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Research article

Medical research

A prospective study to monitor the side effects associated with disease modifying anti rheumatoid drugs in out-patients of tertiary care hospital

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ABSTRACT

BACKGROUND: Rheumatoid arthritis [RA] is a chronic inflammatory disease characterized by progressive jointerosion, resulting in significant disability, morbidity and increased mortality. The introduction of DMARDs in the treatment of rheumatic diseases over the last two decades has significantly improved clinical outcomes. Disease modifying anti-rheumatic drugs [DMARDs] is a group of drugs that slow or stop the immune system from destroying the joints. These agents can retard or prevent disease progression and thus joint destruction and subsequent loss of function. All DMARDs show significant toxicity, such that their use requires regular monitoring.

OBJECTIVES: To identify and evaluate the drug related Side effects with the use of DMARD's in RA patients. To establish role of pharmacist to minimize side effects with DMARDs.

METHODS: A prospective study was conducted on the use of DMARDs and their Side effects. Data was collected between January 2021 – July 2021 from orthopedic and rheumatology clinics within the hospital from out-patient department. The data collected was entered in a data collection form designed for the purpose and included all the required parameters. The obtained information was used to understand the side effects of DMARDs.

RESULTS: In our study 65% of the patients reported side effects and other 35% of the patients didn't have any side effects. In females, age group of 51-60 were mostly affected with RA than other age groups where as in males age group of 41-50 were mostly affected. Other side effects reported in patients taking DMARDs include Vomiting, Acidity, Fever, Dizziness, Dyspepsia, Swelling of tongue, Pigmentation of skin, Insomnia, Blurred vision and increased Appetite.

CONCLUSION: The side effects associated with disease modifying anti rheumatoid drugs in rheumatoid arthritis patients were found to be significant. Out of 40 patients, 26 reported side effects and other 14 didn't have were stable without any side effects. 7 reported Stomachache, 8 reported Dryness of mouth and 11 patients reported other side effects. Among other side effects vomiting and acidity were more commonly reported.

Keywords: DMARDs, Rheumatoid arthritis, Side effects

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic, progressive, and disabling autoimmune disease. Although there are a variety of

systemic manifestations, the characteristic feature of established RA is persistent inflammatory synovitis, usually involving peripheral joints in a symmetric distribution. The potential of the synovial inflammation to cause cartilage

damage, bone erosions and subsequent changes in joint integrity is the hallmark of the disease. Despite its destructive potential, the course of RA can be quite variable. Some patients may experience only mild oligoarticular illness of brief duration with minimal joint damage, but most will have a relentless progressive poly arthritis with marked function impairment.

CLASSIFICATION OF DMARDs: DMARDs can be classified into two types

- 1) Non biologic or conventional DMARDs includes: Hydroxychloroquine, Azathioprine, Sulfasalazine, Methotrexate, Leflunomide, Cyclosporine, Gold salts, D-penicillamine, Minocycline and Corticosteroids.
- 2) Biologic DMARDs includes: These include agents such as: Adalimumab, Certolizumab, Golimumab, Infliximab, Rituximab, Tocilizumab, Anakinra and Etanercept.

MATERIALS AND METHODS

Study design: prospective, cohort and single centered study

RESULTS

Study site: Apollo Hospitals, Jubilee hills, Hyderabad.

Study duration: 6 months [January 2021- July 2021]

Proposed sample size: 100

Inclusion criteria

All out-patients who are >18 years of age undergoing RA treatment with DMARDs.

Exclusion criteria

1. Patients who are < 18 years of age.
2. Excluded pregnant, lactating women, In- patients.

Study procedure: A prospective, cohort and single centered study was conducted to monitor the side effects associated with DMARDs. Data was collected between January 2021- July 2021 from Orthopedic and Rheumatology clinics within the hospital from out-patient department. The data was entered in a data collection form designed for the purpose and included all the required parameters. The obtained information will be used to understand the adverse effects of DMARDs used in the hospital.

