

Review Form 1.6

Journal Name:	Asian Journal of Research in Dermatological Science
Manuscript Number:	Ms_AJRDES_87414
Title of the Manuscript:	Infliximab in the treatment of severe psoriasis vulgaris patients
Type of the Article	Original Research Article

General guideline for Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound. To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

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PART 1: Review Comments

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<u>Compulsory</u> REVISION comments	<p>Dear Authors,</p> <p>This manuscript addresses a current trend that is the treatment of psoriasis with immunobiological medications. Infliximab was the first to be used (already +/- 20 years on the market) and its efficacy, tolerability and safety have already been well documented in previous real-life studies. However, the experience of new centers and in different populations is always interesting. So, some comments, corrections and suggestions are listed below</p> <p>GENERAL COMMENTS</p> <p>A strict review of the English language by an expert (many typographical, grammatical and verbal mistakes) becomes imperative as it is greatly compromising the global understanding and quality of the manuscript.</p> <p>POINT TO POINT COMMENTS</p> <p>TITLE:</p> <p>Better be re-written as:</p> <p>“Infliximab in the treatment of severe psoriasis vulgaris”</p> <p>ABSTRACT</p> <p>Below a new version suggested for the abstract.</p> <p>Remind: It should not exceed 300 words in length (see General Guideline for Authors).</p> <p>Introduction: Psoriasis is a chronic, immune mediated inflammatory disease. The inflammatory activity of the psoriasis plaques is partially triggered by activation of the Th1 lymphocytes which release pro-inflammatory chemokines and cytokines such as tumor necrosis factor alpha (TNF-α). Infliximab is a chimeric monoclonal anti body that neutralize the biologic activity of TNF-α. The aim of this study was to assess the efficacy and tolerability of infliximab in severe cases of psoriasis vulgaris.</p>	<p>All the necessary corrections were done as indicated</p> <p>All the necessary corrections were done as indicated</p> <p>Comment accepted and considered</p>

