OBSERVATIONAL STUDY

Demographic and clinical profiles of adult Filipino patients with psoriasis in Davao City: a cross sectional study

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Background: The Psoriasis Registry (PsorReg) was created by the Psoriasis Foundation of the Philippines with the goal of assessing the true magnitude of psoriasis in Davao City.

Objectives: To determine the demographic and clinical profiles of Filipino patients enrolled in PsorReg.

Methods: Cross-sectional study among adult patients enrolled in PsorReg.

Results: A total of 131 patients were included in the study. Mean age was 43.89 ± 15.8 years old. Chronic plaque psoriasis (96.2%) was the most common clinical pattern. 63.4% had nail involvement, while 35.1% had psoriatic arthritis. BMI was normal in 51.1% of patients. Common co-morbidities were hypertension (19.1%), diabetes (10.7%), and dyslipidemia (9.2%). Most common treatment were topical medications, while biologics were the least common. 42.7%, 49.6% and 37.4% had moderate psoriasis using BSA, PASI, and PGA, respectively. Majority (47.3%) reported a large effect of psoriasis on their quality of life.

Conclusion: This study determined the demographic and clinical profiles of adult Filipino patients registered in PsorReg in Davao City.

Keywords: psoriasis, registry, Davao, Philippines, Psoriasis Foundation of the Philippines

INTRODUCTION

Psoriasis is a non-communicable, chronic inflammatory disease of the skin that can lead to significant morbidity and mortality.[1-3] The World Health Organization (WHO) reported that the worldwide prevalence of psoriasis varies from 0.09% to 11.4%.[3] In 2015, the Philippine Dermatological Society - Health Information System (PDS-HIS) ranked psoriasis as the 5th most common consult among the 11 accredited training institutions in the Philippines.[4]

Psoriasis is a chronic, immune-mediated, papulosquamous disease.[5-7] It results from excessive growth and differentiation of keratinocytes due to the activation of the cellular immune system, specifically T-cells, dendritic cells, various immune mediated cytokines and chemokines.[2,7-9] It has a variable skin presentation, distribution, severity and course.[6-7]

Psoriasis has an equal occurrence in males and females.[7] It is known to have a bimodal pattern, and affects age groups ranging from 15 to 20 and 55–60 years of age.[7,12] The distinction between early-onset and late-onset psoriasis has been proposed by Henseler and Christophers in 1985.[13] Early-onset psoriasis (type 1) begins at age of less than 40 years, while late-onset psoriasis (type 2) begins at age 40 years and above. Such distinction is important because of their differences in disease progression and clinical manifestations.[13-15]

Common clinical patterns of skin presentation include chronic plaque type, guttate, inverse (flexural), erythrodermic, and pustular.[3,6,7] Other rare variants have also been described.[7] Furthermore, some patients may have psoriatic nail disease without any skin manifestations.[6,16]

Psoriasis has a genetic predisposition, but interaction with environmental factors plays an important role in disease severity and progression.[1] Various modifying factors have also been found to be associated with exacerbation of psoriasis including stress, alcohol, pregnancy, sunlight, smoking, obesity, infection, and drugs, which affect disease severity.[17-21]

In recent years, a significant number of research studies have been done to investigate the biology and natural history of psoriasis and its association with various factors.[2,22] This is evidenced by a number of existing literature on psoriasis including immunogenetics, pathogenesis, clinical and demographic profiles, and

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treatment outcomes. Despite these efforts, a gap still exists in terms of research and clinical data on psoriasis in our local setting.

One of the key areas for research is to conduct long-term, prospective studies to determine the prevalence and natural history of psoriasis in various ethnic groups.[22] According to the WHO Global Report, it has been identified that there is a need for quality data on the incidence and prevalence of psoriasis, especially from low- and middle-income countries.[3] Epidemiological data collected through a standardized disease registry is a possible way to address this gap.

Several studies have been conducted to investigate psoriasis in terms of demographic, social, and clinical profiles of patients.[1,10,11,23] However, prevalence studies establishing the true magnitude of psoriasis, its association with various modifying factors and treatment outcome using a robust, large-scale epidemiological study remain limited in our setting.

Patient registries are standardized databases, which are possible sources of data for clinical research, patient management, and health planning.[24-26] They may supply useful information for researchers, healthcare providers, and policymakers. Patient registries on cancer, rare diseases, and injuries have been developed for these reasons. Significantly, these studies could provide patients the much-needed support they deserve from the government through health policies and insurance coverage.

In dermatology, psoriasis has the most number of registries being utilized.[27] In a review of 43 dermatologic registries, 10 were related to psoriasis where 9 out of 10 were used to monitor patients on systemic therapies.[27] These registries are usually maintained by academic institutions, government agencies, and non-government institutions interested in the study of specific disease conditions.[25-28] Numerous registries for psoriasis are being implemented in other countries.[17,23,27] In the Philippines, there is currently no standardized psoriasis registry being implemented.

The Psoriasis Registry (PsorReg), is a registry created in 2015 by the Psoriasis Foundation of the Philippines with the goal of assessing the true or accurate magnitude of psoriasis in Davao City. This registry was adapted from the psoriasis registry used in the National Skin Centre, Singapore. It is an ongoing systematic collection of data pertaining to patients with psoriasis. It includes old and newly diagnosed patients with psoriasis seen at both public and private dermatology hospitals or clinics. The PsorReg form is a data collection tool used to gather demographic and clinical data, which is subsequently recorded and updated. Considering the present limitation of local data about psoriasis in the country, PsorReg is a potential source of standardized, timely, and accurate information for scientific studies.

