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Prescribing Patterns Associated With Biologic Therapies for Psoriasis from a United States Medical Records Database

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ABSTRACT

Introduction: Selecting a systemic therapy for patients with psoriasis is a complex process, based on a variety of factors including psoriasis severity, comorbid health conditions, access to care, and both patient and provider preference. The objective of this study was to use data from electronic health records to understand prescribing patterns associated with biologic therapies for psoriasis and utilization of concomitant non-biologic psoriasis therapies in patients on biologics.

Methods: A retrospective cohort study was performed using OptumInSight's electronic health records database. Patients were classified as having psoriasis if they had 2 diagnosis codes for psoriasis or 1 diagnosis for psoriasis and a subsequent prescription for a systemic psoriasis therapy or phototherapy on a separate day. Only patients with at least 1 prescription for a biologic medication were included. The time between the first and last prescription in each prescription episode was calculated; at least 1 prescription every 180 days was required to be considered continuous therapy. We also identified a subgroup of patients with prescription episodes of at least 12 months duration in which to evaluate concomitant use of topical medications, phototherapy, and other systemic agents in patients receiving prescriptions for biologics.

Results: There were 34,714 eligible psoriasis patients. The median time between first and last prescriptions was 3.3 - 7.0 months, depending on the drug and up to 50% of patients that received a prescription for a biologic medication did not receive a second prescription for the same medication. In a subset of patients with prescription episodes of at least 12 months duration, more than 50% continued to receive prescriptions for topical therapies, most commonly topical steroids.

Discussion: Recognition of prescribing patterns associated with biologic medications for psoriasis is important to understand healthcare utilization and improve health systems practices for patients and providers.

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INTRODUCTION

Selecting a systemic therapy for a patient with psoriasis is a complex process, based on a variety of factors including psoriasis severity, comorbid health conditions, access to care, and both patient and provider preference. Recognition of prescription patterns associated with biologic medications for psoriasis is important to understand healthcare utilization. Much of the previous research regarding the utilization of biologics in the United States comes from analysis of prospective patient registries and adjudicated insurance claims datasets.[1-5] An insurance claim is only generated when a prescription is submitted by the patient to the pharmacy, approved by the insurer, and, if necessary, paid for by the patient. There is ample evidence, however, that biologic prescriptions are often subject to more restrictive coverage policies and/or high out-of-pocket costs leading to the prescription's rejection by the insurer or abandonment by the patient.[6,7] Utilizing electronic health records (EHR) data to examine prescriptions written is a different way to understand drug utilization that captures more of the treatment selection process and is important to understand the full selection process that occurs from the time the first prescription is written until a patient actually starts a medication.

Biologic therapies are highly efficacious treatments for psoriasis, but most treatment guidelines, recommend concomitant use of adjunct therapies as necessary in those with continued disease activity.[8-10] Little has been reported about the actual utilization of concomitant psoriasis therapies including topical medications, phototherapy, and other systemic agents in patients on biologics. Analysis of concomitant prescriptions using claims data would only capture medications picked up from the pharmacy, but electronic health records captures all prescriptions written, signifying any time a provider thought adjuvant therapies were necessary, regardless of whether a patient decided to start the medication. The objective of this study was to utilize data from EHR to understand prescribing patterns associated with biologic therapies for psoriasis and investigate utilization of concomitant psoriasis therapies, including topical medications, phototherapy, and other systemic agents in patients on biologics in the United States. Evaluation of psoriasis medications through EHR will provide a different perspective on drug utilization, increasing the overall understanding of healthcare utilization in psoriasis.

METHODS

Data Source

We used data from OptumInSight's electronic health records database (OEHR), a de-identified dataset containing information from over 81 million individuals in the United States. The OEHR database includes information from healthcare encounters, claims, and prescriptions. Inclusion in the database is based on receiving care within the OEHR network, not a specific insurance provider. Patients can seek medical care from sources outside of the network, but approximately 70% of individuals are from integrated delivery networks and thus all their healthcare encounters are captured. The EHR dataset available for this research was a psoriasis cohort derived from the full EHR dataset including patients with a diagnosis of psoriasis from January 1, 2007 to June 30, 2017 and a 10% random sample of all patients during the same period. This study was deemed exempt from review by the Institutional Review Board of the University of Pennsylvania.

