



Quality of Life in Rheumatoid Arthritis patients taking combination DMARDs

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Abstract

Objective: To assess the QOL of RA patients taking non biological combination DMARDs

Material & Methods

Study Design: Open Label Study

Treatment naïve or chronic cases of RA in age group of 18-60 years of both sex with RA duration ≥ 6 months and Disease Activity Score (DAS28) > 3.2 were included. 131 patients were taken and categorized in 2 study groups for taking of combination of DMARDs. Group-1 patients (n=68) were taking/given Methotrexate weekly with hydroxychloroquine oral daily. Group-2 patients (n=63) were taking/given Methotrexate weekly as in group-1 patients with tablet sulfasalazine oral daily. The patients who were already on these combination DMARDs were also included.

Observations: The mean duration of disease was 4 years in both the groups. On comparing the baseline and end study values, there was significant improvement in all the domains of domains of WHO-QOL BREF within the groups.

There was significant improvement in quality of life in all the domains of WHOQOL BREF within the groups. However, when comparing domain score between treatment groups, both before and after the treatment, the difference is statistically not significant, except in environmental domain score at the end of the study. Also, within the group, the mean scores of various domains of QOL is significantly increasing at the end of the 5th follow up with insignificant differences seen for social domain in group-1 only.

Conclusion: The study recommends that use of conventional DMARDs in different combinations help in improvement of QOL of RA patients and therefore these drugs should be started early in the course of the disease

Keywords– Rheumatoid Arthritis (RA), Disease Modifying Anti-Rheumatic Drugs (DMARDs), World Health Organization- Quality of Life (WHO-QOL), Disease Activity Score (DAS).

Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory disease that causes joint pain, progressive joint destruction and functional disability, due to the combined effect of chronic synovitis and progressive joint damage.^[1] It is an inflammatory disease that exerts its greatest impact on those joints of the body that are lined with synovium a specialized tissue responsible for maintaining the nutrition and lubrication of the joint. Though, any synovial joints can be affected but majorly the small joints of the hands and the feet, and usually both sides are affected in symmetrical distribution. In patients with established and aggressive disease, most joints will be affected over time. The natural course of RA is often incapacitating, and untreated, the disease leads to impaired function, disability and premature death.^[1]

Since the goals in RA management include not only disease remission, but also better functional status, which is strongly linked with radiographic joint damage, an understanding of the impact that the initiation of apt treatment during early RA has on these outcomes is essential.^[2] Hence treatment of rheumatoid arthritis now involves early initiation and aggressive approach of disease modifying anti-rheumatic drugs (DMARDs) to slow the disease progress. Treatment of disease in the first months of synovitis is important to retard radiographic progression.^[3] This window of opportunity suggests that disease activity in patients with early RA is less severe, is characterized by a smaller load of inflammatory cells, and is more responsive to treatment. So, aggressive treatment during this phase is more likely to succeed than is the same treatment applied later in the course of disease, when auto-antigens from damaged joints possibly fuel the disease.^[4] Therefore it is important that RA should be treated and controlled as soon as possible after diagnosis and that this control should be maintained for as long as possible, consistent with patient safety.^[5,6]

In the past, therapy started with non-steroidal anti-inflammatory drugs (NSAIDs). If this treatment was insufficiently effective, second line antirheumatic drugs or disease-modifying antirheumatic drugs (DMARDs) were added. However, an immediate start of DMARDs proved to be more efficacious than a delayed introduction of DMARDs in the disease progress of RA.^[7, 8] More recent therapeutic strategies are based on combination of DMARDs to control inflammation in the critical early stages of RA.^[9, 10, 11]

Glucocorticoids, which also can be considered as DMARDs because they are able to reduce the progression of joint damage, have been included in DMARD combination treatments of RA.^[12, 13]

