TREATMENT SATISFACTION AND ITS RELATION TO DISEASE ACTIVITY AND MEDICATION ADHERENCE AMONG EGYPTIAN RHEUMATOID ARTHRITIS PATIENTS

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Abstract

Objectives: To assess treatment satisfaction among RA patients and determine factors affecting it; aiming at improving the clinical diseaseoutcome.

Methods: A cross-sectional study included 316 Egyptian patients. Patients were subjected to full history, complete clinical examination (general and articular) including assessment of disease activity using (CDAI) & (DAS 28) scores, and routine laboratory investigations. Patients were also subjected to assessment for presence of fibromyalgia using 2016 ACR criteria, assessment of treatment satisfaction using Treatment Satisfaction Questionnaire (TSQM), assessment of functional outcome using the Rheumatoid Arthritis Impact of Disease (RAID) score, assessment of Health-Related Quality of Life HRQoL using Modified Health Assessment Questionnaire (MHAQ) and assessment of medication compliance using (MORISKY) score.

Results: 49 (15.6%) patients were satisfied, and non-satisfied group was 267 (84.4.%) patients. The final multivariate model included only RAID score and CDAI score as significant predictors of non-satisfaction .Most of our patients (48.1%) showed medium compliance to treatment.

Conclusion: The prevalence of burdensome symptoms and adverse impacts on health-related HRQoL observed in this study suggests that there is unmetneed for many patients despite the currently available treatment options, even among those patients who are satisfied with their RA treatment and even among patients who are in clinical remission.

Key messages Patients reported outcome should be Implemented to asses and deal with unmet needs of RA patients. Patient perspective should be included during treatment plan and during appropriate treatment switching and escalation.

Keywords: Rheumatoid Arthritis, treatment satisfaction, TSQM, unmetneeds, HRQoL, RAID.

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Introduction

 Rheumatoid arthritis (RA) is a chronic systemic autoimmune inflammatory disorder of unknown etiology that primarily involves synovial joints. Synovitis is the hallmark feature of the diseased [1]. The arthritis is typically symmetrical and usually leads, if uncontrolled, to destruction of joints due to erosion of cartilage and bone causing joint deformities.

The disease usually progresses from the periphery to more proximal joints and results in significant locomotor disability within 10 to 20 years in patients who do not respond to treatment [2].

 RA is one of the few diseases where subjective patient and physician measures are the best predictors of treatment response and future health outcomes. There is a strong relationship between disease activity and Health Related Quality of Life (HRQoL) including physical and mental components. The disease affects every aspect of a patient's life. Progressing dysfunctions of the musculoskeletal system significantly worsen a patient's work and social life [3]. Even among those who become free from inflammatory joint symptoms, many experience other symptoms such as pain, fatigue, impaired functioning and emotional difficulties. Despite availability of efficacious treatments, unmet needs still exist preventing optimal and comprehensive management of RA [4] The prevalence of burdensome symptoms and adverse impacts on HRQoL suggests that there is unmet need for many patients despite the currently available treatment options. Patient in sights can help physicians and patients discuss and decide upon a course of treatment; this shared decision-making is encouraged for the management of RA [5].Furthermore, the patient perspective is important for identifying the symptoms and impacts of RA and treatment that are most important to patients but remain poorly addressed by currently available

Disease Modifying Antirheumatic Drugs (DMARDs). These include residual pain, fatigue, joint stiffness, sleep disturbances and other patient-reported outcomes. Other factors such as patient coping behavior or perceptions of illness have been shown to affect patient psychosocial outcomes. The patient perspective will be critical to make continuous improvements in the treatment of RA and to encourage appropriate treatment switching and escalation [6].

