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Original Article

Assessment of Response to Therapy and Survival Rate among Pemphigus Patients: A Retrospective Single Centre Study

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ABSTRACT

Background: An autoimmune progressive condition called pemphigus causes the immune system to target cells in the mucous membranes and the epidermis unintentionally. In India it has a greater incidence of 4.4 per 100,000 people. There are very limited data available on pemphigus survival/mortality in India. Thus, the study aimed to analyze the treatment strategy and to determine the response to treatment and survival among pemphigus patients. **Materials and Methods:** A retrospective single-centre study was conducted for eight months at a tertiary care hospital analyzing 10 years of data for all pemphigus patients above 18 years of age. Patients with incomplete clinical or demographic data, as well as those who did not respond to telephone calls made for survival status assessment, were excluded from the study. Data was analyzed using SPSS 29.0 for descriptive and survival outcomes. **Results:** Out of 51 pemphigus patients, females (50.98%) were predominant over males (49.01%) with a mean age of 49.31±14.7 years. Most of the patients had moderate (37.25%) followed by significant severity (62.74%). Further, the majority of patients were treated with corticosteroids followed by adjuvant therapy. Age was found to be a significant predictor (p-value<0.05) of survival among pemphigus patients, i.e. age group ≤ 45 years has improved survival as compared to >45 years of age. **Conclusion:** The overall survival at the end of 10-year was found to be 86.3% which signifies that pemphigus patients can be well managed with corticosteroid and adjuvant therapy.

Keywords: Mortality, PDAI score, Pemphigus, Predictors, Survival, Treatment Response.

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INTRODUCTION

Pemphigus (Greek word: Pemphix meaning blister) is a chronic, autoimmune disorder that can be fatal. They are characterized by the development of splits in the epidermis and surface-close epithelia, as well as acantholysis (separation of keratinocytes). This occurs when autoantibodies target desmogleins (DSG-1 and DSG-3), essential proteins responsible for cell adhesion in the epidermis (Schmidt *et al*., 2019; Antiga *et al*., 2023). According to estimates, there are one to five instances per million people annually, however this number is significantly greater in some Ashkenazi Jewish communities and in Eastern nations like China, Japan, Malaysia, and India. Based on the location and distinguishable features, Pemphigus is categorized into five distinct types: Pemphigus Vulgaris (PV), Pemphigus Foliaceus (PF), Pemphigus vegetans, IgA Pemphigus, and Paraneoplastic Pemphigus (PNP) (Kasperkiewicz *et al*., 2017; Ruocco *et al*., 2013). Pemphigus Vulgaris (PV) is the most prevalent subtype of pemphigus, with an incidence of 0.1 to 0.5 per 100,000 persons annually. It is an autoimmune mucocutaneous condition of the oral cavity that mostly affects patients between the ages of 40 and 60 with a minor female bias. India has a lower prevalence than the rest of the globe, ranging from 0.09 to 1.8% (Silva *et al*., 2019; Thanmai *et al*., 2022).

Diagnosis of the pemphigus consists of clinical presentation that includes collecting the previous health and medical history taking and physical exam, Histopathology, Direct Immunofluorescence (DIF) microscopy results and Serologic detection of autoantibodies against epithelial cell surface antigen which is done by using Enzyme Linked Immunosorbent Essay (ELISA) or Indirect Immunofluorescence (IIF) (Murrell *et al*.,

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2020). The European Academy of Dermatology and Venereology (EADV) has developed general recommendations for treating pemphigus. To lessen long-term adverse effects, systemic corticosteroids continue to be the mainstay of treatment when paired with steroid-sparing immunosuppressants (such as mycophenolate mofetil and azathioprine). Rituximab is advised as a first-line treatment due to its ability to induce remission with fewer adverse effects than long-term steroid therapy. In refractory instances, Intravenous Immunoglobulin (IVIG), plasmapheresis, and immunoadsorption may be taken into consideration (Joly *et al.*, 2020).

