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Profile of adverse effects of corticosteroid therapy in pemphigus and bullous pemphigoid according to the Common Terminology Criteria for Adverse Events (CTCAE) at the Yalgado Ouédraogo University Hospital in Ouagadougou

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Abstract

Introduction: Pemphigus vulgaris and bullous pemphigoid are serious diseases that are mainly treated with systemic corticosteroid therapy. The aim of this study was to describe the profile of adverse effects of corticosteroid therapy in the treatment of pemphigus and bullous pemphigoid.

Materials and Methods: We conducted a descriptive cross-sectional study in the dermatology and venereology department of the CHU-YO (University Hospital of Yaoundé) involving all patients followed for pemphigus or bullous pemphigoid from January[1,] 2018, to December 31, 2022.

Results: We collected data on 41 patients, including 27 cases of pemphigus and 14 cases of bullous pemphigoid. The average age was 56.85 years. The sex ratio was 0.95.

Oral corticosteroids consisting of prednisone and prednisolone were prescribed at a starting dose ranging from 1 to 1.5 mg/kg/day in combination with topical corticosteroids in 16 patients (39.02%). The consolidated side effect profile according to the simplified CTCAE classification showed a predominance of grade 2 effects (55.4%), followed by grade 1 effects (34.8%). Severe effects (grade ≥ 3) accounted for 9.8%. Clinically, general and metabolic disorders as well as skin and systemic infections were the most common. Biological effects were mainly biochemical, with a high frequency of glycemic and ionic disorders.

Conclusion: The use of the simplified CTCAE allowed for a standardized and consolidated analysis of the adverse effect profile, highlighting a predominance of grade 1 and 2 effects in pemphigus and grade ≥ 3 effects in bullous pemphigoid.

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Keywords: Adverse effects; Corticosteroid therapy; CTCAE; Pemphigus; Bullous pemphigoid

1. Introduction

Pemphigus and bullous pemphigoid (BP) are rare but potentially serious autoimmune bullous skin diseases[1] characterized by a breakdown of skin-mucosal adhesion resulting from the action of autoantibodies[2] . Their management is based on systemic corticosteroid therapy, which is the backbone of treatment[3] and has greatly improved the prognosis of these diseases with a major reduction in mortality[4] . However, prolonged exposure or high doses of glucocorticoids lead to numerous clinical and biological, infectious, metabolic, cardiovascular, osteoarticular, neuromuscular, neuropsychiatric, and digestive side effects[5] , some of which are particularly serious, especially in BP due to advanced age and associated comorbidities that may be aggravated by systemic corticosteroid therapy[6] .

In recent years, several international studies and recommendations have highlighted the need for therapeutic strategies aimed at reducing cumulative exposure to corticosteroids. Thus, in bullous pemphigoid, the preferential use of very potent topical corticosteroids, when possible. In pemphigus vulgaris, early introduction of immunomodulatory treatments is recommended in order to limit the duration and doses of corticosteroids[7]. In African countries, the frequency of comorbidities, delayed diagnosis, and limitations in biological monitoring increase the risk of corticosteroid-related effects[8,9] . It is in this context that we undertook the present study, the objective of which is to analyze the profile of adverse effects of corticosteroid therapy in these autoimmune bullous dermatoses, with a view to contributing to the development of prevention strategies adapted to our practice context.

2. Materials and methods

We retrospectively analyzed all patient records for pemphigus and BP followed in the dermatology department of the CHU-YO from January 1, 2018, to December 31, 2022, a period of five years. All patients with a confirmed diagnosis of pemphigus and bullous pemphigoid whose clinical records were usable were included.

2.1. Data collection

The data was collected using a data collection form based on a review of the information available in the selected patient files, hospitalization records, and consultation records. Patient anonymity and confidentiality were respected when using the files. To carry out the collection, we requested and obtained authorization from the general management of the CHU-YO and the head of the Dermatology department.