RA-induced joint damage and its associated disability are irreversible. The goal of RA therapy is to reduce disease activity and mitigate the accumulation of irreversible joint damage. RA treatment should be initiated early and aggressively, with the goal of achieving remission.^[14]

World Health Organization (WHO) has defined Quality Of Life (QOL) as 'individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. RA affects human life in a profound way. They cause structural and functional limitations that may seriously affect the QOL. World Health Organization Quality Of Life , WHOQOL- BREF score provides a measurement of functioning and well-being rather than of diseases and disorders, hence is more comprehensive and compatible with the WHO's concept of health.^[15] It yields a multi-dimensional profile of scores across domains & subdomains (facets) of QOL. WHO-QOL-BREF contains 26 questions based assessment form which was available in both hindi & English version was filled mostly by the patient themselves & sometimes with the help of investigator. In this study, the hindi version WHO-QOL BREF scoring was done at baseline and at 5th follow up along with revealing pattern of concomitant medications used.

Objective: To assess the QOL of RA patients taking non biological combination DMARDs

Material and Methods

Study design: Open Label Study

Study Place: Rheumatology clinic of Medicine OPD of Government Medical College & Susheela Tiwari Memorial Government Hospital (STMGH), Haldwani, Uttarakhand.

Study Period: 1 year (from Jan 2014 to Jan 2015)

Study subjects: Treatment naïve or chronic cases of RA in the age group 18-60 years of both sexes with RA duration ≥ 6 months and Disease Activity score (DAS28) > 3.2

Total number of study subjects: n=131

Exclusion criteria: Patients of both sexes with clinical history of uncontrolled DM, severe CHF, interstitial lung diseases, active peptic ulcers, IBS, malignancies, abnormal RFT, abnormal hepatic functions, anaemia, leucopenia, thrombocytopenia, eye injury pathology and giving history of intolerance to the studied DMARDs before the start of the study were excluded from the study. Also patients on biologic DMARDs were not taken and pregnant & lactating women were also not taken in the study.

Methodology: On following the exclusion criteria and on taking the written consent, the 131 patients of both sexes were taken and categorized in 2 study groups for taking of combination of DMARDs. Group-1 patients (n=68) were Taking/given tablet Methotrexate (Mtx) 0.3mg/kg/week (not a fixed dose to be adjusted according to clinical response & adverse effects) orally with hydroxychloroquine 200mg orally twice daily for first 3 months and thereafter once daily. Group-2 patients (n=63) were taking/given tablet MTX 0.3mg/kg/week not in fixed dose as in group-1 patients with tablet sulfasalazine 30mg/kg orally in divided doses. The patients who were already on these combination DMARDs were also included.

Baseline investigations like Hb, TLC, DLC, Platelet counts, ESR, Rheumatoid factor (RF), serum creatinine, SGOT, SGPT, C-reactive

protein (CRP) along with baseline DAS28 > 3.2 were done on all the patients in both the groups. Then, these patients were followed every month for 6 months with total 5 follow ups. In all these follow ups, the baseline investigations & DAS28 were performed on all the patients. At the baseline & at last follow up i.e 5th follow up were also assessed for the 4 different domains of WHO-QOL for knowing their quality of life. They were asked about their thinking for their life in the last 4 weeks. Apart from the study medications, all patients were also given folate supplements in the form of folic acid tablets, concomitant medications (eg NSAIDS, PPI, Ca & Vitamin D supplements) were given to the patients as and when required by the clinician decisions.

Of the 131 patients enrolled in the study, at the end of 5th last follow up only 100 patients remained as 14 patients developed adverse drug reactions and 17 patients were lost to follow up.

