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ORIGINAL RESEARCH

Treatment Patterns and Outcomes of Acthar Gel in Ankylosing Spondylitis and Psoriatic Arthritis: A Physician-Reported Chart Review

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Purpose: To describe the characteristics of patients with ankylosing spondylitis (AS) or psoriatic arthritis (PsA) treated with Acthar Gel, medication utilization, and physicians' assessments of the effects of Acthar Gel on patients' health status.

Patients and Methods: A prospectively designed, cross-sectional, medical chart review study with a predefined protocol and analysis plan was conducted in November 2024, with data abstracted from patient records between April 2022 and November 2024. Eligible patients were aged ≥18 years, had AS or PsA, and had received Acthar Gel within ≤24 months.

Results: On average, patients with AS were 44 years, and those with PsA were 51 years; patients were primarily Caucasian/non-Hispanic. Most patients with AS were male (67%, 42/63), whereas PsA had a similar gender distribution (49% [38/77] each). Common comorbidities included arthritis/osteoarthritis, chronic joint disease, and hypertension. Before receiving Acthar Gel, physicians reported 41% (26/63) of patients with AS and 44% (34/77) with PsA had fair-to-poor health status. Frequent symptoms in AS were back pain, lower back/hip stiffness, and fatigue, and in PsA were joint swelling and pain, reduced range of motion, and fatigue. Based on physician assessment, 95% (60/63) with AS and 88% (68/77) with PsA had improved health after Acthar Gel treatment. Improvements included reduction in overall symptoms (AS: 70% [42/60]; PsA: 63% [43/68]), decreased pain (AS: 68% [41/60]; PsA: 62% [42/68]), improved physical function (AS: 53% [32/60]; PsA: 54% [37/68], improved fatigue (AS: 35% [21/60]; PsA: 32% [22/68]), and reduced corticosteroid use (AS: 30% [18/60]; PsA: 31% [21/68]).

Conclusion: Based on chart review, Acthar Gel may represent a potential treatment option for appropriate patients with AS or PsA. In this study, among patients with AS or PsA treated with Acthar Gel, physicians documented a reduction in overall symptoms, decreased pain, improved physical function, reduced corticosteroid use, improved strength, and improved fatigue using prespecified assessments.

Plain Language Summary: People living with ankylosing spondylitis (AS) or psoriatic arthritis (PsA) can still have flares or symptoms even after trying several medicines. Acthar Gel is a prescription medicine that may be used for short periods when other options are insufficient. We wanted to understand how physicians use Acthar Gel in everyday practice and how their patients were doing around that time. We asked rheumatologists to review recent charts for adults with AS or PsA who received Acthar Gel. The physicians reported whether patients' overall health was better at a set follow-up point and whether common goals, such as less pain or fatigue, better physical function or strength, and lowering steroid use, were met. Physicians reported that many patients experienced overall improvement after starting Acthar Gel, with notable improvements in pain, fatigue, physical function, and strength for some, as well as reduced steroid use for others. These observations describe what physicians observed in their routine practice after prescribing Acthar Gel to their patients. The findings suggest that physicians use Acthar Gel selectively for short-term needs, highlighting areas where future studies could provide more evidence.

Keywords: Acthar Gel, ankylosing spondylitis, outcomes, psoriatic arthritis, real-world study

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Introduction

Ankylosing spondylitis (AS) and psoriatic arthritis (PsA), while distinct conditions, share underlying inflammatory mechanisms which characterize spondyloarthropathies.[1–3] Their primary symptom presentation may differ, with AS specifically affecting the spine and sacroiliac joints, with a typical onset at <45 years of age,[3,4] while PsA often affects peripheral joints alongside skin psoriasis.[5] In the United States (US), the prevalence of AS is 0.5%–0.7%,[6,7] corresponding to an estimated 1.3–1.8 million US adult patients in 2024.[8] PsA develops in 30% of patients with psoriasis,[9] which has a 3.0% prevalence in US adults.[10] This results in an estimated PsA prevalence of 0.9%, corresponding to about 2.4 million US adults in 2024.[8] Further, the overall incidence of PsA among patients with psoriasis has been estimated to be 2.9 events per 100 patient-years.[11]