Table 1: distribution of patients based on gender

GENDER	NO. OF PATIENTS
MALES	9
FEMALES	31

Distribution of patients based on Gender

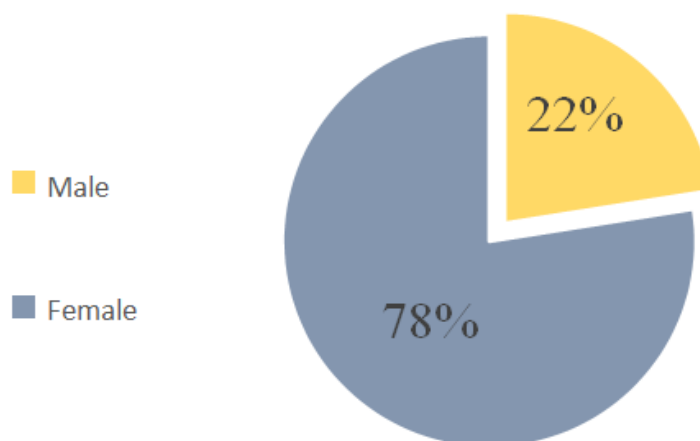


Fig 1: Distribution of patients based on Gender

Table 1: Distribution of male patients based on age

AGE GROUP	NO. OF MALES
21-30	1
31-40	0
41-50	3
51-60	2

61-70	2
71-80	1

Distribution of male population based on Age

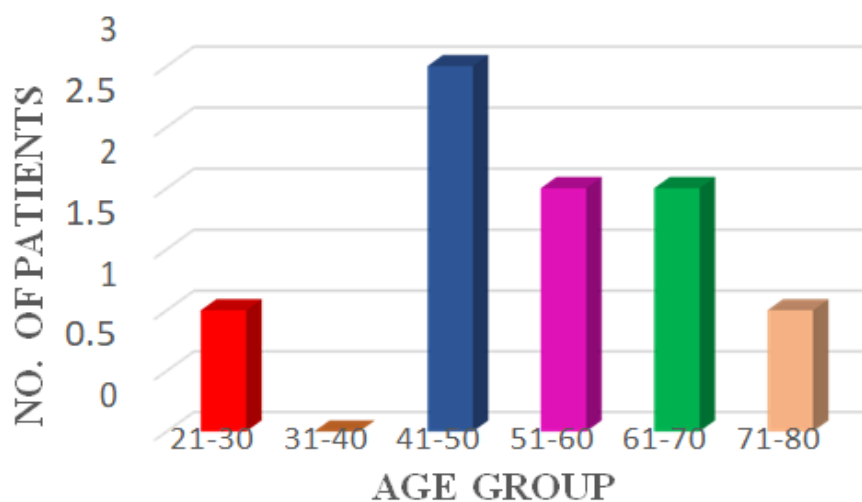


Fig 2: Distribution of male population based on Age

Table 2: Distribution of female patients based on age

AGE GROUP	NO. OF FEMALES
21-30	0
31-40	4
41-50	7
51-60	12
61-70	7
71-80	1