Study Population

Patients were classified as having psoriasis if they had 2 diagnosis codes for psoriasis, on two separate days or 1 diagnosis for psoriasis and a subsequent prescription for a systemic psoriasis therapy or phototherapy on a separate day. Follow-up time began (index date) at the second qualifying event and was continued until the patient left the database or died. Only patients with at least 1 prescription for a biologic medication (adalimumab, etanercept, infliximab, ixekizumab, secukinumab, and ustekinumab) were included in this analysis.

Statistical Analysis

Descriptive statistics were used to examine demographics, medical comorbidities, and psychiatric comorbidities for all patients who received at least 1 prescription for a biologic medication. Medical and psychiatric comorbidities were determined by the presence of at least 1 ICD-9/ICD-10 diagnosis code prior to the index date. A prescription episode was defined as all prescriptions written for a single medication to a single individual. Individuals may have multiple prescription episodes if they received prescriptions for more than one biologic medication; however only the first episode for each drug was included in the analysis. Time between first and last prescription was used as a measure of drug survival in this EHR dataset, because information about drug supply and refills were missing from the majority of prescriptions. At least 1 prescription every 180 days was required to be considered continuous therapy. A time period of greater than 180 days between prescriptions was considered to be a lapse in therapy. Sensitivity analyses including only prescriptions written in the last 3 years of the dataset (2014 – 2017) to look for changes in prescribing practices over time and varying the definition of continuous therapy in the calculation of time between first and last prescription were performed.

To evaluate concomitant use of topical medications, phototherapy, and other systemic agents in patients receiving prescriptions for biologics we identified a subgroup of patients with prescription episodes of at least 12 months duration. Individuals were included in this subgroup if they had two prescriptions for the same biologic within a 12-month period and a third prescription within the next 6 months. All prescriptions written for concomitant psoriasis therapy during this prescription episode were collected. Duplicate prescriptions written for the same medication on the same day were excluded. Prescriptions were analyzed by category of topical medications (any topical, topical steroid, vitamin D analogs, and calcineurin inhibitors) and oral systemic therapies (acitretin, apremilast, cyclosporine, and methotrexate). Additionally, CPT codes for any type of phototherapy during the biologic prescription episode were counted. Sensitivity analyses were performed excluding prescriptions written for topical therapies in the first 6 months of the biologic prescription episode and excluding oral therapies written in the first 3 months to exclude concomitant prescriptions only written during possible disease flares. Sensitivity analyses were also performed excluding patients with a history of psoriatic arthritis.

RESULTS

There were 34,714 patients who met the inclusion criteria for psoriasis and also were prescribed at least one biologic medication (Table 1). Of these patients, 17,888 (51.5%) were female with a mean age of 47.8 years (standard deviation (SD): 14.2) and a median follow-up time in the database of 3.1 years (interquartile range (IQR): 1.5 – 5.1). The majority of patients were Caucasian (84.7%) and non-Hispanic (85.7%). A history of psoriatic arthritis was present in 11,469 (33.0%). Consistent with what has been previously reported in the literature, medical comorbidities including hyperlipidemia (26.7%), hypertension (27.9%), and obesity (15.5%) were common in the biologics cohort. Psychiatric comorbidities, including anxiety (12.4%) and depression (16.5%) were also common. The rates of self-harm, suicidal ideation, and suicide attempt were low.

Overall, there were 19,890 individuals whom received a prescription for adalimumab (43.0%), 14,108 (30.5%) for etanercept, 6561 (14.2%) for ustekinumab, 2787 (6.0%) for infliximab, 2356 (5.1%) for secukinumab, and 539 (1.2%) for ixekizumab. Between 27.7% and 53.1% of patients only received 1 prescription for the drug. Patients prescribed ixekizumab were the least likely to receive a second ixekizumab prescription (Table 2). Patients prescribed infliximab had the longest median time between first and last prescription (7.0 months, IQR: 2.9 – 20.8) and patients prescribed IL-17 inhibitors had the shortest median time with 3.3 months (IQR: 1.4 – 5.1) for ixekizumab and 3.4 months for secukinumab (IQR: 1.3 – 7.3; Table 3). Sensitivity analyses that changed the definition of continuous treatment to < 365 days between each prescription increased the median time between first and last prescription for all drugs (data not shown).

TABLE 1.