The variables collected included sociodemographic data (age, sex, occupation, residence, level of education), clinical data (signs and symptoms, medical history), paraclinical data (blood count, biochemistry, ECG, radiology), therapeutic data (type of corticosteroid, dosage, route of administration, treatment regimens, adjuvant treatment), and evolutionary data (accidents, evolution of lesions). With regard to the adverse effects of corticosteroid therapy, we used the following operational definitions:

An adverse event associated with corticosteroid therapy was defined as any clinical or biological adverse event occurring during or after treatment with corticosteroids that was probably or definitely attributable to glucocorticoids and resulting in clinically significant morbidity, hospitalization, change in therapy, or death. [10]

The severity of adverse events was assessed according to the Common Terminology Criteria for Adverse Events (CTCAE) simplified version adapted to our context at , taking into account the realities and resources (biology, imaging, follow-up) but retaining the structure and spirit of CTCAE v5.0[11]

2.2. Data processing and statistical analysis

The data collected were used to produce descriptive statistics in the form of mean ± standard deviation for quantitative variables and frequencies for qualitative variables, using Microsoft Excel version 2016 and Rstudio version 4.3.2 software.

3. Results

3.1. Epidemiological characteristics

From January[1,] 2018, to December 31, 2022, 8,943 patients consulted the dermatology and venereology department at CHU-YO. We identified 39 cases of pemphigus and 23 cases of bullous pemphigoid, representing a hospital frequency of 0.44% for pemphigus (annual average of 5.4 patients) and 0.26% for BP (annual average of 2.8 patients).

We excluded 12 cases of pemphigus and 9 cases of BP. Thus, we compiled data on 41 patients, including 27 cases of pemphigus and 14 cases of bullous pemphigoid. The sample consisted of 20 men and 21 women, giving a male-to-female ratio of 0.95. The average age was 56.85 years. The average age was 53 years for pemphigus and 73 years for BP. The predominant age group was between 51 and 70 years.

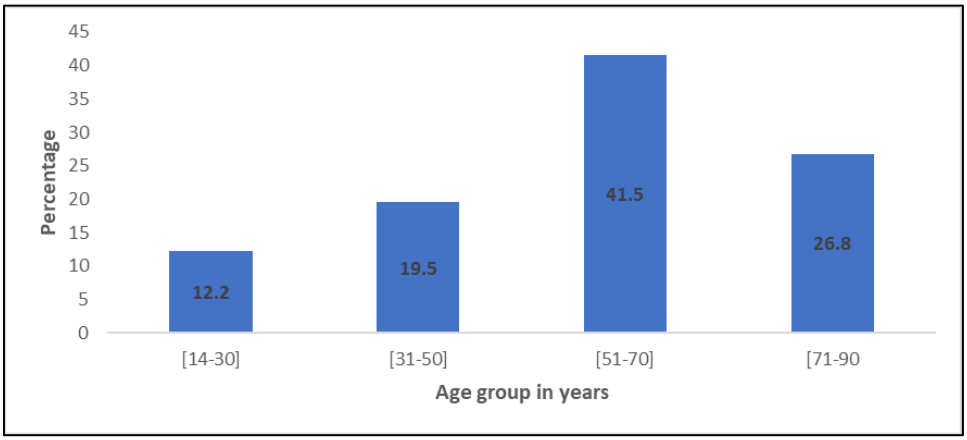


Figure 1 Distribution of patients by age

3.2. Treatment modalities

3.2.1. Corticosteroid therapy

Systemic oral corticosteroid therapy was initiated as initial treatment at doses ranging from 1 to 1.5 mg/kg/day. Prednisone was prescribed in 36 patients (87.80%) and prednisolone in 5 patients (12.21%). Local corticosteroid therapy was used in combination with oral corticosteroid therapy in 16 patients (39.02%) to accelerate the regression of blisters. The most commonly used classes were moderate-strength topical corticosteroids (12.5%) and strong-strength topical corticosteroids (87.5%).