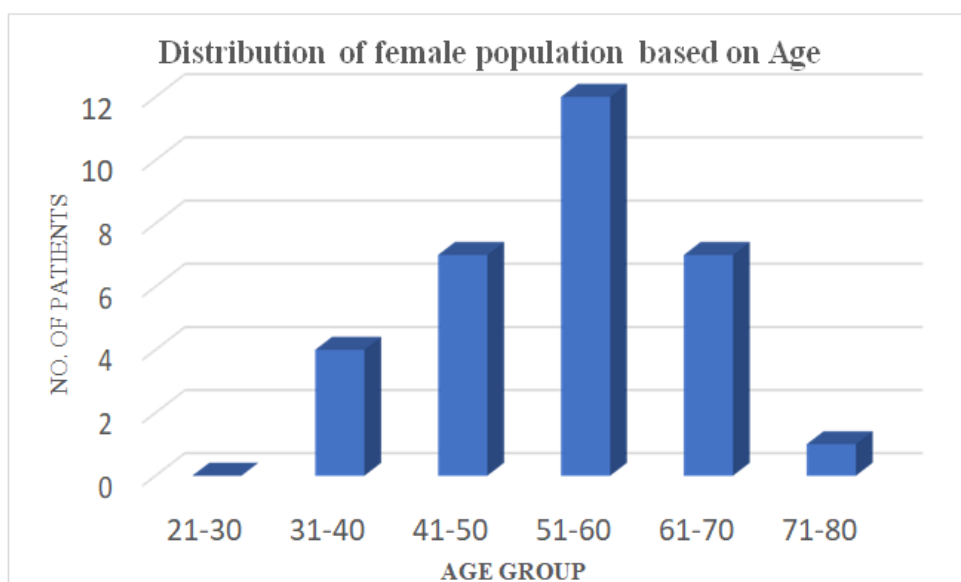


Fig 3: Distribution of female population based on Age

Table 3: Depiction of side effects in patients with DMARDs

CATEGORY	NO. OF PATIENTS
SIDE EFFECTS REPORTED	26
SIDE EFFECTS NOT REPORTED	14

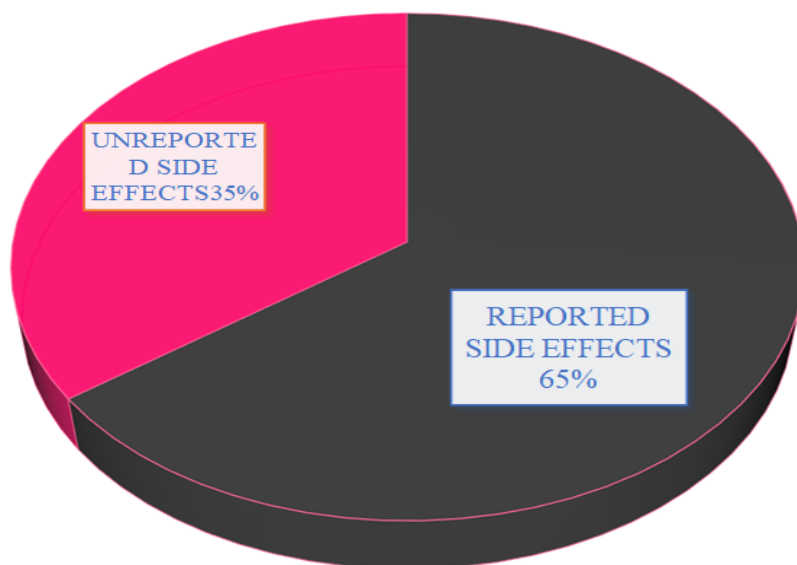


Fig 4: Depiction of side effects in patients with DMARDs

Table 4: side effects reported in patients with DMARDs

SIDE EFFECTS	NO. OF PATIENTS
STOMACHACHE	7
DRYNESS OF MOUTH	8
OTHER SIDE EFFECTS	11

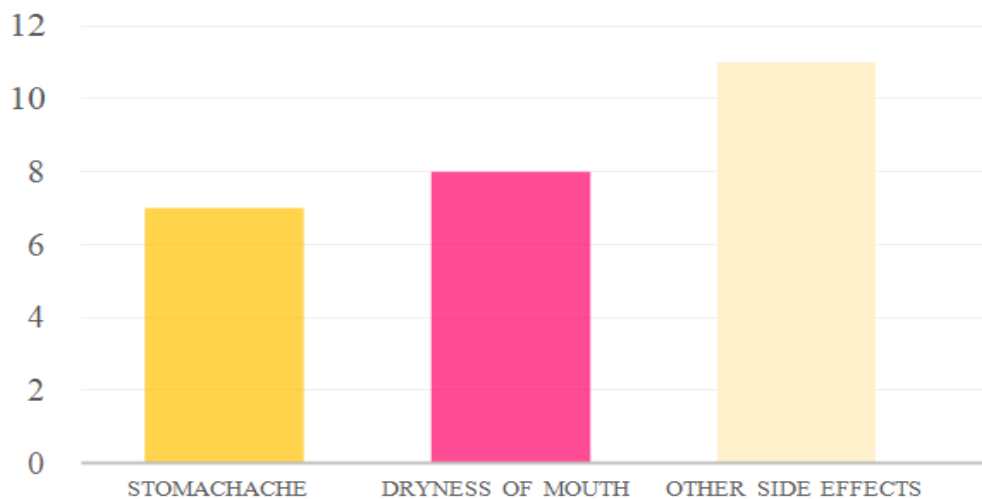


Fig 5: Side effects reported in patients with DMARDs

Table 5: Percentage of patients with Stomachache

STOMACHACHE	NO. OF PATIENTS