The Autoimmune Bullous Skin Disorder Intensity Score (ABSIS) and the Pemphigus Disease Area Index (PDAI) are the main indices used to rate severity. Severity scores have been investigated only on predominately treated patients mainly with mild to moderate activity. ABSIS is the type of scoring system that consists of a maximum score of 206 and employs the rule of 9s together with a weighting factor to determine the proportion of skin involvement with blisters and erosions. The activity score and damage score in the PDAI, which focuses on the skin, scalp, and mucous membranes, can determine the disease's severity. The affected quadrants determine the scalp's activity, which is measured by the activity scores based on the number of erosions, blisters, or fresh erythema at the time of inspection (Daniel *et al.*, 2012; Hebert *et al.*, 2019).

Pemphigus management is challenged by unpredictable disease behavior, treatment-related complications, and uncertain prognostic indicators, particularly in resource-constrained settings. There are very limited pieces of evidence available on pemphigus and its survival/mortality, particularly from India. Most of the published literature is either case reports/case series or review articles which are mainly attributed to the rarity of the disease. Thus, we aimed to conduct a retrospective study to assess the response to therapy and survival rates among pemphigus patients.

MATERIALS AND METHODS

A retrospective single-center study was conducted at the Department of Dermatology at a tertiary care hospital among the pemphigus patients treated from January 2013 to December 2022 (10 years). The study was initiated after the approval of the study by the Ethics Committee on Human Subjects (Ref. No: NGSMIPS/IEC/0024/2023) and verbal consent via telephone mode was obtained from each patient/patient's caretakers before collecting the data. The study was carried out in accordance with the declaration of Helsinki 1964 and revised later.

The estimated sample size for this study was 51 using the prevalence of pemphigus among the Indian population (0.09%-1.8%) (Santoro *et al.*, 2013). The details of patients diagnosed with pemphigus were obtained from the medical record department. The Pemphigus patient case sheets containing information about the demographic details, clinical characteristics, disease severity (PDAI score), and therapy were included in the study, whereas case sheets with incomplete clinical or demographic data, as well as those who did not respond to telephone calls made for survival status assessment, were excluded from the study. All the relevant information for the study was retrieved from the patient's case sheets. Further, the information on the survival status of the patients was obtained via telephonic interview. The PDAI scoring system uses the count of the blisters/erosion, their size, and location to evaluate the severity of the disease. It consists of two domains such as activity score and damage score. The activity score ranges from 0 -250, which considers skin activity (0-120), scalp activity (0-10), and mucous membrane activity (0-120). Damage score ranges from 0-13, considering the skin damage (0-12) and scalp damage (0-1). According to the PDAI activity value, the extent of pemphigus is moderate: 0-15 points, significant:15-45 points, and extensive: >45 points (Hebert *et al.*, 2019).

All the data were analyzed for descriptive statistics and inferential statistics using Statistical Package for Social Sciences (SPSS) version 29. Descriptive statistics such as mean, standard deviation, frequency, and percentage were determined. Further, the Kaplan -Meier, Log Rank test, Chi-square, and Univariate Cox regression were used to carry out survival analysis. A significance level of p-value<0.05 was declared.

RESULTS

Patient demographics and clinical traits

A total of 51 case records of patients diagnosed with pemphigus were included in the study. The mean age of the patients was 49.31 ± 14.7 years. 50.98% of the patients were female and 49.01% were male. Considering social habits, it was observed that the majority of patients, 82.35% had no social habits, compared to 11.76% with smoking habits, 1.96% with alcohol consumption, and 3.92% with smoking along with alcohol consumption. Among the patients with a Body Mass Index (BMI), 52.9%, had a normal body weight in contrast, there were 43.13% overweight patients, and 3.92% underweight patients. Symptoms regarding fluid-filled lesions are prevalent and predominant amongst pemphigus patients upon admission 60.78% were reported along with the associated symptoms of Itchiness 21.56% and painful lesions 47.05%. The site of lesions involving skin was 84.31%, followed by the scalp at 31.37% and mucous membrane at 62.74%. When the disease severity was assessed using the PDAI scoring, most patients reported significant disease severity 62.74%, and 37.25% reported moderate severity (Table 1 and Figure 1). According to the diagnosis, most cases were PV 82.35%, with the remaining being PF 17.64%. Regarding the response to treatment,49.01% had a 25% clearance rate, 29.41% had a 50% clearance rate, and 7.84% had a 75% clearance rate. However, reports of patient deaths included 13.72% (Table 1).