AS and PsA have a substantial impact on patients' lives.[7,12–16] AS is characterized by chronic back pain and stiffness,[17] severely limiting daily activities, work productivity, and quality of life.[12,16,17] AS can also potentially lead to spinal fusion and debilitating fatigue.[1,17–19] PsA, a chronic inflammatory disease, presents with diverse musculoskeletal and nonmusculoskeletal manifestations comprising peripheral arthritis, skin disease, axial disease, dactylitis, enthesitis, and nail disease.[7,20] These clinical manifestations in PsA can cause pain, swelling, and stiffness in various joints, similarly impacting patients' daily lives.[7,20,21] Both AS and PsA also contribute to emotional and social challenges,[12–14] including anxiety, depression, and feelings of isolation, and may affect self-esteem.[13–15,22] Furthermore, maintaining employment becomes difficult due to pain, fatigue, and reduced mobility.[7,12,21]

AS and PsA are incurable[20,23,24] and treatment focuses on symptom management, slowing disease progression, and enhancing the quality of life, typically involving the use of biologics (tumor necrosis factor inhibitors [TNFis] and interleukin-17 [IL-17] antagonists), non-biologic disease-modifying antirheumatic drugs (DMARDs), corticosteroids, and nonsteroidal anti-inflammatory drugs (NSAIDs).[20,23–27] However, achieving low disease activity or remission remains difficult for many patients, and long-term medication adherence is often challenged by secondary inefficacy.[23,25] Consequently, many individuals with AS or PsA continue to experience significant pain, disability, and diminished quality of life.[7,12–15] Current treatment options also have limitations. While corticosteroids may be used to treat mild forms of AS and PsA, systemic corticosteroid use is not recommended, as long-term use of corticosteroids can lead to unwanted side effects.[28] Similarly, the adverse events associated with anti-TNFs and the efficacy/safety of DMARDs for PsA are not fully established.[29] Therefore, addressing the multifaceted challenges faced by patients with AS or PsA necessitates the use of new personalized treatment strategies.

Acthar® Gel (repository corticotropin injection; Mallinckrodt Pharmaceuticals) is approved by the U.S. Food and Drug Administration (FDA) for treating several autoimmune and inflammatory disorders, including AS and PsA.[30] Acthar Gel, a naturally sourced complex mixture of adrenocorticotropic hormone analogs and other pituitary peptides, interacts with all five melanocortin receptors, potentially exerting therapeutic effects through the activation of multiple anti-inflammatory pathways via both glucocorticoid-dependent and independent mechanisms.[30] Acthar Gel is indicated as an adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in AS and PsA when other treatment options are not sufficient.[30]

Although Acthar Gel's safety and efficacy are established across other indications,[31] limited data exist specifically for AS and PsA, despite its FDA-approved indications. A single-site investigator-initiated open-label trial of Acthar Gel in patients with moderately to severely active PsA showed that all those who completed 12 weeks of treatment (n=8) achieved American College of Rheumatology 20 (ACR 20), a 20% improvement on a scale of 28 intervals, at Week 12. While three patients withdrew early due to possible treatment-related adverse events, no adverse events were observed in any of the patients who completed the study.[29] To fill this knowledge gap, this study described the characteristics of patients with AS or PsA treated with Acthar Gel, medication utilization patterns, and physicians' assessments of the effects of Acthar Gel on patients' health status.

Methods

Study Design

This was a prospectively designed physician survey and medical chart review study with a predefined protocol and statistical analysis plan. Further, this study was double-blinded where both the study sponsor and participating physicians were blinded to each other's identities.

The study was conducted in November 2024. Physicians abstracted data from patient records covering the period from April 1, 2022, to November 2024. For patients with AS, 45 rheumatologists reviewed 63 patient charts. For patients with PsA, 49 rheumatologists reviewed 77 patient charts. This study used preexisting fully deidentified data, with no direct involvement of human subjects or access to identifiable private information. Based on the authors' determination and in accordance with the U.S. Department of Health and Human Services (45 CFR 46.102) and FDA (21 CFR 56.102) regulations, this work does not meet the definition of human subjects research. Therefore, approval from an institutional review board or ethics committee was not required.

