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Pregnancy Outcomes in Women With Moderate-to-Severe Psoriasis From the Psoriasis Longitudinal Assessment and Registry (PSOLAR)

Alexa B. Kimball, MD, MPH; Lyn Guenther, MD; Sunil Kalia, MD, MHSc; Elke M. G. J. de Jong, MD, PhD; Kimberly Parnell Lafferty, PharmD, MBA; Dan Y. Chen; Wayne Langholff, PhD; Neil H. Shear, MD

IMPORTANCE Prospective data are limited on pregnancy outcomes among women with psoriasis who may be receiving biologic or conventional systemic therapy.

OBJECTIVE To report pregnancy outcomes observed in the Psoriasis Longitudinal Assessment and Registry (PSOLAR).

DESIGN, SETTING, AND PARTICIPANTS This cohort study used data from PSOLAR, a multicenter, disease-based, observational registry evaluating long-term safety and clinical outcomes for patients receiving or eligible to receive treatment for psoriasis with biologics and/or conventional systemic therapies. Of 12 090 enrollees, 5456 were women (45.1%), and 2224 women were of childbearing age (18-45 years). Participants had a total of 12 929 patient-years of follow-up (median, 7.2 [range, 3.3-8.0] years per patient). Data were collected from June 20, 2007, to August 23, 2019, and analyzed from April 23 to June 23, 2020.

EXPOSURES Exposure to biologics within the prenatal period (≤1 year before birth or ≤6 months before spontaneous abortion) or at any other time.

MAIN OUTCOMES AND MEASURES Descriptive summaries of pregnancies and pregnancy-related outcomes were self-reported in PSOLAR, including births, stillbirths, spontaneous abortions, and elective terminations. Live birth characteristics collected in PSOLAR include whether a birth was full-term (≥37 weeks) or premature (<37 weeks) and whether neonatal adverse events or congenital anomalies occurred.

RESULTS A total of 298 pregnancies occurred among 220 women (mean [SD] age, 27.8 [5.2] years), and the general fertility rate was 18.9 per 1000 women aged 18 to 45 years. Of the 298 pregnancies, 244 (81.9%) resulted in birth, 41 (13.8%) ended in spontaneous abortion, and 13 (4.4%) were electively terminated. Gestational age was available for 243 births; 221 infants (90.9%) were full-term, and 22 (9.1%) were born prematurely. Birth outcomes included 231 healthy newborns, 10 infants with a neonatal problem, 2 infants with a congenital anomaly, and 1 stillbirth. Of the 298 pregnancies, 252 were associated with biologic exposure before or during pregnancy. Pregnancy outcomes for women exposed to biologics were similar to those for women exposed to nonbiologics. Among women who became pregnant, mean (SD) age at the time of pregnancy outcome was 30.9 (4.8) years; at enrollment into the registry, 74 of 219 (33.8%) had obesity, and 121 of 220 (55.0%) were past or current smokers.

CONCLUSIONS AND RELEVANCE The findings of this cohort study suggest that pregnancy outcomes in PSOLAR have remained consistent with previous reports. Overall and live birth outcomes were similar to those for the general population.

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Author Affiliations: Department of Dermatology, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts (Kimball); The Guenther Dermatology Research Centre, London, Ontario, Canada (Guenther); Department of Dermatology and Skin Science, University of British Columbia, Vancouver, British Columbia, Canada (Kalia); Department of Dermatology, Radboud University Medical Center, Nijmegen, the Netherlands (de Jong); Janssen Scientific Affairs, LLC, Horsham, Pennsylvania (Lafferty, Chen); Janssen Research and Development, LLC, Horsham, Pennsylvania (Langholff); Department of Dermatology, University of Toronto, Toronto, Ontario, Canada (Shear).

Corresponding Author: Alexa B. Kimball, MD, MPH, Beth Israel Deaconess Medical Center, 330 Brookline Ave, Shapiro 2nd Floor, Boston, MA 02215 (clears@bidmc.harvard.edu).

