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ASSESSMENT OF TREATMENT STRATEGIES AND PATIENT COUNSELLING IMPACT ON MEDICATION ADHERENCE IN PATIENTS WITH RHEUMATOID ARTHRITIS – A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Introduction: Rheumatoid Arthritis (RA) is a chronic autoimmune disorder characterized by persistent inflammation primarily targeting synovial joints, resulting in progressive joint damage and systemic complications. Affecting approximately 0.4–1.3% of the global population, RA shows higher prevalence among women and older individuals. Multifactorial in origin, it is driven by genetic predisposition, immune dysregulation, and environmental factors like smoking and infections. The cornerstone of RA management includes early diagnosis, effective pharmacological treatments such as DMARDs, and non-pharmacological interventions to mitigate disease progression and improve patient outcomes.

Methods: A Prospective Observational Study was conducted in the department of General Medicine at Pushpagiri Medical College Hospital, Thiruvalla. The study was carried out for a period of 6 months in which data from October 2024 – March 2025 were collected.

Results: The study included 142 patients. Methotrexate emerged as the primary treatment, supplemented with other DMARDs, corticosteroids, and supportive therapies. Key demographic trends included a female

predominance (84.5%) and high prevalence of comorbidities like hypertension (45.8%) and diabetes (24.6%). The Medication Adherence and Quality of Life was measured using MARS and SF-36 questionnaire. Adverse drug reactions (ADRs) were assessed in the study using the Naranjo Adverse Drug Reaction Probability Scale where most ADRs were categorized as "doubtful" or "possible," indicating a relatively low likelihood of direct causation from prescribed medications.

Conclusion: RA management requires a comprehensive approach combining pharmacological interventions and patient education. Pharmacist-led counselling proved instrumental in improving adherence and quality of life. The study emphasizes integrated care models as effective strategies to address the complex challenges of RA, suggesting future research into long-term impacts and digital health tools for enhanced management.

Keywords: Rheumatoid Arthritis, Disease Modifying Anti-Rheumatic drugs, Medication Adherence, Quality of Life, Adverse Drug Reaction

INTRODUCTION

Rheumatoid Arthritis (RA) is a long-term autoimmune condition that predominantly affects the joints. It is marked by progressive, symmetrical joint inflammation, leading to cartilage damage, bone erosion, and functional disability. In the early stages, only a few joints may be affected, but as the disease progresses, multiple joints and extra-articular symptoms become more common. RA affects approximately 0.4% to 1.3% of the population, with prevalence varying by factors such as sex (women are affected two to three times more often than men), age (the highest incidence occurs in the sixth decade of life), and population demographics (RA is more common in northern regions and urban areas compared to southern regions and rural settings) **[1]**.

The development of RA has been associated with a number of host variables, including comorbid host factors and genetic, epigenetic, hormonal, reproductive, and neuroendocrine factors. Conversely, environmental risk factors include infectious agents and microbiota, food, socioeconomic variables, and smoking and other airborne exposures **[2]**. The development of rheumatoid arthritis (RA) is multifaceted, arising from a combination of genetic susceptibility, environmental factors, and immune system dysfunction. A higher risk of RA is closely linked to certain alleles of the HLA-DRB1 gene. Environmental factors, including smoking and certain infections, can act as triggers in individuals with a genetic predisposition. Immune system abnormalities lead to persistent inflammation, predominantly targeting the synovial joints

and causing the hallmark symptoms of RA **[3]**.

The most effective treatment for Rheumatoid Arthritis (RA) involves early diagnosis, optimal non-pharmacological and pharmacological interventions, and regular monitoring of treatment effectiveness and safety. Medications that help preserve joint function are categorized into conventional synthetic disease-modifying antirheumatic drugs (DMARDs), biologic DMARDs (bDMARDs), and targeted synthetic DMARDs (tsDMARDs), which are considered a new class of nonbiologic DMARDs by the American College of Rheumatology (ACR). When symptoms are not adequately controlled, nonsteroidal anti-inflammatory drugs (NSAIDs) and glucocorticoids (GCs) are used as adjuncts to reduce inflammation **[4]**.

The aim of this study is to evaluate the effectiveness of treatment strategies and the impact of patient counselling on medication adherence in individuals with Rheumatoid Arthritis at a tertiary care hospital. The objectives include assessing various therapeutic approaches, analyzing changes in medication adherence before and after pharmacist-led counselling, evaluating patients' quality of life following therapy, and identifying potential drug-drug interactions and related adverse events.

