

Please follow your local copyright law

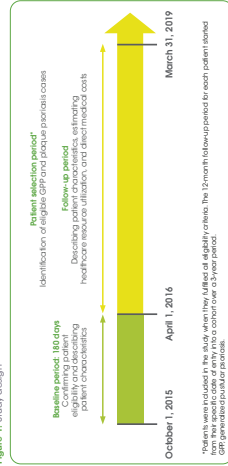
Characteristics of generalized pustular psoriasis (GPP) patients: results from the Optum® Clinformatics™ Data Mart database
 Kotowsky N, Garry EMF, Valdecantos WC, Gao R, Golembesky AK
 Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA; Aetion, Inc., Boston, MA, USA; Boehringer Ingelheim International GmbH, Ingelheim, Germany

Background

- Generalized pustular psoriasis (GPP) is defined as a rare, recalcitrant, skin disease characterized by widespread eruption of sterile, non-infectious, pustules that can occur with or without systemic inflammation and with or without plaque psoriasis.^{1,2}
- GPP is a chronic disease, causing substantial morbidity, and in some cases, mortality.³
- Although GPP is a distinct entity, from plaque psoriasis, phenotypically and genetically patients receive similar treatments to patients with plaque psoriasis.^{4,5}
- There are no treatment options for the specification of GPP in the USA or Europe.
- Despite the lack of treatment options for patients with GPP therapies that are being used are associated with adverse events and/or variable efficacy, making them inappropriate for long-term use.⁶
- To date, there is limited real-world evidence characterizing patients with GPP.
- Our study aimed to describe the real-world burden and treatment needs of patients with GPP by using the US Medicare and Medicaid administrative claims database (MDC20) of patients with GPP compared to those with plaque psoriasis and the general population.

- Methods**
- Patients were diagnosed as having GPP or plaque psoriasis if they had ≥1 inpatient or 7 outpatient diagnostic claim(s) for ICD-10 L40.1 or L40.0, respectively, separated by 30-365 days.
 - All analyses were conducted via the Aetion Evidence Platform v3.11 using Optum® Clinformatics™ Data Mart, a US administrative claims database.⁷
 - The study period was from October 1, 2015 to March 31, 2019, with the first qualifying diagnostic claim(s) for ICD-10 L40.1 or L40.0, respectively, separated by 30-365 days.
 - A cohort of 1,669 patients with GPP was matched to patients with GPP, 4.1, based on age and sex, excluding subjects with any psoriasis other than pustular psoriasis, and the GPP-matched cohort, along with the plaque psoriasis cohort, provided context to the GPP burden of disease.
 - Patient characteristics during the 180-day baseline period and medication use among patients with GPP and the GPP-matched cohort were analyzed.
 - Comorbidities during baseline, including but not limited to hormonal/metabolic conditions, pulmonary conditions, and psychiatric conditions, determined by ICD-10 diagnosis codes.
 - Concomitant medications received during the 12-month follow-up.
 - Dematology treatments received during the 12-month follow-up.
 - Treatments were identified using claims by the Healthcare Common Procedure Coding System.
 - All analyses were descriptive in nature; no formal comparisons were conducted.

Figure 1. Study design



Results

- Patient population and demographics**
- In total, 1,669 patients with GPP, 60,419 with plaque psoriasis, and 667.6 in the GPP-matched cohort were identified at baseline. Overall, 10,14 patients with GPP and 32,665 patients with plaque psoriasis completed the 12-month follow-up period (Figure 2).
 - In the GPP-matched cohort, 4130 subjects completed the 12-month follow-up.
 - Among patients with GPP, 43.9% were male and 56.1% were female. Among patients with plaque psoriasis, 43.9% were male and 56.1% were female (Table 1).