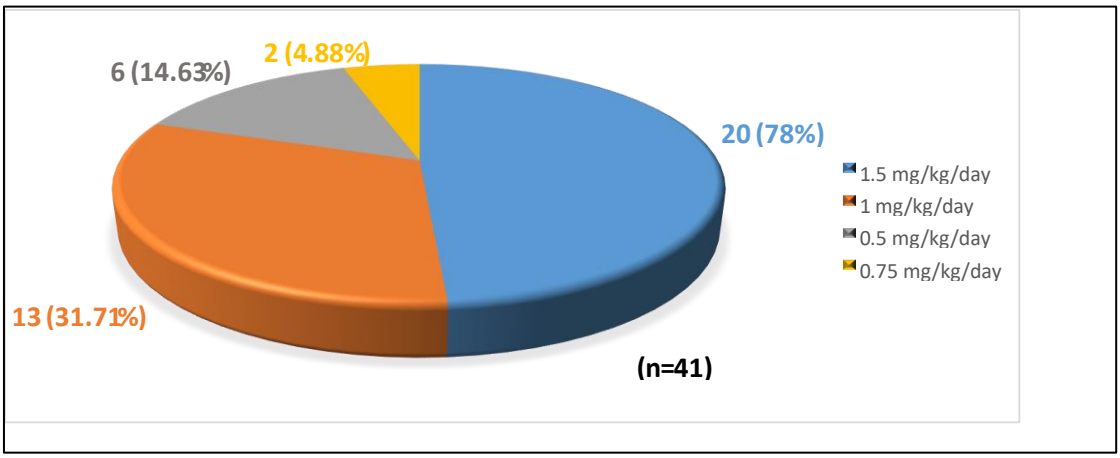


Figure 2 Distribution of patients according to corticosteroid dosage in initial treatment

Adjuvant treatment mainly consisted of aluminum hydroxide, calcium combined with vitamin D, potassium, albendazole, and local antiseptic care.

3.2.2. The time to treatment initiation

The time to initiation of corticosteroid treatment varied from one patient to another and depending on the condition.

It ranged from less than one week to more than three weeks, with the majority of patients (46.3%) receiving treatment within the first week.

Table 1 Distribution of patients according to time to treatment initiation

Time to treatment initiation (days)	Number of patients (n)	Percentage
<7	19	46.3
8-14	15	36.6
15-21	2	4.88
>21	5	12.2
Total	41	10

3.2.3. Adjuvant treatments

Adjuvant treatment mainly consisted of aluminum hydroxide, calcium combined with vitamin D, potassium, albendazole, proton pump inhibitors

and local antiseptic treatments. Immunosuppressants consisting of azathioprine, methotrexate, and mycophenolate mofetil were also used in 14 patients (34.1%). In pemphigus, azathioprine was prescribed in 9 patients, methotrexate in 2 patients, and mycophenolate mofetil in 1 patient. In PB, only methotrexate was prescribed in 2 patients. The time to initiation of immunosuppressive therapy after the start of oral corticosteroid therapy ranged from 10 days to more than 21 days.

3.2.4. Progressive data

The short-term outcome was favorable in 30 patients.

In the medium and long term, recurrence of lesions was noted in 18 patients and 2 patients died.

3.2.5. Length of hospital stay

The average length of hospital stay was 36.43 days, ranging from 5 to 89 days.

3.3. Adverse effects of corticosteroid therapy

3.3.1. Clinical adverse effects

General and metabolic signs were the most common adverse effects in both conditions, with a predominance in pemphigus. These were followed by infectious skin lesions and systemic infections, particularly pulmonary infections.

Table 2 summarizes the distribution of clinical effects in pemphigus and PB.

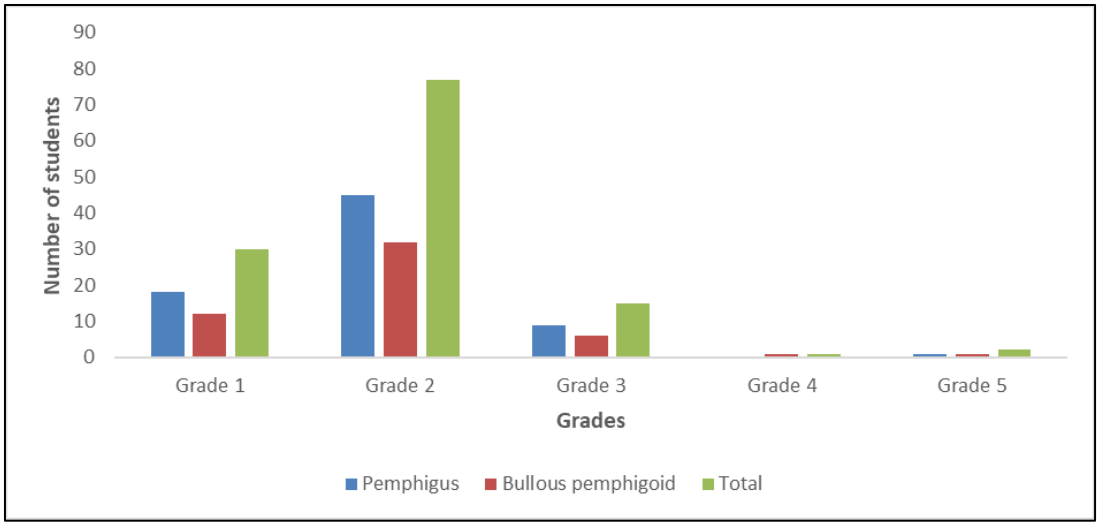
Table 2 Distribution of clinical effects according to disease and organ systems

