

Original Article

VALIDITY OF PATIENT REPORTED OUTCOME MEASUREMENT INFORMATION SYSTEM HEALTH ASSESSMENT QUESTIONNAIRE (PROMIS HAQ) FOR ASSESSING DISEASE ACTIVITY IN IRAQI PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS

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ABSTRACT

Objective: Rheumatoid arthritis (RA) is a chronic systemic autoimmune inflammatory disease that affects all ethnic groups throughout the world. Biochemical and clinical data are required to evaluate the disease activity and responsiveness to treatment. Disease activity score of 28 joints (DAS28) and simplified disease activity index (SDAI) are common tools that used to assess disease activity, whereas the Patient Reported Outcome Measurement Information System health assessment questionnaire (PROMIS HAQ) and HAQDI is a useful tool to assess the extent of the patient's functional ability. This study aimed to evaluate the effectiveness of PROMIS HAQ score for monitoring disease activity and response to therapy in Iraqi patients with active rheumatoid arthritis.

Methods: A cross-sectional study was conducted in Baghdad Teaching Hospital, Rheumatology outpatient Unit from September 2012 to April. A total of 140 patients (40 males and 100 females) with active RA were involved in this study Disease activity was measured by DAS28 and the SDAI whereas functional status of the patients was measured using PROMIS HAQ score.

Results: There was a significant positive correlation of PROMIS HAQ score with clinical parameters like swelling joint count (SJC), tender joint count (TJC), visual analogue scale (VAS) and physician global assessment (EGA). Additionally PROMIS HAQ was significantly correlated with simplified disease activity index (SDAI). Furthermore it correlated with inflammatory marker CRP. Conclusion: PROMIS HAQ score is a valid and useful tool to monitor disease activity and response to treatment in Iraqi patients with highly active RA.

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Keywords: Rheumatoid arthritis, Disease activity, PROMIS HAQ.

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic systemic autoimmune inflammatory disease that affects all ethnic groups throughout the world [1]. It may affect many tissues and organs, but principally attacks flexible (synovial) joints [2]. Although the exact cause of RA remains unknown, recent findings suggest a genetic basis for disease development [3]. Various immune modulators (cytokines and effector cells) and signaling pathways are involved in the pathophysiology of RA [3]. The assessment of patients with RA incorporates multiple domains, which include clinical, functional, biochemical, and imaging parameters. Morning stiffness of the joints is an important symptom that should be documented as well [1]. Activity of the disease in RA patients can be assessed by many valid tools like Disease Activity Score-28 joints (DAS28) and simplified disease activity score (SDAI) [4- 6]; while the Patient Reported Outcome Measurement Information System health assessment questionnaire (PROMIS HAQ) and HAQDI is a useful tool to assess the extent of the patient's functional ability [7, 8], and also assess the disease activity in RA patients [8, 9]. The primary target for treatment of RA should be a state of clinical remission. However, low disease activity may be an acceptable alternative therapeutic goal, particularly in established long-standing disease [10]. Although many effective drugs are available nowadays for treating RA patients [11], but many patients still suffer from a decreased response to disease modifying anti rheumatic drugs (DMARDs) after a period of time [12]; Furthermore some patients may develop disability despite using effective medications [13], this highlight the importance of continuous follow up for RA patients and assessing the disease activity regularly to ensure not only safety of the drug but also to ensure drug effectiveness and patient's response to it; However, this aspect is often neglected [14] may be because it is costly in terms of medical time, expertise and in the use of general health resources and can be inconvenient to the patients especially those who are still in full or part time employment [15].

So, this study aimed to evaluate the validity of simple, cheap, and more convenient tool (The PROMIS HAQ score) for monitoring disability, disease activity and response to therapy in Iraqi patients with active rheumatoid arthritis.

MATERIALS AND METHODS

Study Design

A cross-sectional study was conducted in Baghdad Teaching Hospital, Rheumatology outpatient unit from September 2012 to April 2013. A total of 140 patients (40 males and 100 females) with active RA were involved in this study. Patients were diagnosed to have active RA by the rheumatologist. Ethical approval for research was obtained from the Ethics Committee of Baghdad University, College of Medicine, and Department of Medicine. Patients with diseases other than rheumatoid arthritis were excluded from the study.

Clinical and Laboratory Evaluation

Disease activity was measured by DAS28 and the SDAI [16, 17]. The patients were clinically examined and the number of swelling joints count (SJC) (0-28) and tender joints count (TJC) (0-28) were noted. The 28 joints included bilateral knees, shoulders, elbows, wrists, metatarsophalangeal and proximal interphalangeal joints. The patients were asked to mark on the visual analogue scale (VAS) of 0-10 cm according to their global assessment of pain. The physician marked on the VAS of 0-10 cm according to the physician global assessment (EGA) of the disease activity. Erythrocytes sedimentation rate was measured by Westergren method [18], whereas high sensitive CRP and TNF is measured by using ELIZA technique [19, 20]. DAS28 was calculated using an internet calculator: http://www.das-score.nl/das28/DAS_calculators/dasculators.html. DAS28 values > 2.6 and < 3.2 was considered as low RA disease activity, values > 3.2 and < 5.1 was considered as moderate disease activity and those > 5.1 was considered as high

disease activity [21]. Whereas SDAI was calculated by direct summation of the 5 variables SJC, TJC, VAS, EGA, and CRP [17]. SDAI values > 3.3 and ≤ 11 was considered as low RA disease activity, values > 11 and ≤ 26 was considered as moderate disease activity and those > 26 was considered as high disease activity [21].