Figure 2. Study population

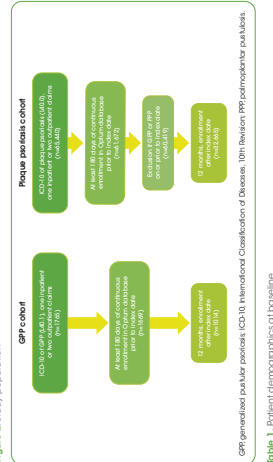


Table 1. Patient demographics at baseline

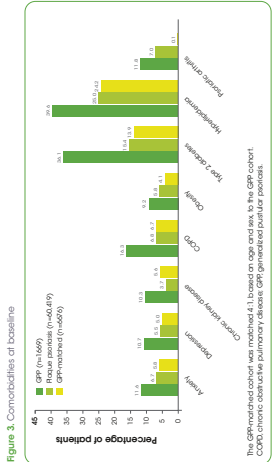
| Demographics (n %) | GPP cohort (n=1669) | GPP-matched cohort* (n=667.6) | Plaque psoriasis cohort (n=60,419) |
|--------------------------------|---------------------|-------------------------------|------------------------------------|
| Female | 1128 (67.6) | 30,621 (45.9) | 45,172 (74.8) |
| Age, years, mean (SD) | 63.9 (15.2) | 64.4 (17.3) | 69.4 (15.9) |
| <18 years | 17 (1.0) | 1135 (1.7) | 66 (0.1) |
| 18-64 years | 739 (44.3) | 37,646 (56.3) | 29,642 (49.0) |
| ≥65 years | 913 (54.7) | 21,637 (32.8) | 36,657 (60.7) |
| Comorbidities/insured patients | 580 (34.8) | 37,774 (56.5) | 3127 (49.8) |
| Medication use | 1899 (113) | 22,446 (33.6) | 3549 (58.7) |

*The GPP-matched cohort was matched 4:1, based on age and sex, to the GPP cohort. GPP generated patient count, SD, rounded down.

Comorbidities

- At baseline, patients with GPP had more comorbidities than patients in the plaque psoriasis and GPP-matched cohorts.
- These included psoriatic arthritis (11.6% vs 7.0% and 0.1%, respectively), anxiety (11.6% vs 6.7%), depression (11.6% vs 7.0% and 0.1%, respectively), type 2 diabetes, obesity, chronic obstructive pulmonary disease, and chronic kidney disease (Figure 3).

Figure 3. Comorbidities at baseline



The GPP-matched cohort was matched 4:1, based on age and sex, to the GPP cohort. GPP generated patient count, SD, rounded down.

Dematology medication use

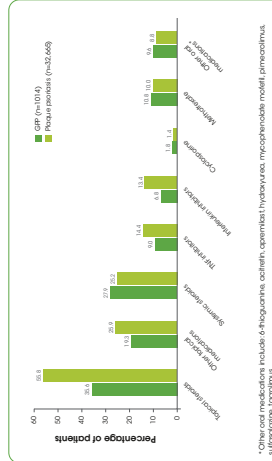
- 265 out of 1014 patients (26.2%) with GPP were treated with combination therapies (topical and/or biologic and/or non-biologic) compared with 11,365 out of 32,665 patients (34.8%) with plaque psoriasis (Table 2).
- Patients with GPP were more likely to be treated with a non-biologic systemic therapy (11.6%) compared with patients with plaque psoriasis (6.0%) and the GPP-matched cohort (5.0%).
- Patients with GPP were also less likely to be treated with a topical medication only compared with patients with plaque psoriasis (11.6% vs 11.6% and 11.6%, respectively).
- Of the biologic therapies, tumor necrosis factor (TNF) inhibitors were the most commonly prescribed in the GPP and plaque psoriasis cohorts (Figure 4).
- Adalimumab was the most commonly prescribed TNF inhibitor in the GPP (6.7%) and plaque psoriasis cohorts (1.2%).
- Of the biologics, TNF inhibitors were the most commonly used individual systemic therapy in the GPP (10.8%) and plaque psoriasis (10.0%) cohorts (Figure 4).

Table 2. Systemic, non-systemic, and topical medication use during the 12-month follow-up period

| Medication (n %) | GPP cohort (n=1669) | GPP-matched cohort* (n=667.6) | Plaque psoriasis cohort (n=60,419) |
|---|---------------------|-------------------------------|------------------------------------|
| No treatment | 419 (25.1) | 718 (23.8) | 8016 (26.5) |
| Topical only | 146 (8.8) | 8016 (24.5) | 2389 (7.2) |
| Non-biologic systemic only | 153 (9.2) | 153 (15.0) | 2389 (7.2) |
| Biologic + non-biologic systemic | 51 (3.0) | 3143 (9.6) | 156 (0.5) |
| Biologic + non-biologic systemic + biologic | 35 (2.1) | 569 (17.4) | 2846 (7.9) |
| Topical + biologic | 35 (2.1) | 30 (3.0) | 1137 (3.5) |
| Non-biologic systemic + biologic | 54 (3.2) | 54 (3.2) | 1933 (6.9) |

*The GPP-matched cohort was matched 4:1, based on age and sex, to the GPP cohort. GPP generated patient count, SD, rounded down.

Figure 4. Dermatology medication use by class for patients with GPP versus plaque psoriasis in the 12-month follow-up period



Other drug categories include: 4-bisphosphonates, corticosteroids, immunosuppressants, microsporidiosis, psoriasis, and other. GPP generated patient count, SD, rounded down.

