SD20.5) in controls ($p<0.001$). Patients who refused TKR had no significant differences at baseline but were younger and had a better health status (mean age 65.4 (SD 9.6) years, BMI 40.9 (SD 3.3) and WOMAC score 54.5 (18.7). After 4 months of TEFR they showed mean improvements in all WOMAC dimensions of >16 points, which was maintained until study completion.

Conclusions: Patients receiving TEFR plus conventional therapy had better health outcomes due to improvements in function showing TEFR to be effective. In 10 who rejected TKR, the health status improved, suggesting the utility of specific programmes to treat patients before inclusion on waiting lists.

Disclosure of Interest: None declared

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FRI0217 COST-EFFECTIVENESS OF BIOLOGICS FOR RHEUMATOID ARTHRITIS PATIENTS: A REAL-WORLD ANALYSIS OF NATIONWIDE JAPANESE CLAIMS DATA

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Background: Tumour necrosis factor inhibitors (TNFi's) such as etanercept (ETN), adalimumab (ADA) and infliximab (IFX) have led to dramatic improvements in the treatment of rheumatoid arthritis (RA), but their impact on medical expenditures remains a concern. It is therefore important to aim for sustained clinical benefits through persistent treatment whilst minimizing the impact of the drug cost on medical expenditures based on initiating the most cost-effective RA treatment.

Objectives: The aim of this study is to evaluate retention rates across three commonly used TNFi's and compare associated cumulative direct biologics and medical costs using a nationwide Japanese claims database containing about two million subscribers from the health insurance society provided by the Japan Medical Data Center Co., Ltd.

Methods: Subjects of this study were patients with rheumatoid arthritis (ICD10 code: M058, M059, M060, M068, M069) prescribed ETN, IFX or ADA as the first biologics between January 2005 and March 2013. Annual average costs of the initial biologics per patient were calculated between 2005 and 2012. Next, the retention rates of ETN, IFX and ADA were examined using Kaplan-Meier survival analysis. Lastly, the cumulative biologics cost including second (or subsequent) biologics (tocilizumab, abatacept, golimumab, certolizumab and three TNFi's) as well as the total medical costs were compared in the year following the initial prescription of ETN, IFX or ADA (The approved dose in Japan for ETN: 10 to 25 mg twice weekly or 25 to 50 mg per week, IFX: 3 to 10mg/kg every 4 to 8 weeks, ADA: 40 to 80mg every 2 weeks).

Results: 524 RA patients initiating selected biologic therapy were identified for

Fig.1 Retention rate of first biologics

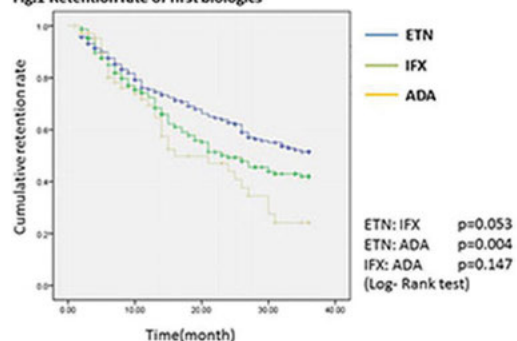
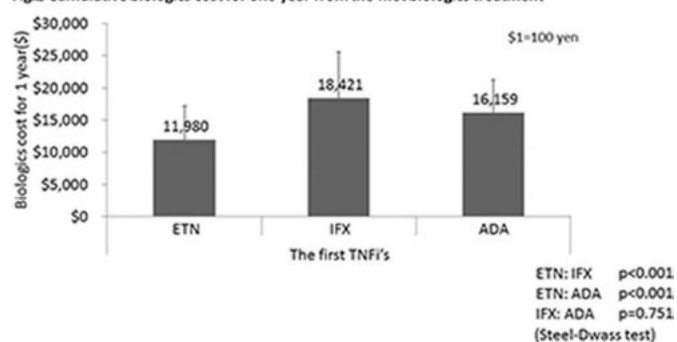


Fig.2 Cumulative biologics cost for one year from the first biologics treatment



this analysis. 238, 217 and 69 patients were prescribed ETN, IFX, ADA as the first biologic, respectively. The annual cost for ETN per patient was about \$10,000 in 2007 and \$7,200 in 2012. The annual cost for IFX per patient was about \$13,000 in 2007, but after approval of dose escalation in 2009, it was \$16,000 in 2012. The retention rate of each TNFi at 36 months was 51.4%, 42.0% and 24.2% for ETN, IFX and ADA, respectively (ETN vs. IFX, $p=0.053$; ETN vs. ADA, $p=0.004$, Log-rank test) (Fig.1). The average cumulative annual cost of biologics for patients initiated with ETN, IFX and ADA as the first biologics treatment was about \$12,000, \$18,000 and \$16,000, respectively (ETNvs IFX, $p<0.001$; ETN vs. ADA, $p<0.001$, IFX vs. ADA, $p=0.751$, Steel-Dwass test) (Fig.2). The average total annual medical cost with ETN, IFX and ADA as the first biologics treatment was \$19,000, \$26,000 and \$23,000, respectively (ETN vs IFX, $p<0.001$, ETN vs. ADA, $p<0.001$, IFX vs. ADA, $p=0.826$, Steel-Dwass test).

