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THE ROLE OF CONSTANT CLINICAL OBSERVATION AND DIET THERAPY IN PREVENTING PEMPHIGUS RELAPSES: A REGIONAL COHORT STUDY FROM THE ANDIJAN REGION, UZBEKISTAN

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ABSTRACT

Objective: To investigate the efficacy of a combined protocol of constant (monthly) clinical observation and structured diet therapy in preventing clinical relapses of pemphigus vulgaris (PV) in patients in remission within the Andijan region. Methods: A 24-month, prospective, controlled cohort study was conducted at the Andijan Regional Dermatovenerological Dispensary. We enrolled 110 PV patients who were in complete clinical remission (on ≤10mg/day prednisone or off therapy). Patients were allocated into two groups. The Intervention Group (IG, n=55) received a strict protocol of: 1) constant, mandatory monthly clinical examinations (oral and cutaneous) and 2) structured diet therapy, involving the strict elimination of thiol-containing foods (e.g., garlic, onion, leeks), strong spices, and highly acidic foods. The Control Group (CG, n=55) received the standard of care (SOC) for the region: clinical follow-up every 3-6 months, or as-needed (PRN) if a relapse was suspected, with standard dietary advice. Results: At 24 months, the clinical relapse rate in the Intervention Group (IG) was 21.8% (12/55 patients). This was significantly lower than the relapse rate in the Control Group (CG), which was 52.7% (29/55 patients; $p < 0.001$). Furthermore, the relapses observed in the IG were predominantly mild (oral) and detected early during monthly visits, requiring only topical or minimal oral steroid pulses. In contrast, 18 of the 29 relapses in the CG were moderate-to-severe, requiring significant systemic therapy escalation. The mean cumulative prednisone dose over 24 months was significantly lower in the IG (3,850 mg) compared to the CG (8,120 mg; $p < 0.01$). Conclusion: A structured, non-pharmacological program combining constant clinical observation with proactive diet therapy is a highly effective, low-cost strategy for preventing pemphigus relapses in a regional setting. This approach facilitates early detection of "micro-relapses," significantly reduces relapse rates, and minimizes long-term corticosteroid toxicity.

Keywords: Pemphigus Vulgaris, Relapse, Prevention, Diet Therapy, Clinical Observation, Thiols, Andijan Region, Prophylaxis, Corticosteroid Sparing.

INTRODUCTION

The long-term management of pemphigus vulgaris (PV) remains a significant challenge for dermatologists, particularly in regional healthcare settings. While modern immunosuppressive therapies have successfully reduced mortality, the chronic, relapsing nature of the disease persists, leading to high cumulative drug toxicity and a severely diminished quality of life (Joly et al., 2017). The primary goal in pemphigus management has, therefore, shifted from acute control to achieving and maintaining long-term, stable, therapy-free remission [1].

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Relapses are common, and various triggers have been implicated, including infections, stress, and specific medications. Among these, dietary factors are increasingly recognized as potential exogenous triggers. Certain foods, particularly those in the Allium family (garlic, onion, leeks) and others containing thiols (compounds with sulfhydryl groups), are hypothesized to induce or exacerbate acantholysis, potentially by interfering with epidermal cell adhesion or through immunological cross-reactivity (Brenner et al., 2011). However, the implementation of a strict "pemphigus diet" as a formal prophylactic tool is not yet standard practice and its efficacy is debated.

Simultaneously, the standard follow-up model for patients in remission—often involving 3 to 6-month intervals—is fundamentally reactive. It relies on the patient identifying a relapse and seeking care, by which time the disease may already be widespread, necessitating high-dose systemic therapy. A model of "constant clinical observation" (e.g., proactive, monthly checks) could theoretically detect subclinical or minimal disease activity (e.g., a single new oral erosion) before it progresses, allowing for minor intervention [4].

In the context of the Andijan region of Uzbekistan, with its specific dietary habits (high consumption of onions and spices) and a regional-based healthcare system, these two factors—diet and clinical monitoring—represent a critical, under-investigated area for relapse prevention [5]. This study aims to evaluate the combined efficacy of these two non-pharmacological approaches in a real-world regional cohort.

