FRI0580

DISCORDANCE BETWEEN OBJECTIVE ELBOW ASSESSMENT AND PATIENTS REPORTED OUTCOMES (PROS) AFTER TOTAL ELBOW ARTHROPLASTY IN PATIENTS WITH RHEUMATOID ARTHRITIS.

R. Harada¹, K. Nishida², Y. Nasu², R. Nakahara². ¹Kurashiki Sweet Hospital, Orthopaedics, Kurashiki City, Okayama Pref., Japan; ²Okayama University Hospital, Orthopaedics, Okayama, Japan

Background: Patient-reported outcomes (PROs) have become widespread in daily clinical evaluation in patients with rheumatoid arthritis (RA). However, there are few reports for the relationship or discordance between the subjective assessment by the physician and the objective assessment by the patient with RA in surgical treatment.

Objectives: We examined the relationship or discordance about the PROs in patients with RA who underwent total elbow arthroplasty (TEA).

Methods: We retrospectively identified 53 elbows of 48 patients with RA who underwent TEA at Okayama University Hospital, collected from January 2012 to December 2016.

We collected clinical data for the grip strength, range of motion, the Mayo Elbow Performance Scale (MEPS) as objective assessments, and the Patient-Related Elbow Evaluation (PREE), Disability of the Arm, Shoulder, and Hand (DASH) Japanese version and Hand20 as subjective assessments.

For statistical analysis, we performed t-tests for pre- and post-operative physical findings and subjective evaluations, and Spearman rank correlation to examine the relationship between objective and subjective assessments.

Results: The mean age of the patients at the time of arthroplasty was 63 years, the average disease duration was 23 years, and the average postoperative observation period was 32 months. The average DAS28-CRP was 3.01, and biological uses were 18 cases.

The range of motion of the elbow joint and the grip strength was significantly improved postoperatively. All outcome assessments improved significantly except for HAQ (see table1).

There was significantly correlated PREE with DASH, Hand20, and MEPS pre-operatively. Postoperative PREE showed a significant and robust correlation in postoperative DASH, Hand20, whereas not associated with postoperative MEPS (see table2).

To investigate the discordance between PREE and MEPS after TEA, we focused on changes in each item of PREE. Pain- and reach-related items improved post-operatively. But, it was difficult to improve in items affected by hand and finger functions, such as "tie shoelaces."

To explore the effects of finger and hand functions on postoperative assessments, we performed multiple regression analyses. Both preoperative grip strength (unstandardized coefficient [B] = -0.07; 95%CI -0.148 to -0.006, t value = -2.18, P=0.03) and preoperative Hand20 (B = 0.27, 95%CI 0.029 - 0.518, t=2.25, p=0.02) were significant predictors of postoperative PREE.

Conclusion: Surprisingly, the PROs of patients and the surgeon's evaluations correlated well before surgery but resulted in discordance after TEA. We improved elbow functions by TEA, but since rheumatoid arthritis was a polyarticular disorder, improvement of a single joint function did not improve utterly subjective assessment in patients with RA. We found that the upper limb functions after TEA were significantly affected by preoperative finger and hand function. A rheumatologist should consider the dysfunctions of finger and hand when planning for elbow surgery in patients with RA.

Table 1. Pre- and postoperative range of motion of elbow and forearm, grip strength, and measurement

Characteristic	Preoperative	Postoperative	P value
Elbow flexion, degree	116 ± 19	134 ± 9	< 0.001
- extension	-34 ± 21	-25 ± 16	0.005
- total arc	82 ± 32	109 ± 19	< 0.001
Grip power, mmHg	106 ± 66	130 ± 74	0.007
DASH	50.5 ± 20.5	35.8 ± 25.4	< 0.001
Hand20	60.4 ± 19.1	38.9 ± 29.6	< 0.001
PREE	55.6 ± 18.8	18.5 ± 17.1	< 0.001
- pain	29.7 ± 11.3	6.5 ± 7.9	< 0.001
- function	25.9 ± 11.5	12.0 ± 11.9	< 0.001
- specific function	56.9 ± 25.5	25.4 ± 25.3	< 0.001
- usual function	20.8 ± 11.3	10.5 ± 11.3	< 0.001
HAQ-DI	1.06 ± 0.70	1.07 ± 0.80	0.607
MEPS	51.3 ± 16.6	97.9 ± 3.6	< 0.001

Table 2. Spearman's correlation coefficients for pre- and postoperative PREE score*

Questionnaire	Preoperative Correlation estimate	P value	Postoperative Correlation estimate	P value
DASH	0.56	< 0.0001	0.84	< 0.0001
Hand20	0.58	< 0.0001	0.84	< 0.0001
MEPS	- 0.39	< 0.01	-0.27	N.S.