Baseline Characteristics of Psoriasis Patients with At Least One Prescription for a Biologic Medication	N = 34,714
Female, N (%)	17,888 (51.5)
Mean age, in years (SD)	47.8 (14.2)
Follow UpTime, in years median (IQR)	3.1 (1.5 – 5.1)
Race	
Caucasian	29,403 (84.7)
African American	1015 (2.9)
Asian	742 (2.1)
Other/Unknown	3554 (10.2)
Ethnicity	
Hispanic	1653 (4.8)
Not Hispanic	29.742 (85.7)
Unknown	3319 (9.5)
History of Medical Comorbidities	
Alcoholism	877 (2.5)
Atherosclerosis	1975 (5.7)
Cancer[1]	1262 (3.6)
Congestive Heart Failure	503 (1.5)
Chronic Kidney Disease	903 (2.6)
Chronic Liver Disease	1428 (4.1)
COPD	1227 (3.5)
History of CVA	794 (2.3)
Dementia	69 (0.2)
HIV	46 (0.1)
Hyperlipidemia	9265 (26.7)
Hypertension	9688 (27.9)
History of MI	491 (1.4)
Non-melanoma skin cancer	528 (1.5)
Obesity	5386 (15.5)
Peptic Ulcer Disease	331 (1.0)
Psoriatic Arthritis	11,469 (33.0)
History of Psychiatric Comorbidities	
Anxiety	4295 (12.4)
Bipolar Disorder	593 (1.7)
Depression	5713 (16.5)
Psychosis	445 (1.3)
Self-harm	4 (0.01)
Suicidal Ideation	26 (0.1)
Suicide Attempt	49 (0.1)

[1]excluding basal cell and squamous cell carcinoma of the skin

TABLE 2.

Summary of Prescribing by Drug, Per Prescription Episode (N = 46,241)	N	Only received 1 prescription N (%)	Total Prescriptions per drug per person Median (IQR, max)
adalimumab	19,890	5737 (28.8)	3 (1-7, 131)
etanercept	14,108	3906 (27.7)	3 (1-9, 119)
infliximab	2787	1121 (40.2)	2 (1-7, 116)
ixekizumab	539	286 (53.1)	1 (1-3, 18)
secukinumab	2356	858 (36.4)	2 (1-4, 35)
ustekinumab	6561	2418 (36.9)	2 (1-5, 53)

TABLE 3.

Median Time Between First and Last Prescription, In Months	Months Between First and Last Prescription Median (IQR)
adalimumab	5.9 (2.0 – 10.5)
etanercept	5.2 (2.3 – 11.5)
infliximab	7.0 (2.9 – 20.8)
ixekizumab	3.3 (1.4 – 5.1)
secukinumab	3.4 (1.3 – 7.3)
ustekinumab	4.2 (1.5 – 9.4)

We then identified a subset of patients (N = 12,857) who were likely on the same biologic medication for at least 12 months to look at prescriptions for concomitant psoriasis medications written during the period of treatment with a biologic medication. In this subset of patients, 6174 (48.0%) were female with a mean age of 47.6 yrs (SD: 13.7) and a median follow-up time of 4.1 years (IQR: 2.5 – 6.1). Patients had lower rates of medical comorbidities as compared to the index population, with the exception of psoriatic arthritis. There were 6150 individuals who received a prescription for adalimumab (47.8%), 5045 (39.2%) for etanercept, 1618 (12.6%) for ustekinumab, 778 (6.1%) for infliximab, and 224 (1.7%) for secukinumab. Because ixekizumab was FDA approved for psoriasis in March 2016, it was excluded from this analysis due to the small number of prescription episodes available (N = 4).

In patients prescribed biologic therapy, almost two thirds received a new prescription for a topical medication, the majority of which were prescriptions for topical steroids (Table 4). About 10% of patients received a prescription for a vitamin D analog and 5% for a calcineurin inhibitor. The rate of topical prescriptions was similar among the different biologic medications. The mean number of prescriptions written annually did not vary significantly among the various biologic therapies (data not shown). Excluding topical prescriptions written within the first 6 months of the initial biologic prescription decreased the percent of people who received a prescription; however, 48.7-60.7% of

TABLE 4.

