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REAL-WORLD TREATMENT PATTERNS IN CUSHING'S DISEASE PATIENTS IN TWO LARGE US NATIONWIDE DATABASES: APPLICATION OF A NOVEL, GRAPHICAL METHODOLOGY

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BACKGROUND

- Untreated Cushing's disease (CD), which results from excessive adrenocorticotropic hormone (ACTH) secretion by pituitary tumor, is associated with substantial morbidity and mortality.[1, 2]
- Treatment of this rare disorder includes surgery, radiotherapy, or pharmacologic therapy.[1]
- Data on real-world treatment patterns for CD in United States are limited.[3]

OBJECTIVE

- To analyze treatment patterns in CD using a novel graphical technique.

METHODS

Study Design and Data Source

- Retrospective cohort study using 2 HIPAA-compliant United States claims databases (Thomson Reuters MarketScan Commercial, IMS Health PharMetrics).

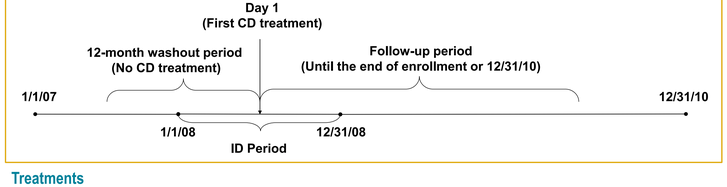
Study Population and Study Timeframe

Inclusion Criteria:

- Cushing's syndrome (ICD-9-CM: 255.0) claim in identification (ID) period of Jan. 1, 2008 through Dec. 31, 2008, and either benign pituitary adenomas (ICD-9-CM: 227.3) diagnosis or hypophysectomy (ICD-9-CM: 07.6x; CPT: 61546, 61548, 62165) in 2007-2010,
- Newly treated in ID period,
- No CD treatment in 12 months prior to the first CD treatment (Day 1), and
- Continuous enrollment for ≥6 months prior to Day 1.

Follow-up Period:

- Patients were followed until the end of enrollment or for 3 years, whichever was first.



Treatments

- Surgery (adrenalectomy, pituitary), radiotherapy, pharmacologic treatment (dopamine agonists, ketoconazole, mitotane).

Analyses

- We analyzed treatment patterns using GRAPHx™, an innovative method which produces high-resolution images combining comprehensive individual patient histories.
- The GRAPHx method uses multi-colored line segments to represent different treatment claims, plotting them over time. Every horizontal line is an individual patient treatment history in the follow-up period.
- The height of each colored section is proportional to the number of users and gray areas represent periods with no claims for the treatments of interest.
- Images were reviewed for segment length and changes in colors to evaluate treatment patterns over time for every patient.
- Graphics were plotted using R version 1.12 and statistical analyses were performed using SAS© version 9.3 (SAS Institute, Cary, NC).

RESULTS

Study Cohort and Characteristics

- 228 newly-treated CD patients, with mean age of 41 years (SD: 14.5 years), 76.75% (175) were female.

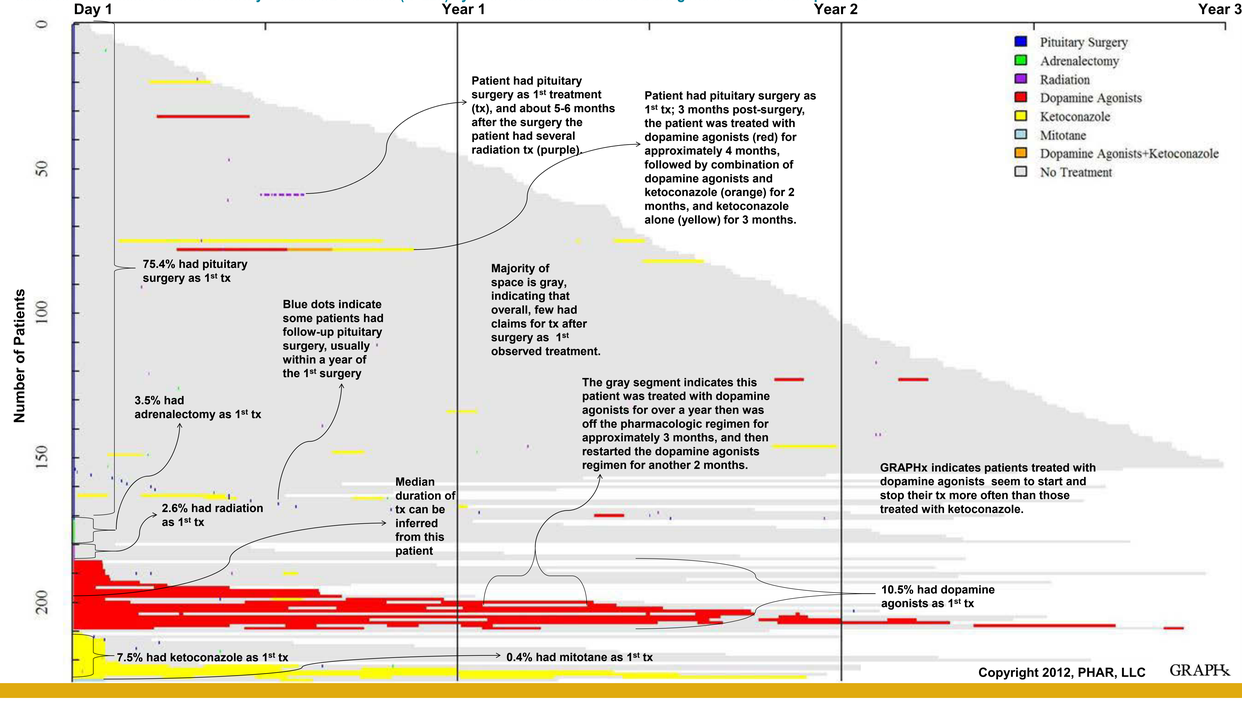
Observed Treatment During the 3-Year Follow-up Period