Research Question

Using a cross-sectional study, what are the demographic and clinical profiles of adult Filipino patients registered in PsorReg?

Significance of the Study

Psoriasis is a common dermatologic condition and is one of the top 10 most common dermatologic conditions seen in PDS-accredited institutions.[3,4,29] There is a limited number of local data on demographic and clinical profiles of patients with psoriasis. This study will add to the limited number of existing data on psoriasis. Such information is useful in patient management and health planning. This may also provide clinicians, researchers and pharmaceutical companies vital information in conducting studies aimed at comparing efficacy and safety of treatments.

This study will be able to identify potential areas for improvement of the PsorReg forms. The findings and recommendations of this study will guide the initiators of PsorReg in instituting changes to improve the quality of data being collected. Finally, knowledge in the existing profile of patients will guide policy-makers and health leaders on resource-allocation, policy development and health-service delivery.

Objectives

The general objective of this study was to determine the demographic and clinical profiles of adult Filipino patients registered in PsorReg.

This study specifically aimed:

1. To describe the demographic profile of adult Filipino patients registered in PsorReg in terms of:
   - 1.1 Sex
   - 1.2 Age
   - 1.4 Occupation
   - 1.5 Smoking status
   - 1.6 Alcohol consumption
2. To describe the clinical profile of adult Filipino patients registered in PsorReg in terms of:
   - 2.1 Skin type
   - 2.2 Age at disease onset
   - 2.3 Family history of psoriasis
   - 2.4 Duration of disease
   - 2.5 Clinical pattern of skin manifestations of psoriasis
   - 2.6 Presence or absence of nail involvement
   - 2.7 Presence or absence of psoriatic arthritis

2.8 Body mass index (BMI)
2.9 Presence of co-morbidities
2.10 Type of psoriasis treatment

3. To determine the severity of the psoriasis disease in adult Filipino patients registered in PsorReg using body surface area (BSA) involvement, psoriasis area severity index (PASI), and physician global assessment (PGA); and
4. To determine the dermatology life quality index (DLQI) of adult Filipino patients registered in PsorReg.

METHODS

Study design

This study used a cross-sectional design conducted from June 2016 to September 2016 among adult Filipino patients with psoriasis enrolled in a local registry using the PsorReg forms.

Setting and study participants

This study was conducted in Davao City, Philippines. All patients registered in PsorReg were eligible to be included in the study.

Inclusion criteria

1. Adult Filipino patients with successfully filled-out PsorReg forms (Appendix 1).

Exclusion criteria

1. Incompletely filled registry forms;
2. Registry forms of patients below 18 years old; and
3. Those who answered "no" on items 4, 5, and 6 from the informed consent form (ICF) (Appendix 2), identified by authorized people in the registry, were excluded.

Study duration

This study was conducted from June 2016 to September 2016.

Study procedure and sampling design

The study included adult Filipino patients with psoriasis registered in the PsorReg since its implementation in 2015. All successfully filled-out PsorReg forms, filed and registered in PsorReg were de-identified and was obtained by the investigator for analysis.

The sampling design of the study was non-probability sampling, specifically purposive sampling where the population to be selected was based on pre-specified criteria.

Data Collection

The source document was the successfully filled-out registry forms. The data collected from the PsorReg forms contained the variables of this study.

Study Variables

The variables of the study were the following: age, sex, occupation, smoking status, alcoholic consumption, age at disease onset, skin type, type of psoriasis, body mass index (BMI), presence or absence of nail involvement, presence or absence of psoriatic arthritis, presence of co-morbidities, type of psoriasis treatment, disease severity and quality of life. The duration of the disease was computed by subtracting age at disease onset from the age of patient.

Study size

Sample size was calculated using Epi info version 7.0 for a population survey. In this study, we assumed that there were 10,000 patients seen at the dermatology department of a tertiary hospital in a year with a 4.8% psoriasis prevalence. The psoriasis prevalence data was from the study of Gelfand et al. where they described that studies done in different countries have an estimated prevalence of psoriasis at 0.6 to 4.8% of population.[30] From this data, we calculated a minimum of 68 patients for the study to have a power of 95% with a confidence level of 0.05. However, we aimed to include all patients registered in PsorReg.

Data analysis

Descriptive statistics such as means, range, and standard deviations for continuous variables were determined. Categorical data were presented as frequencies and percentages.

RESULTS

There were 133 patients who successfully completed the PsorReg forms, but two were excluded because they were below 18 years old. A total of 131 patients were included in the study (Figure 1).

Demographic profile

Table 1 shows the distribution of patients registered in PsorReg by demographic profile. There was almost an equal number of male (50.4%) and female (49.6%) patients registered. The male-to-female ratio was 1.02:1. The mean age of patients was 43.89 years old (SD ± 15.8). The age of the patients ranged from 18 to 87 years old. More than half of the patients were employed (55.7%); one-third were unemployed. A majority were non-smokers (77.86%), while 74.8% did not drink alcohol.

Clinical profile

Table 2 shows the distribution of patients registered in PsorReg by clinical profile. A majority of patients had Fitzpatrick skin type 4. While a minority were types 3 and 5. The average age at disease onset was 36.86 ± 16.28 years old. Almost two-thirds of patients were classified as Type 1 psoriasis, or those who had the onset of the disease before they were 40 years old. A majority of the patients had no family history of psoriasis (66.41%). More than half of them (55.7%) had disease duration of 5 years or less, while 21.4% had had psoriasis for 6 to 10 years.

Chronic plaque psoriasis was the most common clinical presentation among our patients (96.2%). Others clinical patterns were erythrodermic psoriasis (2.3%), inverse (flexural) psoriasis (0.8%), and guttate (eruptive) psoriasis (0.8%).