Signs/symptoms	Pemphigus	Bullous pemphigoid
General/metabolic signs		
Polyuria	12	6
Polydipsia	11	4
Polyphagia	10	7
Weight gain	14	6

Fever	5	3
Anorexia	2	1
Asthenia	3	4
Weight loss	3	3
Infections/skin disorders		
Fungal	11	3
Intertrigo	11	3
Pityriasis versicolor	1	-
Bacterial	6	4
Bacterial dermohypodermitis	2	1
Boil	2	-
Impetigo	2	2
Superficial folliculitis	1	1
Cutaneous herpes	3	-
Skin xerosis	2	2
Lung infections	11	2
Pneumonia	5	2
Urinary tract infections	5	-
Cardiovascular disorders		
Corticosteroid-induced hypertension	6	2
Tachycardia	4	3
Cardiac arrhythmia	1	2
Cardiac arrest	1	-
Ophthalmological disorders		
Purulent conjunctivitis	3	1
Cataract	5	-
ENT disorders		-
Otitis media	2	-
Digestive disorders		
Diarrhea	4	1
Abdominal pain	6	6
Vomiting	2	2
Neurological disorders		
Insomnia	5	3
Headaches	3	1
Cramps	3	-
Mood disorder	3	2
Bones and Muscles		

Bone pain	1	6
Myalgia	2	1
Death		
Death by cardiac arrest	-	1
Pulmonary sepsis	-	1

The clinical adverse effects of corticosteroid therapy presented in table 2 are summarized graphically in figure 3, according to simplified CTCAE grades. Grade 2 is the most common in both conditions, followed by grade 1.



Figures 3 Distribution of clinical adverse effects of corticosteroid therapy according to simplified CTCAE grades in pemphigus and PB

3.3.2. Biological adverse effects

The hematological abnormalities observed in our series are dominated by neutrophilic hyperleukocytosis, which is particularly marked in pemphigus. Biochemical abnormalities were dominated by glycemic and ionic disorders, which are predominant in pemphigus, while renal and hepatic involvement is more common in PB.

NB: These are abnormalities that patients did not have before starting corticosteroid therapy.

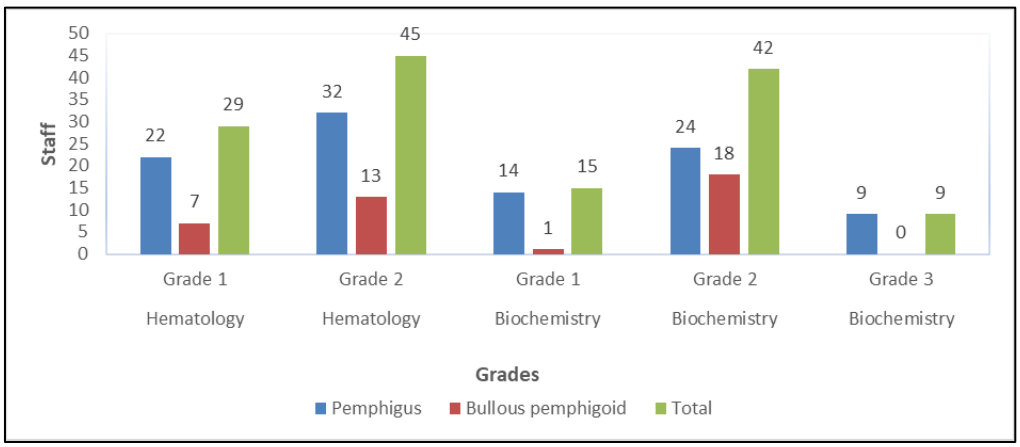
The following table summarizes the biological changes observed during corticosteroid therapy

Table 3 Distribution of clinical and biological abnormalities observed during corticosteroid therapy in pemphigus and bullous pemphigoid

Hematological parameters	**Pemphigus**		**Bullous pemphigoid**	
	Lowered	**Elevated**	**Lowered**	**High**
Number of red blood cells	2		1	-
Hemoglobin level	7	1	2	-
Platelet count	3	5	1	1
Number of white blood cells	2	8	-	4
Neutrophils	1	12	1	6
Eosinophil polynuclear cells	1	2	1	2
Lymphocytes	2	2	-	-