MATERIALS AND METHODS

A single centered, hospital based, prospective observational study was conducted in the department of General Medicine, Pushpagiri Medical College Hospital, Thiruvalla, Kerala for a duration of 6 months including a total of 142 patients.

Inclusion Criteria

- All patients (both IP and OP) diagnosed with RA.
- Patient 18 years and above.

Exclusion Criteria

- Patient who were not willing to give their consent.

The sample size obtained was n= 140 using the formula

Sample size, $n = \frac{Z\alpha^2 PQ}{d^2}$

STUDY PROCEDURE

The study procedure involves several critical steps, starting with patient selection based on predefined inclusion and exclusion criteria. Eligible patients are required to provide informed consent before participation. Data collection encompasses a thorough gathering of demographic details, presenting complaints, social and family history, medication history, and current medications. At the first visit, patients undergo counseling

focused on understanding various treatment modalities, potential drug-drug interactions, and their possible adverse events. A follow-up counselling session is conducted during the second visit, scheduled two months later, to evaluate progress and provide additional guidance. The study also involves a systematic assessment, with statistical analysis performed on the collected data to derive insights about treatment efficacy and safety. Finally, results are compiled and analyzed to draw meaningful conclusions, ensuring a comprehensive understanding of the study's objectives.

STATISTICAL ANALYSIS

Data was properly coded and entered in Microsoft excel and analyzed using SPSS version 23. Data were properly coded and entered in Microsoft Excel and analyzed using SPSS software, version 23. Qualitative variables were summarized as frequencies and percentages. Quantitative variables were expressed as mean (SD) or median (IQR), depending on the distribution. For comparison of medication adherence scores and SF-36 scores in various domains before and after patient counselling, the Wilcoxon signed-rank test was used. A p-value of <0.05 was considered statistically significant.

RESULTS AND DISCUSSION

1. DISTRIBUTION OF STUDY POPULATION BASED ON GENDER

Out of the 142 patients included in the study, a majority were females (84.5%), while males constituted only 15.5% of the population. This finding is consistent with the known higher prevalence of Rheumatoid Arthritis among females compared to males. These results were found to be consistent with the findings of **Black, Rachel J, *et al*.,** (2023) **[5]**.

2. DISTRIBUTION OF STUDY POPULATION BASED ON DRUGS USED FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

In this study, Methotrexate (98.6%) and folic acid (98.6%) were the most frequently prescribed medications, forming the cornerstone of therapy in nearly all patients. Hydroxychloroquine was used in 67.6% of cases, while sulfasalazine (40.1%) and leflunomide (14.1%) were also part of the disease-modifying antirheumatic drug (DMARD) regimen. Deflazacort (56.3%) and prednisolone (17.6%) were prescribed as corticosteroid options for inflammation control. Non-steroidal anti-inflammatory drugs like etoricoxib (47.9%) and supportive agents such as Calcitriol-Calcium-Zinc combinations (48.6%), glucosamine (6.3%), and gastroprotective drugs like esomeprazole-

domperidone (83.1%) were also commonly used. This pattern indicates a multidrug approach focused on controlling inflammation, preventing disease progression, and minimizing side effects. This result positively correlates to the study by **Mittal, Gauri, *et al.,*** (2021) **[6]**.

3. COMPARISON OF MEDICATION ADHERENCE SCORE (MARS) BEFORE AND AFTER PATIENT COUNSELLING

In this study of 142 participants Medication adherence, assessed using the MARS scale, showed a statistically significant improvement following counselling by the clinical pharmacist. The mean adherence score increased from 4.02 ± 1.39 at baseline to 9.6 ± 0.67 after two months of intervention. The median score also improved from 4 (IQR 2) to 10 (IQR 1). The difference was highly significant as per the Wilcoxon Signed Ranks Test ($Z = 10.397$, $p < 0.001$). This indicates that pharmacist-led patient counselling had a strong positive impact on adherence to rheumatoid arthritis treatment. These findings positively correlate to the study by **Taibanguay, Nichapa, *et al.,*** (2019) **[7]**.

