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Original Article

# A Prospective Comparative Study of Rituximab Monotherapy and Dexamethasone-Cyclophosphamide Pulse Therapy in Patients Diagnosed with *Pemphigus vulgaris*

**Rametrika Saha[1], Veeranagoud Biradar[1], Spoorti Konkani[1], Mandati Santhosh Reddy[1,*], Bhavana Doshi[2]**

[1]Department of Pharmacy Practice, KLE College of Pharmacy, Belagavi, KLE Academy of Higher Education and Research, Belagavi, Karnataka, INDIA.
[2]Department of Dermatology, J N Medical College, Belagavi, Karnataka, INDIA.

## ABSTRACT

**Background:** *Pemphigus vulgaris* (PV) is a severe autoimmune blistering disorder traditionally managed with corticosteroids, which are associated with significant adverse effects; as a result, alternative therapies such as Rituximab and Dexamethasone-Cyclophosphamide Pulse (DCP) therapy have gained clinical relevance. **Objectives:** To compare the clinical outcomes, safety profiles, and quality-of-life improvements achieved with Rituximab versus DCP therapy over a 9-month follow-up period. **Materials and Methods:** A prospective observational study was conducted at a tertiary care centre involving 76 patients diagnosed with PV. Of these, 40 received DCP therapy and 36 were treated with Rituximab. The DCP regimen consisted of dexamethasone 100 mg IV for three consecutive days monthly, cyclophosphamide 500 mg IV monthly, and 50 mg oral cyclophosphamide daily (Phase I). Rituximab was administered following the rheumatoid arthritis protocol (1 g IV on days 1 and 15). Outcomes including remission, recurrence, Adverse Drug Reactions (ADRs), and Dermatology Life Quality Index (DLQI) scores were assessed at baseline and at 1, 3, 6, and 9 months. **Results:** Rituximab showed a 42% lower risk of recurrence compared with DCP. ADRs in the Rituximab group were mainly mild and self-limiting infusion-related rashes, while DCP therapy was associated with transient hyper-glycaemia and a slightly higher rate of infections. By 9 months, ADR incidence declined to 30% in the DCP group and 8.33% in the Rituximab group. Clinical response assessment included new lesion formation, healing rate, body surface area involvement, mucosal changes, and recurrence patterns. DLQI scores improved significantly in both groups, with greater improvement in the Rituximab group (16.00 to 4.00) compared with DCP (14.50 to 5.50) ($p$=0.019). **Conclusion:** Rituximab demonstrated faster clinical improvement and superior quality-of-life outcomes at 9 months. However, the limited duration of follow-up restricts conclusions about long-term relapse-free remission.

**Keywords:** Dermatology Life Quality Index, Dexamethasone-cyclophosphamide Pulse, *Pemphigus vulgaris*, Pulse therapy, Rituximab.

**Correspondence:**
**Dr. Mandati Santhosh Reddy**
Assistant Professor, Department of Pharmacy Practice, KLE College of Pharmacy, Basavan Kudachi, Belagavi, KLE Academy of Higher Education and Research, Belagavi, Karnataka, INDIA.
Email: santhoshreddy@klepharm.edu

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## INTRODUCTION

*Pemphigus vulgaris* is the most common and severe form of pemphigus, typically affecting individuals between the ages of 40 and 60 years. Severe cases of PV have a mortality rate 2.36 times higher than the general population, highlighting the importance of timely treatment. In India, the most commonly used treatments are Dexamethasone-Cyclophosphamide Pulse (DCP) and the anti-CD20 chimeric monoclonal antibody rituximab. DCP is cost-effective, provides quick disease control and remission, and has fewer side effects compared to daily oral steroids (Porro *et al.*, 2019; Kridin and Schmidt, 2021).