Treatment Strategies for Pemphigus Patients

The major goal of treating pemphigus is to treat symptomatically / manage the symptoms of the disease using corticosteroids and adjuvant therapy. Adjuvants are immunosuppressant's intended to stop the adverse reactions of long-term steroid use. Systemic corticosteroids are strengthened by adjuvants that inhibit the immune system. Patients with pemphigus were found to be treated along with PPIs and antibiotics most frequently. Of patients diagnosed with Pemphigus, the majority were receiving various treatments or combination drug therapies. Corticosteroids including methylprednisolone (39.12%), dexamethasone (15.68%), prednisolone (31.37%), hydrocortisone (3.92%), Rituximab (5.88%), and azathioprine (33.33%). Prescription antibiotics are frequently given to treat or prevent secondary infections. Antibiotics such as amoxicillin plus potassium clavulanate combinations (58.82%), Dapsone (3.92%), cefixime (3.92%), and doxycycline plus lactic acid (9.80%). Antihistamines are used for managing itchiness and allergic reactions, medication consists of such as hydroxyzine (3.92%), and levocetirizine dihydrochloride (43.13%). Prescription PPIs such as ranitidine (11.76%) and pantoprazole (74.50%) are used to treat gastrointestinal symptoms and avoid stomach ulcers caused by corticosteroid medication. Topical therapy such as clobetasol propionate (5.88%), fusidic acid (58.82%), betamethasone (7.84%), mupirocin (5.88%), Nadifloxacin (7.84%), Triamcinolone (5.88%) and benzocaine (5.88%). Among the supportive treatments, therapy includes such as soluble insulin injection (7.84%), Biphasic isophane insulin injection (3.92%), and liquid paraffin (55.88%), Calcium with magnesium, Zinc, and Vitamin D3 (39.21%), and Paracetamol (27.45%) (Table 2).

Survival analysis of Pemphigus patients

The 10-year overall survival among pemphigus patients was found to be 86.3%. Furthermore, the survival rate remains the same until the end of 9.91 years. Out of 51 Pemphigus patients, 7 were found to be dead, and the lowest time to death was 2 days followed by 15 days, 1 month, 4 months, 12 months, and 94 months, respectively. The mean survival time among pemphigus patients was found to be significantly affected by Age ($p<0.05$). The survival for the age group over 45 years at the end of 10 years was 67.2%. The overall estimated mean survival time among pemphigus patients was 103.21 months (Table 3, Figures 2 and 3).

The univariate Cox regression analysis was carried out for the statistically significant ($p>0.05$) parameters in the log-rank test i.e., Age. In univariate analysis, it was found that the mortality among patients aged over 45 years was 47.69 times higher compared to the patients aged less than or equal to 45 years. Therefore, the survival rates were lower for patients older than 45 years (Table 4).

Table 1: Demographics details and clinical characteristics of the Pemphigus patients.

Parameters	Frequency	Percentage (%)
Gender		
Female	26	50.98
Male	25	49.01
Age group (49.31±14.7)		
≤45	20	39.21
>45	31	60.78
Social habits		
Smoking	6	11.76
Alcohol	1	1.96
None	42	82.35
Smoking and Alcohol	2	3.92
Body Mass Index (BMI)		
Normal weight (18.5-<24.9 kg/m^2)	27	52.9
Overweight (25 to 29.9 kg/m^2)	22	43.13
Under Weight (<18.5 kg/m^2)	2	3.92
Symptoms		
Primary Symptoms		
Fluid-filled lesions	31	60.78
Associated Symptoms		
Itchiness	11	21.56
Painful lesion	24	47.05
Site of Lesions		
Skin	43	84.31
Scalp	16	31.37
Mucous Membrane	32	62.74
Severity of Disease		
Moderate	19	37.25
Significant	32	62.74
Diagnosis		
Pemphigus vulgaris	42	82.35
Pemphigus foliaceus	9	17.64
Response to therapy		
25% Clearance	25	49.01
50% Clearance	15	29.41
75% Clearance	4	7.84
Dead	7	13.72