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FRI0581

IN ELDERLY PATIENTS, CAPS THAT RECORD MEDICATION BOTTLE OPENINGS ARE UNRELIABLE AND THUS NOT THE GOLD STANDARD FOR ADHERENCE

L. Hartman^{1,2}, S. Paolino³, R. Bos⁴, D. Opris-Belinski⁵, M. R. Kok⁶, H. Griep-Wentink⁷, R. Klaasen⁸, C. Allaart⁹, G. Bruyn¹⁰, H. Raterman¹¹, M. Voshaar¹², N. Gomes¹³, R. Pinto¹⁴, T. Klausch¹, W. Lems¹, M. Boers^{1,2}. ¹Amsterdam Rheumatology and Immunology Center, location VUmc, Amsterdam, Netherlands; ²Amsterdam UMC, location VUmc, Epidemiology & Biostatistics, Amsterdam, Netherlands; ³University of Genoa, Genoa, Italy; ⁴Medical Center Leeuwarden, Leeuwarden, Netherlands; ⁵University of Medicine and Pharmacy "Carol Davila", Bucharest, Romania; ⁶Maasstad Hospital, Rotterdam, Netherlands; ⁷Antonius Ziekenhuis, Sneek, Netherlands; ⁸Meander Medical Center, Amersfoort, Netherlands; ⁹LUMC, Leiden, Netherlands; ¹⁰MC Groep, Lelystad, Netherlands; ¹¹Noordwest Ziekenhuisgroep, Alkmaar, Netherlands; ¹²Tools, Amsterdam, Netherlands; ¹³Exatronic, Aveiro, Portugal; ¹⁴Bluepharma, Coimbra, Portugal

Background: Adherence is a serious problem in treatment of inflammatory diseases. To measure adherence, caps that record medication bottle openings may be superior to capsule counts (1). In the ongoing two-year GLORIA trial on the addition of low-dose (5mg) prednisolone or placebo to standard of care in elderly patients (65+ years) with rheumatoid arthritis, adherence was measured in both ways during the whole trial.

Objectives: To describe adherence patterns, and to compare adherence as assessed with adherence caps and with capsule counts in the GLORIA trial.

Methods: The recorded adherence patterns of patients (blinded for treatment group) were classified according to descriptive categories. Overall adherence according to number of bottle openings was compared with adherence according to the capsule count. Good adherence was defined as 80%: i.e. for caps 80% of days one opening recorded, and for counts less than 20% of prescribed tablets returned at the subsequent visit. Each patient has a maximum of 8 periods of 90 days.

Results: Trial inclusion has closed in 2018 at 452 patients; the current dataset contains adherence data of 385 patients. Mean number of recorded 90-day periods per patient was 4 (range 1-8). Based on capsule counts over all periods, 90% of the patients met the 80% threshold of adherence; based on cap data only 31% met this criterion.

The four adherence patterns are shown in a calendar matrix, with yellow for zero, green for one and blue for ≥2 openings on a day (Figure 1). Bottles were supposed to be opened once a day.

Figure 1. Examples of adherence patterns. Yellow = no opening, green=1 opening, blue=≥2 openings

Patients were categorized according to the opening pattern seen in at least 50% of assessed periods:

32% non-use	(<20% of the days an opening);
26% stable use	(≥80% of the days 1 opening);
40% irregular use	(different adherence patterns, in or between periods);
2% weekly use	(1 opening per week).

Conclusion: In our trial of elderly rheumatoid arthritis patients, patients appeared to be mostly adherent according to conventional capsule counts. Results from adherence caps were highly discrepant with the capsule counts, with patterns suggesting patients did not use the bottle for daily dispensing, despite specific advice to do so.

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FRI0582

GM-CSF PRODUCED BY CD4+ T CELLS AS A MARKER OF CLINICAL REMISSION IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH TNF INHIBITORS

B. Hernández-Brejío¹, C. Plasencia¹, C. García-Hoz², C. Sobrino², V. Navarro-Compán¹, A. Martínez-Feito¹, I. Nieto-Gañán², P. Lapuente-Suanzes², J. Bachiller-Corral², G. Bonilla¹, C. Pijoan Moratalla², G. Roy², M. Vázquez Díaz², A. Balsa¹, L. M. Villar², D. Pascual-Salcedo¹, E. Rodríguez-Martín². ¹Immunology & Rheumatology Research Group, IdiPaz, La Paz University Hospital, Madrid, Spain; ²Immunology & Rheumatology Departments, Ramón y Cajal University Hospital and IRYCIS, Madrid, Spain

Background: According to the EULAR recommendations, the therapeutic target in patients with RA should be remission (REM). However, no more than 50% of the patients treated with TNF inhibitors (TNFi) attains this outcome. Previous investigations suggested the peripheral blood mononuclear cells (PBMC) as markers associated with the TNFi treatment success^{1,2}. Granulocyte-monocyte colony-stimulating factor (GM-CSF) plays a relevant role in the pathogenesis of rheumatoid arthritis (RA) because it promotes the macrophage differentiation, survival and activation³.