Assessment of functional ability done by using The PROMIS HAQ questionnaire which is a self-reported instrument comprised of 20 items. Each item is scored from 0 (no difficulty) to 4 (unable to perform), The PROMIS HAQ score is the mean scores of the 20 items. It can be self-administered in five minutes and scored in less than one minute. It has been validated in numerous studies, is sensitive to change, and is widely used in observational studies and clinical trials [22].

Additionally morning stiffness of each patient was calculated according to patient approximate.

Statistical analysis

All data were statistically analyzed using Statistical Package for Social Sciences software version 16 (SPSS v.16); *t*-test was used for two independent samples. Pearson correlation coefficient was used to assess the correlation between continuous variables. All *p* values used were asymptotic and two sided. Values with *p* < 0.05 were considered significant.

RESULTS

Table 1 showed the general demographic data of participated patients.

Table 1: Demographic data of patients

Age (years)	48.52 ± 9.67
F/M ratio	100/40
Duration of RA	9.72 ± 7.59
Disease activity according to DAS28	5.21 ± 1.179
Disease activity according to SDAI	24.3557 ± 8.88251
Drug used	
ETN only number (%)	80(57.14)
ETN plus MTX number (%)	60(42.86)

RA=Rheumatoid arthritis; DAS28=Disease activity score of 28 Joints; SDAI= simplified disease activity index; ETN= Etanercept; MTX= Methotrexate;

Table 2 showed a significant correlation of PROMIS HAQ score with clinical parameters like SJC, TJC, VAS, and EGA. Additionally PROMIS HAQ was significantly correlated with disease activity score SDAI. Furthermore it correlates with inflammatory marker CRP.

Table 2: Correlation of HAQDI score with RA disease activity, and other inflammatory and clinical parameters

Parameter	R	P value
SJC	0.183	0.031
TJC	0.194	0.023
VAS	0.228**	0.007
EGA	0.230**	0.006
DAS28	0.157	0.065
SDAI	0.228**	0.007
ESR	0.058	0.496
CRP	0.209	0.013
TNF	-0.002	0.977

SJC= Swollen joint count; TJC=Tender joint count; VAS=Visual analogue scale; EGA=Evaluator global assessment; SDAI=Simplified disease activity index; DAS28=Disease activity score of 28 joints; ESR=Erythrocyte sedimentation rate; CRP= C - reactive protein.**. Correlation is significant at the 0.01 level (2-tailed).

DISCUSSION

This study showed that PROMIS HAQ score was well correlated with clinical parameters like TJC, VAS, EGA, and SJC, this result may be expected since PROMIS HAQ measure the functional ability of the patient to perform daily activity so its value may be correlated with

number of inflamed joints or swelled joints that inversely effect on functional activity of the patient and the value of the PROMIS HAQ [22].

although there is no any similar study in this regard but there were several studies that measure the correlation of the most widely used Health Assessment Questionnaire Disability Index (HAQDI) with these clinical parameter and showed a significant correlation between HAQDI and these parameters [23, 24, 25]; and since both questionnaire measure disability and there is direct correlation between them[26]; So this result is reasonable and acceptable. The highly significant correlation between PROMIS HAQ and SDAI is easily understood in that PROMIS HAQ is a valid tool for assessing disease activity [24] beside that in many studies it was found that HAQDI is correlated with PROMIS HAQ [26] and since HAQDI is well correlated with SDAI [25], so this correlation between HAQ and SDAI is acceptable and reasonable.

Also RA disease activity which are inversely proportional with the functional ability that measured by PROMIS HAQ that's mean in patients with high disease activity the functional ability will be decreased that will lead to high PROMIS HAQ value.

Meanwhile, the correlation between PROMIS HAQ and VAS or EGA can be rationalized in that both VAS and EGA are measures of the level of pain and since it is well known that the pain is the most important factor that limit the patient ability to perform daily activity which in other words is directly related to PROMIS HAQ which is a valid measure for functional ability.

Regarding hs CRP which is one of the most important inflammatory marker that give an indication about the degree of inflammation caused by RA disease [27].

The significant correlation can be acceptable since the degree of inflammation is a corner stone in the functional ability of the patients [28]

The non-significant correlation between PROMIS HAQ and the clinical parameter (DAS28) and biochemical inflammatory parameters (ESR,TNF) can be attributed to several causes like small sample size, short duration of this study, the difference in parameters used to measure DAS28 and SDAI, further more ESR which is one of the parameter used to calculate DAS28 not correlated with HAQ so it is acceptable that HAQ will not correlate with DAS28.Finally the presence of other factors not only RA disease that effect on the result of some biochemical markers like infection.

In conclusion PROMIS HAQ score is a valid and useful tool to monitor disease activity and response to treatment in Iraqi patients with highly active RA.

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