Nail involvement was seen in 63.4% of patients while psoriatic arthritis was seen in only 35.1%. Half of the patients had normal BMI (51.1%). The other half were either overweight (31.3%) or obese (11.5%).

Associated co-morbidities

Fifty-seven percent (57%) of patients reported an existing co-morbidity. Table 3 shows the associated co-morbidities seen among the patients in PsorReg.

The most common is cardiovascular (44.3%) followed by gastric/hepatic/renal (6.1%), malignancy/infection (6.1%), and neuropsychiatric disorders (0.8%). The most common cardiovascular conditions were hypertension (19.1%) followed by diabetes (10.7%) and dyslipidemia (9.2%).

Non-alcoholic fatty liver disease (NAFLD, 3.1%), peptic ulcer disease (2.3%), and chronic kidney disease (0.8%) were the reported gastro-hepato-renal diseases among the patients in PsorReg.

Only 6.1% of patients had malignancy/infections including pneumonia and other infections other than tuberculosis (4.6%), tuberculosis (0.8%), and other cancers (0.8%).

Psoriasis treatment

Table 4 shows the type of treatments used for the patients in PsorReg. A majority of patients were given topical treatments (97.7%). Less than a third used systemic treatment (26.0%) and phototherapy (19.1%). A limited number of patients had used biologics (6.1%).

The most widely used topical medication were topical steroids (96.9%) followed by vitamin D analogues (13.7%), coal tar (11.5%) and calcineurin inhibitors (3.1%).

Methotrexate was the most common systemic treatment given (24.4%). A few were treated with acitretin (3.8%) and cyclosporine (0.8%). No patient was given hydroxyurea.

Only 9.1% of patients were treated with phototherapy, among which narrowband UVB was used for most of them (18.3%).

Among the patients who were given biologics (6.1%), 5.3% were given etanercept, 1.5% were given ustekinumab, and 0.8% were given infliximab.

Baseline psoriasis disease severity

Psoriasis disease severity was documented using body surface area (BSA) involvement, psoriasis area severity index (PASI), and physician global assessment (PGA).

Figure 2 compares the severity of psoriasis that was assessed using BSA and PASI. Using BSA, 13% had severe psoriasis, 42.7% had moderate psoriasis, and 44.3% had mild psoriasis. In contrast, using PASI as the assessment tool, only 1.5% had severe psoriasis, 49.6% had moderate psoriasis, and 48.9% had mild psoriasis.

On evaluation using physician global assessment (PGA), 37.4% were moderate, 33.6% mild, 17.6% almost clear, 6.9% moderate to severe, 3.1% severe, and only 1.5% were clear. (Figure 3)

Quality of life

Using DLQI to assess the quality of life of patients in PsorReg, 47.3% reported large effect of psoriasis on their quality of life. The rest reported moderate effect (18.3%), mild effect (17.6%), extremely large effect (9.9%), and no effect (6.9%). (Figure 4)

DISCUSSION

The demographic and clinical profiles of the patients in PsorReg are comparable to the observations from other international psoriasis registries. The mean age of patients was 43.80 years. These findings were consistent with other international studies where the mean age of psoriasis patients was observed at the third to fourth decade.[17,31]

The slightly equal male-to-female ratio (1.01:1) was reported by Kho et al. and Tolentino et al., which were locally conducted studies.[10,11] Both the Malaysian Psoriasis Registry and Institute of Dermatology Registry in Thailand reported a slightly different male-to-female ratio at 1.2:1.[17,23]

The peak age at onset of psoriasis occurs between 15 and 30 years of age.[7] This is different from the findings in our study where we noted a slightly higher age of onset at 36.86 years old (SD ± 16.28). This finding was slightly higher compared to the observation from a Malaysian Registry, which was 32.9 years and from Thailand's Registry, which was 32.88 years. [17,23] However, the difference may be attributed to the fact that that those patients below 18 years old were excluded from the study, resulting in selection bias. This selection bias may be addressed by including patients in PsorReg who are below 18 years old in the study analysis. Further, more than half of the patients (59.5%) had early-onset or Type 1 psoriasis. This finding is congruent with other studies where more than half of the patients developed psoriasis at age below 18 years.[7,14,17,32,33] Differentiation between type 1 and type 2 psoriasis and its clinical implications are still not well established. However, clinical associations with age at disease onset have been noted in one study among Asian populations.[14] In a study of 1,017 Thai patients, type 1 psoriasis was associated with family history and guttate psoriasis, while type 2 psoriasis was associated with palmoplantar psoriasis.[14] Whether such correlation exists among our patients needs further investigation.

In our study, most of the patients were employed while 37.4% were unemployed. However, knowing the proportion of unemployed is important because of the high cost and burden of treatment for psoriasis.

Psoriasis has a strong genetic predisposition.[33,34] Among Asians, type 1 psoriasis was reported by patients with a family history of the disease.[14] In our study, type I psoriasis was seen in approximately 60% of patients. Studies determining the association between type 1 psoriasis and family history of psoriasis are well reported in literature.[13-15]

Chronic plaque psoriasis was the most prevalent type, consistent with the reports in literature.[3,7,14,17,21,23] It is also consistent with Malaysian and Thai psoriasis registries with values reported at 89.9% and 85.6%, respectively. [17, 23] However, this was relatively lower than our findings where almost 97% of our patients had plaque-type psoriasis. Other uncommon forms of psoriasis were also seen in our patients. Furthermore, two-thirds of our patients had nail changes, a finding consistent with other reports in literature.[17]

The exact prevalence of psoriatic arthritis is unknown.[35] Our results showed that psoriatic arthritis was present in 35.1% of patients, which was twice the reported number in other Asian populations. Other studies reported a prevalence of 16.7% and 17.3%.[12,17]

More than half (57%) of patients had a significant co-morbidity. Cardiovascular disorders were the most common co-morbidity seen. Hypertension, diabetes mellitus, and hyperlipidemia were our findings that are similar to reports in literature.[7,12,20,36-38] Tseng et al. concluded that these patients, regardless of disease severity, had a higher risk for hypertension, diabetes, and obesity compared to the general population.[39]

Obesity is known to be a common co-morbidity among patients with psoriasis.[37] In our study, majority of the patients had normal BMI although a significant percentage were overweight or obese.

