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Repository Corticotropin Injection in African-Americans with Advanced Symptomatic Sarcoidosis: A Retrospective Analysis of Medical Records

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BACKGROUND

- Sarcoidosis is a multisystem, inflammatory, systemic granulomatous disease with unknown etiology[1-4]
- More than 25,000 patients are diagnosed with sarcoidosis each year in the United States (US)[5]
  Sarcoidosis-related hospitalization rates in the US have increased by about 26% from 2005 to 2014[6]
- In the US, African Americans are more frequently and severely affected; 4 to 17 times more likely to develop sarcoidosis compared with Caucasians[7]
  - It is important to close the gaps in health care disparities through the provision of effective interventions to the underserved populations with sarcoidosis
- Repository corticotropin injection (RCI; Acthar Gel®) is a naturally sourced complex mixture of adrenocorticotropic hormone analogs and other pituitary peptides[8]
  - RCI is approved by the US Food and Drug Administration for the treatment of symptomatic sarcoidosis and is only commercially available in the US[8]
  - RCI is also referenced in the European Respiratory Society treatment guidelines, which list RCI among the various anti-inflammatory treatments for pulmonary sarcoidosis and note it can be used on a case-by-case basis when other therapies are ineffective or not tolerated and the US Sarcoidosis Expert Panel Consensus Statement recommendations for sarcoidosis[9,10]
- Previous studies suggest that RCI is a viable treatment option for advanced symptomatic sarcoidosis[11-13]
  - Real-world data is needed to understand patient characteristics and obtain insights on the optimal applications of RCI therapy for African-Americans with sarcoidosis

OBJECTIVE

To describe patient characteristics, RCI utilization patterns, concomitant therapies, and physicians' assessments of treatment response among African Americans with advanced symptomatic sarcoidosis treated with RCI

METHODS

A **sub-group analysis focusing on African-Americans** utilized retrospective observational medical chart review data with a large case series of patients [details on the overall sample can be found elsewhere][11]

Data Collection

- A representative sample of patients was obtained by merging a national database of RCI prescribers with the American Medical Association Physician Masterfile
- Data obtained from 98 eligible physicians with following specialties: pulmonologists, rheumatologists, primary care physicians, dermatologists, cardiologists, ophthalmologists, gastroenterologists, and neurologists

Patient Eligibility Criteria

- ≥18 years of age
- Diagnosis of advanced symptomatic sarcoidosis
- Presence of ≥1 symptom
- Treatment with RCI in the previous 36 months (either completion of a course of RCI or receipt of RCI for ≥6 months at the time of data collection)

RESULTS

Patient Demographics and Clinical Characteristics

- 168 African Americans with advanced symptomatic sarcoidosis were identified [**Table 1**]
  - A majority of them were 45-64 years of age (59%) and were female (54%)
  - The mean time since the initial diagnosis of sarcoidosis was 5.2 years
  - 72% of patients had ≥1 comorbidity
- 73% of patients had at least one extrapulmonary organ involved; 32% had involvement in multiple (≥2) extrapulmonary organs [**Figure 1A**]
- The most common sites of extrapulmonary involvement were skin (27%), heart (24%), eyes (22%), and joints (21%) [**Figure 1B**]
- The most common signs and symptoms documented among patients who started their most recent course of RCI therapy were shortness of breath (45%), fatigue (44%), bone and joint pain (24%), and wheezing/coughing (21%) [**Figure 2**]
  - Reported symptoms tended to be mild or moderate in severity

Table 1. Patient demographics and clinical characteristics (N=168)

Characteristics	N (%)
Age	
18-24 years	0 (0.0%)
25-34 years	16 (9.5%)
35-44 years	34 (20.2%)
45-54 years	58 (34.5%)
55-64 years	41 (24.4%)
≥65 years	19 (11.3%)
Sex	
Men	77 (45.8%)
Women	91 (54.2%)
Geographic Region	
Northeast	54 (32.1%)
Midwest	46 (27.4%)
South	41 (24.4%)
West	27 (16.1%)
Time since diagnosis in years, mean (SD)	5.2 (7.6)
Time period diagnosis	
Within past 1 year	23 (13.7%)
1-2 years	34 (20.2%)
2-3 years	34 (20.2%)
3-5 years	26 (15.5%)
5-10 years	29 (17.3%)
10 or more years	22 (13.1%)
≥1 comorbid condition	121 (72.0%)

Figure 1. Number of extrapulmonary organs involved (A) and sites of extrapulmonary organ (B) (N=168)

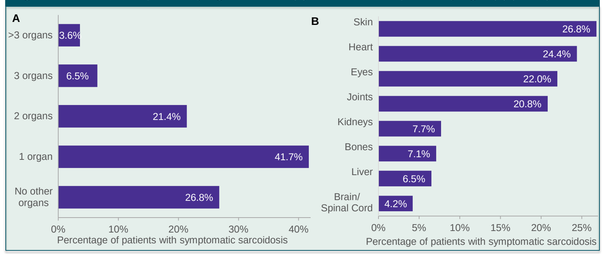


Figure 2. Symptom type and severity of African-Americans prior to RCI initiation (N=168)