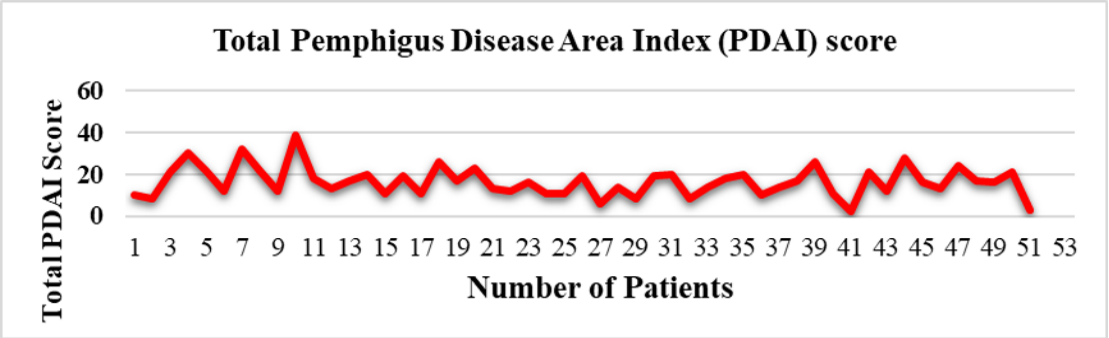


Figure 1: Severity assessment of pemphigus patients via PDAI scoring method.

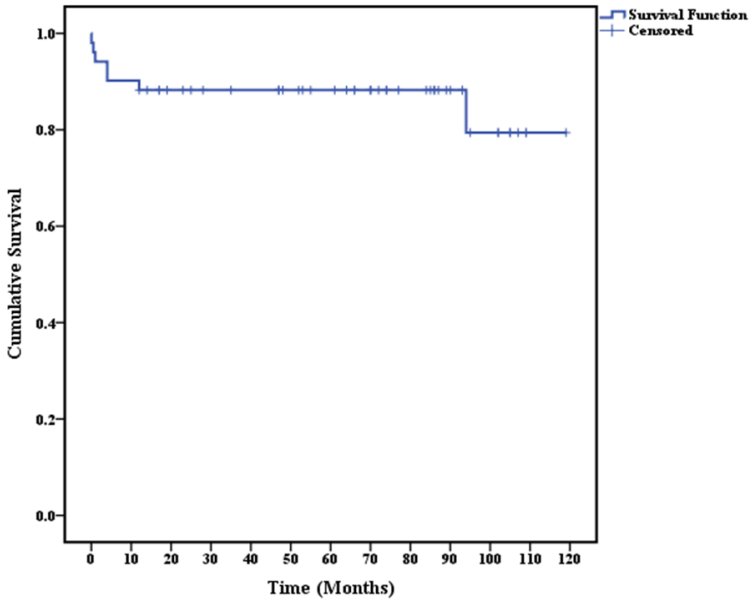


Figure 2: Overall Survival probability of pemphigus patients.