Table 3. Concomitant medication for comorbidities during the 12-month follow-up period

| Medication (n %) | GPP cohort (n=1669) | GPP-matched cohort* (n=667.6) | Plaque psoriasis cohort (n=60,419) |
|--|---------------------|-------------------------------|------------------------------------|
| Antihypertensives | 649 (39.0) | 15,299 (46.8) | 1861 (46.1) |
| Antibiotics | 537 (32.2) | 16,251 (49.8) | 1937 (37.7) |
| Statins | 475 (28.5) | 10,410 (31.2) | 1265 (30.6) |
| Psychiatric medication | 445 (26.7) | 10,917 (33.4) | 1089 (26.4) |
| Opioid pain medication | 404 (24.2) | 8103 (24.8) | 853 (20.7) |
| Asthma medication | 372 (22.3) | 8938 (27.4) | 842 (20.4) |
| Type 2 diabetes medication | 295 (17.6) | 4833 (14.8) | 484 (11.7) |
| COPD medication | 250 (15.0) | 5235 (16.0) | 558 (13.5) |
| Stays in hospital (non-hospitalizations) | 39 (2.3) | 1308 (4.0) | 98 (2.4) |

*The GPP-matched cohort was matched 4:1, based on age and sex, to the GPP cohort. GPP generated patient count, SD, rounded down.

Discussion

- This study summarizes the characteristics of 1,669 patients with GPP in a real-world setting in the USA.
- Our findings suggest that patients with GPP tend to have more comorbidities that require additional management from patients with plaque psoriasis and the general population, including psoriatic arthritis, anxiety, and depression. This may also be explained by the higher mean age of GPP patients compared with plaque psoriasis.
- The medication burden for both dermatologic reasons and comorbidities was higher in patients with GPP compared with patients with plaque psoriasis, suggesting that there are higher healthcare needs in this patient population.
- This study is not without limitations. As data were collected from an administrative claims database for reimbursement purposes, other than scientific research, there may be higher healthcare needs in this patient population.
- Together, these real-world results show that patients with GPP have a different clinical profile than patients with plaque psoriasis as well as substantial disease burden, which has previously been underreported, further highlighting an unmet clinical need in patients with GPP.

References

1. Noveron AA, et al. Eur Acad Dermatol Venereol. 2017;21(1):192-199.
2. Bhatnagar H, et al. J Dermatol. 2018;18(6):614-618.
3. Goodwin JM, et al. Expert Rev Clin Immunol. 2019;15(9):907-919.
4. Johnson A, et al. J Allergy Clin Immunol. 2017;140(1):109-120.
5. Welles S, et al. J Allergy Clin Immunol. 2019;143(1):101-102.
6. Robinson A, et al. J Am Acad Dermatol. 2019;27(2):279-283.
7. Johnson A, et al. J Am Acad Dermatol. 2019;27(2):279-283.
8. Johnson A, et al. J Am Acad Dermatol. 2019;27(2):279-283.
9. Johnson A, et al. J Am Acad Dermatol. 2019;27(2):279-283.
10. Optum® Clinformatics™ Data Mart database. https://www.optum.com/content/dam/optum/healthcare/product/HealthAnalytics/Data_Mart.pdf (accessed July 16, 2020).

Disclosures

This study was funded by Boehringer Ingelheim. At the time of the study, N. Kotowsky, M.C. Valdecantos, R. Gao, and A.K. Golembesky were employees of Boehringer Ingelheim. A.C. Garry is a non-employee of Boehringer Ingelheim. All other authors are employees of Aetion, contracted by Boehringer Ingelheim.

Acknowledgments

Editorial support for the original poster was provided by Amy Hester, PhD, from OHSU Health Medical Communications (London, UK). The authors thank the following individuals for their contributions: Aetion, Boehringer Ingelheim, and Boehringer Ingelheim. The authors also thank the following individuals for their contributions: Aetion, Boehringer Ingelheim, and Boehringer Ingelheim.

Click the icon to access an interactive infographic for this study poster.

