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Baseline Characteristics of Canadian Patients in the Psoriasis Longitudinal Assessment and Registry (PSOLAR)

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Abstract

Background: The Psoriasis Longitudinal Assessment and Registry (PSOLAR) is a global, prospective, longitudinal, disease-based registry. It serves as a post-marketing safety commitment with a focus on patients with moderate to severe plaque psoriasis who are candidates for systemic therapy.

Objectives: To describe the baseline disease demographics and clinical characteristics of a Canadian subgroup of participants enrolled in PSOLAR.

Methods: Baseline demographic/disease characteristics, medical histories, and previous psoriasis treatments for Canadian patients in PSOLAR were summarized using descriptive statistics.

Results: There were 1896 patients analyzed in the Canadian subgroup at 37 clinical sites, accounting for 15.7% of the global PSOLAR population. Baseline disease and clinical characteristics were as expected for a moderate to severe psoriasis population and were generally similar to the global PSOLAR population. Two distinctions were noted in the Canadian subgroup versus those enrolled globally: a higher proportion of patients were overweight/obese (84.7% vs. 80.4%) and male (61.4% vs. 54.7%). In addition, the Canadian subgroup had numerically higher historical peak disease activity (PGA score 3.35 vs. 3.1) and longer disease duration (22.3 years vs. 17.5 years). Canadian PSOLAR patients reported a variety of comorbidities, including psoriatic arthritis (31.5%), hypertension (34.6%), hyperlipidemia (24.3%), mental illness (24.1%), and inflammatory bowel disease (1.6%).

Conclusion: The Canadian subgroup of PSOLAR patients was generally similar to those enrolled globally with respect to baseline disease demographics and clinical characteristics. Multiple comorbidities are noted in the Canadian subgroup, underscoring the need for a holistic approach to the treatment of psoriatic patients.

Keywords

biologics, psoriasis, PSOLAR, systemic therapy, comorbidities

Introduction

Psoriasis is a chronic inflammatory skin disease caused by the interplay of genetic and environmental factors, and is associated with several comorbid conditions.[1-3] Major comorbidities such as psoriatic arthritis (PsA), inflammatory bowel disease (IBD), mental illness, obesity, cardiovascular disease (CVD), and metabolic diseases contribute to impairment in quality of life and complexity of disease management in this population.[4-9] Approximately 3% of the global and Canadian populations have psoriasis[10] and approximately one million Canadians are affected by the disease.[11,12]

The Psoriasis Longitudinal Assessment and Registry (PSOLAR) was initiated by Janssen Biotech, Inc. (Horsham, PA, USA) to address the need for long-term, real-world data on ustekinumab, infliximab, and other biologic therapies. PSOLAR also includes patients on other conventional systemic therapies and phototherapy.[13,14] The registry represents a rich resource of

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comparative demographic, safety, and effectiveness data for analysis, and the results have led to several global publications to date.[13,15-19]

Contemporary disease-based characterization of Canadian patients with psoriasis is limited to regional, survey, or administrative database analyzes.[20-23] PSOLAR represents a robust and unique source of real-world evidence for moderate to severe psoriasis. Characterization of the Canadian subgroup was considered important for country-specific disease understanding and management. To this end, we report a descriptive analysis of baseline disease characteristics, medical history, and treatment details of Canadian patients enrolled in PSOLAR. Key differentiating clinical characteristics of the Canadian and global PSOLAR populations are also reported.

Material and Methods

Study Design

PSOLAR is a prospective, longitudinal, disease-based registry designed to collect safety, efficacy, and health outcomes data from over 12,000 adult patients (≥18 years of age) with psoriasis receiving, or eligible to receive, conventional systemic or biologic therapies.[13,14] Full details regarding the registry design have been previously published.[13,14]

Briefly, patient recruitment into PSOLAR started in 2007 with the objective of following enrolled patients for up to 8 years. Canadian enrollment into PSOLAR began in 2009. All patients provided written informed consent before the start of the study, and an institutional review board or ethics committee approved the registry protocol at participating sites. Data were collected every 6 months, in line with clinical practice, and analyzed yearly. Data included herein were collected through August 23, 2013.

