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Comparison of Biological and Conventional Synthetic DMARDS Treatment Response for Psoriatic Arthritis with Associated Fibromyalgia

Bushra[1], Khurram Rasheed[1], Muhammad Shahid Khan[2], Syeda Kinza Bukhari[1], Irfan Najam Sheen[1], Sidra Batool[1]

[1]Department of Medicine, Combined Military Hospital (CMH), Multan, Pakistan
[2]Department of Medicine, HITEC Institute of Medical Sciences, Taxila Cantt, Pakistan

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Corresponding Author: Bushra, Registrar Medicine, Department of Medicine, Combined Military Hospital (CMH), Multan.
Email: semester678910@gmail.com

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ABSTRACT

Objective: To compare the good treatment responses of biologic and conventional synthetic DMARDs in psoriatic arthritis (PsA) patients with associated fibromyalgia. **Study Design:** Randomized controlled trial. **Duration and Place of Study:** Conducted from January 2024 to December 2024 at the Department of Medicine, CMH Multan. **Methodology**: A total of 110 patients (age 18-70) with confirmed PsA and fibromyalgia for at least 6 months were randomly assigned into two groups (n=55 each). Group A received biologic DMARDs, including adalimumab, etanercept, infliximab, or secukinumab. Group B received conventional synthetic DMARDs, including methotrexate, leflunomide, or sulfasalazine. The primary endpoint was the therapeutic response at 6 months, measured by Clinical Disease Activity Index (CDAI), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), and Health Assessment Questionnaire Disability Index (HAQ-DI). **Results**: Both groups showed significant demographic and clinical variation, but no significant difference was found in the overall therapeutic response between the two groups ($p = 0.127$). Functional disability, as measured by HAQ-DI, emerged as a key predictor of therapeutic response, with patients exhibiting higher functional impairment showing more favorable treatment outcomes. **Conclusion**: Biologic and conventional synthetic DMARDs exhibited comparable therapeutic efficacy in PsA patients with fibromyalgia.

INTRODUCTION

Psoriatic arthritis (PsA) is a psoriasis disease with a long-term, inflammatory disorder with arthritic pain, stiffness, and swelling in joints, a complex, heterogeneous disease with a range of symptoms, including enthesitis, dactylitis, and abnormalities in nails, and, therefore, a disease challenging to manage.[1] Quality of life can become compromised in a substantial way in PsA through its impact both functional and mental state-wise.[2] An interrelationship between pathogenetic factors, including genetic, environmental, and immunologic, with a prevalent role for immune system deregulation, characterizes PsA.[3] Therapy and early intervention can prevent irreversible joint damage and long-term improvement, but in PsA, its heterogeneity renders it a problem in defining for an individual patient the most effective therapeutic approach.[4]

When PsA and fibromyalgia occur together, then the picture is even more complex.[5] Fibromyalgia represents a syndrome of widespread musculoskeletal aches and pains, fatigue, sleep disorder, and impairment of cognition, a syndrome of chronic pain disorder.[6] Patients with PsA and concomitant fibromyalgia have heightened susceptibility to pain, heightened fatigue, and lowered responsiveness to conventional therapy.[7] Overlap can complicate disease activity and therapeutic efficacy evaluation, with symptoms of fibromyalgia having a chance to mimic and exaggerate symptoms of PsA.[8] Overlap can even generate increased psychological burden in terms of dealing with two long-standing conditions, with a consequence of developing anxiety and depression, with an overall impact on general well-being.[9] Therapy for both will have to include a multidisciplinary intervention, with consideration not only for drugs but even lifestyle and psychosocial interventions.