4. COMPARISON OF SF-36 SCORES IN VARIOUS DOMAINS BEFORE AND AFTER PATIENT COUNSELLING

Following patient counselling by a clinical pharmacist, there was a statistically significant improvement in all domains of the SF-36 health-related quality of life scores among patients with rheumatoid arthritis. The median score for physical functioning increased from 5 to 25, and role of limitations due to physical health improved markedly from 0 to 25. Similarly, role of limitations due to emotional problems increased from 0 to 33, indicating fewer emotional constraints on daily activities. Notable enhancements were also observed in energy/fatigue (from 30 to 60), emotional well-being (from 44 to 63), and social functioning (from 25 to 63), reflecting better vitality, mood, and social engagement. Pain scores improved significantly from 23 to 58, and general health perception increased from 35 to 50. The health change domain, which assesses perceived improvement in overall health, showed a substantial rise from 50 to 75. All these changes were statistically significant ($p < 0.001$), indicating that patient counselling had a positive impact on quality of life across physical, emotional, and social dimensions. These findings resonate with **Mudhaliar, Mohanraj Rathinavelu, *et al*.,** (2016) **[8]**, who also reported substantial HRQoL benefits from pharmacist-mediated interventions.

5. DISTRIBUTION OF STUDY POPULATION BASED ON ADVERSE DRUG REACTIONS PROBABILITY AS PER NARANJO SCALE

Among the 142 patients in the study, adverse drug reactions (ADRs) were assessed using the Naranjo scale. The majority of ADRs were classified as doubtful (50.7%), followed by possible ADRs in 38.7% of patients. Probable ADRs were observed in 9.9% of cases, while only one case (0.7%) was categorized as a definite ADR. This is in line with findings by **Sah, Sujit Kumar, *et al.,*** (2023) **[9]**, who highlighted the challenges of managing polypharmacy in RA patients.

Table 1: Distribution of study population based on gender

GENDER	FREQUENCY (n)	PERCENTAGE (%)
Male	22	15.5
Female	120	84.5
Total	142	100.0

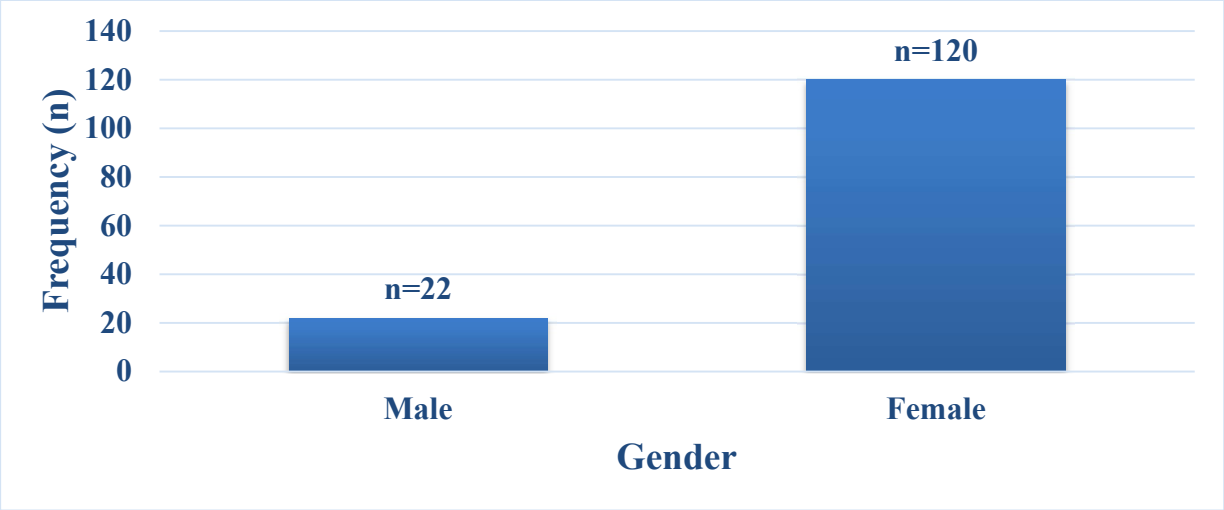

Figure 1: Distribution of study population based on gender

Table 2: Distribution of study population based on drugs used for treatment of Rheumatoid Arthritis

DRUG USED	FREQUENCY (n)	PERCENTAGE (%)
Methotrexate	140	98.6
Folic acid	140	98.6
Hydroxychloroquine	96	67.6
Leflunomide	20	14.1
Etoricoxib	68	47.9
Sulfasalazine	57	40.1
Deflazacort	80	56.3
Calcitriol Calcium Carbonate Zinc Sulphate	69	48.6
Glucosamine	17	6.3
Prednisolone	25	17.6
Esomeprazole Domperidone	118	83.1

