



Clinical and Economic Benefit of Achieving Disease Control in Psoriatic Arthritis and Ankylosing Spondylitis: A Retrospective Analysis from the OM1 Registry

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ABSTRACT

Background: There is limited evidence on the clinical and economic benefit of achieving disease control in psoriatic arthritis (PsA) and ankylosing spondylitis (AS), thus we aimed to assess the impact of disease control on healthcare resource use (HCRU) and direct medical costs among US patients with PsA or AS over 1 year.

Methods: Data were derived from the US OM1 PsA/AS registries (PsA: 1/2013–12/2020; AS: 01/2013–4/2021) and the Optum Insight Clinformatics® Data Mart to identify adult patients with PsA or AS. Two cohorts were created: with disease control and without disease control. Disease control was defined as modified Disease Activity Index for Psoriatic Arthritis (DAPSA28) ≤ 4 for PsA and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) < 4

for AS. Outcomes were all-cause inpatient, outpatient, and emergency department (ED) visits and associated costs over a 1-year follow-up period. Mean costs per person per year (PPPY) were assessed descriptively and adjusted odds ratios (aOR) with 95% confidence intervals (CI) were estimated for the likelihood of HCRU by logistic regression.

Results: The study included 1235 PsA (with disease control: $N = 217$; without: $N = 1018$) and 581 AS patients (with disease control: $N = 342$; without: $N = 239$). Patients without disease control were more likely to have an inpatient (aOR [95% CI]; PsA: 3.0 [0.9, 10.1]; AS: 7.7 [2.3, 25.1]) or ED (PsA: 1.6 [0.6, 4.2]; AS: 3.5 [1.5, 8.3]) visit than those with disease control. Those without disease control, vs. those with disease control, had greater PPPY costs associated with inpatient (PsA: \$1550 vs. \$443), outpatient (PsA: \$1789 vs. \$1327; AS: \$2498 vs. \$2023), and ED (PsA: \$114 vs. \$57; AS: \$316 vs. \$50) visits.

Conclusions: Findings from this study demonstrate lower disease activity among patients with PsA and AS is associated with less HCRU and lower costs over the following year.

Keywords: Administrative claims; Ankylosing spondylitis; Disease control; Disease registry; Economic burden; Healthcare resource utilization; Psoriatic arthritis

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Key Summary Points

Why carry out this study?

The clinical and economic benefit of achieving disease control in psoriatic arthritis (PsA) and ankylosing spondylitis (AS) on healthcare resource use (HCRU) and medical costs has not been well characterized in a US population.

This study sought to characterize HCRU among patients achieving disease control as compared to those who did not in a cross-sectional study, as well as to estimate the impact of disease control status on direct medical costs over the course of the next year.

What was learned from this study?

Patients with PsA and with AS with lower levels of disease activity had fewer inpatient, emergency department, and outpatient visits and lower direct medical costs than those who had higher levels of disease activity.

These findings demonstrate that achieving disease control in PsA and AS may be associated with beneficial clinical and economic outcomes.

INTRODUCTION

Psoriatic arthritis (PsA) and ankylosing spondylitis (AS) are progressive spondyloarthritis diseases characterized by inflammatory pain. Patients with PsA tend to experience peripheral inflammatory arthritis in the hands and feet, as well as psoriatic skin lesions. Patients with AS have more axial inflammatory arthritis, typically localized to the spine [1–3]. For most chronic inflammatory diseases, achieving a target of stable or low disease activity or remission is the primary treatment target [4, 5]. Unfortunately, less than a third of patients with PsA and

AS achieve remission after six months of treatment [6]. Most patients who do achieve remission relapse within a year. Moreover, in patients who relapse and restart therapy, nearly half do not again achieve remission and some do not respond to therapy at all [6–9]. Patients with poor disease control report significantly reduced health-related quality of life (HRQoL) [10, 11]. Aside from improvement in HRQoL, achieving disease control may also result in reduced healthcare resource use (HCRU), such as a reduced number of healthcare visits or medication use. In turn, patients may also have reduced disease-related direct medical costs, which has also been shown to improve patient-reported HRQoL [12]. As such, HRQoL improvements are not only beneficial to the patient, but also the healthcare system and public or private payers. Indeed, patients with AS in Central and Eastern Europe who achieved low disease activity status after 12 months had up to an 83% reduction in the number and length of hospitalizations, as well as a reduced number of healthcare provider visits [13]. Therefore, it is critical to understand the clinical and economic benefit of disease control in patients with PsA and AS, which has not been characterized in a US population. The objective of this study was to assess the impact of achieving disease control on HCRU and associated costs over 1 year among US patients with PsA or AS.