In pemphigus, the body produces IgG autoantibodies that attack proteins in the cell membranes of skin cells, causing them to lose their ability to stick together. These autoantibodies typically target desmogleins, which are part of a family of proteins that help cells stick together (Sinha *et al.*, 2020). The specific cause of PV is still unknown, but it is thought to be influenced by genetics and environmental factors. Certain genes like HLA-DR4 and HLA-DR14 are linked to a higher risk of developing PV. In addition, certain medications and infections have been identified

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as potential triggers for the onset of the disease (Sinha *et al.*, 2015).

The factors that influence which treatment method is chosen include the patient's profile (such as age, reproductive potential, and other health conditions), cost, and drug availability.

Initially, pemphigus was considered fatal until corticosteroids were introduced, which changed the course of the disease. However, long-term use of corticosteroids led to various metabolic issues (Das *et al.*, 2021). The discovery of Rituximab for Pemphigus was accidental when it was originally used for non-Hodgkin's lymphoma (Heizmann *et al.*, 2021). This led to an improvement in mucocutaneous lesions of paraneoplastic pemphigus. Rituximab was first used for pemphigus treatment in 2001 and has since become the preferred option in developed countries (Vinay *et al.*, 2018). Another significant development was the introduction of Dexamethasone Cyclophosphamide Pulse (DCP) therapy by Pasricha *et al.* All India Institute of Medical Sciences (AIIMS) in New Delhi, in 1984 (Pasricha and Poonam, 2008). This treatment method remains one of the most affordable and popular options in India. It involves four phases: Phase 1 (induction phase - DCP monthly plus oral cyclophosphamide and additional oral corticosteroids) continues until clinical remission. Phase 2 (monthly DCP and tablet cyclophosphamide) and Phase 3 (daily tablet cyclophosphamide) each last for 9 months, while Phase 4 is for follow-up to monitor for any relapse. When used correctly, DCP therapy has the ability to lead to lifelong recovery from these diseases (Zeeshan *et al.*, 2013; Craythorne *et al.*, 2011).

Patients with *Pemphigus vulgaris* (PV) often suffer from both physical and psychological distress caused by painful skin erosions, mucosal involvement, and the chronic nature of the disease. The Dermatology Life Quality Index (DLQI) is a valuable tool for evaluating the effectiveness of treatment in PV by measuring improvements in quality of life after therapy (Paradisi *et al.*, 2012).

Numerous studies have demonstrated that PV patients tend to have significantly higher DLQI scores compared to individuals with other skin conditions like psoriasis or eczema. This is due to the extensive blistering, systemic involvement, and the adverse effects of long-term corticosteroid or immunosuppressive treatment (Paradisi *et al.*, 2009; Rencz *et al.*, 2015).

This study aims to compare the safety and effectiveness of Rituximab with Dexamethasone Cyclophosphamide Pulse (DCP) therapy in patients with *Pemphigus vulgaris*. It also seeks to evaluate the quality of life of these patients using the Dermatology Life Quality Index (DLQI).

## MATERIALS AND METHODS

A prospective observational study was conducted over 9 months at the Department of Dermatology at a tertiary care hospital. This study was approved by the Institutional Ethics Committee in accordance with the Declaration of Helsinki (KLECOPBGMEC/D009-2024). The study included patients with PV who were receiving either Dexamethasone Cyclophosphamide Pulse (DCP) therapy or Rituximab.

A total of 76 clinically diagnosed *Pemphigus vulgaris* patients aged ≥20 years were enrolled from the outpatient and inpatient departments after obtaining written informed consent. Of these, 40 patients received Dexamethasone-Cyclophosphamide Pulse (DCP) therapy and 36 were treated with Rituximab. A detailed medical history, along with physical, dermatological, and systemic examinations, was performed for all participants. Disease severity was documented based on the extent of body surface area involvement and the number of mucosal erosions.

Participants were followed at 1, 3, 6, and 9 months after initiation of therapy. At each visit, lesion control, healing progression, Dermatology Life Quality Index (DLQI) scores, adverse drug reactions were recorded. ADR severity, duration, and causality were evaluated using standard pharmacovigilance criteria. Clinical response was assessed using predefined parameters, including the number of new lesions, percentage and rate of re-epithelialisation, body surface area involvement, mucosal involvement, and recurrence patterns.