Data Collection

Physicians were recruited using a web-based questionnaire. Physicians who met the criteria per the instructions in the screening questionnaire provided data on their patients, who had either AS or PsA. Each eligible physician contributed data on a minimum of 2 and a maximum of 7 patients to ensure that high-patient volume physicians did not dominate the study sample. Physicians were eligible to participate in the survey if their primary specialty was in rheumatology, if they were board eligible or board-certified, if they had been in professional practice in the United States post residency or post fellowship between 2 to 45 years, if they had spent a minimum of 50% professional time in direct patient care (seeing, treating, or managing patients), if they had treated patients with rheumatologic conditions, if they had either currently or in the past 24 months treated patients who were receiving Acthar Gel for AS or PsA, and if they were willing to pull a minimum of 2 patient charts for patients treated with Acthar Gel. Data from the medical records of qualified patients were extracted by physicians or their designated staff through a secure online system.

Data collection was standardized through a protocol-driven online survey using a uniform patient summary template covering four domains: demographics, clinical measures, pre- versus post-Acthar Gel health status, and treatment outcomes. The survey was pretested for face and content validity, and physicians received detailed instructions for chart abstraction, eligibility criteria, and systematic patient selection to minimize bias. Respondents were blinded to study endpoints, and all chart data were entered into a standardized electronic template with predefined formats and definitions to ensure consistency and comparability.

Patient Sample

Adults ≥18 years of age who were diagnosed with AS or PsA, who had received treatment with Acthar Gel in the previous 24 months, and who had a completely accessible medical record were included in the study. Patients with contraindications, comprising adrenocortical hyperfunction, congestive heart failure, ocular herpes simplex, osteoporosis, peptic ulcers, primary adrenocortical insufficiency, scleroderma, systemic fungal infections, and uncontrolled hypertension, were excluded.

Study Variables

Patient demographics included age, body mass index (BMI), gender, and race. Other information, such as the patient's geographic region, highest education level completed, employment status, and insurance coverage, were also collected. Clinical characteristics included comorbidities, symptomatology before initiation of Acthar Gel, and the patient's health status before initiation of Acthar Gel. Treatment patterns included concomitant medications before initiation of Acthar Gel and dosage and duration of Acthar Gel treatment.

Treatment response was evaluated using the physician's assessment of the patient's health status, symptoms, and individual treatment outcomes after Acthar Gel initiation. A patient's overall health status was measured using the following questions with response categories being "improved" or "not improved." For patients who had completed their treatment with Acthar—"How was your patient's overall health status at the end of Acthar Gel treatment?" For patients currently undergoing treatment with Acthar —"How has your patient's overall health status changed after initiation of Acthar Gel treatment?".

A reduction in overall symptoms and achievement of treatment goals were measured using the following question. "Please select the treatment goals, if any, that have improved as a result of Acthar Gel therapy".

Data Analyses

Data received from participating physicians were validated for accuracy and completeness. Descriptive statistics were used to summarize the data. Continuous variables were summarized using mean and standard deviation, and frequency

counts and proportions were reported for categorical variables. Data were tabulated using IBM® SPSS Statistics version 23.0 (IBM Corporation, Armonk, NY, USA) for all analyses.

Results

Patient Characteristics

The average age of patients with AS was 44 years; most were male (67%, 42/63) and Caucasian/non-Hispanic (57%, 36/63) (Table 1). The average age of patients with PsA was 51 years, and they had a similar gender distribution (49% [38/77] males, 49% [38/77] females), and most were Caucasian/non-Hispanic (60%, 46/77).

Patients with AS had an average BMI of 28.1 kg/m², while those with PsA had an average BMI of 28.5 kg/m². The average time since diagnosis was 4 years in patients with AS and 4.2 years in patients with PsA. Common comorbidities among patients with AS included arthritis/osteoarthritis (38%, 24/63), chronic joint disease (27%, 17/63), and

Table 1 Demographics and Clinical Characteristics of Patients Before Acthar Gel Initiation