Number of Patients with Prescriptions Written for Topical Therapy Between First and Last Biologic Prescription, by Drug					
	N	Any Topical N (%)	Topical Steroids N (%)	Vitamin D Analogs N (%)	Calcineurin Inhibitors N (%)
adalimumab	6150	3793 (61.7)	3724 (60.5)	647 (10.5)	282 (4.6)
etanercept	5045	3328 (66.0)	3251 (64.4)	688 (13.6)	225 (4.5)
infliximab	778	471 (60.5)	465 (59.8)	72 (9.3)	39 (5.0)
secukinumab	224	137 (61.2)	135 (60.3)	26 (11.6)	12 (5.4)
ustekinumab	1618	1090 (67.4)	1055 (65.2)	166 (10.3)	81 (5.0)

TABLE 5.

Number of Patients with Phototherapy Encounters and Prescriptions Written for Oral Therapy Between First and Last Biologic Prescription, by Drug						
	N	Phototherapy N (%)	Acitretin N (%)	Apremilast N (%)	Cyclosporine N (%)	Methotrexate N (%)
adalimumab	6150	173 (2.8)	109 (1.8)	215 (3.5)	107 (1.7)	1577 (25.6)
etanercept	5045	146 (2.9)	65 (1.3)	167 (3.3)	59 (1.2)	1688 (33.5)
infliximab	778	15 (1.9)	8 (1.0)	31 (4.0)	13 (1.7)	379 (48.7)
secukinumab	224	9 (4.0)	5 (2.2)	15 (6.7)	6 (2.7)	34 (15.2)
ustekinumab	1618	61 (3.8)	30 (1.9)	82 (5.1)	47 (2.9)	232 (14.3)

patients still received at least 1 new prescription for a topical medication (data not shown).

There was also concomitant use of phototherapy and prescriptions written for oral systemic therapies in patients with ongoing prescriptions for biologics. Less than 5% of patients had at least 1 phototherapy procedure during the time of ongoing biologic prescriptions (Table 5). Of the patients with at least 1 phototherapy encounter, the median number of treatments was 7 in patients on secukinumab, 16 in patients on adalimumab and 18 in patients who were prescribed etanercept, infliximab, and ustekinumab. For oral systemic therapies, methotrexate was the most commonly prescribed concomitant oral therapy. The highest percentage of patients receiving at least 1 prescription for methotrexate was seen in patients receiving prescriptions for infliximab (48.7%; Table 5). Patients prescribed secukinumab and ustekinumab were much less likely to be prescribed methotrexate, with 15.2% and 14.3% of patients receiving prescriptions for methotrexate, respectively. Concomitant prescriptions for acitretin, apremilast and cyclosporine, were written for less than 5% of patient on any biologic therapy. The percentage of people who received concomitant prescriptions for oral systemic therapies were similar when excluding prescription written within the first 3 months of the first biologic prescription, with the exception of for people who received prescriptions for etanercept (data not shown).

CONCLUSIONS

In conclusion, this analysis of prescriptions written from electronic health records data from the United States found that up to 50% of patients that received a prescription for a biologic medication did not receive a second prescription for the same medication. The median time between first and last prescriptions was between 3.3 and 7.0 months, depending on the biologic prescribed. In a subset of patients who received continuous prescriptions for the same biologic medication for more than 12 months, more than 50% continued to receive prescriptions of topical therapies, most commonly topical steroids. We also found that methotrexate was commonly prescribed concurrently with biologics, while other oral systemic therapies (acitretin, apremilast, cyclosporine) and phototherapy were not commonly prescribed concurrently.

Previous research examining drug survival has focused on data from patient registries and adjudicated insurance claims datasets. In the PSOLAR prospective patient registry, median drug survival times of 2 years or more was reported for first-line biologic medications.[3] Analysis of private insurance claims data from the United States has shown only about 50-75% of patients are still taking the index biologic 12 months after starting.[4,5] In the Medicare population, this number drops to about 50% of patients at 12 months.[1] The drug survival in our analysis was on the lower end of what has been previously reported, with the median time between first and last prescription for all the biologic therapies of less than 1 year.