Psoriasis is a chronic, immune-mediated inflammatory skin disease that affects more than 7 million adults in the United States.[1] Roughly 50% of patients with psoriasis are women, and in more than 75% of cases, onset of psoriasis occurs at 40 years or younger (ie, during years of childbearing potential).[2,3] Assuming pregnancy rates are similar to those for the age-adjusted US population, an estimated 65 000 to 107 000 births would occur to women with psoriasis each year, including 9000 to 15 000 births to women with moderate-to-severe disease.[4]

Autoimmune inflammation associated with psoriasis and psoriasis-related comorbidities (eg, diabetes, cardiovascular disease, and depression) may increase the risk for adverse pregnancy outcomes.[3,5-7] To reduce these risks, patients should work with clinicians to control psoriasis before and during pregnancy.[2,7,8] However, prospective data on pregnancy outcomes in patients receiving systemic treatment are limited, because many patients discontinue treatment during pregnancy and because pregnant women are usually excluded from clinical trials.[7-9] Herein we report pregnancy outcomes from the Psoriasis Longitudinal Assessment and Registry (PSOLAR), which evaluates long-term safety and clinical outcomes for patients with psoriasis who are receiving or are eligible to receive conventional systemic or biologic therapies at clinics in North America, South America, and Europe.[10]

Key Points

Question Is there an association between pregnancy outcomes and psoriasis or exposure to systemic therapies for moderate-to-severe psoriasis?

Findings This cohort study used data from the Psoriasis Longitudinal Assessment and Registry (PSOLAR) for 220 women with 298 pregnancies, of which 244 (81.9%) resulted in live births. Rates of spontaneous abortion, neonatal problems, and congenital anomalies were similar to rates in the general US population, and pregnancy outcomes for women exposed to biologics were similar to those for women with exposure to nonbiologics.

Meaning Pregnancy outcomes among women with moderate-to-severe psoriasis within PSOLAR appeared to be consistent with previously reported data; pregnancy-specific registries are needed to more fully characterize the effect of psoriasis and its treatment on birth outcomes.

Methods

Study Population

PSOLAR is an observational disease-based registry that collects data related to demographic characteristics, disease activity, clinical outcomes, and safety events.[10] Pregnancies are monitored on a real-time basis. The PSOLAR protocol was approved by appropriate institutional review boards or ethics committees. All patients provided written informed consent at enrollment into the registry. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

A PSOLAR report of outcomes of 83 pregnancies from June 20, 2007, through August 23, 2012, was presented previously.[11] The present analysis includes all pregnancy outcomes from that assessment plus additional data through August 23, 2019.

Assessments

Data were analyzed from April 23 to June 23, 2020. Safety observations captured in PSOLAR support postmarketing regulatory commitments for psoriasis treatments manufactured by the study sponsor (Janssen Scientific Affairs, LLC), including ustekinumab, infliximab, and golimumab. Therefore, exposure to biologic therapy is collected specifically for these drugs and separately for all other biologics approved to treat psoriasis (predominantly etanercept and adalimumab, but also secukinumab, risankizumab, alefacept, efalizumab, tildrakizumab, brodalumab, ixekizumab, and guselkumab). Although it is manufactured by the study sponsor, guselkumab is handled in a separate PSOLAR protocol amendment; therefore, in the present assessment, guselkumab is termed *other biologic*.

Observational data related to demographic and clinical characteristics were collected for all women of childbearing age. For women who became pregnant, pregnancy outcomes (births, stillbirths, spontaneous abortions, and elective terminations) and live-birth characteristics (full-term [≥37 weeks] or premature [<37 weeks], neonatal adverse events, and congenital anomalies) were recorded. Pregnancy data were considered based on exposure to ustekinumab, infliximab or golimumab, other biologics, or nonbiologics within the prenatal period (ie, ≤1 year before birth or ≤6 months before spontaneous abortion) or outside the prenatal period (ie, exposure at any other time).

Results

Patient Characteristics

At the cutoff date for this analysis, 12 090 patients were enrolled in PSOLAR, including 5456 women (45.1%). At enrollment, 2224 women were of childbearing age (18-45 years); collectively, they were followed up for 12 929 patient-years. A total of 220 women became pregnant during the follow-up period. Compared with the overall cohort of women aged 18 to 45 years, women in the pregnancy cohort were younger at enrollment (mean [SD] age, 27.8 [5.2] vs 34.3 [7.5] years); had less severe psoriasis (mean [SD] Physician Global Assessment score, 1.9 [1.2] vs 2.0 [1.2]; scores range from 0 to 5, with higher scores indicating greater severity) and lower rates of psoriatic arthritis (26 [11.8%] vs 312 [14.0%]), obesity (74 [33.8%] vs 927 [42.3%]), depression (31 [14.1%] vs 407 [18.3%]), diabetes (3 [1.4%] with type 2 diabetes vs 117 [5.3%] with type 1 or 2 diabetes), hypertension (12 [5.5%] vs 225 [10.1%]), hyperlipidemia (4 [1.8%] vs 145 [6.5%]), and thyroid dysfunction (8 [3.6%] vs 153 [6.9%]); and were slightly more likely to be current or past smokers (121 [55.0%] vs 1156 [52.0%]) (**Table 1**). Among women of childbearing age, the annual fertility rate was 18.9 per 1000 women.

