Characteristics, treatment patterns, health care resource utilization and costs in patients with bullous pemphigoid: A retrospective analysis of US health insurance claims data

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Background: Real-world data describing the impact of incident bullous pemphigoid (BP) on patients and health care resource utilization (HCRU) are limited.

Objective: To examine characteristics, treatment patterns, HCRU, and costs for incident BP.

Methods: Retrospective analysis of 2015 to 2019 US health insurance claims for patients ≥18 years with an incident BP diagnosis. Patients with BP were matched to those without on demographic and clinical characteristics. Statistics were descriptive.

Results: The mean Charlson Comorbidity Index score was higher for patients with BP (n = 1108) than without (n = 4621) at baseline (mean [SD]: 3.3 [2.7] vs 2.8 [2.4]) and during follow-up (5.0 [4.9] vs 3.7 [3.0]). Hypertension, diabetes, skin ulcers, chronic pulmonary disease, dyslipidemia, sleep disorders, and congestive heart failure were higher with BP. Most patients with BP received antibiotics (>80%) and/or corticosteroids (>90%). Hospitalizations were more common (44.0% vs 17.1%) and monthly all-cause health care costs more than double ($3214 vs $1353) in patients with BP than without.

Limitations: Diagnoses were based on billing codes. HCRU claims data may not reflect the true number of encounters.

Conclusion: Incident BP is associated with considerable morbidity, HCRU, and costs. More effective, targeted treatments are needed to improve quality of life, while minimizing exposure to systemic corticosteroids. (JAAD Int 2023;13:117-25.)

Key words: antibiotics; autoimmune disease; blistering skin disease; bullous pemphigoid; burden of disease; clinical characteristics; comorbidity; costs; health care resource utilization; opioids; steroids; treatment.

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INTRODUCTION

Bullous pemphigoid (BP) is a rare chronic autoimmune disease mainly affecting the elderly.[1] Its occurrence is increasing[2,3]; recent estimates suggest a global incidence of 34.2 per million person-years and incidence of 2.4 cases/100,000 people in North America.[1,4,5] Patients typically present with pruritus or pain, tense blisters, and skin erosions, and experience periodic exacerbations.[6] Topical steroids are first-line therapy, with high-potency options used for more severe disease; systemic corticosteroids may be preferred when disease presentation is extensive and/or more severe, while other immunosuppressants may be added to reduce the risks of long-term steroid use.[7] Antibiotics are another treatment option, and biologic therapy is occasionally used off-label for treatment-resistant disease.[7] However, no therapies are specifically approved for BP treatment.

CAPSULE SUMMARY

- Real-world data describing the impact of bullous pemphigoid on patients and health care resource utilization are limited.
- In this study, bullous pemphigoid was associated with considerable morbidity, health care resource utilization, and costs. More effective treatments are needed that improve quality of life and minimize exposure to systemic corticosteroids.

As BP is largely a disease of the elderly, patients often have a range of comorbidities. The burden is significant, with an increased risk of mortality, as well as morbidity or worsening of comorbidities due to viral and bacterial infections or long-term corticosteroid use.[2,8-10] Despite the serious nature of BP, the only real-world data on treatment characteristics, health care resource utilization (HCRU), and costs come from a few studies primarily focused on incidence and mortality.[4,11-15] Particularly, US data on clinical/treatment characteristics are limited,[4,11,15] and only 1 single-center US study has evaluated real-world HCRU.[11] Therefore, we analyzed US health insurance claims data to assess the characteristics and treatment patterns of patients with BP, and the impact of BP on HCRU and costs.

METHODS

Study design, participants, and procedures

We conducted a retrospective analysis of 2015 to 2019 US health insurance claims data from the Merative MarketScan Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefits databases, which contains medical and drug utilization data across all care settings for nearly 60 million individuals covered by certain employer-sponsored private health insurance schemes. The Medicare database contains data for individuals with supplement insurance paid by employers in both inpatient and outpatient settings, and outpatient prescription drug claims and person-level enrollment data.

