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Medical Resource Utilization in Patients with Infantile Spasms After Receipt of Repository Corticotropin Injection (H.P. Acthar Gel): Results of a Physician Survey

Tara Nazareth, MPH[1]; Michael Philbin, PharmD, MBA, MSc[1]; Jack Gallagher, EdD, MSc[2]; Kylee Heap, BS[2]; Susan Carroll; MA[2]; Elaine A. Böing, BPharm[1]

[1]Mallinckrodt Pharmaceuticals, Hampton, NJ, USA; [2]Clarity Pharma Research LLC, Spartanburg, SC, USA

Mallinckrodt Pharmaceuticals

INTRODUCTION

- Infantile spasms (IS) is a rare condition affecting 1 per 2000 children. There are many causes, including birth injury, genetic disorders, or abnormal metabolism.[1,2]
- After spasms begin, developmental progress may be stopped and skills previously acquired may be lost. Timely diagnosis with appropriate treatment is critical.[3]
- Repository corticotropin injection (RCI), known as H.P. Acthar® Gel (Acthar), is an approved therapy which eliminates spasms and hypsarrhythmia in cryptogenic and symptomatic cases of IS.[4]
- The purpose of this study was to characterize patients with IS treated with Acthar in terms of their treating physicians and their medical resource use (MRU).

METHODS

Study Design and Data Source

- An online survey requiring patient chart abstraction was administered to neurologists and internal medicine (IM) physicians in the US meeting the following criteria:
  - Managing or treating at least one patient who completed Acthar between 3-months and 2-years prior to study enrollment
  - Complete record information available for each patient selected, including Acthar dosing regimens
- Towards obtaining a nationally representative sample, physicians were randomly selected and screened against the study-specific qualifications from:
  - American Medical Association Masterfile of physicians in the target specialties
  - Registry of nationwide prescribers of Acthar
- Physicians were instructed to extract data from charts of qualified IS patients, ages 0 to 2 years old, who had received Acthar in the past 2 years and had completed Acthar at least 3 months prior to the study. Each physician could provide up to four cases, in order of last seen.
- Data were weighted to correct for study segments that were over- or under-represented in the total sample.

Outcomes

- Post-Acthar treatment (during the 3 months immediately after the last regimen was completed) was compared with pre-Acthar treatment (during the 3 months immediately before Acthar treatment was initiated) on each of the following MRU measures:
  - Hospitalizations, including direct admissions to hospital, admissions routed through the emergency room (ER); and length of stay (LOS)
  - ER-only visits, i.e. ER not resulting in hospitalization
  - Outpatient visits, including office visits with physicians, physician assistants and nurses

Statistical Analysis

- Paired-samples t-tests were used to analyze mean MRU differences, comparing 3-months pre- and 3-months post-Acthar treatment.

RESULTS

Physician-level data (Table 1)

- 101 physicians (68 neurologists and 33 IMs) provided patient data for this analysis.
- Physician practices were distributed in the West (44.6%), South (23.8%), Northeast (16.8%), and Midwest (14.9%).
- 67.3% of Acthar-treating physicians were in practice at academic hospitals; 17.8%, in private group practices.
- Neurologists reported being primary decision-makers in prescribing Acthar for 86.2% of patients, making the decision jointly with another physician for 9.3% of patients, and another physician driving the decision for 4.5% of patients.
- 86.2% of physicians said they were either satisfied or completely satisfied with Acthar (scores 4 or 5 on a 5-point scale from not at all satisfied to completely satisfied).

Table 1. Physician Characteristics (n=101)

Characteristic	n (%)
Specialty	
Neurology	68 (67.3)
Internal medicine	33 (32.7)
Practice region*	
West	45 (44.6)
South	24 (23.8)
Northeast	17 (16.8)
Midwest	15 (14.9)
Practice setting	
Academic hospital	68 (67.3)
Private group practice	18 (17.8)
Private solo practice	10 (9.9)
Community hospital	5 (5.0)

**Percentages do not add up to 100% due to rounding*

Patient-level data (Table 2)

- 159 IS patients were captured in this physician survey. Of the n=67 cases with IS causes noted, 31.3% had TSC, followed by 25.4% and 20.9% with other genetic abnormalities and CNS infection, respectively.
- Mean patient age was 8.0 months (standard deviation, SD, 6.4). One third were female; half were Caucasian. Patients were first symptomatic at 7.4 months, on average.
- Patients with 1 or more co-morbidity had most often central nervous system (CNS) conditions (15.1%), gastrointestinal conditions (7.5%), and vision loss (5.0%). 64.8% of patients had no co-morbidities noted.
- 83.5% of patients received Acthar for the first time. 78.5% of patients tried other medications prior to Acthar.
- 72.2% of patients used Acthar for <=1 month, 80.5% for <=2 months, and 89.7% for <=3 months.