METHODS

Study Design and Participants

The data source for this study was the OM1 PsA and AS Registry, a subset of the OM1 Real-World Data Cloud (OM1, Inc, Boston, MA, USA), a large, linked clinical and administrative dataset derived from medical and pharmacy claims and electronic medical record data. This study utilized data collected on patients (age ≥ 18 years) between 2013 and 2021 (PsA: 1/2013–12/2020; AS: 01/2013–4/2021) with an International Classification of Disease, 9th Revision (ICD-9) or 10th Revision (ICD-10), codes for PsA (696.0 and L40.5x, respectively) or AS (720.0 and

M45.x, respectively). This study was conducted in accordance with the ethical principles that have their origin in the current Declaration of Helsinki and was consistent with International Conference on Harmonisation Good Clinical Practice, Good Epidemiology Practices, and applicable regulatory requirements. This study utilized de-identified data from an administrative claims database, thus no ethics committee approval was required.

Patients with PsA or AS meeting the following criteria were included in the study: (1) continuous enrollment in the registry for both baseline and follow-up periods (i.e., pre- and post-index periods) and (2) complete data for all components of the disease activity measures. In patients with PsA, disease activity was measured using the modified Disease Activity Index for PsA with 28 joint counts (DAPSA28; range, 1–154) with a score of ≤ 4 indicating remission [14]. The DAPSA28 includes 28 tender joint count (TJC), 28 swollen joint count (SJC), Patient's Global Assessment of Disease Activity (PtGA) by visual analog scale (VAS, range = 0–10), pain by VAS (range = 0–10), and C-reactive protein (CRP) levels. The following algorithm was used to estimate DAPSA28 [14]:

$$(28 \text{ TJC} \times 1.6) + (28 \text{ SJC} \times 1.6) + \text{PtGA VAS} \\ + \text{Pain VAS} + \text{mg/dL CRP}$$

Eligible patients had ≥ 1 recorded score and/or level for each item. For patients with AS, disease control was defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score < 4 ; a score ≥ 4 is a recognized indication of active disease in clinical practice [15]. The BASDAI questionnaire incorporates patient-reported severity of back pain, fatigue, peripheral joint pain, swelling, localized tenderness, and duration and severity of morning stiffness; scores are assessed by a numerical rating scale (0–10) or by VAS (1–10 cm) [15]. For both cohorts, the index date was a random date selected on or after patients recorded ≥ 2 DAPSA28 or BASDAI scores indicating disease control; patients without disease control (e.g., DAPSA28 > 4 or BASDAI ≥ 4) were randomly assigned an index date on or after the date that a DAPSA28 or

BASDAI measurement indicated poor disease control.

Outcomes

All-cause HCRU, including inpatient, outpatient, and emergency department (ED) visits over 1-year post-index, was analyzed. The likelihood of having inpatient or ED visits during the follow-up period between patients not achieving disease control relative to those who did achieve disease control was also assessed. Mean annual cost data for inpatient, outpatient, and ED visits were obtained from adjudicated administrative claims data using the Optum's de-identified Clinformatics® Data Mart Database (2007–2019); this dataset is derived from a database of administrative health claims for members of large commercial and Medicare Advantage health plans and was used to estimate costs since the OM1 registry only contains charge data (i.e., unadjudicated claims). Mean cost per single event for each HCRU type (i.e., inpatient, outpatient, or ED visit) was derived from the Optum database and used in the regression model to calculate per patient per year (PPPY) costs. For PsA, the mean costs per inpatient, outpatient, and ED visit were \$22,140, \$176, and \$1140, respectively; for AS, mean costs were \$22,430, \$416, and \$1262. PPPY HCRU costs were derived by multiplying the average cost per patient per inpatient/ED visit (from Optum) by the respective number of inpatient/ED visits in the 1-year follow-up period (from OM1). Medication costs were not incorporated into the HCRU costs. All data were stratified by achievement of disease control (i.e., yes or no).

Statistical Analysis of Data

All-cause HCRU are reported as the mean and standard deviation (SD) of number of inpatient, outpatient, or ED visits per 100 patients. Adjusted odds ratios (aOR) and 95% confidence intervals (CI) were calculated for likelihood of inpatient or ED visit using a logistic regression model adjusted for age, sex, region, race, smoking status, body mass index, Charlson Comorbidity Index (CCI), insurance type, baseline medication use (i.e., biologic/conventional

synthetic disease-modifying antirheumatic drugs [b/csDMARD] for PsA and b/csDMARD, nonsteroidal anti-inflammatory drugs [NSAID], and opioids for AS), baseline HCRU, index year, and months from first diagnosis to index date. aORs were not calculated for outpatient visits for people with PsA or AS because nearly all patients had at least one outpatient visit in the follow-up period, therefore logistic regression analyses were infeasible.