A few of our patients had a history of smoking and drinking alcohol. A study done in Germany showed that patients with psoriasis who were smokers had an increased disease severity.[37]

The most common treatment used by patients were topical steroids. This finding was different from the report from the Malaysian registry where emollients were the most common topical agent used.[17] Hence, emollients may be included in the treatment options in the PsorReg form since there are patients who use this type of treatment. Further, this study also reported narrowband UVB and methotrexate as the most common phototherapy and systemic treatments, respectively.[13]

Several measures of disease severity were used to monitor treatment outcome. BSA and PASI were used in determining disease severity. The percentage of patients with severe psoriasis was 13% using BSA compared to only 1.5% using PASI. This difference can be due to the non-standardized assessment of BSA. Upon reviewing the PsorReg form, we noted that a guide to assess BSA was not included in the collection. This finding, therefore, should compel the initiators of this registry to include a BSA guide in the PsorReg forms. (Appendix 1)

Although psoriasis is not a life-threatening condition, it has significant effect on the quality of life of patients.[6] The mean DLQI was 11.63 (SD $\pm$ 6.93). More than 50% had a DLQI of more than 10. This is higher compared to the finding in the Malaysian Registry (8.08 $\pm$ 6.29).[17] Since this is an ongoing registry, the DLQI may be measured on subsequent follow-ups and compared to the baseline value as part of assessing the therapeutic management of patients.

Strengths, Limitations, and Recommendations

To the best of our knowledge, this is the first completed study on psoriasis utilizing the information collected and filed by a psoriasis registry in the Philippines.

Our findings can guide the initiators of PsorReg to evaluate and modify the PsorReg forms to be able to come up with a more standardized data collection system for patients with psoriasis. This study can guide doctors, local health leaders, non-government organizations, and the government on resource allocation so that patients get the medical care they deserve.

However, this study has several limitations. First, this study focused on adult patients with psoriasis, hence, our findings were difficult to compare with the observations from other psoriasis registry, which included patients in the pediatric age group. This may have resulted in a selection bias which could explain the differences in our findings. Second, the PsorReg is a new registry that was started in 2015, hence, it has a relatively smaller number of registered patients compared to other registries. It is important to encourage all private dermatologists to register their patients to reflect the true number of patients seen in private clinics. The quality and generalizability of our findings will be improved with a bigger sample size. Lastly, patient registries, like any source of secondary data, have a potential for biases which a researcher cannot control. The quality, reliability, and validity of data relies greatly on data collection tools and the methods by which data are collected and recorded.

Therefore, the following are the recommendations of this study: (1) increase the sample size of the study by encouraging more dermatologists to register their patients in PsorReg to eliminate selection bias; (2) conduct a more thorough prospective study on psoriasis using the information collected by PsorReg and explore other associations using variables such as hemoglobin, hematocrit, creatinine, and SGPT, which were also recorded by PsorReg; and (3) evaluate and modify the existing PsorReg forms to improve the quality of data collected and to improve the reliability and validity of the data.

Generalizability

Knowledge of the demographic and clinical profiles of patients is helpful to dermatologists in giving the appropriate management to patients. Despite our limitations, the findings of this study may still be valuable for a more holistic approach to patients. Local organizations and policy-makers can use the findings of this study to institute policies and evidence-based resource allocation for the improvement of the quality of life of psoriasis patients.

CONCLUSION

This study determined the demographic and clinical profiles of adult Filipino patients registered in PsorReg in the local setting. It also provided an opportunity to evaluate the newly implemented PsorReg and to identify areas for change and improvement to collect data, which are useful for physicians, researchers, policy makers, and the patients themselves. Finally, this study strengthened the PsorReg as a standardized data collection system among patients with psoriasis, which may be deemed useful in a nationwide scale with active involvement of both public and private dermatologists, government and non-government organizations, and the patients themselves to address the need for local data and unified action on this common and debilitating dermatologic condition.

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APPENDIX 1. PSORIASIS REGISTRY FORM

PSORIASIS REGISTRY* - <u>NEW CASE</u>

CLINIC / HOSPITAL:

DATE: _____

Demographic Data

Name		**Gender**	Male / Female
Address		**Age**	
Ethnicity		**Skin Type** (1 to 6)	
Occupation			

Psoriasis Characteristics

Type of Psoriasis	Chronic plaque psoriasis / Others _____ (eg. pustular, guttate, erythrodermic)
Year of Diagnosis	
Family History (1st degree relative)	Yes / No
Nail involvement	Yes / No
Psoriatic Arthritis	Yes / No ; LOCATION:

Baseline Psoriasis Severity

BSA (%)		**Physician Global Assessment (PGA)**	5. O Severe	2. O Mild
PASI			4. O Moderate to severe	1. O Almost clear
NAPSI				
DLQI			3. O Moderate	0. O Clear

Baseline Physical Data

Height (cm)		**Weight (kg)**	

Past Medical History

(Please **tick** all that apply)

