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Original Research Paper

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RETROSPECTIVE STUDY OF THE EFFICACY AND SAFETY OF INFLIXIMAB IN MODERATE TO SEVERE PLAQUE PSORIASIS PATIENTS

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ABSTRACT This was a retrospective observation study, which evaluated the effectiveness of infliximab in inflammatory plaque psoriasis. Fifty patients, 18 years and older, of both genders who had taken infliximab therapy at an out-patient dermatology department at a tertiary care hospital, Pondicherry were selected. The patients received 80 mg infliximab loading dose and 40 mg maintenance dose at every alternate week. The Psoriasis Area and Severity Index (PASI) was used to measure efficacy at baseline (week 0), 4 weeks, 12 weeks and 52 weeks. The findings were significant with 96%, of the patients showing a PASI 75 at week 52. Also, there were no major differences in the efficacy of the treatment in the biologic-naive and non-naive patients. The results point at the efficacy of infliximab to treat moderate-to-severe forms of the plaque psoriasis and denote the fact that infliximab can be regarded as a worthwhile therapeutic solution to both biologics naive and to non-naive patients. It is suggested that further research involving large sample studies and randomized controlled study should be done to validate long term safety and efficacy of infliximab in the treatment of Psoriasis.

KEYWORDS : Infliximab, plaque psoriasis, PASI Score, Biologic Therapy, Psoriasis Treatment.

INTRODUCTION

The most common type of psoriasis is plaque psoriasis, which is a long-term autoimmune skin disease behind the excessive speedy growth of skin cells [1-3]. The development of thick plaques and scale on the skin that are usually located at the elbow, knees, scalp and lower back. Generally, psoriasis is a multifactorial disease that has been affected by genetic, immunological, and environmental factors. When it comes to plaque psoriasis, it is presented in the shape of clear red or silvery, well-defined plaques, which in most cases are elevated, inflamed and scaled with a white or silvery layer [4]. Such plaques may be painful, itchy, prone to cracks, or bleeding, which to physical and emotional discomfort. The precise etiology of the plaque psoriasis is not fully comprehended yet, though it is reported to be associated with the failure of the immune system [6-9]. The disorder is precipitated by hyperactive immune system in which T-cell, a white blood cell wrongfully assaults normal skin cells. This immune assault generates an inflammatory cascade which speeds the routine renovation of skin cells [10]. In plaque psoriasis this process hastened with skin cells being produced too rapidly and coming to the surface only in a matter of days [11]. This high turnover results to accumulation of dead skin cells that result to thick and scaly patches or plaque.

Some genetic markers related to psoriasis have been known, and the most important is the human leukocyte antigen (HLA)-Cw6 gene that predisposes people to the disease [12-14]. This is also a powerful risk factor, as individuals, whose relative has psoriasis in the first degree, are at risk: they are more likely to have psoriasis compared to the rest.

Psoriasis may progress to psoriatic arthritis when in extreme situations; there is the pain and swelling of joints in addition to the overall well-being of a person [15, 16].

The emphasis of plaque psoriasis treatment lies in treating its symptoms and alleviating the inflammation, because at the moment it is not possible to cure plaque psoriasis yet. Topical therapies, phototherapy, and systemic are the main types of treatment. The initial action is normally topical and could involve corticosteroids, vitamin D analoges (including calcipotriene), and retinoids. The purposes of these treatments are to minimise inflammation, decelerate skin cell turnover and eliminate itching. When moderate or severe plaque occurs, it may be helpful to use phototherapy. Biologics, immunosuppressive medications, and systemic treatments in general are applied in patients who either have severe or refractory disease that is resistant to topical therapies. TNF-alpha inhibitors (e.g., etanercept, infliximab), interleukin (IL)-17 inhibitors (e.g., secukinumab) and IL-23 inhibitors (e.g., guselkumab) are biologics that are revolutionizing the treatment of plaque psoriasis [17]. These biologics attack a particular part of the immune system contributing to the process of inflammation, which gives a considerable degree of improvement in symptoms and quality of life and increases in several patients.

MATERIALS AND METHODS

It was a hospital-based, analytical retrospective observational study where patients aged 18 years and above, irrespective of gender, who were treated with infliximab to manage moderate-severe psoriasis at the outpatient dermatology department at a tertiary care hospital, Pondicherry, participated. Women who were pregnant/lactating, severely immunocompromised; and individuals with active infection were not included in the study. The analysis took place within a 12 month time frame. Extensive patient histories were taken, and findings of different screening activities were considered.