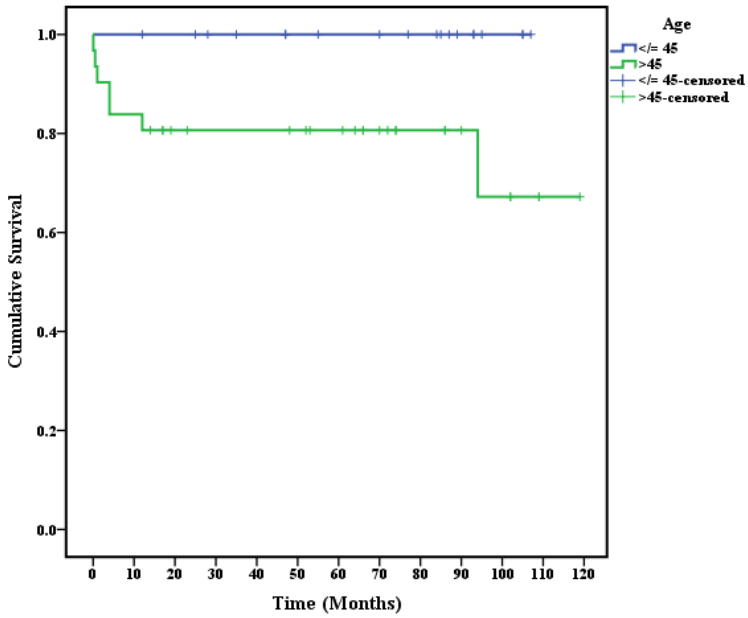


Figure 3: Kaplan-Meier survival estimates of Pemphigus patients for Age.

Table 2: Treatment Strategies for the pemphigus patients.

Drugs	Frequency	Percentage (%)
Line Immunosuppressants		
Methylprednisolone	20	39.21
Dexamethasone	8	15.68
Prednisolone	16	31.37
Hydrocortisone	2	3.92
Azathioprine	17	33.33
Rituximab	3	5.88
Antibiotics		
Amoxicillin plus potassium clavulanate	30	58.82
Dapsone	2	3.92
Cefixime	2	3.92
Doxycycline plus lactic acid	5	9.80
Antihistamines		
Levocetirizine Dihydrochloride	22	43.13
Hydroxyzine	2	3.92
Proton Pump Inhibitors		
Pantoprazole	38	74.50
Ranitidine	6	11.76
Topical therapy		
Clobetasol Propionate	3	5.88
Fusidic acid	30	58.82
Betamethasone	4	7.84
Mupirocin	3	5.88
Nadifloxacin	4	7.84
Benzocaine	3	5.88
Triamcinolone	3	5.88
Supportive therapy		
Soluble insulin injection	4	7.84
Biphasic isophane insulin injection	2	3.92
Liquid paraffin	3	5.88
Calcium with magnesium, Zinc, and Vitamin D_3	20	39.21
Paracetamol	14	27.45

DISCUSSION

In this study, females were predominant over males which is similar to an Indian study conducted by De *et al.* where they reported that the prevalence of pemphigus was higher among females (55.5%) than males (44.5%) (De *et al.*, 2020). In contrast, the study carried out by Baican *et al.* assessed the risk factors for overall mortality in pemphigus patients where they found that female patients (HR=1) had a greater mortality rate than male patients (HR: 0.73) (Baican *et al.*, 2015).

The majority of the patients in this study belongs to the age group of above > 45 years with a mean age of 52.8±15.6 years, which corresponds with the study conducted in Slovakia by Svecova *et al.* where they observed that most of the pemphigus patients belong to the age group of above 40 years (54.8%) (Svecova *et al.*, 2015). The results of the current investigation show that > 45 age had a greater mortality risk than the younger patients (HR=42.924). Conversely, a German study carried out by Papara *et al.* reported that the majority of the patients belong to the age group of 70-79 years with a higher mortality rate (HR=9.37) than< 75 years (Papara *et al.*, 2022).

Based on our findings, non-smokers were found to be higher among pemphigus patients than among smokers, which is concurrent to the study reported by Miyachi *et al.* where they found that majority of pemphigus patients (79.8%) did not smoke and had no history of smoking; yet, there was no discernible difference in their smoking behaviors when compared to controls (79.8%). Multivariate analysis revealed quitting smoking to be a substantial risk factor for PV (Miyachi *et al.*, 2016).

The present study revealed that, most people diagnosed with PV were more prevalent compared to those diagnosed with PF, which corresponds to a Japanese study by Miyachi *et al.* to analyse the clinical results and methods of practice in individuals with Pemphigus patients, where they found that (69%) of patients suffered from PV and (31%) diagnosed with PF (80%) (Miyachi *et al.*, 2023). The study carried out by Behkar *et al.* where they observed that predominant of the patients diagnosed with PV (92.5%) and 7.5% were identified with PF (Behkar *et al.*, 2022). In our study, most of the of the patients had significant severity of PV followed by moderate severity (Figure 1) which is equivalent to the study reported by Boulard *et al.* in France where they reported that (cut off values was 15 and 45) the majority of them belongs to an extensive subgroup (61%) of PDAI activity scores (Boulard *et al.*, 2016). Conversely, in a study conducted by Krain *et al.* the calculated cut-offs were 9 and 24 and reported that the majority of the patients belonged to the mild (42.3%) and moderate (40.4%) subgroups of disease severity (Krain, 1974).