Data Analysis

For this report, epidemiological data (i.e., demographic and disease characteristics, individual and family medical history, social history, and psoriasis treatment history) of Canadian patients at enrolment were summarized, by gender, using descriptive statistics. The following comorbid medical conditions were extracted and reported on: PsA, CVD, diabetes mellitus, obesity, mental illness, malignancy, sleep apnea, chronic obstructive pulmonary disease, hepatic disease, and IBD.

Selected parameters (i.e., mental illness, as well as cardiovascular risks and diseases) were summarized by five age groups: 12-19 years, 20-34 years, 35-44 years, 45-64 years, and ≥65 years. Finally, predefined clinical characteristics (i.e., gender, disease duration and activity, and body mass index [BMI]) of the Canadian subgroup were compared to the entire global cohort.[13]

Results

As of August 23, 2013, PSOLAR enrolled 12,095 patients globally, with an accumulation of 31,818 patient-years of follow-up from 16 countries in North America, Europe, Israel, and Latin America. Canada recruited 1896 patients from 37 clinical sites. This accounted for 15.7% of the total patients, with an average of 2.63 years (SD 1.05) and total of 4990 years of follow-up (Supplemental Figure 1). Baseline parameters for the Canadian PSOLAR subgroup, evaluated by gender- and age-based cohorts, are presented below.

Disease Characteristics

A higher proportion of Canadian patients recruited into the registry were male (61.4%) (Supplemental Table 1). The mean age for the Canadian subgroup was 49.0 years and the

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majority of patients were Caucasian (91.7%). Moreover, 84.7% of the Canadian patients were overweight or obese (mean BMI = 31.3 kg/m^2). Based on the National Heart, Lung, and Blood Institute Obesity Education Initiative criteria, 51.1% of the Canadian patient population was classified in the obesity classes I-III. An additional one third (33.6%) of the patients were included in the overweight category.

Almost all Canadian patients enrolled (99.2%) were affected by plaque psoriasis, with <1% having guttate, erythrodermic, pustular, or inverse psoriasis, and the mean duration of disease was 22.3 years (Supplemental Table 1). The mean body surface area (BSA) involvement at baseline was 7.4%. Mean Psoriasis Area Severity Index (PASI) score at baseline was 5.52 (SD, 6.44).

Comorbidities and Medical History

About one third (31.5%) of the patients reported having active PsA at baseline, with similar proportions of males and females affected by this comorbidity (Supplemental Table 2).

Nearly half (43.8%) of patients reported some form of CVD. The overall occurrence of cardiovascular risk factors and CVD across male and female patients was generally similar. However, roughly two- to three-fold more male than female patients reported a diagnosis of atherosclerosis (5.4%, 2.7%), coronary artery disease (4.4%, 1.9%), myocardial infarction (4.0%, 1.1%), and congestive heart failure (0.8%, 0.4%) (Supplemental Table 2). The incidence of cardiovascular conditions relatively early in life was notable, with individuals in the 20-34-year age group reporting hypertension (6.3%) and hyperlipidemia (3.2%). Further still, first reports of myocardial infarction (0.8%), angina (0.3%), atherosclerotic disease (0.3%), and transient ischemic attack (TIA)/cerebrovascular accident (CVA)/stroke (0.3%) in the 35-44 age group were observed. Coronary artery disease (4.4%, 9.9%), peripheral arterial disease (1.3%, 1.6%) and congestive heart failure (0.7%, 2.6%) were reported only by patients in the 45-64 and >65 year old cohorts (Supplemental Table 3, Supplemental Figure 2).

The proportion of Canadian patients in the registry reported to have IBD was 1.6%, with a higher rate for females than males (2.1%, 1.4%) (Supplemental Table 2). More than three quarters of patients reported current alcohol use (82.7%) and more than one quarter of patients were current smokers (28.4%) (Supplemental Table 2).

A history of mental illness was reported for 24.1% of the overall Canadian patient population enrolled in PSOLAR. Depression (17.4%) followed by anxiety (11.4%) were the most common types of mental illness. A higher proportion of female than male patients (32.8%, 18.5%) reported mental illness (Supplemental Table 2), regardless of age group (data not shown).