RESULTS

Patient Demographics

In total, there were 1235 patients with PsA and 581 patients with AS who met the inclusion criteria and were included in the study (Fig. 1). Among patients in the PsA cohort, patients without disease control were significantly older

(mean \pm SD; 58.6 ± 12.9 vs. 56.4 ± 13.4 , $p = 0.03$), more often female (65.9 vs. 44.7%, $p < 0.01$), had higher mean CCI scores (0.18 ± 0.64 vs. 0.07 ± 0.32 , $p = 0.01$), and were less likely to use bDMARDs at baseline (41.9 vs. 50.7%, $p = 0.02$) compared to patients with disease control (Table 1). Among patients in the AS cohort, patients without disease control were significantly younger than those with disease control (48.8 ± 14.7 vs. 51.2 ± 15.8 , $p = 0.03$). Significantly more patients without disease control were female (57.7 vs. 29.2%, $p < 0.01$) and reported significantly more ($p \leq 0.05$) baseline csDMARD, NSAID, and opioid use.

HCRU at Baseline and 1-Year Follow-Up

Among patients with PsA, the mean number of inpatient and ED visits per 100 patients at baseline was similar between groups (mean \pm SD; inpatient: 1 ± 14 vs. 1 ± 17 ; ED: 2 ± 21 vs.