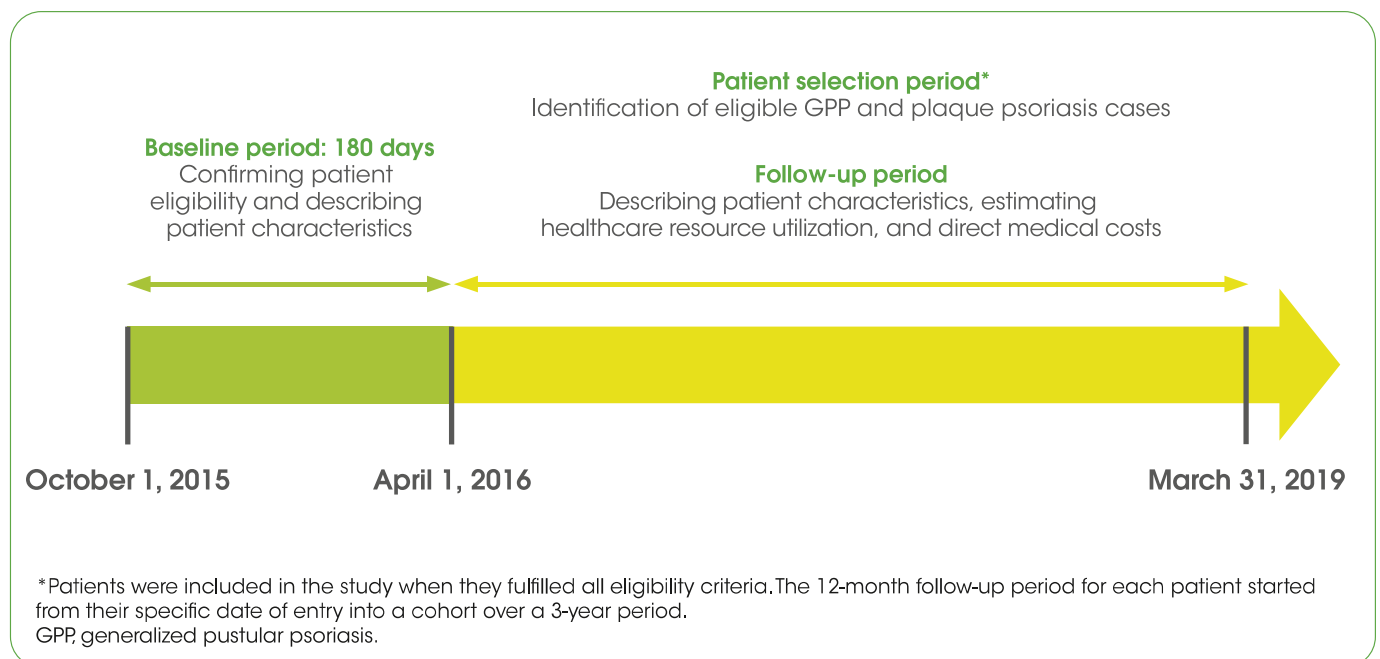
From QR code to an interactive infographic for this study poster. <https://bit.ly/2Z83g3g>

Background

- Generalized pustular psoriasis (GPP) is defined as a rare, neutrophilic skin disease characterized by episodes of widespread eruption of sterile, macroscopically visible pustules that can occur with or without systemic inflammation and with or without plaque psoriasis¹⁻⁴
- GPP is a chronic disease, causing substantial morbidity, and in some cases, mortality⁵
- Although GPP is a distinct entity from plaque psoriasis, phenotypically and genetically, patients receive similar treatments to patients with plaque psoriasis^{1,2,6,7}
- Currently, there are no treatments for the specific indication of GPP in the USA or Europe, highlighting an unmet need in this patient population
- Despite the lack of treatment options for patients with GPP, therapies that are being used are associated with adverse events and/or variable efficacy, making them inappropriate for long-term use^{2,8,9}
- To date, there is limited real-world evidence characterizing patients with GPP
- In order to better understand and evaluate the unmet needs of patients with GPP, this study aims to describe the US clinical burden and healthcare resource utilization (HCRU) of patients with GPP compared to those with plaque psoriasis and the general population

