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A Prospective and Observational Dose Comparative Study of Methotrexate to Evaluate the Quality of Life of Patients with Reumatiod Arthritis

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Abstract: *This Prospective observational dose comparative study was conducted over a period of 6months in 2019 to identify safety and efficacy of methotrexate in rheumatoid arthritis and quality of life of patients affected with rheumatoid arthritis. The necessary data was collected from the patient case notes, treatment charts, patient attendants. A Total of 300 cases were analysed. From this data we found that majority of the patients were in the age group of 30-50, 70% of patients responded positive for rheumatoid factor, having ESR ranging above 70mmhr, a large group of patients i.e., 99 subjects were observed to have deformities and 97 subjects were having fusion of joints due to inflammation and quality of life of 57.14% patients was compromised due to rheumatoid arthritis. Among 300 subjects of RA quality of life study was conducted and it was found that 57.1%subjects quality of life was compromised due rheumatoid arthritis.*

Keywords: Comparative Study, Arthritis, Inflammation, Quality of Life

I. INTRODUCTION

Rheumatoid arthritis (RA) is an autoimmune disease in which the body's immune systemwhich normally protects its health by attacking foreign substances like bacteria and virusesmistakenly attacks the joints. This creates inflammation that causes the tissue that lines the inside of joints (the synovium) to thicken, resulting in swelling and pain in and around the joints. The synovium makes a fluid that lubricates joints and helps them move smoothly. Rheumatoid arthritis most commonly affects the joints of the hands, feet, wrists, elbows, knees and ankles. The joint effect is usually symmetrical. That means if one knee or hand if affected, usually the other one is, too. Because RA also can affect body systems, such as the cardiovascular or respiratory systems, it is called a systemic disease. Systemic means "entire body" [1-9].

Methotrexate (MTX) remains the anchor disease-modifying antirheumatic drug (DMARD) for the treatment of rheumatoid arthritis (RA). MTX has multiple mechanisms of action that contribute to improvement in clinical symptoms and disease control in patients with RA, including inhibition of inflammatory cell proliferation, interference with T-cell activity and cytokine secretion, and augmented release of adenosine, which in turn activates receptors on macrophages and neutrophils to decrease the release of proinflammatory cytokines (eg, tumor necrosis factor [TNF]-a and interleu-kin [IL]-6) and elevate the secretion of anti-inflammatory molecules (eg, IL-10) .[10] To evaluate the efficacy, ADR's, Drug interactions, pain severity and quality of life of patients with Rheumatoid arthritis using methotrexate as main stay of treatment To control inflammation, relieve pain and reduce disability associated with the condition. To improve in range of motion Prevention of correction or deformities in rheumatiod arthritis and assess the severity of disease, determine the outcomes of methotrexate treatment in rheumatiod arthritis.

II. METHODOLOGY

The study was conducted on rheumatoid arthritis patients taking methotrexate in hospital with department of rheumatology.

Study period: 6 Months

Study design: This was a Prospective observational study.

Study population: 300 R.A patients were taken into the study

Study criteria :

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Inclusion criteria:

- Patients diagnosed with Rheumatiod arthritis of both inpatients and outpatients
- Patients of both sero-positive and sero-negative RA
- Patients both male and female genders
- Patients of rhuematoid arthritis associated with sjorens syndrome.

Exclusion criteria:

- Frailty,limiting comorbidity
- Rheumatiod patients using DMARD other than methotrexate as mainstay of treatment in
- Pediatrics, pregnancy and lactating patients.
- Patients not tolerating methotrexate.

Sources of data:

- Patients who are with symptoms of rheumatoid arthritis visiting for the jaya hospital for the diagnosis and treatment.
- Interviewing and interacting with patients and patient care takers.

Primary data through questionnaire which includes:

- Name of the patient
- Age and gender
- Symptoms(pain in joints of hands, legs, stiffness, Swelling tenderness or weakness, anemia)
- Diagnosis(anti-ccp, RF,C-reactive, X-Ray, ESR)
- Complications
- Treatment
- Secondary data through internet, magazines, journals, text books, articles etc

Data collection and assessment of the study results/observations:

A suitable data collection form was designed to collect required information and analyse the data. The data collection form included the information related to patient demographics such as age, weight and name of the patient, date, native place, occupation, complications, symptoms, family members, present living with social history and diagnostic parameters and questions included in quality of life scale.

The analysis was done by observational method which included the details of patient information like symptoms, complications, treatment patterns and quality of life scale.

Digitalization of data collection and assessment:

All the data collected and analyzed was entered into Microsoft excel for the easy accessibility, retrieval and for plotting of charts and graphs.

Procedure of the study:

The study team had approached the head of the hospital and submitted study protocol, data collection form; a written/oral consent was obtained from the head of the hospital. All thecase sheets were thoroughly reviewed about their demographic details, occupation, maritalstatus, symptoms, complications, social history laboratory parameters, anti-ccp ,RF-Factorand treatment pattern by the study team and noted down in data collection form and whennecessary the patients or care takers were interviewed for medical history information, qualityof life . The patients were counseled about the Symptoms, and complications of rheumatoidarthritis and how to manage them. All the collected data was subjected to suitable statisticaltest and analyzed for the results.