Operational definitions used in the study: For treatment naïve RA patients, the new case of RA, the criteria of calling a patient, definite RA was based on 2010 ACR/EULAR criteria & ACR 1987 criteria was used for differentiating established RA from other rheumatic diseases. For the clinical response and severity of disease, the standard DAS28 score was used. DAS28 is calculated from the formula given below :-

$$\text{DAS28} = 0.56 \times \sqrt{\text{tender28}} + 0.28 \times \sqrt{\text{swollen28}} + 0.70 \times \ln(\text{ESR}) + 0.014 \times \text{VAS}$$

The 28 joints assessed were both sides shoulder, elbow, wrist & 1-5 metacarpal and 1-5 proximal interphalangeal joints and tender & swollen 28 joint count was calculated. ESR was measured using westergreen method. Visual analogue scale was also used.^[16]

For quality of life, the WHO-QOL BREF was used^[15] The QOL was assessed using WHOQOL-BREF questionnaire to all patients. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100.

$$\text{Physical domain} = ((6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18) \times 4.$$

Psychological domain= (Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26))x4.

Social Relationships domain= (Q20 + Q21 + Q22)x4.

Environment domain= (Q8+Q9+Q12 +Q13 +Q14 +Q23 +Q24 +Q25)x4.

And subsequently transformed to a 0-100 scale, using the formula.

TRANSFORMED SCORE= (SCORE-4) x (100/16).

Statistical Analysis: The master chart prepared in MS excel and analysis was done using SPSS. The statistical test used is student t test to compare the difference in the mean value of different domains of WHO-QOL in the baseline and at the last follow within and between the 2 groups.

Ethical clearance: Institutional ethical clearance was taken for the study.

Results

Table 1: Demographic and disease profile

| Demographic parameters | Group-1 (n=50) | Group-2 (n=50) |
|---|----------------|-----------------|
| Mean age (in years) | 45.98 ± 9.54 | 45.72 ± 9.65 |
| M:F | 6: 44 | 7 : 43 |
| Disease Parameters | Group-1 (n=50) | Group- 2 (n=50) |
| Mean duration of disease (in years) | 4.04 | 4.74 |
| Mean age of onset of disease (in years) | 41.96 ± 9.15 | 40.99 ± 9.67 |
| Family history positive (n%) | 8 (16%) | 9 (18%) |
| Rheumatoid Factor (RF+) | Group-1 (n=50) | Group-2 (n=50) |
| Male n(%) | 6 (12%) | 6 (12%) |
| Female n(%) | 19 (38%) | 22 (44%) |

The mean age of patients (age range: 18 to 60 years) who participated in the study was 45.98 & 45.72 years in group 1 & 2 respectively with similar mean age of onset of RA is 41.96years in group-1 and 40.99 years in group-2. Equal number of patients (n=18) are present in the age group 51-60 years in both the groups. While n=16 patients and n=13 patients were present in the group-1 & group-2 respectively in the age group of 31-40 years. Age group, 41-50 years had 14 patients in group -1 and 15 patients in group-2. Remaining were of age-group 21-30years with 2 patients in group-1 & 3patients in group-2 and also only in

group-2 there was n=1 patient having age <20years. The mean duration of disease was also similar in the 2 groups i.e almost 4 years. Family history of RA was revealed in 16% patients in group-1 and 18% in group-2. Majority of the studied patients were females being 88% in group-1 & 86% in group-2. The RF positivity was present in 25 patients in group-1 in which 6 were males and 19 were females. And in group-2, 28 patients were RF positive, out of which 6 were males & 22 were females. The CRP was positive in only 21 patients in both the groups.

Table 2 : Profile of DMARDs taken in the 2 groups

| Since when on DMARDs (in years) | Group-1 (n=50) | Group-2 (n=50) |
|--|----------------|----------------|
| New case (never took EDMARD) | 25 | 23 |
| Old case (≤ 1year) | 15 | 12 |
| Old case (1-5 year) | 9 | 13 |
| Old case (≥ 5 years) | 1 | 2 |
| Mean lag time in starting DMARD (in years) | 3.22 | 3.52 |
| Route of administration of MTx (Non Fixed Dose Drug) | Number(n=50) | Number(n=50) |
| Oral | 50 | 48 |
| Parental (I/M or S/C) | 0 | 2 |
| Mean dose (mg) | 14.65 ± 2.85 | 15.15 ± 2.34 |