Methods

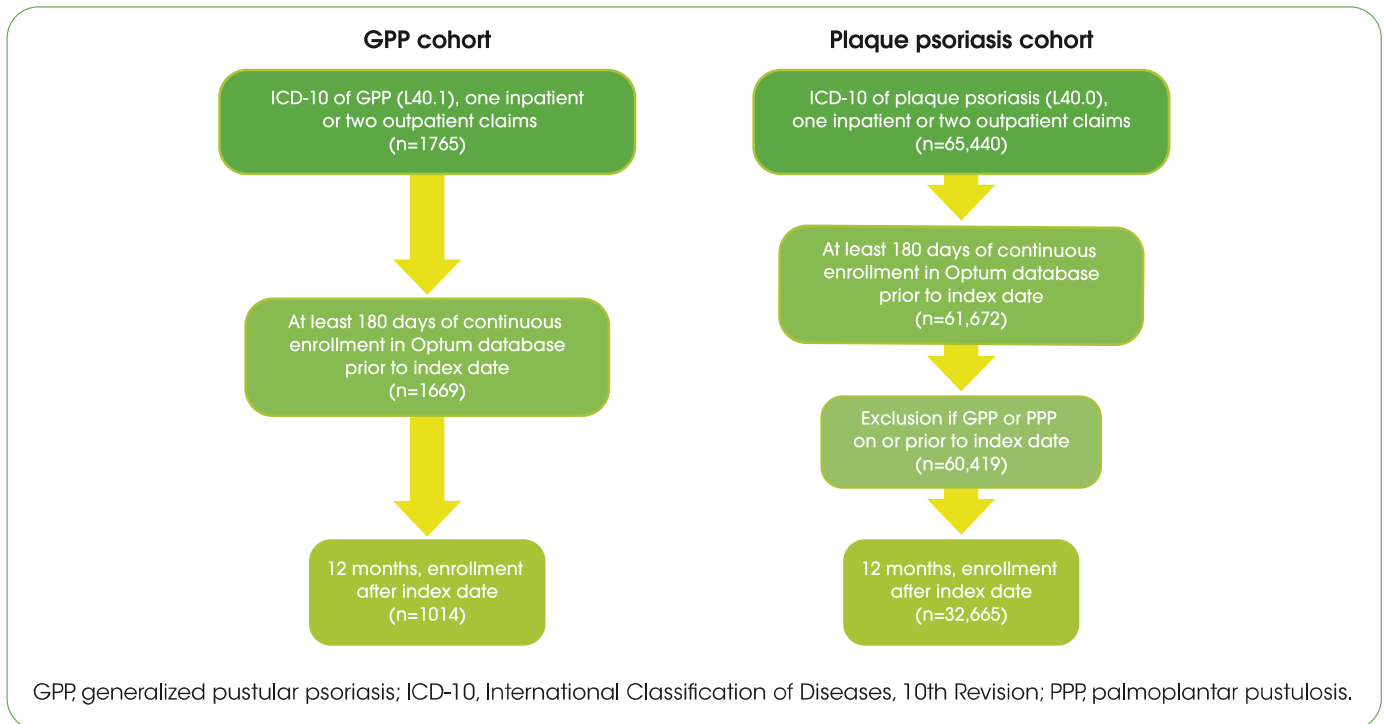
- Patients were diagnosed as having GPP or plaque psoriasis if they had ≥ 1 inpatient or 2 outpatient diagnostic claim(s) for ICD-10 L40.1 or L40.0, respectively, separated by 30–365 days
- All analyses were conducted via the Aetion Evidence Platform[®] v3.11, using Optum[®] Clinformatics[™] Data Mart, a US administrative claims database¹⁰
- The study period was from October 1, 2015 to March 31, 2019, with the first qualifying diagnostic claim marking the index date (**Figure 1**)
- A cohort of the general population was matched to patients with GPP 4:1, based on age and sex, excluding subjects with any psoriasis other than psoriatic arthritis, and the GPP-matched cohort, along with the plaque psoriasis cohort, provided context to the GPP burden of disease
- Patient characteristics during the 180-day baseline period and medication use among patients with 12 months' follow-up were analyzed
- The following outcomes were evaluated:
 - Comorbidities during baseline, including but not limited to hormonal/metabolic conditions, pulmonary conditions, and psychiatric conditions, determined by ICD-10 diagnosis codes
 - Concomitant medications during baseline
 - Dermatology treatments received during the 12 months' follow-up
- Treatments were identified using claims by the Healthcare Common Procedure Coding System and the National Drug Codes
- All analyses were descriptive in nature; no formal comparisons were conducted

Figure 1. Study design

Results

Patient population and demographics

- In total, 1,669 patients with GPP, 60,419 with plaque psoriasis, and 6,676 in the GPP-matched cohort were identified at baseline. Overall, 1,014 patients with GPP and 32,665 patients with plaque psoriasis completed the 12-month follow-up period (**Figure 2**)
 - In the GPP-matched cohort, 4,130 subjects completed the 12-month follow-up
- Patients with GPP were more likely to be female (67.6%) and had a mean age of 63.9 years, compared with the plaque psoriasis cohort in which patients had a mean age of 56.4 years and 50.7% were female (**Table 1**)