Previous Treatment

At baseline, 95.6% of patients had been treated with topical therapy, 72.6% with phototherapy, and 20.7% with the systemic retinoid acitretin. More than half of patients had been exposed to systemic immunosuppressants (55.2%) including methotrexate (47.3%) and cyclosporine (17.5%). A smaller proportion (14.7%) of patients had received systemic nonsteroidal antiinflammatory drugs (NSAIDs) (Supplemental Table 4a). The majority (85.8%) of the psoriatic patients were biologic-experienced and approximately half (49.7%) of these patients had been exposed to ustekinumab. Overall, 44.5% and 25.0% of the patients had been exposed to at least one and two biologics, respectively (Supplemental Table 4b).

Comparison to Global PSOLAR Population

Supplemental Table 5 outlines key clinical characteristics differentiating the Canadian and global PSOLAR populations.[13] While the proportions of male and female patients enrolled in the global cohort were comparable (56% and 44%, respectively), approximately two thirds of patients in the Canadian subgroup were male. Also, the mean duration of psoriasis was greater in the Canadian subgroup compared to the global PSOLAR population (22.3 years vs. 17.5 years, respectively). Similarly, a higher proportion of Canadian patients had more severe disease at the time of historical peak activity than the global population (e.g., 94.5% compared to 79.7% with PGA ≥ 3), which was predominately driven by the higher proportion of patients with moderate to severe disease at baseline. Finally, a slightly higher proportion of Canadian patients (84.7%) were overweight/obese at baseline relative to the global population (80.4%).

Discussion

This is the first report to focus on the baseline demographics and disease characteristics of Canadian patients with psoriasis included in a global, disease-based registry. Canadian recruitment was robust relative to the prevalent psoriasis population. The proportion of Canadian patients in PSOLAR who reported being white (91.7%) was relatively high compared to the general Canadian population (70%).[24] Nearly half of Canadian patients entering PSOLAR had minimal or mild psoriasis, presumably reflecting their disease status on active treatment. Our findings of multiple comorbidities in Canadian patients with psoriasis is consistent with the disease characteristics previously reported in patients with psoriasis.[25]

In this descriptive analysis, 31.5% of patients reported a history of PsA at enrollment, consistent with the prevalence of PsA among patients with psoriasis as reported in the literature.[26-28] While an increased risk of IBD among patients with psoriasis has been established, data on the prevalence of this comorbidity are limited. A recent meta-analysis estimated the global prevalence of IBD among adult patients with psoriasis to be 1.3%,[29]

which is consistent with our finding of 1.6% for Canadian PSOLAR patients.

Psoriasis has been shown to be strongly associated with obesity.[7] A high proportion of patients in the Canadian PSOLAR population was overweight or obese (84.7%). The impact of this on patient health is significant, as obesity seems to play an important role in linking psoriasis with CVD.[30] Epidemiological studies demonstrate a higher prevalence of cardiovascular risk factors among patients with psoriasis.[31-35] Our data suggest this is true for the Canadian PSOLAR population is consistent with this, as numerically higher rates of CVD were observed compared to the general population.[36] In addition, Papp et al. (2010) investigated the epidemiologic features of patients with moderate to severe psoriasis in Canada and reported hypertension, dyslipidemia, and overweight/obesity as common comorbidities among the patients surveyed.[11] Similarly, in our analysis, hypertension (34.6%) and hyperlipidemia (24.3%) were found to represent the most prevalent cardiovascular risk factors among Canadian PSOLAR patients. A subanalysis of cardiovascular risk factors and conditions stratified by age showed that hypertension and hyperlipidemia were present/diagnosed in some patients as young as 20 to 34 years old. Also, the Canadian PSOLAR subgroup showed a substantially higher prevalence of nearly all types of cardiovascular risk factors and conditions with increasing age (20 to ≥65 years). Risk factors such as hypertension and hyperlipidemia in patients with psoriasis should be recognized and managed as early as possible to mitigate potential future progression of CVD.[25]

Previous studies have shown that the prevalence of mental illness in patients with psoriasis ranges from 24% to 90% and that patients with psoriasis are at least 1.5 times more likely to suffer from depressive symptoms compared to the general population.[37,38] The prevalence of mental illness (24.1%) in the Canadian PSOLAR population at baseline was in the lower range of what has been reported in previous studies,[37-39] but higher than the national estimate for the general population in Canada (19.8% in 2008/2009 and 22.3% in 2022).[40,41] Breakdown of the baseline Canadian PSOLAR data by gender revealed the prevalence of mental illness was higher among female than male patients, regardless of age. This contrasts with a previous finding from the United Kingdom (UK) which reported no differences in rates of depression among men and women with psoriasis overall, but that depression was significantly more prevalence in men with severe psoriasis.[42] Further evaluation of differences in mental health status among male and female patients with psoriasis is warranted.

