



Generalized Pustular Psoriasis Flares: Treatment Patterns in the Real-World Setting

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BACKGROUND

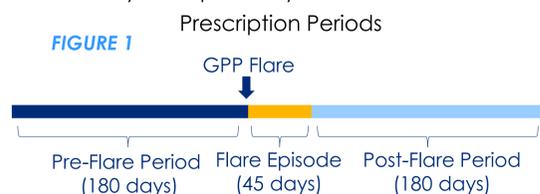
- Generalized pustular psoriasis (GPP) is a rare, chronic, potentially life-threatening, severe multisystemic inflammatory skin disease^{1,2}
- Patients with GPP can experience flares – unpredictable episodes of extensive, sterile pustular eruptions – often accompanied by systemic symptoms, which can be potentially life-threatening^{1,2}
- Accurate patient cohort identification from real-world data is key to performing accurate epidemiologic research³; however, GPP flares often go unreported because there is no specific procedure code for them in structured electronic health records (EHRs)
- As such, prescription and treatment patterns around GPP flares in the real-world setting are not well characterized

STUDY OBJECTIVES

- The objectives of this study were as follows:
 - To characterize prescription patterns before, during, and after GPP flares
 - To quantify the incidence of treatment discontinuation, switching, and augmentation after the start of GPP flares

METHODS

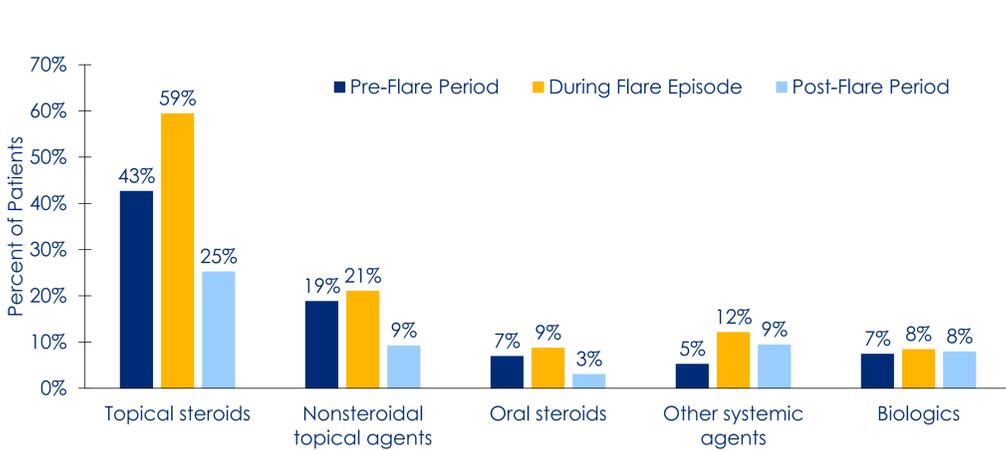
- The data source for this study comprises deidentified EHR data pulled from the OMNY Health Dermatology Platform (OMNY data) that includes data 15 million patients. EHRs from 6 specialty dermatology networks in the OMNY Health real-world data platform from 2017 to January 2023 were accessed
- Encounters from patients with at least 1 GPP diagnosis code (International Classification of Diseases, 10th revision [ICD-10] code: L40.1), ≥ 30 days of data before the first GPP diagnosis code, and available clinical notes were evaluated to identify potential flares
- GPP flares were identified based on previously developed algorithm derived from a combination of natural language processing (NLP) of clinical notes and the presence of structured procedure codes⁴:
 - A trained and validated transformer-based NLP model was deployed on the unstructured clinical notes to generate a score between 0 and 1 corresponding to the notes-based probability of a GPP flare (NLP score)
 - A logistic regression model comprising the NLP score and the presence of a Current Procedural Terminology (CPT) code indicative of moderate or complex disease management) was employed to each encounter to predict overall probability of GPP flare
 - Encounters were marked as GPP flares if they had overall probabilities greater than the threshold that maximized the tradeoff between sensitivity and specificity
- Patients with at least 1 GPP flare were selected and indexed at their first flare (Day 0)
- Proportions of patients prescribed therapies were computed for the following periods around their first flare (Figure 1):
 - Pre-flare period: Day -180 to Day -1
 - During the flare episode: Day 0 to Day 45
 - Post-flare period: Day 46 to Day 225
- Patients exposed to biologics and other nonsteroidal systemic agents at flare start were followed to determine the cumulative incidence while accounting for censoring for the following outcomes:
 - Treatment discontinuation: Gap in scheduled therapy of ≥ 90 days or within-class switch
 - Within-class treatment switch: New therapy initiation in the same class
 - Between-class treatment switch: New therapy initiation in another class
 - Treatment augmentation: Addition of a therapy from another class



RESULTS

- Of approximately 7.4 million patients from specialty dermatology networks with EHR data available, 2,154 had at least 1 diagnosis code for GPP, and 638 of those patients had ≥ 30 days of data before first GPP diagnosis code and an evaluable unstructured clinical note.
 - 404 (63%) of these patients had at least 1 flare, comprising the study population
 - 234 patients had 2 or more flares
- Average age was 58 years (standard deviation: 16 years), and the majority were female (76%) and white (85%)
- The most common comorbidities were plaque psoriasis (42%), systemic infection (35%), and cardiovascular disease (26%)
- Peri-flare prescription patterns are summarized in Figure 2:

FIGURE 2 Prescription Patterns Around GPP Flares (N = 404)