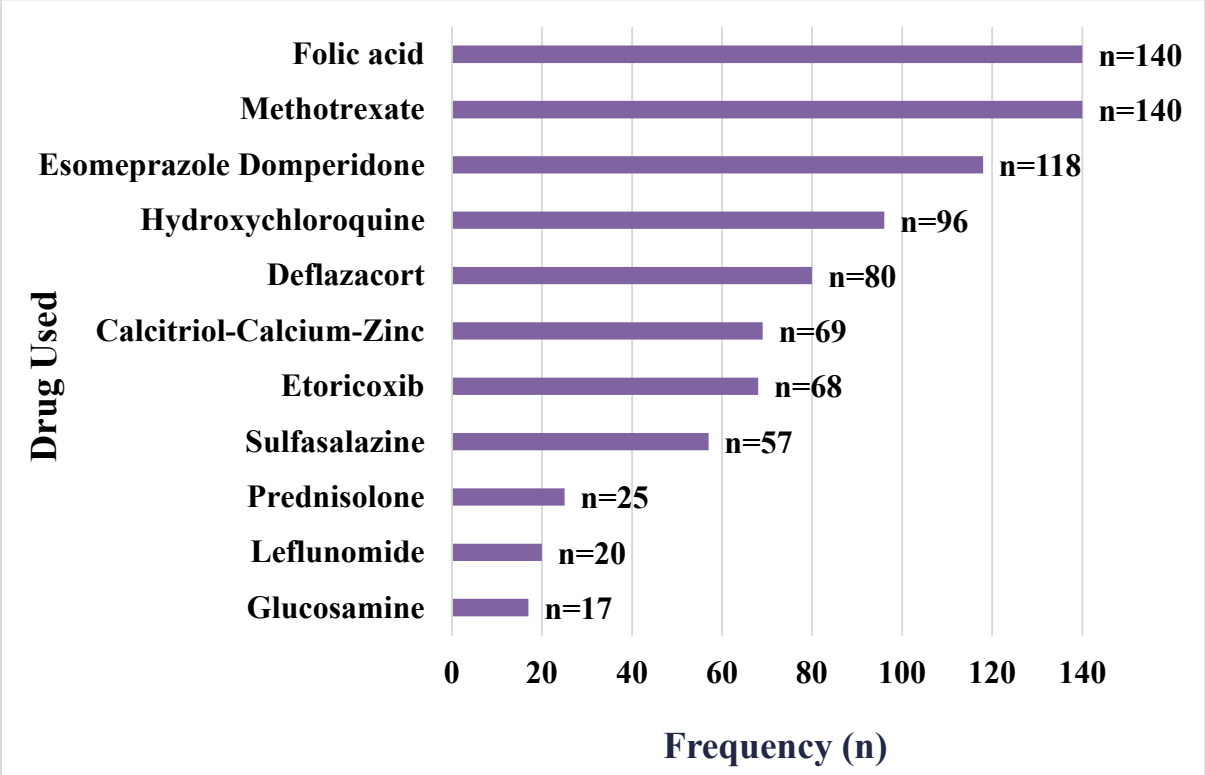

Figure 2: Distribution of study population based on drugs used for treatment of Rheumatoid arthritis

Table 3: Comparison of medication adherence Score (MARS) before and after patient counselling

PARAMETER	TIME	MEAN SCORE (SD)	MEDIAN (IQR)	TEST STATISTIC[#] & P VALUE
Medication adherence (MARS)Score	Before patient counselling	4.02(1.39)	4(2)	Z= 10.397 p<0.001*
	After patient counselling	9.6(0.67)	10(1)	