Disease-Modifying Anti-Rheumatic Drugs (DMARD) represent the pillar of therapy for PsA, with an intention to modulate, slow disease progression, and maximize functional outcomes.[10] DMARDs can broadly be

categorized into conventional synthetic DMARDs (csDMARDs), such as methotrexate and sulfasalazine, and biologic DMARDs (bDMARDs), with a target mechanism for a specific portion of the immune system such as TNF inhibitors or interleukin inhibitors.[11] First-line use of csDMARDs, such as methotrexate and sulfasalazine, is common, with a high level of cost-effectiveness and a proven record of safe use.[12] Not, however, all, and particularly not all with severe disease and comorbidities such as fibromyalgia, will respond to them effectively. In contrast, bDMARDs have potent target therapies but at a high price and with infection and other toxicity complications.[13]

There is less efficacy in systemic suppression of inflammation in conventional DMARDs in comparison with biologic DMARDs, and, therefore, in concomitant fibromyalgia, can produce suboptimal efficacy in such a case.[14] Biologic DMARDs, in contrast, have been shown to have high efficacy in suppression of both joints' and patient-rated improvement, and indirectly, in improvement in symptoms of concomitant fibromyalgia.[15]

This study is significant in terms of knowing the therapeutic challenge in treating psoriatic arthritis (PsA) with concomitant fibromyalgias, a disease that makes disease evaluation and therapeutic response challenging. With the diversity of PsA and heightened pain sensitization in fibromyalgias, knowing the most effective therapeutic modality, conventional synthetic DMARDs, or biologic DMARDs, is significant. Comparing efficacy and impact on patient welfare will enable maximization of individualized therapeutic regimens and overall disease care in such a complex group of patients.

METHODOLOGY

This randomized controlled trial was conducted from January 2024 to December 2024 at the Department of Medicine, CMH Multan. The study adhered to ethical guidelines, and approval was obtained from the institutional review board. Written informed consent was obtained from all participants prior to enrollment. The sample size of 100 patients was determined using the WHO sample size calculator, with an 80% power of test and a 5% significance level, based on assumed good response of 65%[16] with biologic DMARDs and 38%[17] with conventional synthetic DMARDs. A total of 110 patients meeting the inclusion criteria were randomly assigned into two equal groups (n = 55 per group) using a computer-generated randomization sequence. The inclusion criteria consisted of males and females aged 18 to 70 years with a confirmed diagnosis of PsA and associated Fibromyalgia for at least six months. Patients with uncontrolled diabetes, chronic infections, active malignancies, severe cardiovascular disease, chronic liver disease, pregnancy, or a history of prior failure or hypersensitivity to DMARDs were excluded. At baseline, demographic and clinical characteristics, including age, gender, body mass index (BMI), smoking status, disease duration, presence of comorbidities and baseline disease activity scores, were recorded. Disease activity was assessed using validated measure such as the Clinical Disease Activity Index (CDAI), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), and Health Assessment Questionnaire Disability Index (HAQ-DI). Patients in group A received adalimumab (40 mg, two times a week, subcutaneously), etanercept (once a week, 50 mg, subcutaneously), infliximab (intravenous, 5 mg/kg at week 0, 2, and 6, and then at 8 week intervals thereafter), or secukinumab (once a week, 150 mg, for five weeks, then monthly thereafter, subcutaneously), at physician discretion and suitability for use. Patients in group B received methotraxate (once a week, 15–25 mg, orally, or subcutaneously), leflunomide (once a day, 10–20 mg, orally), or sulfasalazine (500–1000 mg twice a day, orally). Concomitant therapies, including non-steroidal anti-inflammatory drugs (NSAIDs) and low-dose prednisolone (≤7.5 mg a day), could be added

The primary endpoint for the study was 6-month therapeutic response, measured in terms of proportion of subjects with CDAI and BASDAI-established low disease activity and remission. Successful therapeutic response was taken to have reached remission and low disease activity, with a CDAI value of ≤10, effective disease control in axes with a value of <4 in BASDAI, and improvement in function with a Health Assessment Questionnaire Disability Index (HAQ-DI) improvement of ≥0.35 at baseline and six months. Data analysis was performed using IBM SPSS version 26. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages and analyzed using chi-square tests. A p-value of <0.05 was considered statistically significant. Correlation analysis of clinical parameters and logistic regression analysis of factors were also done.