YES	7
NO	33

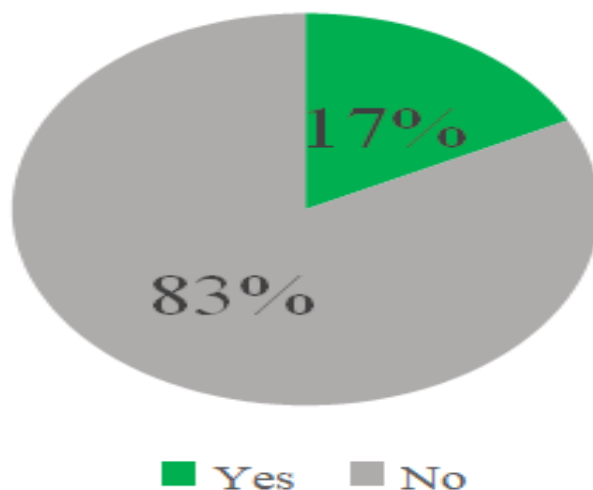


Fig 6: Percentage of patients with stomachache

Table 6: Percentage of patients with dryness of mouth

STOMACHACHE	NO. OF PATIENTS
YES	7
NO	33

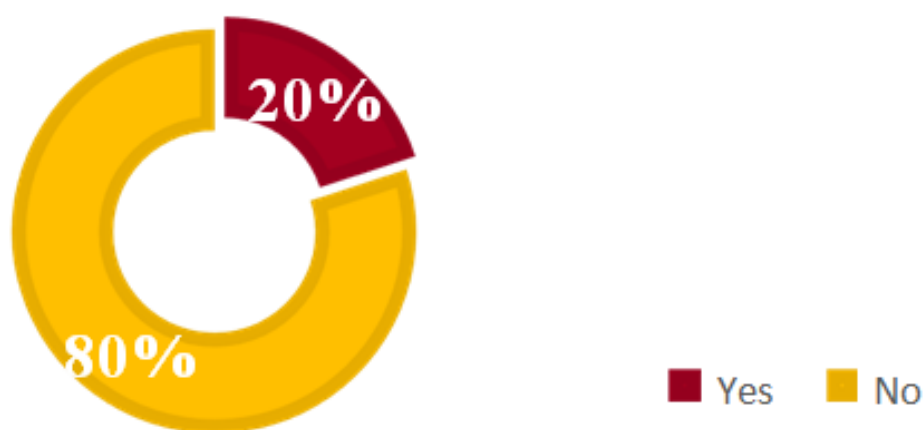


Fig 7: Percentage of patients with dryness of mouth

Table 7: Other side effects reported in patients with DMARDs

OTHER SIDE EFFECTS	NO. OF PATIENTS
VOMITING	2
ACIDITY	2
DIZZINESS AND HEADACHE	1
PIGMENTATION OF SKIN AND PALPITATIONS	1
VOMITINGS AND FEVER	1
INSOMNIA AND DYSPEPSIA	1
HEADACHE AND FEVER	1
SWELLING OF TONGUE AND BLURRED VISION	1
HEADACHE AND INCREASED APPETITE	1