*[#] Wilcoxon Signed Ranks Test, * Statistically significant at p <0.05*

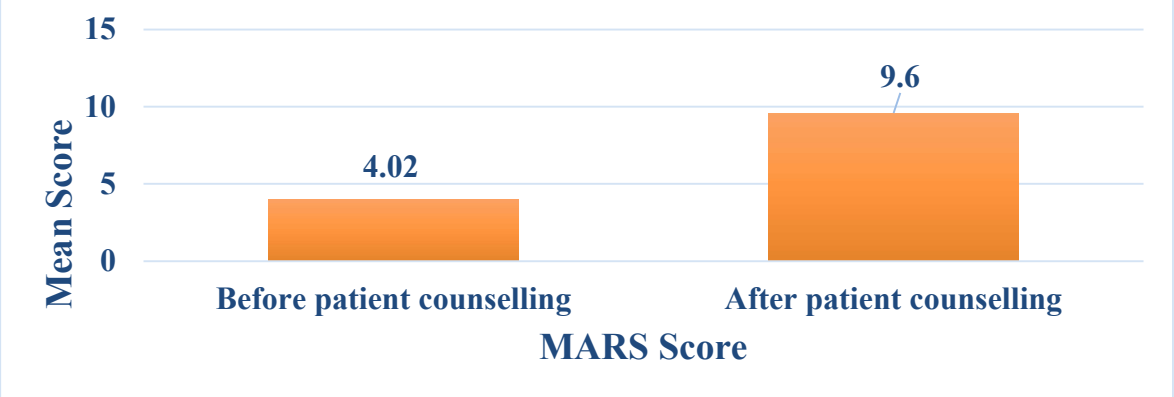

Figure 3: Comparison of medication adherence Score (MARS) before and after patient counselling

Table 4: Comparison of SF 36 scores in various domains before and after patient counselling

SF 36 DOMAIN	TIME OF ASSESSMENT	SF 36 SCORE –		TEST STATISTIC# & P VALUE
		Mean (SD)	Median (IQR)	
Physical function	Before	5.25(6.90)	5(10)	Z=10.164, p<0.001*
	After	28.12(10.91)	25(10)	
Role of limitations due to physical health	Before	4.12(8.28)	0(0)	Z=9.393, p<0.001*
	After	31.41(19.65)	25(26.25)	
Role of limitations due to emotional problems	Before	3.60(9.74)	0(0)	Z=9.611, p<0.001*
	After	36.02(20.03)	33(8.25)	
Energy / fatigue	Before	34.30(11.33)	30(15)	Z=9.781, p<0.001*
	After	59.99(10.13)	60(10)	
Emotional well being	Before	40.52(11.17)	44(18)	Z=9.996, p<0.001*
	After	62.19(9.14)	63(12)	
Social functioning	Before	34.22(14.69)	25(20)	Z=9.805, p<0.001*
	After	59.41(10.76)	63(18)	
Pain	Before	30.17(16.20)	23(12)	Z=9.897, p<0.001*
	After	58.64(11.97)	58(23)	
General health	Before	36.04(14.78)	35(20)	Z=9.491, p<0.001*
	After	54.88(10.37)	50(13)	
Health change	Before	52.47(19.65)	50(42.75)	Z=9.476, p<0.001*