Four patient cohorts were examined during the study period (baseline: 6-month period preindex [date of first observed diagnosis code for BP]; follow-up: index to end of health plan enrollment or database; Fig 1). The prevalent BP cohort comprised all patients with claims containing a BP diagnostic code during the study period (≥1 inpatient claim, or ≥2 outpatient claims ≥30 days apart); aged ≥18 years at index; ≥1 pharmacy claim for BP therapy ±30 days of index; and no pemphigus diagnosis at any time (Supplementary Material, available via Mendeley at https://doi.org/10.17632/994227m9zy.1). The incident BP cohort comprised patients in the prevalent BP cohort with ≥6 months' continuous health plan enrollment preindex and no diagnosis of BP during this time. A cohort of patients without BP were matched to patients in the incident BP cohort (assigned index date of matched BP case) and had a baseline and follow-up period equivalent to their matched BP case, with no diagnosis of BP or pemphigus at any point. An exploratory steroid-treated BP cohort, consisting of patients in the prevalent BP cohort who received ≥30 days' treatment with any corticosteroid postindex, was also analyzed.

Study objectives and end points

Demographic and clinical characteristics, including age, sex, payer type, and duration of continuous health plan enrollment, were assessed at index. Relevant comorbidities and other conditions of interest were reported (Supplementary Material, available via Mendeley at https://doi.org/10.17632/994227m9zy.1); Charlson Comorbidity Index (CCI)[16,17] scores were calculated during the baseline period for the incident BP and matched non-BP cohorts only, and during the follow-up period for all cohorts. Treatment characteristics (classes of BP-related treatments [corticosteroids, immunosuppressants, antiinflammatory agents] and other medications of interest [dipeptidyl-peptidase 4 inhibitors, weak and strong opioids]; detailed

Abbreviations used:

BP: bullous pemphigoid
CCI: Charlson Comorbidity Index
HCRU: health care resource utilization
LOS: length of stay
PPPM: per-patient-per-month

treatment patterns) were assessed in all cohorts during follow-up. All-cause and BP-related HCRU and costs were assessed during follow-up by service setting cited in the claim: hospitalization, ambulatory surgical center visits, emergency department visits, urgent care visits, hospital outpatient visits, physician office visits, home visits, pharmacy prescriptions, and other outpatient care not categorized elsewhere.

Statistical analyses

Incident BP and non-BP cohorts were matched at a ratio of up to 1:5 using direct covariate matching based on demographic and clinical characteristics (birth year, sex, geographic region, CCI score during baseline period, and months of continuous health plan enrollment).

Costs were reported as per-patient-per-month (PPPM) and annualized to 1 year (by multiplying by 12), adjusted to 2020 US dollars using the medical care component of the US Consumer Price index.[18] A subgroup analysis was performed to evaluate HCRU and costs among a cohort of patients who remained enrolled for ≥2 years in their health plan (ie, those with 12 months' continuous health plan enrollment preindex and postindex).

Analyses of patient demographics, clinical characteristics, HCRU, and associated costs were descriptive. The statistical significance of descriptive differences in HCRU and costs between the incident BP and matched non-BP cohorts was measured using the Student *t* test. All-cause cost comparisons between incident BP and matched non-BP cohorts were adjusted for age, gender, payer type, region, year of index, and baseline CCI score using multivariable regression analyses. All analyses were conducted using SAS Studio version 9.4 or later (SAS Institute).

RESULTS

Demographic and clinical characteristics

Overall, 1839 patients with a BP diagnosis met the study inclusion/exclusion criteria (prevalent BP cohort), including 1108 potential incident patients (incident BP cohort) (Supplementary Fig 1, available via Mendeley at https://doi.org/10.17632/994227m9zy.1); patients without BP (n = 4621) were matched to the incident BP cohort. Among the prevalent BP cohort, 1334 patients were included in the exploratory steroid-treated BP cohort.