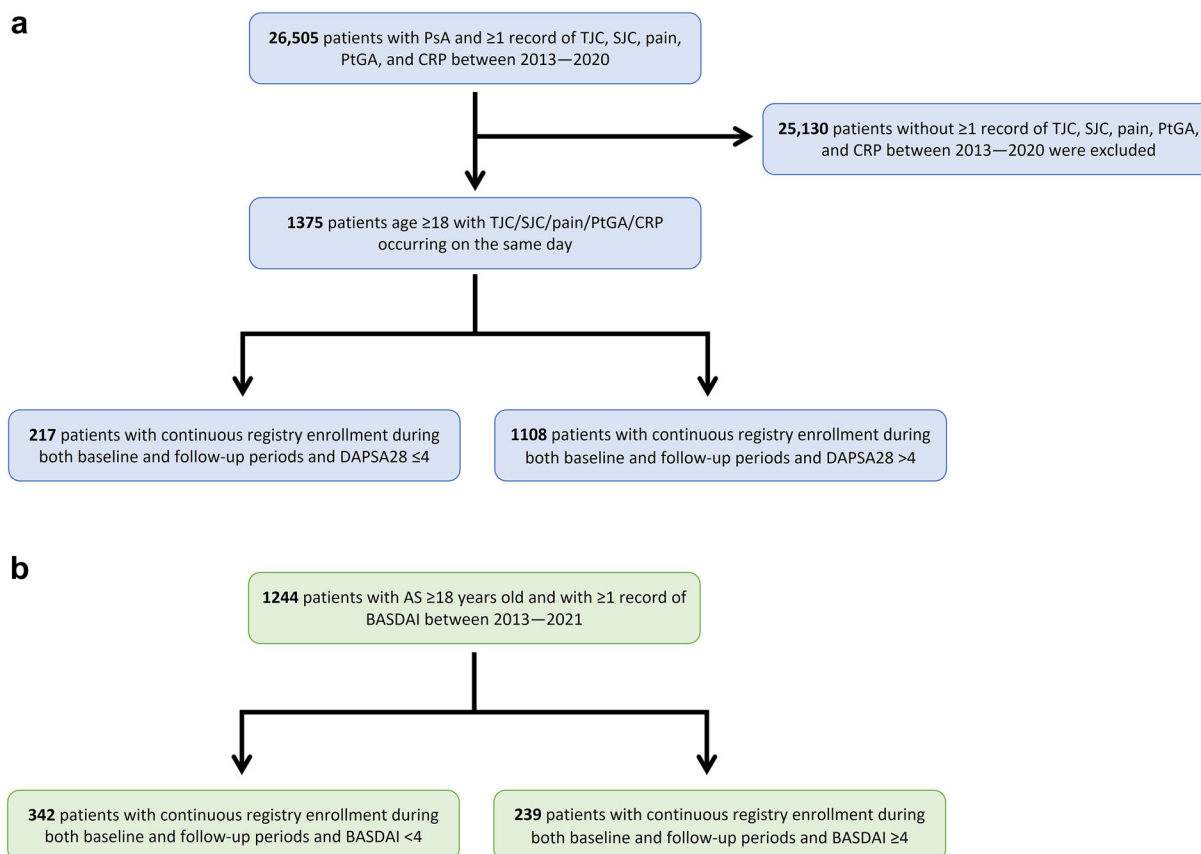


Fig. 1 Patient selection schematic

Table 1 Baseline patient demographic and clinical characteristics

Characteristic	PsA ^a			AS ^a		
	With disease control <i>N</i> = 217	Without disease control <i>N</i> = 1018	<i>p</i> value	With disease control <i>N</i> = 342	Without disease control <i>N</i> = 239	<i>p</i> value
Age [years], mean ± SD	56.4 ± 13.4	58.6 ± 12.9	0.03	51.2 ± 15.8	48.8 ± 14.7	0.03
Female, <i>n</i> (%)	97 (44.7)	671 (65.9)	< 0.01	100 (29.2)	138 (57.7)	< 0.01
Caucasian, <i>n</i> (%)	188 (86.6)	885 (86.9)	0.01	235 (68.7)	176 (73.6)	0.09
Insurance type, <i>n</i> (%)			< 0.01			< 0.01
Other/unknown	119 (54.8)	418 (41.1)		199 (58.2)	117 (49.0)	
Commercial	73 (33.6)	345 (33.9)		141 (41.2)	109 (45.6)	
Medicare/ Medicaid ^b	25 (11.5)	255 (25.1)		2 (0.6)	13 (5.4)	
US census region, <i>n</i> (%)			NC ^c			0.16
South	208 (95.9)	976 (95.9)		243 (71.1)	180 (75.3)	
Midwest	7 (3.2)	34 (3.3)		49 (14.3)	25 (10.5)	
West	1 (0.5)	4 (0.4)		36 (10.5)	18 (7.5)	
Northeast	1 (0.5)	4 (0.4)		14 (4.1)	16 (6.7)	
CCI, mean ± SD	0.07 ± 0.32	0.18 ± 0.64	0.04	0.23 ± 0.65	0.28 ± 0.76	0.33
Obesity, <i>n</i> (%)	41 (18.9)	301 (29.6)	< 0.01	143 (41.8)	115 (48.1)	0.16
Tobacco use, <i>n</i> (%)	41 (19.8)	338 (33.2)	< 0.01	310 (90.6)	204 (85.4)	0.07
Treatment use, <i>n</i> (%)						
csDMARD	62 (28.6)	306 (30.1)	0.72	55 (16.1)	58 (24.3)	0.02
bDMARD	110 (50.7)	427 (41.9)	0.02	238 (69.6)	147 (61.5)	0.05
NSAID ^d				136 (39.8)	132 (55.2)	< 0.01

Table 1 continued

Characteristic	PsA ^a		<i>p</i> value	AS ^a		<i>p</i> value
	With disease control $N = 217$	Without disease control $N = 1018$		With disease control $N = 342$	Without disease control $N = 239$	
Opioid ^d				67 (19.6)	76 (31.8)	< 0.01

AS ankylosing spondylitis, *bDMARD* biologic disease-modifying antirheumatic drug, *CCI* Charlson Comorbidity Index, *csDMARD* conventional synthetic disease-modifying antirheumatic drug, *NC* not calculable, *NSAID* nonsteroidal anti-inflammatory drugs, *PsA* psoriatic arthritis, *SD* standard deviation

^aFor patients with PsA, disease control was defined as DAPSA28 ≤ 4 ; for patients with AS, disease control was defined as BASDAI < 4. The baseline background period was a minimum of 3 months for patients with PsA, and 12 months for patients with AS, prior to the index date

^bFor patients with PsA, those insured by Medicare or Medicaid are grouped together. No patients with AS included in the analysis were insured by Medicare, thus all patients were Medicaid insured

^cDue to limited sample sizes (< 5) among some census regions, a *p* value could not be calculated

^dData not captured in patients with PsA

2 ± 18 ; Fig. 2a); patients without disease control had significantly more outpatient visits per 100 patients than those with disease control (217 ± 267 vs. 153 ± 175 , $p < 0.01$). At the 1-year follow-up, patients without disease control had significantly more inpatient visits (7 ± 34 vs. 2 ± 13 , $p < 0.01$) and outpatient visits (1015 ± 944 vs. 753 ± 509 , $p < 0.01$) and numerically higher ED visits per 100 patients (10 ± 71 vs. 5 ± 35 , $p = 0.14$). While PsA patients without disease control were more likely to have inpatient (aOR [95%CI]: 3.0 [0.9, 10.1]) or ED visits (1.6 [0.6, 4.2]) in adjusted analyses, these results were not statistically significant (Fig. 3). At baseline, patients with AS without disease control reported similar inpatient visits per 100 patients (5 ± 28 vs. 6 ± 29 ; Fig. 2b), statistically higher outpatient visits (802 ± 817 vs. 600 ± 679 , $p < 0.01$), and numerically higher ED visits per 100 patients (32 ± 218 vs. 11 ± 43) compared with patients with disease control. At the 1-year follow-up, AS patients not achieving disease control had significantly higher inpatient visits (12 ± 52 vs. 4 ± 27 , $p = 0.03$) and ED visits (25 ± 114 vs. 4 ± 27 , $p = 0.01$) and numerically higher outpatient visits (600 ± 840 vs. 486 ± 570 , $p = 0.07$) per 100 patients than patients with disease control. In adjusted analyses, patients not achieving disease control were significantly more likely to have inpatient (7.7 [2.3, 25.1];

$p < 0.001$) or ED visits (3.5 [1.5, 8.3]; $p < 0.01$; Fig. 3).