In this study we aimed to assess treatment satisfaction among patients with RA and its relation to disease activity and medication adherence and to study other factors that may be influence treatment satisfaction; aiming to improve the clinical disease outcome and health related quality of life of our patients

Methods

A cross-sectional study included 316 Egyptian patients diagnosed as Rheumatoid Arthritis according to the 2010 ACR-EULAR classification criteria for the diagnosis of RA [7].Patients were recruited from the Rheumatology and Rehabilitation outpatient clinic at Kasr Al Ainy Hospital, where all patients were subjected to full history, complete clinical examination and routine laboratory investigations. Disease activity measured by DAS28 [8] and CDAI score [9]

Patients were also subjected to assessment for presence of fibromyalgia using 2016 ACR criteria [10] .patient satisfaction for treatment was assessed by Treatment Satisfaction Questionnaire for Medications (TSQM): A 14-items questionnaire for measurement of extent of satisfaction to medical treatment. It comprises 14 items across four domains focusing on effectiveness (3 items: 1, 2, and 3), side effects (5 items: 5, 6, 7, and 8), convenience (3 items: 9, 10, and 11) and global satisfaction of the medication over the previous 2–3 weeks or since the patient's last use (3 items: 12, 13, and 14). All items have five or seven responses scored from 1 (least satisfied) to 5 (most satisfied) except item 4 (presence of side effects; yes or no). Item scores are summed to give 4 domain scores, which are in turn transformed to a scale of 0–100 as the following [11]Treatment satisfaction was defined as attainment of scores ≥ 80[12]

Rheumatoid Arthritis Impact of Disease (RAID) score; a composite index, which is a patient-derived differentially weighted seven-item tool assessing seven domains: pain, function, fatigue, physical well-being, psychological well-being, sleep disturbances and coping. Each domain is a 0–10 numeric rating scale (NRS), with higher scores representing greater impact of RA.The final RAID value is 0-10 where higher figures indicate worse status. Cut-off values for Remission (RAID ≤ 3), for Low disease activity (RAID > 3 and ≤ 4), for moderate disease activity (RAID > 4 and ≤ 6) and

for High disease activity (RAID > 6)(was applied to all patients[13] . Medication Adherence Rating Scale (MARS) analyzed patient adherence to treatment: with the four item Morisky Medication Adherence Scale (MMAS-4), a self-reported adherence questionnaire. With questions 1–4 having dichotomous responses (No = 0 score and Yes = 1 score). Total scores are added together and range between 0 and 4 with (0) = high adherence, (1–2) = medium adherence, and (3–4) = low adherence [14]. Assessment of Health-Related Quality of Life HRQoL using Modified Health Assessment Questionnaire (MHAQ). : a shorter, more manageable version, Modified version of the original HAQ score (MHAQ), 8 of the 20 ADL in the HAQ were chosen, 1 from each of the 8 activity categories. Scoring: The MHAQ may be calculated by hand or with a calculator by adding all scored items together (at least 6 of the 8 items are required) and dividing by the total number of items answered to obtain the final score. Score interpretation. Total score is between 0.0–3.0, higher scores indicate worse function and greater disability. MHAQ scores < MHAQ < 1.8) and severe (MHAQ >1.8) functional losses [15].

Statistical analysis: For quantitative variables, data were described using mean ± SD for normally distributed data and median (IQR) for non-normally distributed data. The number and percentages were alternatively use for describing binary data. Missing data were removed from the analysis to avoid potential bias. Normality testing was done for each candidate variable using KolmogorovSmirnov test. For comparing satisfied vs non-satisfied patients, t-test, Wilcoxon rank test and Chi-square test were used to compare normally distributed, non-normally distributed and categorical data, respectively. Logistic regression analysis was performed to identify the different predictors of non-satisfaction to treatment and regression models were developed using forward-addition techniques. To confirm the validity of the developed models, Hosmer-Lemeshow test and receiver operating characteristics curve (ROC) were evaluated independently. Alpha level was set to 0.05 for all the subsequent analyses. SPSS software (version 26, IBM, NY,USA) was applied for performing descriptive statistics and comparisons, while R packages (R Foundation for Statistical Computing, Vienna, Austria) was implemented for building and validation of the developed regression mod.

This study was approved by the local research ethical committee of Cairo university (MD-243-2020) and confirms to the 1995 declaration of Helsinki . Written consent was given by participants .

