THU0668 RELIABILITY OF PATIENT GLOBAL ASSESSMENT IN RHEUMATOID ARTHRITIS PATIENTS

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Background: Patient's global assessment (PtGA) is one of the most widely used patient reported outcomes in rheumatoid arthritis (RA) that reflects both disease activity and other factors. PtGA is onymous and obtained at hospital, which may cause a conscious or unconscious bias, whereas PtGA obtained anonymously may be free from any bias. The credibility of PtGA to report RA patient outcomes has been usually investigated by assessing test-retest reliability. There has been no study comparing routine PtGA and PtGA where patients answered anonymously.

Objectives: The aim of this study was to compare routinely obtained in-hospital PtGA before clinical examination with those answered anonymously at home. Additionally, physician's global assessment (PhyGA) was compared with routine PtGA and anonymized PtGA

Methods: We asked RA patients (n=389) to answer and mail the PtGA test anonymously, Clinical data regarding disease duration, stage, class, swollen joint counts, tender joint counts, pain visual analog scale (VAS), PhyGA, Health Assessment Questionnaire (HAQ), EuroQOL five dimensions questionnaire (EQ5D), Kessler 6 scale (anxiety/ depression), treatment data, laboratory data, and socioeconomic factors were collected simultaneously. We compared the PtGA that is routinely surveyed at hospital before clinical examination with those surveyed anonymously at home. We calculated a discrepancy score by subtracting anonymized PtGA from routine in-hospital PtGA. We defined (1) positive discrepancy when routine PtGA was over-rated relative to the anonymized PtGA; (2) negative discrepancy when routine in-hospital PtGA was under-rated relative to the anonymized PtGA.

Results: The anonymized PtGA score was higher than routinely evaluated in-hospital PtGA ($p<0.0001$). The anonymized PtGA poorly correlated with routine in-hospital PtGA ($r=0.426$, $p<0.0001$). We compared patients who had discordance between in-hospital PtGA and anonymized PtGA. We used 3 models in which the discordance between both PtGAs was set at 10 mm, 20 mm, or 30 mm. If we adopted 30 mm as discordance, the pain scale remained to be a risk factor of positive discrepancy (higher in-hospital PtGA than anonymized PtGA). If we adopted 20 mm or 10 mm as discordance, the pain scale remained to be a risk factor of positive discrepancy and remaining low quality of life (QOL) negative discrepancy (lower in-hospital PtGA than anonymized PtGA) after multivariate analysis. The discordance between PhyGA and routine PtGA are associated with high pain VAS. The discordance between PhyGA and anonymized PtGA is associated with tender joint counts, swollen joint counts, and low QOL.

Discordance Model	Difference between in-hospital PtGA and anonymized PtGA		
	30mm	20mm	10mm
Household income	-0.074 ± 0.18	0.14 ± 0.14	0.09 ± 0.082
Married (yes)	1.0 ± 1.2	1.3 ± 1.0	-0.057 ± 0.06
Tender Joint Counts	-0.3 ± 0.3	-0.12 ± 0.18	0.011 ± 0.14
Swollen Joint Counts	0.5 ± 0.66	0.32 ± 0.37	0.2 ± 0.18
CRP (mg/dl)	-0.42 ± 0.51	-0.26 ± 0.40	-0.18 ± 0.26
Pain VAS	0.11 ± 0.035 **	0.12 ± 0.026 ***	0.081 ± 0.013 ***
Physician's Global Assessment	0.028 ± 0.066	-0.017 ± 0.045	-0.0089 ± 0.026
EQ5D	0.093 ± 0.056	0.093 ± 0.037 *	0.043 ± 0.018 *
K6 scale(Anxiety/Depression)	-0.15 ± 0.14	0.0027 ± 0.091	0.56 ± 0.59

Value are expressed as Estimate ± Standard Error. * p<0.05, *** p<0.0001

Conclusions: Discrepancy exists between routine in-hospital PtGA and anonymized PtGA.

The high pain VAS scale and low QOL are risk factors that could make the difference between routine PtGA from anonymized PtGA. There is a possibility that high pain VAS score and low QOL influence the reliability of PtGA.