Monocytes	1	4	-	2
Biochemical parameters				
Blood glucose	3	9	3	3
Creatinine	1	2	-	3
Sodium ion	3	2	1	-
Potassium ion	5	1	2	-
Chloride ion	4	1	-	-
Calcemia	1	3	0	0
Proteinuria	4	2	5	-
Aspartate aminotransferase	-	1	-	2
Alanine aminotransferase	-	1	-	3

The adverse biological effects presented in table 3 are summarized graphically in figure 4, according to simplified CTCAE grades. Grade 2 biological effects are predominant in both pathologies, followed by grade 1 effects.



Figures 4 Distribution of adverse biological effects of corticosteroid therapy according to simplified CTCAE grades in pemphigus and bullous pemphigoid

3.4. Consolidated assessment of adverse effects according to the simplified Common Terminology Criteria for Adverse Events (CTCAE)

The simplified CTCAE enabled a comprehensive analysis of the adverse effects of corticosteroid therapy by grade during our study. All adverse effects observed in patients showed a predominance of grade 2 events (55.4%), followed by grade 1 events (34.8%). Severe effects (grade ≥ 3) accounted for 9.8%.

Table 4 Distribution of consolidated adverse effects according to the simplified CTCAE classification simplified

CTCAE grade	Consolidated adverse events			Total number (n)	Percentages (%)
	Clinical	Hematological	Biochemical		
Grade 1	52	29	15	96	34.8
Grade 2	66	45	42	153	55.4
Grade 3	15	0	9	24	8.7
Grade 4	1	0	0	1	0.4
Grade 5	2	0	0	2	0.7
Total				276	10

The consolidated adverse effects of corticosteroid therapy presented in table 4 are summarized graphically in figure 5 according to simplified CTCAE grades. Grades 1 and 2 predominate in pemphigus and grades ≥ 3 in PB.

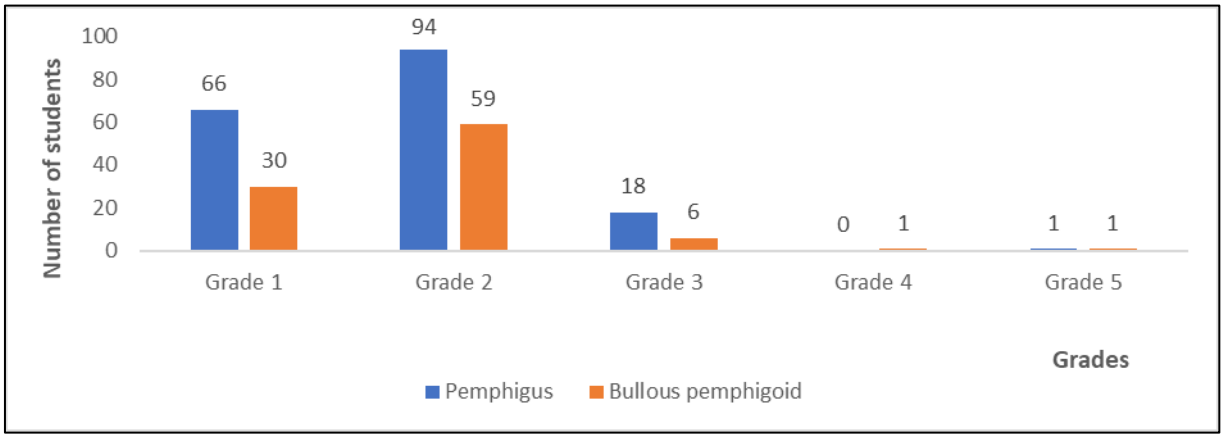


Figure 5 Consolidated adverse effects of corticosteroid therapy according to CTCAE grades in pemphigus and bullous pemphigoid

4. Discussion

As with any retrospective study, the limitations of our study lie in the incompleteness of the clinical records, rendering some of them unusable. In addition, not all of the requested paraclinical tests are always performed by patients. The retrospective nature of our study does not allow us to establish a direct causal link between the administration of glucocorticoids and the occurrence of adverse events. Nevertheless, we have provided some comments.