Mean PPPY at Baseline and 1-Year Follow-up

At baseline, patients with PsA had the same mean [range] estimated inpatient and ED medical costs PPPY (inpatient costs: \$221 [\$0–\$3053]; ED costs: \$23 [\$0–\$853]; Fig. 4a) regardless of disease control status; patients without disease control had numerically higher outpatient costs (\$382 [\$0–\$52,029] vs. \$270 [\$0–\$36,684]) than patients with disease control. However, after 1 year, estimated mean medical costs PPPY for patients without disease control were higher than those reported for patients with disease control (inpatient costs: \$1550 [\$0–\$21,370] vs. \$443 [\$0–\$6106]; ED costs: \$114 [\$0–\$4264] vs. \$57 [\$0–\$2132]; outpatient costs: \$1789 [\$0–\$243,360] vs. \$1327 [\$0–\$180,542]). At baseline, patients with AS without disease control had numerically lower inpatient costs (\$1121 vs. \$1346) and higher estimated outpatient (\$3339 vs. \$2498) and ED costs (\$404 vs. \$139) PPPY as compared to patients with disease control (Fig. 4b). At the 1-year follow-up, mean inpatient (\$2692 [\$0–\$32,381] vs. \$897 [\$0–\$10,794]), outpatient (\$2498 [\$0–\$146,579] vs. \$2023 [\$0–\$118,729]) and ED costs (\$316 [\$0–\$4929] vs. \$50 [\$0–\$789]) were higher for AS patients without