Patient demographics were comparable across all cohorts (Supplementary Table I, available via Mendeley at https://doi.org/10.17632/994227m9zy.1). The mean CCI score was higher in the incident BP than the matched non-BP cohort throughout, although the difference between the cohorts was greater during follow-up (Supplementary Table I, available via Mendeley at https://doi.org/10.17632/994227m9zy.1). During follow-up, the most common comorbidities in the incident BP cohort were hypertension (76.2%) and dyslipidemia (60.2%), occurring more commonly than in the matched non-BP cohort (64.5% and 56.1%, respectively) (Supplementary Table I, available via Mendeley at https://doi.org/10.17632/994227m9zy.1). Diabetes, skin ulcers, chronic pulmonary disease, sleep disorders, and congestive heart failure were also more frequent in the incident BP than the matched non-BP cohort (CCI comorbidities observed during follow-up: Supplementary Table I, available via Mendeley at https://doi.org/10.17632/994227m9zy.1, comorbidities incident during follow-up: Supplementary Table II, available via Mendeley at https://doi.org/10.17632/994227m9zy.1).

Treatment characteristics

Most patients in the prevalent and incident BP cohorts received antibiotics (>80%) and/or corticosteroids (>90%) during follow-up (Table I). In the incident BP cohort, topical corticosteroids were supplied for a mean (SD) of 80.2 (102.6) days and oral corticosteroids for 172.4 (251.4) days (mean starting and ending doses of 41.7 mg/d and 30.6 mg/d, respectively). Intravenous/injectable corticosteroids were supplied for a mean (SD) of 3.0 (3.4) injections.

BP-related medications received most commonly ±30 days of index were antibiotics alone (17.0%), oral corticosteroids alone (16.5%), and topical corticosteroids alone (12.5%). Overall, 369 patients (33.3%) received ≥2 BP-related medications. On average, patients with incident BP continued index treatment regimens for 2 months; most patients who discontinued their index medication switched drug class (60.6%). Among these patients, the most common medications switched to were antibiotics (29.1%) and steroids (oral: 21.3%; injectable: 14.5%; topical: 14.5%).

The use of opioids during follow-up was higher for the incident BP than the matched non-BP cohort (Table I).

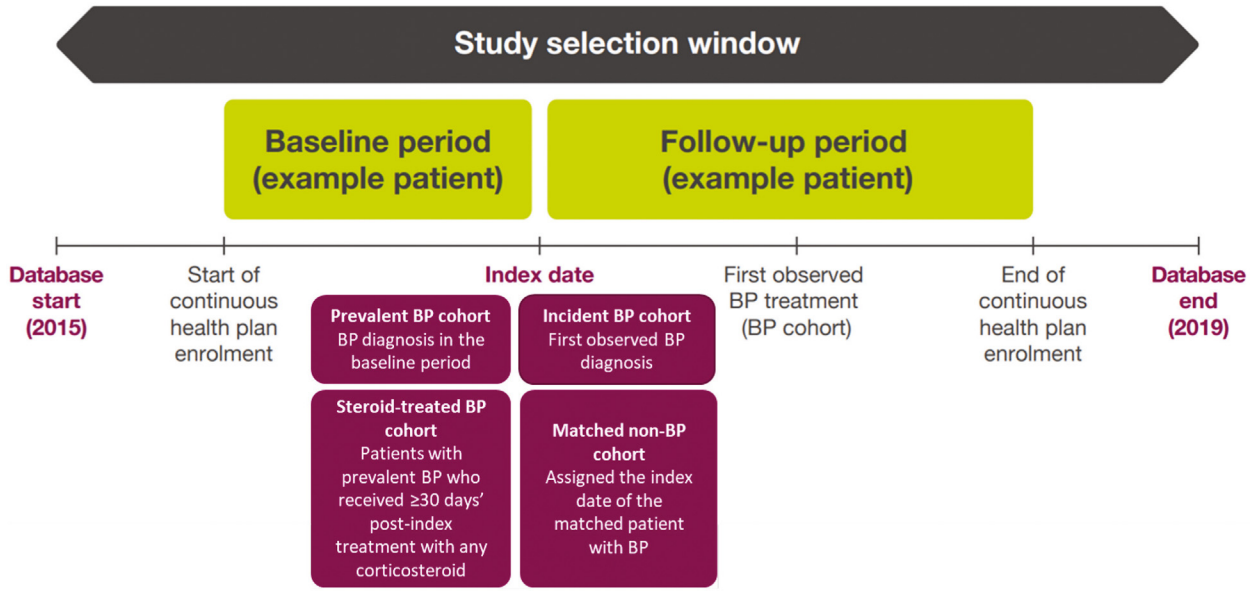

Fig 1. Bullous pemphigoid. Study design and definition of cohorts. *BP*, Bullous pemphigoid.