RESULTS

The demographic data (as shown in Table 1) reveals that patients receiving biological treatments have a mean age of 47.31 ± 9.38 years, a BMI of 27.45 ± 4.59 kg/m², and a disease duration of 8.86 ± 7.31 years, while patients receiving conventional synthetic treatments have a mean age of 52.75 ± 11.35 years, BMI of 28.43 ± 3.76 kg/m², and disease duration of 12.27 ± 7.51 years. The CDAI in the biological treatment group is 18.27 ± 8.78, while in the conventional treatment group it is 22.85 ± 4.59, with the BASDAI in the biological treatment group being 6.77 ± 2.78 and in the conventional treatment group 8.29 ± 1.78. For gender, 45.5% of the biological treatment group are males and 54.5% are females, while 30.9% of

the conventional treatment group are males and 69.1% are females. Smoking is prevalent in 7.3% of the biological treatment group and 5.5% of the conventional treatment group. Regarding comorbidities, 30.9% of the biological treatment group has diabetes compared to 23.6% in the conventional treatment group, and 45.5% of the biological treatment group has hypertension, while 52.7% of the conventional treatment group has hypertension.

Table 1

Demographics of the Patients

Demographics		Group A n=55 Mean±SD	Group B n=55 Mean±SD
Age (years)		47.309±9.38	52.746±11.35
BMI (Kg/m^2)		27.447±4.59	28.433±3.76
Duration of Disease (years)		8.858±7.31	12.271±7.51
CDAI		18.274±8.78	22.853±4.59
BASDAI		6.774±2.78	8.286±1.78
HAQ-DI		1.021±0.31	1.201±0.29
Gender	Male n(%)	25 (45.5%)	17 (30.9%)
	Female n(%)	30 (54.5%)	38 (69.1%)
Smoking	Yes n(%)	4 (7.3%)	3 (5.5%)
	No n(%)	51 (92.7%)	52 (94.5%)
Co Morbidity	Diabetes n(%)	17 (30.9%)	13 (23.6%)
	Hypertension n(%)	25 (45.5%)	29 (52.7%)
	Others n(%)	13 (23.6%)	13 (23.6%)

In Table 2, the comparison of good treatment responses between the two treatment groups shows that 54.5% of patients in the biological treatment group and 40% in the conventional treatment group had a good treatment response, though the p-value is 0.127, indicating no significant difference between the two groups.

Table 2

Comparison of Good Treatment Response between the Two Groups. (n=110)

Good Treatment Response	Group A n=55 n (%)	Group B n=55 n (%)	P value
Yes	30 (54.5%)	22 (40%)	
No	25 (45.5%)	33 (60%)	0.127
Total	55 (100%)	55 (100%)	

Table 3 shows the stratification of good treatment response by demographic variables. For age, 100% of patients aged ≤40 in both treatment groups had a good response (p = 1.000). For those aged >40, there were no significant differences in treatment response (p = 0.529 for the biological treatment group and p = 0.737 for the conventional treatment group). Gender-wise, the response was not significantly different, with p-values of 0.374 for males and 0.471 for females. For BMI, those with a BMI ≤25 showed 100% good response in the biological treatment group and 75% in the conventional treatment group, with a p-value of 0.111. Smoking status showed no significant difference (p = 0.429 for smokers and p = 0.201 for non-smokers). The duration of disease ≤5 years showed 100% good response in both treatment groups, while for those with >5 years, there was no significant difference in response (p = 0.681 for the biological treatment group and p = 0.681 for the conventional treatment group). Co-morbidities such as diabetes, hypertension, and others showed no significant differences in treatment response between the groups.