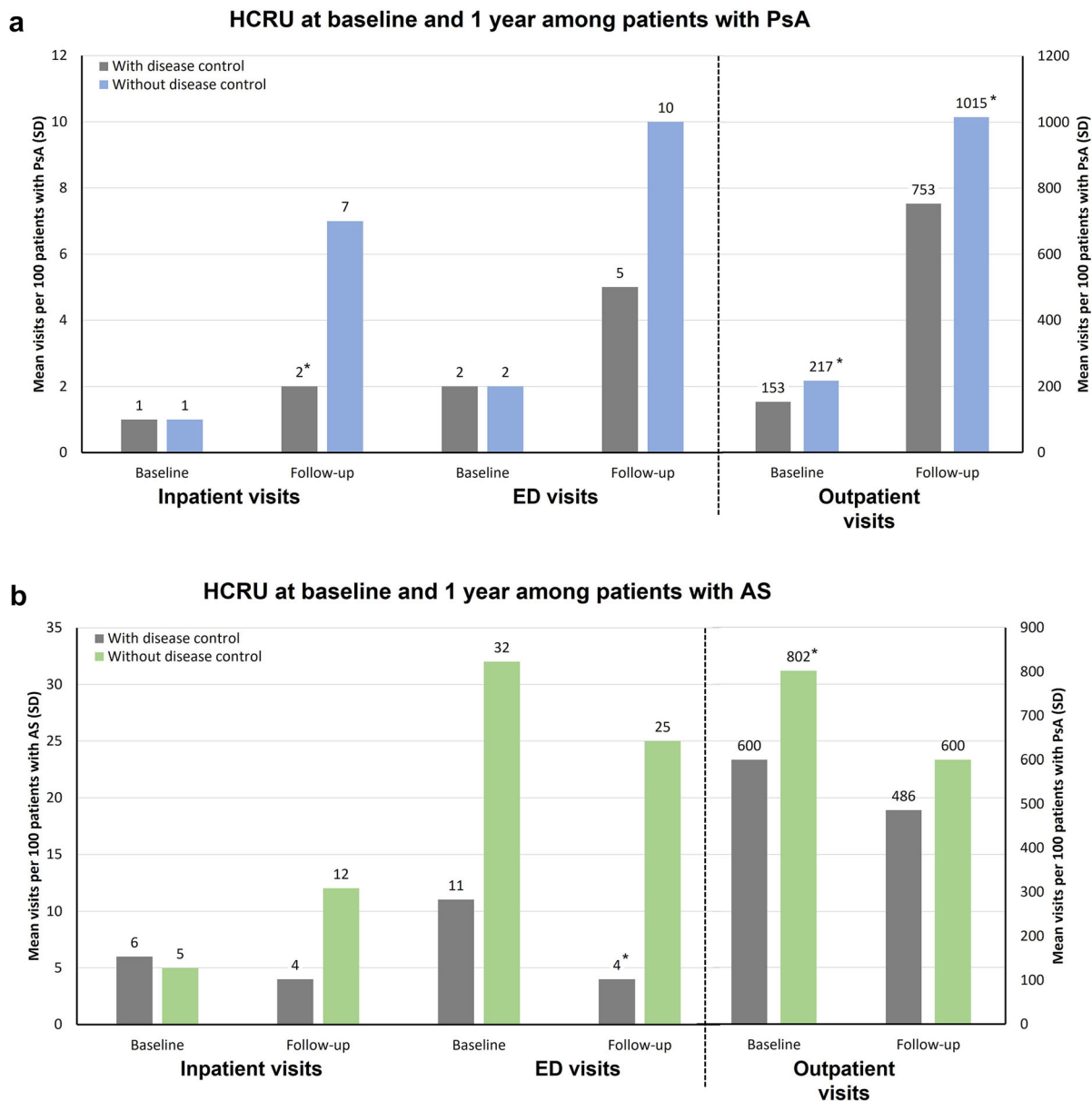


Fig. 2 Mean visits per 100 patients among patients with PsA or AS at baseline and 1 year. *AS* ankylosing spondylitis, *HCRU* healthcare resource utilization, *PsA*

psoriatic arthritis, *SD* standard deviation. * $p < 0.01$ between patients achieving disease control versus those not achieving disease control

disease control versus those with disease control.

DISCUSSION

These data demonstrate that patients with PsA and AS with lower disease activity also had

lower HCRU. Compared with patients without disease control, those with disease control had fewer inpatient and ED visits and lower associated medical costs in the following year. While this study reports findings for PsA and AS, similar findings have been reported in other studies on overall PsA- or AS-related costs [16, 17]. A key takeaway from this study is that, during the

year after achieving disease control, patients had consistently lower medical costs, compared to those who did not achieve disease control. Indeed, a study in patients with AS in Europe demonstrated that patients who responded to treatment had fewer inpatient visits and took fewer sick leave days as compared to those who did not respond to treatment, further substantiating the benefit of achieving disease control [13]. Interestingly, this study also showed that a majority of the patients not achieving disease control were female, which has been demonstrated in other studies of patients with PsA [18–21].

Multiple studies in other rheumatic diseases, such as rheumatoid arthritis, have demonstrated that achieving remission has a significant impact on HCRU and medical costs for the patient, as well as a reduced burden on the healthcare system [22–25]. Likewise, remission is often accompanied by improved physical functioning, and therefore work abilities; thus, disease control also has a societal impact [25]. However, studies have shown that, despite

Fig. 4 Estimated mean costs per person per year at baseline and 1-year follow-up. Cost per single event (i.e., inpatient, outpatient, and ED visit) derived from the Optum database was used to inform the regression model. For PsA, mean costs were \$22,140, \$176, and \$1140, respectively, and for AS mean costs were \$22,430, \$416, and \$1262, per inpatient, outpatient, and ED visit, respectively. *AS* ankylosing spondylitis, *ED* emergency department, *PPPY* per patient per year, *PsA* psoriatic arthritis, *USD* United States dollar. * $p < 0.01$ between patients achieving disease control versus those not achieving disease control

achieving stringent disease control measures, many patients still report residual disease symptoms [26–28]. It is important that providers take a more patient-centered approach, not relying solely on measures of disease activity, but also incorporating patient-reported outcomes, such as pain, fatigue, and functional impairment, as these are outcomes that are important to patients. As such, personalized treatment plans and shared decision making is not only beneficial to the patient and their