Cardiovascular	**Yes?**	**Year of Onset**	**Details (if applicable)**
Diabetes			Type 1 / Type 2
Hypertension			
Dyslipidemia			Tot Chol ≥240 mg/dl
Ischaemic heart disease / Myocardial infarction			
Stroke			
Peripheral vascular disease			

GI / Hepatic / Renal	**Yes?**	**Year of Onset**	**Details (if applicable)**
Peptic ulcer disease			
NAFLD (non-alcoholic fatty liver disease)			Fatty liver / Non-alcoholic steatohepatitis
Alcoholic liver disease			
Viral hepatitis			Hepatitis B / C
Chronic kidney disease			

Malignancy / Infection	**Yes?**	**Year of Onset**	**Details (if applicable)**
Skin cancer			BCC / SCC / Melanoma / Other _____
Other cancer			
Tuberculosis			
Other severe infection (eg. pneumonia, sepsis)			

Neuropsychiatric	Yes?	Year of Onset	Details (if applicable)
Demyelinating neuropathy			Multiple sclerosis / CIDP (chronic inflammatory demyelinating polyneuropathy)
Epilepsy			
Depression / Anxiety			

Others (please specify)	Yes?	Year of Onset	Details (if applicable)

Social History

Smoking	Yes / No	**Alcohol**	Number of years smoking: _____ Number of cigarettes/day: _____
Alcohol	Yes / No	**If Yes →**	Average number of units/week: _____ (see guidance below) **Alcoholic Drink** — **No. of units** 1 can of ordinary beer (330ml): 1.6 units Standard glass of wine (175ml): 2 units Small glass of spirits (25ml): 1 unit

Current Treatment

(Please **tick** all that apply)

TOPICAL		PHOTOTHERAPY		CONVENTIONAL SYSTEMIC		BIOLOGIC	
Topical steroids (including Daivobet, Beprosalic)		**NBUVB**		**Methotrexate**		**Infliximab**	
Calcineurin inhibitors (Protopic, Elidel)		**Oral PUVA**		**Ciclosporin**		**Adalimumab**	

Vitamin D analogues (Daivonex, Silkis, Daivobet)		**Topical PUVA**		**Acitretin**		**Etanercept**	
Coal tar		**UVA1**		**Hydroxyurea**		**Ustekinumab**	

Treatment History (Phototherapy/Systemic/Biologic)

(Please list all **previous** phototherapy/systemic/biologic therapy for psoriasis, **in chronological order**)

Treatment	Start Date	Stop Date	Stop Reason (Inefficacy / Remission / Adverse Effect / Other)

Physical Examination

EXAMINATION	NORMAL?	SPECIFY (If Abnormal)
Cardiorespiratory	Yes / No	
Abdomen	Yes / No	
Lymph Nodes	Yes / No	

Baseline Laboratory Data (within the last 6 months)

Haemoglobin		**Creatinine**	
White cell count		**ALT**	
Platelet count		**AST**	

Miscellaneous Comments

Completed by: _____ Signature: _____

PSORIASIS REGISTRY

NAME: _____

PASI SCORE

DATE						
HEAD						
REDNESS						
THICKNESS						
SCALING						
BSA						
PASI X 0.1						
TOTAL						
TRUNK						
REDNESS						
THICKNESS						
SCALING						
BSA						
PASI X 0.3						
TOTAL						
UPPER EXT.						
REDNESS						
THICKNESS						
SCALING						
BSA						
PASI X 0.2						
TOTAL						
LOWER EXT.						
REDNESS						
THICKNESS						
SCALING						
BSA						
PASI X 0.4						
TOTAL						
TOTAL SCORE						
EXAMINER						

PASI BSA: *0 (0%) *1 (1-9%) *2 (10-29%) *3 (30-49%) * 4 (50-69%) *5(70-89%) *6(90-100%)
CLASSIFICATION: *MILD (PASI <10) *MODERATE (PASI: 11-50) *SEVERE (PASI >50)

PSORIASIS REGISTRY

DERMATOLOGY LIFE QUALITY INDEX

DLQI Score: ☐

Date:
Name:

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick ☑ one circle for each question.

1.	Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been?	Very much A lot A little Not at all	O O O O	
2.	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin?	Very much A lot A little Not at all	O O O O	
3.	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**?	Very much A lot A little Not at all	O O O O	Not relevant O
4.	Over the last week, how much has your skin influenced the **clothes** you wear?	Very much A lot A little Not at all	O O O O	Not relevant O
5.	Over the last week, how much has your skin affected any **social** or **leisure** activities?	Very much A lot A little Not at all	O O O O	Not relevant O
6.	Over the last week, how much has your skin made it difficult for you to do any **sport**?	Very much A lot A little Not at all	O O O O	Not relevant O
7.	Over the last week, has your skin prevented you from **working** or **studying**?	Yes No	O O	Not relevant O
	If "No", over the last week how much has your skin been a problem at **work** or **studying**?	A lot A little Not at all	O O O	
8.	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?	Very much A lot A little Not at all	O O O O	Not relevant O
9.	Over the last week, how much has your skin caused any **sexual difficulties**?	Very much A lot A little Not at all	O O O O	Not relevant O
10.	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	O O O O	Not relevant O

APPENDIX 2: INFORMED CONSENT

Informed consent for participating in the Psoriasis Registry

For the purpose of this Consent *"the patient"* will refer to the person diagnosed with **psoriasis**. *"You"* will refer to the person giving the information. This may be the affected individual or a family member or guardian of the affected individual (the person legally responsible for the care and maintenance of the affected individual).