Pregnancy Outcomes

Data were available for 298 pregnancies in 220 patients enrolled for a median duration of 7.2 (range, 3.3-8.0) years per patient. Among these patients, 159 had 1 pregnancy, 48 had 2 pregnancies, 10 had 3 pregnancies, and 3 had 4 or 5 pregnancies. The 298 pregnancies resulted in 244 births (81.9%) (including 1 stillbirth), 41 spontaneous abortions (13.8%), and 13 elective terminations (4.4%). No elective terminations were known to derive from a congenital anomaly or other medical issue.

Table 2 shows pregnancy outcomes by maternal age group. Among the 243 live-born infants, 221 (90.9%) were full-term and 22 (9.1%) were premature. Birth outcomes among all 244 births included 231 healthy newborns (94.7%), 10 infants with a neonatal problem (4.1%), 1 stillbirth (0.4%), and 2 congenital anomalies (0.8%). One premature newborn (gestational age of 36 weeks) with a small posterior cleft palate required hospitalization for 16 days. There were conflicting reports about whether the infant underwent surgical procedures to correct the soft palate. Subsequent to the initial report, the patient reported that the infant had a left coronal craniosynostosis but had no plans for surgery (no additional details were provided). In addition, a full-term newborn was born with nonketotic hyperglycinemia requiring tube feeding, ventilation, and hospitalization for 3 weeks.

Ten infants had neonatal adverse events, including 3 respiratory issues (2 related to prematurity and 1 to aspiration pneumonia), 2 preterm deliveries related to pre-eclampsia, and 1 of each of the following: ABO blood type mismatch, low birth weight due to early delivery (1 of 2 infants in a twin birth), opioid withdrawal, hyperemesis, and hypoglycemia. No additional information was available on maternal risk factors that may have contributed to adverse events or congenital anomalies.

Two hundred fifty-two pregnancies occurred in women who were exposed to biologic therapy before or during pregnancy, including 168 of 298 pregnancies (56.4%) exposed during the prenatal period (**Table 3**). Forty-six pregnancies occurred in women who were never exposed to biologic therapy but may have received another systemic therapy or phototherapy before or during pregnancy.

Both reported congenital anomalies occurred in infants born to women who received ustekinumab during the prenatal period. The mother of the premature infant with a cleft palate received her last dose of ustekinumab 26 days before birth. The mother of the infant with nonketotic hyperglycinemia realized she was pregnant approximately 10 months after starting ustekinumab therapy; she discontinued treatment at that time and gave birth more than 7 months later.

Discussion

Pregnancy was relatively common in the PSOLAR population of women with moderate-to-severe psoriasis; however, the annual fertility rate of 18.9 per 1000 women aged 18 to 45 years was lower than that in the general US population (59.1 per 1000 women aged 15-44 years in 2018).[12] Exposure to biologic

Table 1. Demographic and Clinical Characteristics in the Pregnancy Cohort and in All Women of Childbearing Age in PSOLAR

Characteristics	Study group[a]	
	Women in pregnancy cohort (n = 220)	Women of childbearing age (n = 2224)
Demographic characteristics		
Age, mean (SD), y	27.8 (5.2)	34.3 (7.5)
Age at pregnancy outcome, mean (SD), y	30.9 (4.8)	NA
Age category, y		
18-24	62 (28.2)	288 (12.9)
25-34	136 (61.8)	751 (33.8)
35-44	22 (10.0)	1046 (47.0)
45	0	139 (6.3)
Race/ethnicity		
White	173 (78.6)	1806 (81.2)
Hispanic or Latino	14 (6.4)	167 (7.5)
Asian	10 (4.5)	87 (3.9)
Black	8 (3.6)	90 (4.0)
Other	15 (6.8)	74 (3.3)
Weight, mean (SD), kg[b]	75.26 (18.87)	81.16 (23.83)
Psoriasis disease characteristics		
Duration of psoriasis, mean (SD), y[c]	12.03 (7.55)	13.81 (9.67)
PGA score, mean (SD)[d]		
At enrollment[e]	1.9 (1.2)	2.0 (1.2)
Most proximal to the pregnancy[f]	1.6 (1.1)	NA
BSA, mean (SD), %		
At enrollment[g]	10.3 (14.2)	12.0 (17.6)
Most proximal to the pregnancy[f]	5.7 (11.2)	NA
Relevant medical history		
Psoriatic arthritis confirmed by a joint specialist	26 (11.8)	312 (14.0)
Obesity[h]	74 (33.8)	927 (42.3)
Depression	31 (14.1)	407 (18.3)
Diabetes[i]	3 (1.4)	117 (5.3)
Hypertension	12 (5.5)	225 (10.1)
Hyperlipidemia	4 (1.8)	145 (6.5)
Thyroid dysfunction	8 (3.6)	153 (6.9)
Smoking (past or current)[j]	121 (55.0)	1156 (52.0)

Abbreviations: BSA, body surface area; NA, not applicable; PGA, Physician Global Assessment; PSOLAR, Psoriasis Longitudinal Assessment and Registry.