Table I. Treatment characteristics during follow-up, by cohort

Patients receiving medications during follow-up, *n* (%)	Prevalent BP cohort (*N* = 1839)	Incident BP cohort (*N* = 1108)	Steroid-treated BP cohort (*N* = 1334)	Matched non-BP cohort (*N* = 4621)
BP-related medications*				—
Corticosteroids				
Any corticosteroid	1685 (91.6)	1020 (92.1)	1334 (100.0)	
Topical	1003 (54.5)	641 (57.9)	815 (61.1)	
Oral	1366 (74.3)	825 (74.5)	1096 (82.2)	
Intravenous/injectable	647 (35.2)	364 (32.9)	587 (44.0)	
Systemic (oral or intravenous/injectable)	1510 (82.1)	905 (81.7)	1227 (92.0)	
Immunosuppressive agents				—
Azathioprine	100 (5.4)	40 (3.6)	85 (6.4)	
Mycophenolate mofetil	324 (17.6)	175 (15.8)	264 (19.8)	
Methotrexate	161 (8.8)	88 (7.9)	137 (10.3)	
Antiinflammatory agents				—
Antibiotics	1509 (82.1)	906 (81.8)	1117 (83.7)	
Nicotinamide	31 (1.7)	21 (1.9)	26 (2.0)	
Dapsone	149 (8.1)	86 (7.8)	111 (8.3)	
Other therapies				—
Intravenous immunoglobulin	24 (1.3)	9 (0.8)	13 (1.0)	
Rituximab	64 (3.5)	30 (2.7)	53 (4.0)	
Medication classes				
DPP4 inhibitors	143 (7.8)	99 (8.9)	106 (8.0)	204 (4.4)
Weak opioids	711 (38.7)	377 (34.0)	564 (42.3)	1187 (25.7)
Strong opioids	319 (17.4)	179 (16.2)	249 (18.7)	435 (9.4)

BP, Bullous pemphigoid; *DPP4*, dipeptidyl peptidase-4.
*Use of BP-related medications was not assessed in the matched non-BP cohort.

Health care costs

More patients in the incident BP cohort (44.0%) had ≥1 hospitalization during follow-up than baseline (14.5%; Table II) and the mean length of stay (LOS) increased from 6.03 to 6.42 days. Fewer patients in the non-BP cohort had hospitalization (8.8% at baseline and 17.1% at follow-up) (Table II) and the LOS was shorter (5.21 and 5.14 days, respectively). Similar findings were reported for other types of inpatient and outpatient care during both periods, with HCRU generally lower in the non-BP cohort (Table II).

Table II. All-cause per-patient-per-month health care resource utilization in all patients included in the incident bullous pemphigoid and matched nonbullous pemphigoid cohorts

Patients with ≥1 claims in each HCRU category, *n* (%)	Baseline period			Follow-up period		
	Incident BP cohort (*n* = 1108)	Matched non-BP cohort (*n* = 4621)	*P* value	Incident BP cohort (*n* = 1108)	Matched non-BP cohort (*n* = 4621)	*P* value
Hospitalization	161 (14.5)	408 (8.8)	<.0001	488 (44.0)	792 (17.1)	<.0001
Ambulatory surgical center visits	59 (5.3)	284 (6.2)	.3009	141 (12.7)	585 (12.7)	.9527
Emergency department visits	288 (26.0)	601 (13.0)	<.0001	456 (41.2)	1201 (26.0)	<.0001
Urgent care visits	67 (6.1)	170 (3.7)	.0004	108 (9.8)	389 (8.4)	.158
Hospital outpatient visits	721 (65.1)	2386 (51.6)	<.0001	910 (82.1)	3026 (65.5)	<.0001
Physician office visits	1036 (93.5)	4078 (88.3)	<.0001	1077 (97.2)	4178 (90.4)	<.0001
Home visits	264 (23.8)	734 (15.9)	<.0001	435 (39.3)	1034 (22.4)	<.0001
Other outpatient care	634 (57.2)	1887 (40.8)	<.0001	894 (80.7)	2593 (56.1)	<.0001
Pharmacy	1095 (98.8)	4037 (87.4)	<.0001	1096 (98.9)	4136 (89.5)	<.0001