The treatment naïve group who took DMARD was 25 in group-1 and 23 in group-2. Amongst the old RA patients, majority of them in group-1 were taking combination DMARD for ≤ 1 year with $n=15$ whereas $n=13$ patients in group-2 were taking DMARD for 1-5 years duration. Although the mean duration of disease in both the groups is 4 years but there was delay in starting of DMARD in these patients with almost 3 years delay in starting of DMARD. Only 2 patients in group -2 were given parental Mtx drug with mean dose of 15.15mg in group-2 and 14.65mg in group-1.

Corticosteroids are potent drugs that have anti inflammatory effect through multiple inhibitory effects along the inflammatory pathway. 18 patients in group-1 and 20 patients in group -2 received oral corticosteroid. 23 patients in group I and 19 patients in group II received intramuscular

corticosteroid. 8 patient in group I and 7 patients in group II received intra-articular steroid. Orally deflazacort was given in two doses 6 and 3 mg. Mean corticosteroid doses in patients given oral corticosteroids (prednisolone) in both the treatment groups decreases in every follow-up. Patients received 80 mg methyl prednisolone (depomedrol) injections intramuscularly once weekly for a month. Patients received 80 mg or 40 mg methyl prednisolone (depomedrol) injections intra-articularly depending on the affected joint.

NSAIDs are drugs that have analgesic effect. 30 patients in group-1 and 32 patients in group -2 received oral NSAIDs (Aceclofenac). 43 patients in group-1 and 39 patients in group -2 received topical NSAIDs (Diclofenac gel).

Table 4 : Improvement in the Quality of life scores within groups

| WHO-QOL Scores | Group-1 (Baseline) Mean \pm SD | Group-1 (End of study) Mean \pm SD | P value | Group-2 (Baseline) Mean \pm SD | Group-2 (End of study) Mean \pm SD | P value |
|---------------------------------|----------------------------------|--------------------------------------|---------|----------------------------------|--------------------------------------|---------|
| Domain-1 (Physical domain) | 40.22 \pm 10.6 | 52.2 \pm 7.65 | 0.007 | 41.92 \pm 14.5 | 49.41 \pm 15.5 | 0.001 |
| Domain-2 (Psychological) | 42.56 \pm 13.2 | 51.76 \pm 11.2 | 0.001 | 46.86 \pm 18.1 | 51.4 \pm 15.5 | 0.001 |
| Domain-3 (Social relationship) | 53.54 \pm 19.8 | 61.78 \pm 19.2 | 0.161 | 57.34 \pm 23.2 | 60.6 \pm 21.7 | 0.001 |
| Domain-4 (Environmental domain) | 41.74 \pm 13.9 | 55.84 \pm 11.5 | 0.001 | 40.34 \pm 22.6 | 48.46 \pm 18.8 | 0.001 |

Table 5 : Improvement in the Quality of life scores between the 2 groups

| | WHO-QOL scores | Group-1 Mean \pm SD | Group-2 Mean \pm SD | P value |
|---------------------|----------------------------|-----------------------|-----------------------|---------|
| Baseline values | Physical domain | 40.22 \pm 10.6 | 41.92 \pm 14.5 | 0.51 |
| | Psychosocial domain | 42.56 \pm 13.2 | 46.86 \pm 18.1 | 0.18 |
| | Social relationship domain | 53.54 \pm 19.8 | 57.34 \pm 23.2 | 0.38 |
| | Environmental domain | 41.74 \pm 13.9 | 40.34 \pm 22.6 | 0.71 |
| End of study values | Physical domain | 52.2 \pm 7.65 | 49.4 \pm 15.5 | 0.26 |
| | Psychosocial domain | 51.76 \pm 11.2 | 51.4 \pm 15.5 | 0.89 |
| | Social relationship domain | 61.78 \pm 19.2 | 60.6 \pm 21.7 | 0.78 |
| | Environmental domain | 55.84 \pm 11.5 | 48.46 \pm 18.8 | 0.02 |