4.1. Epidemiological data

Pemphigus and bullous pemphigoid are conditions encountered in our hospital practice. Over a 5-year period, we obtained a hospital frequency of 0.44% for pemphigus and 0.26% for BP. Pemphigus vulgaris was the most common form in our series (65.8%). This predominance of pemphigus is reported in Africa in hospital series of autoimmune bullous dermatoses. In Europe, however, BP is more common[12] . The average age of patients was 53 years for pemphigus and 73 years for BP. These average ages are also reported in the literature, where pemphigus affects younger adults[13] and BP affects older individuals[14]

4.2. Therapeutic data

In our study, the systemic corticosteroids used to treat pemphigus and PB were prednisone (CORTANCYL®) in 36 patients (87.80%), and prednisolone (PREDNI®) in 5 patients (12.20%) at a loading dose of between 1 and 1.5 mg/kg/day, in accordance with international treatment recommendations, which place oral systemic corticosteroid therapy as the first-line treatment for pemphigus[15] . No patients received parenteral or bolus corticosteroid therapy. In bullous pemphigoid, strong and very strong topical corticosteroids were used.

Immunosuppressants were used in pemphigus to reduce the toxicity of prolonged corticosteroid therapy and also in BP for resistant, severe, or corticosteroid-dependent forms, in accordance with the literature [15]

4.3. Adverse effects of corticosteroid therapy

Our study analyzes the profiles of adverse effects of corticosteroid therapy in two autoimmune bullous dermatoses whose management still relies heavily on systemic corticosteroids. Our results show varied and multisystemic adverse effects and a high frequency of adverse events, mostly grade 1 and 2 according to the CTCAE classification, reflecting mild to moderate toxicity.

4.4. Overall tolerance profile of corticosteroid therapy

Corticosteroid therapy is responsible for significant adverse effects. Certain complications are to be expected given the high doses used and the duration of exposure to corticosteroids[16] .

The predominance of grade 1 and 2 events corroborates the data in the literature, which reports a high frequency of mild to moderate side effects during prolonged treatment.

4.5. Clinical adverse effects

In our series, general and metabolic symptoms were dominated by signs of hypercortisolism (polyuria, polydipsia, polyphagia, and weight gain), which are particularly common in pemphigus. Our results corroborate data from the literature confirming that these general and metabolic symptoms associated with glucocorticoids are common and increase with the duration and cumulative dose of corticosteroid therapy, particularly in pemphigus patients undergoing prolonged treatment[17] .

4.6. Infectious complications

Skin, lung, and urinary tract infections are common in our study. They pose problems in a tropical setting where infectious diseases are endemic and where corticosteroid therapy increases the risk of opportunistic infections.[18,19] . Corticosteroids induce dose-dependent immunosuppression, reducing leukocyte function and thus promoting bacterial, fungal, and viral infections[20] .

In bullous pemphigoid, several studies report that respiratory infections are a major cause of morbidity and mortality[21] .

Skin infections are also common in our population and can be influenced by climatic conditions, humidity, secondary infections of bullous lesions, and poor personal hygiene among our patients with these conditions. In addition, the use of corticosteroids in comorbidities such as diabetes and HIV significantly increases the risk of infection in African contexts, as observed in several hospital dermatology studies[22] .

4.7. Cardiovascular damage

Cardiovascular damage, mainly corticosteroid-induced hypertension and arrhythmias, was observed in our study and is well documented in the literature[23] . Furthermore, the death by cardiac arrest in our series reminds us that corticosteroids can cause serious cardiovascular events, especially in elderly patients.

4.8. Biological adverse effects

In our series, the most common hematological abnormalities were neutrophil-predominant hyperleukocytosis, which is a common iatrogenic effect of corticosteroids, linked to neutrophil demargination, and does not necessarily indicate an infectious process [12]. With regard to the erythrocyte lineage, anemia was observed, which, however, may be multifactorial, linked either to the chronic inflammation inherent to the disease, prolonged skin losses, insufficient nutrition, or the presence of associated comorbidities, as reported in recent data on the links between autoimmune bullous diseases, nutritional status, and associated hematological diseases[24] .

The biochemical abnormalities observed in our series were dominated by glycemic disorders, confirming the central role of systemic corticosteroid therapy in the onset of hyperglycemia and corticosteroid-induced diabetes, which are well-documented adverse effects[25] . The ionic disorders (hyponatremia, hypokalemia), functional renal impairment, and moderate elevations in transaminases observed are related to the metabolic effects of glucocorticoids and hydroelectrolytic losses[26] . These effects were most prevalent in pemphigus, where cumulative doses of corticosteroids are often higher. In contrast, in bullous pemphigoid, renal and hepatic impairment were particularly noted, which could be explained by the advanced age of the patients and associated comorbidities[27] .