Mann Whitney U Test Statistically significant at p <0.05*

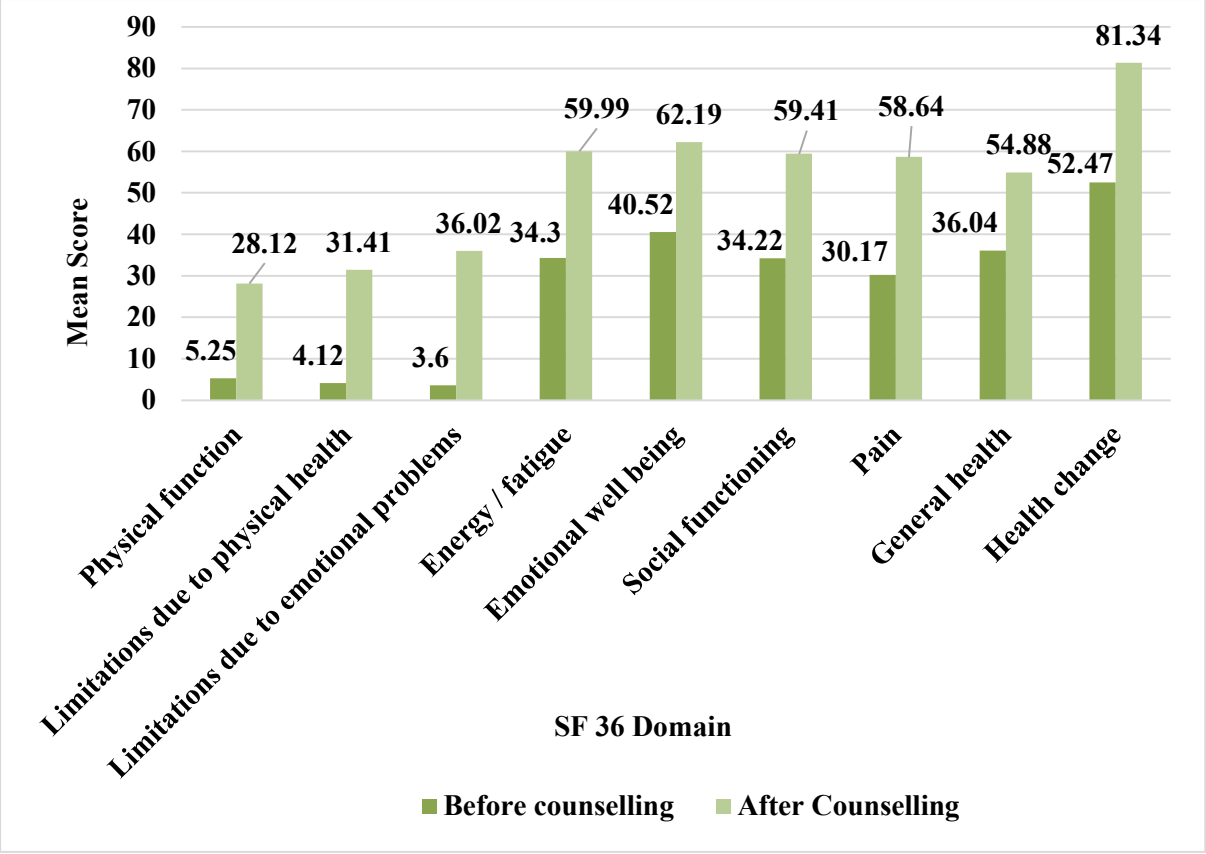

Figure 4: Comparing SF 36 scores in various domains before and after patient counselling

Table 5: Distribution of study population based on adverse drug reactions probability as per Naranjo scale.

ADR PROBABILITY	FREQUENCY (n)	PERCENTAGE (%)
Doubtful ADR	72	50.7
Possible ADR	55	38.7
Probable ADR	14	9.9
Definite ADR	1	0.7
Total	142	100.0

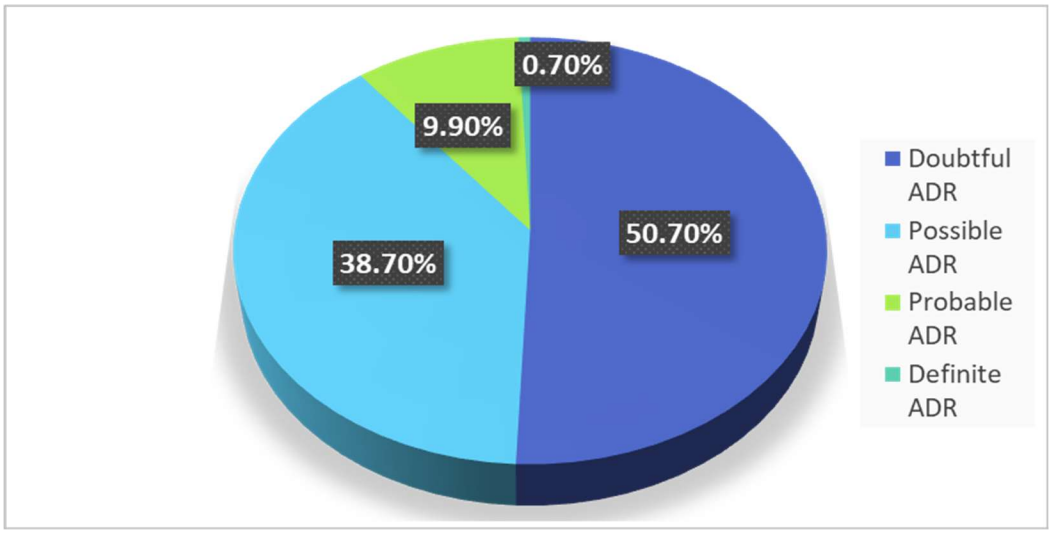

Figure 5: Distribution of study population based on adverse drug reactions probability as per Naranjo scale

CONCLUSION

Rheumatoid Arthritis is a chronic autoimmune disorder requiring long-term care, with pharmacist-led counselling significantly improving medication adherence and quality of life, particularly in pain and emotional well-being. Integrated care, combining pharmacological treatments and patient education, proved effective, with future efforts needed to explore long-term outcomes and digital tools for Rheumatoid Arthritis management. The effectiveness of integrated care models improve adherence, enhance quality of life, and address the multifaceted challenges of Rheumatoid Arthritis.

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Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/ publication of this article.

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Ethical consideration

Institutional Research/ Human Ethics Committee approval was obtained.

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