Patient Characteristics	Ankylosing Spondylitis (n=63)	Psoriatic Arthritis (n=77)
Average age, years	44 (Range: 25–76)	51 (Range: 22–70)
Gender, n (%)		
Female	21 (33%)	38 (49%)
Male	42 (67%)	38 (49%)
Nonbinary	0 (0%)	1 (1%)
Race, n (%)		
Caucasian/non-Hispanic	36 (57%)	46 (60%)
African American	10 (16%)	12 (16%)
Hispanic/Latino	7 (12%)	8 (10%)
American Indian/Alaska Native	4 (6%)	2 (3%)
Asian	4 (6%)	8 (10%)
Native Hawaiian or other Pacific Islander	0 (0%)	0 (0%)
Do not know	2 (3%)	1 (1%)
Average body mass index, kg/m^2	28.1	28.5
Overall health status before initiation of Acthar Gel		
Average rating (out of 5)[a]	3.2	3.2
Rating categories, n (%)		
Excellent	3 (5%)	5 (6%)
Very good	13 (21%)	11 (14%)
Good	21 (33%)	27 (35%)
Fair	22 (35%)	31 (40%)
Poor	4 (6%)	3 (4%)
Patient comorbidities[b], n (%)		
Arthritis/osteoarthritis	24 (38%)	26 (34%)
Chronic joint disease	17 (27%)	17 (22%)
Hypertension	16 (25%)	18 (23%)
Hyperlipidemia	9 (14%)	15 (19%)
Inflammatory eye disorders	9 (14%)	5 (7%)
Diabetes	7 (11%)	10 (13%)
Asthma	6 (10%)	14 (18%)
Heart conditions	3 (5%)	3 (4%)
Mood disorder	3 (5%)	8 (10%)

(*Continued*)

Table 1 (Continued).

Patient Characteristics	Ankylosing Spondylitis (n=63)	Psoriatic Arthritis (n=77)
Chronic obstructive pulmonary disease	2 (3%)	3 (4%)
Cancer	2 (3%)	1 (1%)
Gastrointestinal conditions	2 (3%)	10 (13%)
Thyroid disease	2 (3%)	7 (9%)
Other lung disease	1 (2%)	0 (0%)
Chronic kidney diseases	1 (2%)	8 (10%)
Other renal disease	1 (2%)	2 (3%)
None of the above	15 (24%)	16 (21%)

Notes: [a]Overall health status was measured on a scale of 1=Excellent to 5=Poor rating scale. [b]Comorbidities are not mutually exclusive.

hypertension (25%, 16/63). Common comorbidities among patients with PsA included arthritis/osteoarthritis (34%, 26/77), hypertension (23%, 18/77), and chronic joint disease (22%, 17/77). Before initiation of Acthar Gel treatment, 41% (26/63) of patients with AS and 44% (34/77) with PsA reported fair-to-poor health status, with an average rating of 3.2/5 (where 1 = excellent and 5 = poor) for both conditions (Table 1).

The most frequent symptoms among patients with AS included back pain (89%, 56/63), lower back/hip stiffness (76%, 48/63), and fatigue (62%, 39/63). The most frequent symptoms among patients with PsA included joint swelling and pain (81%, 62/77), reduced range of motion (70%, 54/77), and fatigue (66%, 51/77).

Treatment Patterns

Most patients with AS were previously treated with biologic DMARDs (68%, 43/63), corticosteroids (60%, 38/63), and NSAIDs (51%, 32/63). Most patients with PsA were previously treated with corticosteroids (65%, 50/77), biologic DMARDs (61%, 47/77), and NSAIDs (55%, 42/77) (Figure 1).

Patients with AS received Acthar Gel treatment for an average of 9 months, whereas patients with PsA received Acthar Gel for an average of 8 months. Most patients with AS (67%, 42/63) or PsA (66%, 51/77) were actively undergoing treatment with Acthar Gel at the time of the study (Figure 2). Acthar Gel was administered at a dosage of 40–80 units twice weekly to 98% (62/63) of patients with AS and 100% (all 77) of patients with PsA.

Physicians' Assessments of Improvement

Physicians reported that 95% (60/63) of patients with AS and 88% (68/77) with PsA experienced improved health status after treatment with Acthar Gel (Figure 3).

The achievement of treatment goals was assessed among patients with improved overall health status. Among patients with AS, 70% (42/60) had a reduction in overall symptoms, 68% (41/60) had decreased pain, 53% (32/60) had improved physical function, 37% (22/60) had improved strength, 35% (21/60) had improved fatigue, and 30% (18/60) had reduced corticosteroid use. Among patients with PsA, 63% (43/68) had a reduction in overall symptoms, 62% (42/68) had decreased pain, 54% (37/68) had improved physical function, 38% (26/68) had improved strength, 32% (22/68) had improved fatigue, and 31% (21/68) had reduced corticosteroid use (Figure 3).