[a] All data were collected at registry entry unless otherwise noted. Unless otherwise indicated, data are expressed as number (percentage) of patients. Percentages have been rounded and may not total 100.

[b] Includes 219 women in the pregnancy cohort and 2194 women of childbearing age.

[c] Includes 2211 women of childbearing age.

[d] Scores range from 0 to 5, with higher scores indicating greater severity.

[e] Includes 217 women in the pregnancy cohort and 2210 women of childbearing age.

[f] Includes data for each of 298 pregnancies among 220 women.

[g] Includes 218 women in the pregnancy cohort and 2206 women of childbearing age.

[h] Includes 219 women in the pregnancy cohort and 2193 women of childbearing age. Obesity indicates a body mass index (calculated as weight in kilograms divided by height in meters squared) of 30.0 or greater.

[i] All 3 patients in the pregnancy cohort had type 2 diabetes, whereas 24 women of childbearing age had type 1 (1.1%) and 93 had type 2 (4.2%) diabetes.

[j] Includes 2221 women of childbearing age.

Table 2. Pregnancy Outcomes by Maternal Age Group

	Maternal age group, No./total No. (%)				
Age group	18-25 y	26-30 y	31-35 y	36-40 y	41-45 y
Gave birth	29/35 (82.9)	77/94 (81.9)	104/127 (81.9)	31/35 (88.6)	3/7 (42.9)
Elective termination	3/35 (8.6)	5/94 (5.3)	3/127 (2.4)	1/35 (2.9)	1/7 (14.3)
Spontaneous abortion[a]	3/35 (8.6)	12/94 (12.8)	20/127 (15.7)	3/35 (8.6)	3/7 (42.9)
Birth outcome					
Healthy newborn	26/29 (89.7)	72/77 (93.5)	100/104 (96.2)	30/31 (96.8)	3/3 (100)
Congenital anomaly	1/29 (3.4)	0/77	1/104 (1.0)	0/31	0/3
Neonatal problem	2/29 (6.9)	5/77 (6.5)	2/104 (1.9)	1/31 (3.2)	0/3
Stillbirth	0/29	0/77	1/104 (1.0)	0/31	0/3
Prolonged infant hospitalization	3/29 (10.3)	9/77 (11.7)	8/104 (7.7)	3/31 (9.7)	1/3 (33.3)
Required extra medical therapy[b]	4/29 (13.8)	8/77 (10.4)	7/104 (6.7)	2/31 (6.5)	0/3

[a] Gestational age at the time of spontaneous abortion was available for 26 of 41 events (median calculated based on expected delivery date, 9.6 [range, 0.9-21.6] weeks).

[b] Based on the patient's response to the question, "Did the infant receive any medical therapy different from a normal newborn (yes or no)?"

Table 3. Pregnancy Outcomes by Time of Exposure to Biologic and Nonbiologic Therapies

	Treatment by maternal pregnancies, No./total No. (%)[a]								
	Ustekinumab, time of exposure		Infliximab or golimumab, time of exposure		Other biologic, time of exposure[b]		All biologics, time of exposure		
Pregnancy outcome	Within prenatal period (n = 70)	Outside prenatal period (n = 42)	Within prenatal period (n = 14)	Outside prenatal period (n = 15)	Within prenatal period (n = 84)	Outside prenatal period (n = 27)	Within prenatal period (n = 168)	Outside prenatal period (n = 84)	Nonbiologics within 1 y of birth (n = 46)[c]
Gave birth	56/70 (80.0)	37/42 (88.1)	13/14 (92.9)	14/15 (93.3)	62/84 (73.8)	25/27 (92.6)	131/168 (78.0)	76/84 (90.5)	37/46 (80.4)
Birth outcome									
Healthy newborn	53/56 (94.6)	33/37 (89.2)	13/13 (100)	14/14 (100)	56/62 (90.3)	25/25 (100)	122/131 (93.1)	72/76 (94.7)	37/37 (100)
Congenital anomaly	1/56 (1.8)	1/37 (2.7)	0/13	0/14	0/62	0/25	1/131 (0.8)	1/76 (1.3)	0/37
Neonatal adverse event	2/56 (3.6)	3/37 (8.1)	0/13	0/14	5/62 (8.1)	0/25	7/131 (5.3)	3/76 (3.9)	0/37
Stillbirth	0/56	0/37	0/13	0/14	1/62 (1.6)	0/25	1/131 (0.8)	0/76	0/37
Prolonged infant hospitalization	6/56 (10.7)	7/37 (18.9)	1/13 (7.7)	1/14 (7.1)	8/62 (12.9)	1/25 (4.0)	15/131 (11.5)	9/76 (11.8)	0/37
Required extra medical therapy	5/56 (8.9)	7/37 (18.9)	1/13 (7.7)	0/14	6/62 (9.7)	2/25 (8.0)	12/131 (9.2)	9/76 (11.8)	0/37
Elective termination	4/70 (5.7)	0/42	0/14	1/15 (6.7)	5/84 (6.0)	0/27	9/168 (5.4)	1/84 (1.2)	3/46 (6.5)
Spontaneous abortion	10/70 (14.3)	5/42 (11.9)	1/14 (7.1)	0/15	17/84 (20.2)	2/27 (7.4)	28/168 (16.7)	7/84 (8.3)	6/46 (13.0)