A patient registry is a place where medical information, family history and other related information from patients is collected and stored for medical research. The purpose of the **Psoriasis registry** is to collect and store medical information and other information from individuals with the same disease in order to help health care professionals better understand the condition and improve treatment and management.

Information from patients will be used for medical research and experimental clinical trials to better understand this disease. The registry also addresses other critical needs.

The **Psoriasis registry** is sponsored by the **Psoriasis Foundation of the Philippines (PFPI)** and there is no cost to you to participate. If you join the registry, you will be asked to provide medical information on your disease and diagnosis. The goal of the registry is to share detailed medical and other information with scientists and other researchers, while still protecting your privacy. This is done by hiding the name, address and other "identifying" information from the researchers. We call this information "de-identified" because it has been removed of all personal identifiers. Your personal information such as, your name, address, or other information that identifies you or your family will be labeled with a code number and stored in a secure place and protected with a password. Only authorized people who work in the registry will know the code and be able to identify you if needed. The database will be in hardcopy and electronic form, and that it will be stored indefinitely.

Your identifiable information will not be shared with anyone outside the registry (unless you give your permission to share it). Approved scientists, researchers, and clinicians, will be allowed to see only the de-identified information and may search the de-identified data for patients for their studies. This database will be useful in monitoring clinical progress of patients. If a patient looks like a good match for a study and a researcher wants, to contact you, he can do it only through the **Psoriasis registry**. The **patient in-charge or your attending physician** will then contact you but the researcher will not contact you directly. Your de-identified information (information that has been removed of all identifiers) will be shared with other databases as required by current Philippine laws should you give consent to do so.

Should you change your mind and wish to withdraw your data from the registry, you will be free to do so without having to provide any explanation. Simply contact the registry and all of your data will be removed from the database. Data assigned to a specific study prior to your request for removal cannot be retrieved from researchers that have already accessed it.

There is minimal risk in taking part in the registry. The registry includes questions that can be sensitive and you may feel uncomfortable answering. You do not have to share any information you do not want to.

Another unlikely risk is potential breaches in the computer system. In the event the there is a breach in the registry's computer system all participants will be notified.
Registry information will be collected on patients who are diagnosed **with psoriasis**. Patients over the age 18 who understand the consent form (and thus do not have a legal guardian) are eligible to join the registry on their own. Otherwise, the legal guardian or parent of the patient must sign the consent for the patient to join. When the patient becomes 18 (and if they are able), consent will be obtained directly from them for continued participation.
You will be asked to update your registry information at least once per year. The registry in charge will contact you each year.

Other common questions:
I want to be involved in a clinical trial. If I register, is this guaranteed?
Although one of the main goals of the registry is to make it easier for affected individuals to participate in research, there is no guarantee that those participants will be eligible for a trial.
Please note that even if the coordinators of a clinical trial believe that you might be eligible for the trial, based on the data about you stored in The Psoriasis registry, it is still possible that later on it will turn out that you do not meet the trial requirement criteria after all. Please also be aware that if we inform you about the existence of a trial, this does not imply that we endorse it. In order to participate in any trial, you will need to discuss with the research staff about the trial and fill out a separate informed consent form.

I don't want to be involved in a clinical trial. Should I still register?
Absolutely, we hope that you will still be willing to register, even if you don't want to take part in a trial. Your information may still be useful to researchers who are trying to learn more about patients with the above mentioned psoriasis.

What are my options if I do not want to be in the Registry?
You do not have to join this registry. Participation is voluntary. You do not need to participate in this Registry to remain a member of the psoriasis community of patients. Your decision to participate in this registry or not will not affect your healthcare.

By signing this form, you do not give away any legal rights or benefits to which you are otherwise entitled. If you do join, you can change your mind and withdraw from the registry at any time and request to remove any of your information that has not assigned yet to any specific study. You will not be able to remove any information that already has been assigned to a specific study. If you decide not to sign this form, there will not be any effect on your regular health care, your medical treatment or insurance benefits.

Your signature below means: 1) you have been given the background/supplemental material and the opportunity to ask any questions; 2) you understand the content of the informed consent; 3) you have had the time to consider fully whether you want to join the registry, and 4) you agree to participate.

1. I understand that my participation in the registry is voluntary and that I can change my mind and withdraw at any time. □Yes

2. I understand that all attempts will be made to protect my privacy and my family's privacy. I understand that my personal information will be protected and saved in the registry using a code. However, there is a very small risk that my personal information could be revealed. □ Yes

3. I understand that by agreeing to participate, I will be contacted by the registry to update or correct my health information regularly. □Yes

I would like to be contacted by: Choose one or more.
□Email □ Mail □ Phone □ In Person

4. I am willing to provide my de-identified medical information to be used for clinical trials and other medical studies related to my disease.

□Yes □No

5. I understand that my de-identified information can be used for any approved research study including diseases that are not associated with my disease.

□Yes □No

6. I understand that my de-identified information will be shared with other databases.

□Yes □No

7. I understand that I may not personally benefit from participating in the registry or from the use of my de-identified medical information in any research study.

□Yes □No

8. I understand that I can withdraw from the registry at any time and remove my information. I also understand that any information given previously and already have been assigned to a specific study, cannot be removed.

□Yes □No

9. If it is permitted, I would like to know of any findings or results that may affect my health.

□Yes □No

10. I would like to be contacted of any future clinical trials or other studies that I can participate.

□Yes □No

11. I understand the content of this form, I was given the background information, I had enough time to ask questions, all my questions were answered and I had enough time to decide that I want to participate in this registry and I will be given a copy of this consent.