Discussion

This analysis provides an understanding of patient characteristics and real-world Acthar Gel utilization patterns in individuals with AS or PsA, along with physician assessments of treatment impact on health status. On average, patients with AS were aged 44 years, primarily males, and Caucasian/non-Hispanic. Patients with PsA had an average age of 51 years, had a similar gender distribution, and were primarily Caucasian/non-Hispanic. Comorbidities, including arthritis/osteoarthritis, chronic joint disease, and hypertension, were common in both AS and PsA patient groups. Before initiating Acthar Gel treatment, the most frequently reported symptoms were back pain (56/63, 89%) in AS and joint swelling and

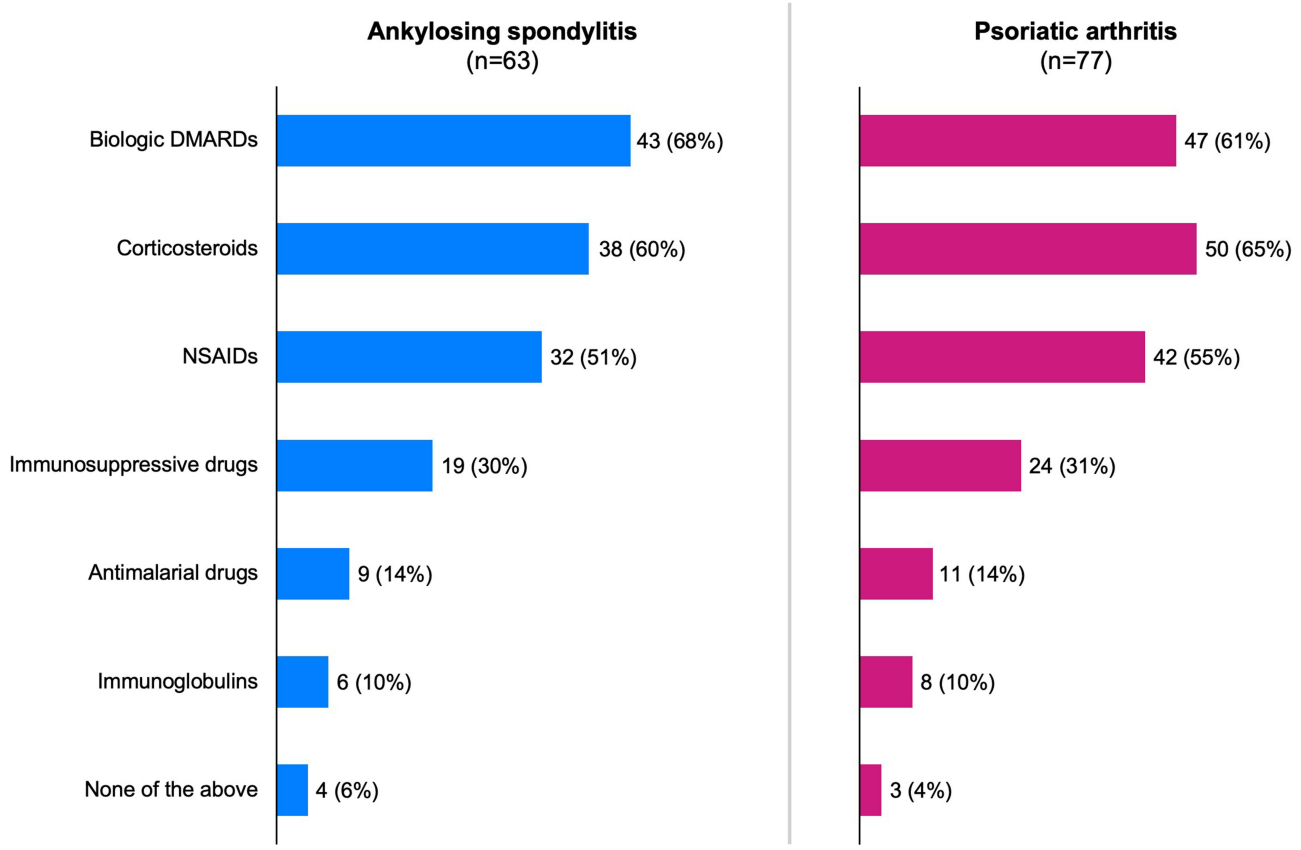

Figure 1 Medication utilization before Acthar Gel initiation.
Note: "None of the above" category refers to other medications not listed above.
Abbreviations: DMARDs, disease-modifying antirheumatic drugs; NSAIDs, nonsteroidal anti-inflammatory drugs.