Table 3

Stratification of Good Treatment Response Based on Demographic Variables across Groups

Demographics variables		Group	Good Treatment Response		P-value
			Yes (n, %)	No (n, %)	
Age (years)	≤40	A	14 (100%)	0 (0%)	1.000*
		B	6 (100%)	0 (0%)	
	>40	A	16 (39%)	25 (61%)	0.529
		B	16 (32.7%)	33 (67.3%)	
Gender	Male	A	18 (72%)	7 (28%)	0.374
		B	10 (58.8%)	7 (41.2%)	
	Female	A	12 (40%)	18 (60%)	0.471
		B	12 (31.6%)	26 (68.4%)	
BMI (Kg/m^2)	≤25	A	15 (100%)	0 (0%)	0.111*
		B	6 (75%)	2 (25%)	
	>25	A	15 (37.5%)	25 (62.5%)	0.737
		B	16 (34%)	31 (66%)	
Smoking	Yes	A	2 (50%)	2 (50%)	0.429*
		B	0 (0%)	3 (100%)	
	No	A	28 (54.9%)	23 (45.1%)	0.201
		B	22(42.3%)	30 (57.7%)	
Duration (years)	≤5	A	18 (100%)	0 (0%)	1.000*
		B	9 (100%)	0 (25%)	
	>5	A	12 (32.4%)	25 (67.6%)	0.681
		B	13 (28.3%)	33 (71.7%)	
Co-Morbidity	Diabetes	A	12 (70.6%)	5 (29.4%)	0.138*
		B	5 (38.5%)	8 (61.5%)	
	Hypertension	A	10 (40%)	15 (60%)	0.676
		B	10 (34.5%)	19 (65.5%)	
	Others	A	8 (61.5%)	5(38.5%)	1.000*
		B	7 (53.8%)	6 (46.2%)	

*Fischer Exact Test

The correlation analysis revealed strong and significant relationships among various clinical parameters in psoriatic arthritis patients with associated fibromyalgia. Duration of disease showed the strongest correlations with other variables, particularly with BASDAI (r = 0.828, p < 0.001) and CDAI (r = 0.815, p < 0.001). BMI demonstrated significant positive correlations with all measures, most notably with duration of disease (r = 0.778, p < 0.001) and BASDAI (r = 0.764, p < 0.001). The Clinical Disease Activity Index (CDAI) showed strong correlations with BASDAI (r = 0.797, p < 0.001). HAQDI demonstrated moderate to strong correlations with all parameters, ranging from r = 0.568 to r = 0.651 (all p < 0.001) as shown in Table 4.

Table 4

Correlation Analysis of Clinical Parameters in Psoriatic Arthritis Patients with Associated Fibromyalgia

Variables		BMI	Duration of Disease	CDAI	BASDAI	HAQ-DI
BMI	Pearson Correlation	1	.778*	.732*	.764*	.619*
	Sig. (2-tailed)		0.000	0.000	0.000	0.000
	N	110	110	110	110	110

Duration of Disease	Pearson Correlation	.778*	1	.815*	.828*	.651*
	Sig. (2-tailed)	0.000		0.000	0.000	0.000
	N	110	110	110	110	110
CDAI	Pearson Correlation	.732*	.815*	1	.797*	.624*
	Sig. (2-tailed)	0.000	0.000		0.000	0.000
	N	110	110	110	110	110
BASDAI	Pearson Correlation	.764*	.828*	.797*	1	.568*
	Sig. (2-tailed)	0.000	0.000	0.000		0.000
	N	110	110	110	110	110
HAQ-DI	Pearson Correlation	.619*	.651*	.624*	.568*	1
	Sig. (2-tailed)	0.000	0.000	0.000	0.000	
	N	110	110	110	110	110

*Correlation is significant at the 0.01 level (2-tailed)