□Yes □No

Name of patient or legal representative: _____

Signature of the of patient/legal representative confirming that he/she understood the content of the consent form

Date: _____

Name of the person (not relative of the patient) who explained the content of the consent form: _____

Date: _____

FIGURES

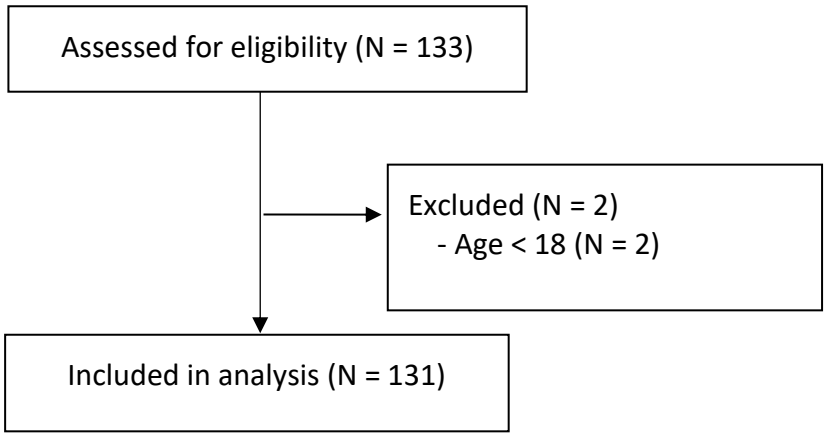

Figure 1. Flow chart of participants.

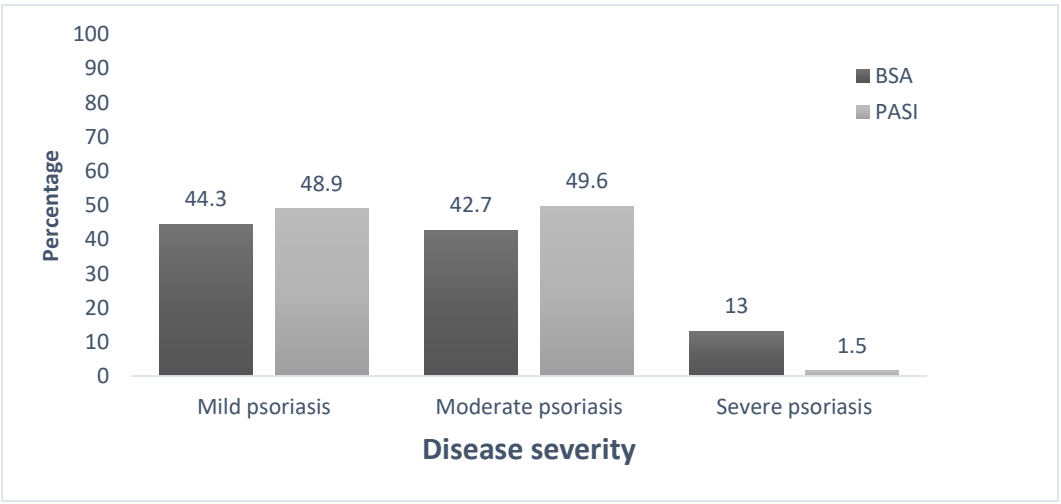

Figure 2. Disease severity using body surface area (BSA) and psoriasis area and severity index (PASI), (N=131)

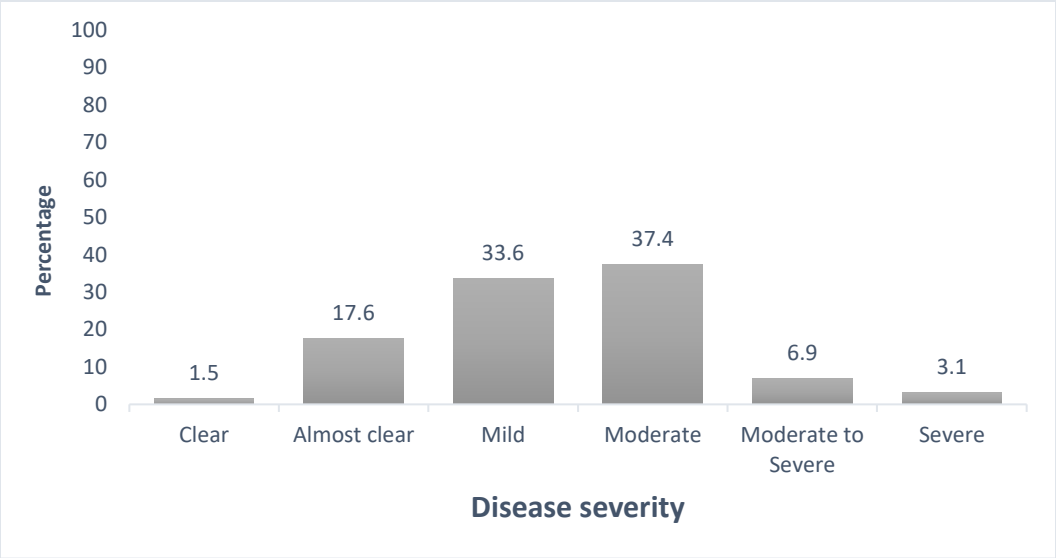

Figure 3. Disease severity in Physician Global Assessment (PGA), (N=131)