Results:

Three hundred and sixteen RA patients were included in this study. They were 261 females and

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55 male with a mean age of 46 (±12) and disease duration of 7.4±5.5 years. Fibromyalgia was present in 92 (29.1%) as shown in table (1). RAID interpretation in this study showed high disease activity in 153(48.5%) patients, moderate disease activity in 87 (27.4%) patients, low disease activity in 22 (7%) patients and remission in 54 (17.1%) patients as shown in fig(1). Distribution of the different domains of RAID score presented in table (2). Ninety-three (29.4%) of the group under study demonstrated high treatment compliance as determined by the Morisky score as shown in fig (2). According to the TSQM score, the majority of the patients were not satisfied with their treatment. Comparing the items of patient satisfaction between unsatisfied and satisfied patients revealed statistically significant higher values of effectiveness score, Convenience as well as Global satisfaction score (p value<0.001) in satisfied group compared to non-satisfied (p value<0.001). There was no significant difference in side effects score between the two groups (p=0.054) as shown in table (3). Regarding disease activity indices, different RAID items & total Morisky score, there was a substantial statistical difference between the satisfied and unsatisfied groups as shown in table(4). There was no statistically significant difference between the levels of satisfaction with different treatment protocols (p=0.8)as shown in fig (3).

Evaluation of several predictors of treatment non-satisfaction by logistic regression analysis: CDAI ($P<0.001$), DAS28 ($P<0.001$), Morisky score ($P=0.026$), RAID score($P<0.001$) and MHAQ score ($P<0.001$) were found to be important predictors of treatment non-satisfaction. All the selected covariates demonstrated statistical significance during univariate analysis; however, the final multivariate model included only RAID score and CDAI score in the final regression model as shown in table(5)&table(6).

Table (1): Clinical and demographic characteristics of the study groups (n=316)

Variable	Mean ± sd/ n,%
Age (years)	46±12
Age at presentation (years)	38.6±11.2
Disease duration (years)	7.4±5.5
Sex (female) (n, %)	261 (82.6%)
(male)(n, %)	55 (17.4 %)
Marital status (n,%)	
Single	28 (8.9%)
Married	276 (87.3%)
Divorced	0 (0%)
Widow	12 (3.8%)
Occupation (n, %)	
Employed	170 (53.8%)
Unemployed	146 (46.2%)
Retired	0 (0%)
Residency (n, %)	
Urban	213 (67.4%)
Rural	103 (32.6%)
Smoking (n,%)	36 (11.4%)
Comorbidities (n,%)	
HTN	76 (24.1%)
DM	46 (14.6%)
Hypothyroidism	25 (7.9%)
Hyperthyroidism	0 (0%)
Bronchial asthma(BA)	14 (4.4%)
IHD	9 (2.9%)
ILD	13(4.1%)
Subcutaneous nodules	30(9.5%)
Fibromyalgia	92(29.1%)

DM: diabetes mellitus; HTN: hypertension; sd: standard deviation; IHD: Ischemic heart disease, ILD: interstitial lung disease.

Table (2) Distribution of RAID score different domains (n =316)

Score	pain	Functional disability assessment	Fatigue	Sleep	Physical well-being	Emotional well-being	Coping
0	16(5.1%)	29(9.2%)	37(11.7%)	57(18%)	31(9.8%)	34(10.8%)	44(13%)
1	14 (4.4%)	6(1.9%)	13(4.1%)	7(2.2%)	9(2.8%)	20(6.3%)	18(5.7%)
2	14(4.4%)	19(6%)	21(6.6%)	25(7.9%)	8(2.5%)	10(3.2%)	19(6%)
3	9(2.8%)	10(3.2%)	24(7.6%)	23(7.3%)	20(6.3%)	15(4.7%)	11(3.5%)
4	15(4.7%)	18(5.7%)	9(2.8%)	6(1.9%)	9(2.8%)	22(7%)	21(6.6%)
5	43(13.6%)	50(15.8%)	45(14.2%)	47(14.9%)	74(23.4%)	56(17.7%)	43(13.6%)
6	27(8.5%)	28(8.9%)	23(7.3%)	25(7.9%)	35(11.1%)	25(7.9%)	25(7.9%)
7	40(12.7%)	30(9.5%)	20(6.3%)	20(6.3%)	31(9.8%)	26(8.2%)	42(13.3%)
8	39(12.3%)	38(12%)	37(11.7%)	29(9.2%)	35(11.1%)	33(10.4%)	35(11.1%)
9	9(2.8%)	31(9.8%)	31(9.8%)	20(6.3%)	25(7.9%)	14(4.4%)	17(5.4%)
10	90(28.5%)	57(18%)	56(17.7%)	57(18%)	39(12.3%)	61(19.3%)	41(13%)