Logistic regression analysis comparing treatment responses between biological and conventional synthetic DMARDs in psoriatic arthritis patients with associated fibromyalgia, the Health Assessment Questionnaire Disability Index (HAQDI) emerged as the only statistically significant predictor (B = 7.735, p = 0.033). The high odds ratio for HAQDI (OR = 2287.131) suggests that disability status strongly influences treatment response outcomes. The analysis also revealed several non-significant but potentially relevant clinical factors. BMI showed a positive association (B = 0.711, p = 0.130, OR = 2.036), as did disease duration (B = 1.275, p = 0.164, OR = 3.580) and smoking status (B = 9.398, p = 0.729, OR = 12066.423). These findings suggest that functional disability, as measured by HAQDI, may be a crucial factor in determining treatment response when choosing between biological and conventional synthetic DMARDs for psoriatic arthritis patients with concurrent fibromyalgia. The model included a constant term of -35.554 (p = 0.114), indicating a baseline relationship between the variables and treatment outcomes as shown in Table 5.

Table 5

Logistic Regression Analysis of Factors Affecting Treatment Response in Psoriatic Arthritis Patients with Associated Fibromyalgia: Biological vs Conventional Synthetic DMARDs

Variable	B Coefficient	S.E.	Wald	p-value	Odds Ratio (95% CI)
HAQDI	7.735	3.631	4.538	0.033*	2287.131
BMI	0.711	0.47	2.289	0.13	2.036
Duration of Disease	1.275	0.916	1.941	0.164	3.58
Smoking	9.398	27.076	0.12	0.729	12066.42
Constant	-35.554	22.478	2.502	0.114	0

DISCUSSION

The results revealed that both groups showed significant variation in both demographics and clinicopathologic factors, but no significant variation in overall group therapy good response (p = 0.127) between them was detected. What such a result signifies is that, even with a general assumption of bDMARDs being a more potent therapy, in such a group of subjects, its effectiveness will not necessarily be markedly larger when overall therapy response is considered.

Several clinical factors, such as disease duration and BMI, have a strong potential to serve as confounding variables in efficacy assessments of treatment, correlating with disease activity indices (BASDAI, CDAI). Association between disease duration and disease activity indices (r = 0.828 for BASDAI, r = 0.815 for CDAI) can, in a scientific context, be understood in terms of psoriatic arthritis's ongoing disease, with a rise in disease severity with increased disease duration. Association between disease activity indices and BMI (r = 0.764 for BASDAI and r = 0.778 for disease duration) is in agreement with the established principle that obesity can intensify disease severity and exacerbate inflammation in autoimmune disease and, in a similar fashion, can serve as a confounding variable in disease activity evaluations in psoriatic arthritis.

Further, the logistic regression analysis revealed that functional disability, measured with the HAQ-DI, is a significant predictor for a favorable therapeutic response (OR = 2287.131, p = 0.033), with a high level of disability predicting a greater likelihood of therapeutic response in a positive manner. The demographic profile of our study shows that biologic-treated and conventional synthetic-treated subjects have a mean age of 47.31 ± 9.38 years and 52.75 ± 11.35 years, respectively, with a significant age difference between them. In agreement with observations in the Nordic biologics registries study in Glintborg et al. [18] initiation with adalimumab in biologic-naïve subjects tends to occur in relatively younger subjects in comparison with initiation with newer b/tsDMARDs. Freites-Nuñez et al. [19] have also stated that in a switch cohort of PsA, the mean age was in the fifties in switchers between biologics, as in our patient group. In our study, a slightly increased mean age in conventional therapy could possibly represent a reflection of physician preference for early initiation with biologics in younger subjects in an attempt to prevent long-term joint damage.

Our study also determined that the BMI in biologic-treated subjects was 27.45 ± 4.59 kg/m², and in conventionally synthetic-treated subjects was slightly higher at 28.43 ± 3.76 kg/m². Vallejo-Yagüe et al. [20] in a study revealed that disease severity is in part determined by BMI, with increased disease activity and diminished quality of life in obese subjects with PsA. In contrast, in our study, no predictive value for a favorable response (p = 0.111) for BMI could be established, even with a trend towards increased response in lower groups of BMI. There is a possibility that such variation may arise from the fact that our study evaluated stratification in terms of a favorable response, not overall disease activity, and that Vallejo-Yagüe et al. [20] analyzed direct associations of BMI with markers of inflammation and quality of life measures.