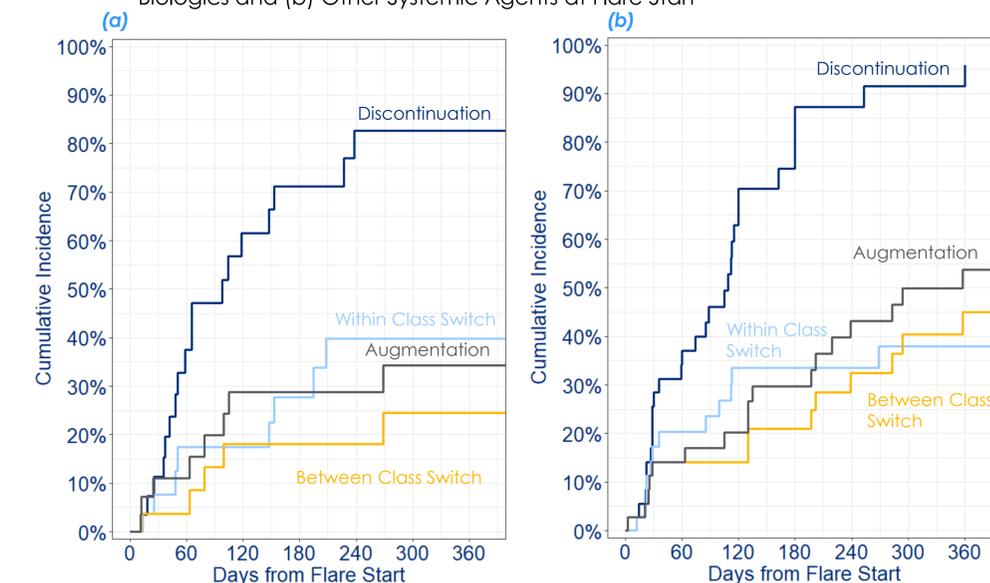


Note: Other systemic agents included apremilast, acitretin, tofacitinib, methotrexate, cyclosporine, chloroquine, hydroxychloroquine, sulfasalazine, azathioprine, hydroxyurea, isotretinoin, methoxsalen, mycophenolate mofetil, and thioguanine.

- Prescriptions of all therapy classes increased from the pre-flare period to the flare episode, then decreased from the flare episode to the post-flare period.
- The most dramatic increases from the pre-flare period to the flare episode were for topical steroids (43% to 59%) and other systemic agents (5% to 12%); relative increases for nonsteroidal topical agents, oral steroids were more modest
- Prescriptions for biologics remained constant during the flare (8%) and post-flare window (8%) as patients may be placed on biologics longer term due to the chronicity of the disease.
- Prescriptions during the flare episode to the post-flare period decreased most notably for topical steroids (59% to 25%), nonsteroidal topical agents (21% to 9%) and oral steroids (9% to 3%)
- Cumulative incidence plots of treatment outcomes for patients exposed to biologics and other systemic agents at flare start are presented in Figures 3a and 3b, respectively.
- 30 patients were exposed to biologics at flare start
 - At Day 90, almost half (47%) of patients had discontinued biologic therapy; 17% had switched from the index biologic to another; while 13% and 20% had switched to or added another class of therapy, respectively
 - At Day 180 and 360, 71% and 83% of patients had discontinued therapy, respectively
 - The cumulative proportion of patients who switched to another biologic increased from 28% at Day 180 to 40% at Day 360; similar increases were observed for switching to another therapy class (18% to 24%) and addition of another therapy class (29% to 34%)

- 41 patients were exposed to other systemic agents at flare start
 - The cumulative proportion of patients who discontinued increased from 46% at Day 90 to 87% at Day 180 and 96% at Day 360
 - Similar increases in cumulative proportion at Days 90, 180, and 360 were observed for switching to another systemic agent (24%, 33%, 38%), switching to a biologic or oral steroid (14%, 12%, 45%), and addition of a biologic or oral steroid (17%, 30%, 54%)

FIGURE 3 Cumulative Incidence of Treatment Outcomes of Patients Exposed to (a) Biologics and (b) Other Systemic Agents at Flare Start



LIMITATIONS

- Only patients with the diagnosis code (ICD-10: L40.1) were included. Given that GPP is a rare disease, underdiagnosis in the real-world setting is possible, which may have resulted in the exclusions of otherwise eligible patients.
- Based on test data, the algorithm to identify GPP flares had a sensitivity and specificity of approximately 70%, which may have resulted in the inclusion of false positives and negatives
- Prescription orders and administrations are observed in EHR data and may not represent whether therapies were taken by the patient
- Exposure to therapy was defined by label conventions and may not represent actual exposure
- Patients may have received care from health systems outside the specialty dermatology network
- Lengthy prior authorization and/or denials in coverage may account for some patient switching and/or biologic discontinuation

CONCLUSIONS

- Results provide insights into real-world treatment patterns around GPP flares. Data suggests the need for more effective long-term treatments for GPP:
 - GPP is a chronic disease, and some patients may continue to experience symptoms warranting continued use of treatment beyond the immediate flare.
 - During the observation period, 58% of study population had additional flares beyond the first flare, indicating existing complications in symptom control and disease management
 - Regardless of index therapy, a large proportion of treatments are discontinued, switched, or augmented within the year following the flare start.

Abbreviations: EHR, electronic health record; CPT, Current Procedural Terminology; GPP, generalized pustular psoriasis; ICD-10, International Classification of Diseases, 10th revision; NLP, natural language processing

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