Table (3): Comparing the items of patient satisfaction between non-satisfied and satisfied patients (n =316)

Parameter	Non-satisfied(n= 267)	Satisfied(n=49)	*P*
Effectiveness (median, IQR)	13 (3-27)	18 (9-27)	<0.001
Side effects (n, %)	152 (59.9%)	17 (34.7%)	0.005
Side effects score (median, IQR)	8 (0-24)	0 (0-20)	0.054
Convenience (median, IQR)	14 (1-27)	16 (11-27)	<0.001
Global satisfaction (median, IQR)	11 (3-14)	16 (15-19)	<0.001
Treatment satisfaction (mean± SD)	45.5±9	55.2±9	<0.001
Scaled Treatment satisfaction(mean± SD)	56.4±17.1	91.4±6.5	<0.001

Table (4): Clinical and demographic characteristics among non-satisfied vs satisfied patients

Variable	Ion-satisfied(n= 267)	Satisfied (n=49)	*P*
Age (years)	45.7±11.7	47.55±13.3	0.32
Age at presentation (years)	38.5±10.9	39.2±13.1	0.67
Disease duration (years)	7.2±5.3	8.3±6.3	0.35
RAID(mean±SD)	42.2±17.5	29.9±19.6	<0.001
Scaled RAID (mean±SD)	6±2.5	4.3±2.8	<0.001
Pain(median, range)	7(0-10)	5(0-10)	<0.001
Functional disability(median, range)	7(0-10)	5(0-10)	<0.001
Fatigue (median, range0	6(0-10)	5(0-10)	<0.001
Sleep (median, range)	6(0-10)	3(0-10)	<0.001
Physical well-being (median ,range)	6(0-10)	5(0-10)	<0.001
Emotional well-being (median, range)	6(0-10)	3(0-10)	<0.001
Coping (median, range)	6(0-10)	4(0-10)	0.009
DAS28(mean±SD)	5.2±1.5	4.3±1.2	<0.001
CDAI (mean±SD)	22.8±14.2	14±9.6	<0.001
MHAQ(mean±SD)	10.1 ±5.8	6.7±5.4	<0.001
Total Morisky score mean±SD)	1.48±1.3	1.04±1.1	0.018
Sex (female) (n, %)	222 (83.1%)	39 (79.6%)	0.56
Fibromyalgia (n, %)	79(29.6%)	13(26.5%)	0.67

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DM: diabetes millets; HTN: hypertension; NS: non-significant; S: significant; SD:standard deviation, CDAI: clinical disease activity index, DAS: Disease activity score, MHAQ: modified health assessment questionnaire.

Table (5): univariate logistic regression for the predictionof treatment non-satisfaction based on area under receiver operating curve (AUROC)

Predictor Variable	AUROC	Standard error	*P*	95% C.I
Occupation	0.58	0.04	0.07	0.5-0.67
CDAI	0.68	0.04	<0.001	0.53-0.69
DAS28	0.68	0.04	<0.001	0.61-0.75
Morisky score	0.6	0.04	0.026	0.51-0.69
RAID score	0.68	0.04	<0.001	0.59-0.76
MHAQ	0.66	0.04	<0.001	0.57-0.75

Table (6): Results of multi-variate regression analysis of the final predictors of treatment non-satisfaction.