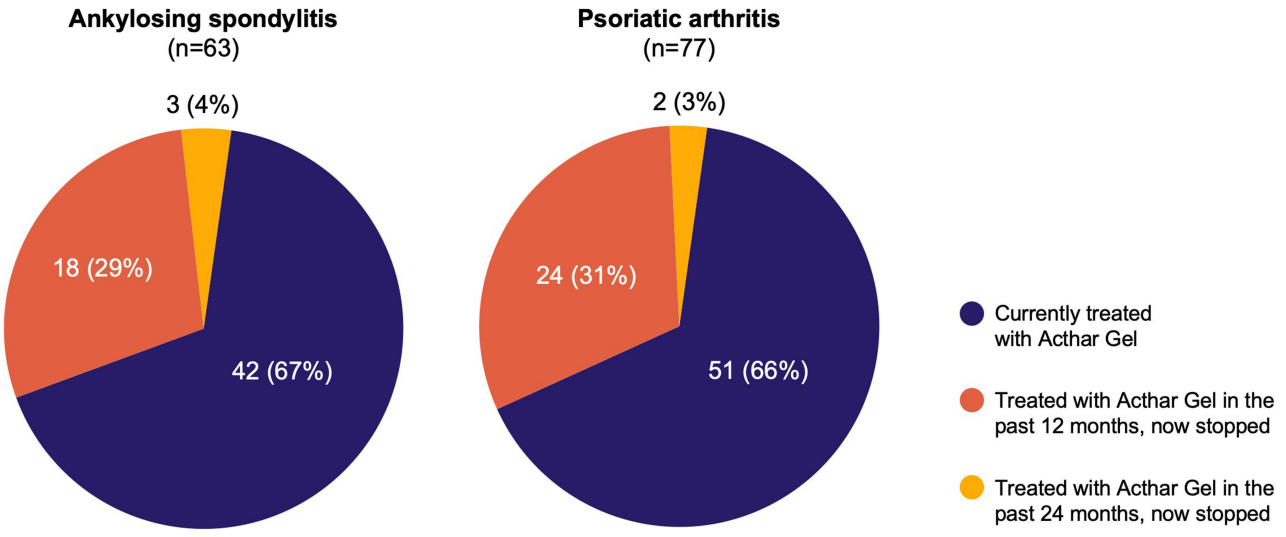

Figure 2 Percentage of patients receiving Acthar Gel therapy.

pain (62/77, 81%) in PsA. Further, before Acthar Gel initiation, biologic DMARDs, corticosteroids, or NSAIDs were frequently used medications among both AS and PsA patient groups. However, biologic DMARDs were the most common pre-Acthar Gel therapy for patients with AS (68%), and corticosteroids were most prevalent in patients with