Data for the prevalent BP cohort were similar to those of the incident BP cohort and are reported in the Supplementary Material, available via Mendeley at https://doi.org/10.17632/994227m9zy.1.
BP, Bullous pemphigoid; *HCRU*, health care resource utilization.

In the incident BP cohort, unadjusted PPPM all-cause health care costs for all patients increased by 12.5% from baseline to follow-up, mainly driven by increased hospitalization costs, while costs in the matched non-BP cohort decreased 13.6% (Table III). Unadjusted PPPM all-cause health care costs at baseline in the incident BP cohort were almost double those in the matched non-BP cohort ($2856 vs $1566; Table III), with an annualized difference of $15,480. Unadjusted PPPM costs at follow-up were almost 2.5 times greater for the incident BP versus the matched non-BP cohort with an annualized difference of $22,332 largely driven by hospitalization.

Adjusted PPPM all-cause health care costs were slightly higher in incident BP but not matched non-BP cohorts during follow-up (Table III). Unadjusted BP-related costs during follow-up for the prevalent and incident BP cohorts accounted for 26.2% and 27.5% of average monthly all-cause health care costs, respectively (Fig 2). Average unadjusted monthly total BP-related costs during follow-up were lower for the exploratory steroid-treated BP cohort than the prevalent and incident BP cohorts (Fig 2), accounting for 23.9% of average monthly all-cause health care costs in this group. In general, HCRU data and associated costs for the prevalent BP cohort were similar to the incident BP cohort (Supplementary Figure II, available via Mendeley at https://doi.org/10.17632/994227m9zy.1).

Subgroup analysis: HCRU and unadjusted health care costs in patients with 24 months' continuous data

Overall, 448 patients in the incident BP and 1946 patients in the matched non-BP cohorts had 24 months' continuous data (12 months in both baseline and follow-up periods). More patients had ≥1 hospitalization during follow-up versus baseline, regardless of cohort (Supplementary Table IV, available via Mendeley at https://doi.org/10.17632/994227m9zy.1). In the incident BP cohort, the mean LOS per hospitalization increased from 5.9 to 6.6 days; 33.9% of patients with incident BP had ≥1 hospitalization during follow-up. The mean LOS per hospitalization was lower in the non-BP cohort and changed little between baseline and follow-up (5.0 vs 5.1 days). Similar proportions of patients reported other types of inpatient and outpatient care at baseline and follow-up (Supplementary Table IV, available via Mendeley at https://doi.org/10.17632/994227m9zy.1). In the incident BP cohort, 78.4% of patients had ≥1 hospital outpatient visit during follow-up and nearly all patients had ≥1 physician office visit (98.4%) or pharmacy claim (99.6%) (Supplementary Table IV, available via Mendeley at https://doi.org/10.17632/994227m9zy.1). Unadjusted all-cause health care costs were ~1.7 times higher at baseline (difference $13,481) and ~1.7 times higher at follow-up (difference $17,092) in the incident BP than the non-BP cohort (Fig 3). Incident BP cohort costs increased 22.9% from baseline to follow-up, while costs in the matched non-BP cohort increased 20.3% (Fig 3). Consistent with overall data, the largest cost increase in both cohorts was for hospitalizations. For the incident BP cohort, hospitalization costs increased 79.8% from baseline to follow-up ($8928 vs $16,054); in the non-BP cohort, hospitalization costs increased from $5068 (baseline) to $9103 (follow-up).