The DCP regimen consisted of dexamethasone 100 mg intravenously for three consecutive days monthly, cyclophosphamide 500 mg IV monthly, and 50 mg oral cyclophosphamide daily as part of Phase I therapy. The Rituximab group received 1 g intravenous infusion on days 1 and 15 following the rheumatoid arthritis protocol.

All collected data were analyzed using SPSS version 20. Outcomes measured included comparative clinical effectiveness, ADR occurrence, quality-of-life changes, treatment costs, and recurrence or disease progression.

## RESULTS

During the study period a total of 76 patients (aged 20-80 years) were enrolled, comprising 46 males and 30 females. Baseline demographic characteristics, including age, gender, locality, recurrence rate, and disease activity, were comparable between the DCP and Rituximab groups. A majority of patients in both groups were from rural areas and had a known history of the disease (Table 1).

Adverse effects were more frequent in the DCP group across all follow-up visits, with statistically significant differences at each time point. At the first follow-up (1 month), adverse effects occurred in 62.5% of DCP patients compared with 38.9% in the Rituximab group ($p$=0.0041). The difference persisted at the second (45.0% vs. 22.2%, $p$=0.0032), third (38.0% vs. 14.0%, $p$=0.0028), and fourth follow-ups (30.0% vs. 8.33%, $p$=0.0019) (Table 2). Hyperglycemia was predominantly associated with DCP and absent in Rituximab patients. Rashes were more

common with Rituximab, whereas infections were slightly more frequent with Rituximab and palpitations with DCP.

The Dermatology Life Quality Index (DLQI) demonstrated progressive improvement in both groups. By the fourth follow-up, 50% of Rituximab-treated patients and 37.5% of those on DCP fell into the "small effect" category (Tables 3A, 3B). Median DLQI scores declined significantly over time in both groups, with Rituximab showing greater improvement. The between-group difference was statistically significant at the fourth follow-up ($p$=0.019) (Table 4).

## DISCUSSION

Managing *Pemphigus vulgaris* can be difficult due to its relapsing and remitting nature, protracted duration and significant impact on individuals' quality of life. The study showed that there were substantial differences in recurrence rates between the two treatment groups. Rituximab had a 21.94% lower absolute recurrence rate compared to DCP, resulting in a 42% reduced risk of recurrence. This is consistent with previous study Joly *et al.*'s the Ritux 3 trial, which found that Rituximab was more effective in achieving long-term remission in PV patients compared to traditional corticosteroid and immunosuppressive treatments (Rao and Lakshmi, 2003). The lower recurrence rate with Rituximab may be due to its targeted impact on CD20+ B cells, which are important in the development of PV (Ellebrecht *et al.*, 2016).

However, there were significant differences in the safety profiles of the two treatments. The DCP group had a higher percentage of hyperglycemia (69.23%), likely due to the use of high-dose corticosteroids in treatment. This aligns with previous reports on the metabolic issues associated with long-term corticosteroid use (Hertl *et al.*, 2015). On the other hand, Rituximab had a higher incidence of rashes (77.78%), possibly due to its effects on the immune system. Infections, although minor, were slightly more common in the Rituximab group, which is consistent with its known immunosuppressive properties (Cianchini *et al.*, 2012). In our study, we assessed Adverse Drug Reactions (ADRs) and found significant patterns related to treatment duration and patient response to therapy over time. Most patients (63.16%) had pre-existing ADRs, this suggests that patients were already dealing with treatment-related issues before starting the study. Two main reasons can explain the rise in Adverse Drug Reactions (ADRs) observed during the first follow-up i.e., after one month newly diagnosed cases (36.84%) started experiencing therapeutic outcomes, leading to additional ADRs. The study therapies, especially corticosteroids in DCP therapy, had cumulative pharmacological effects. This resulted in a notable decrease in hyperglycaemia (from 69.23% to 48% in the DCP group). Significantly, the decrease in ADRs during the fourth follow-up (9 months) highlights a crucial clinical observation. With DCP therapy, ADRs decreased from 62.5% to 30% ($p$=0.0032), indicating a metabolic adjustment to corticosteroids. With Rituximab, ADRs dropped from 38.89% to 8.33% ($p$=0.0019), showing the resolution of infusion-related reactions.