Variable	Slope	aOR	*P*
RAID	0.19	1.21	**0.004**
CDAI	0.04	1.04	**0.005**
Constant	-0.05	-	0.9
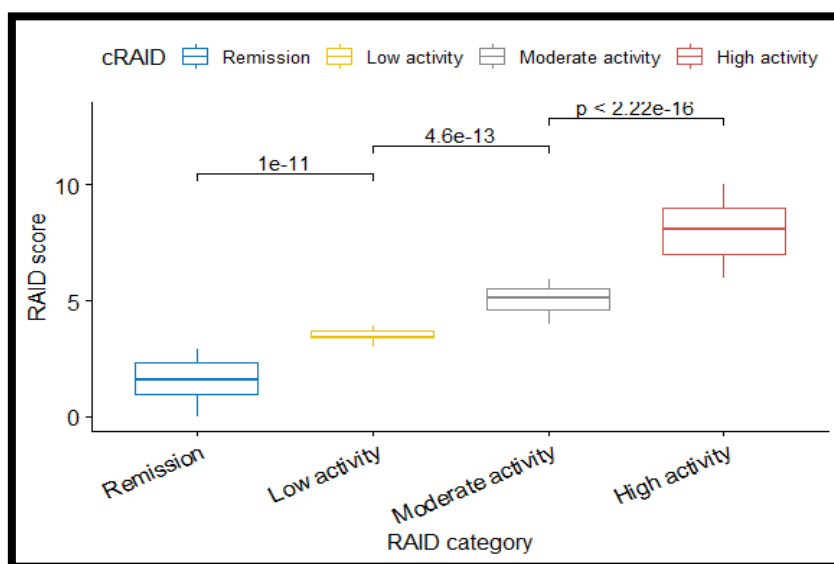
Figure (1): Comparing the different disease activities classified based on RAID scores(n=316)

2008

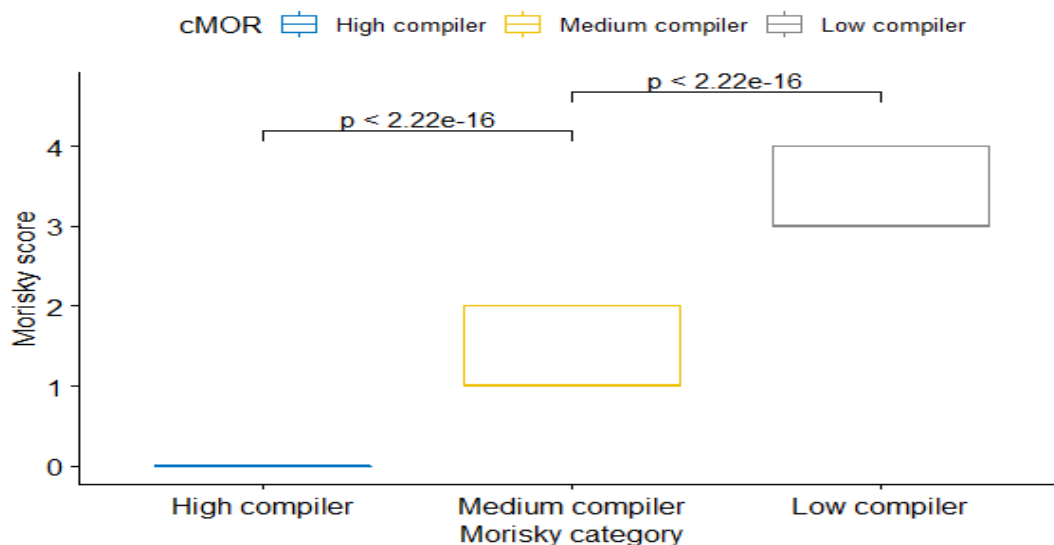*Eur. Chem. Bull. 2023, (Special Issue 12),2004-2012*