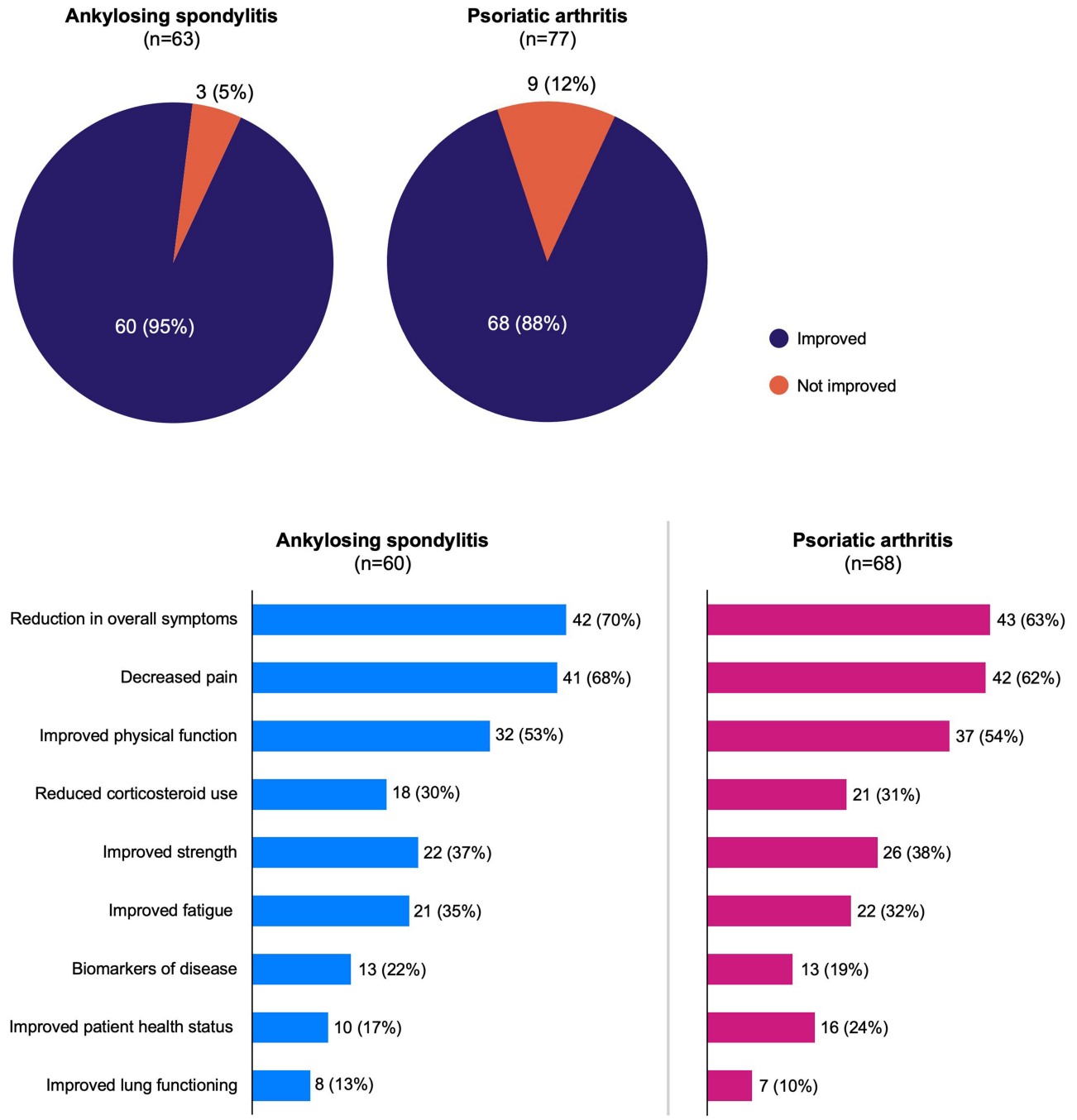

Figure 3 Change in physician's assessment of overall health status and achievement of treatment goals after initiation of Acthar Gel therapy.
Notes: Physician's assessment of the patient's health status was measured based on the following questions. For the past Acthar Gel patient—"How your patient's overall health status was at the end of Acthar Gel treatment?" For the current Acthar Gel patient—"How your patient's overall health status has changed after initiation of Acthar Gel treatment (report either health status at the end of Acthar Gel therapy or the status at 6 months point for patients' ongoing Acthar Gel treatment)?" Improvement in overall symptoms and individual treatment outcomes were measured among those with improvement in health status using the following question. "Please select the treatment goals, if any, that have improved as a result of Acthar Gel therapy."

PsA (65%). Following Acthar Gel treatment, 95% of patients with AS and 88% with PsA demonstrated improved overall health status. The most frequently achieved treatment goals were reduced overall symptoms, decreased pain, and improved physical function. Following the use of Acthar Gel treatment, there was also a reduction in corticosteroid use among this cohort (30% for AS and 31% for PsA).

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This analysis indicates improved overall patient health status following Acthar Gel treatment. Given the challenges of managing AS and PsA, particularly in patients unresponsive to conventional therapies, these results suggest that Acthar Gel may be a treatment option for alleviating symptoms and improving overall health status in refractory cases. This study supports the use of Acthar Gel in clinical practice and may encourage physicians to consider it a treatment option for patients with active AS or PsA.

AS and PsA substantially impair patients' physical, emotional, and social well-being;[7,12–15] therefore, reducing and improving physical well-being is crucial for enhancing quality of life. The achievement of treatment goals in this study suggests that Acthar Gel may be a treatment option in managing the core clinical manifestations of AS and PsA, which are often difficult to treat. While short-term reductions in symptoms and pain are encouraging, further research is necessary to assess the long-term sustainability of these benefits in patients with AS or PsA and to identify patient subgroups that may derive the most significant advantage.