METHODS

Study Design and Setting A 24-month, prospective, controlled cohort study was conducted from June 2022 to June 2024 at the Andijan Regional Dermatovenerological Dispensary, the primary referral center for autoimmune bullous diseases in the region.

Participants A total of 110 patients with a confirmed diagnosis of PV, who were in stable, complete remission (no new lesions and established lesions healed, on ≤10 mg/day prednisone) for at least 3 months, were enrolled. Patients were allocated 1:1 to either the intervention or control group. Intervention Group (IG, n=55) Patients in the IG were enrolled in a high-intensity prophylactic program:

Constant clinical observation - patients were required to attend a mandatory clinical examination by a dermatologist every 30 days, regardless of symptoms. The examination involved a thorough inspection of all oral mucosa and the entire integument.

Structured diet therapy - patients received a detailed, written "Pemphigus Diet Plan" and counseling. This plan mandated the strict elimination of:

- All Allium vegetables (garlic, onion, leeks, chives).
- Foods high in thiols (e.g., mustard, radishes, capers).
- Highly spicy foods (e.g., chili pepper).
- Highly acidic foods (e.g., vinegar, citrus fruits) to reduce oral irritation. Dietary adherence was monitored via patient self-report diaries.

Control Group (CG, n=55) Patients in the CG received the regional standard of care (SOC). This included: 1) Standard clinical observation - scheduled follow-up visits every 3-6 months. 2) Standard dietary advice - general verbal advice to "avoid spicy foods," but no structured plan or list of prohibited items. Patients in both groups were instructed to report immediately if they suspected a relapse.

Primary Outcome: Clinical relapse rate at 24 months. Relapse was defined as the appearance of 3 or more new lesions in a month that did not heal spontaneously, requiring

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escalation of therapy (e.g., increase of prednisone >10mg/day). Secondary Outcomes: 1) Relapse severity (mild, moderate, severe); 2) Mean cumulative prednisone dose over 24 months; 3) Time to first relapse.

Statistical analysis data were analyzed using Stata (Version 16.0). Baseline characteristics were compared using t-tests for continuous data and Chi-square (χ^2) for categorical data. Relapse rates were compared using the χ^2 test. Cumulative steroid dose was compared using the Mann-Whitney U test. A p-value < 0.05 was considered significant.

RESULTS

Baseline Characteristics Of the 110 enrolled patients, 104 (94.5%) completed the 24-month study (IG: 52, CG: 52). The groups were well-matched at baseline for age, gender, disease duration, and remission status (Table 1).

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Intervention Group (IG) (n=55)	Control Group (CG) (n=55)	p-value
Mean Age, years (SD)	51.3 (10.1)	50.9 (11.2)	0.86 (NS)
Gender (% Female)	31 (56.4%)	34 (61.8%)	0.59 (NS)
Mean Disease Duration, years (SD)	3.8 (1.9)	4.0 (2.1)	0.67 (NS)
% in Remission "Off Therapy"	19 (34.5%)	17 (30.9%)	0.72 (NS)

Primary Outcome: Relapse Rates The intervention had a profound effect on relapse rates. In the Control Group, 29 of the 55 patients (52.7%) experienced a clinical relapse during the 24-month period. In the Intervention Group, only 12 of 55 patients (21.8%) relapsed. This represents a 58.6% relative risk reduction ($p < 0.001$).

Secondary Outcomes The nature of the relapses differed significantly. In the IG, 10 of the 12 relapses (83.3%) were detected during the scheduled monthly visits. These were "micro-relapses" (e.g., 1-2 oral erosions) and were managed by re-instituting high-potency topical steroids, with only 2 patients requiring a temporary increase in oral prednisone. In the CG, 29 relapses occurred, 18 of which (62.1%) were classified as moderate-to-severe (i.e., multiple oral and cutaneous lesions), requiring re-initiation of high-dose prednisone (40-60 mg/day).

This difference was reflected in the cumulative steroid consumption. The mean cumulative prednisone dose was significantly lower in the IG (3,850 mg ± 1210) compared to the CG (8,120 mg ± 2350; $p < 0.01$).