DISCUSSION

In this retrospective, real-world analysis of US health insurance claims data, BP was associated with

Table III. All-cause unadjusted per-patient-per-month and adjusted per-patient-per-month health care costs in all patients included in the incident bullous pemphigoid and matched nonbullous pemphigoid cohort

	Baseline period			Follow-up period		
	Incident BP cohort (n = 1108)	Matched non-BP cohort (n = 4621)	P value	Incident BP cohort (n = 1108)	Matched non-BP cohort (n = 4621)	P value
Unadjusted PPPM, mean (SD)						
Hospitalization	$718 (3140)	$396 (2301)	.0001	$1340 (4000)	$387 (2498)	<.0001
Ambulatory surgical center visits	$26 (154)	$32 (219)	.344	$19 (102)	$25 (200)	.3333
Emergency department visits	$92 (379)	$43 (233)	<.0001	$78 (350)	$39 (229)	<.0001
Urgent care visits	$2 (9)	$1 (8)	.0214	$1 (7)	$1 (6)	.4718
Hospital outpatient visits	$762 (4253)	$405 (2526)	.0003	$554 (2492)	$325 (1928)	.0008
Physician office visits	$369 (1132)	$236 (657)	<.0001	$282 (668)	$173 (433)	<.0001
Home visits	$50 (249)	$36 (683)	.5169	$81 (552)	$29 (612)	.0106
Other outpatient care	$365 (2936)	$128 (1171)	<.0001	$446 (2040)	$140 (2157)	<.0001
Pharmacy	$473 (1387)	$288 (857)	<.0001	$412 (1189)	$232 (769)	<.0001
Total health care costs	**$2856 (7360)**	**$1566 (4545)**	**<.0001**	**$3214 (6562)**	**$1353 (4467)**	**<.0001**
Adjusted PPPM, mean (SD)						
Hospitalization	$602 (528)	$415 (361)	<.0001	$1569 (1610)	$424 (483)	<.0001
Ambulatory surgical center visits	$28 (11)	$34 (13)	<.0001	$22 (19)	$31 (26)	<.0001
Emergency department visits	$95 (48)	$44 (22)	<.0001	$89 (95)	$46 (50)	<.0001
Urgent care visits	$3 (1)	$2 (1)	<.0001	$2 (0)	$2 (0)	<.0001
Hospital outpatient visits	$706 (782)	$424 (498)	<.0001	$699 (896)	$371 (499)	<.0001
Physician office visits	$373 (219)	$240 (138)	<.0001	$341 (312)	$200 (185)	<.0001
Home visits	$61 (115)	$35 (77)	<.0001	$116 (233)	$32 (96)	<.0001
Other outpatient care	$614 (1140)	$123 (248)	<.0001	$606 (1028)	$163 (460)	<.0001
Pharmacy	$501 (435)	$298 (241)	<.0001	$495 (580)	$278 (361)	<.0001
Total health care costs	**$2782 (2364)**	**$1601 (1372)**	**<.0001**	**$3725 (4068)**	**$1537 (1883)**	<.0001

Data for the prevalent BP cohort were similar to those of the incident BP cohort. Data for the prevalent BP cohort and the steroid-treated BP cohort (exploratory analysis) are reported in the Supplementary Material, available via Mendeley at https://doi.org/10.17632/994227m9zy.1.
BP, Bullous pemphigoid; *PPPM*, per-patient-per month.

a substantial burden of morbidity and related HCRU and costs. To the best of our knowledge, this is the first real-world estimate of HCRU and costs among patients with BP with comparisons against a matched non-BP cohort.

Patients with incident BP had higher mean CCI scores during follow-up than the matched non-BP cohort. Hypertension was the most common comorbidity in both cohorts, although it was more prevalent in the incident BP cohort. A similar trend was observed for diabetes, skin ulcers, chronic pulmonary disease, dyslipidemia, sleep disorders, and congestive heart failure. Approximately half of all patients with BP had diabetes (one-third had diabetes with complications), and more than one-quarter had congestive heart failure, which presents additional risks with concomitant corticosteroid use. Despite this, >90% of patients with BP received a corticosteroid during follow-up. While this corticosteroid use is consistent with findings from a previous US study,[11] these data underscore the need for targeted BP therapy to minimize corticosteroid use. Opioid use was also higher in the BP cohort than the non-BP matched cohort, suggesting that patients with BP experience severe pain.