Our study examined how quality of life changes over time with different treatments. We found that the improvement in quality of life varied depending on whether patients were treated with DCP or Rituximab. The baseline characteristics of the patients also played a role in how they responded to treatment. At the start of the study, both groups had poor quality of life, with the Rituximab group having slightly worse scores (median=16.00). However, by the first follow-up, this difference was not significant. The small difference at one month follow up ($p$=0.054) is consistent with Strowd *et al.*'s findings that early results in chronic pemphigus are influenced more by the disease itself than by treatment effects (Strowd *et al.*, 2011). In fourth follow up i.e., at the nine-month mark, there was a significant difference ($p$=0.019) between the Rituximab group and the DCP group. Patients on Rituximab had a better median DLQI score and fewer severe cases, showing its advantage in modifying the disease. These results (75% moderate effect) are similar to Joly *et al.*'s 68% remission rate after 6 months, indicating that our shorter follow-up period still captured the point where treatment starts to show benefits (Joly *et al.*, 2017). This is consistent with its ability to provide longer-lasting immunologic control. Although DCP initially showed promising results, its final outcomes were less impressive, indicating limitations in its long-term effectiveness.

Kanwar *et al.* treated 10 patients with pemphigus using the RA protocol (Kanwar *et al.*, 2013). After an average follow-up period of 33.4 weeks, three patients achieved complete remission without

**Table 1: Patient demographics by type of treatment.**

| Characteristic | DCP, n (%) | Rituximab, n (%) |
|---|---|---|
| **Age (years)** | | |
| 20-40 | 7 (17.50) | 8 (22.22) |
| 40-60 | 24 (60.00) | 24 (66.66) |
| 60-80 | 9 (22.50) | 4 (11.11) |
| **Gender** | | |
| Male | 26 (65.00) | 20 (55.55) |
| Female | 14 (35.00) | 16 (44.44) |
| **Locality** | | |
| Urban | 13 (32.00) | 14 (38.89) |
| Rural | 27 (67.00) | 22 (61.11) |
| **Category** | | |
| Newly diagnosed | 15 (37.50) | 13 (36.11) |
| Known | 25 (62.50) | 23 (63.89) |
| **Recurrence** | | |
| Yes | 21 (52.50) | 11 (30.56) |
| No | 19 (47.50) | 25 (69.45) |

**Table 2:** Test of significance of adverse effect prevalence in DCP and Rituximab therapy across all time points.

| Time point | DCP n (%) | Rituximab n (%) | *p*-value |
|---|---|---|---|
| Baseline | 13 (32.50) | 9 (25.00) | - |
| 1st Follow-up (1 month) | 25 (62.50) | 14 (38.89) | 0.0041 |
| 2nd Follow-up (3 months) | 18 (45.00) | 8 (22.22) | 0.0032 |
| 3rd Follow-up (6 months) | 15 (38.00) | 5 (14.00) | 0.0028 |
| 4th Follow-up (9 months) | 12 (30.00) | 3 (8.33) | 0.0019 |

**Table 3A:** Distribution of DLQI total scores over time-DCP group.

| Effect category | Baseline | 1 month | 3 months | 6 months | 9 months |
|---|---|---|---|---|---|
| No effect | 0 | 0 | 0 | 0 | 2 (5.0) |
| Small effect | 0 | 0 | 5 (13.0) | 10 (25.0) | 15 (37.5) |
| Moderate effect | 13 (32.5) | 20 (50.0) | 23 (57.5) | 25 (62.5) | 21 (52.5) |
| Very large effect | 26 (65.0) | 20 (50.0) | 12 (30.0) | 5 (12.5) | 2 (5.0) |
| Extremely large effect | 1 (3.0) | 0 | 0 | 0 | 0 |

