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ORIGINAL ARTICLE

Efficacy and safety of Infliximab biosimilar, REMSIMA® in treatment of chronic plaque psoriasis.

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ABSTRACT… Objective: To assess the efficacy and safety of REMSIMA®, a biosimilar of infliximab in treatment of chronic plaque psoriasis. **Study Design: N**on-randomized Clinical Trial. **Setting:** Departments of Dermatology, GTTH and SIMS Lahore. **Period:** April, 2022 to July, 2023. **Methods:** A multi-centered study was conducted for which Informed consent was obtained for treatment with REMSIMA 120mg S/C given at 0,1,2,3,4,6,8,10 and 12 weeks. PASI was calculated at 0,4,8 and 12 weeks. Efficacy was measured as achievement of PASI-75 at 12 weeks. Relapse was checked on monthly regular follow ups till 24 weeks. **Results:** A total of 51 diagnosed patients of chronic plaque psoriasis were enrolled (1 was lost to follow-up, 1 had continuous fever, 1 discontinued due to elevated LFT's) 48 continued the treatment (72.9% males, 27.1% females) with age 18-59 years. Disease duration was >10 years in 20 patients and <10 years in 28 patients. Prior systemic treatment was taken by 75% patients. Average PASI was 22.50 at baseline. Results at 12 weeks post-treatment showed that PASI-75 was achieved by 93.75% patients with average PASI being 1.24 ($p<0.001$). Adverse events were noted in 4 (8.3%) patients i.e 3 had recurrent upper respiratory tract infections and 1 patient had dizziness and sweating post 1st dose. Relapse was observed in 5 patients. **Conclusion:** Remsima is efficacious and safe, although expensive but the patient can be shifted to cost-effective therapy once the disease is controlled.

Key words: Psoriasis, PASI Score, Remsima.

INTRODUCTION

Psoriasis is a chronic inflammatory, immunologically mediated cutaneous malady which involves multiple systems. Most important factor in initiation and progression of psoriasis is TNF-α.[1] Patients develop plaques and papules on skin of different shapes and sizes.[2] Psoriatic patients may develop psoriatic arthritis approximately at 40 years of age.[3] Early age onset psoriasis leads to more physical impairment.[4] Patients get trapped in a vicious cycle as stress leads to further aggravation of disease.[5]

TNF-α up-regulates vascular endothelial growth factor causing increased micro-vascular permeability with angiogenesis. It also targets lymphocytes towards inflammatory lesions.[6]

The major pathology in psoriasis is hyper-proliferation of epidermis with defective differentiation and dermal and epidermal inflammatory cells infiltration.[7]

INFLIXIMAB is a monoclonal antibody with high affinity and specificity to TNF-α receptors and neutralises its biological activity after binding.[8] INFLIXIMAB has 25% murine and 75% human component and is licensed for use in psoriasis when it is moderate to severe and resistant to systemic treatments including Methotrexate, Cyclosporin, UVB and UVA with psoralen (PUVA).[1,7]

The European Medicine Agency gave approval for use of INFLIXIMAB biosimilar REMSIMA for treating psoriasis after considering its effectiveness for ankylosing spondylitis and rheumatoid arthritis in different studies.[9]

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Dapavo et al, study suggested that 80.0% patients who were INFLIXIMAB naïve and were started on its biosimilar attained 75% amelioration at the end of induction therapy phase from baseline PASI score.[10]

Biosimilars have the same pharmacodynamic and pharmacokinetic properties but are cheaper option than their biological originator. REMSIMA or CTP13 was made considering the FDA and EMA latest guidelines, hence it complies with all the regulations.[11]

Psoriasis is a persistent condition which demands prolonged management, so it puts heavy financial as well as psychological burden on patients.[12]

Severe psoriasis makes work impossible for patients.[13] Lesions on exposed body parts may lead to low self-esteem, social avoidance, and shame.[14] Even mild form of psoriasis has high stigma than other cutaneous diseases.[15] Overall, psoriatic individuals experience greater difficulty in social interactions and employment.[16]

This study is being conducted as no data is present on REMSIMA in patients of psoriasis in Pakistan and aims to determine efficacy and safety of Infliximab biosimilar REMSIMA® in treatment of chronic plaque psoriasis. (NCT06043752)

METHODS

It was non-randomized Clinical trial with non-probability / consecutive sampling. The study was conducted in out-patient Departments of Dermatology of Ghurki Trust Teaching Hospital, Lahore and Services Hospital, Lahore. We included the clinically diagnosed patients of moderate to severe psoriasis from both genders between age of 18-59 years, who were resistant to topical and conventional systemic treatments i.e., methotrexate, cyclosporine & phototherapy and having PASI score >10. We excluded the patients with active systemic lupus erythematosus, positive ANA, active tuberculosis, cardiac disease, extreme immunocompromise, allergy to REMSIMA, pregnant and lactating females. Sample size was 51 calculated with confidence interval 90 %, margin of error 10 % and assumed proportion of patient with improvement in PASI = 75%,.[10]