In our analysis, the majority of the patients received Antibiotics, Proton Pump Inhibitors (PPI), and Corticosteroids along with immunosuppressants which agrees with the treatment strategies of a study conducted by Svecova *et al.* where the majority of the patients were administered with corticosteroids (75%) as monotherapy, and in combination with adjuvant immunosuppressants (29.5%) (Svecova *et al.*, 2015). Additionally, the study carried out by Miyachi *et al.* reported that 37% of patients received Intravenous Immunoglobulin (IVIg), 30%

Table 3: The log-rank test of factors influencing survival of Pemphigus patients (*n*=51).

Variables	Categories	Total	Died	Chi-square	*p*-value
Age	≤ 45 years	20	0	4.893	0.027*
	> 45 years	31	7		

Table 4: Univariate analysis of risk factors for mortality among Pemphigus patients.

Characteristics		Univariate analysis			
		p value	HR	95% CI for HR	
				LB	UB
Age	≤ 45 years		1		
	> 45 years	0.224	47.693	0.095	24113.646

received Immunosuppressive therapy and 16% of patients received steroid pulse therapy (Miyachi *et al.*, 2023). Antibiotics and Proton Pump Inhibitors (PPIs) were the most commonly prescribed medications for Pemphigus treatment. The prolonged use of corticosteroids in pemphigus patients, resulting in gastrointestinal side effects which might contribute to the high consumption of PPIs.

Over a median follow-up duration of 103.21 months, we've retrospectively examined 51 patients with pemphigus. In our study, the survival rate was found to be approximately 86.3% with the mortality rate of 13.7% which agrees with the finding of a study conducted by Kridin *et al.* where they reported that the overall 10-year survival rate was found to be 89.7% (Kridin *et al.*, 2017). Although the global survival rate of the PF subtype was higher than that of PV (91.4% vs. 85.4%). The reported survival rate for patients with PV was 81.5% and the total death rate was almost 26.5%. The report states that the mortality rate in India for pemphigus is between 5% to 20% (Quintarelli, 2022; Krain, 1974).

Although the current study has explored the overall survival among pemphigus patients, the study has certain limitations like retrospective single-centered study with limited sample size. Thus, further prospective study with a large sample size can map the real-world scenario appropriately.

CONCLUSION

The study concludes that pemphigus patients with moderate to significant severity can be well managed with corticosteroids along with adjuvant therapy which has significantly resulted in favorable survival outcomes, i.e. survival rate at the end of 10-year among Pemphigus patients was 86.3%.

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ABBREVIATIONS

ABSIS: Autoimmune Bullous Skin Disorder Intensity Score; **BMI:** Body Mass Index; **CI:** Confidence Interval; **DIF:** Direct Immunofluorescence; **DSG-1:** Desmoglein-1; **DSG-3:** Desmoglein-3; **EADV:** European Academy of Dermatology and Venereology; **ELISA:** Enzyme-Linked Immunosorbent Assay; **HR:** Hazard Ratio; **IIF:** Indirect Immunofluorescence; **IVIG:** Intravenous Immunoglobulin; **LB:** Lower Bound; **PDAI:** Pemphigus Disease Area Index; **PF:** Pemphigus Foliaceus; **PNP:** Paraneoplastic Pemphigus; **PPIs:** Proton Pump Inhibitors; **PV:** Pemphigus Vulgaris; **SPSS:** Statistical Package for the Social Sciences; **UB:** Upper Bound; **IgA:** Immunoglobulin A.

CONFLICTS OF INTEREST

The authors declare that there is no conflict of interest.

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