[a] Pregnancy is included in the "Within the prenatal period" column if exposure to therapy occurred within 1 year before birth or within 6 months before spontaneous abortion and in the "Outside the prenatal period" column if exposure to therapy occurred at any other time. Percentages have been rounded and may not total 100.

[b] Predominantly etanercept and adalimumab but could also include secukinumab, risankizumab, alefacept, efalizumab, tildrakizumab, brodalumab, ixekizumab, and guselkumab.

[c] Includes use of topical corticosteroids (n = 24), phototherapy (n = 17), topical calcipotriene plus betamethasone (n = 3), nonsteroidal anti-inflammatory drugs (n = 3), systemic corticosteroids (n = 2), methotrexate (n = 1), and cyclosporine (n = 1).

therapy occurred during the prenatal period in 56.4% of pregnancies. Outcomes for live births among PSOLAR participants were generally positive and consistent with available prospective data in women exposed to biologics.[7] The observed rate of congenital anomalies (0.8%) was lower than the US annual rate of approximately 3%.[13] Spontaneous abortion and preterm birth rates in PSOLAR were consistent with rates reported in the general US population.[14,15] Pregnancy outcomes were generally consistent across biologic cohorts, and birth outcomes for pregnancies with exposure to a biologic were similar to those with exposure to a nonbiologic.

Strengths and Limitations

Although the PSOLAR population of women exposed to biologics during pregnancy is relatively small (n = 220), it is one of the largest samples of patients with psoriasis reported to date. Published data on the potential risk of harm to pregnant women and infants associated with biologic therapies for psoriasis are limited to a small number of studies of these drugs in predominantly other patient populations (eg, with rheumatoid arthritis and inflammatory bowel disease)[7,16,17] and several small case series in psoriasis.[8,18-20] In addition, a recent global safety database analysis provides data for 238 pregnancies with maternal exposure to secukinumab; however, half of pregnant women (n = 119) had unknown pregnancy outcomes because the pregnancy was ongoing or they were lost to follow-up before giving birth.[21] Overall, results of the present study are consistent with studies reporting no significant differences in the number of live-born infants, spontaneous abortions, elective terminations, or congenital

abnormalities among women with psoriasis exposed to biologics during pregnancy and general populations.[7,8,14,15,18,21]

In terms of limitations, PSOLAR is not a pregnancy-specific registry, and medical history is captured only at baseline. Therefore, potentially relevant details affecting fertility and pregnancy outcomes may not be collected (eg, date of last menstrual period, limited on-registry medical history, nonpsoriasis medications). Because the date of last menstrual period is not collected and because pregnancy-related data collected within PSOLAR are limited to within 1 year before birth or within 6 months of spontaneous abortion, results could not be evaluated by pregnancy trimester. The observational nature of PSOLAR pregnancy data may be limited by reporting inconsistencies and information gaps because pregnancy-related data are self-reported by patients and are not confirmed by independent medical review (eg, obstetricians or neonatologists). Furthermore, because the rate of poor pregnancy outcomes is relatively low in the general US population, the PSOLAR sample size may be too small to detect a true signal of adverse outcomes.

Conclusions

Pregnancy outcomes among women with moderate-to-severe psoriasis in PSOLAR have remained consistent with previously reported data and the general population. Pregnancy-specific registries that include a larger number of pregnant women with psoriasis than PSOLAR are needed to more fully characterize the association between psoriasis and treatment and birth outcomes.

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