Figure (2): Box-Whisker plot Comparing the degree of patient compliance classified accordi ng Morisky scores (n=316)
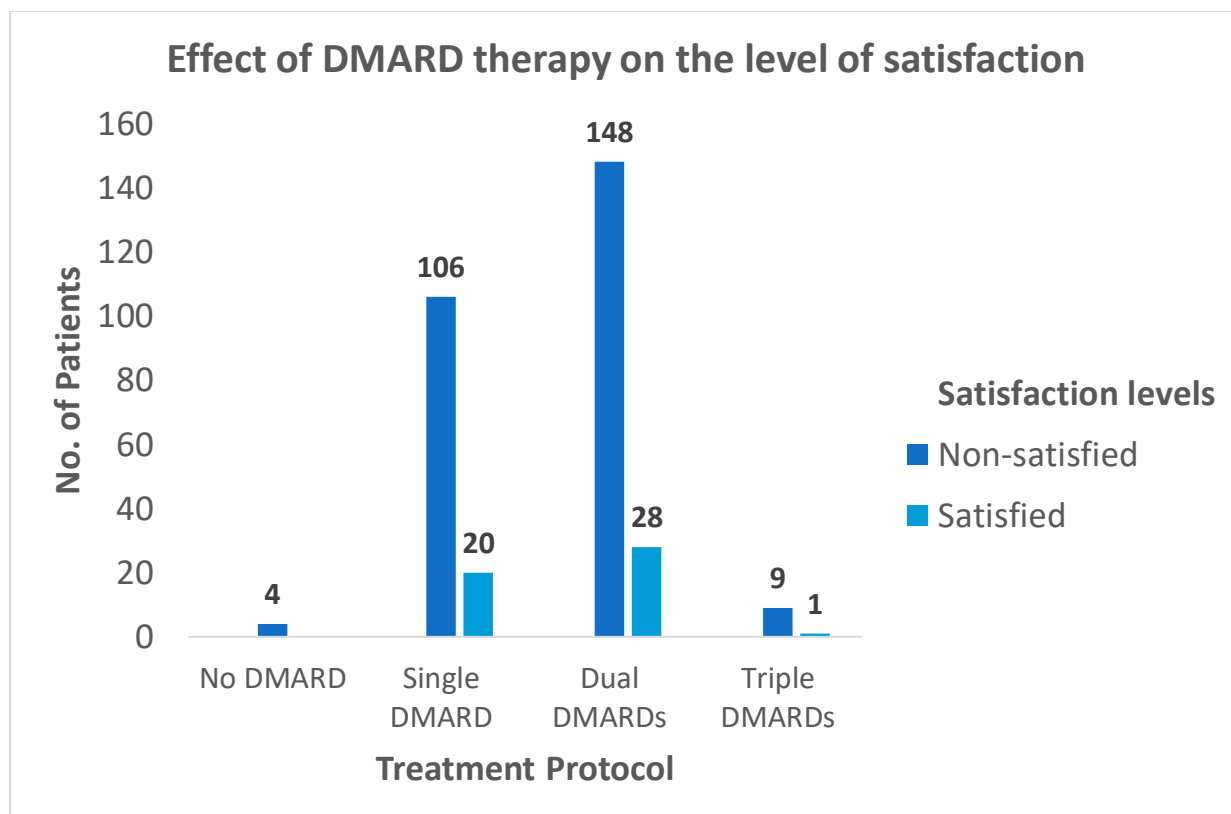

Figure (3): Comparing DMARD protocols in non-satisfied vs satisfied patients.

Discussion

Rheumatoid arthritis (RA) is a progressive inflammatory autoimmune disease that primarily affects the joints and potentially impairs the patient's quality of life (QOL) with pain and fatigue as major consequences. In the last decade, a paradigm shift has been seen in the treatment of RA, the so-called treat-to-target (T2T) strategy, which involves more aggressive tightly controlled therapy early in the disease course guided by a structured assessment of disease activity with the ultimate goal of reaching remission[16]

Despite the major advances in RA therapies, target therapeutic attainment of remission or low disease activities still relatively low in both clinical trials and clinical practice [12]

2009

Understanding the patient's perspective is therefore becoming more and more crucial in clinical settings. A number of studies have been conducted to elicit patient attitudes and expectations on treatment outcomes and preferences for mode ofRA treatment administration [17,18]

Since patient satisfaction is an important determinant of treatment success in RA, assessing patients' perspectives can help identify unmet needs and subsequently enhance the under standing of treatment benefits [19]Thus, the current study objective was to examine treatment satisfaction among cohort of Rheumatoid arthritis patients and factors affecting it.