Differences in baseline features between the Canadian subgroup and global PSOLAR population were observed and included a higher proportion of male patients, a numerically higher level of historical peak disease activity, and longer disease duration for the Canadian subgroup.

The Canadian PSOLAR population also differed from patient populations enrolled in other psoriasis registries. Compared to the Canadian PSOLAR population, the United States (US)-based CorEvitas psoriasis cohort had a lower mean duration of disease of 15.6 years (vs. 22.3 years), higher mean BSA of 9.5% (vs. 7.4%), and a similar mean PASI score of 5.7 (vs. 5.5) at baseline (Strober 2018).[43] In the UK- and Ireland-based BADBIR psoriasis registry, mean disease duration at baseline (21.4 years) was similar to that for the Canadian PSOLAR population, however mean PASI score at baseline (16.1) was much higher in BADBIR.[39,43] Furthermore, differences in treatment exposure across registries were noted, with biologic use highest among patients in the Canadian PSOLAR population (86%) versus BADBIR (60%) and CorEvitas (54%).[39,43] In addition to geographical differences, variation between registries may also reflect temporal differences in disease management since PSOLAR and BADBIR began patient enrollment in 2007 whereas CorEvitas began in 2015.[39,43]

Prevalence of overweight/obese status (BMI ≥ 25) at baseline appeared to be higher in the Canadian PSOLAR subgroup compared to the CorEvitas and BADBIR cohorts (85%, 77%, and 73%, respectively).[39,43] These findings could have implications for treatment of psoriasis, as the Spanish Biobadaderm and US CorEvitas registries have shown increased risk of treatment discontinuation due to lack of effectiveness associated with higher BMI.[44,45] In contrast, the Canadian PSOLAR population had similar or numerically lower proportions of patients with other key comorbidities (diabetes mellitus, hyperlipidemia, hypertension, CVD, depression, and anxiety) than the CorEvitas cohort.[43] However, the prevalence of several common comorbidities (hypertension, diabetes mellitus, hyperlipidemia, and PsA) in the Canadian PSOLAR population was numerically higher compared to the BADBIR registry.[39]

Important limitations of this study include the inherent biases associated with observational studies, including participation, selection, and reporting/recall biases, which may affect data interpretation and weaken comparisons to other registries or the general population. For instance, the Canadian PSOLAR population may have been subject to participation bias, driven by reimbursement for systemic therapy prescriptions (including biologics) being tied to use in moderate to severe disease, or selection bias given that many of the Canadian investigators recruiting patients were clinical trialists who tend to see patients with more advanced disease. Furthermore, PSOLAR began enrollment many years before other registries, including CorEvitas, which may account for differences between the populations.

Nonetheless, this analysis provides a valuable descriptive characterization of Canadian patients receiving various treatments for psoriasis in a real-world setting. Detailing key features of Canadian patients with psoriasis, including comorbid conditions, may help dermatologists in their application of a recent guideline addressing the management of patients with psoriasis, with attention paid to comorbid conditions, mental health, psychosocial wellness, and quality of life.[25]

Furthermore, PSOLAR continues to enroll patients under expanded criteria (including guselkumab- and IL-17

inhibitor-exposed patients),[46] and promises to continue to generate valuable information on the Canadian psoriasis population into the future. The Canadian PSOLAR data presented here, including data on psoriasis-associated comorbidities, reinforces the need for a multidisciplinary and holistic approach towards the diagnosis and treatment of patients with psoriasis.

Data Sharing Statement

The data related to this study will not be shared.

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Supplemental Material

Supplemental material for this article is available online.

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