The mean WHOQOL domain scores of RA patients in group-1 were as follows: in physical health (40.22 \pm 10.6), psychological health (42.56 \pm 13.2), social relationship (53.54 \pm 19.8) and environmental domains (41.74 \pm 13.9) at the initial visit. At the end of study (5th follow-up), the mean WHOQOL domain scores of RA patients in

group I were as follows: in physical health (52.2 \pm 7.65), psychological health (51.76 \pm 11.2), social relationship (61.78 \pm 19.2) and environmental domains (55.84 \pm 11.5).

The mean WHOQOL domain scores of RA patients in group-2 were as follows: in physical health (41.92 \pm 14.5), psychological health

(46.86±18.1), social relationship (57.34±23.2) and environmental domains (40.34±22.6) at the initial visit. At the end of study (5th follow-up), the mean WHOQOL domain scores of RA patients in group-2 were as follows: in physical health (49.4±15.5), psychological health (51.4±15.5), social relationship (60.6±21.7) and environmental domains (48.46±18.8). There was significant improvement in quality of life in all the domains of WHOQOL BREF within the group. However,

when comparing domain score between treatment groups, both before and after the treatment, the difference is statistically not significant, except in environmental domain score at the end of the study. Also, within the group, the mean scores of various domains of QOL is significantly increasing at the end of the 5th follow up with insignificant differences seen for social domain in group-1 only.

Table 6: Comparison of QOL domains in group 1 and group2 (Intention to treat analysis)

| | QOL Domains | Baseline (n=68) Mean ± SD | End of study (n=50) Mean ± SD | P* value |
|---------|---------------|------------------------------|----------------------------------|----------|
| Group-1 | Physical | 40.76 ± 11.04 | 52.2 ± 7.65 | 0.001 |
| | Psychosocial | 42.49 ± 13.9 | 51.76 ± 11.2 | 0.001 |
| | Social | 55.47 ± 18.7 | 61.78 ± 19.2 | 0.076 |
| | Environmental | 42.10 ± 13.9 | 55.84 ± 11.5 | 0.001 |
| Group-2 | QOL Domains | Baseline (n=63) Mean ± SD | End of study (n=50) Mean ± SD | P* value |
| | Physical | 41.33 ± 14.7 | 49.4 ± 15.5 | 0.006 |
| | Psychosocial | 46.73 ± 17.9 | 51.4 ± 15.5 | 0.148 |
| | Social | 57.60 ± 22.5 | 60.6 ± 21.7 | 0.472 |
| | Environmental | 40.15 ± 22.1 | 48.46 ± 18.8 | 0.036 |

*student t test

To avoid attrition bias in the study, intention to treat analysis is carried out including the original cohort at baseline in both the groups. It was found that significant difference was present in the physical and environmental domains in both the groups 1 and 2 with additional significant difference was also observed for psychosocial domain in group-1.

Discussion

Rheumatoid arthritis is a debilitating, autoimmune, inflammatory disease that affects the joints of the body that are lined with synovium. Though it attacks mainly the small joints of hands and feet, however it affects the quality of life of the patients adversely and also decreases the life expectancy.^[17] The disease has low incidence affecting 0.5-2% of the population all over the world and its course is plagued by high incidence of severely debilitating deformities.^[18,19,20]

Methotrexate (MTX) is a very frequently used DMARD for rheumatoid arthritis.^[21] In the Indian scenario, Hydroxychloroquine (HCQ) and MTX

were the most frequently used combination of DMARDS.^[22]

Various global studies had concluded that combination DMARD therapy is effective in RA. The evidence is strongest in established rheumatoid arthritis for combinations of MTX with anti-TNF, Sulfasalazine (SSZ) and HCQ given to patients who have partially responded to DMARD monotherapy.^[23] In the Rheumatology OPD at GMC Haldwani, MTX is widely used for rheumatoid arthritis patients and HCQ is used in combination with MTX. In the present study, an attempt has been made to assess the quality of life in both the old and new RA patients taking combination non-biologic DMARDs therapy.