**Table 3B:** Distribution of DLQI total scores over time-Rituximab group.

| Effect category | Baseline | 1 month | 3 months | 6 months | 9 months |
|---|---|---|---|---|---|
| No effect | 0 | 0 | 0 | 0 | 4 (11.1) |
| Small effect | 0 | 0 | 6 (17.0) | 12 (33.3) | 18 (50.0) |
| Moderate effect | 10 (27.8) | 12 (33.34) | 26 (72.23) | 27 (75.0) | 13 (36.1) |
| Very large effect | 23 (63.8) | 24 (66.67) | 4 (11.11) | 1 (2.77) | 1 (2.77) |
| Extremely large effect | 3 (8.3) | 0 | 0 | 0 | 0 |

**Table 4:** Comparison of DLQI scores between DCP and Rituximab groups over time.

| Time point | DCP Median (IQR) | Rituximab Median (IQR) | *p*-value |
|---|---|---|---|
| Baseline | 14.50 (7.00) | 16.00 (5.75) | 0.015 |
| 1st Follow-up | 10.50 (5.50) | 13.00 (5.50) | 0.054 |
| 2nd Follow-up | 8.00 (4.00) | 7.00 (3.00) | 0.031 |
| 3rd Follow-up | 6.50 (3.50) | 5.00 (3.00) | 0.027 |
| 4th Follow-up | 5.50 (3.00) | 4.00 (2.00) | 0.019 |
| Improvement between groups over time | <0.05** | <0.05** | - |

any treatment, while four others reached complete remission with minimal therapy. The average time to control the disease was 8 weeks. In a 6-year study conducted by Rao and Lakshmi, 29 out of 30 patients who received DCP showed a positive response and completed Phase I after an average of 8 treatment pulses (Rao *et al.*, 2003). Additionally, a study by Roga and Augustine found that the average time to control disease activity with DCP was 6.7 months (Roga *et al.*, 2018). However, there have been very few studies or case series that directly compare these two treatment methods.

The majority of the study population were middle-aged (61.84% aged 41-60 years) and male (60.53%), which is in line with the typical demographics of PV (Zhu *et al.*, 2013). This condition often affects adults with a slight male bias. Interestingly, women were more likely to be prescribed Rituximab (44.44% vs. 35% for DCP).

## LIMITATIONS

This single-centre study limits the generalizability of the findings to broader clinical settings, and the absence of blinding may have introduced bias in symptom reporting and outcome assessment. Additionally, the 9-month follow-up period restricts the ability to evaluate long-term relapse-free remission.

## CONCLUSION

This study compares Rituximab and DCP therapy for *Pemphigus vulgaris*, demonstrating distinct treatment profiles with important clinical implications. Although Rituximab showed greater clinical performance, DCP despite its corticosteroid-related metabolic adverse effects remains a widely used option for rapid symptom control in many clinical settings. The high proportion of rural patients in our study further highlights the need for flexible treatment approaches tailored to diverse healthcare environments. Overall, the findings outline the strengths and limitations of each therapy, offering valuable insights for clinicians and policymakers managing this chronic autoimmune disease.

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## ABBREVIATIONS

**PV:** *Pemphigus vulgaris*; **DCP:** Dexamethasone-cyclophosphamide; **DLQI:** Dermatology Life Quality Index; **QOL:** Quality of Life; **WHO:** World Health Organization; **IgG:** Immunoglobulin G; **ADRs:** Adverse drug reactions; **NSAIDs:** Non-steroidal anti-inflammatory drugs; **IQR:** Interquartile range; **SD:** Standard deviation; **AEs:** Adverse events; **HLA:** Human leukocyte antigen.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## SUMMARY

In this prospective study of 76 patients with *Pemphigus vulgaris*, Rituximab demonstrated lower recurrence rates, fewer adverse drug reactions, and greater improvement in quality of life compared with dexamethasone-cyclophosphamide pulse therapy over a 9-month follow-up. While DCP remains effective for rapid disease control and is more accessible, Rituximab showed superior clinical and patient-reported outcomes.

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