Both unadjusted and adjusted annualized all-cause health care costs were higher in the incident BP cohort than the matched non-BP cohort during both the baseline and follow-up periods, reflecting the higher HCRU observed in the incident BP cohort before and after BP diagnosis. The higher HCRU and costs may in part be due to the slightly higher comorbidity burden (by CCI) in patients with BP at baseline, while postdiagnosis, these patients were also hospitalized more frequently than patients without BP, possibly due to treatment-associated comorbidities and outcomes; hospitalization was the largest cost component for patients with BP during follow-up, accounting for 42% of the total costs. Interestingly, average monthly BP-related costs were lower in the steroid-treated BP cohort than the incident BP cohort, primarily due to lower BP-related hospitalization costs.

The difference in health care costs between patients with BP and matched patients without BP during follow-up was greater when using annualized

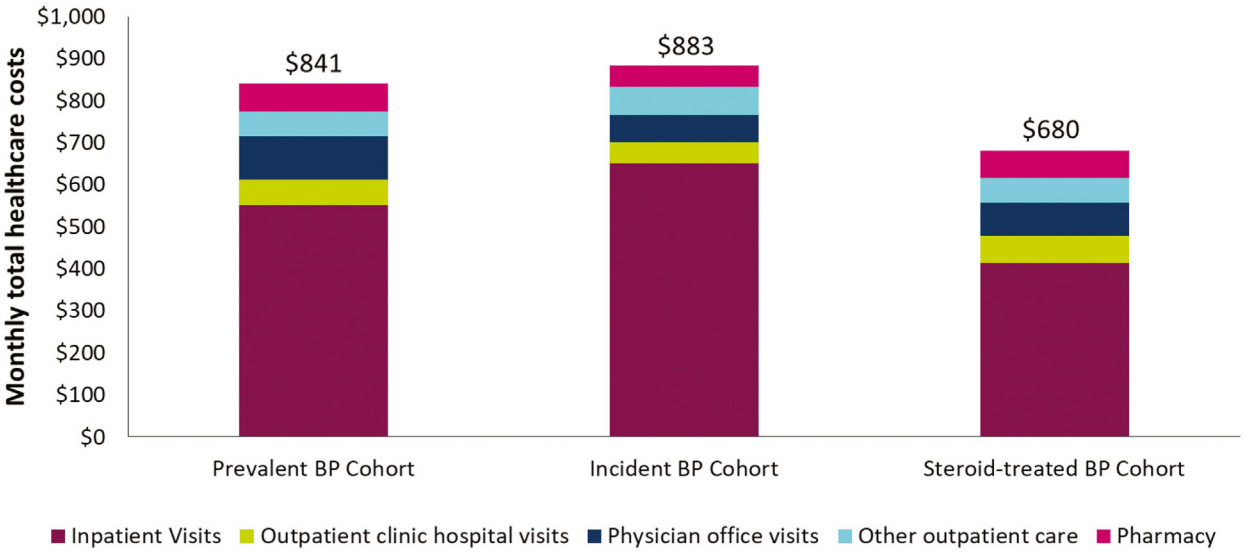

Fig 2. Bullous pemphigoid. Average monthly total bullous pemphigoid–related health care costs in the follow-up period. Other outpatient care includes ambulatory surgical center visits, emergency department visits, urgent care visits, home visits, and other outpatient and ancillary care. Monthly total health care costs, $. *BP*, Bullous pemphigoid.