These results highlight the importance of regular biological monitoring in the prevention of metabolic and visceral complications of corticosteroid therapy.

4.9. Progression

Although marked by an initial improvement observed in 30 patients, the progression is also characterized by a significant number of relapses (18 cases). This finding is reported in the literature and shows the difficulty of achieving prolonged remission without the use of immunosuppressive agents [3].

4.10. Consolidated assessment of adverse effects according to the simplified CTCAE

The consolidated assessment of adverse effects of corticosteroid therapy using the simplified Common Terminology Criteria for Adverse Events (CTCAE) allowed for a comprehensive and standardized assessment of the severity of complications observed during this study.

This approach, which has the advantage of providing an integrated view of corticosteroid-related toxicity according to grades, takes into account both clinical and biological effects. In our series, grade 2 effects (55.4%) were the most common, followed by grade 1 effects (34.8%). This finding reflects mild to moderate corticosteroid toxicity. Our results are consistent with the data in the literature, which report a high frequency of non-severe adverse effects during prolonged corticosteroid treatment, particularly in autoimmune bullous dermatoses[7] . However, this may also be due to effective clinical management. Severe adverse effects (grade ≥ 3) accounted for 9.8% of all events. Although less frequent, these effects are clinically serious. Grade 4 (0.4%) and grade 5 (0.7%) events, although rare, were life-threatening and fatal. Their occurrence highlights that corticosteroid therapy may be associated with indirect mortality, particularly in elderly patients or those with significant comorbidities, as reported in several cohorts. These data reinforce the need for regular and close clinical and biological monitoring according to the patient's risk profile[28] . The graphical representation of consolidated adverse effects (Figure 4) provides a summary visualization of the distribution of CTCAE grades, facilitating comparison between pemphigus and bullous pemphigoid. Indeed, it shows a higher frequency of adverse effects in pemphigus, while the most serious events occur preferentially in bullous pemphigoid, probably related to advanced age and the high frequency of comorbidities in this population[28] . Thus, the use of the simplified CTCAE appears to be a relevant tool for evaluating the effects of corticosteroid therapy in autoimmune bullous dermatoses. It not only allows for objective stratification by grade, but also enables better comparison of results with international data and highlights the need for its systematic integration into clinical studies and routine dermatological practice[29,30] .

4.11. Recommendations from this study for practice in our context

- Importance of systematic and regular clinical and biological monitoring of corticosteroid therapy
- Use of the simplified CTCAE to assess and prioritize adverse effects
- Individualization of treatment regimens according to patient profiles
- Use of corticosteroid-sparing strategies
- Therapeutic education of patients

5. Conclusion

Systemic corticosteroid therapy, used as a mainstay of treatment for pemphigus and bullous pemphigoid in our study, carries a risk of multisystem complications, the severity and lethality of which are influenced by factors such as age, comorbidities, and cumulative doses. Analysis of the profile of clinical and biological adverse effects according to the simplified, standardized, and consolidated CTCAE classification highlights grade 1 and 2 events, which are predominant in pemphigus, and severe effects of grade 3 or higher, which are less frequent but serious in bullous pemphigoid.

These results underscore the need for regular clinical and biological monitoring.

Prospective studies systematically incorporating the CTCAE classification could help improve the tolerance and safety of treatments for these autoimmune skin diseases.

Compliance with ethical standards

Acknowledgments

Our thanks to the patients who agreed to participate in the study

Disclosure of conflict of interest

The authors declare there are no competing interests

Statement of ethical approval

This study was approved by the institutional ethics committees for research at Yalgado Ouédraogo University Hospital. Data collection and analysis were carried out confidentially using an anonymous, coded questionnaire.

Statement of informed consent

Written informed consent was obtained from all study participants. All survey forms were coded to ensure anonymity, and all collected data remained confidential.

Author contributions

All authors designed the study. LZ, FT, MSO contributed equally to this work and are the first authors. BJCO, PT, RB and NCJO participaded in Data collection. Data were analysed and interpreted by ST, RB and NBO. LZ wrote the first draft of the manuscript. LZ, ST, NAO, MSO and, NSK critically reviewed the manuscript, validated the final version of the manuscript. All authors reviewed the manuscript.

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