Disclosure of Interest: None declared

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THU0669 THE ASSOCIATION BETWEEN HARRIS HIP SCORE AND DISEASE ACTIVITY OR HIP MRI FEATURES IN ANKYLOSING SPONDYLITIS

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Background: Hip involvement is a common clinical feature observed in ankylosing spondylitis (AS) patients and it often leads to substantial restriction of the body functions.[1] Hip involvement in AS is mainly assessed by radiographic changes, clinical symptoms or MRI. The Harris hip score (HHS) is a valuable assessment tool to measure health status of AS patients. However, the relationship between HHS and other clinical indices is unknown.

Objectives: To evaluate relationship between HHS and other commonly used clinical indices.

Methods: In this multicentre, observational study, AS patients with hip clinical manifestation are enrolled and randomly assigned to infliximab treatment (group I, with/without DMARDs and/or NSAIDs) or conventional therapy (group II, DMARDs and/or NSAIDs). Primary endpoint: to compare functional improvement of hip joint (HHS) between two treatment groups (infliximab and conventional therapy) at week 30. Secondary endpoint: to compare disease activity and functional improvement of AS and radiologic progression of hip joint between two treatment groups at week 30 and 52. Association between baseline HHS and disease activity measures such as Bath ankylosing spondylitis (BAS)-functional index (BASFI), BAS disease activity index (BASDAI), AS disease activity score (ASDAS), CRP and ESR was analysed using Pearson correlation coefficient. BAS metrology index (BASMI) and hip imaging functions (MRI of hip, BAS radiology hip index [BASRI-h]) were analysed using independent two-sample t-test or ANOVA based on data characteristics.

Results: Study is ongoing; currently, only baseline information is analyzed. Baseline demographics and disease characteristics did not show any significant difference between groups. Almost all baseline disease activity measures showed significant Pearson correlation (high correlation in BASFI=0.646) with HHS, except for BASDAI (table 1). Significant association between HHS and three MRI scores (articular cartilage stripping, bone destruction under joint surface, femoral head bone marrow cavity edema) and BASRI-h was shown (table 2). Also, significant correlation was shown between BASMI and HHS (F value [degree of freedom]=4.70 [4]; p=0.0022).

Table 1. Association between HHS and disease activity measures at baseline

	Mean (SD)	Pearson correlation-HHS	P Value
ASDAS	2.81 (0.904)	-0.449	0.0004
BASDAI	4.60 (1.109)	-0.169	0.1691
BASFI	3.79 (2.050)	-0.646	<0.0001
CRP	12.270 (19.4810)	-0.348	0.0074
ESR	22.1 (24.06)	-0.386	0.0023

Table 2. Association between HHS and hip imaging functions at baseline

		N	HHS, mean (SD)	T-test (degree of freedom)	P value
Articular cartilage stripping	No	29	62.5 (9.13)	2.27 (54.97)	0.0271
	Yes	32	55.9 (13.39)		
Bone destruction under joint surface	No	22	63.8 (4.66)	3.08 (49.29)	0.0034
	Yes	38	56.2 (14.02)		
Femoral head bone marrow cavity edema	No	29	62.4 (9.37)	2.18 (58.00)	0.0332
	Yes	31	55.8 (13.46)		
BASRI-h (at least one Hip ≥1)	_	29	54.7 (14.01)	-3.00 (37.55)	0.0048

Conclusions: The baseline results of HHS were found to be well associated with disease activity scores like BASFI, ASDAS and BASMI and four hip imaging features in AS patients with hip involvement.

References:

[1] Jeong H, et al. Korean J Intern Med. 2017; 32(1): 158–164.

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THU0670 DETECTION OF SERUM ANTI-DNASE I ANTIBODIES IN SYSTEMIC LUPUS ERYTHEMATOSUS USING IMPROVED IMMUNOSORBENT ASSAY

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Background: Diagnosis of systemic lupus erythematosus (SLE) is a sophisticated problem in most of the disease cases. The reasons of this include common diagnostic markers of SLE (ANA, anti-dsDNA, anti-Sm), that are insufficiently reliable itself as well. One of possible ways to overcome these difficulties is searching for new SLE markers. These emerging diagnostic tools are not only to be valuable for diagnosis establishment, but also to provide economical efficiency and facility in common use.

Objectives: To compare diagnostic efficiency of anti-DNase I antibodies measured by conventional ELISA and by originally modified enzyme immunosorbent assay using magnetic polyacrylamide beads as an antigen carrier.