The gender wise distribution of Rheumatoid Arthritis in the present study is 87% female which is approximately same with the Indian scenario (84.5%, 88.6%)^[26, 27] as well as with the global data (86%, 80%).^[21, 28] The mean age of Rheumatoid Arthritis patients in the present study is 45.85 ± 9.54 years with the mean (± SD) age of onset of Rheumatoid Arthritis in patients is 41.48

± 9.38 years. This finding is in accordance with the Indian scenario of mean age of RA 43 ± 4 , 47.2 years^[26, 29] and mean age of onset of RA 43 ± 4 years and 40.57 ± 13.69 years^[29, 30] The incidence of RA increases between 25 and 55 years of age, after which it plateaus until the age of 75 and then decreases¹ which is approximately same with the Indian scenario.^[31] In this study the duration of disease varies from 0.5 to 20 years with mean duration in group I and group II were 4.09 and 4.80 years respectively. A study done by Aletaha D et al reported mean disease duration of 12.1 ± 9.3 years, which varies with the study data.^[21] Whereas in an Indian study, the duration of the disease ranged from 4 months to 12 years with a mean duration of 6.8 years which is comparable with the study observation.^[29] The family history of Rheumatoid Arthritis in patients, in this study is noted to be 17% which is not in concordance with the Indian studies, which state 28.9% family history positive.^[26] This may be influenced by small and limited sample size of this study. On the other hand the, global data shows approximately 10% of patients with rheumatoid arthritis will have an affected first degree relative.^[31]

Rheumatoid factor is an autoantibody targeting the Fc region of IgG antibodies.^[23] About 80% of all patients with rheumatoid arthritis will eventually be seropositive for rheumatoid factor, while only 40% are positive at clinical onset of the disease.^[32, 33]

Rheumatoid factor (RF) positivity was present in 25 (50 %) patient in group I and 28 (56 %) patient in group II. So in total, 53 patients (53%) had RF positivity at presentation. Various studies conducted world-wide, show variation in RF +ve from 59 % to as high as 88%.^[28, 34] In the Asian scenario, RF positive distribution in RA patients in the present study meets with the findings of an Asian study which states the prevalence of IgG RF to be 55.6% among Asian RA Patients.^[35] In Indian scenario, the rheumatoid factor was positive in 22% patients at the time of diagnosis however the incidence increases with time.^[36]

In the present study, the median delay to the institution of DMARD therapy from the time of onset of RA symptoms was 2 years for the patients in both combination-treatment arms. A global study, which shows the median delay to the institution of DMARD therapy was 6 -7 months.^[37]

In the current study corticosteroids and NSAIDs were used as concomitant medications. Corticosteroids have been extensively employed for the treatment of RA as it is one of the most effective treatment against RA, but its use is limited by the adverse effects it produces.^[38] In the present study 20 patients in both group I and group II received oral corticosteroid, 23 patients in group I and 19 patients in group II received intramuscular corticosteroid. A study done by Kavanaugh A et al, have proved the efficacy for radiological and clinical outcomes for low-dose corticosteroids (defined as ≤ 10 mg/day prednisone equivalent) in the treatment of RA.^[39] In the present study, deflazacort was used at a dose of 3 - 6 mg along with study drugs which is comparable to above mentioned study. According to EULAR, in early RA, addition of low dose corticosteroids (< 7.5 mg/day) to DMARDs will lead to a significant reduction to radiographic progression and chronic use of corticosteroids in a dose up to 15 mg/day will improve disease activity.^[40] In the present study, 8 patients in group I and 7 patients in group II received intra-articular steroid. The main role of intra articular steroids in RA is pain relief.^[41] According to CIMESTRA Study, continuous MTX and intra-articular corticosteroid treatment resulted in excellent clinical response and disease control at 2 years, and the radiographic erosive progression was minimal.^[42]