Exploring drug survival by examining prescriptions written, instead of insurance claims or prospective registry data, highlights a different perspective, capturing the full experience from the point at which a prescription is written. Our results highlight

that when a prescription is written for a biologic in a patient with psoriasis, 30-50% of patients will not receive a second prescription for that medication. There are many reasons for the lack of a second prescription including patients not initiating therapy, discontinuation for side effects and lack of, or suboptimal, insurance coverage. All these factors contribute to the difficulty that providers have selecting appropriate systemic treatments for patients with psoriasis.

Additionally, we also found a high percentage of concurrent methotrexate and topical steroid use in patients receiving prescriptions or biologic therapies, and use continued to be high, even after excluding the first 3 months after initiation of a biologic, suggesting ongoing use. Concomitant oral therapy use is consistent with what has been previously reported in the literature. Data from PSONET, a prospective network of psoriasis registries from Europe, found that 9.9% of biologic treatment cycles involved combination with a systemic therapy.[11] Of these treatment cycles with combination therapy, 72.9% involved methotrexate, 25.3% involved UVB phototherapy, acitretin or cyclosporine and 1.8% involved PUVA, fumaric acids or a second biologic.[11] HMO data from Israel showed that 7.1% of patients on adalimumab, 16.2% of patients on etanercept, 19.7% of patients on infliximab and 8% of patients on ustekinumab were taking methotrexate concomitantly, and 2.7% of patients on adalimumab, 2.2 % on etanercept, and 5.8% on ustekinumab were taking concomitant acitretin.[12] Less than 1% of patients in each biologic group were taking cyclosporine, which is similar to what is reported in this study.

Previous research has suggested a benefit from the co-administration of methotrexate with biologics. Treatment guidelines from the medical board of the National Psoriasis Foundation report that combination treatment with etanercept and methotrexate or infliximab and methotrexate is more effective than monotherapy with either TNF inhibitor or methotrexate alone.[13] Additionally, in drug survival analyses, methotrexate has been associated with in increased risk of drug survival.[3,12] There are many reasons why a provider may prescribe concomitant methotrexate including loss of efficacy of the primary therapy, prevention of anti-drug antibodies and to enhance treatment effect in patients with psoriatic arthritis. With the advent of new, more efficacious biologic medications for psoriasis, continued research is necessary to understand the risk and benefits of concurrent methotrexate with newer drugs.

Guidelines also recommend that topical therapies are used as adjunctive therapy for patients with extensive psoriasis undergoing systemic therapy with phototherapy or biologics,[8,14] but little is known about their actual use in clinical practice. An observational study designed to assess prior and concomitant use of psoriasis treatments in subjects receiving secukinumab (PROSPECT) found that at week 16 of treatment with secukinumab, 3.4% of patients were using concomitant therapies, with topical steroids being the most common.[15] The results of our study conclude that more than 50% of patients continue to receive new prescriptions for topical steroids while receiving ongoing prescriptions for biologic medications. It is important to keep in mind that this analysis likely underestimates the percentage of patients who are actually using topical steroids, given that many patients may have remaining topical steroids from previously written prescriptions.

While these results provide novel insight in prescribing practices of biologic medications and concomitant therapies, there are important limitations that must be addressed. First of all, the information about prescriptions includes all prescriptions written and does not ensure that the medication was taken by patients. Additionally, information regarding the quantities of medication dispensed and refills authorized was not available, which may under estimate the duration of biologic therapy for some patients. While all medications analyzed are FDA approved for psoriasis, some medications have additional FDA-approved indications, and it is possible that drug utilization for non-psoriasis indications is different than for psoriasis and may be affecting the results. Finally, previous studies looking at drug survival have found lower rates of drug survival in patients utilizing second and third line biologic therapies. It is possible that reported time between first and last prescription may be longer if only true incident prescriptions were analyzed.

In conclusion, this analysis of EHR prescriptions in the United States found the median time between first and last prescriptions was between 3.3 and 7.0 months, and up to 50% of patients that receive a prescription for a biologic medication did not receive a second prescription for the medication. Additionally, use of concomitant topical steroids and methotrexate was common in patients receiving prescriptions for biologic therapies. By including all prescriptions written, this analysis provides novel insight in prescribing patterns for patients with psoriasis in the United States. The landscape of biologics medications to treat psoriasis is changing rapidly and it is important to understand shifts in prescribing practices as drug therapy continues to evolve.

DISCLOSURES

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Pfizer, Sanofi, Kerecis, and Cell Constructs. None of these activities are associated with the outcomes of this study.

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