Study was started after approval from institutional ethical committee (Ref.No. LM&DC/5366-67/2022, Dated 14.04.2022). We enrolled 51 patients presenting in dermatology out-patient department fulfilling inclusion criteria. An informed written consent was obtained, diseased areas were photographed and baseline PASI was calculated. The patients were given oral pheniramine 25 mg half hour before the injection. The patients were given subcutaneous injection of REMSIMA 120 mg at 0, 1, 2, 3, 4 weeks and afterwards with 2 weeks intervals i.e., at 6, 8, 10 and 12 weeks. The patients were observed for half an hour after giving the injection for any reaction and were discharged afterwards in case of no immediate side effect. The response was assessed at 4, 8 and 12 weeks. Relapse was checked with regular follow up till 24 weeks. Efficacy was measured as percentage reduction in PASI score, with PASI75 as primary endpoint and PASI-90 as secondary endpoint at end of 12 weeks. Relapse was loss of primary end point during follow up period.

Safety was measured in terms of adverse events noted during the study period. Any adverse event including skin changes at injection site, acute and delayed hypersensitivity reactions, infections, reactivation of tuberculosis and biochemical changes were observed and recorded. Data was collected using predefined Pro forma including variables i.e gender, age and disease duration etc.

Data entry along with analysis was commenced with 22.0 version of SPSS. Frequencies and percentages were utilized for qualitative variables e.g gender. For quantitative variables (age, duration of disease, PASI Score, adverse events) calculation of standard deviation and mean was done. Data was stratified for gender, duration of disease and age. After stratification we used paired t-test for PASI score at baseline and end of the treatment period. Chi square test was used to evaluate efficacy and safety with p-value <0.05 as significant.

Variables	N	%	Mean±SD (Range)	P-Value
Gender				
Male	35	72.92		
Female	13	27.08		
Age(years)			38.96±10.35 (17-59)	
Duration				
<10 years	28	58.3		
>10 years	20	41.7		
PASI Score				
Baseline			22.50±11.01 (10-53)	<.001
4 weeks			8.60±10.37 (.40-64)	
8 weeks			2.48±2.96 (0-15)	
12 weeks			1.24±2.18 (0-11.40)	
24 weeks			2.30±4.71 (0-27)	
Side effects				
Yes	4	6.3		
No	44	93.8		
Biochemical Evaluation				
Yes	3	6.3		
No	45	93.8		
Relapse				
Yes	5	10.4		
No	43	89.6		

Table-I. Demographic characteristics of Chronic plaque psoriasis (N=48)

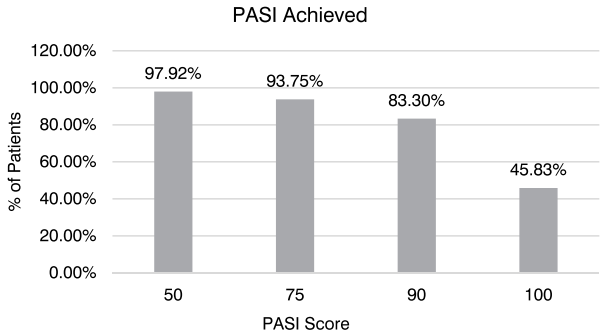
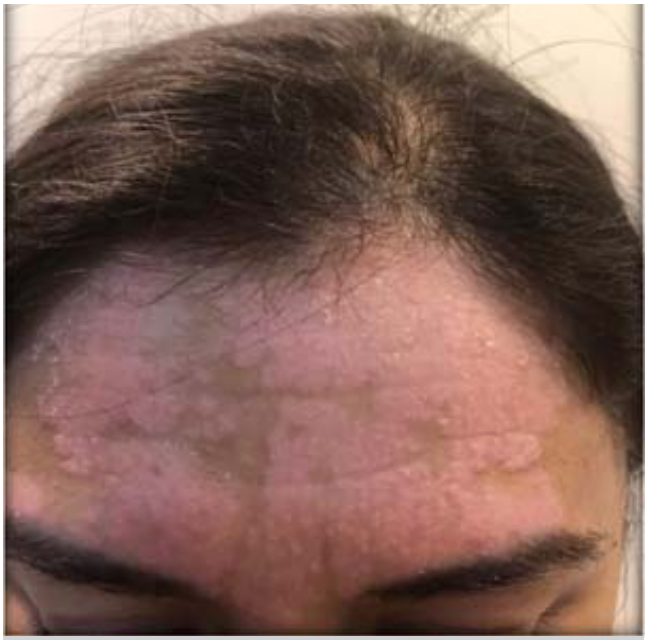
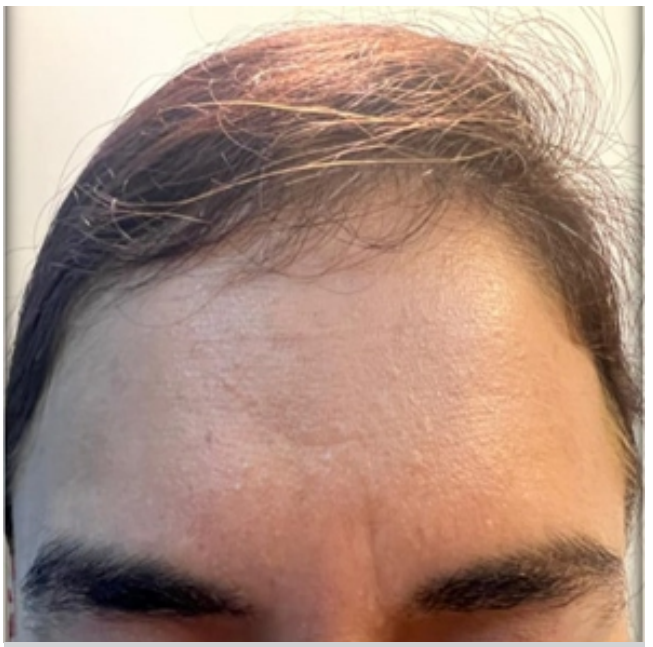