NSAIDs are most widely used drugs for symptomatic treatment.⁴³ In the present study, 30 patients in group I and 32 patients in group II received oral NSAIDs (Aceclofenac+ Paracetamol). A study done by Hunter JA et al states that treatment with aceclofenac was effective in improving the Ritchie articular index,

duration of morning stiffness, joint swelling, function, patient's and physician's global assessments, and pain.^[44] In the present study, 43 patients in group I and 39 patients in group II received topical NSAIDs (Diclofenac gel). Topical NSAID formulations were developed to reduce systemic exposure while preserving efficacy.^[43]

The QOL was assessed using WHOQOL- BREF questionnaire to all patients in both the treatment groups at the baseline i.e. at presentation and at the end of study i.e at 5th follow-up. WHOQOL-BREF is a short version of WHOQOL-100. WHOQOL-100 questionnaire has 100 questions and 7 domains whereas in WHOQOL-BREF questionnaire has only 26 questions and 4 domains (physical health, psychological health, social relationship and environmental domains). The WHOQOL-BREF has been validated against the original WHOQOL-100 and was found to have good test retest reliability.^[45] The mean WHOQOL of all domain scores of RA patients in both the groups showed statistically significant improvement ($p < 0.1$), physical health in group I improved from 40.22 ± 10.6 to 52.2 ± 7.65 , psychological health improved from 42.56 ± 13.2 to 51.76 ± 11.2 , social relationship improved from 53.54 ± 19.8 to 61.78 ± 19.2 and environmental domains improved from 41.74 ± 13.9 to 55.84 ± 11.5 . The physical health in group II improved from 41.92 ± 14.5 to 49.8 ± 15.5 , psychological health improved from 46.86 ± 18.1 to 51.4 ± 15.5 , social relationship improved from 57.34 ± 23.2 to 60.6 ± 21.7 and environmental domains improved from 40.34 ± 22.6 to 48.34 ± 18.8 . The present study revealed that patients with RA had significant compromise in their quality of life which concur with the study done by Haroon N which report the physical health (51.7 ± 18.6), psychological (54.3 ± 20.3), social (66.4 ± 19.7) and environmental (60 ± 15.9) health.^[138]

Furthermore there is significant improvement after taking DMARDs in combination. Our results corroborate with other studies which employed the WHOQOL-BREF instrument to compare QOL in

patients with RA. In a study done at Institute of Post Graduate Medical Education and Research, Kolkata which agrees with the study result reports that, the mean WHOQOL domain scores of RA patients were as follows: in physical health (43.70 ± 16.75), psychological health (44.82 ± 19.48), social relationship (61.02 ± 11.99) and environmental domains (50.51 ± 10.21) at the initial visit. And following 6 months rehabilitation, WHOQOL Domain scores improved significantly except in social relationship domain.^[46] The WHOQOL-BREF score has shown significant improvement in psychological domain of both treatment group. And study have shown that WHOQOL-BREF has adequate psychometric properties in people with RA and hence should be considered as a valid outcome measure for interventions that aim to improve quality of life for people with this disease.^[47]

Conclusion

The intergroup difference of QOL score domains at the initial visit and at 5th follow up in RA patients taking two different drug combinations is statistically insignificant except that of environmental domain. The study recommends that use of conventional DMARDs in different combinations help in improvement of QOL of RA patients and therefore these drugs should be started early in the course of the disease.

Limitations

Though the best information on temporal trends of work disability in RA would be achieved by studying longitudinal, population based materials in a fixed setting; many studies are cross-sectional or carried out in small cohorts.

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