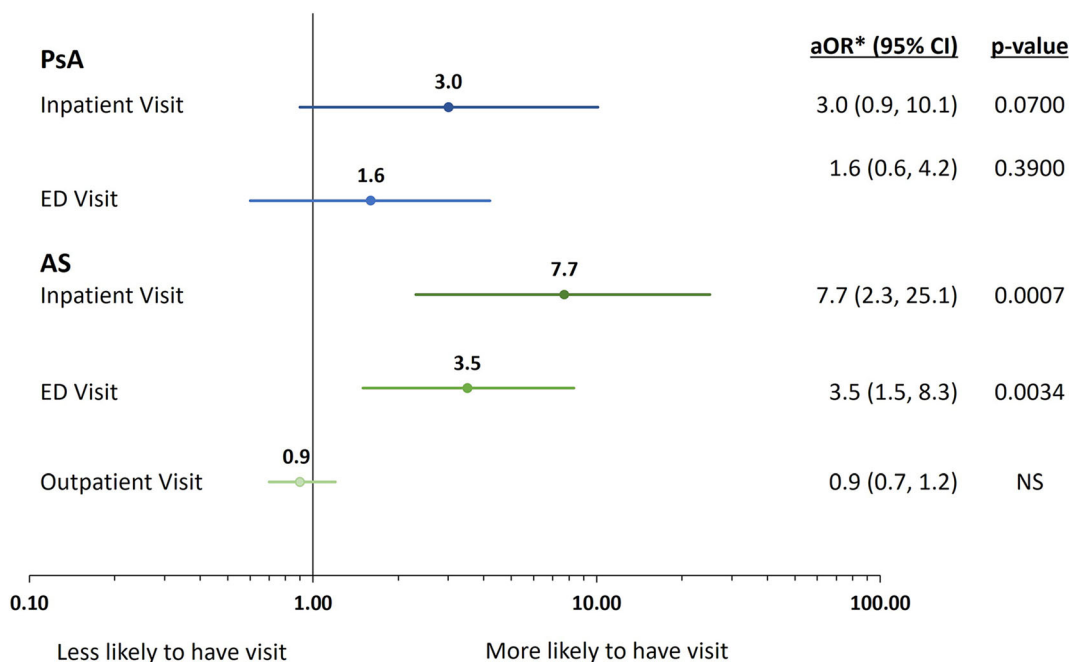
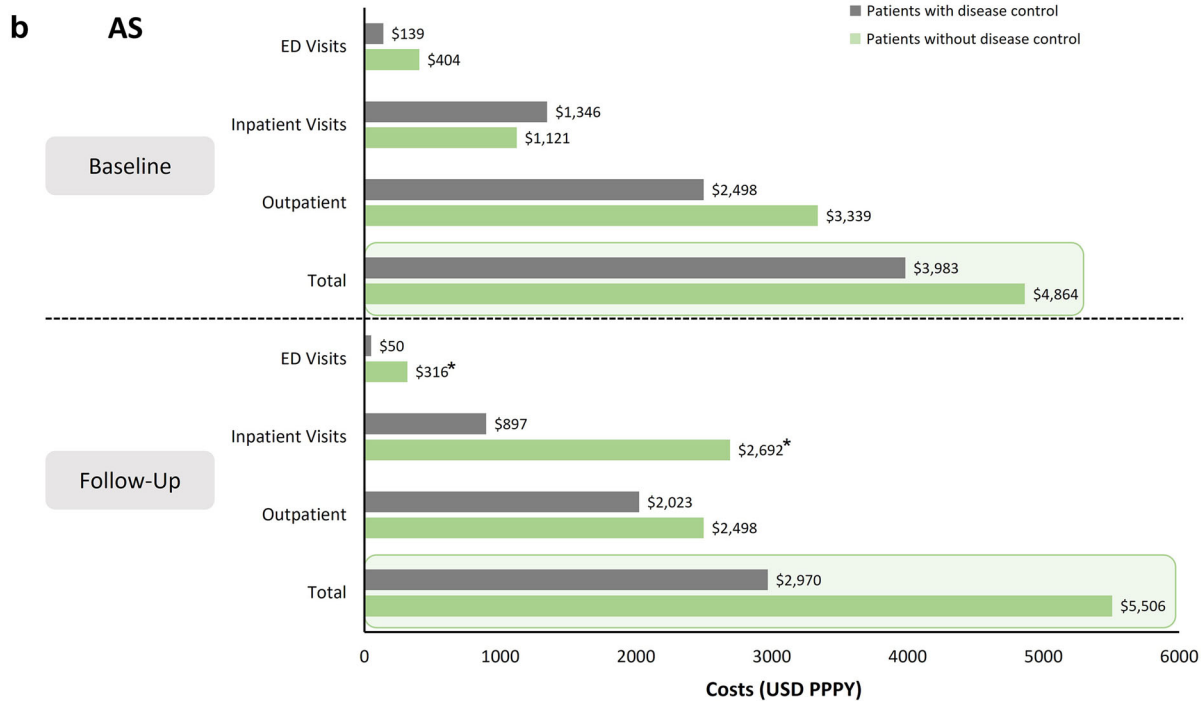
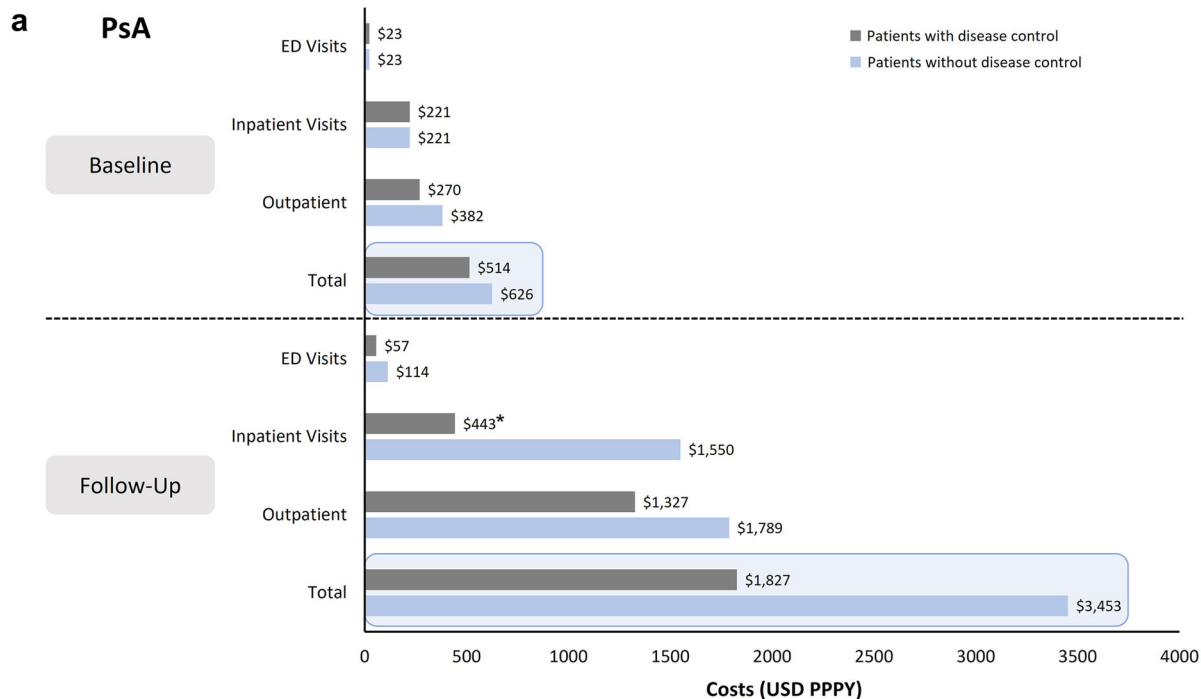