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III. RESULTS

Table 1: Distribution of data according to age

Age	Frequencyof patients	Percentage
0-0	0	0
10-20	16	5.33
20-30	55	18.33
30-40	74	24.66
40-50	62	20.66
50-60	39	13
60-70	50	16.66
70-80	4	1.33
Total	300	100

Table 2: Distribution of data according to gender

Gender	Frequency ofpatients	Percentage
PEDIATRIC	0	0
ADULT: MALE	52	17.33
FEMALE	158	52.66
GERIATRIC: MALE FEMALE	 10 78	 4 26
Total	300	100

Table 3: Distribution of data according to rheumatoid factor criteria

Criteria	**No. of patients**	**Percentage**
Seropositive RA MALE FEMALE	 51 158	 17 52.66
Seronegative RA MALE FEMALE	 13 78	 4.33 26
TOTAL	300	100

Table 4: Distribution of data according to erythrocyte sedimentation values

ESR values	Frequencyof patients	Percentage
<20	13	4.33
20-40	19	6.33
40-60	68	22.66
60-80	21	7
80-100	38	12.66
100-120	84	28
120-140	57	19
Total	300	100

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Table 5: Distribution of data according to x-ray findings

x-ray findings	No. of patients	Percentage
Erosions	104	34.66
Deformity	97	32.33
Fusion of joints	99	33
Total	300	100

Table 6: Adverse effects observed due to methotrexate.

Adverse effect	Frequency byhigh dose	Frequency bylow dose
Hair loss	32	30
Anemia	48	37
Vision problems	8	7
Rash	0	0
Nausea	12	10
Stomach upset	10	18
None	30	71

Table 7: Distribution of data according to WHO QOL score

WHO QOL Score	No. of patients(lowdose)	No. of patients(high dose)
0-20	32	35
20-40	65	37
40-60	24	55
60-80	19	14
80-100	11	10

IV. DISCUSSION

The study provides the insights of trend of safety and efficacy of methotrexate use in rheumatoid arthritis and quality of life of patients affected by rheumatoid arthritis. Rheumatoid arthritis (RA) is an autoimmune disease in which the bodies immune system which normally protects its health by attacking foreign substances like bacteria and viruses mistakenly attacks the joints. This creates inflammation that causes the tissue that lines the inside of joints (synovium) to thicken, resulting in swelling and pain in and around the joints. Chopra et al. the prevalence of 0.51% for RA diagnosed with ACR criteria and prevalence 0.6% for RA diagnosed clinically among nearly 6000 men and women. From our study, it is observed that 51 males and 158 females were seropositive for rheumatoid factor and 15 males and 78 females were seronegative according to our study 69.6% cases were diagnosed clinically seropositive. According to Chopra et al. 62% of theRA cases diagnosed clinically were seropositive[11] From our study it is observed, that (n=2) patients were having least anti-ccp values with in ranges of 0-50, (n=75) patients were having highest reactivity for anti-ccp i.e., 450-500, the next highest reactivity for anti-ccp was observed in (n=54) patients i.e., 400-450, (n=30) patients were observed to show reactivity within a range of 350-400, (n=50) patients were observed to have values with a range of 300-350, (n=45) patients were having values in the range of 250-300, (n=10) patients were having reactivity with in the ranges of 200-250,

From our study it was observed that from the study population of 300 (n=104) patientswere found to have erosions on their x-ray results, and 99 patients were found to have deformities and 97 patients were found to have fusion of joint spaces in their x-ray resultsand it is observed that (n=40) patients were having swan neck deformity, (n=38) patients werehaving boutonnire deformity, (n=11) patients were having ulnar deviation, (n=8) patients were having calw toe and (n=203) patients were having no deformities, according to Pia M. Johnsson, Kerstin Eberhardt et.al., study conducted in 183 early RA patients more than half of the patients developed hand deformities after 10 years, most deformities occur during the first year of disease[12] From our study it is observed that (n=21 and n=19) patients from groups prescribed low vs high dose respectively were having WHO QOL scores within the ranges 0-20, (n=64 an n=110) patients from groups prescribed low vs high dose respectively were having WHO QOL scores within the ranges 20-40, (n=37 and

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n=70) patients from groups prescribed low vs high dose respectively were having WHO QOL scores within the ranges 40-60, (n=130 and n=74) patients were having WHO QOL score within ranges of 60-80, (n=48 and n=27) patients were having WHO QOL scores within the ranges of 80-100. Among 300 subjects of RA quality of life study was conducted and it was found that 57.14% subjects quality of life was compromised due rheumatoid arthritis.

V. CONCLUSION

Among 300 study population 160 subjects were prescribed with low dose methotrexate and 110 patients were prescribed with high dose methotrexate and among these subjects receiving high methotrexate as basic stay for treatment of RA 80 patients were experiencing adverse effects due to methotrexate use and 30 patients were not having any adverse effect due to methotrexate use, and 190 patients were receiving low dose methotrexate as mainstay of treatment and among this subjects 119 patients were experiencing adverse events due to methotrexate use and 71 patients were not having any adverse effects due to low dosemethotrexate thus low dose methotrexate is effective and safer in consideration of lowering disease activity and proposing the risk of adverse events

Among 300 subjects of RA quality of life study was conducted and it was found that 57.1% subjects quality of life was compromised due to rheumatoid arthritis

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