Limited research exists on real-world use and clinical outcomes of Acthar Gel in patients with AS or PsA, leaving a critical gap in understanding its potential role in these conditions. This is the first study that provides valuable real-world insights into clinical and health outcomes of Acthar Gel among 63 AS and 77 PsA patients based on medical chart reviews. The findings from this study on improvement in patients' overall health status are based on physician assessment and symptoms (improved physical function and decreased pain) in patients with PsA, and these findings align with an existing open-label trial of Acthar Gel in patients with active PsA.[29] This research helps address evidence gaps and offers clinicians a better understanding of the potential benefits and limitations of Acthar Gel in managing these complex autoimmune diseases. The findings could inform future clinical decision-making, guide treatment optimization, and contribute to the development of evidence-based guidelines. Furthermore, this study can serve as a foundation for future prospective research and clinical trials that can better define the role of Acthar Gel within the broader treatment landscape. Additional studies, including prospective trials, are needed to further evaluate the long-term efficacy and safety of Acthar Gel treatment for patients with AS or PsA.

Given the descriptive observational design and absence of standardized disease-activity measures in this chart review, future work may examine both the specific labeled role of Acthar Gel as a short-term adjunct during acute episodes as well as its real-world use in patients with difficult-to-treat disease where other options are insufficient. These may include (i) prospective multicenter registries that collect standardized activity and flare metrics, patient-reported outcomes (pain, fatigue, function), and steroid-sparing endpoints, and (ii) a pragmatic flare-anchored clinical study of Acthar Gel plus usual care versus usual care alone, with time-to-clinical improvement, flare duration, success of corticosteroid tapering, and safety as primary outcomes.

This study has several limitations. First, it relies on survey data derived from patient medical records, which may contain inaccuracies or omissions. Second, the study population is limited to patients receiving Acthar Gel and those included in the reviewed records, potentially limiting generalizability to broader AS and PsA populations, particularly those in different healthcare settings or with varying disease severity. Third, this was a real-world chart review; therefore, a uniform disease-activity instrument was not used. Instead, disease status was abstracted as documented in the record (physician assessments and routinely recorded clinical signs/symptoms). Collecting standardized disease activity measures from observational data presents substantial challenges.[32,33] In previously published studies using electronic medical records from two separate rheumatology care management organizations, such measures were available in only up to 20% of patient records. The variability in physician documentation and subjective assessments of patient improvement could introduce bias, especially without standardized objective measures of disease activity. Fourth, the absence of a control group limits the ability to determine the true effectiveness of Acthar Gel. Further, these results should not be interpreted as comparative effectiveness. Finally, the study does not quantify diagnostic or safety outcomes and primarily captures short-term effects, limiting our understanding of the impact of long-term treatment. While some patients may receive Acthar Gel alongside short-term glucocorticoids, this descriptive study did not collect standardized safety endpoints or detailed concomitant dosing and therefore cannot compare adverse events between concomitant-use and non-concomitant-use groups; prospective studies with predefined safety outcomes are needed. However, this chart review study showed that ~30% of patients with AS or PsA had reduced corticosteroid use after initiation of Acthar Gel.

Conclusions

Based on this chart review, Acthar Gel may represent a potential treatment option for appropriate patients with AS or PsA. In this descriptive observational study among patients with AS or PsA treated with Acthar Gel, physicians documented a reduction in overall symptoms, decreased pain, improved physical function, reduced corticosteroid use, improved strength, and improved physical function using prespecified assessments.

Data Sharing Statement

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

Ethics Approval and Informed Consent

This study used preexisting, fully deidentified data, with no direct involvement of human subjects or access to identifiable private information. Based on the authors' determination and in accordance with the U.S. Department of Health and Human Services (45 CFR 46.102) and FDA (21 CFR 56.102) regulations, this work does not meet the definition of human subjects research. Therefore, approval from an institutional review board or ethics committee was not required. This study complies with the Declaration of Helsinki.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Priyanka Shanbhag, Destri Evans, and Amit Patel are employees of Indegene, Inc., and are paid consultants for this study. Kyle Hayes and George J. Wan are employees of Mallinckrodt Pharmaceuticals. Mary Panaccio is a paid consultant of Mallinckrodt Pharmaceuticals for this study. The authors report no other conflicts of interest in this work.

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