Conclusions: The retention rate of ETN as the first biologics treatment was the highest among three TNFi's while cumulative annual cost of biologics and total medical cost following the initial treatment of patients with ETN was significantly lower than comparators. Therefore, ETN may be considered a more cost-effective option to other TNFi's although further research comparing clinical outcomes is warranted.

Disclosure of Interest: N. Sugiyama M.D.,Ph.D. Employee of: Pfizer, T. Murata M.S. Consultant for: Pfizer, Y. Morishima Employee of: Pfizer, Y. Fukuma Employee of: Pfizer, Y. Shibasaki M.S. Employee of: Pfizer, C. Bidad M.Pharm. Employee of: Pfizer, J. Harnett Pharm.D.,M.S. Employee of: Pfizer, L. Marshall Employee of: Pfizer, J. Coindreau M.D. Employee of: Pfizer

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FRI0218 PATIENT SELF-REPORTED FATIGUE AS A DIFFERENTIATOR IN SLE FLARES

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Background: Patient reported outcome (PRO) tools are uniquely informative for management of systemic lupus erythematosus (SLE) patients. Fatigue is an important component of PRO. Patients with SLE experience significant fatigue and its association with standard disease activity measures in SLE is inconsistent.

Objectives: To compare patient self-reported fatigue using two different PRO tools – Multi-dimensional health assessment questionnaire (MDHAQ) and LupusPRO (a disease-specific PRO for SLE) in patients with and without a current SLE flare as determined by the SELENA flare Index (SFI).

Methods: 121 patients meeting ACR criteria for SLE completed MDHAQ and LupusPRO during a routine clinic visit. Disease activity assessments were made by SELENA-SLEDAI Physician global assessment (SLEDAI-PGA), total SLEDAI and SFI. Fatigue on MDHAQ (MDHAQ-F) was marked on a visual analogue scale of 0-10. Fatigue from LupusPRO was calculated on a scale of 0-100 using 5 Pain-Vitality domain questions on pain and fatigue. LupusPRO Pain-Vitality scores were coded to reflect greater fatigue with an increase in scores. Independent sample t-test was used to compare fatigue by SFI status. Data were then stratified by physician diagnosis of fibromyalgia (FM) (yes/no). Spearman rho correlation was used. A p value of ≤ 0.05 was considered statistically significant on two tailed tests.

Results: Mean (SD) age, SLEDAI-PGA and total SELENA-SLEDAI scores were 43.2 (13.3) yrs., 0.6 (0.6) and 4.1 (4.7). 95% of the patients were female and 52% were African-American. Mean (SD) MDHAQ-F was 4.5 (3.4) and on LupusPRO Pain-Vitality was 40.0 (29.3). MDHAQ-F and LupusPRO Pain-Vitality were strongly correlated ($\rho = 0.79$ ($P < 0.001$)). Twenty one percent had a current SFI flare. Nearly 1/4 of SLE patients had a diagnosis of FM. Mean (SD) MDHAQ-F were 3.9 (3.3) and 6.2 (3.0) among patients without and with SFI flare ($p=0.003$) (Table 1). Mean (SD) LupusPRO Pain-Vitality were 35.1 (28.6) and 53.8 (25.8) ($p=0.005$) in patients without and with SFI flare. Patients who did not have FM had mean (SD) MDHAQ-F scores without and with SFI flare of 2.7 (2.7) and 6.2 (2.8) ($p \leq 0.001$) and mean (SD) LupusPRO Pain-Vitality scores without and with SFI flare of 24.0 (22.9) and 51.1 (25.4), ($p < 0.001$). In these patients without FM, MDHAQ-F and LupusPRO Pain-Vitality were correlated significantly with SLEDAI PGA and Total SLEDAI (Table). In patients with FM, MDHAQ-F and LupusPRO Pain-Vitality scores did not differ significantly by SFI status and no significant correlation with SLEDAI-PGA or Total SLEDAI was seen (Table).

	Current SFI Flare	No Current SFI Flare	P value	Correlation with SLEDAI PGA (Rho)	Correlation with total SLEDAI score (Rho)
Fatigue on MDHAQ	6.2 (3.0)	3.9 (3.3)	0.003	0.20 ($p=0.07$)	0.17 ($p=0.16$)
Fatigue on MDHAQ - No FM	6.2 (2.8)	2.7 (2.7)	<0.001	0.26 ($p=0.04$)	0.28 ($p=0.04$)
Fatigue on MDHAQ - FM	5.1 (3.9)	6.9 (2.7)	0.26	0.21 ($p=0.42$)	0.35 ($p=0.24$)
Pain and Vitality on LupusPRO	53.8 (25.8)	35.1 (28.6)	0.005	0.17 ($p=0.12$)	0.10 (0.38)
Pain and Vitality on LupusPRO - No FM	51.1 (25.4)	24.0 (22.9)	<0.001	0.32 ($p=0.01$)	0.26 ($p=0.04$)
Pain and Vitality on LupusPRO - FM	66.0 (28.8)	60.0 (23.5)	0.62	0.06 ($p=0.83$)	0.34 ($p=0.24$)

Conclusions: Patient self-reported fatigue scores are directly related to flares, and should be explored as a possible surrogate marker of SLE flares in patients