In the present study, 316 RA patients were included, only a small fraction of the patients (n=49, 15.5%) were identified as satisfied. Similarly, Radawski et al.2019 reported identifying only 26% of their study group as satisfied based on TSQM globalsatisfaction assessment [12].More recently, The SENSE study assessed patient satisfaction through an analysis of the German biological register (**RABBIT**) database Mean TSQM global satisfaction subs core was 60.9 with only 13.5% of patients reporting good treatment satisfaction (TSQM global ≥80). They concluded that Sub optimal disease control negatively influences treatment satisfaction, aswell as work ability, and quality of life (QoL). [19]. In contrast to our finding, Schäfer et al.2020 expressed high level of treatment satisfaction reaching up to 85% after one year of assessment . The authors attributed this high reported treatment satisfaction to the fact that their patients were all receiving a specialized care in rheumatology care unit instead of being treated as outpatient, closely monitored and were familiar with the use of questionnaires[20]

Furthermore, we noticed a statistically significant lower rates of adverse effects in satisfied vs non-satisfied subpopulation (59.5% vs 34.7%, *P=0.005),* respectively. This should be interpreted as these adverse effects may negatively influence the quality of life of the RA patients and subsequently affect the patient satisfaction. Interestingly, we found no significant differences in the side effect score between non-satisfied and satisfied groups (median 8 vs 0, p=0.054, respectively) despite the higher incidence of side effects in the non-satisfied group. This might be understood in the light of the findings of the SENSE study, which showed that patients with RA place a higher priority on treatment benefits than treatment serious or minor side effects [20]

In this context, we found significantly higher mean RAID scores assessed on 0-10 scale in the non-satisfied (mean 6±2.5) vs satisfied patients (mean 4.3±2.8, P<0.001). Similarly, Radawski et al., 2019 reported significantly higher RAID scores in non-satisfied RA patients and they highlighted this as one of unmet needs of RA patients. In particular, we found that non-satisfied patients had significant

higher values of pain(P<0.001), functional disability (P<0.001), fatigue (P<0.001), sleep (P<0.001), physical well-being (P<0.001), emotional well-being (P<0.001) and coping (P=0.009) compared to satisfied group. The most frequent of these symptoms was pain (94.9%) while the least frequent was sleep disturbance (82%).Other reported symptoms included functional disability (90.8%) and fatigue (88.3%). According to Radawski et al., 2019 study, the RAID domains with highest mean values were pain, sleep and fatigue among RA patients. Those were the major symptoms that had a significant influence on their lives [12]However , our reported symptoms rate is significantly higher than that of Radawski etal, 2019 in their cross –sectional study where they reported pain in 51%, fatigue in 11% and sleep disturbance in 17% of their patients. This suggests that the present treatment management regimens for RA in Egypt appear to underestimate the importance of these symptom management , indicating that physicians are more outcome oriented than patient-centric in their clinical practice.

Adherence to prescribed medication regimens is fundamental to achieve the target therapeutic outcomes in patients with rheumatoid arthritis [21]Therefore, it is crucial that efforts be made to maximize patient's adherence to their advised therapies. Our findings showed a statistically significant difference between those who were satisfied and those who were not regarding total Morisky score (p=0018). The positive relationship between therapy adherence and treatment satisfaction could be explained by the fact that better adherence is linked to significantly reduced disease activity and reduced RA progression, both of which ultimately increase patient satisfaction with prescribed therapy [22]

According to our findings, neither antirheumatic treatments nor co-administrated drugs had a discernible impact on level of patient satisfaction. . No significant difference was found between patients with different treatment protcols as regarding their level of satisfaction. In the final multivariate model, the only significant factors influencing treatment non –satisfaction were RAID score and disease activity as determined by CDAI.

In line with our findings, Schäfer et al.2020 demonstrated in their analysis that the patient satisfaction for both the efficacy and tolerability is neither associated with the current use of biologic nor the protocol of DMARD. Increased disease activity as measured by DAS 28, ESR, pain , reduced physical activity and fatigue were shown to be substantially linked with lower treatment satisfaction[20].

In conclusion, in RA management, it is important to put patient's perspective in consideration. . The demands of patients such as persistent pain fatigue

2010

and sleep disturbance should be adequately addressed.

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