Figure-1: Average PAS1 Score



Before



After

DISCUSSION

Our study showed that primary and secondary end points were achieved in 93.75% and 83.3% of the patients, respectively. A similar study by Dapavo et al. showed no difference in PASI score among 30 patients who were shifted from infliximab to REMSIMA while 80.0% INFLIXIMAB naïve patients who were started on its biosimilar attained 75% amelioration at the end of induction

therapy from baseline PASI score.[10]

Similarly, Panagakis et al. showed 75% decrease in PASI in 28 patients (80%) after 12 weeks of therapy in severe plaque psoriasis with infliximab.[17] EXPRESS trial at 10 weeks demonstrated PASI ≥ 75, PASI 90 and PASI100 in 80%, 57% and 26% respectively with infliximab treatment. Week-24 results showed achievement of PASI 75 and 90 by 82% and 58% patients, respectively. While at 50 weeks 45% and 61% patients achieved PASI 90 and PASI 75, respectively.[4] EXPRESSII trials evaluated infliximab for psoriasis showing at week-10 PASI 75 was seen in 76% patients in 5mg/kg group and 70% in 3 mg/kg group. Continuous therapy showed better response as at week 50, 44% patients with 3 mg/kg dose and 55% with 5 mg/kg dose achieved PASI 75, compared to 25% and 38% on intermittent therapy.[18]

Continuous therapy showed higher efficacy in RESTORE trial. PASI 75 at week-52 was demonstrated in 80% of patients having continuous therapy and 47% patients having intermittent therapy.[19] REALITY study 14 weeks results showed achievement of PASI75 in 60.8%, while PASI90 was achieved in 35.1%. Results at 50 weeks were following; 56.8% achieved PASI75 and PASI90 was seen in 39.4% of patients. These values were lower as compared to our study. Sufficient response was increasingly observed in biologics naïve patients as among eligible patients 42% were previously treated with biologics. Extended therapy phase showed mean PASI change was 84.2% from baseline at 98 weeks with 66.3% achieving PASI75 and 48.5% having achieved PASI90.[20]

Schopf et al. [21] demonstrated an average of 88% improvement at week-14 in PASI and Poulalhon et al.[22] demonstrated 68% of the patients achieved PASI75. The NORSWITCH study switching from Infliximab to the biosimilar CT-P13 has similar outcome as the original drug.[23] In rheumatic diseases biosimilar drugs were equally efficacious, tolerable, and had similar immunogenic potential when compared to originals, but more studies are needed for assessing interchangeability in psoriasis.[24]

The RESTORE trial found similar side effects in intermittent and continuous therapy, but serious ones were more common in continuous therapy. In our study, no serious side effects occurred, with only 3 patients reporting upper respiratory infections.[19]

Similarly, in long-term study headache and arthralgia in 2.7% and pruritus, upper respiratory tract infection and urticaria in 2.3% of patients were noted. During treatment 7.6% patients had serious side effects which were consistent with previous infliximab studies, but our study demonstrated fewer sider effects possibly due to shorter course of the treatment. [20]

Clinical practice gives information that is difficult to acquire from clinical trials. Our study limitations include its open design, limited data, absence of control group and selection bias.

CONCLUSION

A 12-week therapy with biosimilar infliximab shows good efficacy clinically, in patients with chronic psoriasis of plaque type and was safe. Hence infliximab bio similar REMSIMA is safe and effective in our patients of psoriasis.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Nabigha Khalid:** Conceptualization writing majority of the manuscript and overall project management,
2	**Saelah Batool:** Conducted experiment and contributed to data analysis
3	**Sumera Hanif:** Assisted in writing section and provided critical revision
4	**Talat Akbar:** Gathered literature and contributed to discussion section
5	**Faria Asad:** Provided statistical analysis and support for methodology
6	**Haroon Nabi:** Supervisor and head, formatting and final proof reading