Methods: The research was carried out in agreement with the WMA Declaration of Helsinki principles, it was approved by the Regional Committee on Medical Ethics. All the patients signed the informed consent. We have enrolled 54 in-hospital adult patients with SLE, verified by the ACR criteria (1997). Control group (n=52) was comprised of patients with rheumatoid arthritis, systemic sclerosis, systemic vasculitides, dermatomyositis, and Sjogren's disease. Serum

anti-DNase I concentrations were evaluated by conventional ELISA, as described elsewhere [1]. The beads were synthesized using original technique [2], modified ELISA and recovery of the beads for repeating use was performed according to the previously published protocols [2]. Antibody concentrations were expressed as relative optical density units (ODU). The cutoff values for conventional and modified ELISA were 0.061 and 0.057 ODU, respectively. All the means and operation characteristics were expressed as values (95% confidence intervals). Differences were considered significant when $p<0.05$.

Results: Mean anti-DNase I concentrations in SLE patients (negative and positive together) were 0.088 (0.031–0.145) and 0.079 (0.033–0.125) ODU for conventional and modified ELISA, respectively; in the control group they were 0.068 (0.020–0.116) and 0.063 (0.019–0.107) ODU, respectively. Differences within these couples were not significant. Diagnostic sensivity and specificity of modified ELISA were 64.74 (53.09–76.39) and 85.01 (72.95–97.07)%, coinciding with those for conventional ELISA. LOQ for the modified ELISA was slightly lower than for the conventional one. Accuracy and repeatability of modified ELISA were also insignificantly higher than those for conventional approach. There was no substantial change in all the parameters of modified ELISA after single recovery of beads.

Conclusions: The newly developed ELISA for anti-DNase I antibodies was demonstrated to have equivalence or advantage in some analytical parameters over conventional ELISA. Considering some economic and maintenance benefits, our innovation can be an alternative tool to improve SLE diagnostics.

References:

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[2] Gontar IP, Simakova ES, Trofimenko AS, Zborovskaya IA. An approach for removal of DNA-containing immune complexes from blood using composite sorbent. Patent RU2441674 (2010) [in Russian].

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THU0671 CAN AN INNER DISPOSABLE GLOVE BE USED UNDER AN ELECTROGONIOMETRIC GLOVE FOR MEASURING FINGER MOVEMENT WITHOUT LOSS OF ACCURACY?

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Background: Improving joint mobility is an important outcome for patients with arthritis, but finger joint range of motion is rarely measured in clinic. Electronic gloves with movement sensors have been developed to measure joint movement accurately and it is now possible to assess dynamic mobility of the finger joints. However these gloves are expensive and it is likely that when carrying out measurements in the patient population they would be used with inner disposable gloves to avoid nonsocomical infection. Establishing accuracy and usability of electronic gloves whilst wearing disposable inner gloves is therefore an important pre-requisite for studies in patients with arthritis.

Objectives: To establish the accuracy and repeatability of measurements of finger movement obtained using two different electrogoniometric gloves worn with and without an inner disposable glove.

Methods: We used two different types of electrogoniometric glove for the purpose of this study. One is the commercially available 5DT dataglove 14 Ultra (5DT, 2011) and the other was produced to our specifications by Tyndall National Institute, University College Cork. We called this the “IMU glove”. We developed a graphical interface for both devices to facilitate detailed evaluation of joint movement in each finger. Both gloves were tested using a protocol adapted from Dipietro, Sabatini, & Dario, (2003).

Results: Table 1 displays comparison of Coefficient of Variation (CV) readings for both data gloves. Figure shows this information graphically.

Sensor	No surgical glove		Surgical glove underneath	
	5DT	IMU	5DT	IMU
Index MCP	2.97	2.86	3.22	3.88
Middle MCP	7.01	6.77	9.02	6.39
Ring MCP	6.10	4.37	6.28	4.32
Little MCP	24.17	6.07	9.55	8.25
Index PIP	1.96	9.72	2.92	14.69
Middle PIP	4.40	10.29	2.98	12.53
Ring PIP	5.38	9.95	5.00	11.03
Little PIP	9.11	3.71	10.07	5.46

Results show no significant change for 5DT angular readings with and without a surgical glove worn underneath the data glove. Results for PIP sensors show an improvement in repeatability with a surgical glove. CV variance was smaller for MCP sensors with a surgical glove worn underneath the data glove compared with no surgical glove.

CV for the IMU data glove show negligible changes in MCP readings when a surgical glove is worn underneath. PIP readings show small changes when using a surgical glove.