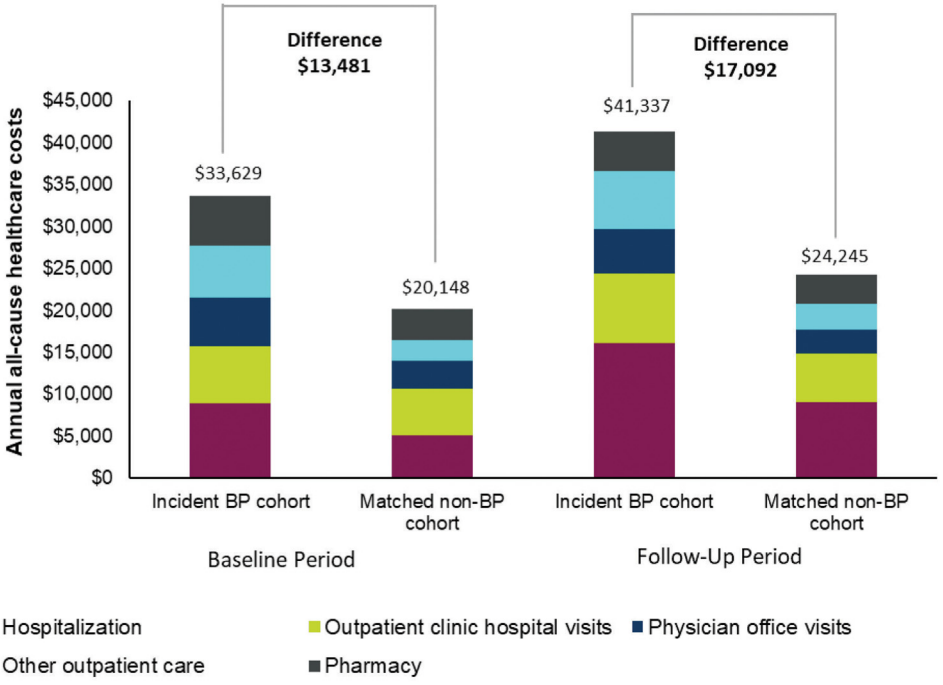

Fig 3. Bullous pemphigoid. All-cause health care costs during 12-month baseline and follow-up periods in the incident bullous pemphigoid and matched nonbullous pemphigoid cohorts. $P < .0001$ for both comparisons. Other outpatient care includes ambulatory surgical center visits, emergency department visits, urgent care visits, home visits, and other outpatient and ancillary care. *BP*, Bullous pemphigoid.

data from PPPM calculations ($22,332) than when using data for the subgroup of patients with 12 months' follow-up ($17,092). Patients may have had higher HCRU at, and shortly after, diagnosis that decreased later in the year, contributing to the larger difference between BP and matched non-BP cohorts

in the PPPM data set. Additionally, as patients with 12 months' follow-up data had to remain alive for ≥12 months postindex, the larger difference in the PPPM data set may have resulted from higher mortality and, therefore, end-of-life costs among patients with BP vs patients without BP. However, it was not possible to assess these proposed explanations empirically.

The strength of this analysis is that it was based on real-world claims data and includes a large number of patients. The limitations are common to all retrospective claims analyses, including that diagnoses were based on billing codes, which are subject to diagnostic or coding inaccuracies. However, the requirement for 2 (outpatient) diagnoses of BP ≥ 30 days apart, plus receipt of a BP-related medication, should have substantially limited inclusion of patients without BP in the study sample. As BP is a relapsing-remitting disease, the date of disease onset may not be accurate. No information on reason for health plan disenrollment (eg, death) was available in the database, meaning that the impact of mortality during the follow-up period could not be assessed directly. It was also not possible to identify the reason for receipt of a medication, and so some BP-related therapies (eg, corticosteroids) may have been prescribed for another indication. Further inaccuracies could have been incorporated due to HCRU data being based on the number of claims, which may not reflect the true number of encounters, and MarketScan data being based on employment-related insurance claims, so some information may be missing from before/after employment for non-retired patients.

CONCLUSION

BP is associated with a considerable burden of morbidity and HCRU, with hospitalization being the primary driver of postdiagnosis costs. More effective and targeted treatments are needed for patients with BP to improve quality of life, while minimizing exposure to systemic corticosteroids.

DATA SHARING STATEMENT

Data underlying the findings described in this manuscript may be obtained in accordance with AstraZeneca's data sharing policy described at https://astrazenecagrouptrials.pharmacm.com/ST/Submission/Disclosure.

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Conflicts of interest

Dr Stirnadel-Farrant, Dr Xu, Dr Kwiatek, Dr Jain, and Dr Datto are full-time employees of, and own stock in, AstraZeneca. Author Meyers, Dr Candrilli, and Dr Mines are employees of RTI Health Solutions, which received funding from AstraZeneca for the conduct of this study.

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