Figure 2. Study population**Table 1.** Patient demographics at baseline

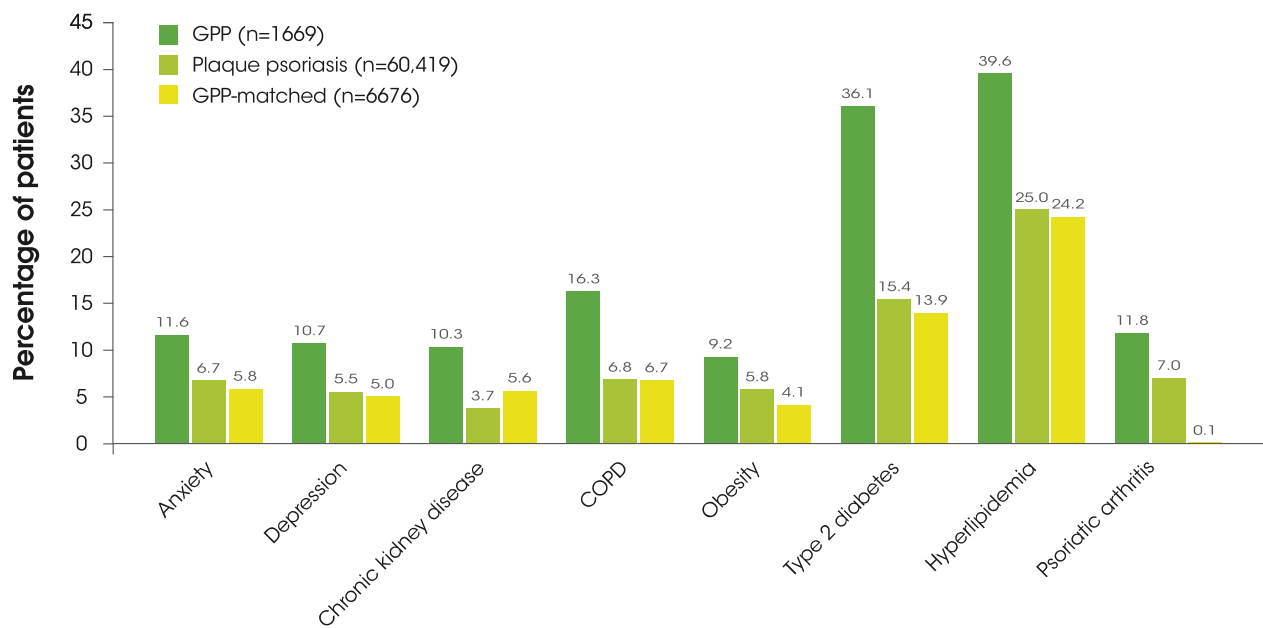
| Demographics, n (%) | GPP cohort (n=1669) | Plaque psoriasis cohort (n=60,419) | GPP-matched cohort* (n=6676) |
|-------------------------------|---------------------|------------------------------------|------------------------------|
| Female | 1128 (67.6) | 30,621 (50.7) | 4512 (67.6) |
| Age, years, mean (SD) | 63.9 (15.2) | 56.4 (17.3) | 59.6 (19.9) |
| <18 years | 17 (1.0) | 1135 (1.9) | 68 (1.0) |
| 18–64 years | 739 (44.3) | 37,645 (62.3) | 2956 (44.3) |
| ≥65 years | 913 (54.7) | 21,637 (35.8) | 3652 (54.7) |
| Commercially insured patients | 580 (34.8) | 37,774 (62.5) | 3127 (46.8) |
| Medicare patients | 1089 (65.2) | 22,645 (37.5) | 3549 (53.2) |

*The GPP-matched cohort was matched 4:1, based on age and sex, to the GPP cohort.
GPP, generalized pustular psoriasis; SD, standard deviation.

Comorbidities

- At baseline, patients with GPP had more comorbidities than patients in the plaque psoriasis and GPP-matched cohorts
 - These included psoriatic arthritis (11.8% vs 7.0% and 0.1%, respectively), anxiety (11.6% vs 6.7% and 5.8%), and depression (10.7% vs 5.5% and 5.0%)
- Patients with GPP were also more likely to suffer from hyperlipidemia, type 2 diabetes, obesity, chronic obstructive pulmonary disease, and chronic kidney disease (**Figure 3**)

Figure 3. Comorbidities at baseline



The GPP-matched cohort was matched 4:1, based on age and sex, to the GPP cohort.
COPD, chronic obstructive pulmonary disease; GPP, generalized pustular psoriasis.

Dermatologic medication use during the 12-month follow-up period

- 245 out of 1014 patients (24.2%) with GPP were treated with combination therapies (topical and/or biologics and/or non-biologics) compared with 11,365 out of 32,665 patients (34.8%) with plaque psoriasis (**Table 2**)
- Patients with GPP were more than twice as likely to be treated with a non-biologic systemic therapy only than patients with plaque psoriasis (15.0% vs 7.2%, respectively); however, the percentage of patients treated with a biologic monotherapy was higher in the plaque psoriasis cohort than in the GPP cohort (5.0% vs 9.6%)
 - Patients with GPP were also less likely to be treated with a topical medication only compared with patients with plaque psoriasis (14.4% vs 24.5%) (**Table 2**)
- Of the biologic therapies, tumor necrosis factor (TNF) inhibitors were the most commonly prescribed in the GPP and plaque psoriasis cohorts (**Figure 4**)
 - Adalimumab was the most commonly prescribed TNF inhibitor in the GPP (6.7%) and plaque psoriasis cohorts (11.2%)
- Of the non-biologic therapies, methotrexate was the most commonly used individual systemic therapy in the GPP (10.8%) and plaque psoriasis (10.0%) cohorts (**Figure 4**)