	<p>Materials and Methods: Twenty patients were included in the study. Twelve men and eight women with severe psoriasis vulgaris, were assigned infliximab infusion 5 mg/kg at weeks 0, 2 and 6, followed by maintenance therapy every 8 weeks. For each patient psoriasis activity and treatment efficacy were assessed by measuring Psoriasis Area Severity Index (PASI) scores.</p> <p>Results: Among the 20 patients enrolled in this study, 2 patients were dropped out from the study after first dose due to acute adverse effects (hypotension and mild urticarial reaction). Eighteen patients had completed the course of treatment (32 weeks). Mean PASI score at baseline was 32.88 ± 10.87. PASI score was greatly reduced from 32.8 to 16.2 in 6 weeks and to 2.2 in 10 weeks time. Fifty percent of improvement in PASI score with the first dose (2 weeks) was achieved in 8 patients (45.5%). About 90% of improvement was seen in most of the patients (16) at sixteenth week and all patients had complete clearance at weeks 24 and 32. Urinary tract and upper respiratory tract infections were delayed adverse effects developed by 2 of 20 patients (10%). All the reported infections were mild and were treated during infliximab course.</p> <p>Conclusion: Infliximab was found to be safe, effective and well tolerated in the treatment of severe, recalcitrant psoriasis vulgaris.</p> <p>*Abstract RESULTS – line 11 (with yellow highlight) Wouldn't it be 18 patients instead of 20? Two patients were dropped out in baseline due to acute adverse effects, weren't they? Please review this data.</p> <p>KEYWORDS Keywords should be reviewed according to <i>MeSH</i> (Medical Subject Headings). Suggestion: Psoriasis; Treatment; Infliximab; Safety; Effectiveness, treatment; Drug tolerance.</p> <p>MAIN TEXT INTRODUCTION 2nd paragraph – 1st line “Burd 2006 has been found...” - not referenced in text and absent in the</p>	<p>Comment accepted and considered</p>
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	<p>references section.</p> <p>2nd paragraph – last sentence Better be re-written as: “Typically, psoriasis plaques are located on the extensor surface of the knees, elbows, hairline, scalp, intergluteal cleft, and lumbosacral area.” Please also insert the reference for this statement.</p> <p>3rd paragraph – last sentence Better be re-written as: “Our aim in this study was to assess the efficacy and tolerability of infliximab monotherapy in Libyan patients with severe psoriasis vulgaris and to report any adverse effects.”</p> <p>MATERIALS AND METHODS*</p> <p>1st paragraph – last sentence Better be re-written as: “All patients signed an informed consent form before participating in the study.”</p> <p>2nd paragraph 1st line Better be re-written as: “Each patient underwent a detailed medical history...”</p> <p>Second line, change the word “chemistries” by “biochemistry” Second paragraph should end at: “Clinical assessment and PASI score were carried out for all patients.”</p> <p>3rd paragraph (original version = 2nd paragraph line 9) 1st and 2nd sentences Better be re-written as: “Infliximab is commercialized in a sterile vial in the form of a white powder that has to be diluted in 10 ml of distilled water; each vial contains 100 mg of infliximab for intravenous administration which is carried out in a hospital by a doctor or a specialist nurse. It is given in a dose of 5 mg/kg mixed with 250 ml saline solution as a slowly intravenous infusion (over a 2- hour period) followed by two more doses at weeks 2 and 6 (induction phase) and then every 8 weeks (maintenance phase).”</p> <p>3rd paragraph - Line 9 (current version)</p>	
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	<p>Better be re-written as: "Careful observation of the patient should be done during the infusion and for two hours afterwards to ensure that the patient will not develop any allergic reactions."</p> <p>Last paragraph (original version) Suggestion: "Statistical analysis was carried out using Statistical Package for the Social Sciences (IBM SPSS) version 1."</p> <p>* Institutional review board approval should be included at the end of this section.</p> <p>RESULTS*</p> <p>Below is a suggestion for a new version of the results section.</p> <p>Among the 20 patients included in this study 12 (60%) were males and 8 (40%) were females. The patients age was ranging from 27 to 51 years (mean: 37.85 years \pm 6.81years). All patients received infliximab 5 mg/kg IV infusion and two patients were withdrawn during the study: one at week 2 due to mild urticarial reaction and the other because of hypotension after first dose. Regarding to the disease duration it ranged from 2 to 37 years (mean: 14.90 years \pm 8.25years), with predominance (30%) in the age group from 10 to 14 years (Fig.1). About 12 patients were previously treated with systemic medications such as methotrexate or cyclosporine. Maximum PASI score at baseline was 64 and minimum PASI score was 14 (mean PASI score: 32.8). Therapeutic response showed a dramatic reduction in PASI score where it became 16.2 after 6 weeks (third dose) and 2.2 between weeks 10 and 16 (Fig. 2). At the second dose, 50% of improvement was seen in 7 patients (38.8%) and 2 patients (11.1%) had 75% of improvement. By week 6 (third dose), 75% of improvement was achieved in 11 patients (60%), at week 10 in 16 patients (88.8%) and almost all patients by week 16 (Fig.3). At weeks 24 and 32, all patients were completely cleared and a 90% to 100% improvement was reported in all treated cases as seen in Figs. 4a, 4b and 4c and Figs. 5a and 5b. No</p>	
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	<p>serious adverse effects were reported. Mild urinary tract infection (UTI) was observed in 2 patients (10%). Upper respiratory tract infection (URTI) was also seen in 2 cases. All infections were mild and treated during infliximab course. Acute urticarial reaction was reported in one case and hypotension in another one and both cases were dropped out from the study.</p> <p>*The percentages in this section should be revised. They should be calculated on 18 and not 20 patients.</p> <p>Line 6 (current version above) “About 12 patients were previously ...” The word “About” (with yellow highlight) should be removed.</p> <p>Line 8 (original version) PASI is not expressed through percentages.</p> <p>FIGURES Figure 2: Rewrite the word “coarse” as “course”.</p> <p>Figure 3: Change “second week, sixth week...” by “week 2, week 6...”</p> <p>Figures 5a and 5b could be merged into one figure.</p> <p>FIGURE LEGENDS (suggestions): Figure 1: Psoriasis duration in years Figure 4a: Extensive and severe psoriasis (baseline PASI) Figure 4b: Dramatic improvement (6th week) Figure 4c: Total clearance, >90%PASI improvement (32nd week) Figure 5a: Extensive and severe psoriasis (baseline PASI) Figure 5b: Total clearance (32nd week)</p> <p>DISCUSSION Discussion with a very confusing text. Lack of care in its writing (many mistakes) and addressing a lot about the design and the result of other studies and not about this study and its findings. Must be reviewed and rewritten.</p> <p>Some other suggestions: 2nd paragraph – last sentence Biological anti-interleukins drugs were not mentioned (Anti IL 17/ Anti IL 23).</p>	
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	<p>Better include them.</p> <p>4th paragraph – 2nd sentence “The frequency of psoriatic arthritis appears to be strongly related to the degree of skin severity.” Should be re-written and re-discussed as:</p> <p>“The frequency of psoriatic arthritis appears to be strongly related to the degree of skin severity and the duration of the disease”.</p> <p>6th paragraph “50% improvement in PASI had been observed in 6 (33.3%) patients...” Re-write as: “Fifty percent of improvement in PASI has been observed in 6 (33.3%) patients...”</p> <p>Do not start sentences with numbers. Please review and correct it throughout main text and abstract.</p> <p>CONCLUSION It also deserves a revision.</p> <p>REFERENCES References should be reviewed, padronized and (if possible) updated.</p>	
Minor REVISION comments		
Optional/General comments		

PART 2:

	Reviewer’s comment	Author’s comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
Are there ethical issues in this manuscript?	(If yes, Kindly please write down the ethical issues here in details)	