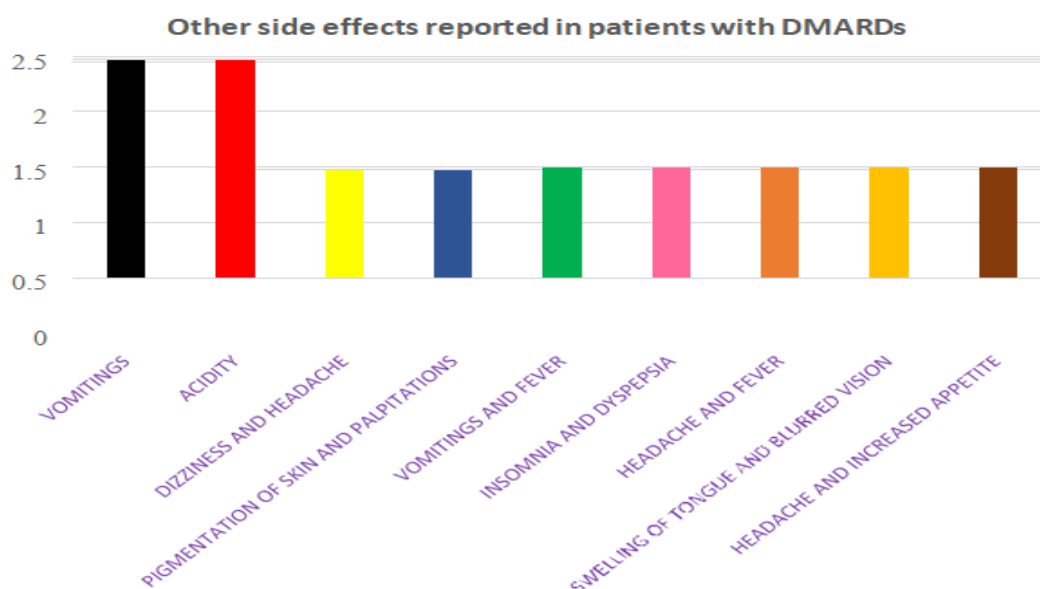


Fig 8: Other side effects reported in patients with DMARDs

DISCUSSION

Our study titled A prospective study to monitor the side effects Associated with Disease modifying Anti-rheumatoid drugs in out-patients of tertiary care hospital was conducted at Apollo Hospitals, to identify and evaluate the DMARDs associated with side effects in patients with RA and to establish the role of pharmacist to minimize side effects. Our study included a total of 40 subjects > 18 years out of which 9 were males and 31 were females. [Table 1] This indicates a high percentage of females undergoing RA treatment with DMARDs. In our study the age of subjects ranged between 20-80 years. In males age group of 40-50 are more affected with RA than other age groups [Table 2] In females age group of 51-60 are more affected with RA than other age groups [Table 3] It was observed that 65% of the people reported side effects while the remaining 35% of the people do not have any side effects [Table 4] our study reveals that out of 40 patients, 7 reported stomachache, 8 reported Dryness of mouth and remaining 11 patients reported other side effects [Table 5] other side effects observed [Table 4.8] from our study includes vomiting, acidity followed by Dizziness, pigmentation of skin, palpitations, Fever, Insomnia, Dyspepsia, Blurred vision and Increased appetite.

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LIMITATIONS: As our study is prospective, due to the present pandemic situation some of the patients are virtually connecting with the doctors because of this we are unable to interact with the patient, therefore our sample size has been limited to 40.

CONCLUSION

In our study titled “A prospective study to monitor the side effects associated with DMARDs in out-patients of tertiary care hospital” we have reviewed the data of population who are undergoing RA treatment with DMARDs. A detailed analysis was done. Our research was conducted in Apollo Hospital, based on the statistical analysis we conclude that the side effects associated with disease modifying anti-rheumatoid drugs in rheumatoid arthritis patients were found to be significant. Out of 40 patients, 26 reported side effects and 14 didn't report any side effects. 7 reported stomachache, 8 reported dryness of mouth and 11 patients reported other side effects. Among other side effects vomiting and acidity was more reported followed by Dizziness, Pigmentation of skin, Palpitations, Fever, Insomnia, Dyspepsia, Swelling of tongue, Blurred vision and increased appetite.

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