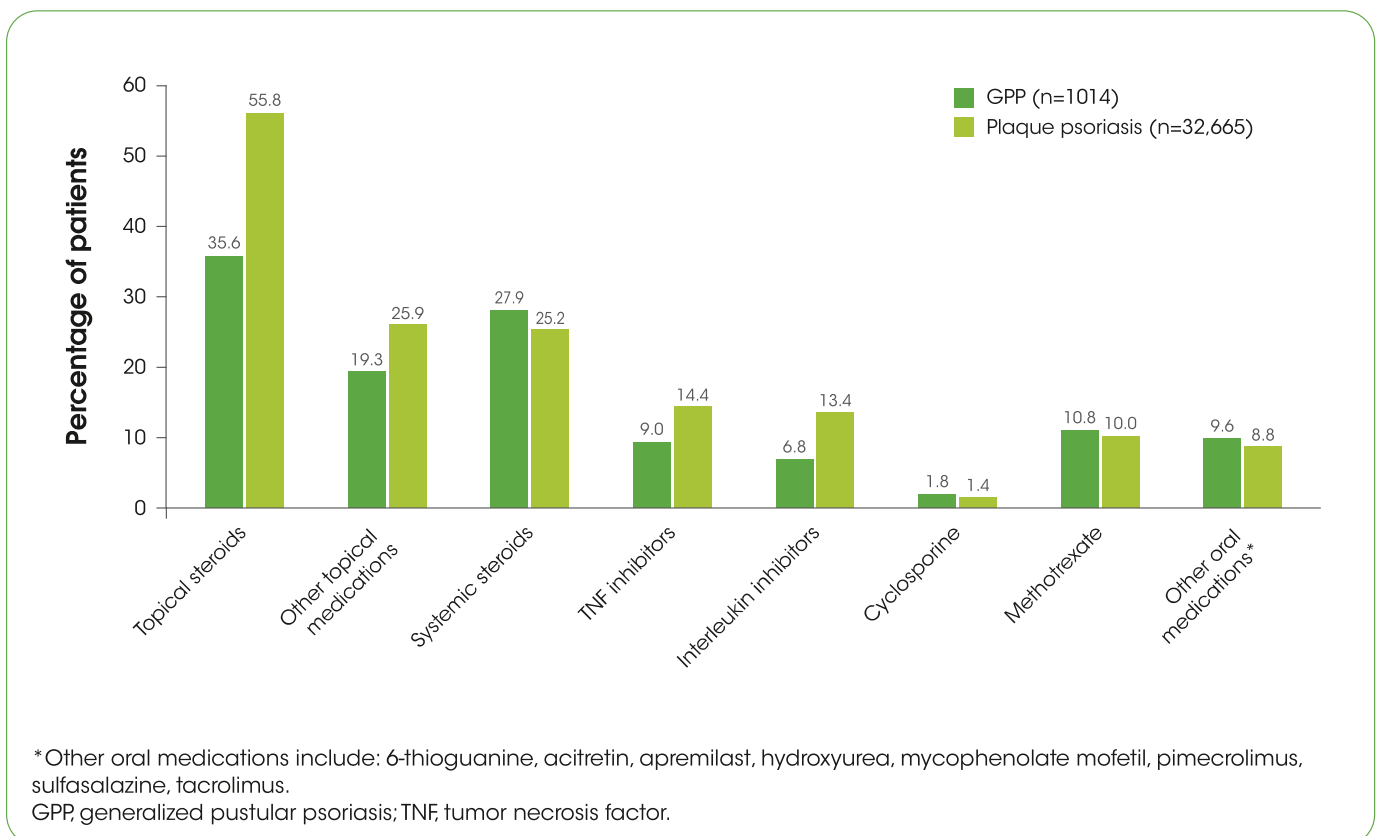
Table 2. Systemic, non-systemic, and topical medication drug use during the 12-month follow-up period on or after the qualifying claim date

| Medication, n (%) | GPP cohort (n=1014) | Plaque psoriasis cohort (n=32,665) |
|--|---------------------|------------------------------------|
| No treatment | 419 (41.3) | 7782 (23.8) |
| Topical only | 146 (14.4) | 8016 (24.5) |
| Non-biologic systemic only | 153 (15.0) | 2359 (7.2) |
| Biologic monotherapy | 51 (5.0) | 3143 (9.6) |
| Topical + non-biologic systemic | 126 (12.4) | 5689 (17.4) |
| Topical + biologic | 35 (3.5) | 2586 (7.9) |
| Non-biologic systemic + biologic | 30 (3.0) | 1157 (3.5) |
| Topical + non-biologic systemic + biologic | 54 (5.3) | 1933 (5.9) |

Medication groups are mutually exclusive.
GPP, generalized pustular psoriasis.