Table 2: Primary and secondary outcomes at 24 months

Outcome measure	Intervention group (IG) (n=55)	Control group (CG) (n=55)	p-value
Clinical relapse (primary)	12 (21.8%)	29 (52.7%)	**< 0.001**
Relapse Severity (mild)	10 (83.3% of relapses)	11 (37.9% of relapses)	< 0.01
relapse Severity (mod/severe)	2 (16.7% of relapses)	18 (62.1% of relapses)	< 0.01
Mean Cumulative prednisone (mg)	3,850	8,120	< 0.01

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DISCUSSION

This study, conducted within the specific socio-cultural context of the Andijan region, provides strong evidence for the efficacy of a non-pharmacological, dual-pronged strategy in preventing pemphigus relapses. The significant reduction in relapse rates (from 52.7% to 21.8%) highlights the critical, and often underestimated, roles of diet and clinical vigilance.

The "constant clinical observation" component proved to be a powerful tool. It shifted the management paradigm from "reactive" to "proactive." By identifying relapses at their earliest subclinical or "micro-relapse" stage, we were able to intervene with minimal, often topical, therapy. This prevented the full-blown immunological cascade that characterizes a severe relapse, thereby sparing the patient from high-dose systemic immunosuppression. This model is particularly valuable in a regional setting, where it is more cost-effective and logistically feasible than frequent, expensive biomarker monitoring (e.g., anti-Dsg ELISA, as discussed in other studies).

The second component, "structured diet therapy," also appears to be a major contributor. While the exact mechanism of diet-induced acantholysis remains debated (Brenner et al., 2011), the elimination of thiol-containing foods, which are staples in the local Andijan diet (e.g., onions, garlic), correlated with a significantly better outcome. It is plausible that for a subset of patients, these dietary antigens act as persistent, low-grade triggers. Removing them may lower the "trigger burden" on the immune system, making a clinical relapse less likely.

The combination of these two approaches created a synergistic effect: the diet reduced the likelihood of a relapse, while the monthly monitoring reduced the severity of any relapses that did occur. This led to the most critical secondary outcome: a profound reduction in cumulative corticosteroid toxicity.

Limitations This study is not without limitations. The non-randomized, controlled-cohort design introduces potential selection bias. Furthermore, dietary adherence was based on self-reported diaries, which can be unreliable. The lack of a "diet-only" or "monitoring-only" arm makes it impossible to disentangle the individual effects of each intervention, although we suspect they are synergistic.

CONCLUSION

The management of pemphigus vulgaris in long-term remission demands a multi-faceted strategy that extends beyond mere pharmacology. This study, conducted in the specific context of the Andijan region, provides compelling evidence that a high-intensity program combining constant (monthly) clinical observation with structured diet therapy (specifically, thiol elimination) is a highly effective, low-cost, and sustainable strategy for preventing pemphigus relapses.

The primary achievement of our research is the dramatic reduction in relapse rates (from 52.7% in the Control Group to 21.8% in the Intervention Group). This outcome is explained by the synergistic effect of two key factors. First, the "constant clinical observation" shifted the management model from "reactive" (treating after a relapse occurs) to "proactive" (early detection). Monthly examinations allowed us to identify "micro-relapses" (e.g., 1-2 oral erosions) before the full immunological cascade could take hold, permitting intervention with minimal, often only topical, therapy.

Second, the structured diet, eliminating thiol-rich foods (e.g., onions, garlic) endemic to the local Andijan diet, likely reduced the "trigger burden" on the patient's immune system.

AMERICAN ACADEMIC PUBLISHER
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Together, these two approaches significantly reduced not only the frequency but also the severity of relapses.

The most critical clinical implication of this is the profound reduction in cumulative corticosteroid consumption (nearly half that of the control group). This not only lowers treatment costs but, more importantly, preserves long-term patient health by mitigating the severe co-morbidities of chronic steroid toxicity (e.g., osteoporosis, diabetes, infections).

This model is particularly well-suited for regional healthcare systems like that in the Andijan region, as it does not rely on expensive biomarker monitoring but rather on the effective use of existing clinical resources (dispensary-based observation). We strongly recommend the integration of this proactive, non-pharmacological approach into the regional standard of care for managing pemphigus patients in remission.

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