The proposed sample size was based on an alpha-error of 0.05, a beta-error of 0.2, a conjectured mean difference of 5.6 in the outcome measure, and an assumed standard deviation of 4.5 of the difference between the groups. Infliximab 80 mg was administered during week 0 and after week 1, followed by 40 mg every two weeks until week 32. The treatment response was assessed at 4-week, 12 weeks, and 52 weeks, by monitoring the Psoriasis Area and Severity Index (PASI) compared to the pre-treatment (baseline) PASI score. There was no comparative group, so PASI scores were compared over time, such as baseline (week 0) and every 4 weeks and 12 weeks, as well as 52 weeks. On data analysis, continuous variables were described in terms of means and their standard deviations, whereas categorical variables were reported in terms of proportions and percentages.

RESULTS

Based on the sample population comprising of 50 patients with moderate-to-severe plaque psoriasis treated with infliximab at the outpatient dermatology department at a tertiary care hospital. Data obtained during the study has consisted of demographics, clinical characteristics and the efficacy of infliximab as shown by Psoriasis Area Severity Index (PASI) at various intervals 4, 12 and 52 weeks.

Gender And Age Distribution Of Patients

According to the demographic characteristics of the study population, 38 (76 percent) out of the total 50 patients sampled in the study were males and 12 (24 percent) were females. Age group of the patients was as follows; 26.3 percent of the patients were between 18-30 years, 31.5 percent were between 31-40 years, 21.1 percent were between 41-50 years and 21.1 percent were between 51-60 years. There were no patients aged more than 60 years. According to these findings psoriasis is mostly common in the males and the peak age group is the 31- 40 years age group.

Baseline Characteristics

The average height of the participants was 155.4 +/- 11.4 cm, and average BMI 23.6 +/- 2.91. Regarding the type of psoriasis, 82 and 18 percent of the patients had chronic plaque psoriasis and chronic plaque psoriasis accompanied by arthritis respectively. Twenty six percent of the cases had a psoriasis family background. The comorbidities were diabetes (22%) and hypertension (6%), indicating that these conditions often coexist with psoriasis

A Comparison Of PASI Scores At Various Weeks

Efficacy in this study was mainly being measured over changes in PASI scores. Table 3 demonstrated a significant increase in people with PASI scores over the time. The baseline value of the PASI score was 23.305 4.37. At week 4, the PASI score decreased to 12.347 +/- 5.11 showing a significant change ($p = 0.0001$). At 12 weeks, the PASI score fell still further (to 4.247 3.39) to testify to the further symptomatic improvement in severity of psoriasis ($p = 0.0001$). At 52 weeks, there had been uplifting in the PASI; it diminished to 0.560 0.96 ($p = 0.0001$). Such a huge decline in the PASI scores indicates that infliximab is very effective in phototherapy of moderate-to-severe plaque psoriasis with almost all of the patients achieving PASI 75 score.

Characteristics Of Biologically Naive And Non-Biologically Naive Patients

Analysis of the age, weight, height, and BMI before the treatment were found to be no significant difference between biologically naive and non-naive patients (previous received biologic therapy patients). The mean age of biologic naive patients was 34 years +7.54, compared to that of non-naive patients which was a little higher to 42.27 years +7.87. The mean weights of the biologic naive patients were 75 +/- 6.49kg, and non-naive patients had a mean weight of 66.55 +/- 8.07kg. Analysis of the findings indicates that the average weight was higher in the biologic naive group but this was not a statistically significant difference ($p = 0.27$). In the same way, no significant difference existed between the groups of BMI and height. These findings indicate that response to infliximab does not depend on past exposure to biologics in patients.

A Comparison Of Different PASI Studies

As compared with the results of other studies, when contrasting this study with other studies, it was established that the infliximab treatment results in a remarkable reduction in the PASI scores in the implementation of diverse clinical settings. In the present research, 96 percent of the patients scored PASI 75.

Table 1: Gender And Age Distribution Of Patients.

