Biochemical Control during Long Term Follow Up of Cushing’s Disease: A Multi-Center Retrospective Study

Eliza B. Geer1, Ismat Shafi2, Murray B. Gordon3, Vivien Bonet4, Alejandro Ayala5, Ronald S. Seerdent2,6,7,8,9, Laurence Katznelson10, Yelena Laluzar11, Ekaterina Manuylova12, Karen J. Pulaski13, John D. Carmichael14, Zeina Hannoush15, Vijaya Suramundu16, Michael S. Gordon17,18,20

1 Icahn School of Medicine at Mount Sinai, New York, NY; 2 University of Rochester School of Medicine and Dentistry, Rochester, NY; 3 Allegheny Neuroendocrinology Center, Allegheny General Hospital, Pittsburgh; 4 Cedars-Sinai Medical Center, Los Angeles, CA; 5 University of Miami and Jackson Memorial Hospital, Miami, FL; 6 Harbor-UCLA Medical Center, Los Angeles, CA; 7 Stanford University School of Medicine, Stanford, CA; 8 Massachusetts General Hospital, Boston, MA; 9 University of Southern California Pituitary Center, Los Angeles, CA; 10 Partnership for Health Analytic Research, LLC, Beverly Hills, CA; 11 Chiasis, Inc., Newton, MA, previously of Novartis Pharmaceuticals Corporation, East Hanover, NJ; 12 Novartis Pharmaceuticals Corporation, East Hanover, NJ.

OBJECTIVE
To describe treatment outcomes in a diverse, multi-center cohort of patients receiving clinical care for CD.

METHODS

Study Design

Retrospective data were collected from patients’ medical records at 8 US pituitary/endocrine centers, including major referral centers and regional/local centers, selected based on adequate number of CD patients treated, geographic location, and diversity of patient populations, across 4 US regions.

The study was approved by the Institutional Review Boards at each site.

Patient Selection

• Patients with initial CD diagnosis or recurrence during the past 20 years and who were ≥18 at the time of diagnosis were included in the study.

Data Collection

• Each site identified eligible patients, and trained site coordinators entered data via a secure eCRF.

• Data were collected from the time of presentation (i.e., the date patient first sought care for symptoms, signs, or comorbidities that were later ascribed to CD) to CD treatment (at end of follow-up, i.e., by study end, 5/2015).

Measure

• Patient demographics and baseline comorbidities were captured from available data recorded during the treatment period (on or before the first CD therapy).

• Laboratory data were recorded based on pituitary MRI before pituitary surgery.

• The dates and types of CD treatments were captured. The first treatment given was classified as primary therapy.

• Biochemical control was defined: 1) following pituitary surgery, any value of ≤5 mcg/dl, or ≤1.8 mcg/dl after 1 mg dexamethasone suppression test; 2) after medical therapy or radiotherapy, any value of 24-hour urine cortisol ≤2.5 mcg/dl (normal), or ≤1 mcg/dl with 24-hour urine cortisol ≤14 mcg/dl in patients with a pituitary macroadenoma.

Statistical Analysis

• Patient characteristics were reported in the full sample and by final biochemical control. Comorbidities were reported in the presentation subgroup with patients having information in the medical records on or before the first CD therapy.

• All statistical analyses were done in SAS® version 9.4 (SAS Institute, Cary, NC).