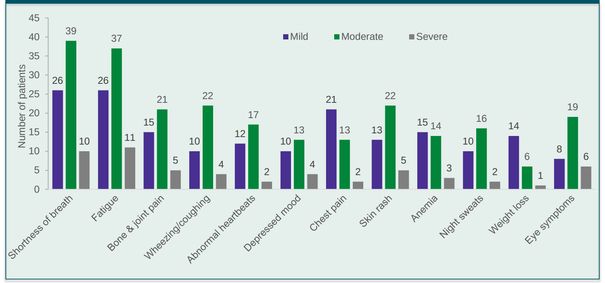
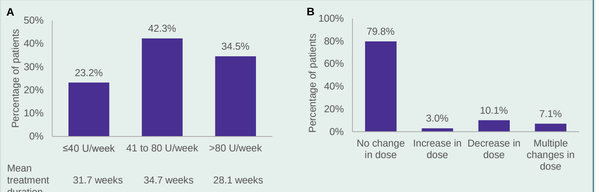


Figure 3. RCI dosing (A) and dose adjustment (B) patterns



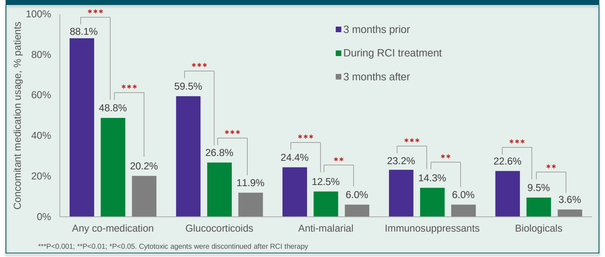
RCI Treatment Patterns

- Of the 168 African Americans included in the study, 82% had used RCI for the first time and 18% had previously used RCI
- At the time of data collection, 44% had completed a course of RCI therapy and 56% were continuing RCI therapy
  - Mean (standard deviation [SD]) duration of RCI treatment was 31.7 ± 32.0 weeks
  - Most patients (n=105, 62.5%) had continued RCI therapy for ≥6 months
- RCI dosing varied because patients had individualized courses of therapy [**Figure 3A**]
- A majority of patients (80%) did not have any dose adjustments [**Figure 3B**]

Concomitant Medications

- There was a significant reduction in use of any co-medication after RCI initiation (p<0.0001) [**Figure 4**].
- The percentage of patients who used glucocorticoids decreased significantly from 59.5% during the 3 months before initiation of RCI to 11.9% 3 months after RCI therapy (p<0.0001).
  - The mean daily dose of glucocorticoids decreased from 18.5 mg to 10.1 mg.

Figure 4. Concomitant medication use before, during, and after RCI therapy (N=168)

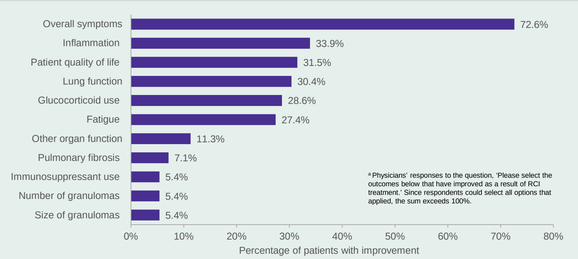


***P<0.001; **P<0.01; *P<0.05. Cytotoxic agents were discontinued after RCI therapy

Physicians' Assessments of Improvement

- According to physicians' assessments of change in patients' health status following RCI treatment,
  - most patients (n=160, 95%) had improved, and
  - 83 patients (49%) had ≥2 types of improvements in sarcoidosis symptoms
- The most commonly reported types of sarcoidosis symptom improvements were overall symptoms (n=122, 73%), inflammation (n=57, 34%), improved patient quality of life (n=53, 32%), improved lung function (n=51, 30%), and reduction or discontinuation of glucocorticoid (n=48, 29%) [**Figure 5**]

Figure 5. Physicians' assessments of improvement for different treatment responses[a] (N=168)



[a] Physicians' responses to the question, 'Please select the outcomes below that have improved as a result of RCI treatment.' Since respondents could select all options that applied, the sum exceeds 100%.

LIMITATIONS

- Retrospective data collection may be incomplete
- Outcomes may be influenced by therapies not documented in the chart
- Patient outcomes and safety were not quantified
- Physician assessment of patient outcomes may be subjective
- Most patients were on multiple therapies; the clinical outcomes may not be solely attributable to RCI

CONCLUSIONS

- The findings among the African-American sub-group were similar to those in the overall population[11]
  - Demographic and clinical characteristics of African Americans were similar to the overall population[11]
  - African Americans with advanced symptomatic sarcoidosis received individualized RCI treatment that was associated with reduced use of other sarcoidosis medications, including glucocorticoids
  - Improvement in current status was reported in 95% of the African Americans, consistent with the overall population[11]
  - Most patients treated with RCI responded to the treatment, especially related to overall symptoms, inflammation, and patients' quality of life, and inflammation
- RCI is a viable treatment option for African-Americans with advanced symptomatic sarcoidosis
- The findings also suggest that the use of RCI may improve health in African-Americans with sarcoidosis, thereby closing the gap on health disparities in these vulnerable and underserved populations

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DISCLOSURES

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