Gender	Age (in years)	Total	18-30	31-40	41-50	51-60	>60
Male	N (%)	38 (76)	10 (26.3)	12 (31.6)	8 (21.1)	8 (21.1)	0 (0)
Female	N (%)	12 (24)	0 (0)	6 (50.0)	6 (50.0)	0 (0)	0 (0)

Table 2: Before Starting Infliximab, The Study Population Had The Following Characteristics

Variables	Findings
Gender	
Male (%)	38 (76)
Female (%)	12 (24)
Age (in years)	**Mean (SD)**
	38.4 (8.31)
Weight (in kg)	**Mean (SD)**
	67.41 (8.02)
Height (in cm)	**Mean (SD)**
	155.4 (11.4)
BMI	**Mean (SD)**
	23.6 (2.91)
Psoriasis type	**%**
Chronic plaque psoriasis	22 (82)
Chronic plaque psoriasis with arthritis	6 (18)
Family history	
Present	8 (26)
Absent	17 (74)
Co-morbidities	%
Nil	17 (72)
Diabetes	6 (22)
Hypertension	2 (6)
Duration of illness (years)	**%**
1	6 (29)
2	3 (15)
3	1 (6)
4	1 (6)
5	4 (22)
6	4 (22)
>7	-

Table 3: A Comparison Of PASI Scores At Various Weeks After Starting Infliximab Treatment

PASI Score (Weeks)	PASI Score (Mean ± SD)	t-value	df	P-value
0 and 4	23.305 ± 4.37 and 12.347 ± 5.11	13.890	24	0.0001
0 and 12	23.304 ± 4.37 and 4.247 ± 3.39	30.337		
0 and 52	24.416 ± 3.26 and 0.560 ± 0.96	36.187		
4 and 12	12.347 ± 4.07 and 3.247 ± 2.39	10.606		
4 and 52	11.247 ± 4.08 and 0.558 ± 0.96	12.652		
12 and 52	3.247 ± 2.38 and 0.558 ± 0.97	7.233		

Table 4: Characteristics Of Biologically Naive And Non-biologically Naive Patients Before Treatment.

Variables	Biologic Naive (Mean ± SD)	Non-Naive (Mean ± SD)	P-value
Age	34 ± 7.54	42.27 ± 7.87	0.34
Weight	75 ± 6.49	66.55 ± 8.07	0.27
Height	167.10 ± 6.13	166.03 ± 11.9	0.66
BMI	24.4 ± 1.4	23.17 ± 4.01	0.19

Table 5: A Comparison Of Different PASI Studies.

Study Design	Treatment Protocol	Baseline Mean PASI	PASI 75 Achievement (%)
Retrospective	80 mg loading, followed by 40 mg every other week	23.3	94
Retrospective	80 mg loading, followed by 40 mg every other week	14.8	93
Retrospective COHORT (15-	20 mg loading, followed by 20 mg eow. (≥30 kg) 40	13.6	54.4

30 kg)	mg loading, followed by 40 mg eow.		
12-week, randomized, double-blind, placebo-controlled	80 mg loading followed by 40 mg every other week	15.6	-

DISCUSSION

Based on the findings of this study, it can be concluded that infliximab is very effective in procuring in managing the moderate-to-severe plaque psoriasis by the drastic decline in the PASI scores at various follow-ups. The observation that 96 percent of patients successfully reached the PASI 75 within 52 weeks is in tandem with other studies that reveal that the use of infliximab may initiate sustained reduction of psoriasis severity [18]. These findings affirm the importance of infliximab as a medical intervention in a difficult-to-treat psoriasis especially one in which patients with previously failed conventional interventions. Biologic therapy in the treatment of psoriasis is also discussed where non-naive patients who experienced the same improvement in PASI level as biologic naive patients was observed. It implies that infliximab may perform well in previously biologic-treated patients, which is another indication of its use in long-term management of psoriasis.

Moreover, the absence of meaningful differences in the patient profiles, including BMI and age, between the biologic naive and non-naive patients indicates the absence of the variability of infliximab effectiveness in terms of having used biologics previously or not, which infers the generalizability of the drug to the broad population of patients [19-21]. The lack of a control group can be considered one of the study limitations: the study compared PASI scores after and before treatment but it was done on the same group of the participants. Although this will give important data on the efficacy of the drug, further investigation using well designed randomized controlled trials may be useful to establish better data on comparative efficacy of infliximab use with other biologic agents.

CONCLUSION

Infliximab is an effective therapy in management of moderate to severe plaque psoriasis which results in large changes in PASI scores and the realization of PASI 75 in most patients. The research indicates that the infliximab treatment is effective to be employed in either the biologic-naive or non-naive patients without any substantial variation in the treatment response. These results again support the use of infliximab in the treatment of psoriasis, as a useful treatment tool, especially in moderate to severe cases. Larger sample size should be used with the research design as randomized controlled trial to further establish these results and ascertain the long term effectiveness and safety of infliximab as a form of psoriasis treatment.

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