Please follow your local copyright law

Figure 4. Dermatologic medication use by class for patients with GPP versus plaque psoriasis in the 12-month follow-up period



Concomitant medication use for comorbidities during the 12-month follow-up

- During the 12-month follow-up period, the use of concomitant medications for comorbidities was higher in patients with GPP than those with plaque psoriasis and the GPP-matched cohort
 - These include cardiovascular medication, type 2 diabetes medication, psychiatric medication, medication for respiratory conditions, and opioid pain medication (**Table 3**)

Table 3. Concomitant medication for comorbidities during the 12-month follow-up period

| Medication, n (%) | GPP cohort (n=1014) | Plaque psoriasis cohort (n=32,665) | GPP-matched cohort* (n=4130) |
|---------------------------------------|---------------------|------------------------------------|------------------------------|
| Antihypertensives | 649 (64.0) | 15,299 (46.8) | 1861 (45.1) |
| Antibiotics | 537 (53.0) | 16,251 (49.8) | 1557 (37.7) |
| Statins | 473 (46.6) | 10,410 (31.9) | 1265 (30.6) |
| Psychiatric medication | 445 (43.9) | 10,917 (33.4) | 1089 (26.4) |
| Opioid pain medication | 404 (39.8) | 8103 (24.8) | 853 (20.7) |
| Asthma medication | 373 (36.8) | 8938 (27.4) | 842 (20.4) |
| Type 2 diabetes medication | 293 (28.9) | 4831 (14.8) | 484 (11.7) |
| COPD medication | 250 (24.7) | 5235 (16.0) | 558 (13.5) |
| Sleep medication (non-benzodiazepine) | 39 (3.8) | 1308 (4.0) | 98 (2.4) |

*The GPP-matched population cohort was matched 4:1, based on age and sex, to the GPP cohort. COPD, chronic obstructive pulmonary disease; GPP, generalized pustular psoriasis.

Discussion

- This study summarizes the characteristics of 1669 patients with GPP in a real-world setting in the USA
- These findings suggest that patients with GPP tend to have more comorbidities that require additional management than patients with plaque psoriasis and the general population cohort, including psoriatic arthritis, anxiety, and depression. This may also be explained by the higher mean age of GPP patients compared with plaque psoriasis
- The medication burden for both dermatological reasons and comorbidities was higher in patients with GPP compared with patients with plaque psoriasis, suggesting that there are higher healthcare needs in this patient population
- This study is not without limitations. As data were collected from an administrative claims database for reimbursement purposes, rather than scientific research, there may be miscoding, thus this should be considered during analyses
- Together, these real-world results show that patients with GPP have a different clinical profile to patients with plaque psoriasis as well as substantial disease burden, which has previously been under-reported, further highlighting an unmet clinical need in patients with GPP

Please follow your local copyright law

References

1. Navarini AA, et al. *J Eur Acad Dermatol Venereol* 2017;31:1792–1799
2. Fujita H, et al. *J Dermatol* 2018;45:1235–1270
3. Bachelez H. *Br J Dermatol* 2018;178:614–618
4. Gooderham MJ, et al. *Expert Rev Clin Immunol* 2019;15:907–919
5. Choon SE, et al. *Int J Dermatol* 2014;53:676–684
6. Johnston A, et al. *J Allergy Clin Immunol* 2017;140:109–120
7. Twelves S, et al. *J Allergy Clin Immunol* 2019;143:1021–1026
8. Robinson A, et al. *J Am Acad Dermatol* 2012;67:279–288
9. Umezawa Y, et al. *Arch Dermatol Res* 2003;295(Suppl 1):S43–S54
10. Optum® Clinformatics™ Data Mart database. https://www.optum.com/content/dam/optum/resources/productSheets/Clinformatics_for_Data_Mart.pdf (accessed July 16, 2020)

Disclosures

This study was funded by Boehringer Ingelheim. At the time of the study, N Kotowsky, WC Valdecantos, R Gao, and AK Golembesky were full-time employees of Boehringer Ingelheim. AK Golembesky is now employed by GlaxoSmithKline. EM Garry is employed by Aetion, contracted by Boehringer Ingelheim.

Acknowledgments

Editorial support for the original poster was provided by Amy Pashler, PhD, from OPEN Health Medical Communications (London, UK) and was funded by Boehringer Ingelheim. Formatting support for the AAFP encore poster was provided by Elevate Scientific Solutions (Fairfield, CT, USA) and was funded by Boehringer Pharmaceuticals, Inc.



Click the icon to access an interactive microsite for this SMART poster

Scan QR code for an interactive electronic device-friendly copy of the poster
<https://bit.ly/2FCHzjg>