- As their first treatment ,78.9% had surgery, 18.4% had pharmacologic treatment, and 2.6% had radiotherapy.
- In 180 patients with surgery as first treatment, 8.3% had radiotherapy and 7.8% had pharmaceutical treatment during follow-up.
- In 42 patients with pharmacologic therapy as first treatment, 23.8% had surgery and 4.8% had radiotherapy during follow-up.
- Mean (median) duration of first pharmacologic therapy varied by medical treatment: 369.5 days (245) for dopamine agonists, 157.1 (30) for ketoconazole, 30.0 (30) for mitotane.

Treatment	1ST treatment N (%)[a]	During Follow-up N (%)[b]			
		>1 treatment	any surgery	any radiation	any pharmacologic treatment
All	228 (100)	38 (16.7)	190 (83.3)	23 (10.1)	56 (24.6)
Surgery	180 (78.9)	26 (14.4)	180 (100)	15 (8.3)	14 (7.8)
Pituitary	172 (75.4)	25 (15.1)	172 (100)	15 (8.7)	14 (8.1)
Adrenalectomy	8 (3.5)	0 (0)	8 (100)	0 (0)	0 (0)
Radiotherapy	6 (2.6)	0 (0)	0 (0)	6 (100)	0 (0)
Pharmacologic	42 (18.4)	12 (28.6)	10 (23.8)	2 (4.8)	42 (100)
Dopamine agonists	24 (10.5)	3 (12.5)	3 (12.5)	1 (4.2)	24 (100)
Ketoconazole	17 (7.5)	8 (47.1)	7 (41.2)	1 (5.9)	17 (100)
Mitotane	1 (0.4)	1 (100.0)	0 (0)	0 (0)	1 (100)

[a] column percent (i.e., % in 228 patients); [b] row percent (i.e., % in patients with the given first treatment).

Observed Treatment Patterns in Newly Treated CD Patients (N=228) by First Treatment Observed During the 3-Year Follow-up Period



LIMITATIONS

- Limited duration of continuous patient enrollment, characteristic of claims databases, does not allow for review of earlier therapies (e.g., an earlier surgery for CD) that may have been provided under different health plans and also limits length of follow-up period.
- This study is based on healthcare claims, without verification in medical charts
- This study included patients with commercial insurance, so the results may not be representative of the general CD population.
- Healthcare claims represent medications purchased, not necessarily those taken.

CONCLUSIONS

- **This study addresses an unmet need for data on real-world treatment patterns and duration for CD patients in the US.**
- **Data were provided for actual treatment rates and duration in a large sample of CD patients (228 newly-treated patients) using two nationwide databases.**
- **The majority of patients (78.9%) had surgery as their first treatment, and up to 85.6% of these patients had no follow-up treatment during the observation period.**
- **Those treated with pharmacologic therapies as their first treatment were often not persistent in their regimen, which may have contributed to why up to 28.6% of these patients received >1 treatment.**
- **Patient-level graphical analysis of individual patient histories over time using GRAPHx provided detailed information on treatment patterns and insights about adherence and persistence of treatment in commercially-insured CD patients in the US.**
- **Future studies of treatment patterns for CD in the US will include evaluation in additional databases, including also retrospective chart reviews.**

References

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