Regarding disease duration, our analysis revealed that biologic therapy patients exhibited a shorter mean

disease duration (8.86 ± 7.31 years) in comparison with conventional synthetic therapy (12.27 ± 7.51 years). In agreement with Künzler et al. [21] who found disease duration to have an inverse relation with a favorable therapeutic response (OR = 0.789, 95% CI: 0.663–0.938), our logistic model affirms this, with disease duration (B = 1.275, p = 0.164, OR = 3.580) having a positive but non-significant association with a favorable therapeutic response. This suggests that early therapy with biologics can have a beneficial role, in agreement with the application of a treat-to-target therapy for PsA management.

When evaluating disease activity, in our study, CDAI in the group of patients under biologic therapy (18.27 ± 8.78) was lower compared with that in the group under conventional synthetic therapy (22.85 ± 4.59). Similarly, in the group under biologic therapy (6.77 ± 2.78), BASDAI was lower compared with that in the conventional group (8.29 ± 1.78). All these observations agree with Glintborg et al. [18] who have demonstrated that adalimumab-treated subjects experienced better disease control and retention compared to newer b/tsDMARDs when used in a second or a third-line therapy. In a similar context, in our study, a higher proportion of a favorable therapeutic response in the group under biologic therapy (54.5%) compared to conventional therapy (40%) was observed, but such a variation did not occur at a level of statistical significance (p = 0.127). Perhaps, a relatively small cohort and a high prevalence of fibromyalgia, a known confounding factor with a documented impact on therapeutic efficacy,[22] may have contributed to the absence of statistical significance in this case.

The influence of gender in our analysis, however, did not have any significant impact (p = 0.374 for males, p = 0.471 for females). However, Künzler et al. [21] revealed that male sex was associated with significant improvement in therapy (OR = 2.188, 95% CI: 1.912–2.503). There may have been a range of explanations for this discrepancy, including differences in sample composition, as our analysis included a cohort with fibromyalgia, a female-predominant disease and one with a documented role in modulating pain perception and affecting efficacy of therapy.[22]

Smoking prevalence in both groups in our study (7.3% in biologic group and 5.5% in conventional group) was low, and smoking status did not have a significant effect on treatment (p = 0.429 for smokers, p = 0.201 for non-smokers). Unlike other studies, such as Costa et al. [23] where it was suggested that TNFi therapy could be affected in a negative manner by smoking, in our study, with a low prevalence of smoking in our population, such an impact was likely not statistically significant.

The correlation analysis in our study revealed significant associations between a number of the clinical parameters, with disease duration having the most significant associations with BASDAI (r = 0.828, p < 0.001) and CDAI (r = 0.815, p < 0.001). There was a strong association between disease duration and BMI (r = 0.778, p < 0.001) and between disease duration and BASDAI (r = 0.764, p < 0.001). All these findings agree with Vallejo-Yagüe et al. [20] who have identified obesity as a predictor for a poor disease prognosis.

This study has several limitations. As a single center study, its generalizability to larger populations with variable access to healthcare and different care delivery protocols is limited. The relatively small cohort reduces statistical power, particularly in subgroup analysis. The presence of fibromyalgia as a confounding variable could have influenced treatment efficacy, and future studies will need to assess its role in larger, multi-center populations. The absence of long-term follow-up data further limits the ability to evaluate sustained treatment effectiveness.

CONCLUSION

Our study has concluded that both biologic and conventional synthetic treatments for psoriatic arthritis exhibit similar overall therapeutic responses, with no significant difference observed between the two groups. However, factors such as disease duration, BMI, and functional disability were found to play a crucial role in predicting treatment outcomes. Specifically, functional impairment, as measured by the HAQ-DI, emerged as a significant predictor of therapeutic response. These findings emphasize the importance of a personalized treatment approach that considers individual patient characteristics and comorbidities, such as fibromyalgia, to optimize therapy in psoriatic arthritis management.

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