Fig. 3 Likelihood of inpatient or ED visits in patients without disease control relative to patients with disease control. *aORs for patients not achieving disease control

relative to those achieving disease control. *aOR* adjusted odds ratio, *AS* ankylosing spondylitis, *CI* confidence interval, *PsA* psoriatic arthritis



physician, but also to the health system and payers [29]. Indeed, findings from the FORWARD observational databank showed that increasing functional disability, as measured by the Health Assessment Questionnaire Disability Index (HAQ-DI), was significantly associated with greater HCRU and medical costs [30].

A strength of this retrospective, cross-sectional observational study is that it utilized a large dataset with detailed information on demographics, clinical and patient-reported outcomes, treatment history, and history of comorbidities. With the OM1 PsA and AS databases, which has more detail available than traditional claims databases, disease control could be defined with clinical data, albeit not with typical psoriatic disease measures. Limitations are that, due to the cross-sectional study design, data were not controlled for all potential confounders and temporal and/or causal links cannot be inferred. Thus, these data are only generalizable to those patients who have insurance within the dataset and do not represent the entirety of the United States population with PsA or AS. Likewise, patient selection criteria (i.e., requirement for complete data including CRP) and the dichotomization by “ever achieved control” vs. “never achieved control” during this study may introduce bias into the study findings as it may increase the likelihood of poorer outcomes in those without disease control. As such, this study randomly selected the date among patients with ≥ 2 recorded disease activity measures who eventually achieved low disease activity as defined in this study. For patients with AS, BASDAI (a patient-reported outcome) was used to assess disease control, whereas a modified DAPSA28 (a composite outcome) was used in patients with PsA. Assessments such as minimal disease activity (PsA) or Ankylosing Spondylitis Disease Activity Score (AS) would be the most ideal measures, however the data source was limited in its disease control metrics, thus DAPSA28 and BASDAI were leveraged. Both measures are routinely used to assess disease activity, but it is important to state that they are not equivalent. Moreover, this study utilized the modified DAPSA28, which incorporates 28 tender joint counts and 28 swollen joint counts, instead of

the full DAPSA, which incorporates 68 tender joint counts and 66 swollen joint counts. As such, the rates of remission may be overestimated in this population. However, studies have shown good correlation between the two measures and highlight that DAPSA28 is a sufficient measure when full DAPSA assessments are not available [14]. OM1 is an open-claims database, thus complete capture of HCRU cannot be guaranteed and the observed HCRU may be underestimated in this study. Likewise, indirect methods of linking costs from a different database to the OM1 resource use may differ from the actual costs incurred.

Conclusions

The findings from this study suggest that achievement of disease control in patients with PsA or AS was associated with fewer inpatient and outpatient visits and lower direct medical costs than those who did not achieve disease control. Highlighting these clinical and economic benefits of achieving disease control in PsA and AS may be of significant benefit in improving patient outcomes, including non-pharmacy healthcare costs and hospitalizations.

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Compliance with Ethics Guidelines This study was conducted in accordance with the ethical principles that have their origin in the current Declaration of Helsinki and was consistent with International Conference on Harmonisation Good Clinical Practice, Good Epidemiology Practices, and applicable regulatory requirements. This study utilized de-identified data from an administrative claims

database, thus no ethics committee approval was required.

Data Availability The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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