Conclusions: Inner disposable gloves can be worn when using electrogoniometric gloves for testing finger movement without loss of accuracy or any significant discomfort in patients with arthritis.

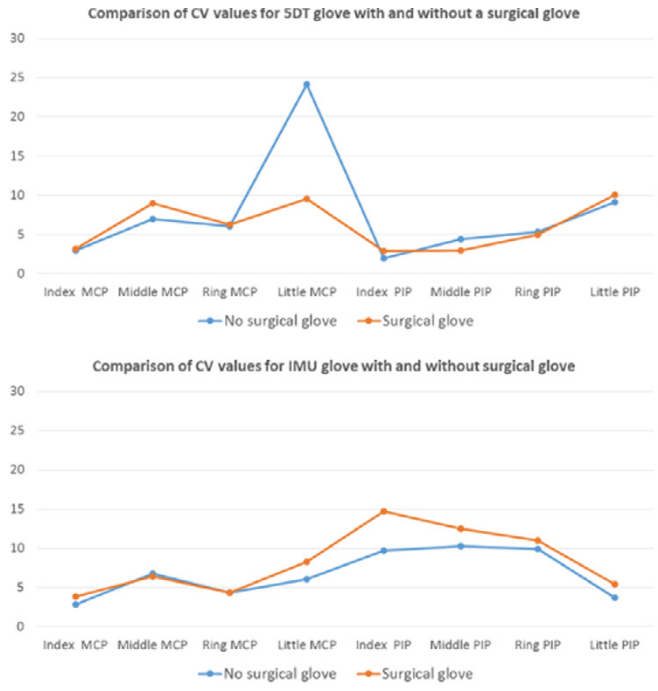

Figure 1: Comparison of Coefficient of Variation (CV) values for mean angular readings for both data gloves, with and without a surgical glove worn underneath.

References:

[1] 5DT, 2011. 5DT Data Glove 14 Ultra [WWW Document]. URL http://www.5dt.com/products/pdataglove14.html (accessed 1.10.12).

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THU0672 REAL WORLD EVIDENCE COMPARING THE PATIENT REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM TO THE CDAI IN RHEUMATOID ARTHRITIS PATIENTS

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Background: Patient (Pt) reported outcomes (PROs) play a role in overall disease evaluation, therapeutic response assessment and care of rheumatoid arthritis (RA) patients (Pts). The Pt Reported Outcomes Measurement Information System (PROMIS [P]) questionnaires developed by the NIH have been validated and are a feasible assessment tool in RA (Bartlett 2015).

Objectives: AWARE (Comparative and Pragmatic Study of Golimumab Intravenous (IV) Versus Infliximab in RA) is a real-world study of golimumab IV (G-IV) vs. infliximab (IFX) in RA and will assess infusion reactions, disease activity and multiple PROs as outcomes measures.

Methods: AWARE is a prospective, noninterventional, ongoing US-based study in which 1,200 adult Pts will be enrolled on initiation of treatment with G-IV or IFX. Objectives include PRO assessments of Pt response to treatment using the PROMIS-29 Profile v2.0 (P29v2), P Pain Interference Short Form-6b (PISF) and P Fatigue Short Form-7a (FSF), 36-Item Short Form Health Survey (SF-36v2) and the Clinical Disease Activity Index (CDAI). We report an interim analysis from the first 353 Pts of baseline PROMIS questionnaire and CDAI scores, and their inter-relationships. PROMIS questionnaire results are scored on a 0 to 100 scale, normed to the US population and reported as a “T-score” (mean of 50 and standard deviation (SD) of 10). PROMIS T scores were compared across CDAI disease activity (DA) categories.

Results: Baseline mean (SD) CDAI score was 33.46 (±15.79), with 73.4% of pts with high DA (HDA), 22.1% with moderate disease activity (MDA), 3.7% with low disease activity (LDA) and 0.8% pts in remission. PROMIS scores are shown below. All P29v2 domains, PISF and FSF scores were significantly worse in pts with CDAI>22 vs. CDAI≤22 ($p<0.05$). The same was true for SF-36 domains (data not shown). PROMIS scores are shown below for all pts, and also based on CDAI DA category. PROMIS T scores across all domains (P29v2 domains, PISF and FSF) were compared to CDAI disease activity category (below). As shown, PROMIS T scores correlated with CDAI disease category, with HDA Pt T scores significantly (*, $p<0.05$) greater than those of MDA, LDA and Remission pts (excepting the Sleep Disturbance domain).