RESULTS

Table 2. Patient Demographics and Clinical Characteristics

Characteristic	n (%)
Age (months) (n=159)	
≤6	89 (56.0)
7-12	42 (26.4)
13-18	15 (9.4)
19-24	13 (8.2)
Female (n=159)	54 (34.0)
Race/Ethnicity (n=157)	
Caucasian/Non-Hispanic	80 (51.0)
African American	30 (19.1)
Hispanic or Latino	19 (12.1)
Asian	17 (10.8)
Other	11 (7.0)
Top 3 co-morbidities (n=159)	
Central nervous system conditions	24 (15.1)
Gastrointestinal conditions	12 (7.5)
Vision loss	8 (5.0)
Top 3 underlying causes (n=67)	
Tuberous sclerosis complex	21 (31.3)
Genetic abnormalities other than tuberous sclerosis complex	17 (25.4)
CNS infection (e.g., herpes simplex virus, meningitis, encephalitis)	14 (20.9)

MRU metrics (Table 3 and Figure 1)

- Physicians reported statistically significant decreases in MRU for their IS patients after Acthar use:
  - 20% fewer hospitalizations (1.64 pre-Acthar vs. 1.31 post-Acthar);
  - 21% fewer ER-only visits (1.69 pre-Acthar vs. 1.34 post-Acthar).
- Among those hospitalized, post-Acthar treatment was significantly associated with:
  - 12% fewer direct admissions to hospital (0.85 pre-Acthar vs. 0.75 post-Acthar);
  - 28% fewer hospital admissions routed through the ER (0.79 pre-Acthar vs. 0.57 post-Acthar);
  - 54% shorter LOS (2.46 days pre-Acthar vs. 1.13 days post-Acthar).
- A non-significant decrease of 10% in outpatient visits was reported (2.77 pre-Acthar vs. 2.49 post-Acthar).

LIMITATIONS

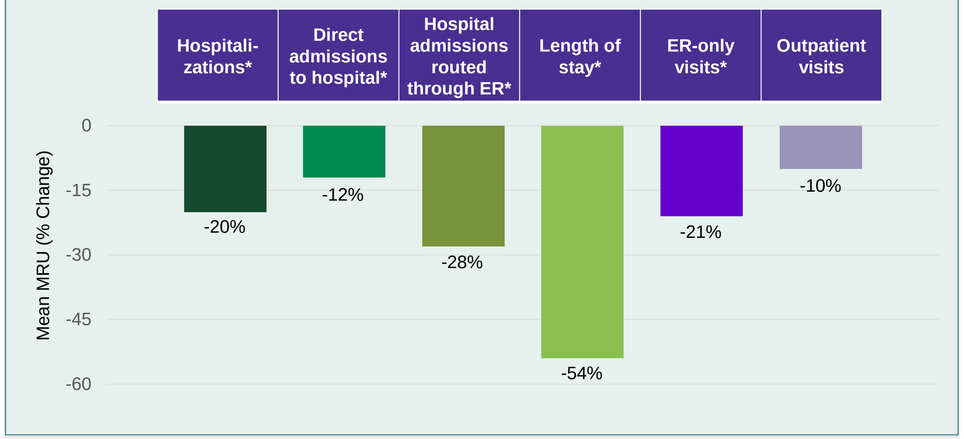
- Exclusive use of Acthar was not mandated, and simultaneous use of other agents was not examined. Therefore, observed MRU reductions may not be attributable solely to Acthar.

Table 3. Pre- vs. Post-Acthar Treatment Medical Resource Utilization Metrics in IS Patients

Pre- vs. Post-Acthar treatment metric	Pre-Acthar treatment mean	Post-Acthar treatment mean	Mean difference (95% confidence interval)	p-value
Hospitalizations	1.64	1.31	-0.33 (-0.46, -0.20)	<0.001
Direct admissions to hospital*	0.85	0.75	-0.11 (-0.20, -0.02)	0.016
Admissions routed through the ER	0.79	0.57	-0.22 (-0.34, -0.11)	<0.001
Length of stay (days)*	2.46	1.13	-1.32 (-2.09, -0.56)	<0.001
ER-only visits	1.69	1.34	-0.35 (-0.53, -0.17)	<0.001
Outpatient visits	2.77	2.49	-0.28 (-0.74, 0.18)	0.225

**Differences observed at the hundredths level (i.e. 0.01) are due to rounding*

Figure 1. Pre- vs. Post-Acthar Treatment Changes in MRU ***(*denotes statistical significance)***



CONCLUSIONS

- Treating physicians reported significant decreases in hospitalizations, ER-only visits, and days hospitalized in their IS patients after Acthar use.
- Decreases in MRU, especially associated with the ER and hospital, are meaningful for patients with IS and their caregivers. Decreased MRU may also be associated with medical cost offset and lower expenditures.
- Our study contributes contemporary data on successful use of Acthar in IS, including TSC, from the treating physician's perspective. Real world data on Acthar use in IS is important for healthcare decision-makers to utilize in their treatment choices.

DISCLOSURE

- The funding for this study was provided by Mallinckrodt Pharmaceuticals.

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