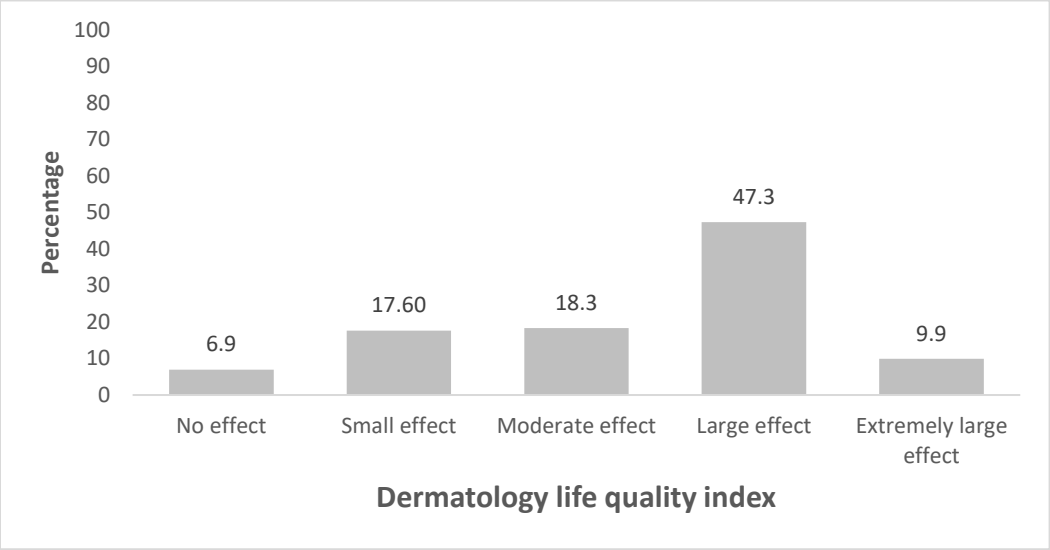

Figure 4. Dermatology life quality index (DLQI) (N=131).

TABLES

Table 1. Demographic profile of patients in PsorReg (N=131)

Characteristic	N, (%)
Gender	
Male	66 (50.4)
Female	65 (49.6)
Age of patients, mean ± SD	43.89 ± 15.81
Occupation	
Employed	73 (55.7)
Unemployed	49 (37.4)
Retired	6 (4.6)
Student	3 (2.3)
Smoking status	
Yes	29 (22.14)
No	102 (77.86)
Alcohol consumption	
Yes	33 (25.2)
No	98 (74.8)

Table 2. Clinical profile of patients in PsorReg (N=131)

Characteristic	N, (%)
Fitzpatrick skin type	
Type 1	0 (0)
Type 2	0 (0)
Type 3	1 (0.8)
Type 4	102 (77.9)
Type 5	28 (21.4)
Type 6	0 (0)
Age at disease onset, mean ± SD	36.86 ± 16.28
18-40 years old	78 (59.5)
>40 years old	53 (40.5)
Family history of psoriasis	
With family history	44 (33.59)
Without family history	87 (66.41)
Disease duration	
0-5 years	73 (55.7)

6-10 years	28 (21.4)
11-15 years	11 (8.4)
16-20 years	6 (4.6)
> 20 years	13 (9.9)
Clinical pattern of skin manifestations	
Chronic plaque psoriasis	126 (96.2)
Erythrodermic psoriasis	3 (2.3)
Inverse (flexural) psoriasis	1 (0.8)
Guttate (eruptive) psoriasis	1 (0.8)
Pustular psoriasis	0 (0.0)
Nail involvement	
With nail involvement	83 (63.4)
Without nail involvement	46 (35.1)
Psoriatic arthritis	
With psoriatic arthritis	43 (35.1)
Without psoriatic arthritis	85 (64.9)
Body mass index (BMI)	
Underweight (18.50 below)	8 (6.1)
Normal (18.5-24.99)	67 (51.1)
Overweight (25-30)	41 (31.3)
Obese (Greater than 30)	15 (11.5)

Table 3. Associated co-morbidities seen among patients in PsorReg.

Co-morbidity	**N, (%)**
Cardiovascular	**58 (44.3)**
Hypertension	25 (19.1)
Diabetes (Type I, Type II)	14 (10.7)
Dyslipidemia	12 (9.2)
Myocardial Infarction	4 (3.1)
Stroke	3 (2.3)
Peripheral Vascular Disease	0 (0.0)
GI/Hepatic/Renal	**8 (6.1)**
NAFLD	4 (3.1)
Peptic Ulcer Disease	3 (2.3)
Chronic Kidney Disease	1 (0.8)
Alcoholic Liver Disease	0 (0.0)

Viral Hepatitis	0 (0.0)
Malignancy/ Infection	**8 (6.1)**
Other infection	6 (4.6)
Other cancer	1 (0.8)
Tuberculosis	1 (0.8)
Skin cancer	0 (0.0)
Neuropsychiatric	**1 (0.8)**
Depression/Anxiety	1 (0.8)
Demyelinating neuropathy	0 (0.0)
Epilepsy	0 (0.0)

Table 4. Type of treatments given to patients in the PsorReg.

Type of treatment use	**N (%)**
Topical medications	**128 (97.7)**
Topical steroid	127 (96.9)
Vitamin D analogues	18 (13.7)
Coal tar	15 (11.5)
Calcineurin inhibitors	4 (3.1)
Phototherapy	**25 (19.1)**
NBUVB	24 (18.3)
Topical PUVA	1 (0.8)
UVA1	1 (0.8)
Oral PUVA	0 (0.0)
Conventional systemic medications	**34 (26)**
Methotrexate	32 (24.4)
Acitretin	5 (3.8)
Cyclosporine	1 (0.8)
Hydroxyurea	0 (0.0)
Biologics	**8 (6.1)**
Etanercept	7 (5.3)
Ustekinumab	2 (1.5)
Infliximab	1 (0.8)
Adalimumab	0 (0.0)