Objectives: To analyse the intracellular cytokine production by PBMC and its association with REM attainment after 6 months (m) of TNFi treatment in patients with RA.

Methods: This was a prospective bi-center pilot study including 36 patients with RA. PBMC were isolated from patients at baseline and after 6m of treatment with TNFi and cryopreserved until studied. Intracellular cytokine production by PBMC was stimulated in the presence of 2µg/mL brefeldin as follow: monocytes were stimulated with 20ng/mL LPS during 4h; and simultaneously lymphocytes were stimulated with 50ng/mL phorbol 12-myristate 13-acetate (PMA) and 750ng/mL ionomycin during 4h at 37°C. To identify IL-10-producing B cells, PBMC were pre-incubated with 3µg/mL of CpG oligonucleotide during 20h at 37°C prior to stimulation in presence of 2µmol/L monensin. Intracellular cytokine production (TNFα, IL6, GM-CSF, IL10) by the different cell subsets (monocytes, CD4+ and CD8+ T cells, naïve and memory B cells) was analysed by flow-cytometry. Clinical activity at baseline and after 6m was assessed by DAS28. REM was defined as DAS28≤2.6 at 6m. The association between REM and the change in cytokine production (Δ, 6m-0m) by each PBMC subset was analysed through univariable and multivariable logistic regression models.

Results: Seventy-eight percent of the patients were female. After 6m of TNFi treatment, 47% patients attained REM. Univariable analyses was performed to investigate the association between REM and the baseline variables. Male sex (OR: 12.6; 95% CI: 1.35-117.57; p=0.03) and having lower baseline DAS28 (OR: 0.4; 95% CI: 0.19-0.85; p=0.02) were independently associated with attaining REM after 6m of TNFi. In the multivariable analysis, only being male (OR: 19.7; 95% CI: 1.4-273.9; p=0.03) remained independently associated with REM after 6m of treatment. Therefore, further analyses were adjusted by sex. Decreased production of GM-CSF by CD4+ T cells percentage was found after 6m of TNFi treatment in REM patients (0m: 6.07%; 6m: 3.87%; p=0.007) while no-REM patients did not show differences with the baseline (0m: 3.70%; 6m: 3.75%; p=0.9). The decrease was significantly associated with attaining REM (OR: 0.56; 95% CI: 0.33-0.95; p:

0.03). No significant association was found between any other analysed intracellular cytokine produced by the different PBMC subsets and REM.

Conclusion: GM-CSF intracellular production by CD4+ T cells was significantly decreased by TNFi treatment only in patients who attained REM. Therefore, our results suggest that GM-CSF production by CD4+ T cells may be a useful marker of REM to TNFi in RA.

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Figure 1: Association between the change in intracellular cytokine production (Δ, 6m-0m) by each PBMC subset and REM. Adjusted logistic regression analyses were performed for each cytokine.

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VALIDATION OF THE MODIFIED FATIGUE IMPACT SCALE IN DANISH PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

C. I. Junker¹, K. Duch², L. Dreyer¹, J. W. Gregersen³, S. Kristensen¹. ¹Aalborg University Hospital, Department of Rheumatology, Aalborg, Denmark; ²Aalborg University Hospital, Unit of Clinical Biostatistics, Aalborg, Denmark; ³Aalborg University Hospital, Department of Nephrology, Aalborg, Denmark

Background: Patients with systemic lupus erythematosus (SLE) experience significant fatigue, a debilitating symptom associated with reduced quality of life. A simple, reliable multidimensional method for assessing fatigue has not yet been validated for Danish patients with SLE.

Objectives: The primary objective was to study the internal consistency, test-retest reliability, and construct validity (convergent and discriminant validity) of the multidimensional Modified Fatigue Impact Scale (MFIS) in patients with SLE. The secondary objective was to investigate the contribution of disease activity and organ damage to fatigue.

Methods: Data from the "Bio and Genome Bank Study in Centre for SLE and Vasculitis" obtained through routine visits were used. Fatigue was assessed using the MFIS and Short Form 36 (SF36). Internal consistency of the MFIS was assessed with Cronbach's alpha (α). Test-retest reliability was evaluated using the intraclass correlation coefficient (ICC). Construct validity was studied using Spearman's rank correlation coefficient (r_s) and Principal Component Analysis (PCA) between MFIS and SF36 vitality (VT-SF36) and mental health (MH-SF36) subscales. Association between MFIS and disease activity and organ damage was estimated with Spearman's rank correlation coefficient.